U.S. Department of Health and Human Services
Office of the Assistant Secretary for Preparedness and Response (ASPR)
Biomedical Advanced Research and Development Authority (BARDA)

BAA-BARDA-08-08

Therapies for Hematopoietic Syndrome, Bone Marrow Stromal Cell Loss, and Vascular Injury Resulting From Acute Exposure to Ionizing Radiation

OMB control number 0990-0115

1. OFFERORS ARE RESPONSIBLE FOR ROUTINELY CHECKING THE FOLLOWING WEBSITE FOR ANY BAA AMENDMENTS. NO ADDITIONAL NOTIFICATION OF ANY AMENDMENTS WILL BE PROVIDED BY THIS OFFICE. http://www.fedbizopps.gov/

2. BAA/CONTRACT FORM – PURCHASE AUTHORITY: FAR 1.602-1
NOTE: The issuance of this BAA does not commit the USG to an award.

3. Issue Date:	**4. Due Date:** April 17, 2008 **Time:** 4:00 p.m. , EST	**5. Small Bus. Set-Aside:** [ ]Yes [X] No **8(a) Set-Aside:** [ ]Yes [X] No **NAICS #:** 541712
March 6, 2008		

6. Reserved	**7. Number of Awards:** [ ] Only 1 Award [X] Multiple Awards	**8. Technical Proposal Page Limits:** Number of Copies: See Attachment 1 (Packaging and Delivery of Proposals) Page Limits: 200 pages, including all appendices, CV's and attachments.

9. Issued By:
David Beck, Contracting Officer
Biomedical Advanced Research and Development Authority (BARDA)
330 Independence Ave., SW, Room G640
Washington, D.C. 20201

10. [X] **BARDA reserves the right to make awards without discussions.**

11. Options:
[X] No
[ ] Yes

12. Period of Performance:
Up to three (3) years beginning on or about September 16, 2008.

13. Primary Point of Contact:
Name : Carl A. Newman
Phone: 202-205-1156
Fax: 202-205-0873
E-Mail: carl.newman@hhs.gov

14. Secondary Point of Contact:
Name: David Beck
Phone: 202-260-0453
E-Mail: david.beck@hhs.gov

15. Protest Officer:
Address: See Block 9

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

17. Offers will be valid for 120 days unless a different period is specified by the Offeror.

DELIVERY ADDRESS INFORMATION

18. Hand Delivery or Overnight Service:
N/A

19. U.S. Postal Service or an Express Delivery Service
Biomedical Advanced Research and Development Authority
Assistant Secretary for Preparedness and Response
U.S. Department of Health & Human Services
330 Independence Ave. S.W., Room G640
Washington, D. C. 20201

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

Updated thru FAC 2001-27 (3/28/2005)

TABLE OF CONTENTS

DESCRIPTION

You are invited to submit a proposal in accordance with the requirements of this Broad Agency Announcement (BAA-BARDA-08-08) entitled **"Therapies for Hematopoietic Syndrome, Bone Marrow Stromal Cell Loss, and Vascular Injury Resulting From Acute Exposure to Ionizing Radiation**". This Broad Agency Announcement (BAA) is authorized by FAR 6.102(d)(2) and further described in FAR 35.016, Broad Agency Announcement. A BAA is a general announcement of an agency's research and development interest. The intent of a BAA is to encourage the submission of creative and innovative approaches to specific research and development areas identified by the United States Government (USG).

A proposal submitted in response to this BAA must present a detailed technical and cost proposal designed to meet the Research and Technical Objectives described in this announcement. The proposal must be signed by an official authorized to contractually commit the submitting organization. The Statement of Work (SOW), including the specific work requirements and performance specifications, is developed and defined by the Offeror, not the USG. The SOW should not exceed ten (10) single spaced-pages (in 12 pt font, Times New Roman) in length within the technical proposal, which is limited to two hundred (200) pages total (including all appendices and attachments).

Proposals are not evaluated against a specific USG need, as in the case of a conventional Request for Proposal (RFP), since they are not submitted in accordance with a common SOW issued by the USG. Instead, Research and Technical Objectives are provided in the BAA that describe the research and development areas in which the USG is interested. Proposals received as a result of the BAA are evaluated by a Technical Evaluation Panel (TEP) in accordance with the Evaluation Factors specified in the BAA. An Order of Merit Ranking is established by the Contracting Officer in lieu of a Competitive Range. Negotiations are conducted with those Offerors selected from the Order of Merit Ranking as set forth in this announcement under Evaluation Factors for Award.

At the conclusion of negotiations with the Offerors selected from the Order of Merit Ranking, those selected Offerors are allowed the opportunity to submit a Final Proposal Revision (FPR) to address weaknesses in the proposal based on issues identified by the TEP and to revise costs as may be appropriate. It is anticipated that multiple awards will result from this announcement and those awards will be multi-year, cost-reimbursement, completion type contracts. BARDA anticipates awarding 5-6 contracts. Awards are expected to be made on or about September 16, 2008. The HHS/BARDA estimates that the average annual total cost (direct and indirect cost combined) for these contracts will be $3 million to $5 million per contract. However, it is anticipated that the total cost for each award may vary depending upon the scope of the project and the technical objectives of the award. The length of time for which funding is requested should be consistent with the nature and complexity of the proposed research and development. The maximum period of performance is three (3) years. The award document will be tailored in the final negotiations with the selected Offeror(s) and modified as appropriate for the type of Offeror organization, cost and/or fee arrangements, and other elements as negotiated prior to award.

INTRODUCTION

On December 19, 2006, President George W. Bush signed into law the Pandemic and All-Hazards Preparedness Act (Public Law 109-417), referred to as PAHPA. Title IV of PAHPA established the **Biomedical Advanced Research and Development Authority (BARDA)** in the Office of the Assistant Secretary for Preparedness and Response (ASPR) in the U.S. Department of Health and Human Services (HHS) to facilitate the research, development, and acquisition of medical countermeasures for chemical, biological, radiological, and nuclear (CBRN) agents and emerging infectious diseases, including pandemic influenza, that threaten the U.S. civilian population. BARDA encourages and facilitates the development and acquisition of medical countermeasures such as vaccines, therapeutics and diagnostics, as well as innovative approaches to meet the threat of CBRN agents and emerging infectious diseases, including pandemic influenza, in support of the mission and priorities of the HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) articulated in the PHEMCE implementation plan (http://www.hhs.gov/aspr/barda/phemce/enterprise/strategy/index.html). As part of its CBRN preparedness mission, BARDA announces a program to encourage advanced research and development aimed at medical countermeasures specifically addressing the hematopoietic and vascular syndromes resulting from acute exposure to ionizing radiation as from a potential bioterrorism act with radioactive materials or nuclear weapons. The increased threat of terrorism underscores the compelling need to develop improved treatments for protecting all segments of the civilian population, and specifically in this case, against radiation injury to the hematopoietic systems, especially neutropenia and thrombocytopenia, bone marrow progenitor cell and stromal cell loss, and vascular injury resulting from acute radiation injury.

HHS/ASPR/BARDA is using this BAA to advance the development of new therapeutics, including the development of new indications for already licensed therapeutics, as novel medical countermeasures for the treatment of large affected

populations who are acutely exposed to ionizing radiation as a result of a nuclear detonation, radiologic dispersive device (RDD; such as a "dirty bomb"), or other radiologic mechanisms, including deliberate contamination.

Specifically, HHS/ASPR/BARDA seeks to acquire developed medical countermeasures that will be clinically useful in a civilian medical emergency situation that results from or involves exposure of a large population to the effects of a nuclear detonation, an RDD, or exposure to ionizing radiation/ radioactive material with or without combined injury or trauma. The purpose of this BAA, entitled "**Therapies for Hematopoietic Syndrome, Bone Marrow Stromal Cell Loss, and Vascular Injury Resulting From Acute Exposure to Ionizing Radiation**", is to solicit proposals for research and development programs that focus on one or more of the following solicited research areas:

- **Research and Development Area 1**: the development of medical countermeasures that can replenish the normal hematopoietic profile, in whole or in part (i.e., treat neutropenia, lymphopenia and thrombocytopenia, etc.) following acute radiation exposure that induces lethal hematopoietic dyscrasias;
- **Research and Development Area 2**: development of medical countermeasures to replenish bone marrow niche and progenitor cells that normally populate the marrow stroma and niche environment and that can, following acute exposure to ionizing radiation that induces lethal hematopoietic dyscrasias, restore normal functioning hematopoietic cell lineages; or
- **Research and Development Area 3**: development of medical countermeasures that address injury to the vascular system induced following acute exposure to ionizing radiation, including changes in intimal integrity and clotting propensity, macrophage repair mechanisms and trafficking, vascular leak, endothelial repair, endovascular surface chemistry, alteration of angiogenesis, and other changes in anatomical or molecular pathology.

This BAA is to provide early development funding opportunities with the hope that some may progress sufficiently to allow BARDA the opportunity to acquire such products as medical countermeasures that can be approved by the Food and Drug Administration (FDA) to treat specific medical conditions resulting from exposure to ionizing radiation. It is therefore anticipated that research and development studies awarded from this BAA will advance therapeutic products toward eventual approval from the FDA for treatments of acute ionizing radiation injury affecting physiologic homeostasis of the hematopoietic and vascular systems.

Offerors are invited to submit proposals that request funding to advance the development of a promising therapeutic product that addresses one of the above three research and development areas. Offerors shall propose a well-defined product development path that must include completion of a Phase 1 clinical trial no later than three (3) years after contract award, unless Phase 1 is completed prior to contact award. The performance of studies in vertebrate animals and clinical studies must be consistent with all applicable Federal regulations and BARDA/NIH policies and guidelines for the conduct and oversight of research in vertebrate animals and human subjects. This announcement will also support post-Phase 1 product development activities in support of a New Drug Application (NDA) or a Biologic License Application (BLA), including:

1) Manufacturing scale-up supporting consistent lot-to-lot manufacturing.
2) Phase 2 clinical trials, if feasible and ethical.
3) Animal studies leading to pivotal animal efficacy studies required to support licensure under the U.S. Food and Drug Administration (FDA) "Animal Rule" (21 CFR 314.600-314.650, 601.90-601.95).

BARDA is interested in the development of advanced (in clinical trials) therapeutic products with the potential to be approved or licensed for ARS treatment indication, and is particularly interested in the development of ARS indications for already-approved or licensed therapeutics. BARDA is also interested in the development of novel preclinical evaluation technologies, i.e., replacement of the nonhuman primate as the gold standard for radiation injury, and the development of radiation injury therapeutics formulated for long-term stability, high bioavailability, simple dosing regimens, and acceptable safety in diverse populations.

Note: Offerors proposing the clinical testing of drugs, biologics, or other treatments that are already in an advanced stage of product development for the indication of ionizing radiation exposure rescue, such as treatments presently or previously in clinical testing or the re-evaluation of existing treatments in the context of biodefense, are encouraged to consider whether their proposal would be more applicable to BARDA's planned Request for Proposals entitled "Medical Countermeasures to Treat Neutropenia Arising as a Subset of the Hematologic Depression Resulting from Exposure to Ionizing Radiation" which can be accessed at the FedBizOpps web site at http://www.FedBizOpps.gov or, for further information, at http://www.medicalcountermeasures.gov.

Offerors may submit a proposal that addresses more than one of the three research areas if the proposal focuses on the development of a single product. However, Offerors may submit a maximum of one drug/biologic per proposal per

research area.

It is anticipated that the majority of studies in each of these areas will involve animal models. These studies are expected to be supported using Institutional Animal Care and Use Committees (IACUC) as required by the US Department of Agriculture (USDA). Radiation exposure studies exceeding occupational limits in normal human subjects are considered unethical and thus surrogate animal models will be used for documentation of efficacy using the Animal Rule (21 CFR 314 and 601).
The following types of proposals are not responsive to this initiative:

- The development of drugs or biologics intended solely for use prior to radiation exposure (prophylaxis),
- The development of drugs or biologics that must be administered within 24 hours of exposure to be effective,
- The development of next generation antibiotics and probiotics, blocking, decorporation, and purgative agents, antiemetics and other comfort or supportive measures,
- The development of therapeutics for the treatment of Gastrointestinal (GI) Syndrome, unless the therapy also addresses one or more of the research areas specifically addressed by the BAA,
- Proposals involving the development of animal models for mechanism discovery unless the models are directly relevant to the therapeutic product development, and,
- Phase 3 clinical trials.

Although the above mentioned research and development areas are not responsive to this announcement, they may be relevant to other BARDA or NIAID Biodefense research and development programs. A listing of such programs can be found on the BARDA web site http://www.hhs.gov/aspr/barda or the NIAID Biodefense funding website: http://www2.niaid.nih.gov/biodefense/research/funding.htm.

BARDA reserves the right to award all or any portion of the Statement of Work proposed based on technical merit, programmatic balance and priorities, and the availability of funds. Furthermore, BARDA recognizes that product development is an iterative process and that the progress of a product through the development pathway requires ongoing evaluation to assess and reassess the likelihood for the product to meet the desired therapeutic objectives. Furthermore, BARDA reserves the right to determine, at any time during the contract period, that a particular candidate therapeutic has not demonstrated sufficient potential to merit further investment by BARDA in the development and evaluation of that product. BARDA, therefore, reserves the right to terminate the contract or make changes as permitted by the contract.

BARDA is aware that no single organization or institution may have the expertise and facilities required to perform all parts of their SOW. Therefore, it may be necessary for the Offeror to subcontract a portion of the work. The Offeror shall be responsible for all work performed under this contract including that performed by any subcontractor(s).

SCOPE

It is anticipated that organizations selected under this BAA will have:

❖ **Identified a promising therapeutic**

For the purposes of this BAA, a promising therapeutic is defined as a single agent that meets the following criteria.

a) A drug (synthetic or natural product) or a biological product intended for use in post-ionizing radiation exposure mitigation, or treatment of neutropenia, progenitor cell and/or niche stromal cell loss, or vascular injury resulting from acute radiation exposure, that is effective when administered not earlier than 24 hours post-exposure, and is the type of agent that is within the regulatory purview of either the Center for Drug Evaluation and Research (CDER) or the Center for Biologics Evaluation and Research (CBER), U.S. Food and Drug Administration (FDA); and,
b) A single agent with demonstrated therapeutic activity in an appropriate animal model for at least one of the three solicited Research and Development Areas. "Therapeutic activity in an appropriate animal model" is defined as the ability of a drug/biologic to provide a statistically and significantly better outcome (i.e. survival improvement) versus relevant controls under well-controlled and documented experimental conditions, and,
c) An agent for which an IND has been filed with FDA for any indication more than 30 days before the Offeror submits its Final Proposal Revision, provided that, at the time of submission of the Final Proposal Revision, FDA has not placed the IND on clinical hold.

❖ **Devised a <u>Comprehensive</u> Staged Product Development Plan**

A Comprehensive Staged Product Development Plan is expected to <u>summarize</u>:

- The intended use or indication of the proposed therapeutic product
- The intended product profile (strength, quality, purity and identity)
- The performance specifications and features of the therapeutic product that provide therapeutic benefit
- A description of the therapeutic product as it is currently configured
- A description and developmental status of the assays for product release which provide characterization, strength, identity, and purity, as well as any needed bioassays for biologic activity and efficacy.
- Data to support the characterization and selection of the therapeutic product for further development. Specifically, a summary of data that demonstrates therapeutic activity in appropriate animal models and assays to address one of the three research and development areas. This includes: a detailed description of the assays and animal models, the radiation exposure (and method of radiation exposure standardization), rationale for the choice of animal model, as well as for the outcome/endpoints selected; documentation that the animal experiments were performed under well-controlled experimental conditions and data that support whether and how the therapeutic specifically addresses the research and development area.
- Discussions with CDER or CBER (FDA) reviewers that are relevant to development activities for the proposed therapeutic product, including plans for developing data to support an Investigational New Drug (IND), BLA or NDA. (Note: It is strongly advised that Offerors seek guidance from the FDA regarding the Animal Rule 21 CFR 314 or 601 as a surrogate for clinical studies where the design may be unethical for inclusion of human subjects.)

BARDA recognizes that the regulatory path to licensure for the proposed therapeutics may not be well defined. The regulatory requirements are likely to be defined in an iterative decision-making process with the appropriate CDER/CBER authorities, based upon the ongoing review of the product during the advanced development process and as specific product-related data emerge. Despite the uncertainty of the development process, the Offeror(s) shall provide a Staged Product Development Plan (Critical Path) to approval or licensure based on current data and/or discussions with the appropriate FDA Division (CDER or CBER) recognizing risks and areas of significant uncertainty. Risk mitigation strategies shall be included.

❖ **Devised a <u>Strategic</u> Staged Product Development Plan**

A <u>Strategic</u> Staged Product Development Plan is expected to <u>detail</u>:

- Activities and stages of product development that the Offeror is proposing to perform under contract funding.
- Distinct stages of the product development pathway that are gates for Go/No Go decisions for advancing to the next stage of the Strategic Staged Product Development Plan.
- The qualitative and quantitative criteria and accompanying data elements to be used to assess the scientific merit and technical feasibility of proceeding to the next stage of product development.

- Milestones and timelines for the initiation, conduct, and completion of product development activities for each stage with a budget (in direct costs) linked to each stage.
- If applicable, a description of product development platform technologies that are proposed to be employed within the Strategic Staged Product Development Plan. These technologies may address development timeframes and productivity, drug efficacy, specificity, safety and stability, delivery, etc. This description should clearly identify how the platform technologies will contribute to and improve the drug development process for the specific indication(s) proposed for development under this contract, as well as generally for other products.

Although it is the responsibility of the Offeror to propose a SOW, the types of product development activities that are within the scope of this BAA include:

Non-Clinical Research and Development
Product development activities in this area include:

a) Evaluate the safety, pharmacokinetics/pharmacodynamics (PK/PD), bioavailability, solubility, formulation, dose, route and schedule of the therapeutic product *in vitro* and in animal models following Good Laboratory Practice guidelines (GLP: as defined in the U.S. Code of Federal Regulations – 21CFR 58).
b) Develop, characterize, and qualify and/or validate reagents and assays required for the clinical and non-clinical evaluation of the therapeutic product.
c) Conduct animal studies to support the evaluation of therapeutic products where efficacy cannot ethically be evaluated in humans. Animal models should be developed in the context of the anticipated indication for which the therapeutic product is being developed.

Manufacturing of Therapeutics
Product development activities in this area include:

a) Develop a Drug Master File (DMF) or Biologics Master File (BB-MF) under current Good Manufacturing Practice guidelines (cGMP: as defined in the U.S. Code of Federal Regulations – 21CFR 314.420).
b) Process development for the manufacture of therapeutic product consistent with cGMP.
c) Manufacture of pilot lots of therapeutic product in amounts sufficient to carry out proposed non-clinical and clinical trials.
d) Formulation of Final Drug Product (FDP).
e) Preparation of and packaging of FDP.
f) Conduct of long-term stability studies of cGMP bulk and FDP.

Phase 1 Clinical Evaluation
Product development activities in this area include:

a) Design a Phase 1 clinical trial to evaluate the safety and pharmacokinetics of the therapeutic product in humans.
b) Prepare and submit an IND application to the U.S. FDA.
c) Conduct a Phase 1 clinical trial in accordance with all federal guidelines, Good Clinical Practice guidelines (GCP: as defined by 21 CFR 312 and ICH Guidelines document ICH E6 (http://www.pharmacontract.ch/support/su_ich_liste.htm). The Phase 1 clinical trial report is to follow the format of International Conference on Harmonization document ICH E3 "Guidelines on Structure and Content of Clinical Study Reports" (http://www.pharmacontract.ch/support/su_ich_liste.htm).

Post-Phase 1 NDA- or BLA-Supporting Activities
Product development activities in this area include:

a) Conduct manufacturing scale-up supporting consistent lot-to-lot manufacturing of the therapeutic product.
b) Design and conduct a Phase 2 clinical trial, if ethical and feasible, in accordance with all Federal regulations and guidelines, Good Clinical Practice guidelines (GCP: as defined by 21 CFR 312 and ICH Guidelines document E6 (http://www.pharmacontract.ch/support/su_ich_liste.htm).
c) Contractor shall create a Target Product Profile (TPP) which will be further defined through discussion and negotiation with the Project Officer

RESEARCH AND TECHNICAL OBJECTIVES

Independently, and not as an agent of the USG, the Offeror shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities, not otherwise provided by the USG under the terms of this contract, as needed to provide the services delineated in the negotiated SOW. The specific components of the SOW and the scope of the product development activities to be undertaken will depend on the status of the individual therapeutic product as part of an overall Strategic Staged Product Development Plan, as well as regulatory requirements. The Offeror shall carry out activities within the contract SOW only as requested and approved by the Contracting Officer, and may not conduct work on the contract without prior approval from the Contracting Officer. Approval to carry out specific activities will be linked to approval by the Project Officer of the Strategic Staged Product Development Plan following contract award, approval of monthly and quarterly Progress Reports, review and approval of Clinical Trial Protocol(s) and supporting materials (see reporting requirements for a description of these reports).

The experimental objectives, approaches, methodology, possible outcomes and alternatives, as well as the personnel, percent of effort, specific duties, work location, supervision, lines of authority, and available equipment, facilities, and other resources should be described separately for each of the research areas. When preparing proposals in response to this BAA, the Offeror must follow the format described in Attachment 3 "Additional Technical Proposal Instructions."

Offerors shall provide the following information for each proposal:

- *Experimental Design*. A detailed description of the experimental design (including the design of any human tissue sample studies), the rationale for experimental approaches, and a description of alternative approaches to be employed if these methods do not achieve the defined goals, is required.

- *Project Plan and Milestones.* The Comprehensive Staged Product Development Plan, i.e., Project Plan (Work Plan) shall include scientific, technical and administrative processes to achieve the goals of the contract. The Plan shall include milestones of the research and development program, including risk identification and mitigation, and time-line implementation of milestones. Milestones, and the expected timelines for achieving each milestone, will be used to assess progress in the product development of the medical countermeasure. The first year Work Plan shall be in sufficient detail to allow for monitoring the success of the research and development project over that interim. Years two and three may be less specific. Program Meetings (see below for description of Program Meetings) shall be incorporated into the Work Plan. An update to the Work Plan is required quarterly and will be part of the Quarterly Reports and the Annual Report.

- *Strategic Staged Product Development* The Offeror shall prepare and implement a Strategic Staged Product Development Plan to advance the therapeutic product along a well-defined development path leading to a therapeutic product suitable for testing in humans in a Phase 1 clinical trial and/or for post-Phase 1 NDA- or BLA-enabling activities within the maximum three (3)-year period of the contract award. The Offeror shall perform all technical, regulatory, management, and administrative activities that are required to implement the Strategic Staged Product Development Plan. In addition, these efforts shall lead to the creation of the Target Product Profile (TPP), which shall be defined by the Project Officer.

  Within fourteen (14) days of the effective date of the BAA award, the Offeror shall submit an updated Strategic Staged Product Development Plan and Work Plan. The Strategic Staged Product Development Plan and Work Plan shall be approved by the Project Officer and the Contracting Officer prior to initiation of any activities related to their implementation. The report shall contain:

  a) Sufficient detail, documentation and analysis to support successful completion of the stage according to the predetermined qualitative and quantitative criteria that have been established for *Go/No Go* decision-making
  b) Costs to complete the stage.
  c) A description of the next stage of product development to be initiated, a revised Work Plan, if necessary, an updated budget and a request for approval to proceed to the next stage of product development.

  In response to a need to change the Strategic Staged Product Development Plan (the Work Plan), the Offeror shall submit a Deviation Report. This report shall request a change in the agreed Work Plan and timelines. This report shall also include:

  a) Discussion of the justification/rationale for the proposed change.

b) Options for addressing the needed changes from the approved timelines, including a cost-benefit analysis of each option.
c) Recommendations for the preferred option that includes a full analysis and discussion of the effect of the change on the entire product development program, timelines, and budget.

- *Regulatory Compliance* As required for the implementation of the Strategic Staged Product Development Plan, the Offeror shall:

a) Be responsible for the regulatory aspects of the development and implementation of data management and quality control systems/procedures, including the transmission, storage, confidentiality, and retrieval of all study data.
b) Provide for the statistical design and analysis of data resulting from the research undertaken.
c) Provide raw data or specific analyses of data generated with contract funding to the Project Officer.
d) Ensure strict adherence to FDA regulations and guidance, including requirements for the conduct of animal studies and assays under GLP, the manufacturing of the therapeutic product under cGMP, and the conduct of clinical trials under GCP standards. The Offeror shall maintain quality assurance documentation to support adherence in these areas.
e) Arrange for independent audits, as needed or as requested by the Project Officer and as concurred by the Contracting Officer. Audits may be requested to assure that Offeror and/or sub-Offeror facilities and all planned procedures comply with the FDA regulations and guidance that are required to meet GLP, cGMP and GCP standards. In addition, the Offeror shall ensure that all Offeror and/or sub-Offeror records and staff are available for site visits or audits. The Offeror shall provide interim and final audit reports to the Project Officer and the Contracting Officer within thirty (30) calendar days of the completion of the audit. BARDA reserves the right to conduct independent audits of the Offeror and its sub-Offerors as needed to evaluate compliance with the FDA regulations and guidance, including those required to meet GLP, cGMP or GCP standards. Such audits may also be conducted prior to contract award as a part of the technical evaluation of the Offerors' Technical Proposal.
f) Comply with FDA regulations and guidance for preparation, format, and submission of all regulatory documents to the FDA.
g) Comply with the NIH Guidelines for Research Involving Recombinant DNA molecules.
h) Provide data-extractable electronic media copies of all contract-generated regulatory documents to BARDA.

- *Radiation Controls and Safety* The Offeror must describe the conditions of use and disposal of radioactive materials anticipated to be used in any of the BAA funded activities as well as operational safety, controls and standardization of devices used for radiation measurement and exposure. The Offeror shall provide evidence of Federal, State and Local health and safety regulatory compliance as well as evidence of holding appropriate institutional license(s) from regulatory authorities and documentation of oversight from a Radiation Safety Committee. This shall also be required of all subcontracted work.

- *Animal Model Studies*. The rationale for proposed animal model studies and a detailed description of their relevance to human radiation injury shall be provided. Offerors proposing an animal model shall comply with all required guidelines for animal welfare. BARDA currently uses the guidelines employed at NIH as found in: http://grants1.nih.gov/grants/funding/phs398/section_1.html#f_vertebrate_animals. An approved Plan for animal care and use is required of all Offerors and each must provide evidence of an ongoing and active Institutional Animal Care and Use Committee (IACUC) with USDA oversight of the facilities. AAALAC certification is a plus.

- *Care of Vertebrate Animals*

a) Before undertaking performance of any contract involving research on live, vertebrate animals, the Contractor shall register with the Secretary of Agriculture of the United Sates in accordance with 7 U.S.C. 2316 and 9 CFR Section 2.30. The Contractor shall furnish evidence of such registration to the Contracting Officer.

b) The Contractor shall acquire animals used in research from a dealer licensed by the Secretary of Agriculture under 7. U.S.C. 2131-2157 and 9 CFR Sections 2.1-2.11, or from a source that is exempt from licensing under those sections.

c) The Contractor agrees that all research involving live, vertebrate animals shall be conducted in accordance with applicable local, state, federal (including 21 CFR 58), or other regulations and policy on humane care and use of laboratory animals.

d) If at any time during performance of this contract, the Contracting Officer determines that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) through (c) above, the

Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may terminate this contract in whole or in part.

- *Data Management*. Data created from this contract shall be stored and managed at the Offerors' site in a Laboratory Management System controlled and maintained by the Offeror, in consultation with the Project Officer. The Database Management System (DMS) shall be commercially available, documented, and supported by a relational database management system.

- *Security Systems and Security Plan.* The Offeror shall provide security systems, firewalls, and computer virus detection systems to be used to ensure database integrity and security. The local database at each Offeror site will contain, at a minimum: a) raw data and original results, and, b) detailed experimental protocols. To ensure database integrity and interoperability, the Offeror shall include bioinformatics experts, in consultation with and approved by the Project Officer, in the research and development team. Key bioinformatics team members shall participate in the annual meetings (described below) in special sessions to define and execute standard operating procedures (SOPs) for data management and analysis. Additionally, during the life of the contract, the Offeror may be required to submit data to a centralized database developed and maintained by BARDA information technology personnel. After contract award, the Project Officer and a BARDA-IT representative will work with the successful Offeror(s) to develop a process for data submission to the BARDA-IT maintained database.

- *Clinical Studies and Associated Clinical Trials*

a) *Human Subjects*

Research involving human subjects shall be conducted in accordance with FDA's regulations governing INDs and human subject research, and shall not be conducted under the contract until the protocol has been approved by HHS, written notice of such approval has been provided by the Contracting Officer, and the Contractor has provided to the Contracting Officer a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

When research involving Human Subjects will take place at collaborating sites or other performance sites, the Contractor shall obtain, and keep on file, a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the research.

b) *Protection of Human Subjects*

i. No contract involving human subjects research shall be awarded until acceptable assurance has been given that the project or activity will be subject to initial and continuing review by an appropriate institutional review committee(s) as described in 45 CFR Part 46. Contracts involving human subjects will not be awarded to an individual unless the individual is affiliated with or sponsored by an institution has an Office for Human Research Protections (OHRP) approved assurance of compliance in place and will assume responsibility for safeguarding the human subjects involved. The OHRP web site is: http://www.hhs.gov/ohrp. The Offeror further agrees to provide certification at least annually that the institutional review board (IRB) has reviewed and approved the procedures which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.

ii. The Offeror shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract in a proper manner and as safely as is feasible. The parties hereto agree that the Offeror retains the right to control and direct the performance of all work under this contract. Nothing in this contract shall be deemed to constitute the Offeror or any subcontractor, agent or employee of the Offeror, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Offeror agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent Offeror without imputing liability on the part of the Government for the acts of the Offeror or its employees.

iii. If at any time during performance of this contract, the Contracting Officer determines, in consultation with the OHRP, that the Offeror is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under the contract until the Offeror corrects such noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing.

iv. If the Offeror fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, in consultation with OHRP, terminate the contract in whole or in part, and the Offeror's name may be removed from the list of those Offerors with approved Health and Human Services Human Subject Assurances.

c) *Offeror Requirements*

i. Comply with all Federal and HHS Clinical Terms of Award, BARDA's Clinical Terms of Award mirror those of NIAID (http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf).
ii. Prior to study initiation (or subsequently with respect to amendments), submit to the BARDA Project Officer, for review and approval by the appropriate BARDA review committee, all clinical trial protocols and supporting documentation (e.g., sample informed consent forms, Investigators Brochure (s) (IB), case report forms, manuals of procedures, site quality management plan, data management plan, safety oversight plan and local Institutional Review Board committee approvals). Monitoring Plans are subject to approval by the Project Officer.
iii. Obtain final approval of all anticipated clinical protocols from the Project Officer prior to submission of an FDA IND, and prior to any trial's participant enrollment.
iv. Serve as the Product Sponsor with responsibility for:
- Preparing materials for, and request, schedule, and participate in all meetings with the FDA (CDER/CBER), including meetings to review IND, NDA, and BLA packages.
- Submitting all documentation to the FDA in a timely manner, consistent with timelines set out in the contract and by the FDA.
- Including BARDA staff, as designated by the Project Officer, in meetings and teleconferences with the FDA.
- Providing copies of all FDA correspondence and meeting minutes that are relevant to the therapeutic product to the BARDA Project Officer.

Although Phase 3 clinical trials will not be funded under this program, the IRB-approved protocol(s) and the Investigators' Brochure(s) (IB) for any parent or core clinical trial(s), e.g., a source for data or materials for the proposed studies, shall be included with the proposal as part of the human subjects section. Drafts of proposed clinical trial informed consent form(s), if available at the time of the proposal submission, should be included as examples.

In order to ensure coordination between the proposed studies and any parent or core clinical trial(s), the Offeror of the parent or core clinical trial (note: often referred to as "Sponsor") shall have a written agreement regarding the conduct of the studies presented in this proposal. Prior to award, the Offeror shall provide to BARDA a "Memorandum of Understanding" signed by the Offeror, an appropriate representative of the applicant institution, the principal investigator of the parent or core clinical site, or core clinical trial site(s), and an appropriate representative of the Offeror attending to the parent or core clinical trial site(s). The Memorandum shall outline the specifics of the agreement between the parties with respect to the following areas:

i. Nature of the biological specimens and the access controls;
ii. Timing and manner of access to data produced by the parent or core clinical trial site(s) that will be used in the proposed studies, including procedures for the prevention of unblinding of the parent trial should blinding be required;
iii. Ownership, analysis, and release of data resulting from the proposed studies;
iv. Documentation of quality assurance procedures for both the parent trial and the proposed studies;
v. Documentation of data and safety monitoring procedures for the parent trial, especially for efficacy trials;
vi. Ownership of intellectual property developed during the proposed studies; and
vii. Publication of the results of the proposed studies.

d) *Human Materials*. Descriptions of any human tissue and/or clinical samples or data to be used in the proposed studies, including how human subjects shall be protected from research risks and justification for the ethnic, gender, and age compositions of the human populations chosen for analysis, is required. BARDA is utilizing and requiring compliance with all NIH guidelines for human subjects research as found in: http://grants1.nih.gov/grants/funding/phs398/section_1.html#e_humansubs. Descriptions of human use shall be

sufficiently detailed to allow the Technical Evaluation Panel to determine the feasibility and appropriateness of the proposed experimental approaches.

It is understood that the acquisition and supply of all human specimen material (including fetal material) used under the resultant contract will be obtained by the Contractor in full compliance with applicable Federal, State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States and that no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

- *Scientific, Technical, Management and Administrative Team* The Offeror shall provide all expertise needed for the implementation of the Strategic Staged Product Development Plan to be performed under the contract, including: research, manufacturing, regulatory, clinical, statistical, management, and administrative activities. The Offerors' team must include strong scientific leadership, as well as experience and expertise in the management, design and execution of a research and development program focused on product development, manufacturing, and testing in humans and in vertebrate animals. The Principal Investigator (PI) shall be responsible for all aspects of project performance and communication with the Project Officer and the Contracting Officer. In addition, the Offeror shall provide a Project Manager who is responsible for the day-to-day monitoring and tracking of progress and timelines, the coordination of project activities and costs incurred.

- *Facilities, Equipment and other Resources* The Offeror shall provide the equipment, facilities, training and other resources required to implement the SOW and the Strategic Staged Product Development Plan in compliance with all Federal regulations. Depending on the stage of development of the therapeutic product, this may include:

  a) The performance of IND-enabling assays and animal studies under GLP.

  b) Production, characterization and release testing of therapeutic agent under cGMP conditions.

  c) Performance of clinical trial(s) in humans under GCP.

  d) The humane care and use of vertebrate animals with IACUC and USDA oversight

  e) The handling, storing and shipping of radioactive agents and radiologic devices. In terms of radiologic operations, BARDA expects operational standards for handling radioactive material, radiologic devices and radioactive waste to be managed under environmental health and safety practices that follow, for example, the guidance of the Department of Energy's Lawrence Berkeley Laboratory Environmental Health and Safety Publication 3000 (http://www.lbl.gov/ehs/pub3000/CH21.html#_Toc407168416) as well as relevant Federal, State and local laws.

  f) The handling and disposal of potentially dangerous biological and chemical agents. These activities shall require Biosafety practices and procedures as described in Biosafety in Microbiology and Biomedical Laboratories, 4th ed., which is available at: http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm. In addition, and if the Offerors propose using Select Agents as named by the Centers for Disease Control and Prevention (CDC) Select Agent Program, the Offerors shall refer to: http://www.cdc.gov/od/sap.

The Offeror is required to undertake all studies with documentation of approvals from all Institutional biosafety, radiologic and animal oversight committees. At the request of the Project Officer, the Offeror shall provide copies of all notes, letters and materials submitted to and from all such committee reviews. Documentation of all approvals of experiments, protocols and procedures shall be copied and forwarded to the Project Officer for retention in the Project File at BARDA.

- *Possession, Use and Transfer of Select Agents or Toxins*. The contractor will not conduct any work involving Select Agents or toxins under this contract until the contractor and any associated subcontractor(s) comply with the following requirements:

a) For prime or subcontract awards to US companies or institutions that will possess, use, and/or transfer Select Agents under this contract: The prime and/or subcontractor must comply with the provisions of 42 CFR Part 73, 7 CFR Part 331, and/or 9 CFR Part 121, as required, before using BARDA funds for any work involving Select Agents. BARDA funds cannot be used for any work associated with Select Agents if the CDC or USDA denies the final registration certificate authorizing work with Select Agents or Toxins.

b) For prime or subcontract awards to **foreign** companies or institutions that will possess, use, and/or transfer Select

Agents under this contract: Before using BARDA funds for any work directly involving the Select Agents or Toxins, the foreign company or institution must meet the safety, security, and training standards equivalent to those described in 42 CFR Part 73, 7 CFR Part 331, and/or 9 CFR Part 121. The contractor or and/or subcontractor must submit a written security plan that meets the requirements of 42 CFR Part 73, 7 CFR Part 331, and/or 9 CFR Part 121 and is sufficient in scope to safeguard Select Agents or Toxins against unauthorized access, theft, loss or release. The foreign company or institution will not use any Select Agents or Toxins associated with this contract until approved by BARDA. Prior to allowing a foreign company or institution to work with Select Agents or Toxins, BARDA must determine that appropriate security measures, as outlined in the company's security plan, are in place. This determination will include an inspection of the foreign facility by a BARDA representative. During this inspection, the contractor must provide the following information: concise summaries of safety, security, and training plans; names of individuals who will have access to the Select Agents, and procedures for ensuring that only approved and appropriate individuals will have access to the Select Agents under the contract. The contractor will also provide copies of or links to any applicable laws, regulations, policies, and procedures applicable to the contactor that provide for the safe and secure possession, use, and/or transfer of Select Agents or Toxins. BARDA will coordinate with the CDC, the US Department of Justice, and/or other federal law enforcement or intelligence agencies prior to making a final determination on allowing the contractor to use BARDA funds for any research involving Select Agents or Toxins. BARDA will make the approval decision and notify the Contracting Officer. The BARDA Contracting Officer will inform the prime contractor of the approval status of the foreign institution.

c) Listings of HHS select agents and toxins, and overlap select agents or toxins as well as information about the registration process for domestic institutions, are available on the Select Agent Program Web site at http://www.cdc.gov/od/sap/ and http://www.cdc.gov/od/sap/docs/salist.pdf. Listings of USDA select agents and toxins as well as information about the registration process for domestic institutions are available on the APHIS/USDA website at http://www.aphis.usda.gov/programs/ag_selectagent/index.html and http://www.aphis.usda.gov/programs/ag_selectagent/ag_bioterr_forms.html. For foreign institutions, an approach similar to the NIAID Select Agent Award information (http://www.niaid.nih.gov/ncn/clinical/default_biodefense.htm) will be employed.

- *Project Meetings*. Each Contractor shall participate in Program meetings organized by the BARDA Project Officer to foster collaborations and the exchange of ideas among the participating researchers. These Program meetings will be held twice in the first year of the contract and once a year thereafter in or near Washington, DC for 1.5 days unless otherwise determined by the Project Officer.

  The Project Officer and Contracting Officer shall attend this meeting. Other relevant NIH and BARDA staff may attend including the Program Manager, other key investigators, key subcontracting staff and other key research personnel up to a maximum of two individuals per contract with prior approval by the Project Officer. In addition there will be a bioinformatics session that will be attended by up to two key bioinformatics staff members (additional to the two key research personnel). The purpose of the bioinformatics session will be to facilitate data sharing between different contractors and to share possible solutions to common problems that may occur with data management.

REPORTING REQUIREMENTS AND DELIVERABLES

Some reports and other deliverables are relevant to specific activities that may or may not be performed during the contract period of performance. The Contractor, the Project Officer and the Contracting Officer shall agree in the final contract negotiations on which reports and other deliverables are relevant and shall be required as deliverables as determined by the negotiated Statement of Work (SOW).

As part of the work to be performed under this BAA, the Contractor shall prepare and deliver the following reports throughout the period of performance. For all reports the Contractor shall submit two (2) paper copies and one (1) electronic copy to the Project Officer and one (1) electronic copy to the Contracting Officer.

A. PROGRESS REPORTS

1. Monthly, Quarterly and Annual Technical Progress Reports
The Contractor(s) shall provide written monthly, quarterly and annual reports of project activities, budget changes and projections of costs, personnel actions in the period of the report, and vendor/subcontractor activities that are conducted by way of the contract to the Contracting Officer and Project Officer.

The Contractor shall submit two (2) copies of the Monthly, Quarterly and Annual Technical Progress Reports on the 15th of the month following the end of each month, 3 months (90 calendar days), and 12 month performance period, respectively. The original shall be submitted to the Contracting Officer with one copy submitted to the Project Officer. Each Monthly, Quarterly and Annual Technical Progress Report shall include the following:

A. Face page, to include the contract number, contract title, performance period covered, Contractor's name and address, telephone number, fax number, email address, the author(s) and any other contact information, and the submission date. In addition provide a brief introduction covering the purpose and scope of the contract effort.

B. Executive summary shall be formatted in Microsoft PowerPoint to include:

- An overview of the status of the project, including adherence to timelines, since the previous reporting period and specific milestones achieved;
- An overview of the activities conducted during the current reporting period, including test results, tasks and other activities achieved, any problems that occurred (technical or financial) and justification for any failure to complete the intended work, as well as any work that was performed beyond that initially planned;
- The extent to which the goals and specific objectives set forth in the SOW were fulfilled.
- Present project issues as headings with each item a talking point bullet.

C. Progress Report, to include a detailed description of:

- The work performed during the reporting period and a brief description of the work proposed for the next reporting period toward Research and Development Area 1, the development of therapies for myeloid lineage repair following ionizing radiation, or, Research and Development Area 2, the development of one or more treatments for progenitor cell repair following acute radiation exposure, or Research and Development Area 3, the development of therapies to counteract the effects of radiation on the vascular system;

- A full disclosure of the results obtained and their relevance, explanations of any differences between planned and actual progress, and, if necessary, what corrective steps are planned or have been implemented to achieve the goals and objectives of the contract;

- A regular update to the Project Plan. The Contractor shall update the milestones of the research program and time-line implementation of milestones for aim/goal/ data and their intermediates for the upcoming 2 quarters, highlighting (in color, bold, italic, etc.) any changes in the previously reported Plan. Alterations in the Plan shall be sufficiently outlined and justified;

- A summary of the meetings, conference calls, and workshops that have taken place during the reporting period. This report shall include the slide presentations and all other meeting materials as well as summaries of all discussions.

•Distribution List-A list of persons receiving the Technical Progress Reports;

•Attachments-Results or protocols developed on the project shall be provided as attachments;

• Annual Technical Progress Report-In addition to the requirements above, the Annual Technical Progress Report shall require the Contractor to update the Project Plans' milestones of the research program and time-line implementation of milestones for aim/goal/ data and their intermediates for the upcoming 4 quarters, highlighting (in color, bold, italic, etc) any changes in the previously reported Plan. Alterations in the Plan shall be sufficiently outlined and justified. Additionally, the Contractor shall update any changes in milestones and plans for the remaining years of the project.

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

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

F. An update of the status of the Intellectual Property Rights Plan shall be provided;

G. A Quarterly Technical Progress Report is not required for the period in which an Annual Technical Progress Report or a Final Report is due;

H. A Monthly Technical Progress Report is not required for the period in which a Quarterly, Annual or a Final Technical Progress Report is due.

2. Draft and Final Report of the Contract

This report is to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Final Report shall be submitted in accordance with the table in Attachment 16. An annual report will not be required for the period when the Final Report is due. This report shall be submitted one week before the completion date of the contract. The Final Report shall include the following:

A. Face page, to include the contract number, contract title, performance period covered, Contractor's name and address, telephone number, fax number, email address, the author(s), and any other contact information, and the submission date;

B. Introduction covering the purpose and scope of the contract effort, including a summary of salient results obtained during the entire performance period. The summary shall not exceed 200 words;

C. Executive summary, to include an overview of the activities conducted during the contract period and the extent to which the goals and specific objectives set forth in the proposal were fulfilled; and

D. A detailed description of the work performed, results obtained, relevance of the results, relation between the results and work in the research area being conducted by other groups, and impact of the findings on the scientific community (based on annual meetings, training sessions, and community feedback).

Draft Final Technical Progress Report: The Contractor is required to submit the Draft Final Technical Progress Report to the Project Officer and Contracting Officer. This report is due 120 calendar days before the completion date of the contract. The Project Officer and Contracting Officer will review the Draft Final Technical Progress Report and provide the Contractor with comments within 45 calendar days after receipt.

Final Technical Progress Report: The Contractor will deliver the final version of the Final Progress Technical Report as specified in the table in Attachment 16.

B. TECHNICAL REPORTS

1. Final Reports for Clinical and Non-Clinical Studies

- The non-clinical and clinical trial reports shall follow the format of International Conference on Harmonization document ICH E3 "Guidelines on Structure and Content of Clinical Study Reports" (http://www.pharmacontract.ch/support/su_ich_liste.htm).
- Draft Final Reports will be submitted to the Project Officer and Contracting Officer (CO) for review and comment no later than 15 working days after the end of the performance period.
- The Contract Officer shall provide written comments within 30 working days after the submission of the Draft Final Report.
- The comprehensive Final Report will be submitted to the Contracting Officer and the Project Officer within 30 calendar days after receiving comments on the Draft Final Report from the Contracting Officer.

2. Audit Reports

Within thirty (30) calendar days of an audit related to conformance to FDA regulations and guidance, including adherence to GLP, GMP, or GCP guidelines, the Contractor shall provide copies of the audit report and a plan for addressing areas of nonconformance to FDA regulations and guidance for GLP, GMP or GCP guidelines as identified in the final audit report.

3. Clinical Trial Protocols

BARDA has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in BARDA-funded clinical trials. Therefore, as described in the NIAID Clinical Terms of Award (http://www.niaid.nih.gov/ncn/pdf/clinterm.pdf), the Contractor shall develop a protocol for each clinical trial and submit all protocols and protocol amendments for approval by the BARDA Project Officer. Important information regarding performing human subjects research are available at http://www3.niaid.nih.gov/healthscience/clinicalstudies/).

The updates are to be included in the Monthly, Quarterly and Annual Technical Progress Reports. The Contractor shall advise the Project Officer or designee in writing and via electronic communication in a timely manner of any issues potentially affecting contract performance.

C. OTHER REPORTS/DELIVERABLES

1. Copies of FDA Correspondence and Meeting Summaries

Within thirty (30) calendar days of receiving correspondence or meeting with the FDA, submit appropriately formatted electronic copies of the correspondence or meeting minutes/summaries to the BARDA Project Officer.

2. Technology Transfer

Animal Models and other technology packages developed under this contract that include complete protocols and critical reagents for animal models developed and/or improved with contract funding must be submitted at the request of the BARDA Project Officer.

3. Institutional BioSafety Approval

The Contractor shall provide documentation of materials submitted for Institutional Biosafety Committee Review and documentation of approval of experiments at the request of the BARDA Project Officer.

4. Data

The contractor shall provide raw data or specific analysis of data generated with contract funding at the request of the BARDA Project Officer.

D. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11, including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, shall be directed to the Extramural Inventions and Technology Resources Branch, OPERA, NIH, 6705 Rockledge Drive, Room 1040-A, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, due on the expiration date of the contract, shall be submitted to the Contracting Officer.

All reports shall be sent to the following address:

Contracting Officer
David Beck
Biomedical Advanced Research and Development Authority
330 Independence Avenue, S.W.
Room G640
Washington, D.C. 20201

If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer at the address listed above.

To assist contractors in complying with invention reporting requirements of the clause, "Interagency Edison," an electronic invention reporting system, has been developed. Use of Interagency Edison is encouraged as it streamlines the reporting process and greatly reduces paperwork. Access to the system is through a secure interactive Web site to ensure that all information submitted is protected. Interagency Edison and information relating to the capabilities of the system can be obtained from the Web (http://www.iedison.gov), or by contacting the Extramural Inventions and Technology Resources Branch, OPERA, NIH.

EVALUATION FACTORS FOR AWARD

1. GENERAL

Selection of an Offeror for contract award will be based on an evaluation of proposals. The evaluation factors in decreasing order of importance are: technical, BARDA program priorities, cost/price, past performance, and Small Disadvantaged Business (SDB) participation. Although technical factors are of paramount consideration in the award of the contract, BARDA program priorities, cost/price, past performance, and SDB participation are also important to the overall contract award decision. All evaluation factors other than cost or price, when combined, are significantly more important than cost or price.

In addition, prior to award, the Offeror's proposal must be considered acceptable for use of human subjects, animal welfare, the use of radioactive materials and ionizing radiation sources anticipated to be used in any of the BAA funded activities, as well as operational safety, controls and standardization of devices used for radiation measurement and exposure, and select agents. In addition, for an Offeror (other than a small business concern) to be selected for award, the Subcontracting Plan required by FAR 52.219-9 must be acceptable. Technical activities must correspond directly to cost/price in the business proposal. The trade off process described in FAR 15.101-1 may be employed. This process permits trade offs among cost/price and non-cost factors and allows the USG to consider award(s) to other than the lowest priced or highest technically rated Offeror. In any case, the USG reserves the right to make an award(s) to that Offeror whose proposal provides the best overall value to the USG.

All technical proposals will undergo evaluation by a Technical Evaluation Panel (TEP). Final selection of awards will depend upon the availability of funds, technical evaluation, past performance, SDB participation, cost/price, and program priorities that BARDA determines to exist at the time of award selection.

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

Offerors must demonstrate in their proposals that they have the necessary expertise and capabilities for conducting the research and development as requested by this BAA. Offerors determined, upon completion of the Technical Review, to be in the Order of Merit Ranking may be subject to auditing of their GLP, cGMP, GCP and QMS capabilities. The decision to audit specific facilities will be made by the Project Officer. If audits are performed during the negotiations, the results of the audits will be a factor in final selection for award of a contract. Offerors, including proposed subcontractors, will be requested to make all records, including previous regulatory inspection reports, and staff, available in response to a pre-award site visit or audit by BARDA or its designee.

2. TECHNICAL EVALUATION CRITERIA

The evaluation criteria are used by the Technical Evaluation Panel (TEP) when reviewing the technical proposals. The criteria below are listed with weights assigned for evaluation purposes.

It is the intention of this BAA to provide a funding vehicle for Offerors to advance their lead candidate products in the development pipeline. The lead candidate must be developed under this BAA to eventually serve as an MCM for injuries sustained from exposure to ionizing radiation. Advanced development funding from BARDA will assist selected candidate products through Phase 2 and not higher.

EVALUATION CRITERIA	**WEIGHT**
CRITERION 1: **Development Stage and Readiness**	**(20 points)**
Development Stage and Readiness	
a) An IND has been filed for any indication	(**10 points**)
b) Offeror has initiated or completed a human Phase 1 trial with the product	(**7 points**)
c) Offeror has initiated or completed a human Phase 2 trial with the product	(**3 points**)

CRITERION 2: **Statement of Work and Strategic Plan** (**40 points**)

2.A. Proposed Statement of Work (SOW) **(20 points)**

The Offerors' proposed Statement of Work shall be measured as follows:

a) The Statement of Work overall content measured in terms of clarity of project objectives, level of detail, linking and flow of tasks, and overall achievability with respect to resources, state of the science and time. (**5 Points**)

b) The itemization of the deliverables, milestones and decision points to achieve a product level of development to Phase 3 studies (**4 Points**)

c) The clarity of the Statement of Work in describing all necessary activities, timelines, services, personnel, materials, equipment and facilities, inclusive of subcontracting activities, used in the performance of the proposed Work Plan (**3 points**)

d) The soundness and feasibility of the Comprehensive Staged Product Development Plan (i.e. identity of all standard and unique project-specific actions and processes, the respective order of operations and precedence, staffing, time management, manufacturing, non-clinical and clinical studies, regulatory obligations, etc) for advancing the therapeutic product toward a Phase 3 program (**2 Points**)

e) The soundness and feasibility of the Strategic Staged Product Development Plan (i.e., development strategy to satisfy a market demand, development time, and operational requirements) for advancing the therapeutic product toward a Phase 3 program (**2 Points**)

f) The feasibility of completing a Phase 1 clinical trial and producing the Final Clinical Study Report within the three (3)-year contract period (if a Phase 1 clinical trial has not already been completed at the time of review), or, the feasibility of completing a Phase 2 clinical trial or Animal Rule study and producing the Final Clinical (Animal Rule) Study Report within the three (3)-year contract period (if a Phase 2 clinical trial or Animal Rule study has not already been completed at the time of review). (**2 Points**)

g) The soundness, feasibility, suitability and completeness of the proposed Work Plan "Go/No Go" evaluations of the therapeutic product, including the qualitative and quantitative criteria to be used to reach "Go/No Go" decisions at the various stages of product development and the budget for each stage of product development. (**2 Points**)

2.B. Implementation of the Strategic Staged Product Development Plan **(20 points)**

Offerors shall provide evidence that

a) The technical methods proposed in the Work Plan are sound, appropriate and feasible (e.g. non-clinical studies, medicinal chemistry, manufacturing, assay development with soundness of the assays described, animal model development, performance of animal studies, clinical evaluation, NDA or BLA-enabling activities). (**4 Points**)

b) The suitability and adequacy of the plans for QMS (quality management system; e.g., quality control and quality assurance) and data management for the conduct of activities proposed in the Work Plan. (**3 Points**)

c) The feasibility of performing the proposed activities within the stated timelines for initiation, conduct, completion and analysis of data. (**3 Points**)

d) The suitability and feasibility of the plans for modifying the Strategic Staged Product Development Plan based on adverse experimental or production results, or on new scientific findings along the development path. (**2 Points**)

e) Adequacy of the plan to communicate and meet with the FDA and to share FDA communications with the Project Officer. (**2 Points**)

f) Adequacy of previous experience of the Offeror, and any proposed subcontractors, in conducting studies in compliance with GLP, cGMP and GCP guidelines as documented by the Offeror with audit histories and reports. (**2 Points**)

g) Adequacy of the plan to conduct audits of facilities and maintain compliance with GLP, cGMP, and/or GCP guidelines, where appropriate, and the inclusion of letters allowing pre-award site visits to Offeror and subcontractor facilities. (**2 Points**)

h) The adequacy of the clinical trial Protocol Synopsis and documented corporate (or subcontracted) clinical experience in performing human subjects research in accordance with the Code of Federal Regulations for the conduct of human trials or the adequacy of

the Animal Rule Protocol Synopsis and documented corporate (or subcontracted) non-clinical experience in performing Animal Rule pivotal trial research in accordance with the Code of Federal Regulations **(2 Points)**

CRITERION 3. Suitability of the Product for an ARS Indication (20 Points)

The suitability of the Offerors' product for one of the specific research areas shall be based upon the Comprehensive Staged Product Development Plan, as described under Scope (see Scope: "Identifying a Promising Therapeutic"). The Offeror shall provide

a) A detailed description of the suitability of the proposed therapeutic product for advanced development. The Offer should utilize the Comprehensive Staged Product Development Plan to elaborate upon the biodefense/public health gap that is being addressed, potential for licensure for a treatment indication, for formulation with long term stability, bioavailability, simple dosing regimen, safety in diverse populations, and broad ARS activity. (**4 Points**)
b) Provide data to support therapeutic efficacy and safety of the proposed product in a relevant ARS animal model(s). (**4 Points**)
c) Provide the proposed mechanism of action (the biochemical pathway compromised by ionizing radiation and where the drug provides the pharmacologic activity). (**4 Points**)
d) Provide the proposed use of the product (dose, route, schedule, bioavailability)[1] (**4 Points**)
e) Provide a narrative on the "goodness of fit" of the product to the proposed research and development area (see "Background Information") (**4 Points**)

CRITERION 4. Capabilities of Staff, Facilities and Project Management (20 Points)

The Offeror shall provide a detailed description of the following:

4. A. Primary Staffing and Company Organization (6 points)

a. Appropriateness of the documented qualifications, knowledge, experience, education, competence, and availability of the Principal Investigator (PI) to carry out the proposed Statement of Work. (**1 point**)
b. Appropriateness of the documented qualifications, knowledge, experience, education, competence and availability of the Project Manager to carry out the proposed Statement of Work. (**1 Point**)
c. Appropriateness of the documented qualifications, knowledge, experience, education, competence and availability of the other key personnel, provided by the Offeror or by subcontractors or consultants (e.g. manufacturing, regulatory, clinical, animal models, assay development, etc.) to carry out the proposed Statement of Work, and the appropriateness of the responsibilities and level of effort of all proposed staff of the Offeror and any proposed subcontractors and consultants. (**2 Points**)
d. Adequacy of the proposed mix of staff, expertise, experience, and training (e.g., research, manufacturing, clinical, regulatory, statistical, management, administrative) to carry out the Work Plan. (**2 Points**)

4. B. Facilities, Equipment and Other Resources (6 Points)

As required and/or appropriate for the Offerors' proposed Statement of Work:

a) Availability and adequacy of facilities, equipment, and other resources, including contracted facilities, to safely and adequately perform all phases of the proposed project including, but not limited to, irradiation, dosimetry, animal care, clinical chemistries and assays. **(2 Points)**
b) Environmental health and safety programs, laboratory and site surveillance, adequacy of containment facilities, and radiologic safety as needed (for guidance refer to, for example, the Department of Energy's Lawrence Berkeley Laboratory Environmental Health and Safety Publication 3000 (http://www.lbl.gov/ehs/pub3000/CH21.html#_Toc407168416. **(2 Points)**

1 See Federal Register http://www.hhs.gov/aspr/barda/documents/phemce_implplan_041607final.pdf to understand the likely "best practices" of medical treatment in a mass casualty environment.

c) Availability and suitability of facilities, and ability to add or delete facilities if needed, to conduct assays and animal studies in accordance with USDA and FDA regulations and guidelines, including GLP guidelines; manufacture therapeutic candidates/products according to cGMP guidelines; and perform clinical trials in accordance with GCP guidelines; AALAS certifications, etc. **(2 Points)**

4. C. Project Management **(8 Points)**

As required and/or appropriate for the Offerors' proposed Statement of Work:

a) Adequacy of the Project Management Plan in terms of staffing, organization, responsibilities, leadership and lines of authority. **(1 Point)**
b) Suitability of systems proposed for tracking project activities and monitoring progress, timelines, and budgets. **(1 Point)**
c) Suitability of the plan for how the key personnel will communicate with the Project Officer and the Contracting Officer, as well as establish lines of communication between all performance sites and activities. **(1 Point)**
d) Suitability of the plan for soliciting, evaluating, negotiating, awarding and managing any proposed subcontracts in accordance with Federal regulations. **(1 Point)**
e) Adequacy of the plan to identify and remediate problems in sub-Offeror performance. **(1 Point)**
f) Completeness of Letter(s) of Understanding between collaborating parties to address intellectual property, facilitate development of commercialization, and resolve disputes. **(1 Point)**
g) Adequacy of the plan to protect and share confidential information with the External Advisory Group members. **(1 Point)**
h) Suitability of the plan to organize the Annual Review Meetings and provide for a thorough assessment of contract status, progress, problems, and approaches to their resolution, and future plans. **1 Point)**

TOTAL POSSIBLE POINTS: **(100 POINTS)**

3. PAST PERFORMANCE FACTOR

An evaluation of the Offerors' past performance information will be conducted subsequent to the technical evaluation. However, this evaluation will not be conducted on any Offeror whose proposal would not be selected for award based on the results of the evaluation of factors other than past performance.

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

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

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

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

The USG will consider the currency and relevance of the information, source of the information, context of the

data, and general trends in the Offerors' performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the Offeror. In this case, past performance will be noted as "No relevant past performance history identifiable."

The following rating method shall be used in the evaluation of past performance information:

Excellent - Based on the Offerors' performance record, no doubt exists that the Offeror will successfully perform the required effort. Sources of information are consistently firm in stating that the Offerors' performance was superior and that they would unhesitatingly do business with the Offeror again.

Good - Based on the Offerors' performance record, little doubt exists that the Offeror will successfully perform the required effort. Sources of information state that the Offerors' performance was good, better than average, etc., and that they would do business with the Offeror again.

Average - Based on the Offerors' performance record, some doubt exists that the Offeror will successfully perform the required effort. Sources of information indicate that the Offerors' performance is average or that favorable reports are offset by unfavorable reports.

Marginal - Based on the Offerors' performance record, some doubt exists that the Offeror will successfully perform the required effort. Sources of information make unfavorable reports about the Offerors' performance and express concern about doing business with the Offeror again.

Poor - Based on the Offerors' performance record, serious doubt exists that the Offeror will successfully perform the required effort. Sources of information consistently stated that the Offerors' performance was entirely unsatisfactory and that they would not do business with the Offeror again.

4. EXTENT OF SMALL DISADVANTAGED BUSINESS PARTICIPATION

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

Evaluation of SDB participation will be assessed based on consideration of the information presented in the Offerors' proposal. The USG is seeking to determine whether each Offeror has demonstrated a commitment to use SDB concerns for the work that it intends to perform.

Offerors' will be evaluated on the following sub-factors:

(a) Complexity and variety of the work SDB concerns are to perform. Greater emphasis will be given for the arrangements where the SDB shall be performing work appropriate to the scientific objectives expressed in the Offerors' proposed Statement of Work.
(b) Extent of participation of SDB concerns in terms of the value of the total acquisition.

5. HUMAN SUBJECT EVALUATION

This research project involves human subjects. BARDA policy requires:

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

Each Offeror's proposal must address the involvement of human subjects and protections from research risk relating to their participation in the proposed research plan or provide sufficient information on the research subjects to allow a determination by BARDA 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, and FDA's regulations governing clinical research, including 21 CFR Parts 50, 54, 56, and 312, the proposal to BARDA 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. 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 the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the USG includes your proposal in the order of merit ranking (for competitive proposals), or if the USG holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the protection of human subjects from research risks is still found to be unacceptable, then your proposal may not be considered further for award.

(b) **Data and Safety Monitoring**

Each Offerors' 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. The establishment of a Data and Safety Monitoring Board (DSMB) is optional for Phase 1 and 2 clinical trials. The reviewers will rely on the Statement of Work as well as any further technical evaluation criteria as applicable, for the BAA's 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 reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the USG includes your proposal in the order of merit ranking (for competitive proposals), or if the USG holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for data and safety monitoring is still found to be unacceptable, then 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. See NIH Guide http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm,.

The proposal must address the proposed outreach programs for recruiting women and minorities as

participants.
Some of the issues the Offeror shall address 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 BAA
- 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 Offerors 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.

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 USG 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 HHS policies) or acceptable. If the reviewers find that this portion of the proposal is "unacceptable" they will provide a narrative supporting their finding.

If the USG includes your proposal in the order of merit ranking (for competitive proposals), or if the USG holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR). Once discussions are closed with the submission of your FPR, if your proposed plan for the inclusion/exclusion of women and minorities is still found to be unacceptable, then your proposal may not be considered further for award.

(d) **Children and the Elderly (Pediatric and Geriatric studies)**

This BAA supports research toward Phase 1 and Phase 2 studies only. Pediatric and geriatric trials may be held as post-approval obligations if the FDA so ascribes to the Offerors in communications on this topic.

If the USG includes your proposal in the order of merit ranking (for competitive proposals), or if the USG holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to address the concerns raised by the reviewers. You will be able to further discuss and/or clarify your position until submission of your Final Proposal Revision (FPR).

6. ANIMAL WELFARE

a) Before undertaking performance of any contract involving research on live, vertebrate animals, the Contractor shall register with the Secretary of Agriculture of the United Sates in accordance with 7 U.S.C. 2316 and 9 CFR Section 2.30. The Contractor shall furnish evidence of such registration to the Contracting Officer.

b) The Contractor shall acquire animals used in research from a dealer licensed by the Secretary of Agriculture under 7. U.S.C. 2131-2157 and 9 CFR Sections 2.1-2.11, or from a source that is exempt from licensing under those sections.

c) The Contractor agrees that all research involving live, vertebrate animals shall be conducted in accordance with applicable local, state, federal (including 21 CFR 58), or other regulations and policy on humane care and use of laboratory animals.

Your plan may be rated “unacceptable or acceptable.” If your plan is rated “unacceptable” and the Government includes your proposal as “technically acceptable” in the Order of Merit Ranking, you will be afforded an opportunity to further discuss and/or clarify your position during such discussions and in any proposal revisions. If, after discussions, any area of animal care is still found to be unacceptable, your proposal may not be considered further for award.

7. COST/PRICE FACTOR

In evaluating any contract line item that is proposed as cost-reimbursement, the Government’s evaluation of the Offeror’s cost and fee (if proposed) will include an analysis of the cost realism and price reasonableness in addition to the total cost and fee. The cost realism and cost reasonableness analysis will be used to determine what the Government should realistically expect to pay for the proposed effort, the Offeror’s understanding of the work and the Offeror’s ability to perform the contract.

INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

General Information

a. Instructions TO OFFERORS--COMPETITIVE ACQUISITION [FAR Provision 52.215-1 (January 2006)]

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

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

"In writing", "writing", or "written" means 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 BAA'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 BAA 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 BAAs. If this BAA is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this BAA 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 BAA, proposals and modifications to proposals shall be submitted in paper media in sealed envelopes or packages (i) addressed to the office specified in the BAA, and (ii) showing the time and date specified for receipt, the BAA 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 BAA 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 BAA 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 BAA; 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 BAA by the time specified in the BAA. If no time is specified in the BAA, 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) Any proposal, modification, or revision received at the Government office designated in the BAA 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 BAA, 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.

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 BAA, and urgent Government requirements preclude amendment of the BAA, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the BAA 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 BAAs may be withdrawn orally. If the BAA 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 BAA, the offeror may propose to provide any item or combination of items.

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

(6) Offerors may submit modifications to their proposals at any time before the BAA 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 BAA will be valid for the number of days specified on the BAA cover sheet (unless a different period is proposed by the offeror).

(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 statements, specifying the particular portions of the proposal which are to be restricted:

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 must 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 statements or statements differing in substance from those cited above may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming statement(s).

(f) Contract award.

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

(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.

(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 Contracting Officer 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.

(11) If a post-award debriefing is given to requesting offerors, the Government

shall disclose the following information, if applicable:

(i) The agency's evaluation of the significant weak or deficient factors in the debriefed offeror's offer.

(ii) The overall evaluated cost or price and technical rating of the successful and debriefed offeror and past performance information on the debriefed offeror.

(iii) The overall ranking of all offerors, when any ranking was developed by the agency;

(iv) A summary of the rationale for award.

(v) For acquisitions of commercial items, the make and model of the item to be delivered by the successful offeror.

(vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether selection procedures set forth in the BAA, applicable regulations, and other applicable authorities were followed by the agency.

(End of Provision)

b. **NAICS CODE AND SIZE STANDARD**

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

2. The North American Industry Classification System (NAICS) code for this acquisition is 541712.

3. The small business size standard is 500.

THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every BAA, (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 BAA.

a. TYPE OF CONTRACT AND NUMBER OF AWARDS

It is anticipated that multiple awards will be made from this BAA and that the awards will be made on/about September 16, 2008.

It is anticipated that each award from this BAA will be a cost reimbursement type completion contract with a period of performance of up to three years and that incremental funding will be used.

b. 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.

c. 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 BAA. Communications with other officials may compromise the competitiveness of this acquisition and result in cancellation of the requirement.

d. RELEASE OF INFORMATION

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

e. PREPARATION COSTS

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

f. SERVICE OF PROTEST (SEPTEMBER 2006) - FAR 52.233-2

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

Contracting Officer
Biomedical Advanced Research and Development Authority (BARDA)
330 Independence Avenue, S.W. Room G640
Washington, D.C. 20201

(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)

INSTRUCTIONS TO OFFERORS
GENERAL INSTRUCTIONS

INTRODUCTION

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

a. **Contract Type and General Clauses**

It is contemplated that a cost-reimbursement completion 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.

b. **Authorized Official and Submission of Proposal**

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this BAA. 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. 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 BAA should be placed in the following order:

I. COVER PAGE

Include BAA title, number, name of organization, DUNS No., identification of the proposal part, and indicate whether the proposal is an original or a copy.

II. TECHNICAL PROPOSAL

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

c. **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 SUMMARY). 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.

d. **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 BAA, shall be clearly identified.

e. **Evaluation of Proposals**

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

f. **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.

g. **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.

h. **Selection of Offerors**

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

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

iii. 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.

iv. 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.

v. BARDA reserves the right to make a single award, multiple awards, or no award at all to the BAA. In addition, the BAA may be amended or canceled as necessary to meet BARDA requirements. Synopses of awards exceeding $25,000 will be published in FedBizOpps.

i. **Past Performance Information**

i. Offerors shall submit the following information as part of their **business** proposal.

A list of the last three (3) contracts completed during the past three years and all contracts currently being performed that are similar in nature to the BAA workscope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial concerns. Offerors may also submit past performance information regarding predecessor companies, key personnel who have relevant experience or subcontractors that will perform major or critical aspects of the requirement when such information is relevant to the instant acquisition. For the purposes of this BAA, a "major subcontract" is defined as a subcontract that exceeds $25,000.

Include the following information for each contract or subcontract listed:

1. Name of Contracting Organization
2. Contract Number (for subcontracts, provide the prime contract number and the subcontract number)
3. Contract Type
4. Total Contract Value
5. Description of Requirement
6. Contracting Officer's Name and Telephone Number
7. Program Manager's Name and Telephone Number
8. North American Industry Classification System Code

The offeror may provide information on problems encountered on the identified contracts and the offeror's corrective actions.

ii. The Government is not required to contact all references provided by the offeror. Also, references other than those identified by the offeror may be contacted by the Government to obtain additional information that will be used in the evaluation of the offeror's past performance.

iii. A Past Performance Questionnaire must be sent by the Offeror to the references for their response. It is the Offeror's responsibility to ensure that the questionnaires are completed and returned to the Government by their references in accordance with the instructions provided in Evaluation Factors for Award, Paragraph 3 (Past Performance Factor).

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

This BAA incorporates one or more BAA 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 BAA provision may be accessed electronically at this address: http://www.acquisition.gov/far/index.html .

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1):

i. *Data Universal Numbering System (DUNS) Number, FAR Clause 52.204-6 (October 2003).*

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

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

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.

a. Technical Discussions

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

Personnel

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. Single 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.

b. Other Considerations

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

i. 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.

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

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

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

v. Recommendations for changing reporting requirements if such changes would be more compatible with the offeror's proposed schedules.

c. IMPORTANT NOTE TO OFFERORS: The following 9 paragraphs shall be addressed, as applicable, in a SEPARATE SECTION of the Technical Proposal entitled, "HUMAN SUBJECTS."

1. **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, HHSAR 352.270-8(a) (January 2006)**

(a) Copies of the Department of Health and Human Services (HHS) regulations for the protection of human subjects, 45 CFR Part 46, are available from the Office for Human Research Protections (OHRP), 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 HHS.

(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 OPDIV 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 consultation with OHRP (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 OHRP an acceptable Assurance of Compliance with the regulations, specifying review procedures and assigning responsibilities for the protection of human subjects. The initial and continuing review of a research project by an institutional review board shall assure that the rights and welfare of the human subjects involved are adequately protected, that the risks to the subjects are reasonable in relation to the potential benefits, if any, to the subjects and the importance of the knowledge to be gained, and that informed consent will be obtained by methods that are adequate and appropriate. HHS regulations for the protection of human subjects (45 CFR Part 46), information regarding OHRP registration and assurance requirements/processes, and OHRP contact information can be accessed at the OHRP Web site: http://www.hhs.gov/ohrp/ .

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

(End of provision)

2. **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 BAA.
    - 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 BAA. Be aware that an IRB-approved recruitment and informed consent documents 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.

3. **Required Education in the Protection of Human Research Participants**

BARDA policy requires education on the protection of human subject participants for all

investigators submitting BARDA proposals for contracts for research involving human subjects. Offerors should review the following policy announcement prior to submission of their offers:

For any BAA 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.

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.

4. **Inclusion of Women and Minorities in Research Involving Human Subjects**

It is BARDA policy that women and members of minority groups and their sub-populations must be included in all BARDA-supported clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. The Director, BARDA, may determine that exclusion under other circumstances is acceptable 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.

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 BAA. 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 Attachment 5)

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.

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 HHS defined Phase III clinical trials * 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 for example NIH Guide:

http://grants.nih.gov/grants/funding/women_min/guidelines_amended_10_2001.htm).
*The definition of an "NIH-Defined Phase III clinical trial" can also be found at this website.)

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 BAA.

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 subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Use the form entitled, "Targeted/Planned Enrollment Table," when preparing your response to the BAA requirements for inclusion of women and minorities. (See List of Documents, Exhibits and Other Attachments of the BAA)

Unless otherwise specified in this BAA, the Government has determined that the work required by this BAA does not involve a sex/gender specific study or a single or limited number of minority population groups. Therefore, BARDA believes that the inclusion of women and minority populations is appropriate for

this project. (See evaluation factors for award for more information.)

Use the form entitled, "Inclusion Enrollment Report," for reporting in the resultant contract .

5. **Inclusion of Children in Research Involving Human Subjects**

It is BARDA 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 BARDA 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.

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 BAA.

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 BAA 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 BAA.

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 BAA is not relevant to children.
    - There are laws or regulations barring the inclusion of children in the research to be conducted under the BAA.
    - 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 BAA, a child is defined as an individual under the age of 21 years.

The definition of child described above will pertain to this BAA (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.

6. **Research Involving Prisoners as Subjects**

i. HHS Regulations at 45 CFR Part 46, Subpart C provide additional protections pertaining to biomedical and behavioral research involving prisoners or those individuals who, during the period of the contract become prisoners, as subjects. These regulations also set forth the duties of the Institutional Review Board (IRB) where prisoners are involved in the research. HHS funded research involving prisoners as subjects may not proceed until the Office for Human Research Protections (OHRP) issues approval, in writing, as required by 45 CFR 46.306(a)(2). In addition, OHRP Guidance on the Involvement of Prisoners in Research may be found at: http://www.hhs.gov/ohrp/humansubjects/guidance/prisoner.pdf .

ii. HHS Waiver for Epidemiological Research Involving Prisoners as Subjects

On June 20, 2003 the Secretary of HHS waived the applicability of certain provisions of Subpart C of 45 CFR Part 46, (Additional DHHS Protections Pertaining to Biomedical and Behavioral Research Involving Prisoners as Subjects) to specific types of epidemiological research involving prisoners as subjects.

The applicability of 45 CFR 46.305(a)(1) and 46.306(a)(2) for certain epidemiological research conducted or funded by DHHS is waived when:

- The sole purposes are:
    a. to describe the prevalence or incidence of a disease by identifying all cases, or
    b. to study potential risk factor associations for a disease, and
- The Institution responsible for the conduct of the research certifies to the OHRP that the Institutional Review Board (IRB) approved the research and fulfilled its duties under 45 CFR 46.305(a)(2 7) and determined and documented that:

a. the research presents no more than minimal risk, and
b. no more than inconvenience to the prisoner subjects, and
c. prisoners are not a particular focus of the research.

For more information about this Waiver see http://www.hhs.gov/ohrp/special/prisoners/Prisoner waiver 6-20-03.pdf

7. **Research Involving Human Fetal Tissue**

Human Fetal Tissue means tissue or cells obtained from a dead human fetus, including human embryonic stem cells, human pluripotent stem cells and human embryonic germ cells.

The governing federal statute is the Public Health Service Act, 42 U.S.C. 289g 1 and 289g 2. Implementing regulations and guidance for conducting research on human fetal tissue may be found at 45 CFR 46, Subpart B and http://grants1.nih.gov/grants/guide/notice-files/not93-235.html and any subsequent revisions to this NIH Guide to Grants and Contracts ("Guide") Notice.

By signing the face page of the proposal, the offeror (authorized institutional official) certifies that researchers using human fetal tissue are in compliance with 42 USC 289g 2. This statute specifically prohibits any person from knowingly acquiring, receiving, or transferring any human fetal tissue for valuable consideration. "Valuable consideration" is a concept similar to profit, and does not include reasonable payment for costs associated with the collection processing, preservation, storage, quality control or transportation of these tissues.

Research involving the transplantation of human fetal tissue must be conducted in accordance with applicable Federal, State and local law.

8. **Research Involving Recombinant DNA Molecules (including Human Gene Transfer Research)**

Compliance with the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (*NIH Guidelines*) is a term and condition of BARDA funding for work involving recombinant nucleic acids. Recombinant DNA Molecules are either 1) molecules that are constructed outside of living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or 2) DNA molecules that result from the replication of those described in 1).

Investigators and institutions must adhere to the NIH Guidelines for Research Involving Recombinant DNA Molecules (see http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html) when they perform research that is conducted or sponsored by a contract involving BARDA support for recombinant DNA research.

Failure to comply with these requirements may result in a) suspension, limitation, or termination of BARDA funding for any work related to Recombinant DNA Research or b) a requirement for the Contracting Officer's prior approval of any or all Recombinant DNA projects under any contract awarded from this BAA. Compliance with the *NIH Guidelines* may necessitate review by an Institutional Biosafety Committee (IBC) and, in some cases, review by the NIH Recombinant DNA Advisory Committee. (See http://www4.od.nih.gov/oba/IBC/IBCindexpg.htm).

Any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses must be reported to the IBC and NIH/OBA within thirty days, as well as to the Project Officer

and Contracting Officer (see http://www4.od.nih.gov/oba/IBC/Incidents.htm). In human gene transfer trials, serious adverse events must be reported to the IBC, the IRB, the NIH Office of Biotechnology Activities, the HHS Office of Human Research Protections, and the Project Officer and Contracting Officer, in keeping with Appendix M-I-C-3 and M-1-C-4 of the *NIH Guidelines* (see http://www4.od.nih.gov/oba/RAC/RAC_FAQs.htm).

9. **Data and Safety Monitoring in Clinical Trials**

BARDA endorses NIH policies regarding data and safety monitoring, including reporting of adverse events. 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 BAA must comply with the NIH Policies cited in these Announcements and any other data and safety monitoring requirements found elsewhere in this BAA.

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 BARDA Contracting Officer and in place before the trial begins. If the protocol will be developed under the contract awarded from this BAA, 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 and the Food and Drug Administration (FDA) in accordance with federal, state, and local regulations. 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 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.

BUSINESS PROPOSAL INSTRUCTIONS

a. 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.

b. Proposal Cover Sheet

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

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

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

c. Salary Rate Limitation in Fiscal Year 2008

Offerors are advised that for this BAA, BARDA is applying a limitation under P.L..110-161 to the effect that no BARDA Fiscal Year 2008 (October 1, 2007 - September 30, 2008) funds be used to pay the direct annual salary of an individual through any contract awarded as a result of this BAA 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, patient 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. 110-161 applies only to Fiscal Year 2008 funds, however, salary rate ceilings for subsequent years may be included in future DHHS appropriation acts. Contracts awarded pursuant to this BAA 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 limitation also applies to individuals proposed under subcontracts, however it does not apply to consultants.

LINK TO EXECUTIVE SCHEDULE SALARIES : http://www.opm.gov/oca/08tables/html/ex.asp

*Note to Offerors : The current Fiscal Year Executive Level I Salary Rate should be adhered to in the preparation of your proposal. All costs associated with any resultant contract award shall be in compliance with the current Fiscal Year Executive Level I Salary rates.

d. Small Business Subcontracting Plan

If the proposed contract exceeds a total estimated cost of $550,000 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 BAA, See ATTACHMENT 11 for an example of such a plan.

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

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

c. The offeror understands that:

1. No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.
2. An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small 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 BAA 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 $550,000 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 BAA.

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

_23_ % for Small Business; _5_ % for Small Disadvantaged Business; _5_ % for Women-Owned Small Business; _3_ % for HUBZone Small Business; and _3_ % for Veteran-Owned Small Business and 3% for Service-Disabled Veteran-Owned Small Business.

e. 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 Additional Contract Clauses of this BAA. Qualified HUBZone firms are identified in the Small Business Administration website at http://www.sba.gov/hubzone .

f. 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 $550,000 ($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 BAA. 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 shall be used for evaluation purposes.

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 for NAICS codes* is: http://www.arnet.gov/References/sdbadjustments.htm .

** Note: Public Law 103-355 which authorized the SDB Price Evaluation Adjustment (PEA) and associated percentages/factors expired on December 9, 2004, therefore, the percentages shown at this website are no longer applicable.*

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 BAA. 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 BAA 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 BAA. An example of the type of information that might be given (in addition to the narrative describing the plan for meeting the targets) follows:

EXAMPLE

Targets for SDB Participation - NAICS Industry Subsector 223

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

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

g. Total Compensation Plan

a. Instructions

1. Total compensation (salary and fringe benefits) of professional employees under service contracts may, in some cases, be lowered by recompetition of these contracts. Lowering of compensation can be detrimental in obtaining the necessary quality of professional services needed for adequate performance of service contracts. It is, therefore, in the best interest of the Government that professional employees, as defined in 29 CFR Part 541, be properly compensated in these contracts. All offerors as part of their Business Proposal shall submit a "Total Compensation Plan" (salaries and fringe benefits) for these professional employees for evaluation purposes.
2. The Government will evaluate the Total Compensation Plan to ensure that this compensation reflects a sound management approach and an understanding of the requirements to be performed. It will include an assessment of the offeror's ability to provide uninterrupted work of high quality. The total compensation proposed will be evaluated in terms of enhancing recruitment and retention of personnel and its realism and consistency with a total plan for compensation (both salaries and fringe benefits).
3. Evaluation for award, therefore, will include an assessment of the Total Compensation Plan submitted by each offeror.

b. Evaluation

1. Total Compensation Plan (Professional Employees)

   In establishing compensation levels for professional employees, the total compensation (both salaries and fringe benefits) proposed shall reflect a clear understanding of the requirements of the work to be accomplished and the suitability of the proposed compensation structure to obtain and retain qualified personnel to meet mission objectives. The salary rates or ranges must recognize the distinct differences in professional skills and the complexity of varied disciplines as well as job difficulty. Proposals offering total compensation levels less than currently being paid by the predecessor Contractor for the same work will be evaluated, in addition to the above, on the basis of maintaining program continuity, uninterrupted work of high quality, and availability of required competent professional employees. Offerors are cautioned that instances of lowered compensation for essentially the same professional work may be considered a lack of sound management judgment in addition to indicating a lack of understanding of the requirement.

2. Cost (Professional Compensation)

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

3. Other (Labor Relations)

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

4. Federal Acquisition Regulation Clauses incorporated by Reference

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

h. Other Administrative Data

a. Property

1. It is HHS policy that Contractors will provide all property necessary for contract performance. Exception may be granted to provide Government property (Government-furnished or Contractor-acquired), but only when approved by the Contracting Officer. If the offeror requests that Government property be provided, other than that specified under "Government Furnished Property," below , the proposal must include a comprehensive justification addressing the following items:
   a. State why the property is essential to contract performance and whether the property will be used exclusively for this contract.

   b. Describe other alternatives (e.g., purchase, lease, etc.) pursued and why they were not viable options.

2. Government Property

   The offeror shall identify Government property in its possession which it proposes to use in the performance of the prospective contract as follows:

   a. A list or description of all Government property that the offeror or its subcontractors propose to use on a rent-free basis. The list shall identify the accountable contract under which the property is held and the authorization for its use (from the Contracting Officer having cognizance of the property);

   b. The dates during which the property will be available for use (including the first, last, and all intervening months) and, for any property that will be used concurrently in performing two or more contracts, the amounts of the respective uses in sufficient detail to support prorating the rent;

   c. The amount of rent that would otherwise be charged in accordance with FAR 52.245-9, Use and Charges; and

   d. The voluntary consensus standard or industry leading practices and standards to be used in the management of Government property, or existing property management plans, methods, practices, or procedures for accounting for property.

NOTE: The Contracting Officer will consider any potentially unfair competitive advantage that may result from the Contractor possessing Government property, and for evaluation purposes only, adjust the offers using a rental equivalent evaluation factor, as appropriate.

3. Government-Furnished Property
   A Listing of Government Furnished Property is provided in the LIST OF ATTACHMENTS.

4. The management and control of any Government property shall be in accordance with the HHS Publication entitled, Contractors Guide for Control of Government Property, which can be found at: http://knownet.hhs.gov/log/AgencyPolicy/HHSLogPolicy/contractorsguide.htm

b. Royalties

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

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

The offeror shall provide, with its offer, the following information that is required to make payment by electronic funds transfer (EFT) under any contract that results from this BAA. 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 BAA 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.

(End of Provision)

d. Financial Capacity

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

e. Incremental Funding

An incrementally funded cost-reimbursement contract is a contract in which the total work effort is to be performed over a multiple year period and funds are allotted, as they become available, to cover discernible phases or increments of performance. The incremental funding technique allows for contracts to be awarded for periods in excess of one year even though the total estimated amount of funds expected to be obligated for the contract are not available

at the time of the contract award. If this requirement is specified elsewhere in this BAA, the offeror shall submit a cost proposal for each year. In addition, the following provision is applicable:

Incremental Funding, HHSAR 352.232-75 (January 2006)

(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 as specified in FAR 52.232-22. 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. The Government intends to allot additional funds up to and including the full estimated cost of the contract for the remaining years of performance by contract modifications. However, the Government is not obligated to reimburse the Contractor for costs incurred in excess of the periodic allotments, nor is the Contractor obligated to perform in excess of the amount allotted.

(b) The Limitation of Funds clause to be included in the resultant contract, as specified in FAR 52.232-22, shall supersede the Limitation of Cost clause found in the Section, Contract Clauses.

(End of provision)

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

(This is applicable if you are a commercial organization.)
(a) Facilities capital cost of money will be an allowable cost under the contemplated contract, if the criteria for allowability in FAR 31.205-10(b) 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.

[ ]Fac Cap Cost of Money (Has) 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).

[ ]Fac Cap Cost of Money (Has Not) The prospective Contractor **has not** specifically identified or proposed facilities capital cost of money in its cost proposal and elects not to claim it as an allowable cost under the contract.

i. Qualifications of the Offeror

You are requested to submit a summary of your "General Experience, Organizational Experience Related to this BAA, 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 BAA**

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 BAA. 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 BAA.

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 BAA.

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 BAA, 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 BAA. 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 BAA 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.

j. 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 BAA 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/FDPclausecover.htm

k. Proposer's Annual Financial Report

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

l. Representations and Certifications

One copy of representations and certifications (which includes FAR Clause 52.204-8 Annual Representations and Certifications) shall be completed and be signed by an official authorized to bind your organization. Additionally, a completed copy of representations and certifications shall be submitted from any proposed subcontractor.

m. 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 BAA 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.

n. Certification of Visas 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 outlying areas, then the offeror must indicate in the proposal that these individuals have the required visas.

o. Information Other than Cost or Pricing Data

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

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

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

LIST OF ATTACHMENTS

The following documents are incorporated into this BAA:

Attachment No.	Title	Location
Attachment 1:	Packaging and Delivery of Proposal	See Attachment Section at the end of this BAA
Attachment 2:	Proposal Intent Response Sheet	See Attachment Section at the end of this BAA
Attachment 3:	Appendix A – Additional Technical Proposal Instructions	See Attachment Section at the end of this BAA
Attachment 4:	Appendix B – Additional Business Proposal Instructions	See Attachment Section at the end of this BAA

TECHNICAL PROPOSAL ATTACHMENTS: (The following attachments must be completed, where applicable, and submitted with the Technical Proposal.)

Attachment No.	Title	Location
Attachment 5	Targeted/Planned Enrollment Table	See Attachment Section at the end of this BAA
Attachment 6:	Technical Proposal Cost Summary	http://www.niaid.nih.gov/contract/forms/form5.rtf See Attachment Section at the end of this BAA
Attachment 7:	Summary of Related Activities	http://www.niaid.nih.gov/contract/forms/form6.rtf See Attachment Section at the end of this BAA
Attachment 8:	Government Notice for Handling Proposals	See Attachment Section at the end of this BAA
Attachment 9:	Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption, OMB Form No. 0990-0263 (formerly Optional Form 310)	http://www.niaid.nih.gov/contract/forms/OF-310.rtf See Attachment Section at the end of this BAA

BUSINESS PROPOSAL ATTACHMENTS: (The following attachments must be completed, where applicable, and submitted with the Business Proposal.)

Attachment No.	Title	Location
Attachment 10:	Proposal Summary and Data Record	See Attachment Section at the end of this BAA
Attachment 11:	Small Business Subcontracting Plan OPDIV is BARDA OPDIV Small Business Specialist is Debra Peters (202-690-8457)	http://www.knownet.hhs.gov/smallbus/SAMPLESUBKPlan-UpdatedMay2007.doc See Attachment Section at the end of this BAA
Attachment 12:	Representations and Certifications	See Attachment Section at the end of this BAA
Attachment 13:	Breakdown of Proposed Estimated Costs (plus Fee) with Excel Spreadsheet	See Attachment Section at the end of this BAA
Attachment 14:	Offeror's Points of Contact	http://www.niaid.nih.gov/contract/forms/form3.rtf See Attachment Section at the end of this BAA

Attachment 15:	Disclosure of Lobbying Activities, OMB Form SF-LLL	http://www.niaid.nih.gov/contract/forms/sf-lll.rtf See Attachment Section at the end of this BAA

Attachment No.	**Title**	**Location**
Attachment 16:	Model Contract	See Attachment Section at the end of this BAA
Attachment 17:	Safety and Health, HHSAR Clause 352.223-70	http://www.niaid.nih.gov/contract/forms/form10.pdf See Attachment Section at the end of this BAA
Attachment 18:	Research Patient Care Costs, NIH(RC)-11	http://www.niaid.nih.gov/contract/forms/nih-rc-11.pdf See Attachment Section at the end of this BAA
Attachment 19:	Inclusion Enrollment Report	http://www.niaid.nih.gov/contract/forms/inclusion_enrollment_report.doc See Attachment Section at the end of this BAA
Attachment 20:	Invoice/Financing Request Instructions	See Attachment Section at the end of this BAA

PACKAGING AND DELIVERY OF THE PROPOSAL

YOUR PROPOSAL SHALL BE ORGANIZED AS SPECIFIED IN "INSTRUCTIONS TO OFFERORS" - GENERAL INSTRUCTIONS. SHIPMENT AND MARKING SHALL BE AS INDICATED BELOW.

EXTERNAL PACKAGE MARKING

IN ADDITION TO THE ADDRESS CITED BELOW, MARK EACH PACKAGE AS FOLLOWS:

"BAA NO. BAA BARDA-08-08 .

TO BE OPENED BY AUTHORIZED GOVERNMENT PERSONNEL ONLY"

PLEASE READ THE FOLLOWING INFORMATION CAREFULLY:

NUMBER OF COPIES:

TECHNICAL PROPOSAL: UNBOUND SIGNED ORIGINAL*, 20 BOUND COPIES AND 2 COMPACT DISCS (CD'S) TO:

CARL NEWMAN
CONTRACTING OFFICER
BIOMEDICAL ADVANCED RESEARCH AND DEVELOPMENT AUTHORITY
ASSISTANT SECRETARY FOR PREPAREDNESS AND RESPONSE
U. S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
330 INDEPENDENCE AVE., S.W., ROOM G640
WASHINGTON, D.C. 20201

BUSINESS PROPOSAL: UNBOUND SIGNED ORIGINAL*, 10 BOUND COPIES AND 1 COMPACT DISC (CD). TO: SAME AS ABOVE

*THE ORIGINALS MUST BE READILY ACCESSIBLE FOR DATE STAMPING PURPOSES.

****

THE PAGE LIMITATION IS 200 PAGES INCLUDING ALL APPENDICES, ATTACHMENTS, OPERATING MANUALS, CV'S, NON-SCANNABLE FIGURES OR DATA AND LETTERS OF INTENT.

PAGES IN EXCESS OF THIS TECHNICAL PROPOSAL PAGE LIMITATION WILL BE REMOVED FROM THE TECHNICAL PROPOSAL AND WILL NOT BE READ OR EVALUATED.

ANY PORTIONS OF THE TECHNICAL PROPOSAL NOT AVAILABLE ELECTRONICALLY ARE CONSIDERED TO BE INCLUDED IN THE TOTAL PAGE LIMITATION.

ATTACHMENT 2

PROPOSAL INTENT RESPONSE SHEET

BAA No.: BAA BARDA-08-08
BAA Title: Therapies for Hematopoietic Syndrome, Bone Marrow Stromal Cell Loss, and Vascular Injury Resulting From Acute Exposure to Ionizing Radiation

Please review the attached Broad Agency Announcement. Furnish the information requested below and return this page by April 4, 2008. Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation.

[ ] 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):
_____
_____

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:

Biomedical Advanced Research and Development Authority
Assistant Secretary for Preparedness and Response
U. S. Department of Health and Human Services
330 Independence Ave. S.W. Room G640
Washington D.C. 20201
Point of Contact: Carl A. Newman
BAA BARADA-08-08
FAX# (202) 205-0873
Email: carl.newman@hhs.gov

ATTACHMENT 3

APPENDIX A: ADDITIONAL TECHNICAL PROPOSAL INSTRUCTIONS

THERAPIES FOR HEMATOPOIETIC SYNDROME, BONE MARROW STROMAL CELL LOSS, AND VASCULAR INJURY RESULTING FROM ACUTE EXPOSURE TO IONIZING RADIATION

BAA-BARDA-08-08

FORMAT FOR TECHNICAL PROPOSAL-TABLE OF CONTENTS

It is strongly recommended that Offerors use the following template as the Table of Contents for the technical proposal. All information presented in the technical proposal should be presented in the order specified below.

The following additional technical proposal instructions reflect the requirements of the BAA and are meant to provide additional instructions as well as a uniform format for technical proposals. The information requested in these instructions should be used as a guide for formatting and preparing the proposal.

Offerors are advised to give careful consideration to the Broad Agency Announcement Description, Introduction, Scope, Research and Technical Objectives, all reference material, appendices and attachments, the technical evaluation criteria, and, the BAA as a whole, in the development of your proposal.

Offerors that propose subcontracts to perform portions of the statement of work should clearly identify the specific tasks for which they plan to utilize subcontractors, as well as the method and level of integration between the prime and subcontractor(s), and the expected advantages of such an approach.

THE TOTAL MAXIMUM NUMBER OF PAGES FOR A TECHNICAL PROPOSAL MAY NOT EXCEED **200** PAGES, INCLUDING ALL APPENDICES. ANY PAGES SUBMITTED THAT EXCEED THE 200 PAGE LIMIT WILL NOT BE READ OR EVALUATED.

OFFERORS ARE ADVISED THAT FULL SOPS, INVESTIGATOR BROCHURES, OR OTHER PERTINENT BROCHURES, ETC. DO NOT NEED TO BE SUBMITTED WITH PROPOSALS. IN THE INTEREST OF KEEPING TO THE PAGE LIMIT, A SUMMARY OF THE PERTINENT PORTIONS OF THESE DOCUMENTS IS REQUIRED.

NOTE 1: Each proposed Research and Development Area will be evaluated separately. As a result, a proposal representing one Research and Development Area must be submitted as a separate and distinct proposal. If an Offeror submits a proposal for Research and Development Area 1, Research and Development Area 2, and Research and Development Area 3, one distinct proposal for each Research and Development Area must be submitted.

NOTE 2: If an Offeror submits a proposal for one Research and Development Area that is considered for award, the Offeror would be awarded a contract representing that Research and Development Area. If an Offeror submits a proposal that includes more than one Research and Development Area and each Research and Development Area is considered for award, the Offeror would be awarded a single contract representing each of those Research and Development Areas.

SECTION 1 - Offerors' Proposed Statement of Work (SOW) (not to exceed-15 pages)

In contracts awarded under this Broad Agency Announcement (BAA), the Statement of Work (SOW) shall be that proposed by the Offeror and negotiated and accepted by the BARDA. This section of the Offerors' Technical Proposal shall outline the steps to be taken by the contractor during performance of the contract. The Offerors' proposed SOW shall begin as follows:

"Independently, and not as an agent of the USG, the Contractor shall furnish all necessary services, qualified professional, technical, and administrative personnel, material, equipment and facilities, not otherwise provided by the USG under the

terms of this contract, as needed to perform the tasks set forth below. Specifically the Contractor shall:"

The opening paragraph shall be followed by a full SOW describing each step that the contractor shall perform **after the award of the contract**, including: the tasks that shall be performed to carry out the research and development project; how these tasks shall be accomplished; and the time frame within which each task shall be accomplished.

Each step described in the SOW shall begin with the words "The Contractor shall...." Where appropriate, divide the SOW into separate tasks and subtasks. An outline format shall be used. Briefly describe the work related to each task and describe the tasks in the sequence in which they shall be carried out. The SOW shall also include a description of all items to be delivered to the USG during performance of the contract, such as progress reports, financial reports, end products, and deliverables.

SECTION 2: COMPREHENSIVE STAGED PRODUCT DEVELOPMENT PLAN

Technical Proposals shall include a Comprehensive Staged Product Development Plan that describes the critical path for the proposed therapeutic product to eventual licensure for progressing the product through the critical path.

Technical Proposals shall provide background information to justify the investment in the further development of the proposed therapeutic product. The Comprehensive Staged Product Development Plan shall include a summary of the following:

1) The intended use/indication of the proposed therapeutic product and the biodefense/public health gap the product is intended to fill.
2) The intended Target Product Profiles defined by the Offeror. Note: This may be refined prior to contract award with the Project Officer.
3) The performance specifications and features the product should have in order to provide therapeutic benefit.
4) A description of the therapeutic product as it is currently configured.
5) Data to support the characterization and selection of the therapeutic product for further development. Specifically, a summary of data that demonstrates therapeutic activity in appropriate animal models and assays to address one of the three research areas. This includes: a detailed description of the assays and animal models, the radiation exposure (and method of radiation exposure standardization), rationale for the choice of animal model, as well as for the outcome/endpoints selected; documentation that the animal experiments were performed under well-controlled experimental conditions and data that support whether and how the therapeutic specifically addresses the research area.
6) Discussions with the appropriate CBER/CDER (FDA), if any, that are relevant to development activities for the proposed therapeutic product.
7) A description of activities that are part of the critical product development path through submission of a NDA or BLA, and are IND-, NDA-, or BLA-enabling or activities that are required to support the execution of IND-, NDA-, or BLA-enabling studies, and identifies distinct stages of the product development pathway for Go/No Go decisions for advancing to the next stage of the Comprehensive and Strategic Staged Product Development Plan.

BARDA recognizes that the regulatory path to licensure for therapeutics for ionizing radiation injury within the scope of this BAA may not be well defined. The regulatory requirements are likely to be defined in an iterative decision-making process with the FDA based on product-specific data as it emerges. Despite this uncertainty, Offerors must propose, to the best of their ability and based on current data and/or discussions with the FDA, a critical path to licensure for their product. Offerors should point out areas of significant uncertainty and propose likely alternatives.

SECTION 3: STRATEGIC STAGED PRODUCT DEVELOPMENT PLAN

Technical Proposals shall include a Strategic Staged Product Development Plan. This plan shall include the specific tasks and stages of the Comprehensive Staged Product Development Plan that the Offeror is proposing to perform with contract funding and that can reasonably be completed in three (3) years. The Strategic Staged Product Development Plan must detail:

1) Activities and stages of product development that the Offeror is proposing to perform under contract funding.
2) Distinct stages of the product development pathway that are Go/No Go decisions for advancing to the next stage of the Strategic Staged Product Development Plan.

3) The qualitative and quantitative criteria and accompanying data elements to be used to assess the merit and feasibility of proceeding to the next stage of product development.
4) Timelines for the initiation, conduct and completion of product development activities for each stage, the analysis of outcomes and findings, and the preparation of detailed reports summarizing the results of work completed and an analysis of the data as it relates to the qualitative and quantitative criteria established for Go/No Go decision-making. If a Phase 1 clinical trial has not been completed, the Offeror should clearly note the time line for completing the Phase 1 clinical trial and the Final Clinical Study Report within the three (3) year contract period.

SECTION 4: WORK PLAN: IMPLEMENTATION OF THE STRATEGIC STAGED PRODUCT DEVELOPMENT PLAN

Technical Proposals shall include a Work Plan describing each step that the Offeror proposes to perform after contract award that is required to implement the Strategic Staged Product Development Plan and complete all proposed work within the three (3) year period of award:

The Work Plan shall include:

1) Key development objectives and defined decision points for the development of the therapeutic product.
2) A detailed discussion of the proposed technical approach for each activity to be performed to achieve the project objectives. The Work Plan shall contain sufficient detail to fully explain and justify the scientific and technical rationale for the proposed approach and methodologies and should reflect a clear understanding of the scope and nature of the work being undertaken.
3) A detailed Gantt chart organized by each specific stage of product development proposed, as well as the overall program. Schedules shall be shown in terms of calendar months from the date of authorization to proceed or, where applicable, the date of a stated event, as for example receipt of a required approval by the BARDA Project or BARDA Contracting Officer.
4) A description of the process for making decisions to proceed or not proceed ("Go/No-Go"), including, specific qualitative and quantitative criteria for advancement of the proposed therapeutic through each stage of the product development process. For example, "Go/No-Go" with human safety study, PK and PD testing.
5) Plans for quality control over the implementation, coordination and conduct of the activities set forth in the Strategic Staged Product Development Plan, including plans to conduct regulatory audits.
6) Approaches to integrate adverse experimental or production results, or new scientific findings into the proposed goals and timelines.
7) A plan for sharing data, reagents, and animal model resources developed with contract funding with the scientific research community.
8) A Technical Proposal Cost Summary to include a list of all subcontracts by activity (e.g., GMP manufacture, IND-enabling toxicologic studies, formulation and fill, etc.), and,
9) A list and description of all items to be delivered to BARDA during the performance of the contract and the timeline for delivery.

SECTION 5: CLINICAL TRIAL PROTOCOL DEVELOPMENT AND IMPLEMENTATION

Work Plans that propose clinical trials must include:

1) A description of previous experience in the conduct of research with human subjects that demonstrates the Offerors' expertise and/or thorough knowledge of Federal regulations for the conduct of research with human subjects. A description of experience in the conduct of human subjects research in accordance with NIH policies and guidelines or a statement acknowledging willingness to conduct clinical research according to NIH policies and guidelines.
2) A clinical trial Protocol Synopsis for each proposed trial. The Synopsis should include: the name(s) of the individual(s), organization(s) and site(s) that will perform the clinical trial, and documentation of their capability and willingness to perform the trial; primary and secondary objectives of the trial, trial design, and assays to be performed. The Offeror shall also address issues of human subjects protection, provisions for data and safety monitoring, recruitment and retention of study participants, informed consent, the quality management plan, clinical monitoring plan and the statistical analysis plan.
3) A plan that specifies at which points in the Strategic Staged Product Development Plan it will be critical to engage in written communications and meetings with the FDA.
4) A plan that specifies the frequency and methods by which BARDA will be kept apprised of progress and provided with documentation of communications with the FDA, including correspondence from the FDA and minutes/summaries of meetings with the FDA. BARDA staff shall be invited to all meetings with the FDA.

SECTION 6: REGULATORY COMPLIANCE, QUALITY ASSURANCE AND DATA MANAGEMENT

Data Management and Quality Assurance:
The Technical Proposal must describe the data management and quality control systems/procedures that will be used for all studies and include a description of the procedures for the data entry and validation, documentation of data corrections, routine maintenance and backup, transmission of data, data reporting and exporting system, access control and confidentiality, and data retrieval and disaster recovery.

The Technical Proposal must also describe the statistical design and analysis resources that will be used to support contract activities.

BARDA is connected to the INTERNET and uses IBM-compatible computers that currently run on the Microsoft XP operating system and Microsoft Office software. MAC users must guarantee that data can be transferred to the BARDA Project Officer without corruption of data or figures.

The Technical Proposal must provide a plan to develop and maintain quality assurance documentation to support adherence to FDA regulatory standards and published guidance documents that bear on the conduct of assays under GLP, manufacturing under GMP and performance of clinical trials under GCP standards, as relevant to the Work Plan. Include information on data management for GLP, cGMP, and GCP activities.

Offerors should document experience with performing studies in accordance with FDA regulations and published guidance documents, including GLP, cGMP, and/or GCP guidelines as appropriate to their proposed Statement of Work.

The Technical Proposal must include:

1) A plan to determine when audits need to be performed, timely scheduling of audits, performance of audits, and responding to audit reports.
2) An audit history of the facilities proposed for use in carrying out contract activities that will be performed under GLP, GMP and/or GCP.
3) Letters signed by the appropriate authority allowing for pre-award site visits to the Offerors' facility and proposed subcontractor's facilities. Site visits may include GLP, cGMP, or GCP audits (as appropriate) performed by independent auditors contracted by BARDA.

SECTION 7: PERSONNEL: RESEARCH, PRODUCTION, REGULATORY, CLINICAL, STATISTICAL, MANAGEMENT and ADMINISTRATIVE TEAM

The Technical Proposal shall describe in detail the responsibilities and level of effort of all personnel who will be assigned to the contract.

The Technical Proposal shall provide documentation of the qualifications, knowledge, experience, education, competence, availability, and decision-making authority of the contracted company's key personnel in research, production, regulatory, clinical, project management, statistical and administrative staff. Resumes, endorsements, and documentation of previous relevant efforts provided on behalf of the contracted company shall clearly demonstrate relevant knowledge, training, experience, and specific accomplishments. Resumes of key personnel shall be limited to three (3) pages, single-spaced.

The Technical Proposal must also identify all proposed subcontractors and consultants and provide the same information and documentation as noted above with respect to the qualifications, knowledge, training, experience, education, availability, level of effort, and specific responsibilities, including documentation of previous work relevant to the proposed tasks to be carried out by all such subcontractors and consultants.

SECTION 8: FACILITIES, EQUIPMENT AND OTHER RESOURCES

As appropriate to the Statement of Work, the Technical Proposal must:

1) Document the availability and adequacy of facilities, equipment and other resources available for performance of the contract, including: (1) detailed laboratory layouts; (2) information regarding ownership/lease of the facility(ies), including documentation of the availability of proposed facilities for the duration of the contract; (3) plans for and procedures to be utilized to insure compliance with all safety guidelines and regulations, including training and monitoring of personnel; and (4) plans for obtaining, adding or deleting facilities as necessary due to progress or performance issues that arise during the course of product development.

2) Document access to facilities for performing assays and animal studies under GLP standards, production of therapeutic material under GMP guidelines, and performance of clinical studies following GCP guidance as required by the Strategic Staged Product Development Plan.
3) Describe provisions for complying with BARDA/NIH guidelines for the housing and humane care and use of laboratory animals as prescribed by the Office of Laboratory Animal Welfare (OLAW) (http://grants.nih.gov/grants/olaw/olaw.htm), the USDA Animal Welfare Act (http://www.aphis.usda.gov/publications/animal_welfare/) or the Association for Assessment and Accreditation of Laboratory Animal Care (http://www.aaalac.org/index.cfm).
4) If applicable, describe provisions for ensuring safe and secure facilities and resources and for conducting select agent work in accordance with the Biosafety in Microbiological and Biomedical Laboratories guidelines, Centers for Disease Control and Prevention and the National Institutes of Health, 4th edition, May 1999 (http://www.cdc.gov/od/ohs/biosfty/bmbl4/bmbl4toc.htm) as well as Department of Health and Human Services (DHHS) regulations regarding the transfer of select agents (42 CFR 72; http://www.cdc.gov/ncidod/srp/specimens/shipping-packing.html). Safety and Health HHSAR 352.223-70 clauses shall apply.
5) Describe provisions for ensuring safe facilities for the conduct of work in accordance with Recommendations for the Safe Handling of Cytotoxic Drugs, NIH Publication No. 92-2621 (http://dohs.ors.od.nih.gov/pdf/Recommendations_for_the_safe_Use_of_Handling_of_Cytotoxic_Drugs_January%202007.pdf) and the NIH Guidelines for the Laboratory use of Chemical Carcinogens, NIH Publication No. 81-2385 (http://grants2.nih.gov/grants/guide/notice-files/not92-070.html) and the controls and provisions to be in place for handling radioactive materials and irradiation equipment, training of personnel in the handling of radioactive materials, especially with respect to proper handling of radioactive animals, cultures and bioassays (see Publication 3000 as a recommended program; http://www.lbl.gov/ehs/pub3000/CH21.html#_Toc407168416).

SECTION 9: PROJECT MANAGEMENT

The Technical Proposal must:

1) Describe how the project will be staffed, organized and managed, including a detailed description of the responsibilities and the level of effort for all proposed personnel who will be assigned to the contract, and an administrative framework indicating clear lines of authority and responsibility for all personnel.
2) Describe project management systems that will be used to track activities and to keep multiple activities on time and budget.
3) Outline how the key personnel will communicate and interact with the BARDA Project Officer and the BARDA Contracting Officer and how the key personnel will communicate, monitor, and manage the project both internally and externally (at subcontractor facilities).
4) Provide a plan for soliciting, evaluating, negotiating, awarding, and managing subcontracts in accordance with FAR Clause 52.244-2.
5) Describe experience and education of contract management staff in the acquisition and management of subcontracts under Federal contracts.
6) Describe experience with identification and remediation of subcontractor performance or noncompliance with subcontract terms and conditions.
7) Provide a Letter of Understanding (LOU) signed by persons with authority to bind each collaborating party involved in the proposed work. The LOU must describe how the collaborating parties will coordinate their efforts to 1) protect intellectual property arising in the performance of the contract, 2) facilitate the development for commercialization of the resulting therapeutic product, and 3) resolve disputes among the collaborating parties should such disputes arise in performance of the contract.

SECTION 10: ANNUAL REVIEW MEETINGS

The Technical Proposal must include a plan for how the Contractor will plan, organize and conduct an Annual Review Meeting that shall include the BARDA Project Officer and Contracting Officer, the External Advisory group (if applicable), the PI, Project Manager(s), key subcontractors, and principal scientists involved on the contract.

ATTACHMENT 4

APPENDIX B: ADDITIONAL BUSINESS PROPOSAL INSTRUCTIONS AND UNIFORM COST ASSUMPTIONS
THERAPIES FOR HEMATOPOIETIC SYNDROME, BONE MARROW STROMAL CELL LOSS, AND VASCULAR INJURY RESULTING FROM ACUTE EXPOSURE TO IONIZING RADIATION

BAA BARDA-08-08

In addition to the format requirements for the business proposal that are contained in Instructions, Conditions and Notices to Offerors of the Broad Agency Announcement (BAA), the information provided in this Appendix is intended to provide uniform cost assumptions and business clarifications.

Offerors are advised to give careful consideration to the Broad Agency Announcement Description, Introduction, Scope, Research and Technical Objectives, all reference material provided as appendices and attachments, the technical evaluation criteria, and the BAA as a whole in the development of your proposal. The information requested in these instructions should be used as a guide for the development and formatting of your business proposal. Offerors should consider and include the information requested in this appendix as well as any other information which will benefit the proposal.

1. BUDGET PRESENTATION

a) Composite Budget: Provide a one-page composite budget itemizing the costs for all proposed activities for each year of requested funding as is required in Business Proposal Instructions.
b) Individual Budgets: Provide individual budget breakdowns for each component being proposed for each year
c) Stage-Specific Budget: Provide a budget for each stage of the Strategic Staged Product Development Plan that is proposed to be performed with contract funding.

Note: The estimated costs associated with subcontractors and collaborative arrangements must be shown separately within each individual budget breakdown as well as within the composite budget.

- Research Area 1: the development of medical countermeasures that can replenish the normal hematopoietic profile, in whole or in part (i.e., treat neutropenia, lymphopenia and thrombocytopenia, etc.) following acute radiation exposure that induces lethal hematopoietic dyscrasias;
- Research Area 2: development of medical countermeasures to replenish bone marrow niche and progenitor cells that normally populate the marrow stroma and niche environment and that can, following acute exposure to ionizing radiation that induces lethal hematopoietic dyscrasias, restore normal functioning hematopoietic cell lineages; or
- Research Area 3: development of medical countermeasures that address injury to the vascular system induced following acute exposure to ionizing radiation, including changes in intimal integrity and clotting propensity, macrophage repair mechanisms and trafficking, vascular leak, endothelial repair, endovascular surface chemistry, alteration of angiogenesis, and other changes in anatomical or molecular pathology.

2. PURCHASE OF EQUIPMENT: Support for the purchase of equipment will be provided.

3. UNIFORM COST ASSUMPTIONS:
Each Proposal for Research Areas 1, 2, and 3:
Year 1 budget ranges from $1,000,000 to $3,400,000 in fiscal year 08 commensurate with the SOW for the period of performance ranging up to 3 years with lifetime costs not to exceed $13,500,000 pending availability of funds.

4. ALTERATIONS AND RENOVATIONS: Support for alterations and renovations will NOT be provided under this contract.

5. SUBMISSION OF PROPOSALS
Major Milestones: The milestones listed below are based upon current information.

ITEM	MILESTONES	DATE
1	BAA Release	3/6/2008

2	Deadline to submit questions	3/14/2008
3	Questions and Answers posted in FEDBIZ OPPS	3/28/2008
4	Pre-Proposal Conference	N/A
5	Proposal Receipt deadline	4/17/2008
6	Contract Award Date (Multiple Awards Planned)	9/16/2008

Note: Actual award dates will vary based on complexity, statutory requirements, quality of proposal, pricing considerations, audits of proposed rates, type of instrument, number of awards, and other considerations. All dates are subject to change.

6. PROGRAM MEETINGS

Each Contractor shall participate in Program meetings organized by the BARDA Project Officer to foster collaborations and the exchange of ideas among the participating researchers. These Program meetings will be held twice in the first year of the contract and once a year thereafter in or near Washington, DC for 1.5 days unless otherwise determined by the Project Officer.

The Project Officer and Contracting Officer shall attend this meeting. Other relevant NIH and BARDA staff may attend including the Program Manager, other key investigators, key subcontracting staff and other key research personnel up to a maximum of two individuals per contract with prior approval by the Project Officer. In addition there will be a bioinformatics session that will be attended by up to two key bioinformatics staff members (additional to the two key research personnel). The purpose of the bioinformatics session will be to facilitate data sharing between different contractors and to share possible solutions to common problems that may occur with data management.

7. SCIENTIFIC MEETINGS

The Contractor shall budget travel for up to three key personnel to attend two scientific meetings per year, not including the Program Meeting.

ATTACHMENT 5

(USE WHEN THE BAA INVOLVES HUMAN SUBJECTS UNLESS IT HAS BEEN DETERMINED BY THE GOV'T THAT THE INCLUSION OF WOMEN & MINORITY GROUPS IN THE STUDY POPULATION IS NOT APPROPRIATE.)

TARGETED/PLANNED ENROLLMENT TABLE

This report format should NOT be used for data collection study participants

Study Title:			
Total Planned Enrollment:			
TARGETED/PLANNED ENROLLMENT: Number of Subjects			
Ethnic Category	**Sex/Gender**		
	Females	**Males**	**Total**
Hispanic or Latino			
Not Hispanic or Latino			
Ethnic Category Total of All Subjects*			
Racial Categories			
American Indian/Alaska Native			
Asian			
Native Hawaiian or Other Pacific Islander			
Black or African American			
White			
Racial Categories: Total of All Subjects*			

*The "Ethnic Category Total of All Subjects" must be equal to the "Racial Categories Total of All Subjects."

ATTACHMENT 6

TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS

DIRECT LABOR:	Year 1	Year 2	Year 3	
Labor Category (Hours)	(Hours)	(Hours)	(Hours)	Total
Total Hours				
DIRECT LABOR COST:	$	$	$	$
MATERIAL COST:	$	$	$	$
TRAVEL COST:	$	$	$	$
OTHER (Specify)	$	$	$	$
OTHER (Specify)	$	$	$	$
TOTAL DIRECT COST:	$	$	$	$

Specific Instructions:

1. Do not include any individual salary information
2. Do not include any indirect cost or fee.
3. Do not submit the total amount of proposal.
4. Submit this information as a portion of the Technical Proposal.

ATTACHMENT 7

SUMMARY OF RELATED ACTIVITIES

The following specific information must be provided by the offeror pertaining to the Project Director, Principal Investigator, and each of any other proposed key professional individuals designated for performance under any resulting contract.

a. Identify the total amount of all presently active federal contracts/cooperative agreements/grants and commercial agreements citing the committed levels of effort for those projects for each of the key individuals***** in this proposal.

Professional's Name and Title/Position:

Identifying Number	Agency	Total Effort Committed
1.		
2.		
3.		
4.		

*****If an individual has no obligation(s), so state.

b. Provide the total number of outstanding proposals, exclusive of the instant proposal, having been submitted by your organization, not presently accepted but in an anticipatory stage, which will commit levels of effort by the proposed professional individuals*****.

Professional's Name and Title/Position:

Identifying Number	Agency	Total Effort Committed
1.		
2.		
3.		
4.		

*****If no commitment of effort is intended, so state.

c. Provide a statement of the level of effort to be dedicated to any resultant contract awarded to your organization for those individuals designated and cited in this proposal.

Name	Title/Position	Total Proposed Effort
1.		
2.		
3.		
4.		

NOTE: This notice is for the Technical Evaluation Review Group who will be reviewing the proposals submitted in response to this BAA. THE OFFEROR SHALL PLACE A COPY OF THIS NOTICE BEHIND THE TITLE PAGE OF EACH COPY OF THE TECHNICAL PROPOSAL.

GOVERNMENT NOTICE FOR HANDLING PROPOSALS

This proposal shall be used and disclosed for evaluation purposes only, and a copy of this Government notice shall be applied to any reproduction or abstract thereof. Any authorized restrictive notices which the submitter places on this proposal shall be strictly complied with. Disclosure of this proposal outside the Government for evaluation purposes shall be made only to the extent authorized by, and in accordance with, the procedures in HHSAR 352.215-1.

(a) If authorized in agency implementing regulations, agencies may release proposals outside the Government for evaluation, consistent with the following:

(1) Decisions to release proposals outside the Government for evaluation purposes shall be made by the agency head or designee;

(2) Written agreement must be obtained from the evaluator that the information (data) contained in the proposal will be used only for evaluation purposes and will not be further disclosed;

(3) Any authorized restrictive legends placed on the proposal by the prospective Contractor or subcontractor or by the Government shall be applied to any reproduction or abstracted information made by the evaluator;

(4) Upon completing the evaluation, all copies of the proposal, as well as any abstracts thereof, shall be returned to the Government office which initially furnished them for evaluation; and

(5) All determinations to release the proposal outside the Government take into consideration requirements for avoiding organizational conflicts of interest and the competitive relationship, if any, between the prospective Contractor or subcontractor and the prospective outside evaluator.

(b) The submitter of any proposal shall be provided notice adequate to afford an opportunity to take appropriate action before release of any information (data) contained therein pursuant to a request under the Freedom of Information Act (5 U.S.C. 552); and, time permitting, the submitter should be consulted to obtain assistance in determining the eligibility of the information (data) in question as an exemption under the Act. (See also FAR Subpart 24.2, Freedom of Information Act.)

OMB No. 0990-0263
Approved for use through 07/31/2005

Protection of Human Subjects
Assurance Identification/IRB Certification/Declaration of Exemption
(Common Rule)

Policy: Research activities involving human subjects may not be conducted or supported by the Departments and Agencies adopting the Common Rule (56FR28003, June 18, 1991) unless the activities are exempt from or approved in accordance with the Common Rule. See section 101(b) of the Common Rule for exemptions. Institutions submitting applications or proposals for support must submit certification of appropriate Institutional Review Board (IRB) review and approval to the Department or Agency in accordance with the Common Rule. Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

1. Request Type	2. Type of Mechanism	3. Name of Federal Department or Agency and, if known, Application or Proposal Identification No.
[ ] ORIGINAL [ ] CONTINUATION [ ] EXEMPTION	[ ] GRANT [ ] CONTRACT [ ] FELLOWSHIP [ ] COOPERATIVE AGREEMENT [ ] OTHER:_____	
4. Title of Application or Activity		5. Name of Principal Investigator, Program Director, Fellow, or Other

6. Assurance Status of this Project *(Respond to one of the following)*

[ ] This Assurance, on file with Department of Health and Human Services, covers this activity:
Assurance Identification No._____, the expiration date_____ IRB Registration No. _____

[ ] This Assurance, on file with *(agency/dept)*_____, covers this activity.
Assurance No._____, the expiration date_____ IRB Registration/Identification No._____*(if applicable)*

[ ] No assurance has been filed for this institution. This institution declares that it will provide an Assurance and Certification of IRB review and approval upon request.

[ ] Exemption Status: Human subjects are involved, but this activity qualifies for exemption under Section 101(b), paragraph_____.

7. Certification of IRB Review (Respond to one of the following IF you have an Assurance on file)

[ ] This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations.
by: [ ] Full IRB Review on (date of IRB meeting) _____ or [ ] Expedited Review on (date)
[ ] If less than one year approval, provide expiration date _____

[ ] This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

8. Comments

9. The official signing below certifies that the information provided above is correct and that, as required, future reviews will be performed until study closure and certification will be provided.	10. Name and Address of Institution
11. Phone No. *(with area code)* 12. Fax No. *(with area code)* 13. Email:	
14. Name of Official	15. Title
16. Signature	17. Date

Authorized for local Reproduction — Sponsored by HHS

Public reporting burden for this collection of information is estimated to average less than an hour per response. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: OS Reports Clearance Officer, Room 503 200 Independence Avenue, SW., Washington, DC 20201. *Do not return the completed form to this address.*

ATTACHMENT 10

PROPOSAL SUMMARY AND DATA RECORD

DEPARTMENT OF HEALTH AND HUMAN SERVICES **BARDA** **PROPOSAL SUMMARY AND DATA RECORD**	BAA NUMBER **BAA-BARDA-08-08**
PROJECT TITLE (Title or BAA or Contract Proposal)	
LEGAL NAME AND ADDRESS OF OFFEROR	PLACE OF PERFORMANCE (Full address including ZIP)
TYPE OF CONTRACT PROPOSED COST-REIMBURSEMENT FIXED PRICE COST-PLUS-FIXED-FEE OTHER	
ESTIMATED TIME REQUIRED TO COMPLETE PROJECT	
ESTIMATED DIRECT COSTS IN PROPOSED YEAR (From Budget	PROPOSED STARTING DATE
DOES THIS PROPOSAL INCLUDE A SUBCONTRACT YES NO (If yes, please furnish name and location of organization, description of services, basis for selection, responsible person employed by subcontractor and cost information.)	

NAME AND TITLE OF PRINCIPAL INVESTIGATOR		EST. HOURS WEEKLY	AREA CODE/TEL.NO.
NAME AND TITLE OF CO-INVESTIGATOR (Use attachment if necessary.)			

NAME AND TITLE OF INDIVIDUAL(S) AUTHORIZED TO NEGOTIATE CONTRACTS	AREA CODE/TELEPHONE NUMBER
NAME AND TITLE OF INDIVIDUAL(S) AUTHORIZED TO EXECUTE CONTRACTS	AREA CODE/TELEPHONE NUMBER

DOES THIS PROPOSAL INVOLVE EXPERIMENTS WITH HUMAN SUBJECTS YES NO
Institution's General Assurance re: Human Subjects DATE APPROVED _____ PENDING
Institution's Review Board's Approval of this Proposal DATE APPROVED _____ PENDING
An example of the informed consent for this study is enclosed YES NO
A Clinical Protocol is enclosed YES NO

OFFEROR'S ACKNOWLEDGMENT OF AMENDMENTS TO THE BAA (Use attachment if necessary)

ERRATA NUMBER	DATE	ERRATA NUMBER	DATE

NAME, ADDRESS, AND PHONE NUMBER OF COGNIZANT GOVERNMENT AUDIT AGENCY	NUMBER OF EMPLOYEES CURRENTLY EMPLOYED
	DOLLAR VOLUME OF BUSINESS PER ANNUM
	THIS OFFER EXPIRES _____ DAYS FROM THE DATE OF THIS OFFER (120 days if not specified)

FOR THE INSTITUTION

SIGNATURE OF PRINCIPAL INVESTIGATOR	SIGNATURE OF BUSINESS REPRESENTATIVE
TYPED NAME AND TITLE	TYPED NAME AND TITLE
	DATE OF OFFER

ATTACHMENT 11

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
SMALL BUSINESS SUBCONTRACTING PLAN

Operating Division (OPDIV): _____

DATE OF PLAN: _____

CONTRACTOR: _____

ADDRESS: _____

_____

_____

DUNN & BRADSTREET NUMBER: _____

BAA OR CONTRACT NUMBER: _____

ITEM/SERVICE (Description): _____

_____

_____

_____

_____

TOTAL CONTRACT AMOUNT: $_____ $ _____
Total Cost of Contract Base Period Cost

$ _____ $_____ $ _____ $ _____
Option #1 (if applicable) Option #2 (if applicable) Option #3 (if applicable) Option #4 (if applicable)

PERIOD OF CONTRACT PERFORMANCE (Month, Day & Year):_____

TOTAL MODIFICATION AMOUNT, IF APPLICABLE $ _____

TOTAL TASK ORDER AMOUNT, IF APPLICABLE $ _____

The following outline meets the minimum requirements of section 8(d) of the Small Business Act, as amended, and implemented by Federal Acquisition Regulations (FAR) Subpart 19.7. While this outline has been

designed to be consistent with statutory and regulatory requirements, other formats of a subcontracting plan may be acceptable. **It is not intended to replace any existing corporate/commercial plan that is more extensive.**

Failure to include the essential information of FAR Subpart 19.7 may be cause for either a delay in acceptance or the rejection of a bid or offer when a subcontracting plan is required. "SUBCONTRACT," as used in this clause, means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime contractor or subcontractor requesting supplies or services required for performance of the contract or subcontract.

If assistance is needed to locate small business sources, contact the OPDIV Small Business Specialist (SBS) at (_____) _____-_____, the Office of Small and Disadvantage Business Utilization (OSDBU) at (202) 690-7300, or visit the OSDBU website (http://www.hhs.gov/osdbu/staff.html). Also, sources may be obtained through the Central Contractor Registration (http://www.ccr.gov/) website.

Please note that the U.S. Department of Health and Human Services (HHS) has subcontracting goals of _____% for small business (SB), ____% for small disadvantaged business (SDB), _____% for women-owned business (WOSB), _____% for HubZone business (HUBZone) and ____service disabled veteran-owned small business (SDVOSB) concerns for fiscal year _____. For this procurement, HHS expects all proposed subcontracting plans to contain the following small business goals, a minimum, ____% for total SB, ____ % for SDB, _____% for WOSB, ____% for HubZone and _____% for SDVOSB concerns. These percentages shall be expressed as percentages of the total estimated subcontracting dollars. **The offeror is required to include an explanation for a category that has zero as a goal.**

1. Type of Plan (check one)

_____ ***Individual plan*** (all elements developed specifically for this contract and applicable for the full term of this contract).

_____ ***Master plan*** (goals developed for this contract) all other elements standardized and approved by a lead agency Federal Official; must be renewed every three years and contractor must provide copy of lead agency approval.

_____ ***Commercial products/service plan*** (goals are negotiated with the initial agency on a company-wide basis rather than for individual contracts) this plan applies to the entire production of commercial service or items or a portion thereof. The contractor sells commercial products and services customarily used for non-government purposes. The plan is effective during the offeror's fiscal year. The contractor must provide a copy of the initial agency approval and must enter an annual SSR into the electronic Subcontracting Reporting System (eSRS) with a breakout of subcontracting prorated for HHS and other Federal agencies.

2. Goals

State separate dollar and percentage goals for Small Business (SB), Small Disadvantaged Business (SDB), Woman-owned Small Business (WOSB), Historically Underutilized Business Zone (HUBZone) Small Business, Service-Disabled Veteran-owned Small Business (SDVOSB) and "Other than small business" (Other) as subcontractors, for the base year and each option year, as specified in FAR 19.704 (break out and append option year goals, if the contract contains option years) or project annual subcontracting base and goals under commercial plans.

a. Total estimated dollar value of ALL planned subcontracting, i.e., with ALL types of concerns under this contract is _____ (Base Year)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option

$ _____ $ _____ $ _____ $ _____

b. Total estimated dollar value and percent of planned subcontracting with SMALL BUSINESSES (including SDB, WOSB, HUBz and SDVOSB): (% of "a") $ _____ and _____% (Base Year)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option

$ _____ $ _____ $ _____ $ _____

c. Total estimated dollar value and percent of planned subcontracting with SMALL DISADVANTAGED BUSINESSES: (% of "a") $ _____ and _____% (Base Year)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option

$ _____ $ _____ $ _____ $ _____

d. Total estimated dollar value and percent of planned subcontracting with WOMAN-OWNED SMALL BUSINESSES: (% of "a") $ _____ and _____% (Base Year)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option

$ _____ $ _____ $ _____ $ _____

e. Total estimated dollar and percent of planned subcontracting with HUBZone SMALL BUSINESSES: (% of "a") $ _____ and _____% (Base Year)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option

$ _____ $ _____ $ _____ $ _____

f. Total estimated dollar and percent of planned subcontracting with SERVICE-DISABLED VETERAN-OWNED SMALL BUSINESSES: (% of "a") $ _____ and _____% (Base Year)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option

$ _____ $ _____ $ _____ $ _____

g. Total estimated dollar and percent of planned subcontracting with "OTHER THAN SMALL BUSINESSES" (% of "a") $ _____ and _____% (Base Year)

FY ___1st Option FY ___2nd Option FY ___3rd Option FY ___4th Option

$ _____ $ _____ $ _____ $ _____

Notes: 1. Federal prime contract goals are:
SB equals ____%; SDB equals ___%; WOSB equals ___%; HUBZone equals ___%; and SDVOSB equals ___% may serve as objectives for subcontracting goal development.

2. SDB, WOSB, HUBZone and SDVOSB goals are subsets of SB and should be counted and reported in multiple categories, as appropriate.

3. If any contract has more four options, please attach additional sheets showing dollar amounts and percentages.

ATTACHMENT 11

Provide a description of ALL the products and/or services to be subcontracted under this contract, and indicate the size and type of business supplying them (check all that apply):

Products and/or Services	Other	Small Business	SDB	WOSB	Hubz	SDVOSB
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						

i. Provide a description of the method used to develop the subcontracting goals for SB, SDB, WOSB, HUBZone and SDVOSB concerns. Address efforts made to ensure that maximum practicable subcontracting opportunities have been made available for those concerns and explain the method used to identify potential sources for BAA purposes. Explain the method and state the quantitative basis (in dollars) used to establish the percentage goals. Also, explain how the areas to be subcontracted to SB, WOSB, HUBZone and SDVOSB concerns were determined, how the capabilities of these concerns were considered contract opportunities and how such data comports with the cost proposal. Identify any source lists or other resources used in the determination process. (Attach additional sheets, if necessary.)

_____

_____

_____

_____

j. Indirect costs have ____ have not ____ been included in the dollar and percentage subcontracting goals above (check one).

k. If indirect costs have been included, explain the method used to determine the proportionate share of such costs to be allocated as subcontracts to SB, SDB, WOSB, HUBZone and SDVOSB concerns:

_____

_____

_____

_____

3. Program Administrator:

NAME/TITLE: _____

ADDRESS: _____

_____

TELEPHONE: _____E-MAIL: _____

Duties: Does the individual named above have general overall responsibility for the company's subcontracting program, i.e., developing, preparing, and executing subcontracting plans and monitoring performance relative to the requirements of those subcontracting plans and perform the following duties? (If NO is checked, please indicate who in the company performs those duties, or indicate why the duties are not performed in your company on a separate sheet of paper and submit with the proposed subcontracting plan.)

a. Developing and promoting company-wide policy initiatives that demonstrate the company's support for awarding contracts and subcontracts to SB, SDB, WOSB, HUBZone and SDVOSB concerns; and for assuring that these concerns are included on the source lists for BAAs for products and services they are capable of providing. ___ yes ____ no

b. Developing and maintaining bidder source lists of SB, SDB, WOSB, HUBZone and SDVOSB concerns from all possible sources; _____ yes _____ no

c. Ensuring periodic rotation of potential subcontractors on bidder's lists; _____ yes _____ no

d. Assuring that SB, SDB, WOSB, HUBZONE and SDVOSB businesses are included on the bidders' list for every subcontract BAA for products and services that they are capable of providing. _____ yes _____ no

e. Ensuring that requests for proposals (RFPs) are designed to permit the maximum practicable participation of SB, SDB, WOSB, HUBZone and SDVOSB concerns. _____ yes _____ no

f. Reviewing subcontract BAAs to remove statements, clauses, etc., which might tend to restrict or prohibit small, 8(a), SDB, WOSB, Hubz and SDVOSB small business participation. _____ yes _____ no

g. Accessing various sources for the identification of SB, SDB, WOSB, HUBZone and SDVOSB concerns to include the Central Contractor Registration (http://www.ccr.gov/), local small business and minority associations, local chambers of commerce and Federal agencies' Small Business Offices; ____ yes _____ no

h. Establishing and maintaining contract and subcontract award records; _____ yes _____ no

i. Participating in Business Opportunity Workshops, Minority Business Enterprise Seminars, Trade Fairs, Procurement Conferences, etc; _____ yes _____ no

j. Ensuring that SB, SDB, WOSB, HUBZone and SDVOSB concerns are made aware of subcontracting opportunities and assisting concerns in preparing responsive bids to the company; _____ yes _____ no

k. Conducting or arranging for the conduct of training for purchasing personnel regarding the intent and impact of Section 8(d) of the Small Business Act, as amended; _____ yes _____ no

l. Monitoring the company's subcontracting program performance and making any adjustments necessary to achieve the subcontract plan goals; _____ yes _____ no

m. Preparing and submitting timely, required subcontract reports; _____ yes _____ no

n. Conducting or arranging training for purchasing personnel regarding the intent and impact of 8(d) of the Small Business Act on purchasing procedures; _____ yes _____ no

o. Coordinating the company's activities during the conduct of compliance reviews by Federal agencies; and _____ yes _____ no

p. Other duties: _____

4. Equitable Opportunity

Describe efforts the offeror will undertake to ensure that SB, SDB, WOSB, HUBZone and SDVOSB concerns will have an equitable opportunity to compete for subcontracts. These efforts include, but are not limited to, the following activities:

a. Outreach efforts to obtain sources:

1. Contact minority and small business trade associations; 2) contact business development organizations and local chambers of commerce; 3) attend SB, SDB, WOSB, HUBZone and SDVOSB procurement conferences and trade fairs; 4) review sources from the Central Contractor Registration (http://www.ccr.gov/); 5) review sources from the Small Business Administration (SBA), Central Contractor Registration (CCR); 6) Consider using other sources such as the National Institutes of Health (NIH) e-Portals in Commerce, (e-PIC), (http://epic.od.nih.gov/). The NIH e-PIC is not a mandatory source; however, it may be used at the offeror's discretion; and 7) Utilize newspaper and magazine ads to encourage new sources.

b. Internal efforts to guide and encourage purchasing personnel:

1. Conduct workshops, seminars and training programs;

2. Establish, maintain, and utilize SB, SDB, WOSB, HUBZone and SDVOSB source lists, guides, and other data for soliciting subcontractors; and

3. Monitor activities to evaluate compliance with the subcontracting plan.

Additional efforts:

_____

_____

5. Flow Down Clause

The contractor agrees to include the provisions under FAR 52.219-8, "Utilization of Small Business Concerns," in all acquisitions exceeding the simplified acquisition threshold that offers further subcontracting opportunities. All subcontractors, except small business concerns, that receive subcontracts in excess of $550,000 ($1,000,000 for construction) must adopt and comply with a plan similar to the plan required by FAR 52.219-9, "Small Business Subcontracting Plan." ***Note:*** In accordance with FAR 52.212-5(e) and 52.244-6(c) the contractor is not required to include flow-down clause FAR 52.219.-9 if it is subcontracting commercial items.

6. Reporting and Cooperation

The contractor gives assurance of (1) cooperation in any studies or surveys that may be required; (2) submission of periodic reports which show compliance with the subcontracting plan; (3) submission of its Individual Subcontracting Report (ISR) and Summary Subcontract Report (SSR); and (4) ensuring that subcontractors agree to submit ISRs and SSRs. **The ISR and SSR shall be submitted via the Electronic Subcontracting Reporting System (eSRS) website https://esrs.symplicity.com/index?_tab=signin&cck=1**

Reporting Period	Report Due	Due Date
Oct 1 - Mar 31	ISR	4/30
Apr 1 - Sept 30	ISR	10/30
Oct 1 - Sept 30	SSR	10/30

Contract Completion	OF 312	30 days after completion

See FAR 19.7 for instruction concerning the submission of a Commercial Plan: SSR is due on 10/30 each year for the previous fiscal year ending 9/30.

a. Submit ISR (bi-annually) for the cognizant awarding Contracting Officer's review and acceptance via the eSRS website https://esrs.symplicity.com/index?_tab=signin&cck=1.

b. Currently, SSR (annually) must be submitted for the HHS eSRS Agency Coordinator review and acceptance via the eSRS website https://esrs.symplicity.com/index?_tab=signin&cck=1. (***Note**:* Log onto the OSDBU website to view the HHS Agency Coordinator contact information (http://www.hhs.gov/osdbu/staff.html).

c. Contractors that do not use the eSRS to submit its reports must also submit a paper copy of the SSR to the appropriate Commercial Market Representative (contact the contracting official (CO) or the CO's eSRS Point of Contact).

7. Record keeping

FAR 19.704(a) (11) requires a list of the types of records your company will maintain to demonstrate the procedures adopted to comply with the requirements and goals in the subcontracting plan. The following is a recitation of the types of records the contractor will maintain to demonstrate the procedures adopted to comply with the requirements and goals in the subcontracting plan. These records will include, but not be limited to, the following:

a. SB, SDB, WOSB, HUBZone and SDVOSB source lists, guides and other data identifying such vendors;

b. Organizations contacted in an attempt to locate SB, SDB, WOSB, HUBZone and SDVOSB sources;

c. On a contract-by-contract basis, records on all subcontract BAAs over $100,000, which indicate for each BAA (1) whether SB, SDB, WOSB, HUBZone and/or SDVOSB concerns were solicited, if not, why not and the reasons solicited concerns did not receive subcontract awards;

d. Records to support other outreach efforts, e.g., contacts with minority and small business trade associations, attendance at small and minority business procurement conferences and trade fairs;

e. Records to support internal guidance and encouragement provided to buyers through (1) workshops, seminars, training programs, incentive awards; and (2) monitoring performance to evaluate compliance with the program and requirements; and

f. On a contract-by-contract basis, records to support subcontract award data including the name, address, and business type and size of each subcontractor. (This item is not required on a *contract – by – contract basis* for company or division-wide commercial plans.)

g. Other records to support your compliance with the subcontracting plan: (Please describe)

_____

_____

_____

_____

8. Timely Payments to Subcontractors

FAR 19.702 requires your company to establish and use procedures to ensure the timely payment of amounts due pursuant to the terms of your

subcontracts with small business concerns, 8(a), SDB, women-owned small business, HubZone and service disabled veteran-owned small business concerns.

Your company has established and used such procedures: _____ yes _____ no

9. Description of Good Faith Effort

Maximum practicable utilization of small, 8(a), small disadvantaged, woman-owned, HubZone small and service disabled veteran owned concerns as subcontractors in Government contracts is a matter of national interest with both social and economic benefits**. When a contractor fails to make a good faith effort to comply with a subcontracting plan, these objectives are not achieved, and 15 U.S.C. 637(d) (4) (F) directs that liquidated damages shall be paid by the contractor.** In order to demonstrate your compliance with a good faith effort to achieve the small, SDB, WOSB, HubZone and SDVOSB small business subcontracting goals, outline the steps your company plans to take. These steps will be negotiated with the contracting official prior to approval of the plan.

_____

_____

_____

SIGNATURE PAGE

Signatures Required:

This subcontracting plan was submitted by:

Signature: _____

Typed Name: _____

Title: _____

Date: _____

This plan was reviewed by:

Signature: _____

Typed Name: _____

Title: Contracting Officer

Date: _____

This plan was reviewed by:

Signature: _____

Typed Name: _____

Title: Small Business Specialist (SBS)

Date: _____

This plan was reviewed by:

Signature: _____

Typed Name: _____

Title: Small Business Administration Procurement Center Representative (PCR)

Date: _____

Is Accepted By:

OPDIV: _____

Typed Name: _____

Title: _____

Date: _____

ATTACHMENT 12

REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

1. Annual Representations and Certifications completed and located at the Online Representations and Certifications Application (ORCA) website at https://orca.bpn.gov/. A hard copy version of the Representations and Certifications shall be submitted with the Proposal.
2. OHRP Federalwide Assurance (FWA) Number _____ .
3. Animal Welfare Assurance Number _____ .

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLETE AND INCLUDE PRESENTATIONS AND CERTIFICATIONS AS PART OF YOUR BUSINESS PROPOSAL

ATTACHMENT 13

BREAKDOWN OF PROPOSED ESTIMATED COST (PLUS FEE)
AND LABOR HOURS

INSTRUCTIONS FOR USE OF THE FORMAT

1. Refer to Business Proposal Instructions of this BAA. The Instructions contain the requirements for proper submission of cost/price data which must be adhered to.

2. This format has been prepared as a guideline. It may require amending to meet the specific requirements of this BAA. For example, this BAA may require the submission of cost/price data for three years listed on this form. If this BAA is phased, identify each phase in addition to each year. Total each year, phase, and sub-element.

3. This format must be used to submit the breakdown of all proposed estimated cost elements. List each cost element and sub-element for direct costs, indirect costs and fee, if applicable. In addition, provide detailed calculations for all items. For example:

   a. For all personnel, list the name, title, rate per hour and number of hours proposed. If a pool of personnel is proposed, list the composition of the pool and how the cost proposed was calculated. List the factor used for prorating Year One and the escalation rate applied between years.

      Offeror's proposal should be stated in the same terms as will be used to account for and record the effort under a contract. If percentages of effort are used, the basis to which such percentages are applied must also be submitted by the offeror. The attached format should be revised to accommodate direct labor proposed as a percentage of effort.

   b. For all materials, supplies, and other direct costs, list all unit prices, etc., to detail how the calculations were made.
   c. For all indirect costs, list the rates applied and the base the rate is applied to.
   d. For all travel, list the specifics for each trip.
   e. For any subcontract proposed, submit a separate breakdown format.
   f. Justification for the need of some cost elements may be listed as an attachment, i.e., special equipment, above average consultant fees, etc.

4. If the Government has provided "uniform pricing assumptions" for this BAA, the offeror must comply with and identify each item.

5. **It is requested that you use the spreadsheet that is provided below to prepare your business proposal. For security purposes, please include a hard copy of the completed spreadsheet and submit the electronic file on a diskette with your proposal.**

BREAKDOWN OF PROPOSED ESTIMATED COST (PLUS FEE) AND LABOR HOURS

COST ELEMENT	Year 1	Year 2	Year 3	
Labor Category Rate	(Hours)	(Hours)	(Hours)	Total
DIRECT LABOR COST:	$	$	$	$
MATERIAL COST:	$	$	$	$
TRAVEL COST:	$	$	$	$
OTHER (Specify)	$	$	$	$
OTHER (Specify)	$	$	$	$
TOTAL DIRECT COST:	$	$	$	$
FRINGE BENEFIT COST: (if applicable) % of Direct Labor Cost	$	$	$	$
INDIRECT COST: % of Total Direct Cost	$	$	$	$
TOTAL COST:	$	$	$	$
FIXED FEE: (if applicable) % of Total Est. Cost	$	$	$	$
GRAND TOTAL ESTIMATED CPFF)	$	$	$	$

ATTACHMENT 14

OFFEROR'S POINTS OF CONTACT

Complete the following and return with the BUSINESS PROPOSAL.

Name, Title and Address* of Business Representative with whom daily contact is required.

Name:	Telephone:
Title:	Fax:
Office:	E-Mail:
Organization:	
*Street Address:	
City, State, Zip Code:	

Name, Institutional Title and Address of Proposed Principal Investigator

Name:	Telephone:
Title:	Fax:
Office:	E-Mail:
Organization:	
*Street Address:	
City, State, Zip Code:	

These exact addresses are necessary to ensure that contact can be made with the proper individual(s) in the most expeditious manner.

*****Please use actual street address, not P.O. Box.

ATTACHMENT 15

DISCLOSURE OF LOBBYING ACTIVITIES **Approved by OMB 348-0046**

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352
(See reverse for public burden disclosure.)

1. Type of Federal Action: a. contract b. grant c. cooperative agreement d. loan e. loan guarantee f. loan insurance	2. Status of Federal Action: a. bid/offer/application b. Initial award c. post-award	3. Report Type: a. initial filing b. material change For Material Change Only: year _____ quarter _____ date of last report_____

4. Name and Address of Reporting Entity: Prime Subawardee Tier_____, if known: Congressional District, if known:	5. If Reporting Entity in No. 4 is Subawardee, Enter Name and Address of Prime Congressional District, if known:
6. Federal Department/Agency:	7. Federal Program Name/Description CFDA Number, if applicable: _____
8. Federal Action Number, if known:	9. Award Amount, if known: $
10. a. Name and Address of Lobbying Entity (if individual, last name, first name, MI): (attach Continuation Sheet(s)	b. Individual Performing Services (including address if different from No. 10a) (last name, first name, MI) SF-LLL-A, if necessary)
11. Amount of Payment (check all that apply): $_____ actual planned	13. Type of Payment (check all that apply): a. retainer b. one-time fee c. commission d. contingent fee e. deferred f. other; specify: _____
12. Form of Payment (check all that apply): a. cash b. in-kind; specify: nature_____ value_____	

14. Brief Description of Services Performed or to be Performed and Date(s) of Service, including officer(s), employee(s), or Member(s) contacted, for payment indicated in Item 11:

(attach Continuation Sheet(s) SF-LLL-A, if necessary)

15. Continuation Sheet(s) SF-LLL-A attached:
Yes No

16. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be reported to the Congress semi-annually and will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than $10,000 and not more than $100,000 for each failure.	Signature:_____ _____ Print Name:_____ _____ Title:_____ _____ Telephone No.:_____Date:_____
Federal Use Only	Authorized for Local Reproduction Standard Form--LLL

DISCLOSURE OF LOBBYING ACTIVITIES

CONTINUATION SHEET
Approved by OMB

0348-0046

Reporting Entity:_____ Page _____ of _____

Authorized for Local Reproduction
Standard Form--LLL-A

ATTACHMENT 15

INSTRUCTIONS FOR COMPLETION OF SF-LLL, DISCLOSURE OF LOBBYING ACTIVITIES

This disclosure form shall be completed by the reporting entity, whether subawardee of prime Federal recipient, at the initiation or receipt of a covered Federal action, or a material change to a previous filing, pursuant to title 31 U.S.C. section 1352. The filing of a form is required for each payment or agreement to make payment to any lobbying entity for influencing of attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with a covered Federal action. Use the SF-LLL-A Continuation Sheet for additional information if the space on the form is inadequate. Complete all items that apply for both the initial filing and material change report. Refer to the implementing guidance published by the Office of Management and Budget for additional information.

1. Identify the type of covered Federal action for which lobbying activity is and/or has been secured to influence the outcome of a covered Federal action.

2. Identify the status of the covered Federal action.

3. Identify the appropriate classification of this report. If this is a follow-up report caused by a material change to the information previously reported, enter the year and quarter in which the change occurred. Enter the date of the last previously submitted report by this reporting entity for this covered Federal action.

4. Enter the full name, address, city, state and zip code of the reporting entity. Include Congressional District, if known. Check the appropriate classification of the reporting entity that designates if it is, or expects to be, a prime or subaward recipient. Identify the tier of the subawardee, e.g., the first subawardee of the prime is the 1st tier. Subawards include but are not limited to subcontracts, subgrants and contract awards under grants.

5. If the organization filing the report in item 4 checks "Subawardee," then enter the full name, address, city, state and zip code of the prime Federal recipient. Include Congressional District, if known.

6. Enter the name of the Federal agency making the award or loan commitment. Include at least one organizational level below agency name, if known. For example, Department of Transportation, United States Coast Guard.

7. Enter the Federal program name or description for the covered Federal action (item 1). If known, enter the full Catalog of Federal Domestic Assistance (CFDA) number for grants, cooperative agreements, loans, and loan commitments.

8. Enter the most appropriate Federal identifying number available for the Federal action identified in item 1 (e.g., Request for Proposal (RFP) number, Invitation for Bid (IFB) number, grant announcement number, the contract, grant, or loan award number, the application/proposal control number assigned by the Federal agency). Include prefixes, e.g., "RFP-DE-90-001."

9. For a covered Federal action where there has been an award or loan commitment by the Federal agency, enter the Federal amount of the award/loan commitment for the prime entity identified in item 4 or 5.

10. (a) Enter the full name, address, city, state and zip code of the lobbying entity engaged by the reporting entity identified in item 4 to influence the covered Federal action.
    (b) Enter the full names of the individual(s) performing services, and include full address if different from 10(a); Enter Last Name, First Name, and Middle Initial (MI).

11. Enter the amount of compensation paid or reasonably expected to be paid by the reporting entity (item 4) to the lobbying entity (item 10). Indicate whether the payment has been made (actual) or will be made (planned). Check all boxes that apply. If this is a material charge report, enter the cumulative amount of payment made or planned to be made.

12. Check the appropriate box(es). Check all boxes that apply. If payment is made through an in-kind contribution, specify the nature and value of the in-kind payment.

13. Check the appropriate box(es). Check all boxes that apply. If other, specify nature.

14. Provide a specific and detailed description of the services that the lobbyist has performed, or will be expected to perform, and the date(s) of any services rendered. Include all preparatory and related activity, not just time spent in actual contact with Federal officials. Identify the Federal official(s) or employee(s) contacted or the officer(s),

employee(s), or Member(s) of Congress that were contacted.

15. Check whether or not a SF-LLL-A Continuation Sheet(s) is attached.

16. The certifying official shall sign and date the form, print his/her name, title and telephone number.

ATTACHMENT 16

MODEL CONTRACT

(This attachment contains terms that are likely to be included as part of the contract awarded under this BAA.)

AWARD/CONTRACT	1 THIS CONTRACT IS A RATED UNDER DPAS (15 CFR 350) ▶	RATING	PAGE OF PAGES 1
2. CONTRACT *(Proc. Inst. Ident.)* NO.	3. EFFECTIVE DATE	4. REQUISITION/PURCHASE REQUEST/PROJECT NO.	

5. ISSUED BY CODE	6. ADMINISTERED BY *(If other than* CODE
Biomedical Advanced Research and Development Authority Assistant Secretary for Preparedness and Response U. S. Department of Health and Human Services 330 Independence Avenue, S.W., Room G640 Washington, D.C. 20201	BARDA

7. NAME AND ADDRESS OF CONTRACTOR *(No. street, county, state and ZIP Code)*	8. DELIVERY ☐ FOB ORIGIN ☒ OTHER *(See* 9. DISCOUNT FOR PROMPT PAYMENT N/A 10. SUBMIT INVOICES *(4 copies unless other-wise specified)* ▶ TO THE ADDRESS SHOWN IN: ITEM
CODE FACILITY CODE	

11. SHIP TO/MARK FOR CODE	12. PAYMENT WILL BE MADE BY CODE

13. AUTHORITY FOR USING OTHER FULL AND OPEN COMPETITION: ☐ 10 U.S.C. 2304(c)( ) **N/A** 41 U.S.C. 253(c)( )	14. ACCOUNTING AND APPROPRIATION DATA EIN # SOC # DOC # CAN #8- Amount: $

15A. ITEM NO.	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
Contract Type: Cost Reimbursement Completion Title: Therapies for Hematopoietic Syndrome, Bone Marrow Stromal Cell Loss, and Vascular Injury Resulting From Acute Exposure to Ionizing Radiation. Period:		FY 2008 $ FY 2009 $ FY 20010 $			
			15G. TOTAL AMOUNT OF CONTRACT ▶		$

16. TABLE OF CONTENTS

(✓)	SE	DESCRIPTION	PAGE(S)	(✓)	SE	DESCRIPTION	PAGE(S)
PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES			
		BAA/CONTRACT FORM				CONTRACT CLAUSES	
		SUPPLIES OR SERVICES AND PRICE/COST		PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.			
		DESCRIPTION/SPECS./WORK STATEMENT				LIST OF ATTACHMENTS	
		PACKAGING AND MARKING		PART IV - REPRESENTATIONS AND INSTRUCTIONS			
		INSPECTION AND ACCEPTANCE				REPRESENTATIONS, CERTIFICATIONS	
		DELIVERIES OR PERFORMANCE				AND OTHER STATEMENTS OF OFFERORS	
		CONTRACT ADMINISTRATION DATA				INSTRS., CONDS., AND NOTICES TO OFFERORS	
		SPECIAL CONTRACT REQUIREMENTS				EVALUATION FACTORS FOR AWARD	

CONTRACTING OFFICER WILL COMPLETE ITEM 17 OR 18 AS APPLICABLE

17. ☒ CONTRACTOR'S NEGOTIATED AGREEMENT *(Contractor is required to sign this document and return __2__ copies to issuing office.)* Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the BAA, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. *(Attachments are listed herein.)*	18. ☐ AWARD *(Contractor is not required to sign this document.)* Your offer on BAA Number _____, including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's BAA and your offer, and (b) this award/contract. No further contractual document is necessary.

19A. NAME AND TITLE OF SIGNER *(Type or print)*	20A. NAME OF CONTRACTING OFFICER Senior Contracting Officer BARDA, ASPR, OS, DHHS
19B. NAME OF CONTRACTOR 19C. DATE _____ *(Signature of person authorized to sign)*	20B. UNITED STATES OF AMERICA 20C. DATE BY

I. SUPPLIES OR SERVICES AND PRICES/COSTS

1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The purpose of this effort is to seek medical countermeasures that will be clinically useful in a civilian medical emergency situation that results from or involves exposure of a large population to the effects of a nuclear detonation, an RDD, or exposure to ionizing radiation/ radioactive material with or without combined injury or trauma.

2. PRICES/COSTS

The final contract will contain the price/cost provisions agreed upon by the Government and the Offeror.

3. PROVISIONS APPLICABLE TO DIRECT COSTS

This article will prohibit or restrict the use of contract funds, unless otherwise approved by the Contracting Officer. The following is a list of items that may be included in the resultant contract as applicable. 1) Acquisition, by purchase or lease, of any interest in real property; 2) Special rearrangement or alteration of facilities; 3) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value; 4) Travel Costs; 5) Consultant Costs; 6) Subcontract Costs; 7) Patient Care Costs; 8) Accountable Government Property; and 9) Research Funding.

4. ADVANCE UNDERSTANDINGS

A. Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost (e.g., foreign travel, consultant fees, subcontracts) will be included in this Article if the Contracting Officer has granted his/her approval prior to contract award.

B. The scope of the work and a funding schedule is based on a Comprehensive Staged Product Development Plan and a Strategic Staged Product Development Plan. The contract will be funded for an initial phase of work with one or more additional phases of the work defined as options. Near the end of each phase, the work will be evaluated by the Project Officer and, at the discretion of HHS, the Contracting Officer may exercise an option to fund the next phase of activity.

II. DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

1. BROAD AGENCY ANNOUNCEMENT

Independently and not as an agent of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work submitted in response to this Broad Agency Announcement (BAA) BARDA 08-08. The Offeror's statement of work may be revised during negotiations leading to award of a contract.

2. REPORTING REQUIREMENTS

In addition to the required reports set forth elsewhere in this Schedule, the preparation and submission of regularly recurring Technical Progress Reports will be required in any contract resulting from this BAA. These reports will require descriptive information about the activities undertaken during the reporting period and will require information about the planned activities for future reporting periods. Please refer to Reporting Requirements and Deliverables in this BAA.

III. PACKAGING, MARKING AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Government specifications. At a minimum, all deliverables shall be marked with the contract number and contractor name. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

IV. INSPECTION AND ACCEPTANCE

a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.

b. For the purpose of this section, the BARDA Project Officer is the authorized representative of the Contracting Officer.

c. Inspection and acceptance will be performed at BARDA, ASPR, U.S. Department of Health and Human Services, 330 Independence Avenue. S.W., Room G640, Washington, D.C. 20201.
Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

d. This contract incorporates the following clauses by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR Clause 52.246-8, Inspection of Research and Development - Cost-Reimbursement (May 2001).

V. DELIVERABLES OR PERFORMANCE

1. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the Statement of Work and upon delivery and acceptance by the Contracting Officer or the duly authorized representative of the deliverables in accordance with the stated delivery schedule.

The deliverables will be required to be delivered F.O.B. Destination as set forth in FAR Clause 52.247-35, F.O.B. Destination, Within Consignees Premises (April 1984), and in accordance with and by the dates specified in the reporting requirements and any specifications stated in the section Packaging, Marking and Shipping of the contract.

2. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. Also, the full text of a clause may be accessed electronically at this address: http://www.acquisition.gov/comp/far/index.html

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (August 1989)

Deliverable Reports	No. of Copies	Addressee/Distribution	Due Dates
Monthly Reports	1 Original 1 CD	*Contracting Officer* BARDA 330 Independence Ave., S.W. Room G640 Washington, DC 20201	Due the 15th of the month following the end of each month's performance.
	1 Copy 1 CD	*Project Officer* BARDA 330 Independence Ave., S.W. Room G640 Washington, D.C. 20201	

Quarterly Reports	1 Original 1 CD 1 Copy 1 CD	*Contracting Officer* BARDA 330 Independence Ave., S.W. Room G640 Washington, DC 20201 *Project Officer* BARDA 330 Independence Ave., S.W. Room G640 Washington, D.C. 20201	Due the 15th of the month following the end of each 3 months of performance.
Annual Technical Progress Reports	1 Original 1 CD 1 Copy 1 CD	*Contracting Officer* BARDA 330 Independence Ave., S.W. Room G640 Washington, DC 20201 *Project Officer* BARDA 330 Independence Ave., S.W. Room G640 Washington, D.C. 20201	Due the 15th of the month following the end of each annual performance period
Draft Final Technical Progress Report	1 Original 1 CD 1 Copy 1 CD	*Contracting Officer* BARDA 330 Independence Ave., S.W. Room G640 Washington, DC 20201 *Project Officer* BARDA 330 Independence Ave., S.W. Room G640 Washington, D.C. 20201	Due 120 calendar days before the completion of the project.
Final Report	1 Original 1 CD 1 Copy 1 CD	*Contracting Officer* BARDA 330 Independence Ave., S.W. Room G640 Washington, DC 20201 *Project Officer* BARDA 330 Independence Ave., S.W. Room G640 Washington, D.C. 20201	Due one week prior to the completion date of the contract.

TECHNICAL REPORTS

Deliverable Reports	**No. of Copies**	**Addressee/Distribution**	**Due Dates**
Draft Final Reports for Clinical and Non-Clinical Studies	1 Original 1 CD 1 Copy 1 CD	*Contracting Officer* BARDA 330 Independence Ave., S.W. Room G640 Washington, DC 20201 *Project Officer* BARDA 330 Independence Ave., S.W. Room G640 Washington, D.C. 20201	Due on or before fifteen (15) working days after the end of the performance period.

Final Reports for Clinical and Non-Clinical Studies	1 Original 1 CD 1 Copy 1 CD	*Contracting Officer* BARDA 330 Independence Ave., S.W. Room G640 Washington, DC 20201 *Project Officer* BARDA 330 Independence Ave., S.W. Room G640 Washington, D.C. 20201	Due on or before thirty (30) calendar days after receiving comments on the Draft Final Report from the Contracting Officer.
Audit Reports	1 Original 1 CD 1 Copy 1 CD	*Contracting Officer* BARDA 330 Independence Ave, S.W. Room G640 Washington, D.C. 20201 *Project Officer* BARDA 330 Independence Ave., S.W. Room G640 Washington, D.C. 20201	Within 30 calendar days of the audit related to conformance to FDA regulations and guidance.
Clinical Trial Protocols	1 Original 1CD 1 Copy 1 CD	*Contracting Officer* BARDA 330 Independence Ave, S.W. Room G640 Washington, D.C. 20201 *Project Officer* BARDA 330 Independence Ave. S.W. Room G640 Washington, D.C. 20201	To be negotiated with the BARDA Project Officer prior to IND submission or enrollment of human subjects.

OTHER REPORTS/DELIVERABLES

Deliverable Reports	**No. of Copies**	**Addressee/Distribution**	**Due Dates**
FDA Correspondence and FDA Meeting Minutes	1 Original 1 CD 1 Copy 1 CD	*Contracting Officer* BARDA 330 Independence Ave., S.W. Room G640 Washington, DC 20201 *Project Officer* BARDA 330 Independence Ave., S.W. Room G640 Washington, D.C. 20201	Within 30 calendar days of receiving correspondence or meeting with the FDA.
Reports of any exceptional issues potentially affecting contract	1 Original 1 CD 1 Copy 1 CD	*Contracting Officer* BARDA 330 Independence Ave., S.W. Room G640 Washington, DC 20201 *Project Officer* BARDA 330 Independence Ave., S.W. Room G640 Washington, D.C. 20201	Within 2 calendar days of knowledge of incident, problem, or issue.

Invention Report- Annual Utilization Report	1 Original 1 CD 1 Copy 1 CD	*Extramural Inventions and Technology Resources Branch* OPERA NIH 6705 Rockledge Drive Room 1040-A MSC 7980 Bethesda, Maryland 20892-7980 *Contracting Officer* BARDA 330 Independence Ave., S.W. Room G640 Washington, DC 20201	Due on or before the 30th of the month following each anniversary of the contract.
Final Invention Statement	1 Original 1 CD 1 Copy 1 CD	*Extramural Inventions and Technology Resources Branch* OPERA NIH 6705 Rockledge Drive Room 1040-A MSC 7980 Bethesda, Maryland 20892-7980 *Contracting Officer* BARDA 330 Independence Ave., S.W. Room G640 Washington, DC 20201	Due on or before the completion date of the contract.

VI. CONTRACT ADMINISTRATION DATA

1. PROJECT OFFICER

The following Project Officer(s) will represent the Government for the purpose of this contract:

[To be specified prior to award]

The Project Officer is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections and acceptances required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its Project Officer designation.

2. KEY PERSONNEL

Pursuant to the Key Personnel clause incorporated in this contract, the following individual(s) is/are considered to be essential to the work being performed hereunder:

Name	Title

[To be specified prior to award]

3. INVOICE SUBMISSION

(a) The Contractor shall submit an original and two copies of contract invoices to the address shown below:

DHHS/OS/ASPR/BARDA

Attn: Contracting Officer

330 Independence Ave., S.W.

Room G640

Washington, D.C. 20201

4. GOVERNMENT PROPERTY

If this BAA will result in the acquisition or use of Government Property provided by the contracting agency or if the Contracting Officer authorizes in the preaward negotiation process, the acquisition of property (other than real property), this ARTICLE will include applicable provisions and incorporate the HHS Publication, entitled, "Contractor's Guide for Control of Government Property," which can be found at:

http://knownet.hhs.gov/log/AgencyPolicy/HHSLogPolicy/contractorsguide.htm .

5. INDIRECT COST RATES

In accordance with Federal Acquisition Regulation (FAR) (48 CFR chapter 1) Clauses 52.216-7(d)(2), “Allowable Cost and Payment, the cognizant Contracting Officer representative responsible for negotiating provisional and/or final indirect cost rates is identified as follows:

Director, Division of Financial Advisory Services
Office of Acquisition Management and Policy
National Institutes of Health
6100 Building, Room 6B05
6100 Executive Boulevard, MSC 7540
Bethesda, MD 20892-7540

These rates are hereby incorporated without further action of the Contracting Officer.

6. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

Interim and final evaluations of contractor performance will be prepared on this contract in accordance with FAR 42.15. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, an interim evaluation shall be submitted March 31, 2010.

Interim and final evaluations will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement. If agreement cannot be reached between the parties, the matter will be referred to an individual one level above the Contracting Officer, whose decision will be final.

Copies of the evaluations, contractor responses, and review comments, if any, will be retained as part of the contract file, and may be used to support future award decisions.

VII. SPECIAL CONTRACT REQUIREMENTS

1. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable State and Local laws and the provisions of the Uniform Anatomical Gift Act in the United States, and no undue inducements, monetary or otherwise, will be offered to any person to influence their donation of human material.

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP-approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

2. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

a. Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds for (1) the creation of a human embryo or embryos for research purposes; or (2) research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.204(b) and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)). The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes or human diploid cells.

   Additionally, in accordance with a March 4, 1997 Presidential Memorandum, Federal funds may not be used for cloning of human beings.

b. **Public Law and Section No.**	**Fiscal Year**	**Period Covered**
P.L. 110-161, Division G, Title V, Section 509	2008	10/1/2007-9/30/2008

3. NEEDLE EXCHANGE

a. Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

b. **Public Law and Section No.**	**Fiscal Year**	**Period Covered**
P.L. 110-161, Division G, Title V, Section 505	2008	10/1/2007-9/30/2008

4. CARE OF VERTEBRATE ANIMALS

(a) Before undertaking performance of any contract involving research on live, vertebrate animals, the Contractor

shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2316 and 9 CFR Section 2.30. The Contractor shall furnish evidence of such registration to the Contracting Officer.

(b)The Contractor shall acquire animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2131-2157 and 9 CFR Sections 2.1-2.11, or from a source that is exempt from licensing under those sections.

(c) The Contractor agrees that all research involving live, vertebrate animals shall be conducted in accordance with applicable local, state, federal (including 21CFR 58), or other regulations and policy on humane care and use of laboratory animals.

If at any time during performance of this contract, the Contracting Officer determines that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may terminate this contract in whole or in part.

5. SUBCONTRACTING PROVISIONS

a. Small Business Subcontracting Plan

1. The Small Business Subcontracting Plan, dated _____ is attached hereto and made a part of this contract.
2. The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8, entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan, will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "Liquidated Damages-Subcontracting Plan."

b. Subcontracting Reports

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at http://esrs.gov/.

1. Individual Subcontract Reports (ISR)

   Regardless of the effective date of this contract, the Report shall be submitted on the following dates for the entire life of this contract:

   April 30th
   October 30th

2. Summary Subcontract Report (SSR)

   Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:

   October 30th

   For both the Individual and Summary Subcontract Reports, the Contracting Officer shall be included as a contact for notification purposes at the following e-mail address: carl.newman@hhs.gov

_____
Contracting Officer

6. SALARY RATE LIMITATION LEGISLATION PROVISIONS

a. Payment of direct salaries is limited to the Executive Level I rate which was in effect on the date(s) the expense was incurred. See the following web site for Executive Schedule rates of pay: http://www.opm.gov/oca/. For current year rates, click on Salaries and Wages / Executive Schedule / Rates of Pay for Executive Schedule. For prior year rates, click on Salaries and Wages / cursor to bottom of page and select year / Executive Schedule / Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted..

b.

Public Law and Section No.	Fiscal Year	Period Covered
P.L. 110-161, Division G, Title II, Section 203	2008	10/1/2007-9/30/2008

c. Payment of direct salaries is limited to the Executive Level I rate which was in effect on the date(s) the expense was incurred.

7. PUBLICATION AND PUBLICITY

The contractor shall acknowledge the support of the Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Biomedical Advanced Research and Development Authority, Department of Health and Human Services, under Contract No. HHSO1002008xxxxxC."

8. PRESS RELEASES

a. Pursuant to the current HHS annual appropriations act, the Contractor shall clearly state, when issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money: (1) the percentage of the total costs of the program or project which will be financed with Federal money; (2) the dollar amount of Federal funds for the project or program; and (3) the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

b. **Public Law and Section No.**	**Fiscal Year**	**Period Covered**
P.L. 110-161, Division G, Title V, Section 506	2008	10/1/2007-9/30/2008

9. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in HHS funded programs is encouraged to report such matters to the HHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS** (**1-800-447-8477).** All telephone calls will be handled confidentially. The e-mail address is **Htips@os.dhhs.gov** and the mailing address is:

Office of Inspector General
Department of Health and Human Services
TIPS HOTLINE
P.O. Box 23489
Washington, D.C. 20026

10. ANTI -LOBBYING

a. Pursuant to Public Law(s) cited in paragraph c., below, contract funds shall only be used for normal and recognized executive-legislative relationships. Contract funds shall not be used for publicity or propaganda purposes; or for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State legislature, except in presentation to the Congress or any State legislature itself.

b. Contract funds shall not be used to pay salary or expenses of the contractor or any agent acting for the contractor, related to any activity designed to influence legislation or appropriations pending before the Congress or any State legislature.

c. **Public Law and Section No.**	**Fiscal Year**	**Period Covered**
P.L. 110-161, Division G, Title V, Section 503	2008	10/1/2007-9/30/2008

11. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

Pursuant to Public Law 101-391, no Federal funds may be used to sponsor or fund in whole or in part a meeting, convention, conference or training seminar that is conducted in, or that otherwise uses the rooms, facilities, or services of a place of public accommodation that do not meet the requirements of the fire prevention and control guidelines as described in the Public Law. This restriction applies to public accommodations both foreign and domestic.

Public accommodations that meet the requirements can be accessed at:
http://www.usfa.fema.gov/hotel/index.htm

12. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The 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 this contract.

13. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING SCIENTIFIC INFORMATION

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to disseminate scientific information that is deliberately false or misleading.

14. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to employ workers described in section 274A(h)(3) of the Immigration and Nationality Act, which reads as follows: "(3) Definition of unauthorized alien. As used in this section, the term 'unauthorized alien' means, with respect to the employment of an alien at a particular time, that the alien is not at that time either (A) an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General."

15. RESTRICTION ON ABORTIONS

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds for any abortion.

VIII. CONTRACT CLAUSES

THE FOLLOWING GENERAL CLAUSE LISTING(S) WILL BE APPLICABLE TO MOST CONTRACTS RESULTING FROM THIS BAA. HOWEVER, THE ORGANIZATIONAL STRUCTURE OF THE SUCCESSFUL OFFEROR(S) WILL DETERMINE THE SPECIFIC GENERAL CLAUSE LISTING TO BE CONTAINED IN THE CONTRACT(S) AWARDED FROM THIS BAA:

General Clauses for a Cost-Reimbursement Contract with Educational Institutions

General Clauses for a Cost-Reimbursement Contract with Non-Profit Organizations Other Than Educational Institutions

General Clauses for a Cost-Reimbursement Research and Development Contract

The complete listing of these clauses may be accessed at:
http://rcb.cancer.gov/rcb-internet/appl/general-clauses/clausesDGS.jsp

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 substitution(s) will be made part of the resultant contract:

a. *FAR Clauses **52.215-15, Pension Adjustments And Asset Reversions** (October 2004); **52.215-18, Reversion Or Adjustment Of Plans For Post Retirement Benefits (PRB) Other Than Pensions** (July 2005); and, 52.215-19, **Notification Of Ownership Changes** (October 1997), are deleted in their entirety.*

b. ***Alternate IV** (October 1997) of FAR Clause **52.215-21, Requirements For Cost Or Pricing Data Or Information Other Than Cost Or Pricing Data--Modifications** (October 1997) is added.*

c. ***Alternate II** (October 2001) of FAR Clause **52.219-9, Small Business Subcontracting Plan** (September 2006) is added.*

d. *FAR Clause **52.232-20, Limitation Of Cost** (April 1984), is deleted in its entirety and FAR Clause **52.232-22, Limitation Of Funds** (April 1984) is substituted therefore. **[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.]***

e. ***Alternate I** (February 2002), of FAR Clause **52.232-25, Prompt Payment** (February 2002) is deleted.*

f. *FAR Clause **52.216-11, Cost Contract--No Fee** (April 1984) is deleted in its entirety and FAR Clause **52.216-8 Fixed Fee** (March1997) is substituted therefore.*

g. *FAR Clause **52.232-17, Interest** (June 1996) is added.*

h. *FAR Clause **52.249-5, Termination For Convenience Of the Government (Educational And Other Non-Profit Institutions)** (April 1984) is deleted in its entirety and FAR Clause **52.249-6, Termination (Cost-Reimbursement)** (May 1986) is substituted therefore.*

i. *HHSAR Clause **352.249-14, Excusable Delays** (January 2006) is deleted in its entirety and FAR Clause **52.249-14, Excusable Delays** (April 1984) is substituted therefore.*

ATTACHMENT 16

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 BAA 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

1*. FAR Clause* ***52.204-9, Personal Identity Verification of Contractor Personnel*** *(November 2006).*

2*. FAR Clause* ***52.219-4, Notice of Price Evaluation Preference for HUBZone Small Business Concerns*** *(July 2005).*

"(c) Waiver of evaluation preference.....
[ ] *Offeror elects to waive the evaluation preference."*

3.*FAR Clause* ***52.219-25, Small Disadvantaged Business Participation Program--Disadvantaged Status and Reporting*** *(October 1999).*

4.FAR Clause **52.230-2, Cost Accounting Standards (April 1998).**

5.*FAR Clause* ***52.230-6, Administration of Cost Accounting Standards (April 2005).***

6.*FAR Clause 52.242-3,* ***Penalties for Unallowable Costs (May 2001).***

7.*FAR Clause 52.247-68,* ***Report of Shipment (REPSHIP) (February 2006).***

8.*FAR Clause 52.246-23****, Limitation of Liability (February 1997).***

9*.. FAR Clause* ***52.246-24, Limitation of Liability - High-Value Items*** *(February 1997)*.

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

1. *HHSAR Clause* ***352.223-70, Safety and Health*** *(January 2006).*

2. *HHSAR Clause* ***352.224-70, Confidentiality of Information*** *(January 2006).*

3. *HHSAR Clause* ***352.270-1, Accessibility of Meetings, Conferences and Seminars to Persons with Disabilities*** *(January 2001).*

4. *HHSAR Clause* ***352.270-8(b), Protection of Human Subjects*** *(January 2006).*

5. *HHSAR Clause* ***352.270-9(b), Care of Live Vertebrate Animals*** *(January 2006).*

ATTACHMENT 16

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 BAA will contain the following:

This contract incorporates the following clauses in full text.

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

1. *FAR Clause **52.203-14 Display of Hotline Poster(s)** (December 2007)*

(a) Definition.

"United States," as used in this clause, means the 50 States, the District of Columbia, and outlying areas.

(b) Display of fraud hotline poster(s). Except as provided in paragraph (c)—

(1) During contract performance in the United States, the Contractor shall prominently display in common work areas within business segments performing work under this contract and at contract work sites—

(i) Any agency fraud hotline poster or Department of Homeland Security (DHS) fraud hotline poster identified in paragraph (b)(3) of this clause; and

(ii) Any DHS fraud hotline poster subsequently identified by the Contracting Officer.

(2) Additionally, if the Contractor maintains a company website as a method of providing information to employees, the Contractor shall display an electronic version of the poster(s) at the website.

(3) Any required posters may be obtained as follows:

Hotline Poster can be obtained (downloaded) from US Department of Health & Human Services, Office of Inspector General at the below website:

http://www.oig.hhs.gov/hotline.html

(c) If the Contractor has implemented a business ethics and conduct awareness program, including a reporting mechanism, such as a hotline poster, then the Contractor need not display any agency fraud hotline posters as required in paragraph (b) of this clause, other than any required DHS posters.

(d) Subcontracts. The Contractor shall include the substance of this clause, including this paragraph (d), in all subcontracts that exceed $5,000,000, except when the subcontract—

(1) Is for the acquisition of a commercial item; or

(2) Is performed entirely outside the United States.

2. *FAR Clause **52.222-39, Notification Of Employee Rights Concerning Payment Of Union Dues Or Fees** (December 2004)*

(a) Definition. As used in this clause --

United States means the 50 States, the District of Columbia, Puerto Rico, the Northern Mariana Islands, American Samoa, Guam, the U.S. Virgin Islands, and Wake Island.

(b) Except as provided in paragraph (e) of this clause, during the term of this contract, the Contractor shall post a notice, in the form of a poster, informing employees of their rights concerning union membership and payment of union

dues and fees, in conspicuous places in and about all its plants and offices, including all places where notices to employees are customarily posted. The notice shall include the following information (except that the information pertaining to National Labor Relations Board shall not be included in notices posted in the plants or offices of carriers subject to the Railway Labor Act, as amended (45 U.S.C. 151-188)).

Notice to Employees

Under Federal law, employees cannot be required to join a union or maintain membership in a union in order to retain their jobs. Under certain conditions, the law permits a union and an employer to enter into a union-security agreement requiring employees to pay uniform periodic dues and initiation fees. However, employees who are not union members can object to the use of their payments for certain purposes and can only be required to pay their share of union costs relating to collective bargaining, contract administration, and grievance adjustment.

If you do not want to pay that portion of dues or fees used to support activities not related to collective bargaining, contract administration, or grievance adjustment, you are entitled to an appropriate reduction in your payment. If you believe that you have been required to pay dues or fees used in part to support activities not related to collective bargaining, contract administration, or grievance adjustment, you may be entitled to a refund and to an appropriate reduction in future payments.

For further information concerning your rights, you may wish to contact the National Labor Relations Board (NLRB) either at one of its Regional offices or at the following address or toll free number:

National Labor Relations Board
Division of Information
1099 14th Street, N.W.
Washington, DC 20570
1-866-667-6572
1-866-316-6572 (TTY)

To locate the nearest NLRB office, see NLRB's website at http://www.nlrb.gov *.*

(c) The Contractor shall comply with all provisions of Executive Order 13201 of February 17, 2001, and related implementing regulations at 29 CFR part 470, and orders of the Secretary of Labor.

(d) In the event that the Contractor does not comply with any of the requirements set forth in paragraphs (b), (c), or (g), the Secretary may direct that this contract be cancelled, terminated, or suspended in whole or in part, and declare the Contractor ineligible for further Government contracts in accordance with procedures at 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures. Such other sanctions or remedies may be imposed as are provided by 29 CFR part 470, which implements Executive Order 13201, or as are otherwise provided by law.

(e) The requirement to post the employee notice in paragraph (b) does not apply to--

(1)Contractors and subcontractors that employ fewer than 15 persons;

(2)Contractor establishments or construction work sites where no union has been formally recognized by the Contractor or certified as the exclusive

bargaining representative of the Contractor's employees;

(3) Contractor establishments or construction work sites located in a jurisdiction named in the definition of the United States in which the law of that jurisdiction forbids enforcement of union-security agreements;

(4)Contractor facilities where upon the written request of the Contractor, the Department of Labor Deputy Assistant Secretary for Labor-Management Programs has waived the posting requirements with respect to any of the Contractor's facilities if the Deputy Assistant Secretary finds that the Contractor has demonstrated that--

(i) The facility is in all respects separate and distinct from activities of the Contractor related to the performance of a contract; and

(ii) Such a waiver will not interfere with or impede the effectuation of the Executive order; or

(5) Work outside the United States that does not involve the recruitment or employment of workers within the United States.

(f) The Department of Labor publishes the official employee notice in two variations; one for contractors covered by the Railway Labor Act and a second for all other contractors. The Contractor shall--

(1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 2021, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;

(2) Download a copy of the poster from the Office of Labor-Management Standards website at http://www.olms.dol.gov *; or*

(3) Reproduce and use exact duplicate copies of the Department of Labor's official poster.

(g) The Contractor shall include the substance of this clause in every subcontract or purchase order that exceeds the simplified acquisition threshold, entered into in connection with this contract, unless exempted by the Department of Labor Deputy Assistant Secretary for Labor-Management Programs on account of special circumstances in the national interest under authority of 29 CFR 470.3(c). For indefinite quantity subcontracts, the Contractor shall include the substance of this clause if the value of orders in any calendar year of the subcontract is expected to exceed the simplified acquisition threshold. Pursuant to 29 CFR part 470, Subpart B--Compliance Evaluations, Complaint Investigations and Enforcement Procedures, the Secretary of Labor may direct the Contractor to take such action in the enforcement of these regulations, including the imposition of sanctions for noncompliance with respect to any such subcontract or purchase order. If the Contractor becomes involved in litigation with a subcontractor or vendor, or is threatened with such involvement, as a result of such direction, the Contractor may request the United States, through the Secretary of Labor, to enter into such litigation to protect the interests of the United States.

(End of Clause)

3. FAR Clause ***52.247-67, Submission of Transportation Documents for Audit*** *(February 2006).*

ATTACHMENT 16

(a) The Contractor shall submit to the address identified below, for prepayment audit, transportation documents on which the United States will assume freight charges that were paid--

(1) By Contractor under a cost-reimbursement contract; and
(2) By a first-tier subcontractor under a cost-reimbursement subcontract thereunder.

(b) Cost-reimbursement Contractors shall only submit for audit those bills of lading with freight shipment charges exceeding $100. Bills under $100 shall be retained on-site by the Contractor and made available for on-site audits. This exception only applies to freight shipment bills and is not intended to apply to bills and invoices for any other transportation services.

(c) Contractors shall submit the above referenced transportation documents to--

Biomedical Advanced Research and Development Authority
Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services
330 Independence Avenue., S.W., Room G640
Washington, D.C. 20201

ATTACHMENT 17

HHSAR 352.223-70 SAFETY AND HEALTH (JANUARY 2006)

(a) To help ensure the protection of the life and health of all persons, and to help prevent damage to property, the Contractor shall comply with all Federal, State and local laws and regulations applicable to the work being performed under this contract. These laws are implemented and/or enforced by the Environmental Protection Agency, Occupational Safety and Health Administration and other agencies at the Federal, State and local levels (Federal, State and local regulatory/enforcement agencies).

(b) Further, the Contractor shall take or cause to be taken additional safety measures as the Contracting Officer in conjunction with the project or other appropriate officer, determines to be reasonably necessary. If compliance with these additional safety measures results in an increase or decrease in the cost or time required for performance of any part of work under this contract, an equitable adjustment will be made in accordance with the applicable "Changes" Clause set forth in this contract.

(c) The Contractor shall maintain an accurate record of, and promptly report to the Contracting Officer, all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; and/or damage to property incidental to work performed under the contract and all violations for which the Contractor has been cited by any Federal, State or local regulatory/enforcement agency. The report shall include a copy of the notice of violation and the findings of any inquiry or inspection, and an analysis addressing the impact these violations may have on the work remaining to be performed. The report shall also state the required action(s), if any, to be taken to correct any violation(s) noted by the Federal, State or local regulatory/enforcement agency and the time frame allowed by the agency to accomplish the necessary corrective action.

(d) If the Contractor fails or refuses to comply promptly with the Federal, State or local regulatory/enforcement agency's directive(s) regarding any violation(s) and prescribed corrective action(s), the Contracting Officer may issue an order stopping all or part of the work until satisfactory corrective action (as approved by the Federal, State or local regulatory/enforcement agencies) has been taken and documented to the Contracting Officer. No part of the time lost due to any stop work order shall be subject to a claim for extension of time or costs or damages by the Contractor.

(e) The Contractor shall insert the substance of this clause in each subcontract involving toxic substances, hazardous materials, or operations. Compliance with the provisions of this clause by subcontractors will be the responsibility of the Contractor.

(End of clause)

Research Patient Care Costs

NIH RC-11 (4/84)

(a) Research patient care costs are the costs of routine and ancillary services provided to patients participating in research programs described in this contract.

(b) Patient care costs shall be computed in a manner consistent with the principles and procedures used by the Medicare Program for determining the part of Medicare reimbursement based on reasonable costs. The Diagnostic Related Group (DRG) prospective reimbursement method used to determine the remaining portion of Medicare reimbursement shall not be used to determine patient care costs. Patient care rates or amounts shall be established by the Secretary HHS or her duly authorized representative.

(c) Prior to submitting an invoice for patient care costs under this contract, the contractor must make every reasonable effort to obtain third party payment, where third party payors (including Government agencies) are authorized or are under a legal obligation to pay all or a portion of the charges incurred under this contract for patient care.

(d) The contractor must maintain adequate procedures to identify those research patients participating in this contract who are eligible for third party reimbursement.

(e) Only those charges not recoverable from third party payors or patients and which are consistent with the terms and conditions of the contract are chargeable to this contract.

INCLUSION ENROLLMENT REPORT

This report format should NOT be used for data collection from study participants

Study Title:	
Total Enrollment:	**Protocol Number:**
Contract Number:	

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race

Ethnic Category	Sex/Gender			
	Females	**Males**	**Unknown or Not Reported**	**Total**
Hispanic or Latino				
Not Hispanic or Latino				
Unknown (Individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More than one race				
Unknown or not reported				
Racial Categories: Total of All Subjects*				

PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)

Racial Categories	**Females**	**Males**	**Unknown or Not Reported**	**Total**
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or not reported				
Racial Categories: Total of Hispanics or Latinos**				
*These totals must agree **These totals must agree				

ATTACHMENT 20

INVOICE/FINANCING REQUEST INSTRUCTIONS FOR COST-REIMBURSEMENT TYPE CONTRACTS

General: The contractor shall submit claims for reimbursement in the manner and format described herein and as illustrated in the sample invoice/financing request.

Format: Standard Form 1034, "Public Voucher for Purchases and Services Other Than Personal," and Standard Form 1035, "Public Voucher for Purchases and Services Other Than Personal-- Continuation Sheet," or reproduced copies of such forms marked ORIGINAL should be used to submit claims for reimbursement. In lieu of SF-1034 and SF-1035, claims may be submitted on the payee's letter-head or self-designed form provided that it contains the information shown on the sample invoice/financing request.

Number of Copies: As indicated in the Invoice Submission Clause in the contract.

Frequency: Invoices/financing requests submitted in accordance with the Payment Clause shall be submitted monthly unless otherwise authorized by the Contracting Officer.

Cost Incurrence Period: Costs incurred must be within the contract performance period or covered by precontract cost provisions.

Billing of Costs Incurred: If billed costs include: (l) costs of a prior billing period, but not previously billed; or (2) costs incurred during the contract period and claimed after the contract period has expired, the amount and month(s) in which such costs were incurred shall be cited.

Contractor's Fiscal Year: Invoices/financing requests shall be prepared in such a manner that costs claimed can be identified with the contractor's fiscal year.

Currency: When payments are made in a currency other than United States dollars, billings on the contract shall be expressed, and payment by the United States Government shall be made, in that other currency at amounts coincident with actual costs incurred. Currency fluctuations may not be a basis of gain or loss to the contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

Costs Requiring Prior Approval: Costs requiring the Contracting Officer's approval, which are not set forth in an Advance Understanding in the contract shall be so identified. In addition, any cost set forth in an Advance Understanding shall be shown as a separate line item on the request.

Invoice/Financing Request Identification: Each invoice/financing request shall be identified as either:

(a) Interim Invoice/Contract Financing Request — These are interim payment requests submitted during the contract performance period.

(b) Completion Invoice — The completion invoice is submitted promptly upon completion of the work but no later than one year from the contract completion date, or within 120 days after settlement of the final indirect cost rates covering the year in which this contract is physically complete (whichever date is later). The completion invoice should be submitted when all costs have been assigned to the contract and all performance provisions have been completed.

(c) Final Invoice — A final invoice may be required after the amounts owed have been settled between the Government and the contractor (e.g., resolution of all suspensions and audit exceptions).

Preparation and Itemization of the Invoice/Financing Request: The contractor shall furnish the information set forth in the explanatory notes below. These notes are keyed to the entries on the sample invoice/financing request.
(a) Designated Billing Office Name and Address — Enter the designated billing office name and address, identified in the Invoice Submission Clause of the contract, on all copies of the invoice/financing request.

(b) Invoice/Financing Request Number — Insert the appropriate serial number of the invoice/financing request.

(c) Date Invoice/Financing Request Prepared — Insert the date the invoice/financing request is prepared.

(d) Contract Number and Date — Insert the contract number and the effective date of the contract.

(e) Payee's Name and Address — Show the contractor's name (as it appears in the contract), correct address, and the title

and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the contractor, or a different payee has been designated, then insert the name and address of the payee instead of the contractor.

(f) Total Estimated Cost of Contract — Insert the total estimated cost of the contract, exclusive of fixed-fee. For incrementally funded contracts, enter the amount currently obligated and available for payment.

(g) Total Fixed-Fee — Insert the total fixed-fee (where applicable). For incrementally funded contracts, enter the amount currently obligated and available for payment.

(h) Billing Period — Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(i) Amount Billed for Current Period — Insert the amount billed for the major cost elements, adjustments, and adjusted amounts for the period.

(j) Cumulative Amount from Inception — Insert the cumulative amounts billed for the major cost elements and adjusted amounts claimed during this contract.

(k) Direct Costs — Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.

(1) Direct Labor — Include salaries and wages paid (or accrued) for direct performance of the contract.

(2) Fringe Benefits — List any fringe benefits applicable to direct labor and billed as a direct cost. Fringe benefits included in indirect costs should not be identified here.

(3) Accountable Personal Property — Include permanent research equipment and general purpose equipment having a unit acquisition cost of $1,000 or more and having an expected service life of more than two years, and sensitive property regardless of cost (see the DHHS Contractor's Guide for Control of Government Property). Show permanent research equipment separate from general purpose equipment. Prepare and attach Form HHS-565, "Report of Accountable Property," in accordance with the following instructions:
List each item for which reimbursement is requested. A reference shall be made to the following (as applicable):

- The item number for the specific piece of equipment listed in the Property Schedule.

- Be preceded by an asterisk (*) if the equipment is below the approval level.

Further itemization of invoices/financing requests shall only be required for items having specific limitations set forth in the contract.

(4) Materials and Supplies — Include equipment with unit costs of less than $1,000 or an expected service life of two years or less, and consumable material and supplies regardless of amount.

(5) Premium Pay — List remuneration in excess of the basic hourly rate.

(6) Consultant Fee — List fees paid to consultants. Identify consultant by name or category, as well as the effort (i.e., number of hours, days, etc.) and rate being billed.

(7) Travel — Include domestic and foreign travel. Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside Canada, the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel.

(8) Subcontract Costs — List subcontractor(s) by name and amount billed.

(9) Other — List all other direct costs in total unless exceeding $1,000 in amount. If over $1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.

(l) Cost of Money (COM) — Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed.

(m) Indirect Costs--Overhead — Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.

(n) Fixed-Fee Earned — Cite the formula or method of computation for the fixed-fee (if any). The fixed-fee must be claimed as provided for by the contract.

(o) Total Amounts Claimed — Insert the total amounts claimed for the current and cumulative periods.

(p) Adjustments — Include amounts conceded by the contractor, outstanding suspensions, and/or disapprovals subject to appeal.

(q) Grand Totals

The Contracting Officer may require the contractor to submit detailed support for costs claimed on one or more interim invoices/financing requests.