TABLE OF CONTENTS

Section B – Supplies or Service and Price/Costs

B.1. Background

Recent, significant changes in the nature, regularity, and degree of the threat posed by the use of infectious agents as weapons of terrorism have generated an increased concern for the safety of the American populace. The urgent need to stockpile appropriate and effective medical countermeasures to safeguard against this potential threat became a reality following the deliberate exposure of United States citizens to *Bacillus anthracis* (anthrax) in 2001. As part of creating a portfolio of safe and effective anthrax vaccines, the United States Government (USG) established a requirement for the procurement of a recombinant protective antigen (rPA) anthrax vaccine. Acceptance of rPA anthrax vaccine into the Strategic National Stockpile (SNS) will be contingent upon the Contractor providing sufficient safety, immunogenicity, efficacy, stability, manufacturing and any other data and information, as determined by the Food and Drug Administration (FDA), Center for Biologics Evaluation and Research (CBER) for potential use of the product in a post-exposure prophylaxis (PEP) scenario in a declared emergency under an Emergency Use Authorization (EUA). The prescribed use of this rPA vaccine will be in adults (includes both genders 18-64 years of age) who are concomitantly being treated with antibiotics (PEP plus antibiotics).

In addition the Contractor will seek licensure for pre-exposure prophylaxis (also referred to as general use prophylaxis or GUP) in adults. Subsequently, the Contractor will seek label indication extension for PEP plus antibiotics in adults. The licensure of the product for GUP and PEP plus antibiotics, in adults, will be required in the base contract. Due to the general lack of information required to pursue licensure of an rPA anthrax vaccine in special populations, pediatric and geriatric, the Contractor shall submit a concept plan to address licensure in the stated populations. Procurement of an rPA anthrax vaccine partially supports the USG's goal of acquiring enough anthrax vaccine to protect 25 Million people. In parallel, the USG will continue to invest in the development and procurement of anthrax vaccines that are efficacious, have an increased shelf life, and represent the best value to the government.

B.2. Project Identification and Purpose

Deliver 25 million doses of an rPA anthrax vaccine, manufactured in accordance with current Good Manufacturing Practices (cGMP), to the SNS. The Final Drug Product (FDP) shall fulfill the requirements as determined by FDA/CBER for potential use of the vaccine in a PEP plus antibiotic scenario, during a declared emergency under an EUA. The vaccine shall also be licensed in accordance to FDA/CBER regulations for GUP and PEP plus antibiotics in adults.

B.3. Specific Technical Requirements

The offeror shall provide the necessary qualified personnel, facilities, material, equipment and services to produce, test, formulate, fill, package, store and deliver the rPA vaccine. This work shall be done in accordance with the contractor's Standard Operation Procedures and all federal statutory and regulatory requirements.

B.4. CLIN Structure

BASE:

CLIN #	Base/Option-Type	Supply or Service	Qty/Unit	Unit Price	Extended Price
0001A	Base-FP	Deliver 25,000,000 rPA doses (minimum 24 months stability) to support appropriate regulatory filing submitted by CDC as described in Section C.1.4.	25,000,000	$	$
0001B	Base-FP	Conduct supportive studies to allow for rolling BLA of rPA product to include, but not limited to, stability, potency, non-clinical, clinical studies	1 job	$	$
0001C	Base-FP	Payment for Licensure for pre-exposure, general use prophylaxis (GUP) difference in discount for doses delivered under CLIN 0001A	25,000,000	$	$
0001D	Base-FP	Payment for Licensure of post-exposure prophylaxis concomitant with antibiotics (PEP plus antibiotics) difference in discount for doses delivered under CLIN 0001A	25,000,000	$	$
0002	Base-FP	Store, Ship, Deliver 25,000,000 rPA doses delivered under CLIN 0001	1 job	$	$
0003	Base-FP	Re-Labeling of IND to Licensed product delivered under CLIN 0001	25,000,000	$	$
0004A	Base-FP	Design and submission of a Phase 4 post-marketing plan	1 each	$	$
0005	Base-FP	Disposition of vaccine inventory	1 job	$	$

			Estimated Cost	Fixed Fee	CPFF
0006	Base-CR	Security of contract operations	$	$	$
0007	Base-CR	Information technology security	$	$	$

OPTIONS:

			Qty/Unit	Unit Price	Extended Price
0004B	Option-FP	Implementation of Plan under CLIN 0004A on a price per person basis	1 job	$	$
0008A	Option-FP	36 month expiry dating BLA submission to FDA	1 job	$	$
0008B	Option FP	Payment for achieving 36 month expiry product	1 job	$	$
0008C	Option-FP	Re-label product to reflect 36 month expiry	25,000,000	$	$

			Estimated Cost	Fixed Fee	CPFF
0009	Option-CR	Concept plan for studies to extend label indication for PEP in geriatric	$	$	$
0010	Option-CR	Concept plan for studies to extend label indication for PEP in pediatric	$	$	$

B.5. Advance Understandings

a. Inspections & Collection of Samples

At the discretion of the USG and independent of testing conducted by the Contractor, the USG reserves the right to conduct site visits and collect samples of product held by the Contractor and in the SNS.

b. Licensure Hold Back

A negotiated dollar amount will be withheld from payment under CLIN 0001A until such time the contractor achieves licensure. This pertains to FDP doses that are delivered to the SNS prior to licensure. After achieving licensure, the monies will be paid to the contractor under CLIN 0001C and or CLIN 0001D.

c. Man in Plant

With 7 days advance notice to the contractor, the government may place a man in plant in the contractor's facility. The man in plant is restricted to observing, verifying, and surveying the contractor's performance under this contract.

d. Reserved

B.6. PAYMENT CONDITIONED ON DELIVERY

a. Delivery of not less than 600,000 rPA doses under CLIN 0001A is a condition for any payment under this contract. The contractor may not invoice for a CLIN prior to the initial delivery of 600,000 rPA doses. Advance Payment and or Milestone Payments will be addressed during negotiations (See H.18.).

b. Payments at a discounted price (CLIN 0001A) may be made to the contractor for product prior to FDA licensure and for FDA licensed product. Upon delivery of FDA licensed product, supplemental payment (CLIN 0001C and CLIN 0001D) will then be made to the contractor.

c. Product accepted into the SNS but which falls into any of the following three categories shall be replaced by the contractor at no cost to the USG:

    i. If the final FDA approved or licensed product is determined by the FDA to be different from the initial delivered product, contractor must replace, at no-cost to the USG, initial not yet approved or licensed product with FDA approved or licensed product prior to final supplemental payment being made by the USG or,

ii. If product does not meet any specified label claims, fails release testing or does not meet 24 month expiry period, or

iii. If product is deemed to be recalled for any reason, as outlined in Product Recalls, Including Removals and Corrections published by U.S. Department of Health and Human Services, Food and Drug Administration, Office of Regulatory Affairs; or based upon Chapter 7 of the Regulatory Procedures Manual of March 2007.

Section C. Statement Of Objectives (SOO)

C.1. General Objectives

C.1.1. The USG is seeking 25 million doses of an rPA anthrax vaccine for the SNS to be delivered with the anticipated period of performance of the base contract (5 year); however, three additional one-year no-cost extensions may be granted for a total up to a maximum of 8 total years (per the Project BioShield Act).

C.1.2. The USG seeks proposals for the most cost effective rPA anthrax vaccine. The final drug FDP shall be packaged as single dose units or multi-dose vials, provide for the most cost effective product life-cycle value and performance, and allow for ease of distribution and use during a mass vaccination program.

C.1.3. The rPA anthrax vaccine shall require a maximum of three (3) doses to show efficacy and shall have an expiry period of no less than 24 months with a minimum of 20 months remaining when delivered to the SNS.

C.1.4. The rPA anthrax vaccine shall be developed for potential pre-licensure use in a PEP plus antibiotics scenario (in adults) under EUA in a declared emergency. Please consult the following, http://www.fda.gov/oc/guidance/emergencyuse.html, for information concerning EUA. The information and data needed to potentially support this use will be determined by the FDA/CBER. The offeror(s) should note that the submission to potentially support use under an EUA will be submitted by the Centers for Disease Control and Prevention(CDC) and the Contractor(s) shall be obligated to supply the CDC with the data needed to support the submission, as well as a right of reference to the Contractor's Investigational New Drug (IND) application that contains the supporting data.

C.1.5. The initial licensed label indication shall be for GUP in adults.

C.1.6. There is also a requirement for a label extension for the PEP plus antibiotics indication in adults within the base contract.

C.2. Manufacturing Objectives

C.2.1. The offeror(s) shall deliver 25 million doses of FDP, manufactured in accordance with cGMP, to the SNS. The vaccine shall require a maximum of three (3) doses to show efficacy. The FDP shall fulfill the requirements as determined by FDA/CBER for potential use of the vaccine in a PEP plus antibiotic scenario in a declared emergency under an EUA. The vaccine shall also be licensed in accordance to FDA/CBER regulations for GUP and PEP plus antibiotics in adults.

C.2.2. The offeror(s) shall facilitate cGMP site-visit or inspection, as determined by FDA/CBER, at the time of production of vaccine lots destined for the SNS; should the FDA/CBER determine that this is warranted.

C.2.3. The offeror(s) shall develop a stability testing plan, in consultation with FDA, CDC and BARDA, for IND and FDA licensed product delivered to the SNS. Plan should maximize the useable life of rPA product, through periodic stability and potency testing.

C.2.4. The offeror(s) shall develop a labeling strategy in consultation with FDA, CDC, and BARDA to allow ease of transition from IND to licensed product. The labeling strategy shall be submitted to FDA/CBER and the Project Officer far enough in advance of labeling product to be delivered to the SNS to allow for a complete review and concurrence by FDA/CBER. For additional information, offeror(s) may consult the interim final rule "Exceptions or Alternatives to labeling Requirements for products held by the Strategic National Stockpile", published in the Federal register as Docket No. 2006N-0466 on December 28, 2007 at http://edocket.access.gpo.gov/2007/pdf/e7-25165.pdf . Offeror(s) shall note that this interim rule is open to public comment and possible future modification by the FDA.

C.3. Assay Validation Objectives

C.3.1. The offeror(s) shall validate critical assays required for Bulk Drug Substance (BDS) and FDP release and stability testing, assessment of immune responses in animals and humans, and potency evaluation. FDA will assist in the identification of parameters for validation of critical assays to support an EUA and subsequent Biologics License Application (BLA).

C.3.2. The offeror(s) shall conduct stability studies on the BDS (stored by Contractor) and FDP lots placed in the SNS in conformance with FDA requirements throughout the contract lifetime. Testing will be performed in accordance with current regulatory guidelines to support an expiry dating of no less than 24 months, with options available to extend expiry dating to 36 months.

C.4. Regulatory, Non-Clinical, and Clinical Objectives

C.4.1. Offeror(s) shall submit evidence of an effective Quality Management System (QMS). Offeror(s) must ensure that the details in the submitted proposal incorporate the QMS in all aspects of the proposal to fulfill the proposal objectives.

C.4.2. The offeror(s) shall develop, submit, and execute non-clinical and clinical study plans, as determined by FDA, to support the potential PEP (concomitant with antibiotic) use of the product in adults during a declared emergency under EUA.

C.4.3. The offeror(s) shall develop, submit, and execute non-clinical plans to demonstrate efficacy under the Animal Efficacy Rule and human safety and immunogenicity studies adequate to support FDA licensure. Note that in May 2002, the FDA published "Approval of Biological Products when Human Efficacy Studies are not Ethical or Feasible" [21 CFR 601 Subpart H, as well as 21 CFR 314 Subpart I for New Drugs]. This rule, known simply as the "Animal Rule," was designed to permit approval or licensing of drugs and biologics that are intended to reduce or prevent serious or life-threatening conditions caused by exposure to biological, chemical, radiological, or nuclear substances. This rule amends the new drug and biological product regulations to identify the information needed to provide substantial evidence of the efficacy of new drug and biological products only when human efficacy studies are not ethical and field

trials are not feasible. The new rule does not address the need for human safety and immunogenicity data which still must be established. When the contractor develops these plans, they shall be designed in consultation with appropriate USG agencies and the data from these studies should support licensure of rPA, as well as support the potential PEP (concomitant with antibiotic) use of the product during a declared emergency under EUA in adults. Licensure will initially be sought for GUP of adults followed by a label extension for the PEP plus antibiotics indication. Further, these plans will include studies to demonstrate safety and efficacy of an optimized dosing regimen, based on supporting data to justify such studies.

C.4.4. In addition, as mandated under the Animal Rule, the offeror shall develop a Phase 4 post-marketing plan to continue testing the study drug or treatment to collect information about its effect in various populations and any side effects associated with actual use. This "post-marketing plan" should describe, in general terms, the collection of human safety and efficacy data when the product is used in the event of a declared emergency, which warrants its use. The Phase 4 post marketing plan may be revised in consultation with BARDA, FDA/CBER and CDC post contract award.

C.5. Shipment, Storage, and Disposition Objectives

C.5.1. The offeror(s) shall develop a plan that ensures product will be stored and shipped in compliance with cGMP. Particular attention should be placed on determining what, if any, USG and/or foreign country permits/documents will be required for shipment of product to the SNS. The USG will assume responsibility for long-term storage and emergency distribution of finished product.

C.5.2. The offeror(s) shall develop a delivery schedule that meets the objectives of this RFP. Offeror(s) should propose an optimum product delivery schedule that maximizes level of product in the SNS over the duration of the contract. The Contractor may be required to store FDP at its own facility for up to 4 months. The Contractor shall propose a delivery schedule that may not exceed 1 delivery per month. Thirty (30) days advance notice is required prior to shipment to the SNS.

C.5.3. The offeror(s) shall develop a quality control/quality assurance monitoring plan that shall ensure appropriate storage conditions of the product until product is licensed. The Contractor shall be required to enter into a Quality Agreement with the SNS after contract award. In addition, this Quality Agreement shall outline the responsibilities of both the Contractor and the USG (i.e., SNS- Quality Control). These documents shall be drafted and signed by both parties at least 120 days prior to the transport and storage of the product.

C.5.4. At the discretion of the USG and independent of testing conducted by the Contractor, the USG reserves the right to conduct site visits and collect samples of product held by the Contractor and in the SNS.

C.5.5. Upon expiration or termination (including partial termination) of this contract, the USG may effect final distribution of any vaccine produced under this contract, and remaining in storage at the Contractor's facility. Disposition of the vaccine shall be negotiated upon expiration, or if the contract is terminated.

C.6. Business Management Objectives

C.6.1. The offeror(s) shall propose an integrated management plan for the entire rPA anthrax vaccine team, including subcontractors. Management of personnel should include, but is not limited to providing a list of key individuals and their qualifications to carry out the work detailed in the business proposals.

C.7. Project Management & Risk Mitigation Objectives

C.7.1. The offeror(s) shall develop an integrated project plan (tabular and Gantt form) that clearly indicates the critical path to support an EUA, and licensure. Attention should be placed on the amount of time that will be needed by the USG (BARDA, FDA, CDC) for review of critical documentation. The contractor shall integrate to demonstrate interdependencies and the plan will be used to monitor performance of the contract. The Contractor's project plan shall be incorporated into the contract.

1. Work breakdown structure (WBS) shall be at level 5 for the overall plan and level 6 for manufacturing.

C.7.2. The offeror(s) shall develop a risk mitigation plan highlighting potential problems and/or issues that may arise during the life of the contract, their impact on cost, performance and timelines, and appropriate remediation plans.

C.7.3. The offeror(s) shall develop an Earned Value Management system, or similar plan, to monitor cost against schedule by task. Plan shall include a USG-Contractor Integrated Baseline Review (IBR).

C.7.4. The offeror(s) shall participate in regular meetings to coordinate and oversee the contracting effort as requested by the Project Officer. Such meetings may include, but are not limited to, meetings of all Contractors and Subcontractors to discuss study designs, site visits to the Contractor's facilities, and meetings with individual Contractors and other HHS officials to discuss the technical, regulatory, and ethical aspects of the program. The Contractor shall provide data, reports, and presentations to groups of outside experts and USG personnel as required by the Project Officer in order to facilitate review of contract activities.

C.7.5. The offeror(s) shall provide a list of individuals to serve as primary and secondary points of contact that will be available 24 hours per day, seven days per week, to be notified in case of a public health emergency.

C.8. Option Objectives

C.8.1. The USG may exercise options to increase the expiry period of the product to 36 months.

1. The offeror(s) shall develop a plan to conduct stability testing on BDS and FDP in conformance with FDA requirements to extend expiry dating to 36 months, and seek approval of BLA Supplement to extend the expiry dating period as appropriate. If the option is exercised, contractor shall implement the proposed plan to seek extended expiration dating.

2. The contractor shall develop and implement a plan to address any FDA labeling requirements, such as re-labeling product, associated with obtaining 36-month expiration dating.

C.8.2. The USG may exercise options to extend the PEP plus antibiotic label indication to both pediatric and geriatric populations.

1. The offeror(s) shall develop a concept plan to conduct post-licensure studies to extend the PEP plus antibiotic label indication to include pediatric and geriatric populations.

C.8.3. The USG may exercise an option to implement the Phase 4 Post-Marketing Commitment plan, as described in Section C.4.4., to collect human safety and efficacy data when the product is used in the event of a declared emergency.

C.9. Delivery Schedule

To be negotiated.

C. 10. Reporting Requirements

See F.4

Section D – Packaging and Marking

D.1. Delivery of Reports

Unless otherwise specified by the Contracting Officer, delivery of the monthly reports, the risk mitigation plan, the annual report, and invoices under this contract, shall be made by e-mail and one copy by first class mail.

D.2. Packaging of Product

Packaging shall be consistent with the FDA approved labeling and packaging for this product. Packaging shall be designed to promote quality during long-term temperature-controlled storage at the SNS.

Section E – Inspection and Acceptance

FAR Source	Title and Date
FAR Clause 52.246-1	Contractor Inspection Requirements (Apr 1984)
FAR Clause 52.246-2	Inspection of Supplies – Fixed Price (Aug 1996)
FAR Clause 52.246-16	Responsibility for Supplies (Apr 1984)

E.1. Inspection and Acceptance

Inspection and acceptance of the articles, services, and documentation called for herein shall be accomplished by the Contracting Officer, or his duly authorized representative (who for the purposes of this contract shall be the Project Officer) at the destination of the articles, services or documentation.

Section F - Deliveries or Performance

FAR Source	Title and Date
FAR Clause 52.211-17	Delivery of Excess Quantities (Sept 1989)
FAR Clause 52.242-15	Stop Work Order (Aug 1989)
FAR Clause 52.242-15, Alt 1	Stop Work Order, Alternate 1 (Apr 1984)
FAR Clause 52.242-17	Government Delay of Work (Apr 1984)
FAR Clause, 52.247-34	FOB Destination (Nov 1991)

F.1. Period of Performance

a. The base period of contract performance of this contract is anticipated to be 5 years.

F. 2. Place and Method of Delivery

a. The delivery of the rPA product shall be F.O.B. Destination.

b. The place of delivery shall be a Strategic National Stockpile site that will be provided to the Contractor no less than 90 days prior to shipping.

F.3. Contract Deliverables

a. The following deliverables are applicable to CLIN 0001: 25,000,000 doses of rPA in accordance with the delivery schedule in C.9.
b. In accordance with Section C.7.1 , an Integrated Project Plan (IPP), a Work Breakdown Structure (WBS) in tabular form clearly indicating critical path milestones to fulfill requirements for EUA and licensure and a complete Gantt chart for the entire SOO to WBS level 5.
c. In accordance with Section C.4.4, a Phase 4 post-marketing plan
d. In accordance with Section C.5.3, a Quality Control/Quality Assurance Monitoring Plan
e. In accordance with Section C.7.2, a Risk Management Plan
f. In accordance with Section C.7.3, a Earned Value Management Plan
g. In accordance with Section H.8, a Security Plan
h. In accordance with Section H.9, a Office of Human Research Protections (OHRP) approved assurance of compliance
i. In accordance with Section H.11, a written Animal Welfare Assurance with the Office for Laboratory Animal Welfare (OLAW).
j. In accordance with Section H. 12, evidence of registration with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2316 and 9 CFR Section 2.30.
k. In accordance with Section H.14, for prime or subcontract awards to domestic institutions that possess, use, and/or transfer Select Agents under this contract, final CDC Select Agent registration certificate(s)

l. In accordance with Section H.14, for prime or subcontract awards to foreign institutions that possess, use, and/or transfer Select Agents under this contract, the foreign institution must provide information satisfactory to BARDA, that safety, security, and training standards equivalent to those described (in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at: http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf) are in place.
m. See F.4.
n. Reserved.

F.4. Reporting Requirements

1. Monthly Reports

On the tenth of each month for the previous calendar month, the contractor shall submit a Monthly Technical Progress Report to the Project Officer and the Contracting Officer. The contractor shall submit one copy of the Monthly Progress Report electronically via e-mail. A monthly report will not be required for the period when the final report is due. Any attachments to the e-mail report shall be submitted in Microsoft Word, Excel, Project, or compatible versions. Such reports shall include the following specific information: The contract number and title, the period of performance being reported, the contractor's name and address, the author(s), and the date of submission.

The Monthly Technical Progress Report shall include an Executive Summary in MS PowerPoint format, highlighting the progress, issues, and actions relevant to: manufacturing, non-clinical, clinical, regulatory, and security. The Executive summary should be limited to 2-3 slides and only highlight critical issues for that reporting period. The Monthly Technical Progress report shall address each of the below items and be cross-referenced to the Critical Path Gantt Chart, Earned Value Management, WBS/Project Plan and the Risk Mitigation plan.

The report shall detail the planned progress and actual progress during the period covered, explaining why any differences between the two occurred, and if behind schedule what corrective steps and actions are planned. The project's plans and schedule must reflect FDA regulatory requirements and guidance.

These reports are subject to the technical inspection and requests for clarification by the Project Officer. These reports shall be brief and factual and provide the following information:

a. Progress in assay development and validation, and process development and validation of BDS and FDP manufacture to support scale-up to full production capacity, including raw material procurement status.
b. Quality control/quality assurance monitoring.
c. FDA/CBER inspections and consultation results or recommendations.
d. Storage and stability studies for expiration date results (accelerated, stress, and long-term storage conditions).
e. Security assessment, problems, and recommendations.
f. Progress, results, and final reports of expanded human safety studies.
g. Progress, results, and final reports of efficacy studies performed in animals if following the Animal Rule, or clinical studies required for Accelerated FDA/CBER Approval.
h. Progress, results, and final reports of any other studies deemed necessary by FDA/CBER.
i. Progress in providing data to CDC to support an EUA.
j. Progress in obtaining FDA/CBER approval/licensure for post-exposure prophylaxis, concomitant with antibiotics (PEP), in adults considered to be at risk subsequent to a known

or suspected anthrax release. In addition, for general use prophylaxis (GUP) of healthy individuals considered to be at risk to anthrax exposure.

k. Progress in execution of any product disposition directions provided by the USG.
l. Progress, results, and final reports of any necessary additional animal and human studies to obtain expanded labeling in special populations, including pediatric and geriatric populations;
m. Potency and stability testing results.
n. Inventory report of total number of vaccine doses in storage during the month, to include: lot number, expiration date, and bulk quantity (if applicable).

o. Quantity of out-of-date FDP, assessment and recommendations to replacement FDP orders to maintain required stockpile quantities.
p. Physical storage facilities (Contractor and SNS) assessments.
q. Overall project assessment, problems encountered and recommended solutions, etc.

2. Annual Report

The contractor shall be required to submit an annual technical progress report within 15 days after the anniversary of the contract award date. The final technical progress report shall be submitted within 15 days of the end date of the contract.

3. Weekly teleconferences

The contractor shall participate in weekly teleconferences with BARDA to discuss the performance of the contract.

4. Periodic Site Visits

The contractor shall accommodate for periodic site visits by BARDA on an ad hoc basis.

5. Rotating Quarterly Site Visits

The contractor shall visit BARDA twice a year to brief the government on its contract performance and progress to date. The contractor shall also provide an opportunity for BARDA management to visit the contractor's plant twice a year on an ad hoc basis.

6. Annual meeting

BARDA will meet with the contractor's board of directors once a year to discuss the contract. The meetings shall take place within 30 days of the anniversary of the contract award date.

7. Audits

The contractor will allow for and provide requested information to support security, quality, regulatory, and GMP audits on an ad hoc basis. A summary of these audits will be provided within 25 business days to contractor. The Contractor shall take the necessary corrective action

within a timely manner. In addition, the contractor shall provide all information requested to the Project Officer and/or the FDA/CBER to facilitate a cGMP inspection at the time of production of vaccine lots destined for the SNS.

8. FDA Submissions and meetings

a. The contractor shall forward the initial draft minutes and final draft minutes of any formal meeting with the FDA to BARDA.

b. The contractor shall forward the final draft minutes of any informal meeting with the FDA to BARDA.

c. The contractor shall forward the dates and times of any meeting with the FDA to BARDA and make arrangements for appropriate BARDA staff to attend FDA meetings.

d. The contractor shall provide BARDA the opportunity to review and comment upon any documents to be submitted to the FDA. The contractor shall provide BARDA with a 72 hour period in which to review and provide comments back to the contractor.

9. Point of contact

The contractor shall provide primary and secondary points of contact that will be available 24 hours per day, 7 days per week, to be notified in case of a public health emergency.

10. Sample Inspections

At the discretion of the USG and independent of testing conducted by the contractor, the USG reserves the right to conduct site visits and collect samples of product held by the contractor and/or stored by the SNS.

11. Disposition of Vaccine Inventory

Upon expiration or termination (including partial termination) of this contract, the USG may effect final distribution of any vaccine produced on this contract, and remaining in storage at the Contractor's facility by any one or combination of the following methods:

a. The USG may elect to direct the contractor to ship to a consignee(s) designated by the USG, all vaccine remaining in storage at the Contractor's facility.

b. The USG may offer the vaccine to be repurchased by the Contractor at the original purchase price.

c. The USG may dispose of the vaccine in the SNS or direct the Contractor to dispose of unshipped vaccine developed in support of this contract but above the 25 Million doses requested.

12. Security and Quality Systems Audits

BARDA shall perform a pre-award security and QA audit in addition to periodic security and QA audits during the performance of the contract on an ad hoc basis.

Section G – Contract Administration

G.1. Project Officer

The following Project Officer will represent the Government for the purpose of this solicitation:

To Be Determined

Performance of the work hereunder shall be subject to the technical directions of the designated Project Officer for this contract.

As used herein, technical directions are directions to the Contractor, which fill in details, suggests possible lines of inquiry, or otherwise completes the general scope of work set forth herein. These technical directions must be within the general scope of work, and may not alter the scope of work or cause changes of such a nature as to justify an adjustment in the stated contract price/cost, or any stated limitation thereof. In the event that the Contractor feels that full implementation of any of these directions may exceed the scope of the contract, he or she shall notify the originator of the technical direction and the Contracting Officer in a letter separate of any required report(s) within two (2) weeks of the date of receipt of the technical direction and no action shall be taken pursuant to the direction. If the Contractor fails to provide the required notification within the said two (2) week period that any technical direction exceeds the scope of the contract, then it shall be deemed for purposes of this contract that the technical direction was within the scope. No technical direction, nor its fulfillment, shall alter or abrogate the rights and obligations fixed in this contract.

The Government Project Officer is not authorized to change any of the terms and conditions of this contract. Changes shall be made only by the Contracting Officer by properly written modification(s) to the contract. Any changes in Project Officer delegation will be made by the Contracting Officer in writing with a copy being furnished to the Contractor.

(End of Clause)

G.2. Payment by Electronic Funds Transfer – Central Contractor Registration

(a) The Government shall use electronic funds transfer to the maximum extent possible when making payments under this contract. FAR 52.232-33, Payment by Electronic Funds Transfer in Section I, requires the contractor to designate in writing a financial institution for receipt of electronic funds transfer payments.

(b) The contractor shall make the designation by submitting the form titled "ACH Vendor/Miscellaneous Payment Enrollment Form" to the address indicated below. Note: The form is either attached to this contract (see Section J, List of Attachments) or may be obtained by contacting the Contracting Officer.

(c) In cases where the contractor has previously provided such designation, i.e., pursuant to a prior contract/order, and been enrolled in the program, the form is not required.

(d) The completed form shall be mailed after award, but no later than 14 calendar days before an invoice is submitted, to the following address: See G.3

G.3. Invoice Submission

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

HHS/OS/ASPR/BARDA

Attn: Brian K. Goodger, Contracting Officer

330 Independence Ave., S.W.

Room G640

Washington, D.C. 20201

(b) The Contractor agrees to include (as a minimum) the following information on each invoice:

(1) Contractor's Name & Address
(2) Contractor's Tax Identification Number (TIN)
(3) Contract Number
(4) Invoice Number
(5) Invoice Date
(6) Contract Line Item Number
(7) Quantity
(8) Unit Price & Extended Amount for each line item
(9) Total Amount of Invoice
(10) Name, title and telephone number of person to be notified in the event of a defective invoice
(11) Payment Address, if different from the information in (c)(1).

The contractor may not invoice more often than on a monthly basis once B.6 is fulfilled.

See Attachment 04, in Section J for more instructions on invoicing.

(End of Clause)

G.4. Evaluation of Contractor Performance (Service)

(a) Purpose

In accordance with FAR 42.1502, the Contractor's performance will be periodically evaluated by the Government, in order to provide current information for source selection purposes. These evaluations will therefore be marked "Source Selection Information."

(b) Performance Evaluation Period

The Contractor's performance will be evaluated at least annually.

(c) Evaluators

The performance evaluation will be completed jointly by the Project officer and the Contracting officer.

(d) Performance Evaluation Factors

The contractor's performance will be evaluated in accordance with the attachment listed in Section J titled Performance Evaluation Report.

(e) Contractor Review

A copy of the evaluation will be provided to the contractor as soon as practicable after completion of the evaluation. The contractor shall submit comments, rebutting statements, or additional information to the Contracting Officer within 30 calendar days after receipt of the evaluation.

(f) Resolving Disagreements Between the Government and the Contractor

Disagreements between the parties regarding the evaluation will be reviewed at a level above the Contracting Officer. The ultimate conclusion on the performance evaluation is a decision of the contracting agency. Copies of the evaluation, contractor's response, and review comments, if any, will be retained as part of the evaluation.

(g) Release of Contractor Performance Evaluation Information

The completed evaluation will not be released to other than Government personnel and the contractor whose performance is being evaluated. Disclosure of such information could cause harm both to the commercial interest of the Government and to the competitive position of the contractor being evaluated as well as impede the efficiency of Government operations.

(h) Source Selection Information

Departments and agencies may share past performance information with other Government departments and agencies when requested to support future award decisions. The information may be provided through interview and/or by sending the evaluation and comment document to the requesting source selection official.

(i) Retention Period

The agency will retain past performance information for a maximum period of three years after completion of contract performance for the purpose of providing source selection information for future contract awards.

(End of Clause)

G.5. Contracting Officer

(a) The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the Contracting Officer can make any changes to the terms, conditions, general provisions, or other stipulations of this contract.

(b) No information, other than that which may be contained in an authorized modification to this contract, duly issued by the Contracting Officer, which may be received from any person employed by the United States Government, or otherwise, shall be considered grounds for deviation from any stipulation of this contract.

(End of Clause)

G.6. Contract Communications/Correspondence

The Contractor shall identify all correspondence, reports, and other data pertinent to this solicitation by imprinting thereon the contract number from Page 1 of the contract.

(End of Clause)

G.7. Notice Prior to Publication

The Contractor shall not release any reports, manuscripts, press releases, or abstracts about the work being performed under this contract without 48 hours written notice in advance to the Contracting Officer.

G.8. Press Releases

1. Pursuant to Public Law(s) cited in paragraph (2), below, 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: the percentage of the total costs of the program or project which will be financed with Federal money; the dollar amount of Federal funds for the project or program; and the percentage and dollar amount of the total costs of the project or program that will be financed by nongovernmental sources.

2.

Public Law and Section No.	**Fiscal Year**	**Period Covered**
P.L. 109-149, Title V, section 506, as Directed by P.L. 110-5, Div. B, title I, Section 104.	2008	10/1/07 - 9/30/08

G.9. Reporting Matters Involving Fraud, Waste, and Abuse

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in BARDA 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

Section H – Special Contract Requirements

H.1. Prohibition on the Use of Appropriated Funds for Lobbying Activities HHSAR 352.270-10 Anti – Lobbying (Jan 2006)

The contractor is hereby notified of the restrictions on the use of Department of Health and Human Service's funding for lobbying of Federal, State and Local legislative bodies.

Section 1352 of Title 31, United Stated Code (Public Law 101-121, effective 12/23/89), among other things, prohibits a recipient (and their subcontractors) of a Federal contract, grant, loan, or cooperative agreement from using appropriated funds (other than profits from a federal contract) to pay any person for influencing or 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 any of the following covered Federal actions; the awarding of any Federal contract; the making of any Federal grant; the making of any Federal loan; the entering into of any cooperative agreement; or the modification of any Federal contract, grant, loan, or cooperative agreement. For additional information of prohibitions against lobbying activities, see FAR Subpart 3.8 and FAR Clause 52.203-12.

In addition, the current Department of Health and Human Services Appropriations Act provides that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, 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 or Local legislature except in presentation to the Congress, or any State or Local legislative body itself as stated in P.L. 109-149, Title V, section 503(a), as directed by P.L. 110-5, Div. B, Title I, section 104.

The current Department of Health and Human Services Appropriations Act also provides that no part of any appropriation contained in this Act shall be used to pay the salary or expenses of any contract or grant recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress, or any State or Local legislature as stated in P.L. 109-149, Title V, section 503(b), as directed by P.L. 110-5, Div. B, Title I, section 104. (End of Clause)

H.2. Representations, Certifications and Other Statements of Offerors

The Representations, Certifications and Other Statements of Offerors submitted by (contractor) dated (XX/XX/08) are hereby incorporated by reference, with the same force and effect as if they were given in full text.

(End of Clause)

H.3. Laboratory License Requirements

The Contractor shall comply with all applicable requirements of Section 353 of the Public Health Service Act (Clinical Laboratory Improvement Act as amended). This requirement shall also be included in any subcontract for services under the contract.

(End of Clause)

H.4. Dissemination of Information

No information related to data obtained under this contract shall be released or publicized without the prior written consent of the Contracting Officer, which approval shall not be unreasonably withheld, conditioned, or delayed; provided, however, that no such consent is required to comply with any law, rule, regulation, court ruling or similar order; for submission to any government entity' for submission to any securities exchange on which the Contractor's (or its parent corporation's) securities may be listed for trading; or to third parties relating to securing, seeking, establishing or maintaining regulatory or other legal approvals or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

(End of Clause)

H.5. Identification and Disposition of Data

The Contractor will be required to provide certain data generated under this contract to the Department of Health and Human Services (HHS). HHS reserves the right to review any other data determined by HHS to be relevant to this contract. The contractor shall keep copies of all data required by the Food and Drug Administration (FDA) relevant to this contract for the time specified by the FDA.

H.6. Incorporation of Technical Proposal

The Contractor's Technical Proposal included in its Final Proposal Revision dated _____, along with subsequent change pages dated _____ submitted in response to RFP-HHS-BARDA-08-01, is hereby incorporated into the contract by reference. The Contractor shall perform the work substantially as set forth in the technical proposal. Any revisions to the technical proposal that would significantly alter the technical approach must be approved in writing by the Contracting Officer. In the event of a conflict between Section C, Statement of Objectives, and the Contractor's technical proposal, Section C will take precedence.

(End of Clause)

H.7. Year 2000 Compliance

Unless elsewhere exempted, information technology (if any) to be acquired under this contract/purchase order, which will be required to perform date/time processing involving dates subsequent to December 31, 1999, shall be Year 2000 compliant as defined in Federal Acquisition Regulation Part 39.002.

(End of Clause)

H.8. Security Plan Requirements

The work to be performed under this contract will involve access to sensitive BARDA program information. Therefore, the Offeror(s) shall develop and submit a written Draft Security Plan that describes their procedures and policies to defend against theft, tampering, or destruction of product-

related material, equipment, documents, information, and data. The Draft Security Plan will include, at a minimum:

a. Personnel Security Policies and Procedures including but not limited to:

recruitment of new employees; interview process; background checks; suitability / adjudication policy; access determination; rules of behavior; termination procedures; and non-disclosure agreements.

b. Physical Security Policies and Procedures including but not limited to: internal / external access control; identification policies; facility visitors; parking areas; barriers; shipping, receiving and transport; security lighting; restricted areas; signage; intrusion detection systems; closed circuit television; other control measures. The plan shall include the security measures to be used to protect the product to be stored at the Contractor's facility (e.g., refrigeration/freezer alarm systems, backup electrical power generator systems, etc.), and the contingency plan to accommodate any manufacturing and storage problems caused by natural or man-made disasters, power loss, refrigerant loss, equipment failures, etc..

c. Information Security Policies and Procedures including but not limited to:

identification of sensitive information; access control / determination; secure storage procedures; document control; destruction procedures.

d. Information Technology Security Policies and Procedures including but not limited to: intrusion detection and prevention systems; encryption systems; identification of sensitive information; passwords; removable media; laptop policy; access control / determination; secure storage procedures; document control; backup procedures; disaster recovery.

e. Security Reporting Requirement - Violations of established security protocols will be reported to the Contracting Officer upon discovery. The Contractor will investigate violations to determine the cause, extent, loss or compromise of sensitive program information, and corrective actions taken to prevent future violations. BARDA will determine if the severity of the violation requires further government intervention.

The Security Plan shall be incorporated into the Technical proposal. After the initial evaluations of proposals and after Offeror(s) in the competitive range have been identified, the BARDA Program Protection Officer will review the plan and submit comments to the Contracting Officer for the offeror(s) within 10 business days after receipt. In addition, pre-award site visits to assess security may be conducted. The Offeror(s) shall revise the Security Plan, if required, and submit a Final Security Plan to the Government within 30 days after receipt of the Governments comments. The final security plan will be incorporated into the contract. Performance of the work under this contract shall be in accordance with this written Security Plan. Contractor (s) shall not commence performance of work under this contract until the Contractor(s) has received written notification from the Contracting Officer that the Security Plan has been accepted.

H.9. Protection of Human Subjects

(a) 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 that 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.

(b) 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.

(c) If at any time during performance of this contract, the Contracting Officer determines, in consultation with the OHRP, that the Offeror if 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 this contract until the Offeror corrects such noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing.

(d) 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 this 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.

H.10. Information on Compliance with Animal Care Requirements

Registration with the U. S. Dept. of Agriculture (USDA) is required to use regulated species of animals for biomedical purposes. The USDA office contact information is available at http://www.aphis.usda.gov/ac/acorg.html. They are responsible for the enforcement of the Animal Welfare Act (7 U.S.C. 2131 et. seq.), http://www.nal.usda.gov/awic/legislat/awa.htm.

The Public Health Service (PHS) Policy is administered by the Office of Laboratory Animal Welfare (OLAW) http://grants2.nih.gov/grants/olaw/olaw.htm. An essential requirement of the PHS Policy http://grants2.nih.gov/grants/olaw/references/phspol.htm is that every institution using live vertebrate

animals must obtain an approved assurance from OLAW before they can receive funding from any component of the U. S. Public Health Service.

The PHS Policy requires that Assured institutions base their programs of animal care and use on the *Guide for the Care and Use of Laboratory Animals* http://www.nap.edu/readingroom/books/labrats/ and that they comply with the regulations (9 CFR, Subchapter A) http://www.nal.usda.gov/awic/legislat/usdaleg1.htm issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act. The *Guide* may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of this Policy.

The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) http://www.aaalac.org is a professional organization that inspects and evaluates programs of animal care for institutions at their request. Those that meet the high standards are given the Accredited status. As of the 2002 revision of the PHS Policy, the only accrediting body recognized by PHS is the AAALAC. While AAALAC Accreditation is not required to conduct biomedical research, it is highly desirable. AAALAC uses the *Guide* as their primary evaluation tool. They also use the *Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching*. It is published by the Federated of Animal Science Societies http://www.fass.org.

H.11. Notice to Offerors of Requirements for Adequate Assurance of Protection of Vertebrate Animal Subjects

The PHS Policy on Humane Care and Use of Laboratory Animals requires that applicant organizations proposing to use vertebrate animals file a written Animal Welfare Assurance with the Office for Laboratory Animal Welfare (OLAW), establishing appropriate policies and procedures to ensure the humane care and use of live vertebrate animals involved in research activities supported by the PHS. The PHS Policy stipulates that an applicant organization, whether domestic or foreign, bears responsibility for the humane care and use of animals in PHS-supported research activities. Also, the PHS policy defines “animal” as “any live, vertebrate animal used, or intended for use, in research, research training, experimentation, biological testing or for related purposes.” This Policy implements and supplements the U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training, and requires that institutions use the Guide for the Care and Use of Laboratory Animals as a basis for developing and implementing an institutional animal care and use program. This Policy does not affect applicable State or local laws or regulations that impose more stringent standards for the care and use of laboratory animals. All institutions are required to comply, as applicable, with the Animal Welfare Act as amended (7 USC 2131 et. seq.) and other Federal statutes and regulations relating to animals. These documents are available from the Office of Laboratory Animal Welfare, National Institutes of Health, Bethesda, MD 20892, (301) 496-7163. See http://grants.nih.gov/grants/olaw/olaw.htm.
No PHS supported work for research involving vertebrate animals will be conducted by an organization, unless that organization is operating in accordance with an approved Animal Welfare Assurance and provides verification that the Institutional Animal Care and Use Committee (IACUC) has reviewed and approved the proposed activity in accordance with the PHS policy. Applications may be referred by the PHS back to the institution for further review in the case of apparent or potential violations of the PHS Policy. No award to an individual will be made unless that individual is affiliated with an assured organization that accepts responsibility for compliance with the PHS Policy. Foreign applicant organizations applying for PHS awards for activities involving vertebrate animals are required to

comply with PHS Policy or provide evidence that acceptable standards for the humane care and use of animals will be met. Foreign applicant organizations are not required to submit IACUC approval.

H.12. Care of Live Vertebrate Animals

1. 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.

2. 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.

3. The Contractor agrees that the care and use of any live, vertebrate animals used or intended for use in the performance of this contract will conform with the PHS Policy on Humane Care and Use of Laboratory Animals, the current Animal Welfare Assurance, the Guide for the Care and Use of Laboratory Animals prepared by the Institute of Laboratory Animal Resources, and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR Subchapter A, Parts 1-3). In case of conflict between standards, the more stringent standard shall be used.

4. If at any time during performance of this contract, the Contracting Officer determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (1) through (3) 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, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those Contractors with approved Public Health Service Animal Welfare Assurances.

The Contractor may request registration of its facility and a current listing of licensed dealers from the Animal Care Sector Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the sector in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program, may be obtained by contacting: Animal Care Staff USDA/APHIS 4700 River Road, Unit 84 Riverdale, MD 20737 (301) 734-4980. Offerors proposing research that involves live, vertebrate animals will be contacted by OLAW and given detailed instructions on filing a written Animal Welfare Assurance with the PHS. Offerors are encouraged to visit the OLAW website at http://grants.nih.gov/grants/olaw/olaw.htm for additional information. OLAW may be contacted at the National Institutes of Health at (301) 594-2289.

H.13. Approval of Required Assurance by OLAW

Under governing regulations, federal funds which are administered by the Department of Health and Human Services, Biomedical Advanced Research & Development Authority (BARDA) shall not be expended by the contractor for research involving live vertebrate animals, nor shall live vertebrate animals be involved in research activities by the contractor under this award unless a satisfactory assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.27 is submitted within 30 days of the date of this award and approved by the Office of Laboratory Animal Welfare (OLAW). Each performance site (if any) must also assure compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.27 with the following restriction: Only activities which do not directly involve live vertebrate animals (i.e. are clearly severable and independent from those activities that do involve live vertebrate animals) may be conducted by the contractor or individual performance sites pending OLAW approval of their respective assurance of compliance with 7 U.S.C. 2316 and 9 CFR Sections 2.25-2.27. Additional information regarding OLAW may be obtained via the Internet at http://grants2.nih.gov/grants/olaw/olawaddr.htm.

H.14. Possession, Use and Transfer of Select Biological Agents or Toxins

The contractor shall not conduct work involving select agents or toxins under this contract until it and any associated subcontractor(s) comply with the following:

For prime or subcontract awards to domestic institutions that possess, use, and/or transfer Select Agents under this contract, the institution must comply with the provisions of 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 (http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf) as required, before using BARDA funds for research or production and testing involving Select Agents. No BARDA funds can be used for research involving Select Agents if the final registration certificate is denied.

For prime or subcontract awards to foreign institutions that possess, use, and/or transfer Select Agents under this contract, before using BARDA funds for any work directly involving the Select Agents, the foreign institution must provide information satisfactory to BARDA, that safety, security, and training standards equivalent to those described (in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121 at: http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf) are in place and will be administered on behalf of all Select Agent work sponsored by these funds. The process for making this determination includes inspection of the foreign laboratory facility by a BARDA representative. During this inspection, the foreign institution must provide the following information: concise summaries of safety, security, and training plans; names of individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals, in accordance with institution procedures, will have access to the Select Agents under the contract; and copies of or links to any applicable laws, regulations, policies, and procedures applicable to that institution for the safe and secure possession, use, and/or transfer of select agents. An BARDA chaired committee of U.S. federal employees (including representatives of BARDA grants/contracts and scientific program management, CDC, Department of Justice and other federal intelligence agencies, and Department of State) will ultimately assess the results of the laboratory facility inspection, and the regulations, policies, and procedures of the foreign institution for equivalence to the U.S. requirements described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121

(http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf). The committee will provide recommendations to the BARDA Director. The BARDA Director will make the approval decision and notify the Contracting Officer. The Contracting Officer will inform the prime contractor of the approval status of the foreign institution. No BARDA funds can be used for research involving Select Agents at a foreign institution until BARDA grants this approval.

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, see the NIAID Select Agent Award information:

http://www.niaid.nih.gov/ncn/clinical/default_biodefense.htm

H.15. Manufacturing Standards

The Current Good Manufacturing Practice Regulations (cGMP)(21 CFR Parts 210-211)and regulations pertaining to biological products (21 CFR Part 600) will be the standard to be applied for manufacturing, processing, packaging, storage and delivery of this product.

If at any time during the life of the contract, the Contractor fails to comply with cGMP in the manufacturing, processing, packaging, storage and delivery of this product and such failure results in a material adverse effect on the safety, purity or potency of the product (a material failure) as identified by CBER or CDER, the Offeror shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If the offeror fails to take such an action within the thirty (30) calendar day period, then the contract may be terminated.

H.16. Prohibition on Contractor Involvement with Terrorist Activities

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to Executive Order 13224 and Public Law 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.

H.17. Key Personnel

The personnel specified in this contract are considered to be essential to the work being performed hereunder. Prior to diverting any of the specified individuals to other programs, the Contractor shall notify the Contracting Officer reasonably in advance and shall submit justification (including proposed substitutions) in sufficient detail to permit evaluation of the impact on the program. No diversion shall be made by the Contractor without the written consent of the Contracting Officer; provided, that the Contracting Officer may ratify in writing such diversion and such ratification shall constitute the consent

of the Contracting Officer required by this clause. The contract may be modified from time to time during the course of the contract to either add or delete personnel, as appropriate.

Contractor Key Personnel:

	Name	Position
1.	TBD	TBD
2.	TBD	TBD
3.	TBD	TBD

H.18. Project BioShield Act (P.L. 108-276, dated 7/21/04) and Pandemic All Hazards Preparedness Act (P.L. 109-417, dated 12/19/06) Implementation

Advance payment (up to 10%) and/or milestone payments (in increments of 5% up to 50% of the negotiated contract amount) in response to this RFP may be allowable under this solicitation. In order for requests to be granted, financial need must be demonstrated.

Approvals for advance payments and or milestone payments will be decided at time of negotiations.

PART II – CONTRACT CLAUSES

Section I – Contract Clauses

52.252-1 Solicitation Provisions Incorporated by Reference (Feb 1998)
This solicitation incorporates one or more solicitation provisions by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. The offeror is cautioned that the listed provisions may include blocks that must be completed by the offeror and submitted with its offer. In lieu of submitting the full text of those provisions, the offeror may identify the provision by paragraph identifier and provide the appropriate information with its offer. Also, the full text of a solicitation provision may be accessed electronically at these addresses: **http://www.arnet.gov** or **http://www.dhhs.gov/oamp/dap/hhsar.html/**

I.1. General Clauses for a Negotiated Fixed Price & Cost Reimbursement Supply Contract

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

FAR CLAUSE NO.	DATE	TITLE
52.202-1	Jul 2004	Definitions
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Sept 2006	Restrictions on Subcontractor Sales to the Government (Over $100,000)
52.203-7	Jul 1995	Anti-Kickback Procedures (Over $100,000)
52.203-8	Jan 1997	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity (Over $100,000)
52.203-10	Jan 1997	Price or Fee Adjustment for Illegal or Improper Activity (Over $100,000)
52.203-12	Sept 2005	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.203-13	Dec 2007	Contractor Code of Business Ethics and Conduct
52.203-14	Dec 2007	Display of Hotline Posters
52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over $100,000)
52.204-7	Jul 2006	Central Contractor Registration
52.204-10	Sept 2007	Reporting Subcontract awards ($500,000,000 or more)
52.209-6	Sept 2006	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over $25,000)
52.211-5	Aug 2000	Material Requirements
52.215-2	Jun 1999	Audit and Records - Negotiation (Over $100,000)
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Oct 1997	Price Reduction for Defective Cost or Pricing Data

52.215-12	Oct 1997	Subcontractor Cost or Pricing Data (Over $500,000)
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Oct 2004	Pension Adjustments and Asset Reversions
52.215-18	Jul 2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 1997	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data – Modifications
52.216-7	Dec 2002	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee
52.219-8	May 2004	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Sept 2006	Small Business Subcontracting Plan (Over $500,000)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000)
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.
52.222-19	Jan 2006	Child Labor--Cooperation with Authorities and Remedies
52.222-20	Dec 1996	Walsh-Healey Public Contracts Act
52.222-21	Feb 1999	Prohibition of Segregated Facilities
52.222-26	Mar 2007	Equal Opportunity
52.222-35	Sept 2006	Equal Opportunity for Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-36	Jun 1998	Affirmative Action for Workers with Disabilities
52.222-37	Sept. 2006	Employment Reports on Special Disabled Veterans, Veterans of the Vietnam Era, and Other Eligible Veterans
52.222-50	Aug 2007	Combating Trafficking in Persons
52.223-6	May 2001	Drug-Free Workplace
52.223-14	Aug 2003	Toxic Chemical Release Reporting (Over $100,000)
52.225-1	Jun 2003	Buy American Act - Supplies
52.225-13	Feb 2006	Restrictions on Certain Foreign Purchases
52.227-1	Jul 1995	Authorization and Consent
52.227-2	Aug 1996	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)
52.227-3	Apr 1984	Patent Indemnity
52.227-14	Jun 1987	Rights in Data – General
52.229-3	Apr 2003	Federal, State and Local Taxes (Over $100,000)

52.232-1	Apr 1984	Payments
52.232-8	Feb 2002	Discounts for Prompt Payment
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-11	Apr 1984	Extras
52.232-17	Jun 1996	Interest (Over $100,000)
52.232-20	Apr 1984	Limitation of Cost
52.232-23	Jan 1986	Assignment of Claims
52.232-25	Oct 2003	Prompt Payment
52.232-33	Oct 2003	Payment by Electronic Funds Transfer--Central Contractor Registration
52.233-1	Jul 2002	Disputes
52.233-3	Aug 1996	Protest After Award
52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2001	Penalties for Unallowable Costs (over $650,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.243-1	Aug 1987	Changes - Fixed-Price
52.243-2	Aug 1987	Changes - Changes Cost Reimbursement
52.244-2	Jun 2007	Subcontracts *If written consent to subcontract is required, the identified subcontracts are listed in ARTICLE B, Advance Understandings.
52.244-5	Dec 1996	Competition in Subcontracting (over $100,000)
52.244-6	Mar 2007	Subcontracts for Commercial Items
52.245-1	Jun 2007	Government Property
52.245-2	Jun 2007	Government Property (Fixed-Price Contracts)
52.245-9	Jun 2007	Use and Changes
52.249-2	May 2004	Termination for the Convenience of the Government (Fixed-Price)
52.249-6	Sep 1996	Termination (Cost-Reimbursement)
52.249-8	Apr 1984	Default (Fixed-Price Supply and Service)(Over $100,000)
52.249-14	Apr 1984	Excusable Delays
52.253-1	Jan 1991	Computer Generated Forms

I.2. Department of Health and Human Services Acquisition Regulation (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

Full text of these clauses can be found at http://www.dhhs.gov/oamp/dap/hhsar.html/

HHSAR Clause No.	Date	Title
352.202-1	Jan 2006	Definitions
352.216-72	Jan 2006	Additional Cost Principles
352.223-70	Jan 2006	Safety and Health
352.224-70	Jan 2006	Confidentiality of Information
352.228-7	Dec 1991	Insurance – Liability to Third Persons
352.232-9	Jan 2006	Withholding of Contract Payments
352.242-71	Apr 1984	Final Decisions on Audit Findings
352.249-14	Jan 2006	Excusable Delays
352.270-4	Jan 2001	Pricing of Adjustments
352.270-5	Jan 2006	Key Personnel
352.270-6	Jan 2006	Publication and Publicity
352.270-7	Jan 2006	Paperwork Reduction Act
352.270-8	Jan 2006	Protection of Human Subjects

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

352.270-9	Jan 2006	Care of Live Vertebrate Animals
352.270-10	Jan 2006	Anti-Lobbying (over $100,000)
352.270-11	Jan 2006	Privacy Act

I.3. ADDITIONAL CONTRACT CLAUSES

The following clause(s), as applicable, will be made part of the resultant contract. Please note that any contract resulting from this solicitation is not limited to the clauses listed below. These clauses represent some of the most commonly used. Any additional clauses deemed necessary by the Government will be discussed during negotiations.

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

(1) **52.217-7 Option for Increased Quantity - Separately Priced Line Item (Reserved) (Mar 1989).**
"....The Contracting Officer may exercise the option by written notice to the Contractor within 60 days prior to the expiration of this contract ...."

(2) **52.215-17 Waiver of Facilities Capital Cost of Money (October 1997)**

(3) **52.224-1, Privacy Act Notification (April 1984)**

(4) **52.224-2, Privacy Act (April 1984)**

(5) **52.227-14, Rights in Data - General (June 1987)**

I.3. ADDITIONAL CONTRACT CLAUSES

Any authorized substitutions or modifications of the General Clauses will be based on the type of contract and contractor will be determining during negotiations.

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

FAR 52.216-7. Allowable Cost & Payment (Dec 2002) (Deviation). Paragraph (a)(1) is modified to read:

> In accordance with Public Law 108-276, the Contractor may not invoice for payment under contract line item number (CLIN's) 0006 and 0007 prior to satisfying the paragraph "Payment conditioned on delivery" (see B.6.). After satisfaction of the paragraph "Payment conditioned on delivery," the USG will make payments to the contractor when requested as work progresses, but (except for small business concerns) not more than once every 2 weeks, in amount determined to be allowable by the Contracting Officer in accordance with Federal Acquisition Regulation (FAR) Subpart 31.2 in effect on the date of this contract and the terms of the contract. The contractor may submit to an authorized representative of the Contracting Officer, in such form and reasonable detail as the representative may require, an invoice or voucher supported by a statement of the claimed allowable cost for performing this contract.

PART III – List of Documents, Exhibits, and other attachments

SECTION J - LIST OF ATTACHMENTS

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

1. Summary of Related Activities
2. Protection of Human Subjects
3. Disclosure of Lobbying Activities
4. Invoice Instructions for Fixed Price Contracts
5. Contractor Performance Evaluation Report
6. ACH Vendor/Miscellaneous Payment Enrollment Form
7. Technical Proposal Cost Information/Summary of Labor & Direct Costs

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

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

1. REPRESENTATIONS AND CERTIFICATIONS

Federal Acquisition Circular (FAC 2001-26), published on December 20, 2004, implements the ***Online Representations and Certifications Application (ORCA)*** effective on January 1, 2005. The ORCA became a Federal mandate as published in the Federal Acquisition Circular 2001-26, FAR case 2002-024, and now requires the use of ORCA in Federal solicitations as a part of the proposal submission process.

ORCA is part of the Business Partner Network (BPN) which is a component of the Integrated Acquisition Environment (IAE) E-Gov initiative. It is a web-based system that centralizes and standardizes the collection, storage and viewing of many of the FAR required representations and certifications previously found in solicitations. With ORCA, you now have the ability to enter and maintain your representation and certification information, at your convenience, via the Internet at http://orca.bpn.gov. In addition, rather than receiving and reviewing paper submissions, government contracting officials can access ORCA and review your information online as a part of the proposal evaluation process. You will no longer be required to submit representations and certifications completed in ORCA with each offer.

The final rule requires Offerors to: (a) provide representations and certifications electronically via the BPN website (www.bpn.gov/orca) thus reducing the administrative burden on vendors who have been submitting the same reps and certs repeatedly for various solicitations, (b) to maintain the representations and certifications at least annually so they stay current, (c) to make changes that affect only one solicitation by completing sections of specific provisions that are required by the FAR, included in the solicitation. This will result in a reduced paperwork burden for both Offerors and contracting officers thus fulfilling one of the goals of IAE to re-use data as much as possible throughout the Federal procurement life cycle.

To comply with this requirement and to register in ORCA, you will need to have two items: an active Central Contractor Registration (CCR) record and a Marketing Partner Identification Number (MPIN) identified in that CCR record. Your DUNS number and MPIN act as your company's ID and password into ORCA. (Visit www.ccr.gov for more information on creating and entering your MPIN). The basic information provided in your CCR record is used to pre-populate a number of fields in ORCA. Vendors are reminded to protect their MPIN from unauthorized use. Once in ORCA you will be asked to review pertinent information pre-populated from CCR, provide a point of contact, and answer a questionnaire that contains up to 26 questions. The questionnaire is to help you gather information you need for the clauses. The questionnaire is not the official version. Be sure to read the provisions carefully.

The answers you provide are then automatically entered into the actual FAR provisions. You are required to review your information, as inserted, in context of the full-text provisions for accuracy; acknowledge three additional read-only provisions; and click a time/date stamp before final submission. You will need to review and/or update your ORCA record when necessary, but at least annually in order to maintain its active status. Detailed information regarding ORCA, how to submit your record, and whom to call for assistance can be found on ORCA's homepage at http://orca.bpn.gov under "Help." The ORCA site contains an ORCA Application Handbook and an ORCA Quick Reference Guide. To access them, simply click on the "Help" link at the top of the ORCA homepage.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

The following information is specific to this solicitation.

I. GENERAL INFORMATION

L.1. PROPOSAL INFORMATION

The Offeror(s) shall submit a proposal describing how they will meet the Statement of Objectives (SOO). In addition the Offeror(s) shall propose a time line for achieving the SOO. The USG anticipates the base period to be 5 years. Offeror(s) shall propose a time line which is appropriate and reflects their ability to achieve the licensure goals of the USG. However, offeror(s) can request up to a maximum of 8 years, subject to HHS approval. The Offeror(s) proposal shall detail how they will fulfill the SOO. The technical proposal may be revised during negotiations and will be incorporated into the resultant contract. The Offeror(s) shall also submit: 1) a Business Proposal detailing all costs associated with performance of the work plan, 2) a request and justification for advance, milestone, and/or performance payments, and 3) appropriate consideration to the USG if such payment(s) are granted.

Independently, and not as an agent of the USG, the Offeror(s) shall furnish all the necessary services, qualified personnel, materials, supplies, equipment, facilities, transportation and travel not otherwise provided by the USG as required to fulfill the programmatic objectives.

L.2. FAR Clause 52.215-1, INSTRUCTIONS TO OFFERORS-COMPETITIVE ACQUISTION, and its Alternate I are applicable to this solicitation.

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

(e) Restriction on disclosure and use of data.
(1) The proposal submitted in response to this request may contain data (trade secrets; business data, e.g., commercial information, financial information, and cost and pricing data; and technical data) which the Offeror, including its prospective subcontractor(s), does not want used or disclosed for any purpose other than for evaluation of the proposal. The use and disclosure of any data may be so restricted; provided, that the Government determines that the data is not required to be disclosed under the Freedom of Information Act, 5 U.S.C. 552, as amended, and the Offeror marks the cover sheet of the proposal with the following legend, specifying the particular portions of the proposal which are to be restricted in accordance with the conditions of the legend. The Government's determination to withhold or disclose a record will be based upon the particular circumstances involving the record in question and whether the record may be exempted from disclosure under the Freedom of Information Act. The legend reads: Unless disclosure is required by the Freedom of Information Act, 5 U.S.C. 552, as amended, (the Act) as determined by Freedom of Information (FOI) officials of the Department of Health and Human Services, data contained in the portions of this proposal which have been specifically identified by page number, paragraph, etc. by the Offeror as containing restricted information shall not be used or disclosed except for evaluation purposes.
The Offeror acknowledges that the Department may not be able to withhold a record (data, document, etc.) nor deny access to a record requested pursuant to the Act and that the

Department's FOI officials must make that determination. The Offeror hereby agrees that the Government is not liable for disclosure if the Department has determined that disclosure is required by the Act.
If a contract is awarded to the Offeror as a result of, or in connection with, the submission of this proposal, the Government shall have right to use or disclose the data to the extent provided in the contract. Proposals not resulting in a contract remain subject to the Act.
The Offeror also agrees that the Government is not liable for disclosure or use of unmarked data and may use or disclose the data for any purpose, including the release of the information pursuant to requests under the Act. The data subject to this restriction are contained in pages (insert page numbers, paragraph designations, etc. or other identification).
(2) In addition, the Offeror should mark each page of data it wishes to restrict with the following statement: "Use or disclosure of data contained on this page is subject to the restriction on the cover sheet of this proposal or quotation."
(3) Offerors are cautioned that proposals submitted with restrictive legends or statements differing in substance from the above legend may not be considered for award. The Government reserves the right to reject any proposal submitted with a nonconforming legend.

As prescribed in FAR 15.209(a)(1), the following paragraph (f)(4) is substituted for the paragraph (f)(4) of the basic provision:

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

L.3. NAICS CODE AND SIZE STANDARD

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

(1) The NAICS Code is 325414.
(2) The small business size standard is 500 employees.

L.4. THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS. However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

L.5. TYPE OF CONTRACT AND NUMBER OF AWARD(S)

It is anticipated that one or more awards will be made from this solicitation, subject to the availability of funds, and the award(s) will be made in September, 2008.

It is anticipated that the award from this solicitation will be a hybrid with firm fixed price items and some cost reimbursable items, with a period of performance of five (5) years as agreed to during negotiations.

L.6. 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.

L.7. COMMUNICATIONS PRIOR TO CONTRACT AWARD

Offerors shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. **Communications with any other Government official regarding this RFP is strictly prohibited and may disqualify your proposal for further consideration.**

L.8. SERVICE OF PROTEST (AUGUST 1996) - FAR 52.233-2

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the General Accounting Office (GAO), shall be served on the Contracting Officer (*Complete address and contact information can be found on the SECTION A SOLICITATION/CONTRACT FORM cover page, Block 13, of the RFP*) by obtaining written and dated acknowledgment of receipt.

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

L.9. LATE PROPOSALS AND REVISIONS, HHSAR 352.215-70, is applicable to this solicitation.

II. GENERAL INSTRUCTIONS

L.10. AUTHORIZED OFFICIAL AND SUBMISSION OF PROPOSAL

The proposal must be signed by an official authorized to bind your organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. Your proposal shall be submitted in the number of copies, to the addressees, and marked as indicated in the Attachment entitled,

PACKAGING AND DELIVERY OF PROPOSAL, Part III, Section J hereof. Proposals will be paginated, reproduced on letter size paper, and shall be legible in all required copies. In addition to the original signed copy, seven (7) hard copies and electronic copies of the technical and business proposal are required. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE
Include RFP title, number, name of organization, 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 Statement of Objectives.

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 Statement of Objectives associating cost with identified task.

L.11. Alternate Proposals (May 1998)

The Offeror may, at its discretion, submit alternate proposals or proposals that deviate from this solicitation's requirements; provided that the Offeror also submits a proposal for performance of the work as specified in the statement of objectives. Alternate proposals may be considered if performance would be improved or not compromised, and if they are in the best interest of the Government. Alternate proposals, or deviations from any requirements of this RFP, must be clearly identified.

L.12. 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.

L.13. Potential Award Without Discussions, The Government reserves the right to award a contract without discussions.

L.14. Prohibition on Contractor Involvement with Terrorist Activities, is applicable to this solicitation. See Section H.

L.15. Solicitation Provisions Incorporated by Reference: The following provisions are applicable to this solicitation.
Facilities Capital Cost of Money, FAR Clause 52.215-16, (October 1997).
Order of Precedence-Uniform Contract Format, FAR Clause 52.215-8, (October 1997).

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

III. TECHNICAL PROPOSAL INSTRUCTIONS

***General Comment*: The technical proposal should be prepared and submitted, in a format to facilitate proposal evaluation, in accordance with the criteria specified in Section M. hereof, i.e., the proposal should also contain a separate section addressing the Offerors ability to meet the mandatory criterion for eligibility (See M.1.).**

The technical proposal shall address the Offerors understanding of the SOO and propose a detailed technical approach to fulfilling the SOO; a separate section addressing the Offerors facilities and equipment; a separate section addressing the Offerors management plan and personnel; a separate section outlining the proposed delivery schedule; a separate section addressing the objectives for contract options. As appendices a separate section addressing the Offerors Gantt chart, tabular project plan, earned value management plan, risk mitigation plan, security plan, qualification of key personnel, use of human subjects, animal welfare assurance, and certification of select agents.

Offerors may identify tasks, among those described in this solicitation, for which they plan to utilize subcontractors. This approach is encouraged if it allows the Offeror to more efficiently perform the numerous responsibilities required by this project. Offerors should describe the activities to be subcontracted, the method and level of integration between the prime and any proposed subcontractor(s), and the expected advantages of such an approach.

Base and Option work should be formatted in separate sections.

The **technical proposal may not exceed 200 pages and 200 pages of appendices**. Pages shall be number consecutively starting with page 1. Blank tabbed divider pages do not count. Pages shall be single-spaced, single sided, 8.5 by 11 inch pages of 10 or 12-point font. Also, the technical proposal should provide specific information addressing the elements listed in the Statement of Objectives and those specified below.

Proposals which merely offer to conduct a program in accordance with the Government's statement of objectives will not be eligible for award. The technical proposal should contain an explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives.

L.16. Offeror(s) shall describe fulfillment of the Mandatory Criterion for Eligibility (section M.1.)

L.17. Offeror(s) proposal shall describe how the Offeror will fulfill the objectives in the SOO.

L.18. Technical approach to manufacturing 25 million doses of recombinant protective antigen anthrax vaccine. A detailed plan indicating how each aspect of the statement of objective shall be accomplished. This plan should be in as much detail as considered 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. This information should demonstrate your understanding of important events or tasks and their management. You must explain how the management and coordination of consultant and/or subcontractor efforts will be accomplished.

L.19. The technical proposal must contain a discussion of present or proposed facilities and equipment that will be used in the performance of the contract.

L.20. Personnel Management. The technical proposal must list the names and proposed duties of the professional personnel, consultants, and key subcontractor employees assigned to the project. Their resumes should be included, as appendices, and be limited to 2 pages for each individual. The resumes should contain information on education, background, recent experience, and specific or technical accomplishments as they pertain to their ability to support the objectives of this project. The approximate percentage of time each individual will be available for this project must be stated. The proposed staff hours of each individual should be allocated against each project task or subtask.

L.21. The technical proposal must contain a proposed delivery schedule.

L.22. Technical approach shall describe how the Offeror will fulfill the Option Objectives (Section C.8).

IV. Appendices to Technical Proposal

L.23. A Gantt chart presented as an integrated project plan (a copy must also be provided on CD). The Gantt chart must contain sufficient detail to permit reviewers to make a realistic evaluation of the Offeror's likelihood of success.

L.24. A tabular project plan which outlines key, critical path milestones. The project plan should include, but is not limited to, milestones in manufacturing, non-clinical, clinical, regulatory submissions, and delivery of product to the SNS.

L.25. An earned value management, or similar, plan tying cost and schedule to specific task which can be monitored during contract performance.

L.26. A risk mitigation plan. The risk mitigation plan should address potential problems that may arise and remediation plans to circumvent major time disruption to the project. Each of these documents can be revised during negotiations with the successful Offeror and will be incorporated into the contract.

L.27. Security Plan which covers physical, personnel, and Information Technology (IT) infrastructure security.

L.28. *Curriculum vitae* of key personnel. There should be enough detail to ensure the USG that key individuals will be able to perform the work described in the Technical Proposal.

L.29. Protection of Human Subjects is applicable to this solicitation. See the Statement of Objectives and Section M.5 for additional information concerning human subjects.

L.30. Animal Welfare Assurance. The Contractor shall obtain, prior to the start of any work under this contract, an approved Animal Welfare Assurance from the Office of Protection from Research Risks (OPRR), Office of the Director, NIH, as required by Section I-43-30 of the Public Health Service Policy on Humane Care and Use of Laboratory Animals. The Contractor shall maintain such assurance for the duration of this contract, and any subcontractors performing work under this contract involving the use of animals shall also obtain and maintain an approved Animal Welfare Assurance.

Offerors must submit their plan on how they will comply with all requirements concerning the use of animals for experimentation and be in accordance with any requirements specified in the **http://grants.nih.gov/grants/olaw/olaw.htm.**

L.31. Compliance with regulations on the Possession, Use and Transfer of Select Biological Agents or Toxins

If the proposed contract will not involve Select Agents, the offeror must include a statement in its technical proposal that the work does not now nor will it in the future (i.e. throughout the life of the award) involve Select Agents.

Domestic Institutions

For prime or subcontract awards to domestic institutions that possess, use, and/or transfer Select Agents under this contract, the domestic institution must:

- include details about the select agent in their technical proposal, including the quantity proposed to be used during contract performance.
- comply with 42 CFR part 73, 7 CFR part 331 and/or 9 CFR part 121 at: http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf , as required, before using BARDA funds for research involving Select Agents.

Foreign Institutions

For prime or subcontract awards to foreign institutions that possess, use, and/or transfer Select Agents under this contract, the foreign institution must:

- include details about the select agent in their technical proposal, including the quantity proposed to be used during contract performance.
- when requested during negotiations, provide information satisfactory to BARDA that safety, security, and training standards equivalent to those described in 42 CFR part 73, 7 CFR part 331,

and/or 9 CFR part 121 at: http://www.aphis.usda.gov/programs/ag_selectagent/FinalRule3-18-05.pdf for U.S. institutions are in place and will be administered on behalf of all Select Agent work under the resulting contract.

V. BUSINESS PROPOSAL INSTRUCTIONS

L.32. Proposal Cover Sheet, is applicable to this solicitation and is included under Section J

L.33. The business proposal shall specify the cost of production per unit for 25 million doses of rPA anthrax vaccine for the base contract.

L.34. Requirements for Cost or Pricing Data or Information Other than Cost and Pricing Data [FAR Clause 52.215-20 (October 1997)], is applicable to this solicitation**.**

L.35. Small Business Subcontracting Plan is applicable to this solicitation and the following information is provided to supplement this item to assist in proposal preparation. A Subcontracting Plan must be submitted with the original business proposal and will be subject to negotiations if your proposal is determined to be in the competitive range. Small Business Subcontracting Plan Format (must be submitted with your original Business Proposal) http://www.hhs.gov/osdbu/forms.html
The anticipated minimum subcontracting goals for this RFP are as follows:

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

L.36. Extent of Small Disadvantaged Business Participation in applicable to this solicitation.

L.37. Past Performance Information is applicable to this solicitation and the following information is provided to supplement this item to assist in proposal preparation:

Past Performance information shall be submitted as part of the Business proposal. Similar or related contracts, subcontracts, or grants should be included and contain the name of the customer, contract or grant number, dollar amount, time of performance, and the names and telephone numbers of the project officer and contracting officer/grants officer.

L.38 The following personnel in the business unit, at a minimum, shall be identified. Contractor shall provide resumes and a percentage of time each individual will commitment to the contract.

i. Chief Executive Officer
ii. President
iii. Chief Operating Officer
iv. Chief Financial Officer

L. 39 A pre-proposal conference will be held on March 18, 2008 at 9am in Washington D.C.

An amendment to the RFP will be posted on March 11 to announce the address and room number of the pre-proposal conference.

By March 12, 2008 offerors shall submit any questions they would like addressed at the pre-proposal conference to Brian Goodger, Contracting Officer at Brian.Goodger@hhs.gov

SECTION M - EVALUATION FACTORS FOR AWARD

Selection of an Offeror for contract award will be based on an evaluation of proposals against the evaluation factors identified in this section. The non-cost factors in order of importance are: technical proposal evaluation, past performance, and Small Disadvantaged Business (SDB) participation. In addition, prior to award, the Offeror's proposal must be considered acceptable for use of human subjects, animal welfare, and the use of 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. All evaluation factors other than cost or price, when combined, are approximately equal to cost or price. 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. The USG reserves the right to make an award to that Offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Contractor to translate the Statement of Objectives into a functional and executable technical proposal. The proposal must document the Contractor's implementation plan to perform the work thereby meeting the Statement of Objectives. Offerors must submit information sufficient to evaluate their proposals for technical completeness to carry out or perform criteria being evaluated.

M.1. Mandatory Criterion for Eligibility

The Offerors shall provide a dedicated section in the technical proposal that addresses the mandatory criterion for eligibility. The mandatory criterion for eligibility must be met at the time of proposal submission. Offeror's proposals that do not meet the mandatory criterion for eligibility will not be eligible for further evaluation.

Evidence that the Offeror has obtained FDA/CBER "current thinking" for an rPA anthrax vaccine that describes the minimum product information and data that must be submitted to the FDA for review in order to potentially consider use of their product in a declared emergency under EUA.

M.2. Technical Proposal Evaluation (out of 320 points)

Offeror's technical proposals will be evaluated with points assigned as indicated in the following 6 categories. The categories are listed in order of importance; however, the sub-categories are not.

I. Technical Merit of the Offeror(s) proposal and time line (30 points)

a. Proposal does not fulfill Statement of Objectives (0 points)
b. Proposal does fulfill Statement of Objectives but does not appear to be technically feasible within the base contract period of performance and needs revision (maximum of 10 points)
c. Proposal does fulfill Statement of Objectives and does appear to be technically feasible within the base contract period of performance and may or may not need revision (maximum of 30 points)

II. Technical Approach for manufacturing 25 million doses of rPA anthrax vaccine and obtaining licensure (Maximum of 180 points)

90 points for the overall technical proposal

a. Production and cGMP compliance
b. Details of proposed packaging of FDP, performance, and associated life cycle value
c. Assay validation and stability testing of finished vaccine
d. Safety, efficacy, and immunogenicity studies, including execution of studies to support an EUA
e. Safety and efficacy studies to support the Biologics License Application
f. Regulatory submission plans and timelines
g. Phase 4 Post-Marketing Commitment plan
h. Shipment of rPA to the SNS, delivery schedule, and short term storage
i. Disposition of vaccine inventory

In addition, the USG has determined that three specific technical criteria will be evaluated and are deemed critical for the Offeror to successfully fulfill the SOO within proposed base performance period. Additional points will be awarded to the following three specific areas of the technical proposal:

<u>Maximum</u> of 90 points for the three, specific, categories listed below:

i. Contractor has demonstrated validated bulk drug substance (BDS) production at proposed commercial scale.
ii. Planned, ongoing, or completed non-clinical studies generating proof-of-concept efficacy data using anthrax spore aerosol challenge in relevant animal models.
iii. Planned, ongoing, or completed Phase 2 clinical studies under an FDA IND to evaluate safety and immunogenicity of rPA anthrax vaccine.

Each of the specific criteria, (i., ii., and iii), will be weighted in accordance with the following scheme:

5 points (maximum) for submission of a plan to perform or carry out studies
20 points (maximum) for submission of summary data from ongoing studies which supports the efficacy of the product for the indicated use
30 points (maximum) for submission of summary data from completed studies which supports the efficacy of the product for the indicated use

III. Personnel (30 points)

a. The Offerors shall provide personnel who possess the necessary education, training, and experience to successfully perform the work identified in the technical proposal.
b. A resume shall be provided for critical staff necessary to perform the SOO (as defined in section L) and be easily identified in the project management section of the proposal. Proposal should indicate percentage of individual's time to be dedicated to performance of this contract.
c. Proposed personnel can be either members of the Offerors organization or subcontractors.
d. At a minimum the following key personnel should be identified:
    v. Chief Scientific Officer
    vi. Program Manager (PM)

vii. Head of Manufacturing
viii. Head of Fill/Finish
ix. Head of Quality Assurance (QA)
x. Head of Quality Control (QC)
xi. Head of Regulatory Affairs
xii. Head of Supply Chain Management

IV. Facilities and Equipment (25 points)

a. The Offeror must demonstrate it has, or can obtain the necessary space and qualified facilities and equipment to successfully perform the SOO.
b. The following facilities and characteristics must be identified:
    i. Product manufacturing facilities compliant with cGMP
    ii. Non-clinical and potency test facilities compliant with:
        a. Biosafety Level (BSL) 2 and 3 guidelines and HHS regulations regarding the transfer of Select Agents (42 CFR part 73); and,
        b. Compliance with federal regulations for the housing and care of laboratory animals.
    iii. Facilities or Capabilities (if sub-contracted out) to conduct clinical studies in accordance with Good Clinical Practices
    iv. Quarantine and storage space
c. In addition to FDA regulations the potential Contractor shall be compliant with regulatory requirements in the country of production if the Contractor is located outside the United States.

V. Project Management and Risk Mitigation (20 points)

a. Gantt Chart
b. Project Plan
c. Risk Mitigation Plan
d. Earned Value Management Plan

VI. Security (15 points)

a. Security of contract operations
b. Personnel Security
c. Information technology security

VII. Options Evaluation (20 points)

1. Label extension for expiry period for 36 months (10 points)

a. Technical completeness to perform stability assessments to support the proposed product dating period beyond the life of the base contract, using validated assays and to perform quality control and quality assurance monitoring of the product in the SNS. (10 points)

2. Label indication extension for use in pediatric and geriatric populations (10 points)

a. Technical completeness and the feasibility of the plan to conduct human and animal studies for licensure supplement(s) for PEP plus antibiotics indication in pediatric population. (5 points)
b. Technical completeness and the feasibility of the plan to conduct human and animal studies for licensure supplement(s) for PEP plus antibiotics indication in geriatric population. (5 points)

M.3. Past Performance Factor

An evaluation of Offeror's past performance information will be conducted during the technical evaluation. The evaluation will be based on information obtained from references provided by the Offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the Offeror concerning problems encountered on the identified contracts and corrective action taken.

The government will assess the relative risks associated with each Offeror. Performance risks are those associated with an Offeror's likelihood of success in performing the acquisition requirements as indicated by that Offeror's record of past performance. The assessment of performance risk is not intended to be a product of a mechanical or mathematical analysis of an Offeror's performance on a list of contracts but rather the product of subjective judgment by the Government after it considers relevant information.

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

The Government will consider the currency and relevance of the information, source of the information, context of the data and general trends in the Offeror's performance. The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the Offeror. 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:

+10 Excellent - Based on the Offeror's performance record, no doubt exists that the Offeror will successfully perform the required effort. Sources of information are consistently firm in stating that the Offeror's performance was superior and that they would unhesitatingly do business with the Offeror again.

+5 Good - Based on the Offeror's performance record, little doubt exists that the Offeror will successfully perform the required effort. Sources of information state that the Offeror's performance was good, better than average, etc., and that they would do business with the Offeror again.

+2 Average – Based on the Offeror's performance record, some doubt exists that the Offeror will successfully perform the required effort. Sources of information indicate that the Offeror's performance is average or that favorable reports are offset by unfavorable reports.

+1 Marginal - Based on the Offeror's performance record, some doubt exists that the Offeror will successfully perform the required effort. Sources of information make unfavorable reports about the Offeror's performance and express concern about doing business with the Offeror again.

+0 Poor - Based on the Offeror's performance record, serious doubt exists that the Offeror will successfully perform the required effort. Sources of information consistently stated that the Offeror's performance was entirely unsatisfactory and that they would not do business with the Offeror again.

M.4. Extent of Small Disadvantaged Business Participation

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

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

Offers will be evaluated on the following sub-factors:

a. Extent to which SDB concerns are specifically identified
b. Extent of commitment to use SDB concern
c. Complexity and variety of the work SDB concerns are to perform
d. Realism of the proposal
e. Past performance of Offeror(s) in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation
f. Extent of participation of SDB concerns in terms of the value of the total acquisition.

M.5. Studies That Involve Human Subjects

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

HHS Policy requires:

a. Protection of Human Subjects from Research Risks

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

If you claim that this research should be considered exempt from coverage by the Federal Regulations at 45 CFR 46, the proposal should address why you believe it is exempt, and under which exemption it applies.
The reviewers will evaluate the proposal and provide a narrative with regard to four issues: Risks to Human Subjects, Adequacy of Protection Against Risks, Potential Benefits of the Proposed Research to the Subjects and Others, and Importance of the Knowledge to be Gained. Based on the response to this criterion, this section of the proposal may be rated "unacceptable" (i.e., concerns are identified as to the protections described against risk to human subjects or no discussion is found regarding protections against risk to human subjects) or "acceptable".

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

b. Data and Safety Monitoring

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

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

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

c. Women and Minorities

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

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

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

a. whether the plan proposed includes minorities and both genders in adequate representation
b. how the Offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation
c. the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects
d. 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.
e. in addition, for gender exclusion, the reviewers will examine the rationale to determine if it is because:

i. the purpose of the research constrains the Offeror's selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single

gender; very small numbers of subjects are involved); or

ii. overriding factors dictate selection of subjects; or

iii. gender representation of specimens or existing datasets cannot be accurately determined, and this does not compromise the scientific objectives of the research.

f. for minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:

i. inclusion of those groups would be inappropriate with respect to their health; or

ii. inclusion of those groups would be inappropriate with respect to the purpose of the research.

g. for defined Phase III clinical trials, reviewers will also address whether there is an adequate description of plans to conduct analyses to detect significant differences of clinical or public health importance in intervention effect(s) by sex/gender and/or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is not expected in the primary analyses.

Determination that inclusion of women and minority populations is not feasible will require submission a detailed rationale and justification for exclusion of one or both groups from the study population with the technical proposal. The Government will review the rationale to determine if it is appropriate with respect to the health of the subjects and/or the purpose of the research.

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

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

d. Children

Children (i.e. individuals under the age of 18) must be included in all human subject research unless there are clear and compelling reasons not to include them.

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

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

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

M.6. Animal Welfare

If the Offeror proposes to use contract funds to conduct animal studies, the Offeror must demonstrate its understanding and ability to comply with the PHS Policy on Humane Care and Use of Laboratory Animals (http://grants.nih.gov/grants/olaw/olaw.htm). If the Offeror has an Animal Welfare Assurance on file with the Office of Extramural Research (OER), Office of Laboratory Animal Welfare (OLAW), provide the Assurance number with the proposal. If the Offeror proposes animal studies, the Offeror must submit a plan that describes how the Offeror will comply with the PHS Policy and addresses the five points listed below:

a. Provide a detailed description of the proposed use of the animals in the work outlined in the experimental design and methods section. Identify the species, strains, ages, sex, and numbers of animals to be used in the proposed work.
b. Justify the use of animals, the choice of species, and the numbers used. If animals are in short supply, costly, or to be used in large numbers, provide an additional rationale for their selection and their numbers.
c. Provide information on the veterinary care of the animals involved.

d. Describe the procedures for ensuring that discomfort, distress, pain, and injury will be limited to that which is unavoidable in the conduct of scientifically sound research. Describe the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices where appropriate to minimize comfort, distress, pain, and injury.

e. Describe any euthanasia method to be used and the reasons for its selection. State whether this method is consistent with the recommendations of the Panel on Euthanasia of the American Veterinary Medical Association (http://www.avma.org/resources/euthanasia.pdf). If not, present a justification for not following the recommendations.

Your plan may be rated "unacceptable or acceptable." If your proposal is rated "unacceptable" and the Government includes your proposal in the competitive range, 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.

M.7. Use of Select Agent

An HHS chaired committee of contracting, security, safety and scientific program management will assess the applicability of the facilities, regulations, policies, and procedures for meeting the U.S. requirements described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121.

If your proposal is rated "acceptable" and the Government includes your proposal in the competitive range a committee will inspect your facility (s). The committee will provide a recommendation to Contracting Officer concerning the status of the Offeror to meet the select agent requirements. No BARDA funds will be used involving Select Agents until BARDA grants approval.

M.8. Relative Importance of Cost or Price and Other Evaluation Factors

All evaluation factors other than cost or price, when combined, are approximately equal to cost or price.

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.