DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary

Assistant Secretary for
Preparedness & Response
Washington, D.C. 20201

Date: _____

Re: Request for Proposal (RFP) Number RFP-HHS-BARDA-08-09 entitled
"Building Domestic Cell-based Influenza Vaccine Manufacturing Facilities"

Dear Prospective Offeror:

This RFP represents HHS's commitment to support the expansion of the domestic capacity to manufacture pandemic influenza vaccines. The successful Offeror(s) will be required to design, construct, validate and perform regulatory activities that will lead to FDA-licensure of new U.S.-based bulk influenza vaccine manufacturing facilities. The requirement will include pre-construction document development, construction, commissioning, validation and licensing.

This RFP is posted on the General Services Administration's (GSA's) Federal Business Opportunities Internet website known as FedBizOpps Electronic Posting System (www.FedBizOpps.gov). Any amendments to this RFP shall also be posted on the same internet website. No other notice shall be given to prospective Offerors and it is incumbent on Offerors to make periodic inquiries.

The RFP includes Mandatory Criteria for Eligibility, which is located sre Section M.1.

Prospective Offerors are advised that HHS is operating under stringent security requirements applied to all incoming mail and packages. This includes all proposals submitted under HHS solicitations by regular mail, express mail delivery, or hand-delivered directly by an Offeror or by a courier service. Please note that personal identification of couriers or Offerors is required for delivery of proposals.

In accordance with the attached RFP, Offerors are required to submit their proposals to the Contracting Officer no later than _____, at 3:00 PM local time.

Any questions concerning the RFP should be submitted in writing to Paquetta Myrick-Hancock, no later than _____ at the address specified below or you may also email your questions to Paquetta.Hancock@hhs.gov. Questions should be marked "Questions Regarding RFP-HHS-BARDA-08-09". Any questions and answers will be made available via the FedBizOpps website.

Letters of Intent to submit a proposal must be received by _____. Section J of the RFP contains a copy of the Proposal Intent Response Sheet. Please note that your expression of intent is not binding but will greatly assist us in planning for the proposal evaluation process.

Sincerely yours,

Paquetta N. Myrick-Hancock
Contracting Officer
Biomedical Advanced Research and Development Authority

SOLICITATION, OFFER AND AWARD

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES 1 | 103

2. CONTRACT NO.	3. SOLICITATION NO.	4. TYPE OF SOLICITATION	5. DATE ISSUED	6. REQUISITION/PURCHASE NO
	HHS-BARDA-08-09	☐ SEALED BID (IFB) ☒ NEGOTIATED (RFP)		

7. ISSUED BY CODE	8. ADDRESS OFFER TO *(If other than ARTICLE 7)*
Department of Health and Human Services (HHS) OS/ASPR/BARDA 330 Independence Ave. SW, Room G644 Washington, DC 20201	See ITEM 7

NOTE: In sealed bid solicitations "offer" and "offeror" mean "bid" and "bidder."

SOLICITATION

9. Sealed offers in original and 8 copies for furnishing the supplies or services in the Schedule will be received at the place specified in ARTICLE 8 , or if handcarried, in the depository located in Block 7 until 3:00pm local time 05/16/2008 *(Hour)* *(Date)*

CAUTION -- LATE Submissions, Modifications, and Withdrawals: See Section L, Provision No. 52.214-7 or 52.215-1. All offers are subject to all terms and conditions contained in

10. FOR INFORMATION CALL:	A. NAME	B. TELEPHONE *(NO COLLECT CALLS)* AREA CODE NUMBER EXT:	C. E-MAIL ADDRESS
	Paquetta N. Myrick-Hancock	(202) 260-0534	Paquetta.Hancock@hhs.gov

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OFFER *(Must be fully completed by offeror)*

NOTE: ARTICLE 12 does not apply if the solicitation includes the provisions at 52.214-16, Minimum Bid Acceptance Period.

12. In compliance with the above, the undersigned agrees, if this offer is accepted within 120 calendar days *(60 calendar days unless a different period is inserted by the offeror)* from the date for receipt of offers specified above, to furnish any or all ARTICLEs upon which prices are offered at the price set opposite each ARTICLE, delivered at the designated point(s), within the time specified in the schedule.

13. DISCOUNT FOR PROMPT PAYMENT *(See Section I, Clause No. 52-232-8)*	10 CALENDAR DAYS	20 CALENDAR DAYS	30 CALENDAR DAYS	CALENDAR DAY

14. ACKNOWLEDGMENT OF AMENDMENTS *(The offeror acknowledges receipt of amendments to the SOLICITATION for offerors and related documents numbered and dated:*	AMENDMENT NO.	DATE	AMENDMENT NO.	DATE

15A. NAME AND ADDRESS OF OFFEROR	CODE	FACILI	16. NAME AND ADDRESS OF PERSON AUTHORIZED TO SIGN OFFER *(Type or Print)*

15B. TELEPHONE NO. AREA CODE NUMBER EXT.	☐ 15C. CHECK IF REMITTANCE ADDRESS IS DIFFERENT FROM ABOVE - ENTER	17. SIGNATURE	18. OFFER DATE

AWARD *(To be completed by Government)*

19. ACCEPTED AS TO ARTICLES NUMBERED	20. AMOUNT	21. ACCOUNTING AND APPROPRIATION

22. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: ☐ 10 U.S.C. 2304(c)( ) ☐ 41 U.S.C. 253(c)( )	23. SUBMIT INVOICES TO ADDRESS SHOWN IN *(4 copies unless otherwise specified)*	ARTICLE

24. ADMINISTERED BY *(If other than* CODE	25. PAYMENT WILL BE MADE BY CODE

26. NAME OF CONTRACTING OFFICER *(Type or print)*	27. UNITED STATES OF AMERICA *(Signature of Contracting Officer)*	28. AWARD DATE

IMPORTANT -- Award will be made on this form, or on Standard Form 26, or by other authorized official written notice.

SECTION B--SUPPLIES OR SERVICES AND PRICES/COSTS

B.1. Brief Description of Supplies or Services

The Department of Health and Human Services (HHS), Office of the Assistant Secretary for Preparedness and Response (ASPR), Biomedical Advanced Research and Development Authority (BARDA) requires the services of a contractor(s) to design, construct, validate and perform regulatory activities that will lead to FDA-licensure of new U.S.-based bulk influenza vaccine manufacturing facilities. The requirements will include pre-construction document development, land use and zoning licensure, construction, commissioning, validation and licensing of the facility, and the licensure, manufacture and release of at least one (1) lot of pandemic and/or pre-pandemic vaccine product.

B.2. Contract Line Item Numbers (CLINs):

(a) Cost Sharing – CLINS (Base Period)

In consideration for the completion of the work to be performed under the Contract Line Item Numbers (CLINs) shown below, and in accordance with the Statement of Work (see Section C), the Contractor shall be paid in accordance with the schedule shown below. In no event shall the Government's share of the cost exceed 40% of the total cost for these line items:

Item	Supplies / Services	Qty / Unit	Government Share of Cost	Offeror Share of Cost	Total Cost
0001	**Overall Project Plan** (Milestone 1)	1 Job	$	$	$
0002	**Regulatory and Clinical Bridging Study Plan** (Milestone 2)	1 Job	$	$	$
0003	**Facility Operation Feasibility Plan** (Milestone 3)	1 Job	$	$	$
0004	**Detailed Manufacturing Facility Plan** (Milestone 4)	1 Job	$	$	$
0005	**Contactor Defined Milestones** (Milestone 5)	1 Job per Program			
0005A	**Seasonal Influenza Vaccine Program** (Milestone 5a)	1 Job	$	$	$
0005B	**Pandemic Influenza Vaccine Program** (Milestone 5b)	1 Job	$	$	$
0006	**Final Technical Closeout Report** (Milestone 6)	1 Report	$	$	$
0007	**Technical Progress Report** and **Executive Summary** (12 of each per year)	60 Reports	$	$	$
	TOTAL Cost (Items 0001 – 0007):		$	$	$

(b) Cost Plus Fixed Fee (CPFF) CLINS (Option Periods)

Should the Government decide to exercise an option(s) upon completion of Milestone 6 [Final Technical Closeout Report], the Contractor shall be paid in accordance with the schedule shown

below. These estimates shall be revised to reflect the actual cost to manufacture influenza vaccine product and adjuvant (if applicable) as determined in Milestone 6. The actual cost of each option shall not exceed the estimated cost plus fixed fee for each line item:

Item	Supplies / Services	Qty / Unit	Est. Cost	Fixed Fee	Total Est. CPFF
0008	**Annual Warn Base Vaccine Production** (Milestone 6)	1 Lot per Year			
0008A	1st Annual Warm Based Vaccine Production**	1 Lot	$	$	$
0008B	2nd Annual Warm Based Vaccine Production**	1 Lot	$	$	$
0008C	3rd Annual Warm Based Vaccine Production**	1 Lot	$	$	$
0008D	4th Annual Warm Based Vaccine Production**	1 Lot	$	$	$
0008E	5th Annual Warm Based Vaccine Production**	1 Lot	$	$	$
0008F	6th Annual Warm Based Vaccine Production**	1 Lot	$	$	$
0008G	7th Annual Warm Based Vaccine Production**	1 Lot	$	$	$
0008H	8th Annual Warm Based Vaccine Production**	1 Lot	$	$	$
0008I	9th Annual Warm Based Vaccine Production**	1 Lot	$	$	$
0008J	10th Annual Warm Based Vaccine Production**	1 Lot	$	$	$
0008K	11th Annual Warm Based Vaccine Production**	1 Lot	$	$	$
0008L	12th Annual Warm Based Vaccine Production**	1 Lot	$	$	$
0008M	13th Annual Warm Based Vaccine Production**	1 Lot	$	$	$
0008N	14th Annual Warm Based Vaccine Production**	1 Lot	$	$	$
0008O	15th Annual Warm Based Vaccine Production**	1 Lot	$	$	$
0008P	16th Annual Warm Based Vaccine Production**	1 Lot	$	$	$
0008Q	17thAnnual Warm Based Vaccine Production**	1 Lot	$	$	$
0008R	18th Annual Warm Based Vaccine Production**	1 Lot	$	$	$
0008S	19thAnnual Warm Based Vaccine Production**	1 Lot	$	$	$
0008T	20thAnnual Warm Based Vaccine Production**	1 Lot	$	$	$
	TOTAL Cost Plus Fixed Fee (Items 0008A – 0008T):		$	$	$

B.3. Advanced Understandings

(a) Priority Rating

HHS intends to assign a priority rating to any contract awarded under this RFP. The Contracting Officer may unilaterally modify the contract to add FAR Clause 52.211-15, Defense Priority and Allocation Requirements (Sep 1990) AND ASSIGN A DO PRIORITY RATING UNDER 15 CFR 700.

(b) Costs

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

SECTION C - DESCRIPTION/SPECIFICATIONS

C.1. STATEMENT OF WORK

"Building Domestic Cell-based Influenza Vaccine Manufacturing Facilities"

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

The Contractor shall perform the work in accordance with the Contractor's Work Plan (CWP), or Summary of the CWP, and the Gantt Chart referenced in **Section J** and attached to this contract.[1]

C.2. MILESTONES (also see Section F.3)

The following Milestone Plans are required to describe the activities that the Offeror will perform to successfully meet the objectives of the contract. The Contracting Officer may modify this contract, as described in **Milestone 5a** and **Milestone 5b**, to incorporate the Contractor-Defined Milestones, Work Breakdown Structures (WBS) and Gantt Charts provided in **Milestone 1**, **Milestone 2**, **Milestone 3**, and **Milestone 4**.

Milestone 1: Within one (1) month of contract award, the Contractor shall submit to HHS for review and acceptance, an **Overall Project Plan**. The Overall Project Plan shall present a preliminary Work Breakdown Structure (WBS) and Gantt Chart that includes all key regulatory and quality events, all contractual Milestone driven deliverables, and contractor-defined, project-specific elements in sufficient detail to outline the full scope of the effort.

Milestone 2: Within three (3) months of contract award, the Contractor shall submit to HHS for review and acceptance, a comprehensive, integrated **Regulatory and Clinical Bridging Study Plan**. The following issues shall be addressed in the Regulatory and Clinical Bridging Study Plan:

1. A **detailed description of regulatory activities** shall be integrated with all products, clinical testing and manufacturing activities using the most current and available information, including consultation with the Center for Biologics Evaluation and Research (CBER) in FDA. A risk assessment and mitigation plan addressing potential manufacturing, clinical and regulatory obstacles that might prevent or delay licensure as well as a plan for the production and distribution of vaccine in the case of emergency use authorization (EUA) shall be included. Issues suitable for risk assessment include cell line qualification, assay development, process yields and facility management. Mitigation plans should include decision trees where applicable.

2. A **summary of pre-clinical studies** including consultation(s) with the CBER should be incorporated as an appendix to the milestone report.

3. A **detailed description of planned clinical bridging studies** leading to licensure by the CBER of the cell-based seasonal and pandemic influenza vaccine(s) produced in the new facility(s) should be presented. Clinical bridging studies of cell-based influenza vaccines manufactured and licensed at other sites, including abroad, is necessary to provide data in support of FDA licensure of this product in the newly created cell-based influenza vaccine manufacturing facility(s) located within the U.S.

[1] Will be submitted as a part of the Offeror's proposal in response to solicitation and is subject to negotiation. Attachment will be provided at contract award.

4. A **detailed description of clinical evaluation** should be integrated with the manufacturing plans using the most current and available information including consultation with the CBER. A summary of clinical lot manufacturing results, provisional lot release specifications, and any additional stages of product development that have been completed should be incorporated as an appendix to the milestone report.

Many of the required elements of **Milestone 2** may be satisfied by inclusion of the Contractor's Investigational New Drug (IND) application and relevant supplements, if available.

Milestone 3: Within six (6) months of contract award, the Contractor shall provide HHS for review and acceptance a **Facility Operation Feasibility Plan** to manufacture, test, and release final container commercial biological products and vaccines for USG purchases during inter-pandemic and pandemic periods. In addition, the **Facility Operation Feasibility Plan** shall address, in specific terms, the time required to deliver a pandemic influenza vaccine following the declaration of a pandemic with an overall surge capacity that can release and deliver at least 150 million finished doses within six (6) months of the declared pandemic. The purchase of any finished doses manufactured by the Contractor beyond the mandatory 150 million finished doses shall be negotiated at a later date, subject to funding and applicable appropriations rules and regulations. The **Facility Operation Feasibility Plan** should include the following elements:

1. A detailed **process description**, including a summary of process data that describes the yield and purification efficiencies of key process steps.

2. An **integration plan** that outlines the addition of new facility(s) within the Contractor's biological product franchise.

3. A **comparison of process data** that describes the significance of process scale-up and strain variability on production capacity.

4. Proposed **production schedules** including detailed timelines for each production step from accessibility of pandemic influenza viral nucleotide sequence or receipt of pandemic influenza virus reference strain to release of initial lot(s) of 150 million doses of final container vaccine product during a pandemic. Additionally, a description of material management and the number of doses of vaccine released each week after pandemic declaration should be provided.

5. A detailed bulk upstream, bulk downstream, formulation, fill, and finish **manufacturing capacity analysis** for pandemic influenza vaccines.

6. An **operational cost structure** for pre-pandemic influenza vaccine lot production that includes the anticipated cost breakdown for a single dose of the vaccine.

7. A description of ongoing and/or anticipated **process optimization activities**.

8. **Dose calculations and contingency plans** to address the need for higher dosages of the active product ingredient.

9. A **pre-pandemic facility management plan** including a pandemic preparedness plan.

10. A **pandemic facility management plan** including change procedures from seasonal to pandemic operations under Emergency Use Authorization (EUA).

11. A **change control plan** in the event the bulk manufacturing facility would be required by the USG for emergency production of an emerging, non-influenza infectious disease vaccine candidate.

Milestone 4: Within eight (8) months of contract award, the Contractor shall provide HHS for review and acceptance a **Detailed Manufacturing Facility Plan** describing the design, permitting approval, construction, commissioning, qualification and validation of a U.S.-based facility to produce the Contractor's seasonal and pandemic influenza vaccine. The Detailed Manufacturing Facility Plan shall contain appropriate information concerning the following elements:

1. **Site selection criteria**, including site user requirement specifications, descriptions of site utilities and infrastructure, descriptions of local, state and federal land use, zoning and permitting issues and timelines, and security planning considerations.

2. A **facility regulatory compliance plan** that addresses any and all applicable local zoning, land use and construction standards, cGMP standards, NIH, CDC, USDA and WHO bio-safety standards, USDA animal testing standards, National Fire Protection Agency standards, DHS security issues and OSHA and EPA compliance.

3. A **subcontractor use plan** that contains a thorough discussion of the use and qualifications of known subcontractors and equipment vendors used in this contract as well as the criteria to be used for the future selection of anticipated subcontractor activities.

4. **Manufacturing processes** that include detailed descriptions of upstream and downstream processing, formulation, filling and finishing/packaging unit operations, bulk and finished product acceptance specifications, overall capacity needed to meet contract requirements, manufacturing support operations such as adjuvant solution/ media preparation, storage and distribution, glassware/equipment washing and sterilization, clean-in-place and steam-in-place operations, a risk management plan at each stage of production, process flow diagrams, equipment capacity calculations, an automation plan, and an equipment list detailing sizing capacity criteria, utility requirements, dimensions, clearances weights, mounting and purchasing lead times.

5. **Architectural/ structural plans** that include concept functional designs, descriptions, and diagrams of space requirements, adjacency plans, floor plans, equipment layouts, material, product and personnel flows, solid, liquid contaminated and other waste flows, and an air balance description or diagram detailing zoning, pressurization, air flows and air quality classification.

6. **Process and building/ mechanical engineering** including energy balances, utility flow diagrams, automation plan, equipment lists and a preliminary layout.

7. A **proposed construction schedule** including permitting, installation, commissioning and installation/operational/performance qualification and a risk mitigation analysis.

8. A **description of the manufacturing facility quality assurance and regulatory acceptance** including quality systems, the validation master plan (VMP) and regulatory milestones.

9. A copy of **referenced procedures** that govern the creation of quality driven documents and decisions in support of the contract efforts.

10. The work to be performed under this contract will involve access to sensitive *Biomedical Advanced Research and Development Authority* [BARDA] program information. Upon contract award, the Program Protection Officer (PPO) will review the **Draft Security Plan** (*submitted as part of the*

Contractor's Technical Proposal) in detail and submit comments within ten (10) business days to the Contracting Officer (CO) to be forwarded to the Contractor. The Contractor shall review the **Draft Security Plan** comments, if required, and submit a **Final Security Plan** to the U.S. Government within thirty (30) calendar days after receipt of the Program Protection Officer's (PPO) comments. The **Final Security Plan** shall include a timeline for compliance of all the required security measures. Upon completion of initiating all security measures, the Contractor shall supply to the U.S. Government's Project Officer a letter certifying compliance to the elements outlined in the **Final Security Plan**. The execution of the work under this contract shall be in accordance with the approved **Final Security Plan**. As outlined above, the content of the **Final Security Plan** shall be a continuation of the **Draft Security Plan** submitted as part of the Contractor's Technical Proposal. Therefore, at a minimum, the **Final Security Plan** shall address the following items:

a. *Personnel Security Policies and Procedures* including, but not limited to: Recruitment of new employees; Interview process; Personnel background checks; Suitability/ adjudication policy; Access determination; Rules of behavior/ conduct; Termination procedures; Non-disclosure agreements.

b. *Physical Security Policies and Procedures* including but not limited to: Internal/ external access control; Identification/ badge requirements; Facility visitor access; Parking areas and access; Barriers/ perimeter fencing; Shipping, receiving and transport (on and off-site); Security lighting; Restricted areas; Signage; Intrusion detection systems; Closed circuit television; Other control measures.

c. *General Information Security Policies and Procedures* including but not limited to: Identification of sensitive information; Access control/ determination; Secured storage infrastructure; Document control; Retention/ destruction requirements.

d. *Information Technology Security Policies and Procedures* including but not limited to: Intrusion detection and prevention systems; Encryption systems; Identification of sensitive information/ media; Passwords; Removable media; Laptop policy; Media access control/ determination; Secure storage; System document control; System backup; System disaster recovery.

e. The following instruction/ intent shall be incorporated: *Security Reporting Requirement* - Violations of established security protocols shall be reported to the Contracting Officer (CO) and Project Officer (PO) upon discovery. The Contractor will investigate violations to determine the cause, extent, loss or compromise of sensitive and/or program information, and corrective actions taken to prevent future violations. BARDA will determine if the severity of the violation requires further U.S. Government (USG) intervention.

The manufacturing facility and process shall be maintained in compliance with current Good Manufacturing Practices (cGMP), World Health Organization (WHO) guidelines for pandemic influenza vaccine manufacturing and current bio-safety guidelines from the CDC, NIH, and the USDA. Ability to meet standards for Bio-Safety Level (BSL) 2+ [enhanced] as described in relevant guidelines may be necessary, if the Contractor will be handling and testing pathogenic influenza viruses or derivatives to generate pandemic influenza vaccines.

Milestone 5a and 5b: Contactor Defined Milestones. Within nine (9) months of contract award, the Contractor shall propose milestones, at which time data will be presented, summarizing results of prior activities and new plans/protocols that will be submitted for review and approval in order to guide all

subsequent activities. Milestones for seasonal (5a) and pandemic (5b) influenza vaccine programs shall be provided to track program progress and cost reimbursements. Potential milestones may include the following:

- Architectural and Engineering (A&E) activity [e.g. 60% Design, 90% Design, 100% Design/Build],
- Facility permitting and construction,
- Validation of facilities, systems and equipment,
- Validation of Quality Control product lot release methods,
- Manufacturing of an investigational lot of vaccine,
- Completion of appropriate clinical trials,
- Validation of manufacturing processes,
- Stability study programs,
- Engineering lot manufacturing,
- Validation/Consistency lot manufacturing,
- Submission of a biologics license application (BLA).
- Within one (1) week of submission to CBER, the Contractor shall provide a copy of the Biologics License Application (BLA) to the Contracting Officer.*

* Note, this contract will not fund costs associated with the Prescription Drug User Fee Act (PDUFA) for submittal of the BLA to CBER

Following the Project Officer's acceptance of the Contractor Defined Milestones, the Contracting Officer may modify this contract to incorporate the Contractor Defined Milestones along with a current version of the Work Breakdown Structure (WBS) and Gantt Chart. Reporting of these activities will be required on a monthly basis as a part of the contractor's monthly technical report.

Milestone 6: Within two (2) months of completion of last acceptable consistency/ validation lot in the new bulk facility, the Contractor shall submit to HHS for review and acceptance, a comprehensive, integrated **Final Technical Closeout Report**. The following items shall be addressed, in detail, via this report:

1. Equipment qualification/validation summary with supporting documentation (this includes, but is not limited to, stand alone/ off-the-shelf equipment, custom built process skids, qualified utility/HVAC systems, validated automation systems).

2. Process qualification/validation summary with supporting documentation referring to the manufacture of both engineering/demonstration lots and consistency/validation lots.

3. Proposed process schedule for the sequential manufacture of four (4) seasonal bulk vaccine lots. The schedule shall include a table that specifies all the raw materials necessary to manufacture the bulk, perform the necessary release testing, formulate the bulk, and complete all filling and packaging activities.

4. Accelerated proposed process schedule for the sequential manufacture of four (4) pandemic bulk vaccine lots to include change-over from seasonal manufacturing. Schedule shall include all steps required to reach final filled product.

5. Detailed production schedule for master and working viral seed production (seasonal or pandemic).

6. A table outlining the cost of all raw materials (including disposables), labor, overhead and depreciation for a bulk lot of vaccine.

7. A table outlining the cost of raw materials (including disposables), labor, overhead and depreciation for the formulation and filling for a finished lot of vaccine [adjusted for 15μg/dose].

8. A table outlining the cost of raw materials (including disposables), labor, overhead and depreciation for a bulk lot of adjuvant (if applicable).

9. A table outlining the cost of raw materials (including disposables), labor, overhead and depreciation for the formulation and filling for a finished lot of adjuvant (if applicable).

10. **Maintaining Facility Operation Plan**: This plan shall demonstrate a commitment from the Contractor to manufacture and release at least one (1) lot of vaccine product per year post-licensure of the facility in order to maintain cGMP compliance and licensure to produce sufficient doses of the vaccine depending on Federal regulatory guidelines. Any pandemic and/or pre-pandemic vaccines, as defined by the U.S. Government (USG), that result from potential future contracted production activities shall be delivered to a USG-designated site. The Contractor shall incorporate this requirement into their work plan and timeline and include an updated cost breakdown per dose.

Pandemic Preparedness

Upon declaration of a pandemic by the Secretary of HHS or the President, the Contractor shall provide to the U.S. Government 150 million finished doses of the targeted pandemic vaccine strain within six months. The pricing of those doses will be negotiated based upon, and will not exceed, the unit price calculated from the cost plus fixed fee of doses under the last executed Option Period. Any pandemic vaccine doses manufactured in excess of the original 150 million doses shall be offered to the U.S. Government for purchased based on the same or lower pricing. The U.S. Government reserves the right to direct the disposition of those doses if they are not purchased directly by the U.S. Government.

Emerging Infectious Diseases

The USG reserves the right to direct the Contractor to manufacture a vaccine candidate for an emergining infectious disease to address a public health emergency. If modification of the facility to manufacture the new vaccine candidate is required, then the cost-sharing of those modification will be negotiated with the Contractor.

Surveillance and Monitoring / Maintain Manufacturing Standards: The USG reserves the right to inspect the Offeror's facilities for cGMP compliance. HHS will audit manufacturing, testing and other relevant activities and sites as part of the overall surveillance and monitoring of contractor progress. Focus areas will include manufacturing, quality systems and regulatory affairs relative to the contract milestone activities within six (6) months of contract award. Any deficiencies observed in the audit will require remediation. Within three (3) months, a time-plan for remediation must be in place and remediation shall be complete within twelve (12) months of award unless otherwise extended in the sole discretion of the Contracting Officer. These on-site audits will supplement the HHS detailed review of technical progress reports and milestone deliverables to monitor progress against the contract and overall contractor performance. Furthermore, any official notices or reports that reference or result from a Federal, State, or local agency inspection or audit of the Contractor's facility(s) shall be provided to the Contracting Officer within two (2) business days of receipt by the Contractor.

Meetings and Conferences: The Contractor shall participate in regular meetings to coordinate and oversee the contract effort as directed by the Project Officer. Such meetings may include, but are not limited to, meetings of all contractors/ subcontractors to discuss progress of the program, meetings with individual

contractors and other HHS officials to discuss the technical, regulatory and ethical aspects of the program, and meetings with technical consultants to discuss technical data provided by the Contractor. Monthly teleconferences between the Contractor/ key subcontractors and HHS officials shall be held at times and dates to be determined to review technical progress, except during engineering and validation lot manufacturing when meetings shall be held on a weekly basis.

SECTION D--PACKAGING, MARKING AND SHIPPING

D.1. SHIPPING

I. Method of Delivery

Unless otherwise specified by the Contracting Officer or the Contracting Officer's representative, delivery of items, to be furnished to the Government under this contract (including invoices), shall be made by the United States Postal Service mail delivery, overnight mail delivery or courier service.

For delivery of the vaccine lots under Milestone 6 and optional CLIN 0008, the Contracting Officer or the Contracting Officer's Technical Representative (COTR) will provide delivery instructions prior to the delivery date.

II. Addressees – For all contract deliverables.

[To be completed at contract award]

SECTION E--INSPECTION AND ACCEPTANCE

The Contracting Officer or a duly authorized representative (who for purposes of this contract will be the Project Officer) will inspect and accept materials and services to be delivered under the contract.

FAR 52.252-2 CONTRACT CLAUSES INCORPORATED BY REFERENCE (Feb 1998)

This contract incorporates one or more solicitation clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

http:// www.acquisition.gov or http://www.hhs.gov/oamp/policies/ or http://www.gpoaccess.gov/cfr/index.html

FAR CLAUSE	TITLE	DATE
52.246-03	Inspection of Supplies – Cost Reimbursement	MAY 2001
52.246-12	Inspection of Construction	AUG 1996
52.246-15	Certificate of Conformance	APR 1984

SECTION F--DELIVERIES OR PERFORMANCE

F.1. PERIOD OF PERFORMANCE

Base Period:

The period of performance for contract line item numbers (CLINs) 0001 through 0007 of this contract is from the date of contract award to sixty (60) months after contract award. Each option, if exercised will extend the contract for an additional 12 month period. Each option will be exercised in accordance with FAR Clause 52.217-09 entitled "Option to Extend the Term of the Contract (MAR 2000). "

Option Periods:

ITEM No.	PERIOD	PERFORMANCE PERIOD
0008A	Option Year 1	Sixty (60) months and one day after the effective date of contract through seventy-two (72) months after the effective date of contract.
0008B	Option Year 2	Seventy-two (72) months and one day after the effective date of contract through eighty-four (84) months after the effective date of contract.
0008C	Option Year 3	Eighty-four (84) months and one day after the effective date of contract through ninety-six (96) months after the effective date of contract.
0008D	Option Year 4	Ninety-six (96) months and one day after the effective date of contract through one-hundred eight (108) months after the effective date of contract.
0008E	Option Year 5	One-hundred eight (108) months and one day after the effective date of contract through one-hundred twenty (120) months after the effective date of contract.
0008F	Option Year 6	One-hundred twenty (120) months and one day after the effective date of contract through one-hundred thirty-two (132) months after the effective date of contract.
0008G	Option Year 7	One-hundred thirty-two (132) months and one day after the effective date of contract through one-hundred forty-four (144) months after the effective date of contract.
0008H	Option Year 8	One-hundred forty-four (144) months and one day after the effective date of contract through one-hundred fifty-six (156) months after the effective date of contract.
0008I	Option Year 9	One-hundred fifty-six (156) months and one day after the effective date of contract through one-hundred sixty-eight (168) months after the effective date of contract.
0008J	Option Year 10	One-hundred sixty-eight (168) months and one day after the effective date of contract through one-hundred eighty (180) months after the effective date of contract.
0008K	Option Year 11	One-hundred eighty (180) months and one day after the effective date of contract through one-hundred ninety-two (192) months after the effective date of contract.
0008L	Option Year 12	One-hundred ninety-two (192) months and one day after the effective date of contract through two-hundred four (204) months after the effective date of contract.
0008M	Option Year 13	Two-hundred four (204) months and one day after the effective date of contract through two-hundred sixteen (216) months after the effective date of contract.
0008N	Option Year 14	Two-hundred sixteen (216) months and one day after the effective date of contract through two-hundred twenty-eight (228) months after the effective date of contract.
0008O	Option Year 15	Two-hundred twenty-eight (228) months and one day after the effective date of contract through two-hundred forty (240) months after the effective date of contract.
0008P	Option Year 16	Two-hundred forty (240) months and one day after the effective date of contract through two-hundred fifty-two (252) months after the effective date of contract.
0008Q	Option Year 17	Two-hundred fifty-two (252) months and one day after the effective date of contract through two-hundred sixty-four (264) months after the effective date of contract.
0008R	Option Year 18	Two-hundred sixty-four (264) months and one day after the effective date of contract through two-hundred seventy-six (276) months after the effective date of contract.
0008S	Option Year 19	Two-hundred seventy-six (276) months and one day after the effective date of contract through two-hundred eighty-eight (288) months after the effective date of contract.

0008T	Option Year 20	Two-hundred eighty-eight (288) months and one day after the effective date of contract through three-hundred (300) months after the effective date of contract.

F.2. Technical Report Distribution

CLIN	Deliverable	Quantity	Due Date
0006	**Final Technical Closeout Report** (Milestone 6)	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – Sent to C.O. and P.O.	Within two (2) months of completion of last acceptable consistency/ validation lot in the new bulk facility.
0007	**Technical Progress Report** (12 of each per year)	1 Electronic Copy – Sent to C.O. and P.O.	The initial Technical Progress Report due on/before _____; thereafter, due on/before the 15th of the month or milestone following each reporting period. *NOTE:* A Technical Progress Report is not due when the Final Technical Closeout Report is due.
0007	**Executive Summary** (12 of each per year)	1 Electronic Copy – Sent to C.O. and P.O.	The initial Executive Summary due on/before _____; thereafter, due on/before the 15th of the month or milestone following each reporting period. *NOTE:* An Executive Summary is not due when the Final Technical Closeout Report is due.
0008A	**Manufacturing Summary Report - Option Year 1**	Original – C.O. Copy – P.O. 1 Electronic Copy – Sent to C.O. and P.O.	Within six (6) weeks of completion of the manufacture of the lot for HHS, a written report summarizing the campaign, cost of goods, and release documents must be submitted.
0008B	**Manufacturing Summary Report - Option Year 2**	Original – C.O. Copy – P.O. 1 Electronic Copy – Sent to C.O. and P.O.	Within six (6) weeks of completion of the manufacture of the lot for HHS, a written report summarizing the campaign, cost of goods, and release documents must be submitted.
0008C	**Manufacturing Summary Report - Option Year 3**	Original – C.O. Copy – P.O. 1 Electronic Copy – Sent to C.O. and P.O.	Within six (6) weeks of completion of the manufacture of the lot for HHS, a written report summarizing the campaign, cost of goods, and release documents must be submitted.
0008D	**Manufacturing Summary Report - Option Year 4**	Original – C.O. Copy – P.O. 1 Electronic Copy – Sent to C.O. and P.O.	Within six (6) weeks of completion of the manufacture of the lot for HHS, a written report summarizing the campaign, cost of goods, and release documents must be submitted.
0008E	**Manufacturing Summary Report - Option Year 5**	Original – C.O. Copy – P.O. 1 Electronic Copy – Sent to C.O. and P.O.	Within six (6) weeks of completion of the manufacture of the lot for HHS, a written report summarizing the campaign, cost of goods, and release documents must be submitted.
0008F	**Manufacturing Summary Report - Option Year 6**	Original – C.O. Copy – P.O. 1 Electronic Copy – Sent to C.O. and P.O.	Within six (6) weeks of completion of the manufacture of the lot for HHS, a written report summarizing the campaign, cost of goods, and release documents must be submitted.
0008G	**Manufacturing Summary Report - Option Year 7**	Original – C.O. Copy – P.O. 1 Electronic Copy – Sent to C.O. and P.O.	Within six (6) weeks of completion of the manufacture of the lot for HHS, a written report summarizing the campaign, cost of goods, and release documents must be submitted.
0008H	**Manufacturing Summary Report - Option Year 8**	Original – C.O. Copy – P.O. 1 Electronic Copy – Sent to C.O. and P.O.	Within six (6) weeks of completion of the manufacture of the lot for HHS, a written report summarizing the campaign, cost of goods, and release documents must be submitted.
0008I	**Manufacturing Summary Report - Option Year 9**	Original – C.O. Copy – P.O. 1 Electronic Copy – Sent to C.O. and P.O.	Within six (6) weeks of completion of the manufacture of the lot for HHS, a written report summarizing the campaign, cost of goods, and release documents must be submitted.

0008J	**Manufacturing Summary Report - Option Year 10**	Original – C.O. Copy – P.O. 1 Electronic Copy – Sent to C.O. and P.O.	Within six (6) weeks of completion of the manufacture of the lot for HHS, a written report summarizing the campaign, cost of goods, and release documents must be submitted.
0008K	**Manufacturing Summary Report - Option Year 11**	Original – C.O. Copy – P.O. 1 Electronic Copy – Sent to C.O. and P.O.	Within six (6) weeks of completion of the manufacture of the lot for HHS, a written report summarizing the campaign, cost of goods, and release documents must be submitted.
0008L	**Manufacturing Summary Report - Option Year 12**	Original – C.O. Copy – P.O. 1 Electronic Copy – Sent to C.O. and P.O.	Within six (6) weeks of completion of the manufacture of the lot for HHS, a written report summarizing the campaign, cost of goods, and release documents must be submitted.
0008M	**Manufacturing Summary Report - Option Year 13**	Original – C.O. Copy – P.O. 1 Electronic Copy – Sent to C.O. and P.O.	Within six (6) weeks of completion of the manufacture of the lot for HHS, a written report summarizing the campaign, cost of goods, and release documents must be submitted.
0008N	**Manufacturing Summary Report - Option Year 14**	Original – C.O. Copy – P.O. 1 Electronic Copy – Sent to C.O. and P.O.	Within six (6) weeks of completion of the manufacture of the lot for HHS, a written report summarizing the campaign, cost of goods, and release documents must be submitted.
0008O	**Manufacturing Summary Report - Option Year 15**	Original – C.O. Copy – P.O. 1 Electronic Copy – Sent to C.O. and P.O.	Within six (6) weeks of completion of the manufacture of the lot for HHS, a written report summarizing the campaign, cost of goods, and release documents must be submitted.
0008P	**Manufacturing Summary Report - Option Year 16**	Original – C.O. Copy – P.O. 1 Electronic Copy – Sent to C.O. and P.O.	Within six (6) weeks of completion of the manufacture of the lot for HHS, a written report summarizing the campaign, cost of goods, and release documents must be submitted.
0008Q	**Manufacturing Summary Report - Option Year 17**	Original – C.O. Copy – P.O. 1 Electronic Copy – Sent to C.O. and P.O.	Within six (6) weeks of completion of the manufacture of the lot for HHS, a written report summarizing the campaign, cost of goods, and release documents must be submitted.
0008R	**Manufacturing Summary Report - Option Year 18**	Original – C.O. Copy – P.O. 1 Electronic Copy – Sent to C.O. and P.O.	Within six (6) weeks of completion of the manufacture of the lot for HHS, a written report summarizing the campaign, cost of goods, and release documents must be submitted.
0008S	**Manufacturing Summary Report - Option Year 19**	Original – C.O. Copy – P.O. 1 Electronic Copy – Sent to C.O. and P.O.	Within six (6) weeks of completion of the manufacture of the lot for HHS, a written report summarizing the campaign, cost of goods, and release documents must be submitted.
0008T	**Manufacturing Summary Report - Option Year 20**	Original – C.O. Copy – P.O. 1 Electronic Copy – Sent to C.O. and P.O.	Within six (6) weeks of completion of the manufacture of the lot for HHS, a written report summarizing the campaign, cost of goods, and release documents must be submitted.

F.3. OTHER CONTRACT DELIVERABLES:

CLIN	Deliverable	Quantity	Due Date
0001	**Overall Project Plan** (Milestone 1)	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – Sent to C.O .and P.O.	Within one (1) month after contract award.

0002	**Regulatory and Clinical Bridging Study Plan** (Milestone 2)	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – Sent to C.O. and P.O.	Within three (3) months after contract award.
0003	**Facility Operation Feasibility Plan** (Milestone 3)	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – Sent to C.O. and P.O.	Within six (6) months after contract award.
0004	**Detailed Manufacturing Facility Plan** (Milestone 4)	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – Sent to C.O. and P.O.	Within eight (8) months after contract award.
0005a	**Contactor Defined Milestones** (Milestone 5a – Seasonal Influenza Vaccine Program)	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – Sent to C.O. and P.O.	Within nine (9) months after contract award.
0005b	**Contactor Defined Milestones** (Milestone 5b – Pandemic Influenza Vaccine Program)	Original – C.O. 2 Copies – P.O. 1 Electronic Copy – Sent to C.O. and P.O.	Within nine (9) months after contract award.

F.4 PLACE AND METHOD OF DELIVERY

(a) Delivery of contract deliverables specified in F.2 and F.3 above shall be F.O.B. destination, within consignee's premises.

(b) Unless otherwise specified, deliveries shall be Monday through Friday (excluding Federal Holidays) between the hours of 8:30 a.m. and 5:00 p.m. EST only. Contract deliverables scheduled for delivery on a Federal holiday shall be made the following business day.

(c) Deliveries shall be made to the address specified in Section D.1.II.

F.5 FAR 52.252-2 CONTRACT CLAUSES INCORPORATED BY REFERENCE (Feb 1998)

This contract incorporates one or more solicitation clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

http:// **www.acquisition.gov** or http://www.hhs.gov/oamp/policies/ or http://www.gpoaccess.gov/cfr/index.html

FAR CLAUSE	TITLE	DATE
52.242-15	Stop Work Order	AUG 1989
52.242-15	Stop Work Order Alternate I	AUG 1984
52.247-35	F.O.B. Destination, Within Consignee's Premises	APR 1984

SECTION G.--CONTRACT ADMINISTRATION DATA

G.1. CONTRACTING OFFICER

1) 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.

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

3) 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.

G.2. PROJECT OFFICER

The Government's Project Officer(s) will be:

[To be completed at contract award]

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

G.3. KEY PERSONNEL

Contractor personnel considered by the Government to be essential to contract performance will be identified here. The Contracting Officer must be notified prior to replacing any of these individuals on the contract:

NAME **TITLE**

[To be completed at contract award]

G. 4. INVOICE SUBMISSION

Billing instructions are attached and made part of this contract. The Contractor shall follow the attached "Guide for Preparing Vouchers Under Cost-Reimbursement Type Contracts" to meet the requirements of a "proper invoice" pursuant to FAR Subpart 32.9, Prompt Payment. Invoices should be submitted to the following designated billing address:

[To be completed at contract award]

G. 5. INDIRECT COST RATES

Profit making and non-profit organizations will negotiate provisional and/or final indirect cost rates with their cognizant Government Agency.

Indirect cost rate ceilings are hereby established on indirect costs reimbursable under this contract. The Government shall not be obligated to pay the Contractor any additional amount in excess of the ceiling rates listed below:

[To be completed at contract award]

G. 6. POST AWARD EVALUATION OF PAST PERFORMANCE

Interim and final evaluations of contractor performance shall be conducted on this contract in accordance with FAR 42.15. The final performance evaluation shall be completed at the time of completion of work. Interim and final evaluations will be submitted to the Contractor as soon as practicable. The Contractor will be permitted thirty days to review the document and to submit additional information or a rebutting statement.

SECTION H--SPECIAL CONTRACT REQUIREMENTS

H. 1. SUBCONTRACTING PROVISIONS

(a) Small Business Subcontracting Plan

The Small, Small Disadvantaged and Women Owned Small Business Subcontracting Plan, dated _____ is attached hereto and made a part of this contract.

The failure of any Contractor or subcontractor to comply in good faith with FAR Clause 52.219-8 entitled "Utilization of Small Business Concerns" incorporated in this contract and the attached Subcontracting Plan will be a material breach of such contract or subcontract and subject to the remedies reserved to the Government under FAR Clause 52.219-16 entitled, "LIQUIDATED DAMAGES--SUBCONTRACTING PLAN."

H. 2. 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, than 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 approval or compliance, financing and capital raising activities, or mergers, acquisitions, or other business transactions.

H. 3. 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 (DHHS). DHHS reserves the right to review any other data determined by DHHS 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. 4. EPA ENERGY STAR REQUIREMENTS

In compliance with Executive Order 12845 (requiring Agencies to purchase energy efficient computer equipment) all microcomputers, including personal computers, monitors, and printers that are purchased using Government funds in performance of a contract shall be equipped with or meet the energy efficient low-power standby feature as defined by the EPA Energy Star program unless the equipment always meets EPA Energy Star efficiency levels. The microcomputer, as configured with all components, must be Energy Star compliant.

This low-power feature must already be activated when the computer equipment is delivered to the agency and be of equivalent functionality of similar power managed models. If the equipment will be used on a local area network, the vendor must provide equipment that is fully compatible with the network environment. In addition, the equipment will run commercial off-the-shelf software both before and after recovery from its energy conservation mode.

H. 5. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

Anyone who becomes aware of the existence or apparent existence of fraud, waste and abuse in DHHS 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 HHSTips@oig.hhs.gov.

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

H. 6. ACKNOWLEDGMENT OF FEDERAL FUNDING

A. Section 507 of P.L. 110-161 mandates that contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. Contractors are required to state (1) the percentage and dollar amounts of the total program or project costs financed with Federal money, and (2) the percentage and dollar amount of the total costs financed by nongovernmental sources.

This requirement is in addition to the continuing requirement to provide an acknowledgment of support and disclaimer on any publication reporting the results of a contract funded activity.

B. Publication and Publicity

The Contractor shall acknowledge the support of the Department of Health and Human Service, Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. *[insert #]*"

H. 7. NEEDLE EXCHANGE

Pursuant to Section 505 of Public Law 110-161, contract funds shall not be used to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug. Section 505, however, is subject to the condition stated in Section 506. Specifically, Section 506 states that after March 31, 1998, a program for exchanging needles and syringes for used hypodermic needles and syringes may be carried out in a community if: (1) the Secretary of Health and Human Services determines that exchange projects are effective in preventing the spread of HIV and do not encourage the use of illegal drugs; and (2) the project is operated in accordance with criteria established by the Secretary for preventing the spread of HIV and for ensuring that the project does not encourage the use of illegal drugs.

H. 8. 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 provisions 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. 9. MANUFACTURING STANDARDS

The Current Good Manufacturing Practice requirement (CGMP) of the Federal Food, Drug and Cosmetic Act (FDCA section 501(a)(2)(B); the CGMP regulations for finished pharmaceuticals (21 CFR Parts 210-211); and applicable regulations governing biological products (21 CFR Parts 600-610) will be the standards to be applied for manufacturing, processing and packing of this vaccine product.

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

H. 10. ANTI-LOBBYING PROVISIONS

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 32, United States 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.

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 and State or Local legislature.

H. 11. POSSESSION, USE AND TRANSFER OF SELECTED BIOLOGICAL AGENTS OR TOXINS

The following notice is applicable when contract performance is expected to involve possession, use and/or transfer of select biological agents or toxins: Notice to Offerors of Requirements of: 42 CFR Part 73, Select Agents and Toxins (relating to public health and safety); Agricultural Bioterrorism Protection Act of 2002, which consists of 7 CFR Part 331, Possession, Use, and Transfer of Biological Agents and Toxins (relating to plant health or plant products); and 9 CFR Part 121, Possession, Use, and Transfer of Biological Agents and Toxins (relating to human and animal health, animal health or animal products) - December 13, 2002
For prime or subcontract awards to domestic institutions who possess, use, and/or transfer Select Agents under this contract, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before using DHHS funds for research involving Select Agents. No DHHS funds can be used for research involving Select Agents if the final registration certificate is denied. For prime or subcontract awards to foreign institutions who possess, use, and/or transfer Select Agents under this contract, the institution must provide information satisfactory to the DHHS that a process equivalent to that described in 42 CFR 73 (http://www.cdc.gov/od/sap/docs/42cfr73.pdf) for U.S. institutions is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. In the technical proposal, the offeror must include details about the select agent and the quantity proposed to be used during contract performance. When requested by the contracting officer during negotiations, potential awardees must provide information addressing the following key elements for the foreign institutions: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations and policies equivalent to

42 CFR 73. An NIAID-chaired committee of U.S. federal employees (including representatives of DHHS grants/contracts and scientific program management, CDC, Department of Justice and other federal intelligence agencies, and Department of State) will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. Toward this end, when requested during negotiations, potential awardees will be asked to provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes concise summaries of safety, security, and training plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, foreign institutions must provide the names of all individuals who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals have access to Select Agents under the resulting contract. If the proposed contract work will not involve Select Agents, the offeror must include a statement in their technical proposal that the proposed work does not now nor will it in the future (i.e. throughout the life of the award) involve Select Agents. Listings of HHS Select Agents and Toxins, biologic agents and toxins, and Overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program.

H.12. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

Pursuant to the current HHS annual appropriations act, the Contractor shall not use contract funds to employ workers described in section274A(h)(3) of the Immigration and Nationality Act, which reads as follows:"(3) Definition of unauthorized alien.-As used in this section, the term 'unauthorized alien' means, with respect to the employment of an alien at a particular time, that the alien is not at that time either (A) an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General.

H.13. HUMAN SUBJECTS

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

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

H.14. 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 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.15. HUMAN MATERIALS

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

H.16. 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 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.

5. 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.17. 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.18. APPROVAL OF REQUIRED ASSURANCE BY OLAW

Under governing regulations, federal funds which are administered by the HHS, 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 2.25-2.28 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 2.25-2.28 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 2.25-2.28. Additional information regarding OLAW may be obtained via the Internet at http://grants2.nih.gov/grants/olaw/olawaddr.htm.

H.19. 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. 20. EARNED VALUE MANAGEMENT SYSTEM (52.234-4) (Jul 2006)

(a) The Contractor shall use an earned value management system (EVMS) that has been determined by the Cognizant Federal Agency (CFA) to be compliant with the guidelines in ANSI/EIA Standard - 748 (current version at the time of award) to manage this contract. If the Contractor's current EVMS has not been determined compliant at the time of award, see paragraph (b) of this clause. The Contractor shall submit reports in accordance with the requirements of this contract.

(b) If, at the time of award, the Contractor's EVM System has not been determined by the CFA as complying with EVMS guidelines or the Contractor does not have an existing cost/schedule control system that is compliant with the guidelines in ANSI/EIA Standard - 748 (current version at time of award), the Contractor shall—

(1) Apply the current system to the contract; and

(2) Take necessary actions to meet the milestones in the Contractor's EVMS plan approved by the Contracting Officer.

(c) The Government will conduct an Integrated Baseline Review (IBR). If a pre-award IBR has not been conducted, a post award IBR shall be conducted as early as practicable after contract award.

(d) The Contracting Officer may require an IBR at—

(1) Exercise of significant options; or

(2) Incorporation of major modifications.

(e) Unless a waiver is granted by the CFA, Contractor proposed EVMS changes require approval of the CFA prior to implementation. The CFA will advise the Contractor of the acceptability of such changes within 30 calendar days after receipt of the notice of proposed changes from the Contractor. If the advance approval requirements are waived by the CFA, the Contractor shall disclose EVMS changes to the CFA at least 14 calendar days prior to the effective date of implementation.

(f) The Contractor shall provide access to all pertinent records and data requested by the Contracting Officer or a duly authorized representative as necessary to permit Government surveillance to ensure that the EVMS conforms, and continues to conform, with the performance criteria referenced in paragraph (a) of this clause.

(g) The Contractor shall require the subcontractors specified below to comply with the requirements of this clause:

[*Insert list of applicable subcontractors.*]

_____

_____

_____

_____

PART II – CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

I.1 SECTION I – FAR 52.252-2 CONTRACT CLAUSES INCORPORATED BY REFERENCE (FEB 1998)

This contract incorporates one or more solicitation clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

http:// www.acquisition.gov or http://www.hhs.gov/oamp/policies/ or http://www.gpoaccess.gov/cfr/index.html

I.2. GENERAL CLAUSES

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

FAR CLAUSE NO.	DATE	TITLE
52.202-1	Jul 2004	Definitions (Over $100,000)
52.203-3	Apr 1984	Gratuities (Over $100,000)
52.203-5	Apr 1984	Covenant Against Contingent Fees (Over $100,000)
52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government (Over $100,000)
52.203-7	Sep 2006	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	Sep 2007	Limitation on Payments to Influence Certain Federal Transactions (Over $100,000)
52.203-13	Dec 2007	Contractor Code of Business Ethics and Conduct (Over 5,000,000)
52.203-14	Dec 2007	Display of Hotline Posters (Over 5,000,000)
52.204-4	Aug 2000	Printed or Copied Double-Sided on Recycled Paper (Over $100,000)
52.204-7	Apr 2008	Central Contractor Registration
52.204-10	Sep 2007	Reporting Subcontract Awards (Over 500,000,000)
52.207-5	Feb 1995	Option to Purchase Equipment

52.209-6	Sep 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
52.215-11	Oct 1997	Price Reduction for Defective Cost or Pricing Data - Modifications
52.215-13	Oct 1997	Subcontractor Cost or Pricing Data - Modifications
52.215-14	Oct 1997	Integrity of Unit Prices (Over $100,000)
52.215-15	Oct 2004	Pension Adjustments and Asset Reversions
52.215-18	Jul 2005	Reversion or Adjustment of Plans for Postretirement 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 (Alternate IV) (Oct 1997) [see Section J]
52.216-7	Dec 2002	Allowable Cost and Payment
52.216-8	Mar 1997	Fixed Fee
52.216-12	Apr 1984	Cost-Sharing Contract – No Fee
52.219-4	Jul 2005	Notice of Price Evaluation Preference for HUBZone Small Business Concerns
52.219-8	May 2004	Utilization of Small Business Concerns (Over $100,000)
52.219-9	Apr 2008	Small Business Subcontracting Plan (Over $500,000, $1,000,000 for Construction) (Alternate II) (Oct 2001)
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan (Over $500,000, $1,000,000 for Construction)
52.219-28	Jun 2007	Post-Award Small Business Program Representation (Over $100,000)
52.222-1	Feb 1997	Notice to the Government of Labor Disputes
52.222-2	Jul 1990	Payment for Overtime Premium (Over $100,000) (Note: The dollar amount in paragraph (a) of this clause is $0 unless otherwise specified in the contract.)
52.222-3	Jun 2003	Convict Labor
52.222-4	Jul 2005	Contract Work Hours and Safety Standards Act – Overtime Compensation

52.222-6	Jul 2005	Davis-Bacon Act
52.222-7	Feb 1988	Withholding of Funds
52.222-8	Feb 1988	Payrolls and Basic Records
52.222-9	Jul 2005	Apprentices and Trainees
52.222-10	Feb 1988	Compliance with Copeland Act Requirements
52.222-11	Jul 2005	Subcontracts (Labor Standards)
52.222-12	Feb 1988	Contract Termination-Debarment
52.222-13	Feb 1988	Compliance with Davis-Bacon and Related Act Regulations
52.222-14	Feb 1988	Disputes Concerning Labor Standards
52.222-15	Feb 1988	Certification of Eligibility
52.222-16	Feb 1988	Approval of Wage Rates (Over $2,000)
52.222-19	Feb 2008	Child Labor – Cooperation with Authorities and Remedies
52.222-20	Dec 1996	Walsh-Healy Public Contracts Act (Over $10,000)
52.222-21	Feb 1999	Prohibition of Segregated Facilities
52.222-26	Mar 2007	Equal Opportunity
52.222-27	Feb 1999	Affirmative Action Compliance Requirements for Construction
52.222-30	Dec 2001	Davis-Bacon Act-Price Adjustment (None or Separate Specified Pricing Method
52.222-35	Sep 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	Sep 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
52.223-2	Dec 2007	Affirmative Procurement of Biobased Products Under Service and Construction Contracts
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	Jun 2008	Restrictions on Certain Foreign Purchases
52.227-1	Dec 2007	Authorization and Consent
52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement (Over $100,000)

52.227-3	Apr 1984	Patent Indemnity
52.227-4	Dec 2007	Patent Indemnity – Construction Contracts
52.227-11	Dec 2007	Patent Rights - Ownership by the Contractor (Short Form) (Note: In accordance with FAR 27.303(a)(2), paragraph (f) is modified to include the requirements in FAR 27.303(a)(2)(i) through (iv). The frequency of reporting in (i) is annual.
52.227-14	Dec 2007	Rights in Data - General
52.228-1	Sep 1996	Bid Guarantee
52.228-11	Feb 1992	Pledge of Assets
52.228-12	Oct 1995	Prospective Subcontractor Requests for Bonds
52.228-14	Dec 1999	Irrevocable Letter of Credit
52.228-15	Nov 2006	Performance and Payment Bonds-Constructions (Over $100,000)
52.229-8	Mar 1990	Taxes – Foreign Cost Reimbursement Contracts
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, Alternate I (Feb 2002)
52.232-27	Sep 2005	Prompt Payment Act for Construction Contracts
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, Alternate I (Jun 1985)
52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
52.236-5	Apr 1984	Material and Workmanship
52.236-7	Nov 1991	Permits and Responsibilities
52.236-12	Apr 1984	Cleaning Up
52.236-13	Nov 1991	Accident Prevention
52.236-15	Apr 1984	Schedules for Construction Contracts
52.236-18	Apr 1984	Work Oversight in Cost-Reimbursement Construction Contracts
52.236-19	Apr 1984	Organization and Direction of the Work
52.236-22	Apr 1984	Design Within Funding Limitations
52.236-23	Oct 1995	Responsibility of the Architect-Engineer Contractor

52.236-24	Oct 1995	Work Oversight in Architect-Engineer Contracts
52.236-25	Jun 2003	Requirements for Registration of Designers
52.242-1	Apr 1984	Notice of Intent to Disallow Costs
52.242-3	May 2001	Penalties for Unallowable Costs (Over $500,000)
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy (Over $100,000)
52.243-2	Aug 1987	Changes—Cost Reimbursement
52.244-2	Jun 2007	Subcontracts, Alternate I (January 2006)
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
52.245-9	Jun 2007	Use and Charges
52.246-23	Feb 1997	Limitation of Liability (Over $100,000)
52.248-3	Sep 2006	Value Engineering - Construction
52.249-6	May 2004	Termination (Cost-Reimbursement) Alternate I (SEP 1996)
52.253-1	Jan 1991	Computer Generated Forms

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

HHSAR CLAUSE NO.	DATE	TITLE
352.202-1	Jan 2006	Definitions - with Alternate paragraph (h) (Jan 2001)
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	Apr 1984	Withholding of Contract Payments
352.233-70	Jan 2006	Litigation and Claims
352.242-71	Apr 1984	Final Decisions on Audit Findings
352-249-14	Jan 2006	Excusable Delays

352.270-5	Jan 2006	Key Personnel
352.270-6	Jan 2006	Publications and Publicity
352.270-7	Jan 2006	Paperwork Reduction Act
352.270-8	Jan 2001	Protection of Human Subjects
352.270-9	Jan 2006	Care of Live Vertebrate Animals
352.270-10	Jan 2006	Anti-Lobbying
352.333-7001	Undated	Choice of Law (Overseas)

I.3 Additional Contract Clauses of SECTION I – Added in full text

52.217-8 Option to Extend Services (Nov 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within _____ [*insert the period of time within which the Contracting Officer may exercise the option*].

52.217-9 Option to Extend the Term of the Contract (Mar 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within the period of performance; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least _____ days [*60 days unless a different number of days is inserted*] before the contract expires. The preliminary notice does not commit the Government to an extension.

(b) If the Government exercises this option, the extended contract shall be considered to include this option clause.

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed _____ (months) (years).

52.222-39 Notification of Employee Rights Concerning Payment of Union Dues or Fees (Dec 2007)

Notification of Employee Rights Concerning Payment of Union Dues or Fees

(a) Definition. As used in this clause—

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

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

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

Notice to Employees

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

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

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

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

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

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

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

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

(1) Contractors and subcontractors that employ fewer than 15 persons;
(2) Contractor establishments or construction work sites where no union has been formally recognized by the Contractor or certified as the exclusive bargaining representative of the Contractor's employees;

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

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

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

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

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

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

(1) Obtain the required employee notice poster from the Division of Interpretations and Standards, Office of Labor-Management Standards, U.S. Department of Labor, 200 Constitution Avenue, NW, Room N-5605, Washington, DC 20210, or from any field office of the Department's Office of Labor-Management Standards or Office of Federal Contract Compliance Programs;

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

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

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

52.225-11 Buy American Act—Construction Materials under Trade Agreements (Aug 2007)

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

"Caribbean Basin country construction material" means a construction material that—

(1) Is wholly the growth, product, or manufacture of a Caribbean Basin country; or

(2) In the case of a construction material that consists in whole or in part of materials from another country, has been substantially transformed in a Caribbean Basin country into a new and different construction material distinct from the materials from which it was transformed.

"Component" means an article, material, or supply incorporated directly into a construction material.

"Construction material" means an article, material, or supply brought to the construction site by the Contractor or subcontractor for incorporation into the building or work. The term also includes an item brought to the site preassembled from articles, materials, or supplies. However, emergency life safety systems, such as emergency lighting, fire alarm, and audio evacuation systems, that are discrete systems incorporated into a public building or work and that are produced as complete systems, are evaluated as a single and distinct construction material regardless of when or how the individual parts or components of those systems are delivered to the construction site. Materials purchased directly by the Government are supplies, not construction material.

"Cost of components" means—

(1) For components purchased by the Contractor, the acquisition cost, including transportation costs to the place of incorporation into the construction material (whether or not such costs are paid to a domestic firm), and any applicable duty (whether or not a duty-free entry certificate is issued); or

(2) For components manufactured by the Contractor, all costs associated with the manufacture of the component, including transportation costs as described in paragraph (1) of this definition, plus allocable overhead costs, but excluding profit. Cost of components does not include any costs associated with the manufacture of the construction material.

"Designated country" means any of the following countries:

(1) A World Trade Organization Government Procurement Agreement country (Aruba, Austria, Belgium, Bulgaria, Canada, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hong Kong, Hungary, Iceland, Ireland, Israel, Italy, Japan, Korea (Republic of), Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Singapore, Slovak Republic, Slovenia, Spain, Sweden, Switzerland, or United Kingdom);

(2) A Free Trade Agreement country (Australia, Bahrain, Canada, Chile, Dominican Republic, El Salvador, Guatemala, Honduras, Mexico, Morocco, Nicaragua, or Singapore);

(3) A least developed country (Afghanistan, Angola, Bangladesh, Benin, Bhutan, Burkina Faso, Burundi, Cambodia, Cape Verde, Central African Republic, Chad, Comoros, Democratic Republic of Congo, Djibouti, East Timor, Equatorial Guinea, Eritrea, Ethiopia, Gambia, Guinea, Guinea-Bissau, Haiti, Kiribati, Laos, Lesotho, Madagascar, Malawi, Maldives, Mali, Mauritania, Mozambique, Nepal, Niger, Rwanda, Samoa, Sao Tome and Principe, Senegal, Sierra Leone, Solomon Islands, Somalia, Tanzania, Togo, Tuvalu, Uganda, Vanuatu, Yemen, or Zambia); or

(4) A Caribbean Basin country (Antigua and Barbuda, Aruba, Bahamas, Barbados, Belize, British Virgin Islands, Costa Rica, Dominica, Grenada, Guyana, Haiti, Jamaica, Montserrat, Netherlands Antilles, St. Kitts and Nevis, St. Lucia, St. Vincent and the Grenadines, or Trinidad and Tobago).

"Designated country construction material" means a construction material that is a WTO GPA country construction material, an FTA country construction material, a least developed country construction material, or a Caribbean Basin country construction material.

"Domestic construction material" means—

(1) An unmanufactured construction material mined or produced in the United States; or

(2) A construction material manufactured in the United States, if the cost of its components mined, produced, or manufactured in the United States exceeds 50 percent of the cost of all its components. Components of foreign origin of the same class or kind for which nonavailability determinations have been made are treated as domestic.

"Foreign construction material" means a construction material other than a domestic construction material.

"Free Trade Agreement country construction material" means a construction material that—

(1) Is wholly the growth, product, or manufacture of a Free Trade Agreement (FTA) country; or
(2) In the case of a construction material that consists in whole or in part of materials from another country, has been substantially transformed in a FTA country into a new and different construction material distinct from the materials from which it was transformed.

"Least developed country construction material" means a construction material that—

(1) Is wholly the growth, product, or manufacture of a least developed country; or

(2) In the case of a construction material that consists in whole or in part of materials from another country, has been substantially transformed in a least developed country into a new and different construction material distinct from the materials from which it was transformed.

"United States" means the 50 States, the District of Columbia, and outlying areas.

"WTO GPA country construction material" means a construction material that—

(1) Is wholly the growth, product, or manufacture of a WTO GPA country; or

(2) In the case of a construction material that consists in whole or in part of materials from another country, has been substantially transformed in a WTO GPA country into a new and different construction material distinct from the materials from which it was transformed.

(b) Construction materials.

(1) This clause implements the Buy American Act (41 U.S.C. 10a-10d) by providing a preference for domestic construction material. In addition, the Contracting Officer has determined that the WTO GPA and Free Trade Agreements (FTAs) apply to this acquisition. Therefore, the Buy American Act restrictions are waived for designated country construction materials.

(2) The Contractor shall use only domestic or designated country construction material in performing this contract, except as provided in paragraphs (b)(3) and (b)(4) of this clause.

(3) The requirement in paragraph (b)(2) of this clause does not apply to the construction materials or components listed by the Government as follows:

_____

[*Contracting Officer to list applicable excepted materials or indicate "none"*]

(4) The Contracting Officer may add other foreign construction material to the list in paragraph (b)(3) of this clause if the Government determines that—

(i) The cost of domestic construction material would be unreasonable. The cost of a particular domestic construction material subject to the restrictions of the Buy American Act is unreasonable when the cost of such material exceeds the cost of foreign material by more than 6 percent;

(ii) The application of the restriction of the Buy American Act to a particular construction material would be impracticable or inconsistent with the public interest; or

(iii) The construction material is not mined, produced, or manufactured in the United States in sufficient and reasonably available commercial quantities of a satisfactory quality.

(c) Request for determination of inapplicability of the Buy American Act.

(1)(i) Any Contractor request to use foreign construction material in accordance with paragraph (b)(4) of this clause shall include adequate information for Government evaluation of the request, including—

(A) A description of the foreign and domestic construction materials;
(B) Unit of measure;
(C) Quantity;
(D) Price;
(E) Time of delivery or availability;

(F) Location of the construction project;
(G) Name and address of the proposed supplier; and
(H) A detailed justification of the reason for use of foreign construction materials cited in accordance with paragraph (b)(3) of this clause.

(ii) A request based on unreasonable cost shall include a reasonable survey of the market and a completed price comparison table in the format in paragraph (d) of this clause.

(iii) The price of construction material shall include all delivery costs to the construction site and any applicable duty (whether or not a duty-free certificate may be issued).

(iv) Any Contractor request for a determination submitted after contract award shall explain why the Contractor could not reasonably foresee the need for such determination and could not have requested the determination before contract award. If the Contractor does not submit a satisfactory explanation, the Contracting Officer need not make a determination.

(2) If the Government determines after contract award that an exception to the Buy American Act applies and the Contracting Officer and the Contractor negotiate adequate consideration, the Contracting Officer will modify the contract to allow use of the foreign construction material. However, when the basis for the exception is the unreasonable price of a domestic construction material, adequate consideration is not less than the differential established in paragraph (b)(4)(i) of this clause.

(3) Unless the Government determines that an exception to the Buy American Act applies, use of foreign construction material is noncompliant with the Buy American Act.

(d) *Data.* To permit evaluation of requests under paragraph (c) of this clause based on unreasonable cost, the Contractor shall include the following information and any applicable supporting data based on the survey of suppliers:

FOREIGN AND DOMESTIC CONSTRUCTION MATERIALS PRICE COMPARISON

Construction Material Description	**Unit of Measure**	**Quantity**	**Price (Dollars)***
Item 1:			
Foreign construction material	_____	_____	_____
Domestic construction material	_____	_____	_____
Item 2:			
Foreign construction material	_____	_____	_____
Domestic construction material	_____	_____	_____

[*List name, address, telephone number, and contact for suppliers surveyed. Attach copy of response; if oral, attach summary.*]

[*Include other applicable supporting information.*]
[* *Include all delivery costs to the construction site and any applicable duty (whether or not a duty-free entry certificate is issued).*]

(End of clause)

Alternate I (Aug 2007). Add the following definition of "Bahrainian or Mexican construction material" to paragraph (a) of the basic clause, and substitute the following paragraphs (b)(1) and (b)(2) for paragraphs (b)(1) and (b)(2) of the basic clause:

"Bahrainian or Mexican construction material" means a construction material that—

(1) Is wholly the growth, product, or manufacture of Bahrain or Mexico; or

(2) In the case of a construction material that consists in whole or in part of materials from another country, has been substantially transformed in Bahrain or Mexico into a new and different construction material distinct from the materials from which it was transformed.

(b) *Construction materials.* (1) This clause implements the Buy American Act (41 U.S.C. 10a - 10d) by providing a preference for domestic construction material. In addition, the Contracting Officer has determined that the WTO GPA and all the Free Trade Agreements except NAFTA apply to this acquisition. Therefore, the Buy American Act restrictions are waived for designated country construction materials other than Bahrainian or Mexican construction materials.

(2) The Contractor shall use only domestic or designated country construction material other than Bahrainian or Mexican construction material in performing this contract, except as provided in paragraphs (b)(3) and (b)(4) of this clause.

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. PACKAGING AND DELIVERY OF PROPOSALS (Attachment 1)

2. PROPOSAL INTENT RESPONSE SHEET [SUBMIT ON/BEFORE: _____] (Attachment 2)

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

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

- **Technical Proposal Cover Sheet (Attachment 3)**
- **Technical Proposal Cost Information (Attachment 4)**
- **Summary of Related Activities (Attachment 5)**
- **Government Notice for Handling Proposals (Attachment 6)**
- **IRB Certification Form (Attachment 7)**

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

- **Proposal Summary and Data Record (Attachment 8)**
- **Breakdown of Proposed Estimated Cost (plus fee) and Labor Hours, proposed Subcontracts and all other items of costs (i.e., travel, materials and supplies, etc.) (Attachment 9)**
- **Offeror's Points of Contact (Attachment 10)**
- **Disclosure of Lobbying Activities, OMB Form LLL (Attachment 11)**
- **ACH Vendor/Miscellaneous Payment Enrollment Form (Attachment 14)**

5. **BILLING INSTRUCTIONS FOR COST REIMBURSEMENT CONTRACTS (Attachment 12)**

6. **PAST PERFORMANCE QUESTIONNAIRE (Attachment 13)**

Attachment 1

PACKAGING/DELIVERY/ELECTRONIC SUBMISSION OF THE PROPOSAL

Read all instructions on this page and in the RFP before mailing or submitting forms, proposals, or CDs.

Your proposal will have **two separate parts**.

- Business proposal
- Technical proposal

In addition, several other forms are required -- see the RFP and the table below for details.

You will submit your proposal in **two formats**: paper and CDs or USB Drives.

- **The paper proposal with original signatures is the official, legally binding copy. There are no acceptable substitutes.**
- The CD or USB memory stick versions of the proposal are for the benefit of BARDA. Electronic versions may or may not be used for review, at the discretion of BARDA.

As a potential offeror, you must routinely check the FedBizOpps for amendments because we do not notify you directly of changes.

Send your proposal to BARDA at the address shown below. If you have any questions, ask the primary or secondary BARDA contacts specified in the RFP.

Hand written proposals will not be accepted.

PAPER SUBMISSION: The paper copy is the official copy for recording timely receipt of proposals.

SUBMISSION OF PROPOSALS BY FACSIMILE IS NOT ACCEPTABLE

WARNING: You are advised to read and carefully follow the instructions listed in this RFP. Failure to adhere to these instructions and to the specified limitations for size of paper and electronic proposals may result in the rejection of your proposal. Proposals will not be returned to the Offeror.

NUMBER OF COPIES:

Document	Number of Copies	Page Limits	File Size
Technical Proposal	One (1) bound SIGNED ORIGINAL. Eleven (11) copies bound in three ring binders CDs or USB Drives	Not-to-exceed 50 Pages	Unlimited
Technical Proposal Appendices All materials shall be available electronically (i.e. SOPs, Pertinent Manuals, Figures or Data, and Letters of Collaboration/Intent).	One (1) bound SIGNED ORIGINAL. Eleven (11) copies bound in three ring binders . CDs or USB Drives	Not-to-exceed 500 pages	Unlimited
Business Proposal	One (1) bound SIGNED ORIGINAL. Eleven (11) bound copies. in three ring binders CDs or USB Drives	Not-to-exceed 250 pages	Unlimited

Representations and Certifications	Provide representations and certifications electronically via the BPN website (www.bpn.gov/orca)	N/A	N/A

TECHNICAL PROPOSAL PAGE LIMITS INCLUDE: The technical approach to be used by the Offeror(s) in order to implement the requirements stated in the Statement of Work. **TOTAL PAGE COUNT DOES NOT INCLUDE**: 1 Cover and Back Page; 1 Table of Contents; Section Dividers that do not contain information other than title of Section.
PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE PROVIDED TO THE REVIEWERS TO BE READ OR EVALUATED.

DELIVERIES BY United States Postal Service (USPS), DHL, FedEx, AND United Parcel Service (UPS) WILL BE TO THE FOLLOWING ADDRESS:

Attn:
Paquetta N. Myrick-Hancock
Contracting Officer
HHS/ASPR/BARDA
330 Independence Ave. SW, Rm G640
Washington, D.C. 20201
Phone: 202-260-0534

ALL OTHER COURIER DELIVERIES WILL BE MADE TO THE FOLLOWING ADDRESS. ALLOW 30 MINUTES FOR PROCESSING PACKAGES THROUGH SECURITY:

Hubert H. Humphrey Building
200 Independence Ave. SW Lobby
Washington, D.C. 20201

Marked for Attn:
Paquetta Myrick-Hancock
Contracting Officer
HHS/ASPR/BARDA
330 Independence Ave. SW, Rm G640
Washington, D.C. 20201
Phone: 202-260-0534

Attachment 2

PROPOSAL INTENT RESPONSE SHEET

RFP No.: RFP-HHS-BARDA-08-09
RFP Title: "Building Domestic Cell-based Influenza Vaccine Manufacturing Facilities

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

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

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

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

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

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

RETURN VIA FAX OR E-MAIL TO:
HHS/ASPR/BARDA
330 Independence Avenue
Room G640
Washington, D.C. 20201
Attn: Paquetta Myrick-Hancock
RFP-HHS-BARDA-08-09
FAX# (202) 260-0534
Email: Paquetta.Hancock@hhs.gov

Attachment 3

TECHNICAL PROPOSAL COVER SHEET

IN RESPONSE TO RFP-HHS-BARDA-08-09

TITLE: "Building Domestic Cell-based Influenza Vaccine Manufacturing Facilities"

OFFEROR (Primary organization/institution):

Name and Address:

PRINCIPAL INVESTIGATOR:

OFFEROR PERSONNEL Name (Last, First, Initial) and Degree(s)*

SUBCONTRACTOR ORGANIZATIONS (If more than one, list each organization and its personnel separately):

Name and Address:

PRINCIPAL INVESTIGATOR:

SUBCONTRACTOR PERSONNEL Name (Last, First, Initial) and Degree(s)*

COLLABORATORS or CONSULTANTS:

Name [Last, First, Initial) Degree(s)] Organization

* List all co-investigators/key personnel

Attachment 4

TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS (**Sample**)

COST SHARING LINE ITEMS ONLY

COST ELEMENT	Milestone Government Share (Period Covered)	Milestone Contractor Share (Period Covered)	Milestone Government Share (Period Covered)	Milestone Contractor Share (Period Covered)	Milestone Government Share (Period Covered)	Milestone Contractor Share (Period Covered)	TOTAL
Labor Category	(Hours)	(Hours)	(Hours)	(Hours)	(Hours)	(Hours)	(Hours)
DIRECT LABOR COST:	$		$	$	$	$	$
MATERIAL COST:	$		$	$	$	$	$
TRAVEL COST:	$		$	$	$	$	$
CONSULTANTS:	$		$	$	$	$	$
SUBCONTRACTS:	$		$	$	$	$	$
CLINICAL TRIAL/PATIENT CARE COSTS:	$		$	$	$	$	$
EQUIPMENT	$		$	$	$	$	$
OTHER DIRECT COSTS	$		$	$	$	$	$
OTHER (Specify)	$		$	$	$	$	$
TOTAL DIRECT COST:	$		$	$	$	$	$
TOTAL COST:	$		$	$	$	$	$
TOTAL DIRECT COST:	$		$	$	$	$	$

Specific Instructions:

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

TECHNICAL PROPOSAL COST INFORMATION/SUMMARY OF LABOR AND DIRECT COSTS (**Sample**)

COST PLUS FIXED FEE LINE ITEMS ONLY

COST ELEMENT	Milestone (Period Covered)	Milestone (Period Covered)	Milestone (Period Covered)	Milestone (Period Covered)	Milestone (Period Covered)	Milestone (Period Covered)	Total
DIRECT LABOR:							
Labor Category	(Hours)	(Hours)	(Hours)	(Hours)	(Hours)	(Hours)	Total
(Title and Name– use additional pages as necessary)							
DIRECT LABOR COST:	$	$	$	$		$	$
MATERIAL COST:	$	$	$	$		$	$
TRAVEL COST:	$	$	$	$		$	$
CONSULTANTS:	$	$	$	$		$	$
SUBCONTRACTS:	$	$	$	$		$	$
CLINICAL TRIAL/PATIENT CARE COSTS:	$	$	$	$		$	$
EQUIPMENT	$	$	$	$		$	$
OTHER DIRECT COSTS	$	$	$	$		$	$
OTHER (Specify)	$	$	$	$		$	$
TOTAL DIRECT COST:	$	$	$	$		$	$
TOTAL COST:	$	$	$	$		$	$
TOTAL DIRECT COST:	$	$	$	$		$	$

Specific Instructions:

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

Attachment 5

SUMMARY OF RELATED ACTIVITIES

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

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

Professional's Name and Title/Position:

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

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

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

Professional's Name and Title/Position:

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

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

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

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

Attachment 6

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

GOVERNMENT NOTICE FOR HANDLING PROPOSALS

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

(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 [[Page 4256]] 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.

IRB Certification Form

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

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

Institutions must have an assurance of compliance that applies to the research to be conducted and should submit certification of IRB review and approval with each application or proposal unless otherwise advised by the Department or Agency.

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

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

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

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

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

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

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

☐ This activity has been reviewed and approved by the IRB in accordance with the Common Rule and any other governing regulations. By: ☐ Full IRB Review on (date of IRB meeting) _____or ☐ Expedited Review on (date)
☐ If less than one year approval, provide expiration date _____
☐ This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by the Common Rule will be reviewed and approved before they are initiated and that appropriate further certification will be submitted.

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

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

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

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

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

DOES THIS PROPOSAL INVOLVE EXPERIMENTS WITH HUMAN SUBJECTS ☐ YES ☐ NO

Institution's General Assurance re: Human Subjects DATE APPROVED _____ ☐ PENDING
Institution's Review Board's Approval of this Proposal DATE APPROVED _____ ☐ PENDING

An example of the informed consent for this study is enclosed ☐ YES ☐ NO
A Clinical Protocol is enclosed ☐ YES ☐ NO

OFFEROR'S ACKNOWLEDGMENT OF AMENDMENTS TO THE RFP (Use attachment if necessary)			
ERRATA NUMBER	DATE	ERRATA NUMBER	DATE
NAME, ADDRESS, AND PHONE NUMBER OF COGNIZANT GOVERNMENT AUDIT AGENCY		NUMBER OF EMPLOYEES CURRENTLY EMPLOYED	
		DOLLAR VOLUME OF BUSINESS PER ANNUM	
		THIS OFFER EXPIRES _____ DAYS FROM THE DATE OF THIS OFFER (120 days if not specified)	

FOR THE INSTITUTION

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

Provision of the Social Security Number is voluntary. Authority for requesting this information is provided by Title III, Section 301, and Title IV of the Public Health Service Act, as amended.

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

INSTRUCTIONS FOR USE OF THE FORMAT

Proposals submitted under this RFP will require analyses of each element of cost proposed. Offeror(s) will be asked to submit supporting documentation to verify the accuracy of all proposed costs. Supporting documents will be required for labor rates, equipment, subcontracts, consultant costs, clinical trials costs, and any other significant category.

1. Refer to Business Proposal Instructions, Section L of this solicitation. The Instructions contain the requirements for proper submission of information other than cost/price data which must be adhered to.

2. This format has been prepared as a universal guideline for all solicitations issued by the BARDA. It may require amending to meet the specific requirements of this solicitation. For example, this solicitation may require the submission of cost/price data for three years listed on this form. (See Section L.1., General Information for the estimated duration of this project.) If this solicitation is phased, identify each phase in addition to each year. Total each year, phase, and sub-element.

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

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

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

   b. For all materials, supplies, equipment (including binding bids for all equipment greater than $5,000), and other direct costs, list all unit prices, etc., to detail how the calculations were made.
   c. For all indirect costs, list the rates applied and the base the rate is applied to.
   d. For all travel, list the specifics for each trip.
   e. **For any subcontract proposed, submit a separate breakdown format. This shall include cost support, full breakdown of all cost related to subcontracts, and all other internal costs.**
   f. Justification for the need of some cost elements may be listed as an attachment, i.e., special equipment, above average consultant fees, etc.

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

5. **It is requested that you use the ELECTRONIC SPREADSHEET that is provided below to prepare your business proposal in lieu of the hardcopy contained in this Attachment. It is in EXCEL format and has instructions for use and submission.**

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

   For security purposes, please include a hard copy of the completed spreadsheet and submit the electronic file with your proposal.

BREAKDOWN OF PROPOSED ESTIMATED COST AND LABOR HOURS (**Sample**)

COST ELEMENT	Milestone Government Share (Period Covered)	Milestone Contractor Share (Period Covered)	Milestone Government Share (Period Covered)	Milestone Contractor Share (Period Covered)	Milestone Government Share (Period Covered)	Milestone Contractor Share (Period Covered)	Total
DIRECT LABOR:							
Labor Category Rate	(Hours)	(Hours)	(Hours)	(Hours)	(Hours)	(Hours)	Total
(Title and Name– use additional pages as necessary)							
DIRECT LABOR COST:	$	$	$	$	$	$	$
MATERIAL COST:	$	$	$	$	$	$	$
TRAVEL COST:	$	$	$	$	$	$	$
CONSULTANTS:	$	$	$	$	$	$	$
SUBCONTRACTS:	$	$	$	$	$	$	$
CLINICAL TRIAL/PATIENT CARE COSTS:	$	$	$	$	$	$	$
EQUIPMENT	$	$	$	$	$	$	$
OTHER DIRECT COSTS	$	$	$	$	$	$	$
OTHER (Specify)	$	$	$	$	$	$	$
TOTAL DIRECT COST:	$	$	$	$	$	$	$
FRINGE BENEFIT COST: (if applicable) % of Direct Labor Cost	$	$	$	$	$	$	$
INDIRECT COST: % of Total Direct Cost	$	$	$	$	$	$	$
GRAND TOTAL ESTIMATED COST	$	$	$	$	$	$	$

COST SHARING LINE ITEMS ONLY

***The above breakdown shall be used for each milestone in the Statement of Work, including any proposed Offeror milestones (refer to milestone five (5) of the statement of work).**

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

COST ELEMENT	Milestone (Period Covered)	Milestone 2(Period Covered)	Milestone (Period Covered)	Milestone 4(Period Covered)	Milestone (Period Covered)	Milestone (Period Covered)	Total
DIRECT LABOR:							
Labor Category Rate	(Hours)	(Hours)	(Hours)	(Hours)	(Hours)	(Hours)	Total
(Title and Name– use additional pages as necessary)							
DIRECT LABOR COST:	$	$	$	$			$
MATERIAL COST:	$	$	$	$			$
TRAVEL COST:	$	$	$	$			$
CONSULTANTS:	$	$	$	$			$
SUBCONTRACTS:	$	$	$	$			$
CLINICAL TRIAL/PATIENT CARE COSTS:	$	$	$	$			$
EQUIPMENT	$	$	$	$			$
OTHER DIRECT COSTS	$	$	$	$			$
OTHER (Specify)	$	$	$	$			$
TOTAL DIRECT COST:	$	$	$	$			$
FRINGE BENEFIT COST: (if applicable) % of Direct Labor Cost	$	$	$	$			$
INDIRECT COST: % of Total Direct Cost	$	$	$	$			$
TOTAL COST:	$	$	$	$			$
FEE: % of Total Est. Cost (where applicable)	$	$	$	$			$
GRAND TOTAL ESTIMATED CPFF	$	$	$	$			$

COST PLUS FIXED FEE LINE ITEMS ONLY

***The above breakdown shall be used for each milestone in the Statement of Work, including any proposed Offeror milestones (refer to milestone five (5) of the statement of work).**

Attachment 10

OFFEROR'S POINTS OF CONTACT

Complete the following and return with the BUSINESS PROPOSAL.

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

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

Name, Institutional Title and Address of Proposed Principal Investigator

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

Subcontractor(s): Name, Institutional Title and Address of Proposed Principal Investigator

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

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

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

DISCLOSURE OF LOBBYING ACTIVITIES

Approved by OMB 0348-0046

Complete this form to disclose lobbying activities pursuant to 31 U.S.C. 1352

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

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

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

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

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

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

DISCLOSURE OF LOBBYING ACTIVITIES

Reporting Entity:_____ Page _____ of _____

CONTINUATION SHEET
Approved by OMB

0348-0046

Authorized for Local Reproduction
Standard Form--LLL-A

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

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

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

2. Identify the status of the covered Federal action.

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

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

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

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

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

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

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

10. (a) Enter the full name, address, city, state and zip code of the lobbying entity engaged by the reporting entity identified in item 4 to influence the covered Federal action.

    (b) Enter the full names of the individual(s) performing services, and include full address if different from 10(a); Enter Last Name, First Name, and Middle Initial (MI).

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

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

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

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

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

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

Public reporting burden for this collection of information is estimated to average 30 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the Office of Management and Budget, Paperwork Reduction Project (0348-0046), Washington, D.C. 20503.

BILLING INSTRUCTIONS

Guide for Preparing Vouchers Under Cost-Reimbursement Type Contracts

I. INTRODUCTION

A. GENERAL

This Guide presents procedures for the preparation of Contractor's reimbursement claims under (1) cost-reimbursement type contracts; (2) the cost-reimbursement portions of fixed-price contracts; (3) letter contracts which provide for reimbursement of costs; (4) time and material contracts; (5) labor-hour contracts; and (6) cost-sharing contracts. The term "cost-reimbursement type contracts" as used in this Guide includes all of the foregoing contractual arrangements.

B. DESK AUDIT

To expedite final payment on contracts subject to desk audit, the contractor may be required to provide the information set forth in III.C. of this guide.

C. PRESCRIBED GOVERNMENT FORMS

Standard Form 1034 "Public Voucher for Purchases and Services Other Than Personal" and Standard Form 1035, "Public Voucher for Purchases and Services Other Than Personal - Continuation Sheet" should be utilized by Contractors to show the amount claimed for reimbursement under cost-reimbursement type contracts, and to provide the necessary supporting detail, respectively. The SF 1035 may also be used to furnish any additional information as may be required by the Contracting Officer in accordance with the terms of the contract. The voucher and continuation sheet may be on reproduced copies of the forms providing they conform to the official Government forms in format and are marked "original".

D. TIME OF SUBMISSION

Vouchers may be submitted at the beginning of each billing period for costs incurred during the preceding billing period. Costs incurred earlier than the preceding billing period, but not previously billed for, may be included, but the amount and month(s)in which such costs were incurred must be stated in the SF 1035 or equivalent form. Vouchers shall not be submitted more frequently than once each month unless such arrangements are made with the Contracting Officer.

E. COST INCURRANCE PERIOD

Costs must be incurred within the contract performance period or the period covered by pre-contract cost provisions.

F. CONTRACTOR'S FISCAL YEAR

Vouchers must be prepared in such a manner that costs claimed can be associated or identified with the Contractor's fiscal year. This will ensure proper application of indirect cost rates to the direct costs of a particular fiscal year.

II. PREPARATION OF PUBLIC VOUCHERS

A. GENERAL

This information which a Contractor is required to submit in its public vouchers (SF 1034 and 1035) is set forth in the explanatory notes which follow.

B. COMPLETION OF SF 1034

The following information is required to be submitted on SF 1034 or equivalent:

(a) U. S. Department, Bureau of Establishment and Location enter the complete address as shown in the contract.

(b) Date Voucher Prepared - insert the date on which the voucher was prepared.

(c) Contract Number and Date - insert the number and the date of the contract under which reimbursement is claimed.

(d) All blocks lettered (d) should normally be left blank.

(e) Voucher No. - insert the appropriate serial number of each voucher including the completion and final voucher. A separate series of consecutive numbers, beginning with number 1, shall be used by the Contractor for each contract.

(f) Payee's Name and Address - insert name and address of Contractor to which payment should be made. In the case of an assignment of claims, also insert the organization to which payments have been assigned.

(g) Payee's Account Number - this space may be used by the Contractor to record the account or job number assigned to the contract.

(h) Number and Date of Order - enter the number and date of the applicable order. (Applicable only when billings are consequent to work assignments of the cost occurrence period.)

(i) Date of Delivery/Services - show the month and year, beginning and ending dates of the cost incurrence period.

(j) Articles and Services - insert the following: "For detail see attached page(s)".

(k) Amount and Total - insert the amount claimed for the period indicated in (i) above. For the cost-sharing portion of the contract, indicate the total amount, cost-sharing amount for the contractor, and the amount due for payment (Government cost-sharing amount).

(l) Identification - each voucher submitted must be prominently identified as one of the following:

(i) Interim Voucher - "Cost Reimbursable - Provisional Payment".

(ii) Completion Voucher - "Cost Reimbursable Completion Voucher".

(iii) Final Voucher - "Cost Reimbursable - Final Voucher".

(m) Type the following certification, signed by an authorized official, on the face of the SF 1034:

"I certify that all payments requested are for appropriate purposes and in accordance with the applicable); Total Contract Value; and Amount of Fee payable (if applicable).

Name of Official and Title

C. COMPLETION OF SF 1035

The following information is required to be submitted on SF 1035 or equivalent:

(1) Insert the name of the Government Agency as shown under of the SF 1034.

(2) Insert the voucher number as shown on the SF 1034.

(3) Schedule No. - Leave blank.

(4) If more than one sheet is used, insert the sheet number in numerical sequence, showing Page of . Use as many sheets as necessary to show the required information.

(5) Insert payee's name and address as in the SF 1034.

(6) Insert the contract number as shown on the SF 1034.

(7) Insert the latest: total estimated cost; total fee (if applicable); total contract value; and amount of fee payable (if applicable).

(8) Insert: "Summary of claimed current and cumulative cost" and "fee earned", if applicable.

(9) Unless otherwise required by the contract, insert the major elements of incurred cost which are defined as follows:

(1) Direct Costs

(a) Direct Labor: This consists of salaries and wages for direct performance of the contract.

(b) Fringe Benefits: This represents fringe benefits applicable to direct labor and billed as direct cost. Fringe benefits included in indirect costs should not be identified here.

(c) Capitalized Nonexpendable Equipment: This represents personal property of a capital nature; i.e., property acquired at a cost of $1000 or more and that has a service life of more than two years.

(d) Material, Supplies and Non-capitalized Equipment: These are consumable materials, supplies and equipment other than those described in (c) above.

(e) Premium Pay: This is remuneration in excess of the basic hourly rate.

(f) Consultant's Fee: These are fees paid to consultants. List names, time, and charges for the current billing period. If required by the terms and conditions of the contract, cite the applicable COA number.

(g) Travel: Domestic travel is travel within the United States, its territories, possessions, and Canada. It should be billed separately from foreign travel.

(h) Other: List all other direct costs in total unless significant in amount. If significant, list costs elements and dollar amount separately; i.e., subcontracts.

2. Indirect Costs

(a) Overhead: Cite the formula (rate and bass) in effect during the time the costs were incurred and for which reimbursement is claimed.

(10) Insert the current costs claimed by major cost elements. Costs claimed for reimbursement can be only those amounts that are consistent with the term "costs" as defined in allowable cost and payment clause. Where it is found that amounts laimed do not meet this definition, such costs together with their associated costs and fee will be disallowed. All adjustments included herein must be explained in detail.

(11) Insert the cumulative costs claimed to date by major cost elements.

(12) Costs claimed for cost-typed subcontracts must be supported by information similar to the SF 1035 for each subcontractor. Costs for fixed-price subcontracts shall be on the basis of items delivered or services received, accepted and paid by the prime contractor.

(13) Insert the total costs for the current and cumulative periods.

(14) If the contract provides for an incentive or fixed-fee, insert the fee earned for the current and cumulative periods and the formula for such computation; e.g., if payment of the fee is based on a percentage of costs, the target incentive fee or fixed-fee earned shall be determined by applying the percentage ration of target incentive fee or fixed-fee to the total estimated cost of the contractor. However after payment of 85% of the fee, the Contracting Officer may withhold further payment of fee to establish a reserve to protect the interests of the Government. This reserve may not exceed 15% of the total fee, or $100,000, whichever is less.

	For Example	
Contract Estimated Cost	$100,000	
Fixed-Fee		6,000
Total CPFF		$106,000
Maximum Fee Payable	$ 5,100	
Fixed-Fee		$ 6,000 – 6%
Estimated Cost	$100,000	

Therefore, fixed-fee may be billed at 6% of actual costs incurred until the maximum fee of $5,100 has been paid. Any fee withheld is payable upon submission of appropriate closing documents after final audit of the contract has been completed and all audit exceptions have been resolved.

(15) Insert the total costs claimed and the fee due for the current ad cumulative periods.

(16) If applicable, resubmission of any previously claimed amounts which were suspended should be shown below the current amount claimed and footnoted to cite the number of the public voucher on which the deduction was made and the date and number of the related suspension notice. Suspensions from which the contractor has successfully appealed shall be identified by referencing the Contracting Officer's letter of approval.

(17) Insert the current amount claimed. Transfer this amount to SF 1034.

III. GENERAL INSTRUCTIONS

A. Costs Requiring Prior Authorization and Approval

The contractor should be aware of the requirements for prior written approval from the Contracting Officer for certain costs (e.g., premium pay, foreign travel). Whenever the voucher includes such costs not authorized by the contract, reference must be made to the Contracting Officer's Authorization letter (COA).

B. Withholding and Releases of Contract Reserves

Contractual provisions covering fees, patents, royalties, etc., usually provide for the accumulation of a withholding reserve until certain contract requirements are met to the satisfaction of the Contracting Officer. It is the contractor's responsibility to include appropriate adjustments in his reimbursement claims to cover the required accumulation and release of contract withholding reserves. The contractor should resolve any questions regarding the amount of these reserves with the Contracting Officer.

C. Contractor's Completion Voucher

After all costs have been assigned to the contract and all contract performance provisions have been completed, the Contractor shall promptly submit, but in any event within twelve (12) months from the date of such completion, its completion voucher to the office designated in the contract directly to the Contracting Officer to finalize the financial settlement of the contract). This voucher must be specifically identified as the completion voucher and should include the remaining cost, fees, and reserves claimed to be due by the Contractor. It will not include items and amounts which may be set out in any qualifications in the Contractor's release of claims. A separate completion voucher shall be submitted for each individual project or task order for which a separate series of public vouchers has been submitted.

Final payment on prescribed contracts may be made on the basis of a desk audit. To expedite final settlement on these contracts, the Contracting Officer may request the Contractor to submit detailed support for costs claimed under one or more interim vouchers.

D. Contractor's Final Voucher and Closing Documents

After completion of the final audit and all suspensions and/or audit exceptions have been resolved and there is mutual agreement between the Contractor and the Contracting Officer on the final allowable cost and fee, if any, the Contractor shall submit its final voucher and the appropriate closing documents to the office designated in the contract. This voucher shall be specifically identified as the final voucher, and must be supported by the following documents:

(1) Contractor's Release
(2) Assignee's Release, if applicable
(3) Contractors Assignment of Refuns, Rebates, Credits and Other Amounts
(4) Assignee's Assignment of Refunds, Rebates, Credits, and Other Amounts, if applicable
(5) Contractor's Affidavit or Waiver or Lien, when required by contract

If final settlement of the contract is in the amount shown on the completion voucher, the Contractor need not submit a final voucher, but only the additional closing documents cited above.

E. Currency

All Department contracts are expressed in the United States dollars. Where expenditures are made in a currency other than United States dollars, billings on the contract shall be expressed, and reimbursement by the United States Government shall be made, in that other currency at amounts coincident with the actual costs incurred. Currency fluctuation may not be on a basis
of gain or loss to the Contractor. Notwithstanding the above, the total of all invoices paid under this contract may not exceed the United States dollars authorized.

F. Government Liaison

Any questions concerning delays in payment of Contractor's vouchers should be addressed to the office designated to receive the voucher; matters relative to performance or the instructions set forth in this Guide, should be addressed to the Contracting Officer.

Exhibit A to Billing Instructions

In addition to the requirements of the billing Instructions for Cost-Reimbursement Type Contracts, the contractor agrees to included the following supplemental information on each invoice for the cost categories shown below:

Direct Labor

(1) Position Category
(2) Employee Identification Number or Name
(3) Hours Expended
(4) Hourly Rate

Travel

(1) Detail purpose of travel (i.e. seminar, course, site visit, etc.)
(2) Dates and duration of travel
(3) Point of departure and destination
(4) Names of individuals
(5) Per diem rate
(6) Travel costs (airfare, car rental (including mileage), taxis, etc.

Material or Equipment (Rental or Purchase)

(1) Description, quantity and amount of each item
(2) COA letter number, if applicable

Consultants

(1) Name
(2) Rate
(3) Number of days and dates
(4) COA letter number, if applicable

Indirect Costs

(1) Rate
(2) Base
(3) Cost

Other Direct Costs

All other expenditures must be described and the respective amounts shown.

Billing Instruction to be included in any subcontracts shall call for the supplemental information cited above The prime Contractor shall provide, with each invoice that contains subcontract costs, a copy of the supplemental information provided by the subcontractor.

Contractor's Fiscal Year

Invoices must be prepared in such a manner that costs claimed can be associated or identified with the Contractor's fiscal year.

Attachment 13

PAST PERFORMANCE QUESTIONNAIRE

Please complete the following questionnaire and return via email to the attention of:

HHS/OS/ASPR/BARDA

Attn: Paquetta N. Myrick-Hancock, Contracting Officer
330 Independence Ave, SW Rm G640
Washington, DC 20201
Paquetta.Hancock@hhs.gov

This survey pertains to: **(VENDOR NAME)**

Department/Component: _____

Contract Number: _____

Date of Survey: _____

Name of Person Completing Survey: _____

Signature of Person Completing Survey: _____

Your Company/Agency: _____

Your Role in this Contract *(circle one)*:

Contracting Officer Contract Specialist Project Officer Other _____

Contract Value *(including options)*: $_____

Performance Period: _____
(including option periods)

Type of Contract: _____

Approximate percentage of work being performed (or completed) by subcontractor(s): _____%

Information on subcontractor(s) *(where more than ____% of work was completed by the subcontractor)*:

_____	_____	_____
Subcontractor	Program Manager	Phone
_____	_____	_____
Subcontractor	Program Manager	Phone

General description of products/services required under the contract: _____

RATINGS

Please answer each of the following questions with a rating that is based on objective measurable performance indicators to the maximum extent possible. Commentary to support rating may be noted at the end of the questionnaire under 'additional comments'.

Assign each area a rating of 0 (Unsatisfactory), 1 (Poor), 2 (Fair), 3 (Good), 4 (Excellent) or 5 (Outstanding). Use the attached Rating Guidelines as guidance in making these evaluations. Circle the appropriate rating. If you do not have enough personal knowledge or feedback from internal customers who directly received products and services from the contractor to make a determination on any of the performance criteria below, please circle "N/A" (not applicable /no opinion).

QUALITY OF SERVICE

1. Compliance with contract requirements
   0 1 2 3 4 5 N/A

2. Accuracy of reports
   0 1 2 3 4 5 N/A

3. Effectiveness of personnel
   0 1 2 3 4 5 N/A

4. Technical excellence
   0 1 2 3 4 5 N/A

COST CONTROL

1. Record of forecasting and controlling target costs
   0 1 2 3 4 5 N/A

2. Current, accurate and complete billings
   0 1 2 3 4 5 N/A

3. Relationship of negotiated costs to actuals
   0 1 2 3 4 5 N/A

4. Cost efficiencies
   0 1 2 3 4 5 N/A

TIMELINESS OF PERFORMANCE

1. Met interim milestones
   0 1 2 3 4 5 N/A

2. Reliability
   0 1 2 3 4 5 N/A

3. Responsive to technical direction
   0 1 2 3 4 5 N/A

4. Completed on time including wrap-up and contract administration
   0 1 2 3 4 5 N/A

5. Met delivery schedules
   0 1 2 3 4 5 N/A

BUSINESS RELATIONS

1. Effective management, including subcontracts
   0 1 2 3 4 5 N/A

2. Reasonable/cooperative behavior
   0 1 2 3 4 5 N/A

3. Responsive to contract requirements
   0 1 2 3 4 5 N/A

4. Notification of problems
   0 1 2 3 4 5 N/A

5. Flexibility
   0 1 2 3 4 5 N/A

6. Pro-active vs. reactive
   0 1 2 3 4 5 N/A

7. Effective small/small disadvantaged business subcontracting program
   0 1 2 3 4 5 N/A

SECURITY

1. Compliance with physical security requirements
   0 1 2 3 4 5 N/A

2. Compliance with communication and Information Security
   0 1 2 3 4 5 N/A

CUSTOMER SATISFACTION

1. The contractor is committed to customer satisfaction.
   Yes No *(circle one)*

2. Would you recommend selection of this firm again?
   Yes No *(circle one)*

ADDITIONAL COMMENTS

RATING GUIDELINES

RATING	QUALITY OF PRODUCT OR SERVICE	COST CONTROL	TIMELINESS OF PERFORMANCE	BUSINESS RELATIONS	SECURITY
0 – Unsatisfactory	Contractor is not in compliance and is jeopardizing achievement of contract objectives	Contractor is unable to manage costs effectively	Contractor delays are jeopardizing performance of contract objectives	Response to inquiries, technical/service/ administrative issues is not effective	Contractor is not in compliance and is jeopardizing achievement of contract objectives
1 – Poor	Major problems have been encountered	Contractor is having major difficulty in managing costs effectively	Contractor is having major difficulty meeting milestones and delivery schedules	Response to inquiries, technical/service/ administrative issues is marginally effective	Major problems have been encountered
2 – Fair	Some problems have been encountered	Contractor is having some problems in managing costs effectively	Contractor is having some problems meeting milestones and delivery schedules	Response to inquiries, technical/service/ administrative issues is somewhat effective	Some problems have been encountered
3 – Good	Minor inefficiencies/error s have been identified	Contractor is usually effective in managing costs	Contractor is usually effective in meeting milestones and delivery schedules	Response to inquiries, technical/service/ administrative issues is usually effective	Minor inefficiencies/ errors have been identified
4 – Excellent	Contractor is in compliance with contract requirements and/or delivers quality products/services	Contractor is effective in managing costs and submits current, accurate and complete billings	Contractor is effective in meeting milestones and delivery schedules	Response to inquiries, technical/service/ administrative issues is effective	Contractor is in compliance with security requirements
5 – Outstanding: The contractor has demonstrated an outstanding performance level in any of the above four categories that justifies adding a point to the score. It is expected that this rating will be used in those rare circumstances when contractor performance clearly exceeds the performance levels described as "Excellent".					

Attachment 14

ACH Vendor/Miscellaneous Payment Enrollment Form

Instructions for Completing SF 3881 Form

1. Agency Information Section - Federal agency prints or types the name and address of the Federal program agency originating the vendor/miscellaneous payment, agency identifier, agency location code, contact person name, and telephone number of the agency. Payee prints or types the Grant Number.

2. Payee/Company Information Section - Payee prints or types the name of the payee/company and address that will receive ACH vendor/miscellaneous payments, social security or taxpayer ID number, contact person name, and telephone number of the payee/company. Payee also verifies depositor account number, account title, and type of account entered by your financial institution in the Financial Institution Information Section.

3. Financial Institution Information Section - Financial institution prints or types the name and address of the payee/company's financial institution who will receive the ACH payment, ACH coordinator name and telephone number, nine-digit routing transit number, depositor (payee/company) account title and account number. Also, the box for type of account is checked, and the **signature, title, and telephone number of the appropriate financial institution official are included.**

Burden Estimate Statement

The estimated average burden associated with this collection of information is 15 minutes per respondent or record keeper, depending on individual circumstances. Comments concerning the accuracy of this burden estimate and suggestions for reducing this burden should be directed to the Financial Management Service, Facilities Management Division, Property and Supply Branch, Room B-101, 3700 East West Highway, Hyattsville, MD 20782 and the Office of Management and Budget, Paperwork Reduction Project (1510-0056), Washington, DC 20503.

ACH VENDOR/MISCELLANEOUS PAYMENT ENROLLMENT FORM

OMB No. 1510-0056

This form is used for Automated Clearing House (ACH) payments with an addendum record that contains payment-related information processed through the Vendor Express Program. Recipients of these payments should bring this information to the attention of their financial institution when presenting this form for completion.

PRIVACY ACT STATEMENT

The following information is provided to comply with the Privacy Act of 1974 (P.L. 93-579). All information collected on this form is required under the provisions of 31 U.S.C. 3322 and 31 CFR 210. This information will be used by the Treasury Department to transmit payment data, by electronic means to vendor's financial institution. Failure to provide the requested information may delay or prevent the receipt of payments through the Automated Clearing House Payment System.

AGENCY INFORMATION		
FEDERAL PROGRAM AGENCY		
AGENCY IDENTIFIER:	AGENCY LOCATION CODE (ALC):	ACH FORMAT: ☐ CCD+ ☐ CTX ☐ CTP
ADDRESS:		

CONTRACT PERSON NAME:	TELEPHONE NUMBER
ADDITIONAL INFORMATION	

PAYEE/COMPANY INFORMATION	
NAME	SSN NO. OR TAXPAYER ID NO.
ADDRESS	
CONTACT PERSON NAME:	TELEPHONE NUMBER: ( )

FINANCIAL INSTITUTION INFORMATION	
NAME:	
ADDRESS:	

ACH COORDINATOR NAME:	TELEPHONE NUMBER: ( )
NINE-DIGIT ROUTING TRANSIT NUMBER:	
DEPOSITOR ACCOUNT TITLE:	
DEPOSITOR ACCOUNT NUMBER:	LOCKBOX NUMBER:
TYPE OF ACCOUNT: ☐CHECKING ☐ SAVINGS ☐ LOCKBOX	

SIGNATURE AND TITLE OF AUTHORIZED OFFICIAL:
(Could be the same as ACH Coordinator)

TELEPHONE NUMBER:
( )

SF 3881 (Rev. 12/90)
NSN 7540-01-274-9925

3881-102

Prescribed by Department of Treasury

PART IV – REPRESENTATIONS AND INSTRUCTIONS

Section K - Representations, Certifications, and Other Statements of Offerors or Quoters (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.

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST COMPLY WITH THE ABOVE REQUIREMENT.

2. FAR 52.204-8 Annual Representations and Certifications (Jan 2006)

(a)(1) The North American Industry Classification System (NAICS) code for this acquisition is 236210.

(2) The small business size standard is $31M.

(3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

(b)(1) If the clause at 52.204-7, Central Contractor Registration, is included in this solicitation, paragraph (c) of this provision applies.

(2) If the clause at 52.204-7 is not included in this solicitation, and the offeror is currently registered in CCR, and has completed the ORCA electronically, the offeror may choose to use paragraph (c) of this provision instead of completing the corresponding individual representations and certifications in the solicitation. The offeror shall indicate which option applies by checking one of the following boxes:

[ ] (i) Paragraph (c) applies.

[ ] (ii) Paragraph (c) does not apply and the offeror has completed the individual representations and certifications in the solicitation.

(c) The offeror has completed the annual representations and certifications electronically via the Online Representations and Certifications Application (ORCA) website at http://orca.bpn.gov. After reviewing the ORCA database information, the offeror verifies by submission of the offer that the representations and certifications currently posted electronically have been entered or updated within the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer and are incorporated in this offer by reference (see FAR 4.1201); except for the changes identified below [*offeror to insert changes, identifying change by clause number, title, date*]. These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

FAR CLAUSE #	TITLE	DATE	CHANGE

Any changes provided by the offeror are applicable to this solicitation only, and do not result in an update to the representations and certifications posted on ORCA.

3. FAR 234-3 Notice of Earned Value management System – Post Award IBR (Jul 2006)

(a) The offeror shall provide documentation that the Cognizant Federal Agency has determined that the proposed earned value management system (EVMS) complies with the EVMS guidelines in ANSI/EIA Standard - 748 (current version at time of solicitation).

(b) If the offeror proposes to use a system that has not been determined to be in compliance with the requirements of paragraph (a) of this provision, the offeror shall submit a comprehensive plan for compliance with the EVMS guidelines.

(1) The plan shall—

(i) Describe the EVMS the offeror intends to use in performance of the contracts;

(ii) Distinguish between the offeror's existing management system and modifications proposed to meet the guidelines;

(iii) Describe the management system and its application in terms of the EVMS guidelines;

(iv) Describe the proposed procedure for administration of the guidelines, as applied to subcontractors; and

(v) Provide documentation describing the process and results of any third-party or self-evaluation of the system's compliance with the EVMS guidelines.

(2) The offeror shall provide information and assistance as required by the Contracting Officer to support review of the plan.

(3) The Government will review and approve the offeror's plan for an EVMS before contract award.

(4) The offeror's EVMS plan must provide milestones that indicate when the offeror anticipates that the EVM system will be compliant with the ANSI/EIA Standard - 748 guidelines.

(c) Offerors shall identify the major subcontractors, or major subcontracted effort if major subcontractors have not been selected, planned for application of the guidelines. The prime Contractor and the Government shall agree to subcontractors selected for application of the EVMS guidelines.

SECTION L - INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

The following information is specific to this solicitation.

I. GENERAL INFORMATION

ITEM 1: FAR Clause 52.215-1, INSTRUCTIONS TO OFFERORS-COMPETITIVE ACQUISTION (Jan 2004), 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 proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

ITEM 2: 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.

ITEM 3: TYPE OF CONTRACT AND NUMBER OF AWARD(S)

It is anticipated that one or more awards will be made from this solicitation and that the award(s) will be made on/about _____.

It is anticipated that the award(s) from this solicitation will be a multiple-year, modified cost-reimbursement, completion type hybrid contract, with a period of performance of 60 months, with 20, 12-month options periods.

ITEM 4. PRE-PROPOSAL CONFERENCE

The decision to have this conference depends largely on the lead-time available to the Government for research in connection with questions submitted by offerors. If a pre-proposal conference is planned, a notice will be posted on the Federal Business Opportunities website for this RFP.

Questions about this RFP should be submitted to the primary point of contact specified in Block 10 of page 1 of the solicitation and the envelope/subject line should be marked, "RFP No. RFP-HHS-BARDA-08-09." Letters containing questions may also be emailed to Paquetta.Hancock@hhs.gov. A set of all questions and answers will be posted as an amendment to the RFP in the FedBizOpps at the conclusion of the conference. Any questions concerning the RFP should be submitted in writing to Paquetta Myrick-Hancock, Contracting Officer, no later than _____.

In the event a pre-proposal conference is held, because of space limitations, each prospective offeror shall be limited to a total of three representatives. Attendance at the pre-proposal conference is recommended; however, attendance is not a prerequisite for proposal submission and will not be considered a factor in proposal evaluation.

ITEM 5: PRE-AWARD SITE VISIT

A pre-award site visit **MAY** be held to inspect the proposed facilities of offerors determined to be within the competitive range. The pre-award site visit will be held for the purpose of verifying the information presented in the proposal including but not limited to the condition, size, security and feasibility of the facility being proposed under this RFP.

Reasonable notification will be given to the offerors within the competitive range, prior to a planned pre-award site visit. In the event of a pre-award site visit, the Offeror should plan on a one (1) day site-visit by Government personnel to the facility being proposed in this RFP.

ITEM 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.

ITEM 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.**

ITEM 8: SERVICE OF PROTEST (SEP 2006) - 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 SOLICITATION/OFFER and AWARD cover page, Block 7, 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.

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

II. GENERAL INSTRUCTIONS

ITEM 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 typewritten, paginated, reproduced on letter size paper and will be legible in all required copies. To expedite the proposal evaluation, all documents required for responding to the RFP should be placed in the following order:

I. COVER PAGE

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

II. TECHNICAL PROPOSAL

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

III. BUSINESS PROPOSAL

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

ITEM 11: Alternate Proposals

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 work. 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.

ITEM 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.

ITEM 13: Potential Award Without Discussions, The Government reserves the right to award a contract without discussions if the Contracting Officer determines that the initial prices are fair and reasonable and that discussions are not necessary.

ITEM 14: 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 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:

- 39.9% 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.

ITEM 15: Extent of Small Disadvantaged Business Participation is applicable to this solicitation.

ITEM 16: 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.

1. Offerors shall submit the following information as part of their business proposal for both the Offeror and proposed major subcontractors.

2. The Offeror shall provide a list of the last three (3) contracts completed during the past three years and/or three contracts currently in process. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial customers. Offerors that are newly formed entities without prior contracts should list contracts as required above for all key personnel:

a. Name of Contracting Organization

b. Contract Number

c. Total Contract Value

d. Description of Requirement

e. Contract Officer's name and telephone number

ITEM 17: FAR 52.252- SOLICITATION PROVISIONS INCORPORATED BY REFERENCE (Feb 1998)

This contract incorporates one or more solicitation clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically at this/these address(es):

http:// www.acquisition.gov or http://www.hhs.gov/oamp/policies/ or http://www.gpoaccess.gov/cfr/index.html

Request for Information or Solicitation for Planning Purposes (FAR 52.215-3) (Oct 1997)

Data Universal Numbering System (FAR 52.204-6) (Apr 2008)

Notice of Priority Rating for National Defense Emergency Preparedness, and Energy Program Use (FAR 52.211-14) (Apr 2008)

Order of Precedence-Uniform Contract Format (FAR 52.215-8) (Oct 1997)

Facilities Capital Cost of Money (FAR 52.215-16) (Jun 2003)

Single or Multiple Awards (FAR 52.216-27) (Oct 1995)

Preaward On-Site Equal Opportunity Compliance Evaluation, (Over $10,000,000), (FAR 52.222-24) (Feb 1999)

FAR 52.222-23 Notice of Requirement for Affirmative Action to Ensure Equal Employment Opportunity for Construction (Feb 1999)

Site Visit (Construction) (FAR 52.236-27) (Feb 1995)

ITEM 18: Additional Contract Clauses of SECTION L – Added in full text:

Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data (FAR 52.215-20) (Alternate IV) (Oct 1997)

(a) Exceptions from cost or pricing data.

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

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

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

(A) For catalog items, a copy of or identification of the catalog and its date, or the appropriate pages for the offered items, or a statement that the catalog is on file in the buying

office to which the proposal is being submitted. Provide a copy or describe current discount policies and price lists (published or unpublished), *e.g.,* wholesale, original equipment manufacturer, or reseller. Also explain the basis of each offered price and its relationship to the established catalog price, including how the proposed price relates to the price of recent sales in quantities similar to the proposed quantities;

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

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

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

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

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

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

Alternate IV (Oct 1997). As prescribed in 15.408(l), replace the text of the basic provision with the following:

(a) Submission of cost or pricing data is not required.

(b) Provide information described below:

[See Section J Attachments]

FAR 52.222-5 Davis-Bacon Act—Secondary Site of the Work (Jul 2005)

(a)(1) The offeror shall notify the Government if the offeror intends to perform work at any secondary site of the work, as defined in paragraph (a)(1)(ii) of the FAR clause at 52.222-6, Davis-Bacon Act, of this solicitation.

(2) If the offeror is unsure if a planned work site satisfies the criteria for a secondary site of the work, the offeror shall request a determination from the Contracting Officer.

(b)(1) If the wage determination provided by the Government for work at the primary site of the work is not applicable to the secondary site of the work, the offeror shall request a wage determination from the Contracting Officer.

(2) The due date for receipt of offers will not be extended as a result of an offeror's request for a wage determination for a secondary site of the work.

(a) The offeror's attention is called to the Equal Opportunity clause and the Affirmative Action Compliance Requirements for Construction clause of this solicitation.

(b) The goals for minority and female participation, expressed in percentage terms for the Contractor's aggregate workforce in each trade on all construction work in the covered area, are as follows:

Goals for Minority Participation for Each Trade	**Goals for Female Participation for Each Trade**
[*Contracting Officer shall insert goals*]	[*Contracting Officer shall insert goals*]

These goals are applicable to all the Contractor's construction work performed in the covered area. If the Contractor performs construction work in a geographical area located outside of the covered area, the Contractor shall apply the goals established for the geographical area where the work is actually performed. Goals are published periodically in the *Federal Register* in notice form, and these notices may be obtained from any Office of Federal Contract Compliance Programs office.

(c) The Contractor's compliance with Executive Order 11246, as amended, and the regulations in 41 CFR 60-4 shall be based on (1) its implementation of the Equal Opportunity clause, (2) specific affirmative action obligations required by the clause entitled "Affirmative Action Compliance Requirements for Construction," and (3) its efforts to meet the goals. The hours of minority and female employment and training must be substantially uniform throughout the length of the contract, and in each trade. The Contractor shall make a good faith effort to employ minorities and women evenly on each of its projects. The transfer of minority or female

employees or trainees from Contractor to Contractor, or from project to project, for the sole purpose of meeting the Contractor's goals shall be a violation of the contract, Executive Order 11246, as amended, and the regulations in 41 CFR 60-4. Compliance with the goals will be measured against the total work hours performed.

(d) The Contractor shall provide written notification to the Deputy Assistant Secretary for Federal Contract Compliance, U.S. Department of Labor, within 10 working days following award of any construction subcontract in excess of $10,000 at any tier for construction work under the contract resulting from this solicitation. The notification shall list the—

(1) Name, address, and telephone number of the subcontractor;
(2) Employer's identification number of the subcontractor;
(3) Estimated dollar amount of the subcontract;
(4) Estimated starting and completion dates of the subcontract; and
(5) Geographical area in which the subcontract is to be performed.

(e) As used in this Notice, and in any contract resulting from this solicitation, the "covered area" is _____ [*Contracting Officer shall insert description of the geographical areas where the contract is to be performed, giving the state, county, and city*].

52.225-12 Notice of Buy American Act Requirement—Construction Materials under Trade Agreements (Jan 2005)

(a) *Definitions.* "Construction material," "designated country construction material," "domestic construction material," and "foreign construction material," as used in this provision, are defined in the clause of this solicitation entitled "Buy American Act—Construction Materials Under Trade Agreements" (Federal Acquisition Regulation (FAR) clause 52.225-11).

(b) *Requests for determination of inapplicability.* An offeror requesting a determination regarding the inapplicability of the Buy American Act should submit the request to the Contracting Officer in time to allow a determination before submission of offers. The offeror shall include the information and applicable supporting data required by paragraphs (c) and (d) of FAR clause 52.225-11 in the request. If an offeror has not requested a determination regarding the inapplicability of the Buy American Act before submitting its offer, or has not received a response to a previous request, the offeror shall include the information and supporting data in the offer.

(c) Evaluation of offers.

(1) The Government will evaluate an offer requesting exception to the requirements of the Buy American Act, based on claimed unreasonable cost of domestic construction materials, by adding to the offered price the appropriate percentage of the cost of such foreign construction material, as specified in paragraph (b)(4)(i) of FAR clause 52.225-11.

(2) If evaluation results in a tie between an offeror that requested the substitution of foreign construction material based on unreasonable cost and an offeror that did not request an exception, the Contracting Officer will award to the offeror that did not request an exception based on unreasonable cost.

(d) Alternate offers.

(1) When an offer includes foreign construction material, other than designated country construction material, that is not listed by the Government in this solicitation in paragraph (b)(3) of FAR clause 52.225-11, the offeror also may submit an alternate offer based on use of equivalent domestic or designated country construction material.

(2) If an alternate offer is submitted, the offeror shall submit a separate Standard Form 1442 for the alternate offer, and a separate price comparison table prepared in accordance with paragraphs (c) and (d) of FAR clause 52.225-11 for the offer that is based on the use of any foreign construction material for which the Government has not yet determined an exception applies.

(3) If the Government determines that a particular exception requested in accordance with paragraph (c) of FAR clause 52.225-11 does not apply, the Government will evaluate only those offers based on use of the equivalent domestic or designated country construction material, and the offeror shall be required to furnish such domestic or designated country construction material. An offer based on use of the foreign construction material for which an exception was requested—

(i) Will be rejected as nonresponsive if this acquisition is conducted by sealed bidding; or

(ii) May be accepted if revised during negotiations.

III. TECHNICAL PROPOSAL INSTRUCTIONS

ITEM 19: Technical Proposal Instructions

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

General Comment: 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 perform the numerous responsibilities required by this project more efficiently. 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.

The technical proposal may not exceed 50 pages. The appendix of the technical proposal may not exceed 500 pages. The technical proposal should provide specific information addressing the elements listed in the Statement of Work and those specified below:

Minimum Mandatory Requirements:

The Offeror must demonstrate that it fully meets the mandatory criteria for eligibility. The Offeror shall include a summary that clearly addresses each mandatory criterion. This section of your technical proposal shall be clearly marked and shall not exceed one (two-sided) page in length and will be used alone to evaluate and establish if the Offeror meets the mandatory criteria for eligibility. Those summaries failing to meet the mandatory criteria for eligibility will be eliminated from further review and consideration. Offerors that DO NOT demonstrate that they meet these mandatory criteria for eligibility will be ineligible for award, and the proposal submitted by these Offerors will not be further evaluated. This evaluation shall be subjective and based upon the content, completeness, and thoroughness of the data submitted. In order to be considered for further evaluation as shown under the technical evaluation criteria, Offerors shall fully meet all of the mandatory criteria for eligibility of this solicitation.

Technical Discussions

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

Statement of Work

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

Methodology and Approach: Describe, in detail, the Offeror's approach to the design, construction and validation of facilities for manufacturing of seasonal and pandemic influenza vaccines in the continental United States. The proposal shall address the current product development status of the proposed candidate influenza vaccine and how it will affect the design of the facility:

1. The product shall be presented in terms of its clinical effectiveness. This will include detailed analysis of non-clinical as well as clinical potency, safety and stability issues associated with the product to be produced at the proposed facility.

2. A rationale should be given for each unit operation for the manufacture of a seasonal and pandemic influenza vaccine in the form of a process flow diagram, to include operating parameters and the quality measures necessary to ensure the process is in a state of control. Issues such as changes in yield with scale and repeatability/ variability of results shall be fully discussed in terms of a root cause analysis.

3. Describe, in detail, the manufacturing process for seasonal or pandemic influenza vaccine. Such description shall be in as much detail as considered necessary to support the proposed design approach. Any required technology transfer activities, quality control methods development, and proposed area/ equipment qualification associated with each manufacturing step shall be provided. Overall, the proposal shall reflect a clear understanding of the proposed manufacturing methods and the facility design supporting the process.

4. Include a detailed analysis of the facility design to support the production process to produce at least 150 million doses of pandemic vaccine as presented. Offeror may propose dosage ranges for the design of the facility, provided they are substantiated by clinical data. Data and tables are included as appendices, with concise summaries included in the proposal itself. If antigen sparing technologies are being proposed by the Offeror (e.g. adjuvant), then the proposal shall include a detailed summary of the dose sparing effect and formulary specifications.

5. Provide a Contractor's Work Plan (CWP) that describes the activities to be performed in response to the Request for Proposal (RFP) requirements and a single Gantt chart to include all activities described in the CWP with a time-phased and task-linked budget specifying activities to be supported by the U.S. Government. Previously accomplished tasks/ milestones shall be outlined. This CWP shall be in as much detail as considered necessary to explain fully the proposed design approach. The level of detail contained in the CWP and the corresponding Gantt charts shall be sufficient to facilitate management and execution of the contract by the successful Offeror.

6. Include a discussion of the key scientific, technical and managerial risks posed by the project, as well as the ranking of risks (e.g. Low, Medium, and High) and a comprehensive plan to mitigate such risks.

7. A "Go/ No Go" decision tree with quantitative and qualitative criteria for evaluating the scientific and engineering merit of progressing to the next stage of the project shall be included.

8. Describe the extent to which the Offeror has unencumbered access to intellectual property (IP) necessary to fulfill its obligations under the contract. Accordingly, the U.S. Government requires written evidence of the extent to which the Offeror has secured access to such IP, expertise and tangible materials for influenza vaccine manufacturing at the proposed, newly licensed manufacturing facility. The U.S. Government expects and intends to require that the Offeror will take all steps necessary to secure this access.

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

Facilities: Describe the Offeror's current manufacturing facility(s) and any new facility(s) that will be used in the performance of the contract.

1. A concept plan that describes feasibility for production of commercial biological

products and vaccines for U.S. Government purchases during pre-pandemic and pandemic periods shall be included. The plan shall describe how the new facility(s) is/are integrated into the Offeror's biological product franchise. The plan shall describe warm base operation with one commercial lot production each year.

2. If the construction is to be carried out at an active licensed site, then the proposal shall describe the current manufacturing activities, including the findings of FDA's last three inspections.

3. The proposal shall discuss cleaning and changeover procedures between production of commercial biological products and pandemic influenza vaccines.

4. The proposal shall address the regulatory approval path for all relevant laws and regulations.

5. The proposal shall describe a comprehensive Validation Master Plan (VMP) for facility(s) and equipment/ systems affected.

6. If antigen sparing technologies are being proposed by the Offeror (e.g. adjuvant), then the proposal shall include a thorough explanation of the manufacturing capabilities (and/or sourcing requirements) of the Offeror to produce the raw material necessary to achieve the antigen sparing effect and satisfy the 150 million dose requirement.

7. The Offeror shall submit a **Draft Security Plan** addressing Security of Contract Operations. The plan shall include, at a minimum:

    - *Personnel Security Policies and Procedures* including, but not limited to: Recruitment of new employees; Interview process; Personnel background checks; Suitability/ adjudication policy; Access determination; Rules of behavior/ conduct; Termination procedures; Non-disclosure agreements.

    - *Physical Security Policies and Procedures* including but not limited to: Internal/ external access control; Identification/ badge requirements; Facility visitor access; Parking areas and access; Barriers/ perimeter fencing; Shipping, receiving and transport (on and off-site); Security lighting; Restricted areas; Signage; Intrusion detection systems; Closed circuit television; Other control measures.

    - *General Information Security Policies and Procedures* including but not limited to: Identification of sensitive information; Access control/ determination; Secured storage infrastructure; Document control; Retention/ destruction requirements.

    - *Information Technology Security Policies and Procedures* including but not limited to: Intrusion detection and prevention systems; Encryption systems; Identification of sensitive information/ media; Passwords; Removable media; Laptop policy; Media access control/ determination; Secure storage; System document control; System backup; System disaster recovery.

- The following instruction/ intent shall be incorporated in the **Draft Security Plan**: *Security Reporting Requirement* - Violations of established security protocols shall be reported to the Contracting Officer (CO) and Project Officer (PO) 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 U.S. Government (USG) intervention.

Organizational Experience: The proposal shall provide the general background, experience, and qualifications of the organization and its principle subcontractors as follows:

1. The Offeror shall provide a brief history of the firm including successful vaccine manufacturing programs.

2. The Offeror should provide a detailed table listing vaccine/ pharmaceutical products currently in development and those already licensed (domestic and international) including trade name, generic name, date licensed and with whom.

3. Similar or related contracts, subcontracts, or grants are included, in tabular format, and contain the name of the customer, contract/ grant number, dollar amount, time of performance, and the names & telephone numbers of the Project Officer (PO) and Contracting Officer/ Grants Officer (CO/ GO).

4. The Offeror shall describe the rationale for all preferred major subcontractors and equipment vendor choices.

Personnel: The proposal shall list the names and proposed duties of the professional personnel, consultants and key subcontractor employees directly assigned to the project.

1. The resumes/ curricula vitae do contain information on education, background, recent experience and specific, technical accomplishments for all key personnel.

2. The approximate percentage of time each individual will be available for this project is stated.

3. The proposed staff hours of each individual to be allocated against each project task or subtask are provided.

4. Principal Investigator (PI): Appropriateness, adequacy, and relevance of the documented education, training, expertise, experience, qualifications and availability of the PI (based on percent effort devoted to this project) to lead, direct and coordinate all contract activities, including activities carried out by subcontractors. This includes: appropriate knowledge and expertise in design, construction and validation of commercial vaccine manufacturing facilities including prior successful interactions with the FDA, including Biologics License Application (BLA) submissions; and the capacity to monitor progress, assess

performance, identify performance problems and implement corrective actions.

5. Project Manager (PM): The documented training, expertise, experience, qualifications and availability (based on percent effort devoted to this project) of the Project Manager to monitor day-to-day activities of the program. This includes: monitoring and tracking of progress and timelines relative to both schedule and budget, including use of project management software, coordinating project and subcontractor activities, organizing meetings and teleconferences, and maintaining lines of communication with the Department of Health and Human Services (HHS).

6. Other Scientific/ Engineering/ Technical Personnel: Appropriateness, adequacy and relevance of the documented education, training, expertise, experience, qualifications and availability of proposed other scientific and technical personnel of the Offeror and any proposed consultants/ subcontractors to carry out specific duties and responsibilities, as follows: execution of key vaccine production activities and assays; experience with products of a similar nature regulated by the FDA; regulatory requirements that govern the production of cGMP materials and testing in compliance with GLP and GCP; and experience and expertise in managing Quality Systems, Quality Assurance (QA) and Quality Control (QC) procedures.

7. The letter of commitment does include the following four elements: (1) the specific items or expertise they will provide; (2) their availability to the project and the amount of time anticipated; (3) their willingness to act as a subcontractor/ consultant; (4) how the rights to publication and patents will be handled.

Technical Evaluation

Proposals will be technically evaluated in accordance with the factors and weights as described in **SECTION M** Evaluation Factors for Award of this solicitation.

Additional Technical Proposal Information

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

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

IV. BUSINESS PROPOSAL INSTRUCTIONS

ITEM 20: Proposal Cover Sheet, is applicable to this solicitation and is included under Section J

ITEM 21: The Contractor shall provide a cost breakdown of all key elements in their proposal to meet the milestones as specified in the statement of work. Contractor shall list cost sharing and cost plus fixed fee for these elements on the table in Section B.2.

ITEM 22: The Contractor shall provide audited financial statements for its most recently completed fiscal year as a part of its proposal.

SECTION M - EVALUATION FACTORS FOR AWARD

GENERAL

Selection of an Offeror for contract award will be based on an evaluation of proposals against four factors. The non-cost factors in order of importance are: technical, past performance and Small Disadvantaged Business (SDB) participation. In addition, the Offeror's small business plan must be acceptable (see Section L, item 14). Offerors whose small business plan is considered unacceptable will be ineligible for contract award. If clinical or pre-clinical studies are proposed, the Offeror's proposal must also be considered acceptable for use of human subjects and animal welfare, respectively. Offerors are advised that in the evaluation process, all evaluation factors other than cost or price, when combined, are significantly more important than cost or price. Technical activities must connect directly to costs in the business proposal. The trade off process described in FAR 15.101-1 may be employed. This process permits tradeoffs among cost/price and non-cost factors and allows the USG to consider award (s) to other than the lowest priced or highest technically rated Offeror. In any case, the Government reserves the right to make an award(s) to that Offeror whose proposal provides the best overall value to the Government. For the purposes of section C and M of this RFP, the U.S. is defined as the fifty states, the District of Columbia, and Puerto Rico.

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

Contract(s) will be awarded to the Offeror(s) whose proposal is considered to be the most advantageous to the Government, cost and other factors (identified below) considered. Each Offeror must submit a proposal that separately addresses evaluation criteria specified below as they relate to the statement of work and delivery requirements.

M.1. Mandatory Criteria for Eligibility

The Offeror shall include all information which documents and/or supports the mandatory criteria for eligibility in one clearly marked section of their proposal. The mandatory criteria for eligibility establish conditions that must be met at time of proposal submission in order for your proposal to be considered any further for award.

The Offeror shall provide an index, matrix, or dedicated section in the technical proposal that will address each particular mandatory criterion for eligibility:

Demonstration of Advanced Development/U.S. Vaccine Product Licensure

It is essential that efforts funded as a result of this request shall lead to U.S. licensure of a domestic cell-based influenza vaccine manufactured within a domestic facility that can be used to protect the U.S. population in the event of an influenza pandemic. The Offeror shall have proficiency in the licensure and manufacturing of vaccines or biologicals. For the purpose of this solicitation, cell-based influenza vaccine candidates shall be manufactured using reassortant influenza virus that is produced utilizing well-characterized mammalian cell lines. The Offeror's clinical manufacturing proficiency shall be demonstrated by producing an influenza vaccine licensed in the United States or having initiated clinical trials of a cell-based influenza vaccine candidate with successful completion of Phase I clinical trials for safety and immunogenicity of an influenza strain at the time of proposal submission. Vaccine immunogenicity shall be based on raising immunity to the influenza hemagglutinin (HA) protein. In addition, the Offeror shall provide a clear and comprehensive plan and timeline for filing of a Biologics License Application (BLA) with CBER for a cell-based influenza virus vaccine.

U.S. Vaccine Manufacturing

The Offeror must provide in its proposal written evidence of a firm commitment to establish and maintain the necessary facilities in the U.S. for the manufacture of bulk and final container pandemic influenza virus vaccine for human use throughout the amortized lifetime of the facility. In order to satisfy the U.S.-based manufacturing requirement, the Offeror may be:

A single, fully-integrated, and independent pharmaceutical company that performs U.S.-based vaccine manufacturing and/or clinical studies;

A prime contractor with a subsidiary or subcontractor that performs U.S.-based vaccine manufacturing and/or clinical studies; or

A prime contractor with contract manufacturing organizations (CMO) and/or contract research organizations (COR) as subcontractors that performs U.S.-based vaccine manufacturing and/or clinical trials.

Cost Sharing

The Offeror shall be required to propose cost sharing for this requirement. At a minimum, the contractor will be required to fund sixty percent (60%) of the total cost of the project.

Production Capacity

The Offeror shall demonstrate the likelihood of vaccine manufacturing cycle timeline to lot release with the overall capacity to produce at least 150 million doses of finished pandemic influenza vaccine within six (6) months of a declared influenza pandemic. Dose sparing

technologies may be utilized to achieve the minimum 150 million dose requirement (e.g. antigen sparing adjuvants); however, adjuvant manufacturing capabilities must be fully disclosed.

Failure to adequately document compliance for any of the above mandatory requirements will result in the elimination of the Offeror's proposal from further consideration.

M.2. Technical Evaluation Criteria

The Offeror shall discuss in detail a work plan that indicates how each aspect of the Statement of Work (SOW) is to be accomplished. The Offeror shall demonstrate their full understanding of the key elements essential to complete the requirement, including how the project will be organized, staffed and managed. The completeness and quality of the Offeror's proposal and supporting data will be evaluated and scored in terms of relative risk and the likelihood of successful completion of the project. All proposals will be evaluated and scored in accordance with the technical factors and points set forth below.

Evaluation Criteria	Points
Current Product Development Status of the Proposed Pandemic Influenza Candidate Vaccine	20
Methodology and Approach	20
Facilities	25
Organizational Experience	10
Personnel	10
Timeline to licensure and use	15
TOTAL:	**100**

1. **<u>Current Product Development Status of the Proposed Pandemic Influenza Candidate Vaccine</u> – 20 Points**

   a. The product is presented in terms of its clinical effectiveness. The immunogenicity of the HA antigen shall be demonstrated by data showing its potency and, where possible, cross protection, and includes a detailed analysis of non-clinical as well as clinical potency, safety and stability of the product to be produced at the proposed facility. These data are presented in tabular form to show all studies to support these claims.

   b. A detailed analysis of the facility design to support the production process to produce at least 150 million doses of pandemic vaccine shall be presented. Offerors may propose dosage ranges for the design of the facility, provided they are substantiated

by clinical data. Data and tables shall be included as appendices, with concise summaries included in the proposal itself.

c. The proposal shall include a detailed summary of dose sparing techniques, if any, that will be employed to satisfy the 150 million dose requirement. For example, if the Offeror proposes the use of an antigen sparing adjuvant, then its safety and effectiveness must be proven, the formulary disclosed, and the anticipated dose ranges specified.

d. Each unit operation shall be clearly presented showing a detailed analysis of previous developmental work for each step of the proposed process. Process scale (batch size), yield and impurity removal data are included. Completed process validation reports and regulatory submissions shall be submitted as attachments, where appropriate. A rationale shall be given for each unit operation, to include operating parameters and the quality measures necessary to ensure the process is in a state of control. Issues such as changes in yield with scale and repeatability/ variability of results shall be fully discussed in terms of a root cause analysis.

e. The proposal shall include a proposed process flow diagram and/or process flow description highlighting the key process steps in relation to the facility design.

f. The proposal shall reflect a clear understanding of the proposed manufacturing methods and the facility design supporting the process and includes a detailed analysis of previous process developmental work, a rationale for each process step, required technology transfer activities, and proposed area/ equipment qualification associated with each manufacturing step.

g. Preference shall be given to those Offerors that have completed Phase I clinical trials for safety, immunogenicity and cross-reactivity or cross-neutralization of antigenically drifted influenza strains using cell-based methodologies.

2. <u>Methodology and Approach</u> – 20 Points

a. The proposal shall describe, in detail, the Offeror's work plan to complete all activities identified in the statement of work (SOW). This plan shall indicate anticipated difficulties in carrying out the work and potential approaches to overcome these difficulties. Decision trees for the critical pathway shall be provided for design, construction, commissioning and validation as well as process development, product

assay development, clinical evaluation, master validation plan, and regulatory licensure plan.

b. The proposal shall include a detailed work plan indicating how each aspect of the statement of work is to be accomplished by Milestone.

c. The proposal shall include information on how the project is to be organized, staffed and managed. This information shall demonstrate understanding of important events/ tasks, their critical path and their management.

d. The proposal shall include a Project Management Plan for overall project organization, staffing, leadership, responsibilities, management, and lines of authority, including the plan to manage the work of consultants and/or subcontractors to meet the overall production, non-clinical and clinical testing (e.g. responsibility matrix).

e. The proposal shall include an outline of the project management systems and quality control methods to ensure the effective initiation, implementation, and conduct of contract requirements, and to monitor, track and report the Offeror, consultant, and/or subcontractor costs and performance. The resulting project status reports shall be communicated with the U.S. Government as required by the terms of the contract (e.g. monthly technical reports).

f. The proposal shall include a plan for soliciting, evaluating, negotiating, awarding and managing any proposed subcontracts in accordance with the Federal Acquisition Regulation (FAR).

g. The proposal shall include a plan to identify and remediate problems in consultant and/or subcontractor performance.

h. The proposal shall describe, in detail, the Offeror's work plan, including cost-sharing ratios, to complete all activities identified in the statement of work (SOW). The work plan shall discuss phasing and integration of development of pandemic vaccines and facility related activities in the form of a single Gantt chart with a time-phased and task-linked budget specifying activities to be supported by the U.S. Government.

i. The proposal shall include a discussion of any previous work completed by the Offeror in support of the project.

j. The proposal shall include a Contractor's Work Plan and corresponding Gantt chart with the level of detail sufficient to facilitate management and execution of the contract by the successful Offeror.

k. The proposal shall include a discussion of the key scientific, technical and managerial risks posed by the project and a comprehensive plan to mitigate such risks. The proposal shall address and provide data on relevant topics, such as, cell line qualification, viral inactivation or host DNA/protein clearance.

l. The proposal shall include a "Go/ No Go" decision tree with quantitative and qualitative risk-based criteria and mitigation alternatives for evaluating the scientific and engineering merit of progressing to the next stage of the project.

m. The proposal shall describe the extent to which the Offeror has unencumbered access to intellectual property necessary to fulfill its obligations under the contract. The U.S. Government expects and intends to require that the Offeror will take all steps necessary to secure access to all intellectual property, know-how and tangible materials. Accordingly, the U.S. Government requires written evidence that the Offeror has secured access to such intellectual property, know-how and tangible materials to suitable cell culture and/or recombinant DNA technology unencumbered by legal or patent constraints.

3. <u>Facilities</u> – 25 Points

a. As required and/or appropriate, the Offeror's proposal shall include documented availability, suitability, capacity and adequacy of proposed facilities, equipment and other resources for the development, manufacture and final packaging of at least 150 million doses of the influenza vaccine candidate. An option for pilot-scale facility(s) may be provided in the proposal to optimize the process upon an influenza strain change. Additional options may include Quality Control laboratories and Formulation/ Fill/ Finish facilities in order to accomplish the 150 million dose requirement. The Offeror shall ensure that capacity of all facilities, equipment and other resources dedicated to the project (as proposed) will be able to perform the required production activities in a timely and efficient manner.

b. The proposal shall include a proposed influenza vaccine production schedule that adequately and rapidly responds to an emerging pandemic threat.

c. The proposal shall include information regarding ownership/lease of facilities, systems or apparatus, including demonstrated availability for the duration of the contract.

d. The proposal shall describe, in detail, the risk management strategy for biocontainment and overall security of the proposed biocontainment facilities. All bio-safety procedures to conduct studies shall be in accordance with EPA, WHO, USDA and HHS regulations regarding the transfer of Select Agents.

e. The proposal shall provide adequate assurance of compliance with all safety guidelines and regulations, including training and monitoring of personnel for exposure to infectious and other hazardous materials.

f. As required, the proposal shall list all facilities within the Quality Control Laboratories that house laboratory animals.

g. The proposal shall include a Draft Security Plan addressing Security of Contract Operations.

h. The proposal shall include a comprehensive Validation Master Plan (VMP) for the facility(s) and equipment/ systems affected.

i. If an antigen-sparing adjuvant is proposed by the Offeror to satisfy the 150 million dose requirement, then the proposal shall detail the domestic capabilities of the Offeror to either manufacture or source the adjuvant bulk.

4. <u>Organizational Experience</u> – 10 Points

a. The proposal shall provide the general background, experience, and qualifications of the organization and its principle subcontractors.

b. The proposal shall provide a brief history of the firm including successful vaccine manufacturing programs.

c. The proposal shall provide a detailed table listing vaccine/ pharmaceutical products currently in development and those already licensed (domestic and international) including trade name, generic name, date licensed and with whom.

d. Similar or related contracts, subcontracts, or grants shall be included, in tabular format, and contain the name of the customer, contract/ grant number, dollar amount, time of performance, and the names, email address, telephone numbers, and fax numbers the Project Officer (PO) and Contracting Officer/Grants Officer (CO/GO).

e. The proposal shall describe the rationale for all preferred major subcontractors and equipment vendor choices.

5. <u>Personnel</u> – 10 Points

a. The proposal shall list the names and proposed duties of the professional personnel, consultants and key subcontractor employees directly assigned to the project.
b. The resumes/ curricula vitae shall contain information on education, background, recent experience and specific, technical accomplishments for all key personnel.

c. The proposal shall state the approximate percentage of time each individual will be available for this project.

d. The proposal shall provide a list of anticipated staff hours, for each individual, to be allocated against each project task or subtask.

e. The proposal shall specify a Principal Investigator (PI). The appropriateness, adequacy, and relevance of the documented education, training, expertise, experience, qualifications and availability of the PI (based on percent effort devoted to this project) is sufficient to lead, direct and coordinate all contract activities, including activities carried out by subcontractors. These activities include: appropriate knowledge and expertise in design, construction and validation of commercial vaccine manufacturing facilities including prior successful interactions with the FDA, including execution of clinical bridging studies and Biologics License Application (BLA) submissions; and the capacity to monitor progress, assess performance, identify performance problems and implement corrective actions.

f. The proposal shall specify a Project Manager (PM). The documented training, expertise, experience, qualifications and availability (based on percent effort devoted to this project) of the Project Manager is sufficient to monitor day-to-day activities of the program. These activities include: monitoring and tracking of progress and timelines relative to both schedule and budget, including use of project management

software, coordinating project and subcontractor activities; organizing meetings and teleconferences; and maintaining lines of communication with the Department of Health and Human Services (HHS).

g. The proposal shall specify other key Scientific, Engineering and Technical personnel. The appropriateness, adequacy and relevance of the documented education, training, expertise, experience, qualifications and availability of proposed other scientific, engineering and technical personnel of the Offeror and any proposed consultants/ subcontractors is sufficient to carry out specific duties and responsibilities, as follows: execution of key vaccine production activities and assays; experience with products of a similar nature regulated by the FDA; regulatory requirements that govern the production of cGMP materials and testing in compliance with GLP and GCP; and experience and expertise in managing Quality Systems, Quality Assurance (QA) and Quality Control (QC) procedures.

h. The letter of commitment shall include the following four elements: (1) the specific items or expertise they will provide; (2) their availability to the project and the amount of time anticipated; (3) their willingness to act as a subcontractor/ consultant; (4) how the rights to publication and patents will be handled.

6. <u>Timeline to FDA licensure and use</u> – 15 Points

The proposal shall provide a realistic timeline that includes a task-based schedule and potential risks for seeking FDA licensure for the use of the facility to manufacture influenza vaccine. The potential risks and a mitigation strategy shall be included. The timeline shall be evaluated for completeness and timeliness. Furthermore, the timeline shall be assessed across all project stages (e.g. execution of clinical bridging studies, submission of the BLA, and post licensure activities) for realism as well as a schedule that will present the best value to the U.S. Government.

M.3. Past Performance Information

Offerors shall submit the following information as part of their business proposal for both the Offeror and proposed major subcontractors:

1. The Offeror shall provide a list of three (3) contracts completed during the past three years or contracts currently in process that are similar in nature to the solicitation work scope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments and commercial customers. Offerors that are newly formed entities without prior contracts should list contracts as required above for all key personnel:

a. Name of Contracting Organization

b. Contract Number

c. Total Contract Value

d. Description of Requirement

e. Contract Officer's name and telephone number

f. Program Manager's name and telephone number

2. Each Offeror will be evaluated based on their performance under existing and prior contracts for similar products or services. Past performance will not be scored, but performance information will be used for both responsibility determinations and as an evaluation factor against which Offerors' relative rankings will be compared to assure the best value to the Government. The Government will focus on information that demonstrates quality of performance relative to the size and complexity of the acquisition under consideration. The Government is not required to contact all references provided by the Offeror, and references other than those identified by the Offeror may be contacted by the Government to obtain additional information that will be considered in the evaluation of the Offerors past performance.

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

4. 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 the 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 all available and 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.

The rating methodology that will be used to evaluate past performance can be found in Attachment 12 to this solicitation.

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:

- Extent to which SDB concerns are specifically identified
- Extent of commitment to use SDB concerns
- Complexity and variety of the work SDB concerns are to perform
- Realism of the proposal
- Past performance of Offerors in complying with subcontracting plan goals for SDB concerns and monetary targets for SDB participation
- Extent of participation of SDB concerns in terms of the value of the total acquisition.

M. 5. Studies that Involve Human Subjects

This research project may involve human subjects. 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. The adult population is considered to be 18 – 64 years.

M.6. Human Subject Evaluation

1. This research project may involve human subjects. 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 BARDA that a designated exemption is appropriate. If you claim that this research should be considered exempt from coverage by the Federal Regulations at 45 CFR 46, 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 USG includes your proposal in the competitive range (for competitive proposals), or if the USG holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss 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 trails be monitored to ensure the safe and effective conduct of human subjects research, and to recommend conclusion of the trial when significant benefits or risks are identified or if it is unlikely that the trial can be concluded successfully. Risks associated with participation in research must be minimized to the extent practical and the method and degree of monitoring should be commensurate with risk. Additionally, all plans must include procedures for adverse event reporting. Finally, generally, for Phase III clinical trials, the establishment of a Data and Safety Monitoring Board (DSMB) is required, whereas for Phase I and II clinical trials, the establishment of a DSMB is optional. The reviewers should refer to the Statement of Work (SOW) and Section L in the solicitation, as well as any further technical evaluation criteria in this Section M, as applicable, for the solicitations specific requirements for data and safety monitoring. As a part of the evaluation for proposals, the reviewers will provide a narrative that describes the acceptability of the proposed data and safety monitoring plan with respect to the potential risks to human participants, complexity of study design, and methods or 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 USG includes your proposal in the competitive range (for competitive proposals), or if the USG holds discussions with the selected source (for sole source acquisitions), you will be afforded the opportunity to further discuss 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 Phase III clinical trials, all proposals or protocols must provide a description of plans to conduct analyses, as appropriate, to detect significant differences in intervention effect (see NIH Guide http://grants.nih.gov/grants/funding/women_min/women_min.htm Definitions - Significant Difference) by sex/gender, racial/ethnic groups, and relevant subpopulations, if applicable, unless the USG has specified that this solicitation involves a sex/gender specific study or a single or limited number of minority population groups. The proposal also must include one of the following plans:

Plans to conduct valid analysis to detect significant differences in intervention effect among sex/gender or racial/ethnic subgroups when prior studies strongly support these significant differences among subgroups,

OR

Plans to include and analyze sex/gender or racial/ethnic subgroups when prior studies strongly support no significant differences in intervention effect between subgroups (representation of sex/gender or racial/ethnic groups as subject selection criterion is not required; however, inclusion and analyses are encouraged),

OR

Plans to conduct valid analyses of the intervention effect in sex/gender or racial/ethnic subgroups (without requiring high statistical power for each subgroup) when the prior studies neither support nor negate significant differences in intervention effect between subgroups.

Also, the proposal must address the proposed outreach programs for recruiting women and minorities as participants. Reviewers will address the areas covered here and in Section L of the solicitation in narrative form in their evaluation. Some of the issues they will evaluate include:

- whether the plan proposed includes minorities and both genders in adequate representation

– how the Offeror addresses the inclusion of women and members of minority groups and their subpopulations in the development of a proposal that is appropriate to the scientific objectives of the solicitation

– the description of the proposed study populations in terms of sex/gender and racial/ethnic groups and the rationale for selection of such subjects

– if exclusion is proposed, that the rationale is appropriate with respect to the health of the subjects or to the purpose of the research.

– In addition, for gender exclusion, the reviewers will examine the rationale to determine if it is because:

– the purpose of the research constrains the Offeror's selection of study participants by gender (e.g., uniquely valuable stored specimens or existing datasets are single gender; very small numbers of subjects are involved;

OR,

– overriding factors dictate selection of subjects);

OR,

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

– For minority group exclusion, the reviewers will examine the rationale to determine if those minority groups are excluded because:

– inclusion of those groups would be inappropriate with respect to their health,;

OR,

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

– For 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 or racial ethnic subgroups when the intervention effect(s) is expected in the primary analyses, or if there is an adequate description of plans to conduct valid analyses of the intervention effect in subgroups when the intervention effect(s) is not expected in the primary analyses.

If you determine that inclusion of women and minority populations is not feasible, you must submit a detailed rationale and justification for exclusion of one or both groups from the study population with the technical proposal. The USG will review the rationale to determine if it is appropriate with respect to the health of the subjects or the purpose of the research

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

If the information you provide in your proposal regarding the inclusion of women and minorities is rated "unacceptable" and the USG includes your proposal in the competitive range (for competitive proposals), or if the USG 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 USG 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 USG includes your proposal in the competitive range (for competitive proposals), or if the USG 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 USG after discussions, your proposal may not be considered further for award.

M.7. 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). It is expected that the studies done under this contract will require animal research as the research question cannot ethically be addressed using human subjects. The Offeror(s) are instructed to follow the FDA guidance on the use of animals in studies which are unethical to conduct in human subjects (the "Animal Rule" as found in 21 CFR § 610). 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:

- 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.

- 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.

- Provide information on the veterinary care of the animals involved.

- 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 or comfortable restraining devices where appropriate to minimize comfort, distress, pain, and injury.
- 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 USG includes your proposal in the competitive range, you will be afforded an opportunity to further discuss 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.8. RELATIVE IMPORTANCE OF COST OR PRICE AND OTHER EVALUATION FACTORS

All evaluation factors other than cost or price, when combined, are significantly more important than cost or price.

M.9. EVALUATION OF OPTIONS (FAR 52.217-5) (Jul 1990)

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