

2. CONTRACT NUMBER	3. SOLICITATION NUMBER 15-100-SOL-00014	4. TYPE OF SOLICITATION <input type="checkbox"/> SEALED BID (IFB) <input checked="" type="checkbox"/> NEGOTIATED (RFP)	5. DATE ISSUED 03/16/2015	6. REQUISITION/PURCHASE NUMBER
7. ISSUED BY HHS\OS\ASPR\AMCG WASHINGTON, DC 20201		CODE	8. ADDRESS OFFER TO (If other than item 7) SEE ARTICLE L.9	

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

SOLICITATION

9. Sealed offers in original and SEE L.9 copies for furnishings the supplies or services in the Schedule will be received at the place specified in item 8, or if hand carried, in the depository located in N/A until 5:00 PM local time 04/30/2015
(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 this solicitation.

10. FOR INFORMATION CALL:	A. NAME MATTHEW MCCORD	B. TELEPHONE (NO COLLECT CALLS)			C. E-MAIL ADDRESS
		AREA CODE 202	NUMBER 2600689	EXTENSION	

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OFFER (Must be fully completed by offeror)

NOTE: Item 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 _____ 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 items upon which prices are offered at the set opposite each item, delivered at the designated point(s), within the time specified in the schedule.

13. DISCOUNT FOR PROMPT PAYMENT <small>(See Section I, Clause No. 52.232-8)</small>	10 CALENDAR DAYS (%)	20 CALENDAR DAYS (%)	30 CALENDAR DAYS (%)	CALENDAR DAYS(%)
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14. ACKNOWLEDGMENT OF AMENDMENTS <small>(The offeror acknowledges receipt of amendments to the SOLICITATION for offerors and related documents numbered and dated):</small>	AMENDMENT NO.	DATE	AMENDMENT NO.	DATE

15A. NAME AND ADDRESS OF OFFEROR	CODE	FACILITY	16. NAME AND THE TITLE OF PERSON AUTHORIZED TO SIGN OFFER <small>(Type or print)</small>
15B. TELEPHONE NUMBER AREA CODE NUMBER EXTENSION			17. SIGNATURE
15C. CHECK IF REMITTANCE ADDRESS IS DIFFERENT FROM ABOVE - ENTER SUCH ADDRESS IN SCHEDULE. <input type="checkbox"/>			

AWARD (To be completed by Government)

19. ACCEPTED AS TO ITEMS NUMBERED	20. AMOUNT	21. ACCOUNTING AND APPROPRIATION
22. AUTHORITY FOR USING OTHER THAN FULL OPEN COMPETITION: <input type="checkbox"/> 10 U.S.C. 2304 (c) <input type="checkbox"/> 41 U.S.C. 3304(a) ()		23. SUBMIT INVOICES TO ADDRESS SHOWN IN <small>(4 copies unless otherwise specified)</small> ITEM
24. ADMINISTERED BY (If other than Item 7)		25. PAYMENT WILL BE MADE BY CODE
26. NAME OF CONTRACTING OFFICER (Type or print)		27. UNITED STATES OF AMERICA <small>(Signature of Contracting Officer)</small>
		28. AWARD DATE

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

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SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The United States Department of Health and Human Services (DHHS), Office of the Assistant Secretary for Preparedness and Response (ASPR), Biomedical Advanced Research and Development Authority (BARDA) and Office of Acquisition Management, Contracts & Grants (AMCG) contemplate single or multiple awards of cost plus fixed fee contracts or other transactional authority arrangements to develop more effective/ universal influenza vaccine candidates towards FDA licensure.

ARTICLE B.2. CONTRACT LINE ITEM NUMBERS (CLINs)

A. BASE PERIOD

CLIN	Deliverable	Estimated Cost	Fixed Fee	Extended CPFF
0001	Milestone 1. Product Development Plan			
0002	Milestone 2. Clinical Development and Regulatory Plan			
0003	Milestone 3. Product Manufacturing Plan including Master Production Record of drug substance and drug product planned for Phase 2 studies			
0004	Milestone 4. Manufacturing Facility Plan describing the design, construction, commissioning, qualification and validation of, or technology transfer to a US-based facility			
0005	Milestone 5. Production Feasibility Plan to manufacture, test and release finish up to 50 million doses of vaccine within 4 months, first doses within 12 weeks			
0006	Milestone 6. Base Period Contractor defined milestones. Contractor shall include plan with initial proposal and if			

	acceptable to the government perform milestones in accordance with plan			
0007	Security Plan			
0008	Technical Progress Reports with Executive Summary			
0009	Earned Value Management (EVM) Data			
0010	Final Report			

B. OPTION PERIOD

CLIN	Deliverable	Estimated Cost	Fixed Fee	Extended CPFF
1001	Milestone 7. Option Period Contractor defined milestones. Contractor shall include plan with initial proposal and if acceptable to the government perform milestones in accordance with plan			
1002	Technical Progress Reports with Executive Summary			
1003	Earned Value Management (EVM) Data			
1004	Final Report			

C. FEE

Fixed fee shall be paid at a rate equal to __% of actual costs incurred each invoicing period. The balance, if any, of fixed fee is payable upon successful completion of all work. Nothing in this section alters the Government’s rights to withhold fee under FAR 52.216-8 Fixed Fee.

D. OPTION

The Government may require the delivery of the numbered line item, identified in the Schedule as an option item, in the quantity and at the price stated in the Schedule, and extend the term of the contract

to allow performance of that line item. The Contracting Officer may exercise the option by written notice to the Contractor no later than 30 days after expiration of the base period of performance.

ARTICLE B.3. ADVANCE UNDERSTANDINGS

Other provisions of this contract notwithstanding, approval of the following items within the limits set forth is hereby granted without further authorization from the Contracting Officer.

a. Man-in-Plant

With seven (7) days advance notice to the Contractor in writing from the Contracting Officer, the Government may place a man-in-plant in the Contractor's facility, who shall be subject to the Contractor's policies and procedures regarding security and facility access at all times while in the Contractor's facility. As determined by federal law, no Government representative shall publish, divulge, disclose, or make known in any manner, or to any extent not authorized by law, any information learned in the course of his/her official duties, while stationed in a Contractor plant. The man-in-plant may observe and provide technical direction on any activity within the Contract scope of work only.

b. Subcontracts and Consultants

Award of any FFP subcontract or FFP consulting agreement **in excess of \$150,000** or any flexibly priced subcontract or consulting agreement shall not proceed without the prior written consent of the Contracting Officer via a Contracting Officer Authorization (COA) Letter upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract or consulting agreement shall be provided to the Contracting Officer within ten (10) days.

c. Invoices - Cost and Personnel Reporting, and Variances from the Negotiated Budget

The Contractor agrees to provide a detailed breakdown on invoices of the following cost categories:

- a. Direct Labor - List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or % of effort), breakdown by task performed by personnel, and amount claimed.
- b. Fringe Benefits - Cite rate and amount
- c. Overhead - Cite rate and amount
- d. Materials & Supplies - Include detailed breakdown when total amount is greater than \$1,000.
- e. Travel - Identify travelers, dates, destination, purpose of trip, and amount. Cite COA, if appropriate. List separately domestic travel, general scientific meeting travel, and foreign travel.
- f. Consultant Fees - Identify individuals and amounts.
- g. Subcontracts - Attach Subcontractor invoice(s). Cite applicable COA or notification.
- h. Equipment - Cite authorization and amount.
- i. Other Direct Costs - Include detailed breakdown when total amount is greater than \$1,000.
- j. G&A - Cite rate and amount.
- k. Total Cost

Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government. In order to verify allowability, further breakdown of costs may be requested at the Government's discretion.

The Contractor agrees to immediately notify the Contracting Officer in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10 percent) of the amount allotted to the contract, and the reasons for the variance. Also refer to the requirements of the Limitation of Cost Clauses in the contract.

d. Confidential Treatment of Sensitive Information

The Contractor shall guarantee strict confidentiality of any information/data of a sensitive nature that is provided to the Contractor by the Government during the performance of the contract. The Government has determined that the information/data that the Contractor will be provided during the performance of the contract is of a sensitive nature.

Disclosure of information/data that is sensitive in nature, in whole or in part, by the Contractor can only be made after the Contractor receives prior written approval from the Contracting Officer. Whenever the Contractor is uncertain with regard to the proper handling of information/data under the contract, the Contractor shall obtain a written determination from the Contracting Officer. (See also HHSAR clause 352.224-70).

Notwithstanding the foregoing, such information/data shall not be deemed of a sensitive nature with respect to the Contractor for purposes of this contract if such information/data: (a) was already known to the Contractor; (b) was generally available or known, or was otherwise part of the public domain, at the time of its disclosure to the Contractor; (c) became generally available or known, or otherwise became part of the public domain, after its disclosure to, or, with respect to the information/data by, the Contractor through no fault of the Contractor; (d) was disclosed to the Contractor, other than under an obligation of confidentiality or non-use, by a third party who had no obligation to the Government that controls such information/data not to disclose such information/data to others; or (e) was independently discovered or developed by the Contractor, as evidenced by its written records, without the use of information/data belonging to the Government.

Contractor may disclose information/data of a sensitive nature provided by the Government to the extent that such disclosure is: (a) made in response to a valid order of a court of competent jurisdiction or other supra-national, federal, national, regional, state, provincial or local governmental or regulatory body of competent jurisdiction; provided, however, that the Contractor shall first have given notice to the Government and give the Government a reasonable opportunity to quash such order and to obtain a protective order requiring that the information/data of a sensitive nature that is the subject of such order be held in confidence by such court or agency or, if disclosed, be used only for the purposes for which the order was issued; and provided further that if a disclosure order is not quashed or a protective order is not obtained, the information/data disclosed in response to such court or governmental order shall be limited to that information which is legally required to be disclosed in response to such court or governmental order; (b) otherwise required by law, in the opinion of legal counsel to the Contractor as expressed in an opinion letter in form and substance reasonably satisfactory to the Government, which shall be provided to the Government at least two (2) business days prior to the Contractor's disclosure of the information/data; or (c) made by the Contractor to the Regulatory Authorities as required in connection with any filing, application or request for Regulatory Approval; provided, however, that reasonable measures shall be taken to assure confidential treatment of such information/data.

e. Reserved

f. Earned Value Management System (EVMS) Implementation Requirements

The Contractor and BARDA agree that the EVMS implementation requirements that are contained in this contract are limited to the implementation requirements outlined by the 7 Principles of Earned Value Management **Tier 2** System Implementation Intent Guide contained as an Attachment to the contract. The total amount of this contract reflects the use of the 7 Principles of EVMS Implementation. Any EVMS implementation requirements that are beyond the intent of the 7 Principles of EVMS Implementation shall not proceed until the Contracting Officer sends a written request for a proposal to the Contractor and a bilateral modification is issued to the contract for the purposes of incorporating the additional costs for the performance of these requirements into the contract.

g. **Overtime Compensation**

No overtime (premium) compensation is authorized under the subject contract.

h. **Establishment of Indirect Cost Rate**

(1) The Contractor may bill indirect costs at **temporary billing rates** in the following table until such time as approved indirect cost rates have been established. If the indirect cost proposal is not submitted in a timely manner, any temporary indirect costs billed after that due date will be suspended until such time as the indirect cost proposal is submitted.

(2) RATE TYPE BASE

i. **Contract Number Designation**

On all correspondence submitted under this contract, the Contractor agrees to clearly identify the contract number that appears on the face page of the contract.

ARTICLE B.4. PROVISIONS APPLICABLE TO DIRECT COSTS

a. **Items Unallowable Unless Otherwise Provided**

Notwithstanding the clause, ALLOWABLE COST AND PAYMENT, AND FIXED FEE incorporated in this contract, unless authorized in writing by the Contracting Officer, the costs of the following items or activities shall be unallowable as direct costs:

- (1) Conferences and Meetings;
- (2) Food for Meals, Light Refreshments, and Beverages;
- (3) Promotional Items [includes, but is not limited to: clothing and commemorative items such as pens, mugs/cups, folders/folios, lanyards, and conference bags that are sometimes provided to visitors, employees, grantees, or conference attendees.];
- (4) Acquisition, by purchase or lease, of any interest in real property;
- (5) Special rearrangement or alteration of facilities;
- (6) Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value. (General purpose equipment is defined as any items of personal property which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.);
- (7) Travel to attend general scientific meetings;

- (8) Foreign travel;
- (9) Reserved;
- (10) Reserved;
- (11) Reserved;
- (12) Accountable Government Property (defined as non-expendable personal property with an acquisition cost of \$1,000 or more and "sensitive items" (defined as items of personal property (supplies and equipment that are highly desirable and easily converted to personal use), regardless of acquisition value; and
- (13) Printing Costs (as defined in the Government Printing and Binding Regulations).

b. Travel Costs

- (1) Travel
 - (a) Total expenditures for travel (transportation, lodging, subsistence, and incidental expenses) incurred by the Prime Contractor in direct performance of this contract shall not exceed \$0.00 without the prior written approval of the Contracting Officer.
 - (b) Subject to the annual dollar limitation specified under B.3.b.1.a. above, the Contactor shall invoice and be reimbursed for all travel costs in accordance with Federal Acquisition Regulation (FAR) 31.2, Contracts with Commercial Organizations, Subsection 31.205-46, Travel Costs.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF OBJECTIVES

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government as needed to perform the Statement of Objectives set forth below.

a. Introduction.

The United States Department of Health and Human Services (DHHS), Office of the Assistant Secretary for Preparedness and Response (ASPR), Biomedical Advanced Research and Development Authority (BARDA) contemplates single or multiple awards of contracts or other transactional authority arrangements to develop more effective/ universal influenza vaccine candidates towards FDA licensure.

b. Background.

Disease caused by seasonal influenza and emerging/re-emerging pandemic influenza viruses is an ongoing and significant public health threat. Globally, seasonal influenza causes approximately three to five million cases of severe illness with approximately 250,000 to 500,000 deaths per year. Vaccination is currently the best way to prevent influenza associated illness. However, licensed seasonal influenza vaccines have variable efficacy, estimated between 30-70%, in healthy adults when the vaccine is well matched to circulating influenza viruses. As influenza viruses evolve rapidly to evade existing population immunity, these licensed influenza vaccines need to be updated on a yearly basis in order to prevent excess morbidity and mortality caused by influenza viruses.

BARDA's goals are to support the advanced development of influenza vaccines that are more effective compared to the currently licensed influenza vaccines, with a vision towards a truly universal influenza vaccine that elicit long-lasting broad spectrum protective immunity in humans against the widest range of antigenically divergent influenza strains across and within virus types and subtypes. BARDA anticipates that the more effective/universal influenza vaccine will become the cornerstone for pandemic influenza preparedness. This vaccine, in the face of a pandemic onset, should immunize, or at minimum prime, the population such that 1) protective or partially protective immunity pre-exists, and/or 2) a single booster of a pandemic vaccine will be sufficient to induce protective immunity against the pandemic virus threat.

These improved influenza vaccines will offer greater effectiveness over a wider array of strains across and within influenza virus types and subtypes, as well as and greater duration of protection over the currently licensed influenza vaccines. They will also have greater effectiveness in populations like the young, elderly, and immunocompromised which do not consistently respond well to the currently licensed influenza vaccines. More effective/universal influenza vaccine candidates capable of eliciting heterosubtypic immune responses will have all of these characteristics and show effectiveness against multiple influenza virus types and subtypes.

c. Applicable Documents. Reports / Policy Documents:

- *The National Strategy for Pandemic Influenza* (November 2005)
- Pandemic All-Hazard Preparedness Act of 2006 (PL109-417)
- Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (PL113-5)
- *Implementation Plan for the National Strategy for Pandemic Influenza* (May 2006)

- PCAST Report: *Reengineering the Influenza Vaccine Production Enterprise to Meet the Challenges of Pandemic Influenza* (August 2010)
- *Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Implementation Plan* (December 2012)

d. Scope and Requirements:

Independently and not as an agent of the government, the Contractor shall furnish all the necessary services, qualified personnel, materials, equipment, and facilities not otherwise provided by the government as needed to perform the work necessary to develop and file for license for an influenza vaccine candidate that meets at a minimum the primary attributes in the Target Product Profile (TPP) below.

1. Target Product Profile for More Effective/Universal Influenza Vaccines

The following table outlines the desired characteristics for the target product profile of universal influenza vaccine candidates. Initial evaluations will be based on the candidate's ability to meet the primary attributes of the Target Product Profile (TPP). The advanced development process will guide the vaccine candidate toward meeting both the desired primary and secondary attributes of the TPP

Property/Vaccine	Desired Primary Attributes
Breadth of Protection	<i>Protects against antigenically divergent influenza A viruses and viruses from both influenza B virus lineages</i>
Efficacy	<i>Shows 20% or greater efficacy above a licensed influenza vaccine comparator as measured by clinical endpoints or surrogate endpoints (e.g. seroprotection or seroconversion rates)</i>
Duration of Immunity	<i>Protects for two years or more against influenza A subtypes and influenza B lineages</i>
Priming Immunity	<i>Primes for baseline immunity such that a single dose of pandemic influenza vaccine will boost immune response to protective levels against the pandemic influenza virus</i>
Safety	<i>Comparable to licensed influenza vaccines</i>
	Desired Secondary Attributes
Age Indication	<i>6 months (or younger) and above</i>
Route of Administration	<i>Intramuscular, intradermal, intranasal, transdermal, oral Preference given to route of administration most easily executed during an emergency</i>
Manufacture to Release	<i>12 weeks</i>

The Contractor shall provide details of the activities necessary to fully develop their proposed influenza vaccine candidate. The Contractor's Work Plan (CWP) shall outline activities to be performed in the contract base and option period. Activities suitable for the 36 to 48 month base period of performance include process development, early process scale up activities, non-clinical and clinical evaluations of vaccine performance and regulatory activities to include an End-of-Phase 2 testing meeting with the FDA. The Contractor will be asked to test their proposed influenza vaccine candidate against US Government designated influenza virus panels for H1, H2, H3, H5, H7, H9 and B. The base period proposal should include contractor activities to do these evaluations. Activities suitable for the 36 to 60 month option period include final process scale up, process validation, assay validation, Phase

3 clinical testing and regulatory activities up to but not including submission of the Biological License Application (BLA) with the FDA. The work plan outlined by the Contractor for the project including options should not exceed nine years.

The Contractor may request funds for activities that could include manufacturing process development, analytical testing, production, clinical and assay development and evaluation of pilot and commercial scale lots of vaccine candidates using influenza virus genes or proteins (including, but not limited to, plasmid DNA, virus-vectors, peptides, subunit proteins, and virus-like particles). Funds may also be used for production scale-up development, equipment, and manufacturing facility design, however shall not be used for facility construction or regulatory filing fees.

The Contractor must meet the following milestones to properly detail their proposed development plan:

2. Base Period Milestones

Milestone 1: Within three (3) months of contract award, the Contractor shall provide to DHHS for review and acceptance a comprehensive milestone-driven Product Development Plan for an influenza vaccine candidate that addresses all aspects of the desired the TPP. The Plan must be inclusive of pre-clinical and clinical activities performed and completed prior to contract award and those clinical and manufacturing activities to be performed post-contract awarding. The Plan shall be a high-level overview and include the following:

- A. A Gantt chart timeline or equivalent.
- B. A description of the process development and scale-up of vaccine manufacturing.
- C. A description of clinical and consistency lot manufacturing for FDA product licensure.
- D. A description of the general clinical development plan including development and validation of clinical sample assays.
- E. A description of product lot release assay development including lot release product assay specifications and validation.
- F. A complete regulatory master plan that details the pathway to product licensure.

Milestone 2: Within six (6) months of contract award, the Contractor shall submit to DHHS for review and acceptance, a comprehensive, integrated Clinical Development and Regulatory/Quality Plan. The following issues shall be addressed in the Plan:

- A. All prior communications with Center for Biologics Evaluation and Research (CBER) at FDA should be incorporated as an appendix to the milestone report, including the original submission IND and all amendments.
- B. All prior pharmacovigilance communications with previous independent safety monitors (ISMs), safety monitoring committees (SMCs), and/or data safety monitoring boards (DSMBs) related to any Phase 1 or 2 trials for the vaccine candidate under contract should be incorporated as an appendix to the milestone report.

- C. A detailed description of clinical development shall be integrated with the manufacturing plans using the most current and available information including consultation with CBER. Clinical trials performed as a result of this solicitation shall include any clinical trials necessary to achieve U.S. licensure. Clinical trials should be designed to support licensure for both low and high-risk populations. Given the duration, cost, and importance of clinical trials, the plan for each clinical trial must clearly indicate key outcomes, populations, study sites and collaborators, analytic strategy, sample size, timelines, and other key components. Studies shall be included demonstrating where the proposed candidate meets one or more of the TPP desired primary criteria. A summary of all completed clinical trials and any additional stages of product development that have been completed should be incorporated as an appendix to the milestone report. Assays to measure immune response of human participants in the clinical trials should also be included as an appendix as well as proposed approaches for assay validation.
- D. 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 CBER. A risk assessment and mitigation plan addressing manufacturing, clinical and regulatory obstacles that may prevent or delay licensure must be included. Issues suitable for risk assessment include expression systems and cell lines, assay development, process yields and facility management. Mitigation plans should include decision trees where applicable.
- E. A detailed description of Quality Assurance and associated plans/activities, including organizational structure, master list of standard operating procedures (SOPs), quality management plan, internal quality audits/reviews for both product manufacturing and conduct/execution of clinical trials.

Milestone 3: Within six (6) months of contract award, the Contractor shall provide HHS for review and acceptance a Product Manufacturing and Quality Plan describing the raw materials, upstream, downstream, purification, inactivation (if applicable), formulation/fill/finish for drug substance and drug product at pilot and/or current scale production. The Plan shall contain appropriate information concerning the following elements:

- A. Characterization of cell substrate and other biological materials (ie raw materials) used in vaccine production, including details such as its origin, passage history, stability, results of adventitious agents testing
- B. Certificates of analysis for critical raw materials and QC testing that clears raw materials for use in production process, including chromatography columns used in the production process
- C. Characterization of source material such as virus reference strains and candidate vaccine viruses – information may be obtained through collaborating partners if necessary.
- D. A detailed description of manufacturing processes for Phase 1/2 studies, including Master Production Records and amendments (and other relevant SOPs) for drug substance (vaccine bulk) and drug product (final container)
 - i. Detailed information on GMP master and working cell banks
 - ii. Detailed information on GMP master and working viral banks
 - iii. Detailed information regarding host cell protein/DNA levels as well as the capacity of the production process to remove residual host cell protein/DNA and adventitious/extraneous agents should be incorporated as an appendix
 - iv. Viral inactivation information for any vaccine derived from viral seeds or viral vectors should be incorporated into the appendix as well.

- E. Detailed information regarding any in-process quality control testing and final container lot release testing protocols, including assay SOPs, and plans for assay validation.
- F. Detailed description on process for product manufacturing deviation investigations as well as subsequent corrective action/preventative action approaches for resolution
- G. Detailed information on any environmental testing to ensure that bioburden or cross-contamination is minimal and does not adversely impact product quality

Milestone 4: Within eighteen (18) months of contract award, the Contractor shall provide DHHS for review and acceptance all details related to the Manufacturing Facility Plan describing the Contractor's current or contract manufacturing (CMO) capabilities, or facility design, construction, commissioning (if applicable), and qualification/validation of the facilities (including domestic facilities) to produce, formulate, fill and finish the Contractor's influenza vaccine candidate. The Plan shall contain appropriate information concerning the following elements:

- A. Site selection criteria, including site user requirement specifications, descriptions of site utilities and infrastructure, descriptions of local, state and federal permitting issues and security planning considerations.
- B. A facility regulatory compliance plan that addresses cGMP standards, NIH, CDC, USDA and WHO biosafety standards, USDA animal testing standards, National Fire Protection Agency standards, DHS security issues and OSHA compliance.
- C. Full scale manufacturing processes that includes descriptions of upstream and downstream processing, formulation, filling and finishing unit operations, bulk and finished product acceptance specifications, overall capacity needed to meet contract requirements, manufacturing support operations such as solution preparation, storage and distribution, glassware 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. Master Production Records and amendments used for manufacturing drug substance and drug product should be incorporated as an appendix.
- D. Architectural/ structural plans that includes 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.
- E. Process and building/ mechanical engineering including energy balances, utility flow diagrams, automation plan, equipment lists and a preliminary layout.
- F. A proposed construction schedule including installation, commissioning and installation/operational/performance qualification and a risk mitigation analysis for planning purposes only.
- G. A description of the manufacturing facility quality assurance and regulatory acceptance including quality systems, the validation master plan and regulatory milestones.
- H. The manufacturing facility and process shall be maintained in compliance with current Good Manufacturing Practices, World Health Organization guidelines for pandemic influenza

vaccine manufacturing and current biosafety/research guidelines from the CDC, NIH, and the USDA.

Milestone 5: Within eighteen (18) months of contract award, the Contractor shall provide DHHS for review and acceptance a Product Feasibility Plan (also referred to as a Pandemic Product Plan) for technology transfers and/or to establish a domestic capability to manufacture the proposed influenza vaccine. The Plan should include the following elements:

- A. A process description, including a summary of process data that describes the yield and purification efficiencies of key process steps. Master Production Record for phase 3 trials (where appropriate), technology transfers and relevant subcontracts should be included as an appendices.
- B. Comparison of process data that describes the significance of process scale-up and variability on production capacity.
- C. Proposed schedules including detailed timelines for each step for production, targeting release of 50 million vaccine doses within 4 months of a pandemic declaration with first doses released within 12 weeks. A description of material management and the number of doses of vaccine released each week after pandemic declaration should be provided. A plan for the production and distribution of vaccine in the case of emergency use authorization shall be included.
- D. A bulk and fill-finish manufacturing capacity analysis.
- E. A description of process optimization activities.

Milestone 6: Base Period Contractor Defined Milestones. The Contractor shall provide a work breakdown structure including comprehensive and integrated timelines (Gantt chart) and major milestones to complete the remaining scope of work as relevant given the stage of vaccine development and evaluation toward product licensure. The Contractor shall propose milestones, at which time data will be presented, summarizing results of prior activities and new plans and protocols that will be submitted for review and approval in order to guide all subsequent activities. Potential milestones may include manufacturing of an investigational lot of vaccine, validation of facilities, systems and equipment, validation of Quality Control and product lot release methods, validation of manufacturing processes, stability study programs, consistency lot manufacturing, completion of a clinical trial and progress to a new phase of vaccine evaluation, submission of a license application, etc.

3. Option Period Milestones

Milestone 7: Option Period Contractor Defined Milestones. The Contractor shall provide a work breakdown structure including comprehensive and integrated timelines (Gantt chart) and major milestones to complete the scope of work as defined in the Options period and relevant to the stage of vaccine development and evaluation toward product licensure. The Contractor shall propose milestones, at which time data will be presented, summarizing results of prior activities and new plans and protocols that will be submitted for review and approval in order to guide all subsequent activities. Potential milestones may include (but not limited to) manufacturing of consistency lots of vaccine, validation of facilities, systems and equipment, validation of Quality Control and product lot release methods, validation of manufacturing processes, stability study programs, consistency lot

manufacturing, completion of Phase 3 studies and progress to a new phase of vaccine evaluation, submission of a license application, etc.

ARTICLE C.2. REPORTING REQUIREMENTS

All reports required herein shall be submitted in electronic format. In addition, one hardcopy of each report shall be submitted to the Contracting Officer.

All electronic reports submitted shall be compliant with Section 508 of the Rehabilitation Act of 1973. Additional information about testing documents for Section 508 compliance, including specific checklists, by application, can be found at: <http://www.hhs.gov/web/508/index.html> under "Helpful Resources."

All paper/hardcopy documents/reports submitted under this contract shall be printed or copied, double-sided, on at least 30 percent post consumer fiber paper, whenever practicable, in accordance with FAR 4.302(b).

a. Technical Reports

In addition to those reports required by the other terms of this contract, the Contractor shall prepare and submit the following reports in the manner stated below and in accordance with the DELIVERIES Article in SECTION F of this contract:

1. Monthly Progress Report

This report shall include a description of the activities during the reporting period, and the activities planned for the ensuing reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.

The Contractor shall submit a Monthly Progress Report according to the dates set forth in ARTICLE F.2 of this contract. The format should include:

A cover page that includes the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission; The progress report shall conform to the requirements set forth in the DELIVERIES Article in SECTION F of this contract.

- SECTION I – EXECUTIVE SUMMARY - The Executive Summary shall accompany each Technical Progress Report, be formatted as a Microsoft PowerPoint presentation, and include the following:
 - a. Title page containing Executive Title, the contract number and title, the period of performance or milestone being reported, the contractor's name and the date of submission.
 - b. Project Progress presented as milestone events, test results, tasks and other activities achieved during the reporting period as talking point bullets.
 - c. Project Issues presented headings and each item as a talking point bullet.
- SECTION II - PROGRESS
- SECTION II Part A: OVERALL PROGRESS - A description of overall progress.
- SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g., evaluating, and managing subcontractor performance, and personnel changes).
- SECTION II Part C: TECHNICAL PROGRESS - For each activity related to Gantt chart, document the results of work completed and cost incurred during the period covered in relation to proposed progress, effort and budget. The report shall be in sufficient detail to explain comprehensively the

results achieved. The description shall include pertinent data and/or graphs in sufficient detail to explain any significant results achieved and preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the contract. The report shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress, why the differences have occurred and what corrective actions are planned; preliminary conclusions resulting from analysis and scientific evaluation of data accumulated to date under the project.

- SECTION II Part D: PROPOSED WORK - A summary of work proposed related to Gantt chart for the next reporting period and preprints/reprints of papers and abstracts.

SECTION III: Earned Value Management Reporting: Contractor will provide a monthly Contract Performance Report (CPR) at an agreed upon reporting level (WBS level 3) using the BARDA provided WBS and a Variance Analysis Report. EVMS shall be applied to all Cost Plus Fixed Fee CLINs as part of the Integrated Master Project Plan following the Seven Principles of Earned Value Management. In accordance with FAR 52.215-2, Audit and Records-Negotiation, BARDA may request, on a quarterly or ad hoc basis that the Contractor provide raw data. BARDA may request additional data at a reporting level or at lower levels, as BARDA deems necessary.

2. Reserved

3. Draft Final Technical Progress Report and Final Technical Progress Report

These reports are to include a summation of the work performed and results obtained for the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Draft Final Report and Final Report shall be submitted in accordance with the DELIVERIES Article in SECTION F of the contract. The Draft Final Technical Progress Report and the Final Technical Progress Report shall be submitted in accordance with the dates set forth in ARTICLE F.2 of this contract. The report shall conform to the following format:

1. Cover page to include the contract number, contract title, performance period covered, Contractor's name and address, telephone number, fax number, email address and submission date.
2. SECTION I: EXECUTIVE SUMMARY - Summarize the purpose and scope of the contract effort including a summary of the major accomplishments relative to the specific activities set forth in the Statement of Work.
3. SECTION II: RESULTS - A detailed description of the work performed related to the Gantt chart, the results obtained, and the impact of the results on the scientific and/or public health community including a listing of all manuscripts (published and in preparation) and abstracts presented during the entire period of performance and a summary of all inventions.

Draft Technical Progress Report: The Contractor is required to submit the Draft Final Technical Progress Report to the Contracting Officer's Representative and Contracting Officer. The Contracting Officer's Representative and Contracting Officer will review the Draft Final Technical Progress Report and provide the Contractor with comments in accordance with the dates set forth in ARTICLE F.2 of this contract.

Final Technical Progress Report: The Contractor shall deliver the final version of the Final Technical Progress Report in accordance with the dates set forth in ARTICLE F.2 of this contract. The final version shall include or address the Contracting Officer's Representative comments and Contracting Officer comments on the draft report.

4. Summary of Salient Results

The Contractor shall submit, with the Final Report, a summary of salient results achieved during the performance of the contract.

5. Report on Select Agents or Toxins and/or Highly Pathogenic Agents

For work involving the possession, use, or transfer of a Select Agent or Toxin and/or a Highly Pathogenic Agent, the following information shall also be included in each Monthly Progress Report:

1. Any changes in the use of the Select Agent or Toxin including initiation of "restricted experiments," and/or a Highly Pathogenic Agent, that have resulted in a change in the required biocontainment level, and any resultant change in location, if applicable, as determined by the IBC or equivalent body or institutional biosafety official.
2. If work with a new or additional Select Agent or Toxin and/or a Highly Pathogenic Agent will be conducted in the upcoming reporting period, provide:
 - a. A list of each new or additional Select Agent or Toxin and/or a Highly Pathogenic Agent that will be studied;
 - b. A brief description of the work that will be done with each new or additional Select Agent or Toxin and/or a Highly Pathogenic Agent and whether or not the work is a Select Agent or Toxin restricted experiment as defined in the Select Agents Regulation 42 CFR Part 73, Section 13.b (<http://www.selectagents.gov/Regulations.html>);
 - c. The name and location for each biocontainment resource/facility, including the name of the organization that operates the facility, and the biocontainment level at which the work will be conducted, with documentation of approval by your IBC or equivalent body or institutional biosafety official. It must be noted if the work is being done in a new location or different location.
 - d. For work with Select Agents performed in the U.S., provide documentation of registration status and inspectional reports/outcomes for all domestic organizations where Select Agent(s) will be used. For work with Select Agents performed in a non-U.S. country prior BARDA approval is required.

If the IBC or equivalent body or institutional biosafety official has determined, for example, by conducting a risk assessment, that the work that has been performed or is planned to be performed under this contract may be conducted at a biocontainment safety level that is lower than BSL3, a statement to that affect shall be included in each Monthly Progress Report.

If no work involving a Select Agent or Toxin and/or a Highly Pathogenic Agent has been performed or is planned to be performed under this contract, a statement to that affect shall be included in each Monthly Progress Report.

- b. Reports shall be sent in accordance with SECTION D.

ARTICLE C.3. INVENTION REPORTING REQUIREMENT

All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification, shall be directed to the Division of Extramural Inventions and Technology Resources (DEITR), OPERA, OER, NIH, 6705 Rockledge Drive, Suite 310, MSC 7980, Bethesda, Maryland 20892-7980 (Telephone: 301-435-1986). In addition, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. The final invention statement (see FAR27.303(b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

The annual utilization report shall be submitted in accordance with the DELIVERIES Article in SECTION F of this contract. The final invention statement (see FAR 27.303(b)(2)(ii)) shall be submitted on the expiration date of the contract. All reports shall be sent to the following address:

Contracting Officer
HHS/ASPR/AMCG
330 Independence Avenue, S.W.
Room G644
Washington, D.C. 20201

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

SECTION D - PACKAGING, MARKING AND SHIPPING

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

Unless otherwise specified by the Contracting Officer or the Contracting Officer's designee, delivery of reports to be furnished to the Government under this contract shall be addressed as follows:

- a) Contracting Officer's Representative
- b) Contracting Officer

SECTION E - INSPECTION AND ACCEPTANCE

- a. The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided.
- b. For the purpose of this SECTION, the BARDA Contracting Officer's Representative (COR) is the authorized representative of the Contracting Officer (CO). The COR will assist in resolving technical issues that arise during performance. The COR is not authorized to change any contract terms or authorize any changes in Statement of Work, modify or extend period of performance, or authorize reimbursement of any costs incurred during performance.
- c. Inspection and acceptance will be performed at:

Department of Health & Human Services
Office of the Assistant Secretary for Preparedness and Response
Biomedical Advanced Research and Development Authority
Office of Acquisition Management, Contracts & Grants
330 Independence Avenue,
S.W. Room 644G
Washington, D.C. 20201
- d. This contract incorporates the following clause by reference, with the same force and effect as if it were given in full text. Upon request, the CO will make its full text available.

FAR Clause No.52.246-9, INSPECTION OF RESEARCH AND DEVELOPMENT (SHORT FORM) (APR 1984)

SECTION F - DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

- a. The period of performance of this contract shall begin on the **Date in Block 20C** and end on _____.

ARTICLE F.2. DELIVERIES

Satisfactory performance of the final contract shall be deemed to occur upon performance of the work described in the Statement of Work Article in SECTION C of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule:

- a. The items specified below as described in the REPORTING REQUIREMENTS Article in SECTION C of this contract will be required to be delivered F.o.b. Destination as set forth in FAR 52.247-35, F.o.b. DESTINATION, WITHIN CONSIGNEES PREMISES (APRIL 1984), and in accordance with and by the date(s) specified below:

Item Description	Delivery Date	Deliver To
<i>Initial Project Management Deliverables</i>		
1. Performance Measurement Baseline Package	60 days after award effective date	CO via email
2. Risk Register	60 days after award effective date	
<i>Monthly Deliverables</i>		
1. Technical Progress Report in the format requested by the Contracting Officer describing project progress over the previous month	The 15 th of each month of Contract performance	CO and COR via e-mail and FedEx/UPS. Additionally, email invoices to PSC_Invoices@psc.hhs.gov
2. EV-CPR, Format 1, Format 5, and Supplemental CAP Report, and Integrated Master Schedule in MS excel and .xml export of the raw EVMS data out of their EVMS database	The 15 th of each month of Contract performance	
3. Monthly Conference Call Minutes	Within 10 days following each conference call	
4. Monthly Invoices	Within 60 days of the end of each month	
<i>Periodic or As-Necessary Deliverables</i>		
1. Study Documents for each clinical trial	No later than 10 days before submission to the FDA	CO and COR via e-mail and, if requested, CD-ROM
2. Formal FDA Submissions of any kind pertaining to the scope of the project as necessary during Contract performance	No later than 10 days before submission to the FDA	
3. Memo with Date and Time of Scheduled Meetings with FDA	As soon as possible after scheduling	

4. Minutes for Formal Meetings with FDA	Within 48 hrs of receipt from FDA	
5. Raw Data and Analysis Pertaining to Scope of the Project Generated Using USG Funds	Within a reasonable time after request	CO via method requested
6. Regulatory or Legal Strategies Pertaining to Scope of the Project	Within a reasonable time after request	CO via method requested
7. Draft Final Report	No later than 45 days prior to contract expiration	CO and COR via e-mail
8. Final Report	No later than contract expiration	CO and COR via e-mail
9. Publications/Presentations	No later than 30 days before submission for publications and 15 days for presentations	CO and COR via e-mail
9. Technology Transfer Procedure Documents	Within a reasonable time after request	CO and COR via e-mail

CLINs

	Deliverable	Due Date	Quantity
0001.	Milestone 1. Product Development plan	Three (3) months after contract award.	Original – CO 2 Copies – COR 1 Electronic Copy – COR
0002.	Milestone 2. Clinical Development and Regulatory/Quality Plan.	Six (6) months after contract award.	Original – CO 2 Copies – COR 1 Electronic Copy – COR
0003.	Milestone 3. Product Manufacturing Plan including Master Production Record of drug substance and drug product planned for Phase 2 studies	Six (6) months after contract award.	Original – CO 2 Copies – COR 1 Electronic Copy – COR
0004.	Milestone 4. Manufacturing Facility Plan describing the design, construction, commissioning, qualification and validation of a US-based facility.	Within eighteen (18) months after contract award.	Original – CO 2 Copies – COR 1 Electronic Copy – COR

0005.	Milestone 5. Production Feasibility Plan (also referred to as the Pandemic Production Plan) to manufacture, test and release finish up to 50 million doses of vaccine within 16 weeks, first doses within 12 weeks. Activities that support this Plan, including tech transfers and subcontracts should be included as appendices.	Within eighteen (18) months after contract award.	Original – CO 2 Copies – COR 1 Electronic Copy – COR
0006.	Milestone 6. Contractor defined milestones. Contractor shall include plan with initial proposal and if acceptable to the government perform milestones in accordance with plan.	Performance of Contractor Defined Milestones within (TBD by contract award) months after contract award.	Original – CO 2 Copies – COR 1 Electronic Copy – COR
0007.	Security Plan	Final within 30 days of receipt of comments on the draft plan.	Original – CO 1 Copy – COR 1 Copy – Security 1 Electronic Copy – COR
0008.	Technical Progress Reports with Executive Summary	Monthly	Original – CO 2 Copies – COR 1 Electronic Copy – COR
0009.	EVM data	Monthly	Electronic copy – CO and COR
0010.	Final Report	One report by end of base period	Original – CO 2 Copies – COR 1 Electronic Copy – COR
1001.	Milestone 7. Contractor defined milestones. Contractor shall include plan with initial proposal and if acceptable to the government perform milestones in accordance with plan	Performance of Contractor Defined Milestones within (TBD by contract award) months after option period award.	Original – CO 2 Copies – COR 1 Electronic Copy – COR
1002.	Technical Progress Reports with Executive Summary	Monthly	Original – CO 2 Copies – COR 1 Electronic Copy – COR
1003.	Earned Value Management (EVM) Data	Monthly	Electronic copy – CO and COR

1004.	Final Report	One report by end of Option period	Original – CO 2 Copies – COR 1 Electronic Copy – COR
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b. The above items shall be addressed and delivered in accordance with SECTION D.

ARTICLE F.4. CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

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

FEDERAL ACQUISITION REGULATION (48 CFR CHAPTER 1) CLAUSE:

52.242-15, Stop Work Order (AUGUST 1989) with ALTERNATE I (APRIL 1984).

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER (CO)

The following Contracting Officer (CO) will represent the Government for the purpose of this contract:

Contracting Officer
HHS/ASPR/AMCG
330 Independence Avenue, S.W.
Room G644
Washington, D.C. 20201

E-mail:

- 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 the 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 reimburse to the Contractor of any costs incurred during the performance of this contract; (5) otherwise change any terms and conditions of this contract.
- 3) No information, which may be received from any person employed by the US Government, or otherwise, shall be considered grounds for deviation from any stipulation of this contract, unless it is information which may be contained in an authorized modification to this contract, duly issued by the Contracting Officer.
- 4) The Government may unilaterally change its Contracting Officer's Representative designation.

ARTICLE G.2. CONTRACTING OFFICER'S REPRESENTATIVE (COR)

The following Contracting Officer's Representative (COR) will represent the Government for the purpose of this contract:

Contracting Officer's Representative
HHS/ASPR/BARDA
330 Independence Avenue, S.W.
Room G644
Washington, D.C. 20201

E-mail:

The COR 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) Assisting the Contracting Officer in interpreting the statement of work and any other technical performance requirements;
- 3) Performing technical evaluation as required;
- 4) Performing technical inspections and acceptances required by this contract; and
- 5) Assisting in the resolution of technical problems encountered during performance.

The Contracting Officer is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of work; (2)

modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; or (5) otherwise change any terms and conditions of this contract.

The Government may unilaterally change its COR designation.

ARTICLE G.3. KEY PERSONNEL

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to diverting any of the specified individuals to other programs or contracts (or as soon as possible, if an individual must be replaced, for example, as a result of leaving the employ of the Contractor), the Contractor shall notify the Contracting Officer and shall submit comprehensive justification for the diversion or replacement request (including proposed substitutions for key personnel and CVs or any additional information the Contracting Officer requires) to permit evaluation by the Government of the impact on performance under this contract. The Contractor shall not divert or otherwise replace any key personnel without the written consent of the Contracting Officer. The Government may modify the contract to add or delete key personnel at the request of the Contractor or Government.

The following individuals are considered to be essential to the work being performed hereunder:

1. Principal Investigator
2. Program Manager
3. Production Director Upstream
4. Production Director Downstream
5. Formulation Director
6. Fill/Finish Director
7. Quality Assurance Director
8. Regulatory Director
9. Clinical Director

ARTICLE G.4. INVOICE SUBMISSION/CONTRACT FINANCING REQUEST

- a. The Payment requests shall be submitted to the offices identified below. Submit supporting documentation (e.g., receipts, time sheets, vendor invoices, etc.) with your payment request unless otherwise specified elsewhere in the contract or requested by the Contracting Officer.
- b. The original invoice shall be submitted to the following approving official:
Contracting Officer
- c. The Contractor shall submit an electronic copy of the payment request to the approving official. The payment request shall be transmitted as an attachment via e-mail to the address listed above in one of the following formats: MSWord, MS Excel, or Adobe Portable Document Format (PDF). Only one payment request shall be submitted per e-mail and the subject line of the e-mail shall include the Contractor's name, contract number, and unique invoice number.
[Note: The original payment request must still be submitted in hard copy and mailed to the approving official to meet the requirements of a "proper invoice."]
- d. Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government.
- e. In addition to the requirements specified in FAR 32.905 for a proper invoice, the Contractor shall include the

following information on the face page of all payment requests:

1. Federal Taxpayer Identification Number (TIN). If the Contractor does not have a valid TIN, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. [Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.] If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.
 2. DUNS or DUNS+4 Number. The DUNS number must identify the Contractor's name and address exactly as stated in the contract and as registered in the System for Award Management (SAM) database. If the Contractor does not have a valid DUNS number, it shall identify the Vendor Identification Number (VIN) on the payment request. The VIN is the number that appears after the Contractor's name on the face page of the contract. [Note: A VIN is assigned to new contracts awarded on or after June 4, 2007, and any existing contract modified to include the VIN number.] If the Contractor has neither a TIN, DUNS, or VIN, contact the Contracting Officer.
 3. Invoice Matching Option. This contract requires a **three-way match**.
 4. Unique Invoice Number. Each payment request must be identified by a unique invoice number, which can only be used one time regardless of the number of contracts or orders held by an organization.
- f. Inquiries regarding payment of invoices shall be directed to the approving official.

ARTICLE G.5. RESERVED

ARTICLE G.6. REIMBURSEMENT OF COST

- 1) The Government shall reimburse the Contractor the cost determined by the Contracting Officer to be allowable (hereinafter referred to as allowable cost) in accordance with the clause entitled Allowable Cost and Payment in Section I, Contract Clauses, and FAR Subpart 31.7. Examples of allowable costs include, but are not limited to, the following:
 - a) All direct materials and supplies that are used in the performing of the work provided for under the contract, including those purchased for subcontracts and purchase orders.
 - b) All direct labor, including supervisory, that is properly chargeable directly to the contract, plus fringe benefits.
 - c) All other items of cost budgeted for and accepted in the negotiation of this basic contract or modifications thereto.
 - d) Travel costs including per diem or actual subsistence for personnel while in an actual travel status in direct performance of the work and services required under this contract subject to the following:
 - i. Air travel shall be by the most direct route using "air coach" or "air tourist" (less than first class) unless it is clearly unreasonable or impractical (e.g., not available for reasons other than avoidable delay in making reservations, would require circuitous routing or entail additional expense offsetting the savings on fare, or would not make necessary connections).
 - ii. Rail travel shall be by the most direct route, first class with lower berth or nearest equivalent.
 - iii. Costs incurred for lodging, meals, and incidental expenses shall be considered reasonable and allowable to the extent that they comply with FAR 31.7.

- iv. Travel via privately owned automobile shall be reimbursed at not more than the current General Services Administration (GSA) FTR established mileage rate.

ARTICLE G.7. GOVERNMENT PROPERTY

- a. In addition to the requirements of the clause, GOVERNMENT PROPERTY, incorporated in SECTION I of this contract, the Contractor shall comply with the provisions of HHS Publication, "HHS Contracting Guide for Contract of Government Property," which is incorporated into this contract by reference. This document can be accessed at: http://www.hhs.gov/hhsmanuals/logisticsmanual/Appendix Q_HHS Contracting Guide.pdf

Among other issues, this publication provides a summary of the Contractor's responsibilities regarding purchasing authorizations and inventory and reporting requirements under the contract.

Requests for information regarding property under this contract should be directed to the Contracting Officer.

- b. Notwithstanding the provisions outlined in the HHS Publication, "HHS Contracting Guide for Contract of Government Property," which is incorporated in this contract in paragraph a. above, the Contractor shall use the form entitled, "Report of Government Owned, Contractor Held Property" for submitting summary reports required under this contract, as directed by the Contracting Officer or his/her designee. This form is included as an attachment in SECTION J of this contract.

ARTICLE G.8. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

- a. Contractor Performance Evaluations

Interim and final evaluations of Contractor performance will be prepared on this contract in accordance with FAR Subpart 42.15.

- b. Electronic Access to Contractor Performance Evaluations

Contractors may access evaluations through a secure Web site for review and comment at the following address: <http://www.cpars.gov>

SECTION H - SPECIAL CONTRACT REQUIREMENTS

ARTICLE H.1. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4 (January 2006)

- a. The Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Contractor's current Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.
- b. The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in a proper manner and as safely as is feasible. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. The Contractor shall not deem anything in this contract to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor 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 Contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.
- c. If at any time during the performance of this contract, the Contracting Officer determines, in consultation with OHRP that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation 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, after consultation with OHRP, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those contractors with approved Human Subject Assurances.

ARTICLE H.2. RESERVED

ARTICLE H.3. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE)

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

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

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

required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310).

ARTICLE H.4. NEEDLE DISTRIBUTION

The Contractor shall not use contract funds to carry out any program of distributing sterile needles or syringes for the hypodermic injection of any illegal drug.

ARTICLE H.5 RESERVED

ARTICLE H.6. RESTRICTION ON ABORTIONS

The Contractor shall not use contract funds for any abortion.

ARTICLE H.7. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

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

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

ARTICLE H.8. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

The Contractor shall not use contract funds to disseminate information that is deliberately false or misleading.

ARTICLE H.9. ACCESS ELECTRONIC AND INFORMATION TECHNOLOGY ACCESSIBILITY, HHSAR 352.239-73(b) (January 2010)

- a. Pursuant to Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998, all electronic and information technology (EIT) products and services developed, acquired, maintained, or used under this contract/order must comply with the "Electronic and Information Technology Accessibility Provisions" set forth by the Architectural and Transportation Barriers Compliance Board (also referred to as the "Access Board") in 36 CFR part 1194. Information about Section 508 provisions is available at <http://www.section508.gov/> . The complete text of Section 508 Final provisions can be accessed at <http://www.access-board.gov/sec508/provisions.htm> .
- b. The Section 508 standards applicable to this contract/order are identified in the [Statement of Work/Specification/Performance Work Statement]. The Contractor must provide a written Section 508 conformance certification due at the end of each contract/order exceeding \$100,000 when the contract/order duration is one year or less. If it is determined by the Government that EIT products and services provided by the Contractor do not conform to the described accessibility standards in the Product Assessment Template, remediation of the products or services to the level of conformance specified in the Contractor's Product Assessment Template will be the responsibility of the Contractor at its own expense.
- c. In the event of a modification(s) to this contract/order, which adds new EIT products or services or revises the type of, or specifications for, products or services the Contractor is to provide, including EIT deliverables such as electronic documents and reports, the Contracting Officer may require that the Contractor submit a

completed HHS Section 508 Product Assessment Template to assist the Government in determining that the EIT products or services support Section 508 accessibility standards. Instructions for documenting accessibility via the HHS Section 508 Product Assessment Template may be found under Section 508 policy on the HHS Office on Disability Web site (<http://www.hhs.gov/od/>).

[(End of HHSAR 352.239-73(b))]

- d. Prior to the Contracting Officer exercising an option for a subsequent performance period/additional quantity or adding funding for a subsequent performance period under this contract, as applicable, the Contractor must provide a Section 508 Annual Report to the Contracting Officer and Project Officer. Unless otherwise directed by the Contracting Officer in writing, the Contractor shall provide the cited report in accordance with the following schedule. Instructions for completing the report are available in the Section 508 policy on the HHS Office on Disability Web site under the heading Vendor Information and Documents. The Contractor's failure to submit a timely and properly completed report may jeopardize the Contracting Officer's exercising an option or adding funding, as applicable.

Schedule for Contractor Submission of Section 508 Annual Report: To be included annually in the Monthly Report or with the Final Reports.

[(End of HHSAR 352.239-73(c))]

ARTICLE H.10 RESERVED

ARTICLE H.11. INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST

The Institution (includes any contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position, who is responsible for the design, conduct, or reporting of research funded under DHHS contracts, or proposed for such funding, which may include, for example, collaborators or consultants) will not be biased by any Investigator financial conflicts of interest. 45 CFR Part 94 is available at the following Web site: <http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?c=ecfr&rgn=div5&view=text&node=45:1.0.1.1.52&idno=45>

As required by 45 CFR Part 94, the Institution shall, at a minimum:

- a. Maintain an up-to-date, written, enforceable policy on financial conflicts of interest that complies with 45 CFR Part 94, inform each Investigator of the policy, the Investigator's reporting responsibilities regarding disclosure of significant financial interests, and the applicable regulation, and make such policy available via a publicly accessible Web site, or if none currently exist, available to any requestor within five business days of a request. A significant financial interest means a financial interest consisting of one or more of the following interests of the Investigator (and those of the Investigator's spouse and dependent children) that reasonably appears to be related to the Investigator's institutional responsibilities:
1. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure and the value of any equity interest in the entity as of the date of disclosure, when aggregated, exceeds \$5,000. Included are payments and equity interests;
 2. With regard to any non-publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the twelve months preceding the disclosure, when aggregated, exceeds \$5,000, or when the Investigator (or the Investigator's spouse or dependent children) holds any

equity interest; or

3. Intellectual property rights and interests, upon receipt of income related to such rights and interest.

Significant financial interests do not include the following:

1. salary, royalties, or other remuneration paid by the Institution to the Investigator if the Investigator is currently employed or otherwise appointed by the Institution, including intellectual property rights assigned to the Institution and agreements to share in royalties to relate to such rights;
 2. Any ownership interest in the Institution held by the Investigator;
 3. Income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes with an Institution of higher learning; and
 4. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.
- b. Require each Investigator to complete training regarding the Institution's financial conflicts of interest policy prior to engaging in research related to any DHHS-funded contract and at least every four years. The Institution must take reasonable steps [see Part 94.4(c)] to ensure that investigators working as collaborators, consultants or subcontractors comply with the regulations.
 - c. Designate an official(s) to solicit and review disclosures of significant financial interests from each Investigator who is planning to participate in, or is participating in, the DHHS-funded research.
 - d. Require that each Investigator who is planning to participate in the DHHS-funded research disclose to the Institution's designated official(s) the Investigator's significant financial interest (and those of the Investigator's spouse and dependent children) no later than the date of submission of the Institution's proposal for DHHS-funded research. Require that each Investigator who is participating in the DHHS-funded research to submit an updated disclosure of significant financial interests at least annually, in accordance with the specific time period prescribed by the Institution during the period of the award as well as within thirty days of discovering or acquiring a new significant financial interest.
 - e. Provide guidelines consistent with the regulations for the designated official(s) to determine whether an Investigator's significant financial interest is related to DHHS-funded research and, if so related, whether the significant financial interest is a financial conflict of interest. An Investigator's significant financial interest is related to DHHS-funded research when the Institution, through its designated official(s), reasonably determines that the significant financial interest: Could be affected by the DHHS-funded research; or is in an entity whose financial interest could be affected by the research. A financial conflict of interest exists when the Institution, through its designated official(s), reasonably determines that the significant financial interest could directly and significantly affect the design, conduct, or reporting of the DHHS-funded research.
 - f. Take such actions as necessary to manage financial conflicts of interest, including any financial conflicts of a subcontractor Investigator. Management of an identified financial conflict of interest requires development and implementation of a management plan and, if necessary, a retrospective review and mitigation report pursuant to Part 94.5(a).
 - g. Provide initial and ongoing FCOI reports to the Contracting Officer pursuant to Part 94.5(b).
 - h. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures, and all actions under the Institution's policy or retrospective review, if applicable, for at least 3 years from the date of final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

- i. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.
- j. Complete the certification in Section K - Representations, Certifications, and Other Statements of Offerors entitled "Certification of Institutional Policy on Financial Conflicts of Interest."

If the failure of an Institution to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the DHHS-funded research, the Institution must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will consider the situation and, as necessary, take appropriate action or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the DHHS-funded research project.

The Contracting Officer and/or HHS may inquire at any time before, during, or after award into any Investigator disclosure of financial interests, and the Institution's review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interests. The Contracting Officer may require submission of the records or review them on site. On the basis of this review of records or other information that may be available, the Contracting Officer may decide that a particular financial conflict of interest will bias the objectivity of the DHHS-funded research to such an extent that further corrective action is needed or that the Institution has not managed the financial conflict of interest in accordance with Part 94.6(b). The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that DHHS-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was managed or reported by the Institution, the shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

ARTICLE H.12. PUBLICATION AND PUBLICITY

In addition to the requirements set forth in HHSAR Clause **352.227-70, Publications and Publicity** incorporated by reference in SECTION I of this contract, 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 [insert Contract No.]."

Any manuscript or scientific meeting abstract containing data generated under this contract must be provided to BARDA prior to submission.

Contracting Officer's Representative review will have no less than thirty (30) calendar days for manuscripts and fifteen (15) calendar days for abstracts for public presentation or publication. Contract support shall be acknowledged in all such publications. A "publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information.

ARTICLE H.13. 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 DHHS Inspector General's Office in writing or on the Inspector General's Hotline. The toll free number is **1-800-HHS-TIPS (1-800-447-8477)**. All telephone calls will be handled confidentially. The e-mail address is Htips@os.dhhs.gov and the mailing address is:

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

ARTICLE H.14. HIGHLY PATHOGENIC AGENTS

The work being conducted under this contract may involve a Highly Pathogenic Agent (HPA). The NIAID defines an HPA as a pathogen that, under any circumstances, warrants a biocontainment safety level of BSL3 or higher according to either:

1. The current edition of the CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL) and can be accessed at <http://www.cdc.gov/OD/ohs/biosfty/bmbl5/bmbl5toc.htm>
2. The Contractor's Institutional Biosafety Committee (IBC) or equivalent body, or
3. The Contractor's appropriate designated institutional biosafety official, and
4. Documentation of compliance with CDC and USDA Select Agent Programs, where appropriate, for example in the case of testing with highly pathogenic avian influenza viruses (e.g. H5N1 and H7N9).

If there is ambiguity in the BMBL guidelines and/or there is disagreement among the BMBL, an IBC or equivalent body, or institutional biosafety official, the highest recommended containment level must be used.

ARTICLE H.15. HOTEL AND MOTEL FIRE SAFETY ACT OF 1990 (P.L. 101-391)

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

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

ARTICLE H.16. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

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

ARTICLE H.17. USE OF FUNDS FOR PROMOTIONAL ITEMS

The Contractor shall not use contract funds to purchase promotional items. Promotional items include, but are not limited to: clothing and commemorative items such as pens, mugs/cups, folders/folios, lanyards, and conference bags that are sometimes provided to visitors, employees, grantees, or conference attendees. This includes items or tokens given to individuals as these are considered personal gifts for which contract funds may not be expended.

ARTICLE H.18. REVIEW OF PRESS RELEASES

The contractor agrees to accurately and factually represent the work conducted under the contract in all press releases. Misrepresenting contract results or releasing information that is injurious to the integrity of BARDA may be construed as improper conduct. Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. The contractor shall ensure that the CO and COR have received an advance copy of any press release related to the contract not less than five (5) working days prior to the issuance of the press release.

ARTICLE H.19. PRIVACY ACT APPLICABILITY

1. Notification is hereby given that the Contractor and its employees are subject to criminal penalties for violation of the Privacy Act to the same extent as employees of the Government. The Contractor shall assure that each of its employees knows the prescribed rules of conduct and that each is aware that he or she can be subjected to criminal penalty for violation of the Act. A copy of 45 CFR Part 5b, Privacy Act Regulations, may be obtained at <http://www.gpoaccess.gov/cfr/index.html>
2. The COR is hereby designated as the official who is responsible for monitoring contractor compliance with the Privacy Act.
3. The Contractor shall follow the Privacy Act guidance as contained in the Privacy Act System of Records number **09-25-0200**. This document may be obtained at the following link: <http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm>

ARTICLE H.20. 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.

ARTICLE H.21. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5(b) (October 2009)

- a. Before undertaking performance of any contract involving animal-related activities where the species is regulated by USDA, the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR sections 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.
- b. The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR Sections 2.1-2.11, or from a source that is exempt from licensing under those sections.
- c. The Contractor agrees that the care, use and intended use of any live vertebrate animals in the performance of this contract shall conform with the Public Health Service (PHS) Policy on Humane Care of Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC) 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 1-4). In case of conflict between standards, the more stringent standard shall govern.

- d. 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 (a) through (c) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the
- e. 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 Assurances.

Note: The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region 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 the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (E-mail: ace@aphis.usda.gov); Web site: (http://www.aphis.usda.gov/animal_welfare).

ARTICLE H.22. ANIMAL WELFARE

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). The PHS Policy can be accessed at: <http://grants1.nih.gov/grants/olaw/references/phspol.htm>

ARTICLE H.23. SECURITY

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 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, and if changes are required, 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 Contracting Officer and Contracting Officer's Representative 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 when requested by BARDA after contract award. The Contractor shall ensure that the storage, generation, transmission or exchanging of BARDA sensitive information has the appropriate security controls in place. At a minimum, the Final Security Plan shall address the following items:

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.

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; firewalls, 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:

Security Reporting Requirement - Violations of established security protocols shall be reported to the Contracting Officer (CO) and Contracting Officer's Representative (COR) upon discovery within 24 hours of its receipt of any compromise, intrusion, loss or interference of its security processes and procedures. The Contractor shall ensure that all software components that are not required for the operation and maintenance of the database/control system have been removed and/or disabled. The Contractor shall provide to the CO and the COR information appropriate to Information and Information Technology software and service updates and/or workarounds to mitigate all vulnerabilities associated with the data and shall maintain the required level of system security.

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. The Contracting Officer in coordination with BARDA will determine the severity of the violation. Any contractual actions resulting from the violation will be determined by the Contracting Officer.

ARTICLE H.24. CLINICAL RESEARCH

These Clinical Terms apply to all grants and contracts that involve clinical research.

The Government shall have unlimited rights to all protocols, data generated from the execution of these protocols, and final reports, funded by the Government under this contract, as defined in Rights in Data Clause in FAR 52.227-14. The Government reserves the right to request that the Contractor provide any contract deliverable in a non-proprietary form, to ensure the Government has the ability to review and distribute the deliverables, as the Government deems necessary.

ARTICLE H.25. SAFETY AND MONITORING ISSUES

Institutional Review Board (IRB) or Independent Ethics Committee (IEC) Approval

Before award and then with the annual progress report, the Contractor must submit to the Government a copy of the current IRB or IEC approved informed consent document, documentation of continuing review and approval and the Office of Human Research Protections (OHRP) FWA number for the institution or site.

If other institutions are involved in the research (e.g., a multicenter clinical trial or study), each institution's IRB or IEC must review and approve the protocol. They must also provide the Government initial and annual documentation of continuing review and approval, including the current approved informed consent document and FWA number.

The grantee institution must ensure that the applications as well as all protocols are reviewed by their IRB or IEC.

To help ensure the safety of participants enrolled in BARDA-funded studies, the Contractor must provide the Government a summary explanation and copies of documents related to all major changes in the status of ongoing protocols, including the following:

1. All amendments or changes to the protocol, identified by protocol version number, date, or both and date it is valid.
2. All changes in informed consent documents, identified by version number, date, or both and dates it is valid.
3. Termination or temporary suspension of patient accrual.
4. Termination or temporary suspension of the protocol.
5. Any change in IRB approval.
6. Any other problems or issues that could affect the participants in the studies.

Contractors must notify BARDA through the Contracting Officer's Representative (COR) or Contracting Officer (CO) of any of the above changes within 24 hours by email, followed by a letter signed by the institutional business official, detailing notification of the change of status to the local IRB and a copy of any responses from the IRB or IEC.

If a clinical protocol has been reviewed by an Institutional Bio-safety Committee (IBC) or the NIH Recombinant DNA Advisory Committee (RAC), the Contractor must provide information about the initial and ongoing review and approval, if any. See the NIH Guidelines for Research Involving Recombinant DNA Molecules.

ARTICLE H.26. DATA AND SAFETY MONITORING REQUIREMENTS

The Contractor may be required to conduct independent safety monitoring for clinical trials of investigational drugs, devices, or biologics; clinical trials of licensed products; and clinical research of any type involving more than minimal risk to volunteers. Independent monitoring can take a variety of forms. Phase III clinical trials must have an assigned independent data and safety monitoring board (DSMB); other trials may require DSMB oversight as well. The Contractor shall inform the Government of any upcoming site visits and/or audits of Contractor facilities funded under this effort. BARDA reserves the right to accompany the Contractor on site visits and/or audits of Contractors and Subcontractors as the Government deems necessary.

The type of monitoring to be used shall be mutually agreed upon between the Contractor and the Government before enrollment starts. Discussions with the responsible BARDA COR regarding appropriate safety monitoring and approval of the final monitoring plan by BARDA must occur before patient enrollment begins and may include discussions about the appointment of one of the following:

1. **Independent Safety Monitor (ISM)** – a physician or other appropriate expert who is independent of the study and available in real time to review and recommend appropriate action regarding adverse events and other safety issues.
2. **Independent Monitoring Committee (IMC) or Safety Monitoring Committee (SMC)** – a small group of independent investigators and biostatisticians who review data from a particular study.
3. **Data and Safety Monitoring Board (DSMB)** – an independent committee charged with reviewing safety and trial progress and providing advice with respect to study continuation, modification, and termination. The Contractor may be required to use an established BARDA DSMB or to organize an independent DSMB. All phase III clinical trials must be reviewed by a DSMB; other trials may require DSMB oversight as well. Please refer to: NIAID Principles for Use of a Data and Safety Monitoring Board (DSMB) For Oversight of Clinical Trials Policy. The Government retains the right to place a nonvoting member on the DSMB.

When a monitor or monitoring board is organized, a description of it, its charter or operating procedures (including a proposed meeting schedule and plan for review of adverse events), and roster and *curriculum vitae* from all members must be submitted to and approved by the Government before enrollment starts.

Additionally, the Contractor must submit written summaries of all reviews conducted by the monitoring group to the Government within 30 days of reviews or meetings.

ARTICLE H.27. BARDA PROTOCOL REVIEW PROCESS BEFORE PATIENT ENROLLMENT BEGINS

BARDA has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in BARDA-supported clinical trials. Therefore, before patient accrual or participant enrollment, the Contractor must provide the following (as applicable) for review and approval by the Government:

1. IRB or IEC approved clinical research protocol identified by version number, date, or both, including details of study design, proposed interventions, patient eligibility, and exclusion criteria.
2. Documentation of IRB or IEC approval, including OHRP FWA number, IRB or IEC registration number, and IRB or IEC name.
3. IRB or IEC approved informed consent document, identified by version number, date, or both and date it is valid.
4. Plans for the management of side effects.
5. Procedures for assessing and reporting adverse events.
6. Plans for data and safety monitoring, and monitoring of the clinical study site, pharmacy, and laboratory.
7. Documentation that the Contractor and all study staff responsible for the design or conduct of the research have received Good Clinical Practice (GCP) training in the protection of human subjects.

BARDA comments will be forwarded to the Contractor within two weeks (10 business days) of receipt of the above information. The Contractor must address in writing all study design, safety, regulatory, ethical, and conflict of interest concerns raised by the BARDA COR to the satisfaction of the Government before patient accrual or participant enrollment can begin. After the Government receives the corrected documentation, a written Contract Officer Authorization (COA) Letter will be provided to the Contractor. This COA provides authorization to the Contractor to execute the specific clinical study funded in part or in whole by the Government.

ARTICLE H.28. REQUIRED TIME SENSITIVE NOTIFICATION

Under the contract, the Contractor must submit to the Contracting Officer's representative (COR) as follows:

1. *Expedited safety report of unexpected or life-threatening experience or death* – A copy of any report of unexpected or life-threatening experience or death associated with the use of an IND drug, which must be reported to FDA by telephone or fax as soon as possible but no later than seven days after the IND sponsor's receipt of the information, must be submitted within 24 hours of the occurrence of the event.
2. *Expedited safety reports of serious and unexpected adverse experiences* – A copy of any report of unexpected and serious adverse experience associated with use of an IND drug or any finding from tests in laboratory animals that suggests a significant risk for human subjects, which must be reported in writing to FDA as soon as possible but no later than 15 days after the IND sponsor's receipt of the information, must be submitted to the BARDA Contracting Officer's Representative within 24 hours of the occurrence of the event.
3. *IDE reports of unanticipated adverse device effect* – A copy of any reports of unanticipated adverse device effect submitted to FDA must be submitted to the BARDA Contracting Officer's Representative within 24

hours of the occurrence of the event.

4. *Expedited safety reports* – should be sent to the BARDA COR concurrently with the report to FDA.
5. Other adverse events documented during the course of the trial should be included in the annual IND or IDE report and reported to the BARDA annually.

In case of problems or issues, the BARDA COR will contact the Contractor within 10 working days by email, followed within 7 calendar days by an official letter to the Contractor. The Contractor shall forward the official letter to the principal investigator listing issues and appropriate actions to be discussed.

In a future task order where BARDA is not the IND sponsor, the reporting requirements would be defined accordingly.

Safety reporting for research not performed under an IND or IDE

Ongoing safety reporting requirements for research not performed under an IND or IDE shall be mutually agreed upon by the BARDA Contracting Officer's Representative and the Contractor.

ARTICLE H.29. BARDA CLINICAL TRIAL DATABASE INFORMATION REPORTING

The contractor must be prepared to provide initial information on each clinical study conducted under this contract to BARDA. Study specific information is required at study start-up and regular updates on site by site enrollment will be required. Study specific information may include phase of study, ages of subjects being study, number of subjects planned, estimated start and completion dates, subcontractor information and role on study, clinical site information. Clinical site information may include site Principal Investigator, location, FWA number and expiration date, certification of site human subjects training as required by OHRP.

Updated information on enrollment will include site by site enrollment including the number of subjects screened, enrolled (dosed), withdrew, and completed. Enrollment information will be provided on a regular basis as determined by BARDA prior to study start.

PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

ARTICLE I.1. GENERAL CLAUSES FOR A COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available. Also, the full text of a clause may be accessed electronically as follows: FAR Clauses at: <https://www.acquisition.gov/far/> HHSAR Clauses at: <http://www.hhs.gov/policies/hhsar/subpart352.html>.

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

<u>FAR CLAUSE NO.</u>	<u>DATE</u>	<u>TITLE</u>
52.202-1	Nov 2013	Definitions
52.203-3	Apr 1984	Gratuities
52.203-5	May 2014	Covenant Against Contingent Fees
52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government
52.203-7	May 2014	Anti-Kickback Procedures
52.203-8	May 2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity
52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity
52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions
52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper
52.204-7	Jul 2013	System for Award Management
52.204-10	Jul 2013	Reporting Executive Compensation and First-Tier Subcontract Awards
52.204-13	Jul 2013	System for Award Management Maintenance
52.209-6	Aug 2013	Protecting the Government's Interests When Subcontracting With Contractors Debarred,
52.215-2	Oct 2010	Audit and Records - Negotiation [Note: Applies to ALL contracts funded in whole or in part with Recovery Act funds, regardless of dollar value, AND contracts over the Simplified Acquisition Threshold funded exclusively with non-Recovery Act funds.]
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Aug 2011	Price Reduction for Defective Certified Cost or Pricing Data
52.215-12	Oct 2010	Subcontractor Cost or Pricing Data
52.215-14	Oct 2010	Integrity of Unit Prices
52.215-15	Oct 2010	Pension Adjustments and Asset Reversions
52.215-18	Jul 2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data - Modifications
52.215-23	Oct 2009	Limitations on Pass-Through Charges
52.216-7	Jun 2013	Allowable Cost and Payment
52.216-8	Jun 2011	Fixed Fee
52.216-12	Apr 1984	Cost Sharing Contract – No Fee
52.217-8	Nov 1999	Option to Extend Services
52.219-8	May 2014	Utilization of Small Business Concerns
52.219-9	Jul 2013	Small Business Subcontracting Plan
52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan
52.219-28	Jul 2013	Post-Award Small Business Program Rerepresentation

52.222-2	Jul 1990	<i>Payment for Overtime Premium (Over the Simplified Acquisition Threshold) (Note: The dollar amount in paragraph (a) of this clause is \$0 unless otherwise specified in the contract.)</i>
52.222-3	Jun 2003	<i>Convict Labor</i>
52.222-21	Feb 1999	<i>Prohibition of Segregated Facilities</i>
52.222-26	Mar 2007	<i>Equal Opportunity</i>
52.222-35	Jul 2014	<i>Equal Opportunity for Veterans</i>
52.222-36	Jul 2014	<i>Affirmative Action for Workers with Disabilities</i>
52.222-37	Jul 2014	<i>Employment Reports on Veterans</i>
52.222-40	Dec 2010	<i>Notification of Employee Rights Under the National Labor Relations Act (Over the Simplified Acquisition Threshold)</i>
52.222-50	Feb 2009	<i>Combating Trafficking in Persons</i>
52.222-54	Aug 2013	<i>Employment Eligibility Verification</i>
52.223-6	May 2001	<i>Drug-Free Workplace</i>
52.223-18	Aug 2011	<i>Encouraging Contractor Policies to Ban Text Messaging While Driving</i>
52.225-13	Jun 2008	<i>Restrictions on Certain Foreign Purchases</i>
52.227-1	Dec 2007	<i>Authorization and Consent, Alternate I (Apr 1984)</i>
52.227-2	Dec 2007	<i>Notice and Assistance Regarding Patent and Copyright Infringement</i>
52.227-11	May 2014	<i>Patent Rights - Ownership by the Contractor (Note: In accordance with FAR 27.303(b)(2), paragraph (e) is modified to include the requirements in FAR 27.303(b)(2)(i) through (iv). The frequency of reporting in (i) is annual.)</i>
52.227-14	May 2014	<i>Rights in Data – General, Alternate II (Dec 2007): Insert in para. (g)(3)(b)(i) “Use (except for manufacture) by support service contractors.”</i>
52.230-2	May 2014	<i>Cost Accounting Standards</i>
52.230-6	Jun 2010	<i>Administration of Cost Accounting Standards</i>
52.232-9	Apr 1984	<i>Limitation on Withholding of Payments</i>
52.232-17	May 2014	<i>Interest</i>
52.232-20	Apr 1984	<i>Limitation of Cost</i>
52.232-23	May 2014	<i>Assignment of Claims</i>
52.232-25	Jul 2013	<i>Prompt Payment, Alternate I (Feb 2002)</i>
52.232-33	Jul 2013	<i>Payment by Electronic Funds Transfer—System for Award Management</i>
52.233-1	May 2014	<i>Disputes</i>
52.233-3	Aug 1996	<i>Protest After Award, Alternate I (Jun 1985)</i>
52.233-4	Oct 2004	<i>Applicable Law for Breach of Contract Claim</i>
52.242-1	Apr 1984	<i>Notice of Intent to Disallow Costs</i>
52.242-3	May 2014	<i>Penalties for Unallowable Costs</i>
52.242-4	Jan 1997	<i>Certification of Final Indirect Costs</i>
52.242-13	Jul 1995	<i>Bankruptcy</i>
52.243-2	Aug 1987	<i>Changes - Cost Reimbursement, Alternate V (Apr 1984)</i>
52.244-2	Oct 2010	<i>Subcontracts, Alternate I (June 2007)</i>
52.244-5	Dec 1996	<i>Competition in Subcontracting</i>
52.244-6	Jul 2014	<i>Subcontracts for Commercial Items</i>
52.245-1	Apr 2012	<i>Government Property</i>
52.245-9	Apr 2012	<i>Use and Charges</i>
52.246-23	Feb 1997	<i>Limitation of Liability</i>
52.249-6	May 2004	<i>Termination (Cost-Reimbursement)</i>
52.249-14	Apr 1984	<i>Excusable Delays</i>
52.253-1	Jan 1991	<i>Computer Generated Forms</i>

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

<u>HHSAR CLAUSE NO.</u>	<u>DATE</u>	<u>TITLE</u>
352.202-1	Jan 2006	Definitions - with Alternate paragraph (h) (Jan 2006)
352.203-70	Mar 2012	Anti-Lobbying
352.216-70	Jan 2006	Additional Cost Principles
352.222-70	Jan 2010	Contractor Cooperation in Equal Employment Opportunity Investigations
352.227-70	Jan 2006	Publications and Publicity
352.228-7	Dec 1991	Insurance - Liability to Third Persons
352.233-71	Jan 2006	Litigation and Claims
352.242-70	Jan 2006	Key Personnel
352.242-73	Jan 2006	Withholding of Contract Payments
352.242-74	Apr 1984	Final Decisions on Audit Findings

ARTICLE I.2 AUTHORIZED SUBSTITUTION OF CLAUSES

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

This contract incorporates the following clauses by reference, with the same force and effect, as if they were given in full text. Upon request, the contracting officer will make their full text available.

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

- (1) FAR Clause **52.203-13, Contractor Code of Business Ethics and Conduct** (April 2010).
- (2) FAR Clause **52.203-14, Display of Hotline Poster(s)** (December 2007).
".....(3) Any required posters may be obtained as follows:

Poster(s)	Obtain From"
DHHS Contractor Code of Ethics and Business Conduct Poster	http://oig.hhs.gov/fraud/report-fraud/OIG_Hotline_Poster.pdf

- (3) FAR Clause **52.210-1, Market Research** (April 2011)..
- (4) FAR Clause **52.215-17, Waiver of Facilities Capital Cost of Money** (October 1997).
- (5) FAR Clause **52.219-28, Post-Award Small Business Program Rerepresentation** (April 2012).
- (6) Reserved
- (7) FAR Clause **52.242-3, Penalties for Unallowable Costs** (May 2001).
- (8) FAR Clause **52.247-63, Preference for U.S. Flag Air Carriers** (June 2003).
- (9) FAR Clause **52.251-1, Government Supply Sources** (April 2012).

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

Full text of these clauses can be found at <http://edocket.access.gpo.gov/2009/E9-26948.htm>

- (1) HHSAR Clause 352.201-70, Paperwork Reduction Act (January 2006).
- (2) HHSAR Clause 352.223-70, Safety and Health (January 2006).

- (3) HHSAR Clause 352.231-70, Salary Rate Limitation (August 2012).
Note: The Salary Rate Limitation is at the Executive Level II Rate.

See the following Web site for Executive Schedule rates of pay: <http://www.opm.gov/oca/>.

(For current year rates, click on Salaries and Wages/Executive Schedule/Rates of Pay for the Executive Schedule. For prior year rates, click on Salaries and Wages/select Another Year at the top of the page/Executive Schedule/Rates of Pay for the Executive Schedule. Rates are effective January 1 of each calendar year unless otherwise noted.)

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

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

This contract incorporates the following clauses in full text.

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

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

- a. Reserved
- b. HHSAR Clause 352.237-73, Non-Discrimination in Service Delivery (March 2012).

It is the policy of the Department of Health and Human Services that no person otherwise eligible will be excluded from participation in, denied the benefits of, or subjected to discrimination in the administration of DHHS programs and services based on non-merit factors such as race, color, national origin, religion, sex, gender identity, sexual orientation, or disability (physical or mental). By acceptance of this contract, the Contractor agrees to comply with this policy in supporting the program and in performing the services called for under this contract. The Contractor shall include this clause in all sub-contracts awarded under this contract for supporting or performing the specified program and services. Accordingly, the Contractor shall ensure that each of its employees, and any sub-contractor staff, is made aware of, understands, and complies with this policy.

PART III**SECTION J – LIST of ATTACHMENTS**

The following documents are attached and incorporated in this contract:

1. Past Performance Questionnaire
2. Reserved
3. Safety and Health, HHSAR Clause 352.223-70, (1/06), 2 pages.
4. Disclosure of Lobbying Activities, SF-LLL, dated 7/97, 2 pages.
5. Report of Government Owned, Contractor Held Property, dated 3/2008, 1 page. Located at: <http://oamp.od.nih.gov/DGS/FORMS/Govt-Owned-Prop.pdf>.
6. Earned Value Management Reports
7. Seven Principals of Earned Value Management Tier 2 System Implementation Guide, 26 pages.

PART IV

SECTION K - REPRESENTATIONS AND CERTIFICATIONS

ARTICLE K.1 INCORPORATED BY REFERENCE

The following documents are incorporated by reference in this contract:

1. Annual Representations and Certifications completed and located at The System for Acquisition Management (SAM) website (<http://www.sam.gov>).
2. Human Subjects Assurance Identification Numbers
3. Animal Welfare Assurance Number

ARTICLE K.2 SYSTEM FOR AWARD MANAGEMENT

The System for Award Management (SAM) is the Official U.S. Government system that consolidated the capabilities of CCR/FedReg, ORCA, and EPLS.

Prospective contractors shall be registered in the SAM database at <https://www.sam.gov> prior to submission of an initial offer.

ARTICLE K.3 ANNUAL REPRESENTATIONS AND CERTIFICATIONS

- (a) FAR 52.204-8 Annual Representations and Certifications (Dec 2014) is incorporated into and made a part of this solicitation.
- (b) FAR 52.204-8(a)(1) insert the North American Industry classification System (NAICS) code for this acquisition is 541711, Research and Development in Biotechnology.
- (c) FAR 52.204-8(a)(2) insert the small business size standard is 500 employees.
- (d) FAR 52.204-8(c)(2) insert no checked paragraphs.
- (e) Prospective contractors shall complete electronic annual representations and certifications at SAM accessed via <https://www.sam.gov> as a part of required registration.
- (f) The contracting officer will incorporate the representations and certifications by reference in the contract.

SECTION L – INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

ARTICLE L.1 **52.252-1 SOLICITATION PROVISIONS INCORPORATED BY REFERENCE (FEB 1998)**

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

<http://www.acquisitions.gov>

<i>Provision</i>	<i>Date</i>	<i>Title</i>
FAR 52.204-7	Jul 2013	System for Award Management
FAR 52.215-1	Jan 2004	Instructions to Offerors -- Competitive Acquisition
FAR 52.215-6	Oct 1997	Place of Performance
FAR 52.215-8	Oct 1997	Order of Precedence -- Uniform Contract Format
FAR 52.215-16	Jun 2003	Facilities Capital Cost of Money
FAR 52.215-20	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data
FAR 52.215-22	Oct 2009	Limitations on Pass-Through Charges – Identification
FAR 52.215-16	Jun 2003	Facilities Capital Cost of Money
FAR 52.217-5	Jul 1990	Evaluation of Options
FAR 52.222-22	Feb 1999	Previous Contracts and Compliance Reports
FAR 52.222-24	Feb 1999	Pre-award On-Site Equal Opportunity Compliance Evaluation, (Over \$10,000,000)
FAR 52.222-25	Apr 1984	Affirmative Action Compliance
HHSAR 352.215-70	Jan 2006	Late Proposals and Revisions
HHSAR 352.270-5	Jan 2006	Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals

ARTICLE L.2 **ADDITIONAL CONTRACT PROVISIONS – FULL TEXT**

FAR 52.216-1 Type of Contract (APR 1984)

The Government contemplates award of a Cost plus Fixed Fee contract or an other transactional authority agreement resulting from this solicitation.

FAR 52.233-2 Service of Protest (Sep 2006)

(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 Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from both Kevin.Nilles@hhs.gov and a Fed Ex/UPS delivery to the address for receipt of proposals.

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

ARTICLE L.3 SUBCONTRACTING PLAN

The apparently successful offeror must submit an acceptable subcontracting plan prior to award. If the apparently successful offeror fails to negotiate a subcontracting plan acceptable to the contracting officer within the time limit prescribed by the contracting officer, the offeror will be ineligible for award. However, a subcontracting plan is not required from a small business concern.

Each offeror, except small business concerns, shall submit a subcontracting plan with the initial offer. The offeror shall use the template at <http://www.hhs.gov/asfr/ogapa/osbdu/Small%20Business/subcontractplan.html>.

The offeror should submit subcontracting goals as follows:

Small Business: 33%
 Small Disadvantaged Business: 5%
 WOSB: 5%
 HUBZone: 3%
 SDVOSB: 3%
 VOSB: 3%

ARTICLE L.4 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.

ARTICLE L.5 COMMUNICATIONS PRIOR TO CONTRACT AWARD

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

ARTICLE L.6 SUBCONTRACTING

Offerors may identify tasks 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.

ARTICLE L.7 PAST PERFORMANCE INFORMATION

Offerors shall submit the following information as part of initial proposals for both the prime contractor and proposed major subcontractors:

For contracts of a similar scale and scope, the Contractor shall provide a list of the last three (3) contracts completed during the past three (3) years and all contracts currently in process. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments, or commercial customers.

For each contract, please provide

- a. Name of Contracting Organization
- b. Contract Number
- c. Total Contract Value
- d. Description of Requirement to include performance period
- e. Contracting Officer's name, email and telephone number
- f. Statement from the Contractor as to why this contract is relevant to our project.

In addition to the above information, the Offeror shall cause the customer/reference to submit to the Government a completed questionnaire for each of the contracts listed (See Attachments for letter/questionnaire). **It is the responsibility of the Offeror to ensure the questionnaires are delivered *directly from the reference to the Government.***

All questionnaires shall be submitted to Matthew.McCord@hhs.gov no later than the closing date and time for proposals.

The Government reserves the right not to consider any past performance questionnaires that are received after the due date or by means other than email.

The Government reserves the right to consider past performance information from any source.

ARTICLE L.8 ORAL PRESENTATIONS

All Contractors will be required to participate in an oral presentation as part of their technical evaluation and mandatory criteria evaluation. The slides that will be used in the presentation shall be included under a separate section in the Technical Proposal. The Contractors will not be able to deviate from these slides although they can elaborate verbally during their presentations. Any new slides or changes to a slide presented at the oral presentation that were not included with the Contractor's original Technical Proposal will not be permitted. The presentation shall cover the following items:

- Capabilities on Mandatory Criteria
- Demonstration of how their proposal meets the Government's SOO

While there is no limitation to the number of slides that can be presented, there is a time limitation. All Contractors will have no more than 60 minutes to present the items listed above. The purpose of this presentation is for the USG to have clear understanding of the Contractor's proposed capabilities. The presentation will end after 60 minutes regardless of whether the Contractor has completed their slide presentation.

The CO will provide at least one week advanced notice of the date and time Contractors are scheduled to present. The CO will determine the order in which Contractors are scheduled. Each Contractor will be permitted to have no more than five (5) participants due to space limitation. Requests to reschedule will be at the discretion of the CO. Each oral presentation may be videotaped. If the presentations are videotaped, a copy of only the Contractor's presentation will be made available to the Contractor.

Oral presentations are considered part of the Contractor's technical proposal and mandatory criteria proposal, as applicable. The proceedings will be formal and structured, consisting of a 60 minute timed presentation by the Contractor. Clarification questions (not proposal discussions) may be asked by the Technical Evaluation Panel at the conclusion of each oral presentation. The total amount of time allocated to each Oral Presentation shall be 90 minutes (60 minutes presentation by Contractor and 30 minutes of clarification questions).

ARTICLE L.9 PROPOSAL INSTRUCTIONS**(a) General**

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 solicitation.

The Proposal must contain a statement to the effect that it is firm for a period of at least 120 days from the date of receipt by the Government.

(b) Delivery

Proposals shall be delivered only by FedEx or UPS to the following address (hand delivery is not permissible):

Matthew McCord
ASPR – AMCG – 202-260-0689
200 C St SW
Washington DC 20024

(c) Volumes and Submission

Your proposal shall have three separate volumes:

1. Mandatory Criteria proposal
2. Technical proposal
3. Business proposal

Hard Copies

Volumes 1, 2, and 3 shall be in separate three-ring binders with tabbed divider pages separating each section.

Submit a total of six (6) hard copies of Volume 1.

Submit a total of six (6) hard copies of Volume 2.

Submit a total of two (2) hard copies of Volume 3.

Electronic Copies

Volumes 1 and 2 shall be in a single thumb/flash drive.

Volume 3 shall be in a separate single thumb/flash drive.

Submit a total of two (2) thumb/flash drives containing the combined Volumes 1 and 2.

Submit a total of two (2) thumb/flash drives containing the separate Volume 3.

All electronic copies shall be in MS Office 2010 or Adobe Acrobat 11 format.

(d) Formatting

Proposals shall be typewritten, paginated, and shall be legible in all required copies.

Proposals shall be prepared on 8½ x 11 inch paper except for foldouts used for charts, tables or figures, Process Flow Diagrams (PFD) or other detailed design drawings, which shall not exceed 11 x 17 inches. Foldouts shall not be used for text, and shall count as two pages.

A page is defined as one side of an 8 ½ by 11 inch paper. Therefore, a piece of paper with printing on both sides is considered two pages.

Text shall be printed using a font size no less than 12 dpi.

Page margins shall be a minimum of one inch top, bottom and each side.

(e) Content

No cost/price data shall be included in VOLUME I or II.

Cover pages, tables of contents, and blank dividers do not count against the page limitations.

Pages shall be numbered consecutively starting with page 1, encompassing the entire submission, including appendices.

VOLUME I- MANDATORY CRITERIA PROPOSAL

The mandatory criteria proposal shall consist of a cover page, a table of contents, and the information required to address the corresponding evaluation criterion.

The mandatory criteria proposal comprises two sections: (1) Mandatory Criteria Plan and (2) Oral presentation slides covering both Mandatory Criteria and Technical Evaluation Criteria.

The page count of the Mandatory Criteria Plan shall not exceed 50 pages; in the event a Contractor exceeds the 50 page limitation, the Government will evaluate only the first 50 pages of the proposal. The oral presentation slides have no page limit, but are time-limited to what may be presented during the 60 minute presentation.

In the Mandatory Criteria Plan, the Offeror shall discuss in detail how each aspect of the Mandatory Criteria is satisfied.

For the Oral Presentation slides, see the Article entitled “Oral Presentations” for more information.

VOLUME II- TECHNICAL EVALUATION PROPOSAL

The technical proposal shall consist of a cover page, a table of contents, and the information required to address the corresponding evaluation criteria. All appendices shall be noted in the Table of Contents.

The technical proposal comprises two sections: (1) Work Plan and (2) Appendices.

The Work Plan shall not exceed 100 pages. The Appendices shall not exceed 500 pages in total. In the event a Contractor exceeds the page limitations, the Government will not evaluate the excess pages of the proposal.

In the Work Plan, the Offeror shall discuss in detail how each aspect of the Statement of Objectives is to be accomplished.

In the Appendices, the Offeror shall provide information necessary to support the Work Plan, including, without limitation, information such as CVs, regulatory documents, study reports, facilities information, scientific data, etc.,

as requested in Section M, Criterion 3, or as applicable. Additionally, a Work Breakdown Structure to level 3 is required to be provided in an Appendix.

Section M, Criterion 3, Technical Evaluation, describes more fully under the headings "Offeror Instructions" what should be presented in the Work Plan and Appendices.

The Offeror's technical proposal should be in as much detail as necessary to fully explain the proposed technical approach. 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 the ability to understand and manage key deliverables and tasks.

Offerors must prepare their technical proposals in a format that directly corresponds to the requirements listed in the SOO and the Evaluation Factors, and should provide an index that cross-links the proposal with the SOO and Evaluation Factors.

VOLUME III- BUSINESS PROPOSAL

The business proposal shall consist of a cover page, a table of contents, cost or pricing data, additional information necessary to determine responsibility and a fair and reasonable price, Small Disadvantaged Business Plan, Past Performance information, and Small Business Subcontracting Plan (if applicable).

For instructions on submitting cost or pricing data, Offerors shall see FAR 52.215-20 Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data (Oct 2010).

Offerors must submit any information reasonably required to explain the estimating process, including the judgmental factors applied and the mathematical or other methods used in the estimate, including those used in projecting from known data.

Offerors must submit cost-element breakdowns for each proposed line item, and for the contract in total.

If you have reached an agreement with Government representatives on use of forward pricing rates, identify the agreement, include a copy, and describe its nature.

As soon as practicable after final agreement on price or an earlier date agreed to by the parties, but before the award resulting from the proposal, you must, under the conditions stated in FAR 15.406-2, submit a Certificate of Current Cost or Pricing Data.

The Offeror must demonstrate that it has the necessary financial capacity, working capital, and other resources to perform the contract. In addition to the submission of financial statements, this includes submission of information regarding available line of credit, bonding capability/information, and available plant and facilities for contract performance.

SECTION M – EVALUATION FACTORS FOR AWARD

(1) Basis of Award

Selection of all Contractors for contract awards will be based on an evaluation of proposals against the Factors in this section. The non-cost factors in descending order of importance are: Mandatory criteria, Technical criteria, Past Performance, and Small Disadvantaged Business (SDB) participation. In addition, prior to award, the Contractor's proposal must be considered acceptable for use in human subjects and animal welfare. Contractors 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 which is required. The trade off process described in FAR 15.101-1 may be employed. This process permits tradeoffs among cost/price and non-cost factors and allows the Government to consider award(s) to other than the lowest priced or highest technically rated Contractor. In any case, the Government reserves the right to make an award(s) to that Contractor whose proposal provides the best overall value to the Government. In the case of multiple awards, the Government will make its determination of best overall value to the Government by considering, as a part of its award determination, different technological capabilities that best satisfies the Government's overarching technological capability needs.

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 and confidence ratings of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements of the RFP. Each Contractor must submit a proposal that separately and sufficiently addresses evaluation criteria specified below as they relate to the Statement of Objectives and delivery requirements.

The Contracting Officer intends to evaluate proposals and make an award without discussions. However, the Government reserves the right to conduct discussions if it is determined to be in the best interest of the Government. Therefore, Contractors are encouraged to ensure that initial proposals contain the Contractor's most favorable terms and reflect its best possible performance potential.

Pre-Award Survey and/or Site-Inspections.

The Government reserves the right to conduct announced pre-award survey and/or site inspection of the Contractor's or subcontractors' facilities, production capabilities, financial capabilities, accounting system, management systems, safety program, and quality assurance systems. Findings from any pre-award survey will be considered in determining the Contractor's responsibility in accordance with FAR Subpart 9.1. The purpose of the pre-award survey and/or site-inspection will be to supplement the Government's evaluation of the Contractor's proposal. The results will be incorporated in the overall evaluation of the Contractor's proposal for use in the source selection decision. By submission of a proposal, an Contractor authorizes such pre-award survey and/or site-inspection deemed appropriate by the Government.

Subcontracting Plan

For a Contractor (other than a small business concern) to be selected for award, the Subcontracting Plan required by FAR 52.219-9 must be acceptable prior to contract award.

(2) Mandatory Criteria.

The Offeror shall provide information demonstrating their eligibility in one clearly marked section of their proposal.

The term 'Offeror' is defined as follows: 1) a single, fully integrated and independent pharmaceutical company; 2) partnership of a prime Contractor with legitimate subsidiary or corporate partner that performs U.S.-based vaccine manufacturing and/or clinical studies; 3) a teaming arrangement with the Offeror as the prime Contractor partnered with subcontractors such as contract manufacturing organizations (CMOs) and/or contract research organizations (CROs) as members that perform U.S.-based biopharmaceutical product development, manufacturing, and/or clinical trials.

The term 'candidate' is defined as but not limited to: 1) a single antigen or set of antigens formulated into a non-adjuvanted or adjuvanted vaccine or series of vaccines; 2) a vector, virus or DNA expressing an immunogen(s) or a combination of vectors, viruses or DNAs expressing an immunogen(s); and 3) combinations of formulated antigens/adjuvants, vectors/viruses expressing immunogens and/or DNAs expressing immunogens.

The mandatory eligibility criteria must be met at time of proposal submission. The minimum mandatory eligibility criteria are as follows:

1. Evidence of Greater Cross-reactive Immune Responses to the Proposed Influenza Vaccine Candidate

The Offeror must provide proof-of-concept data from *in vitro* and relevant animal studies supporting the ability of the candidate vaccine intended for clinical development to elicit greater cross-reactive immune responses compared to U.S.-licensed influenza vaccines against antigenically diverse influenza A viruses. For example, candidate vaccine will show cross-clade immunity within a subtype (e.g. H5 or H3) and/or cross-subtype immunity (e.g. against both H1 and H5 viruses).

2. Demonstration of Advanced Development of the Proposed Influenza Vaccine Candidate

The Offeror must demonstrate significant progress towards advanced development of the proposed influenza vaccine candidate by completion of a Phase 1 dose-ranging clinical study that shows the vaccine candidate is well tolerated and able to induce cross-reactive immune responses to a range of antigenically divergent influenza viruses. This is to be documented by submission of a final clinical study report for the Phase 1 study, as well as any supportive clinical data.

3. Plans for U.S. Vaccine Product Licensure

It is essential that efforts funded as a result of this RFP shall lead towards U.S. licensure of the proposed influenza vaccine. The Offeror must demonstrate this commitment by documenting an active/in-effect investigational new drug (IND) submission to the U.S. Food and Drug Administration for the influenza vaccine candidate.

4. U.S. Vaccine Manufacturing Capability

The Offeror must submit evidence of domestic manufacturing capability, either alone or in partnership with other manufacturers, or plans for technology transfer to a domestic production site.

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. The proposal will be considered to be non-responsive and the Offeror will be disqualified.

(3) Technical Evaluation

The Offeror shall discuss in detail a Contractor Work Plan that indicates how each aspect of the Statement of Work 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 in terms of relative risk and the likelihood of successful completion of the project.

Number	Evaluation Factors
I	Target Product Profile
II	Technical Methodology and Approach
III	Development Plan
IV	Facilities
V	Organizational Experience
VI	Personnel

General

Evaluators will assign both a merit and a confidence rating to the Evaluation Factors I to VI. The ratings for merit and confidence will be considered of equal importance. Evaluation Factor I will be considered higher than all other evaluation factors combined. EFI Sub Factors I-V corresponds to the primary desired attributes of the Target Product Profile and will be weighted equally. The ratings assigned to the sub-factors in EFI will be consolidated by the evaluators into a single, overall EFI rating. Evaluation Factors II and III are considered of equal importance and will be consider at a higher level of importance than IV, V, and VI. Evaluation Factors IV, V, and VI are considered of equal importance.

Merit and Confidence Ratings:

Merit Ratings for Evaluation Factor (EF) I:

-  **Outstanding:** By design the proposed universal vaccine candidate will exceed two or more and meet all of the rest of the TPP desired primary attributes
-  **Excellent:** By design the proposed universal vaccine candidate will meet all of the TPP desired primary attributes
-  **Acceptable:** By design the proposed universal vaccine candidate will meet at least three of five of the TPP desired primary attributes
-  **Marginal:** By design the proposed universal vaccine candidate will meet will meet fewer than half of the TPP desired primary attributes

 **Unacceptable:** By design the proposed universal vaccine candidate will meet none of the TPP desired primary attributes.

Merit Rating for EFI Sub Factors only:

The following color-code/adjectival rating will be used in rating the merit portion of the Evaluation Criteria I, Target Product Profile Sub Factors I-V:

 **Outstanding:** By design and level of supportive data, the proposed universal vaccine candidate will greatly exceed the TPP desired primary attribute

 **Excellent:** By design and level of supportive data, the proposed universal vaccine candidate will exceed the TPP desired primary attribute

 **Acceptable:** By design and supportive data, the proposed universal vaccine candidate will adequately meet the TPP desired primary attribute

 **Marginal:** By design and level of supportive data, the proposed universal vaccine candidate may meet the TPP desired primary attribute

 **Unacceptable:** By design the proposed universal vaccine candidate will not meet the TPP desired primary attribute.

Confidence Ratings for EFI and EFI Sub Factors:

The following color-code/adjectival ratings will be used in rating the confidence portion of Evaluation Criteria I, Target Product Profile only:

 **High Confidence:** There is a high degree of confidence that the Offeror will deliver a product that will meet the proposed Target Product Profile and the proposed product will be transformational for influenza vaccines, based upon the robustness of data and plans that are predictive of success

 **Significant Confidence:** There is significant confidence the Offeror will deliver a product that will meet the proposed Target Product Profile and the proposed product will clearly be more effective within various parameters than currently licensed influenza vaccines, as supported by both data and plans that are predictive of success.

 **Confidence:** The Offeror can successfully deliver on the proposed Target Product Profile with minimal tradeoffs in product performance and timeline delays. The product delivered will be incrementally better currently licensed influenza vaccines.

 **Little Confidence:** Substantial doubt exists that the Offeror can successfully deliver on the proposed Target Product Profile without significant tradeoffs in product performance and timeline delays. The product delivered will be an incremental improvement over currently licensed influenza vaccines.

 **No Confidence:** Extreme doubt exists that the Offeror can successfully perform deliver on the proposed Target Product Profile without significant tradeoffs in product performance and timeline delays. The product delivered will be of little improvement over currently licensed influenza vaccines.

Merit Ratings for Evaluation Factors II-VI:

The following color-code/adjectival ratings will be used in rating the merit portion of all of the remaining factors:

-  **Outstanding:** Greatly exceeds the minimum performance or capability requirements in a beneficial way to the USG. There are no weaknesses or deficiencies.
-  **Excellent:** Exceeds the minimum performance or capability requirements in a beneficial way to the USG. There are no significant weaknesses.
-  **Acceptable:** Meets the minimum performance or capability requirements. There may be minor but correctable weaknesses.
-  **Marginal:** May meet the performance or capability requirements. There are apparent or moderate weaknesses that are correctable.
-  **Unacceptable:** Fails to meet the performance or capability requirements. There are unacceptable weaknesses.

Confidence Ratings for Evaluation Factors II-VI:

The following color-code/adjectival ratings will be used in rating the confidence portion of all of the remaining factors:

-  **High Confidence:** Evaluated that no doubt exists that the Offeror will successfully perform the proposed effort.
-  **Significant Confidence:** Evaluated with a certainty that the Offeror will successfully perform the proposed approach with minor potential cause for disruption of schedule, increased cost or degradation of performance.
-  **Confidence:** Offeror can successfully perform the proposed approach with little potential cause for disruption of schedule, increased cost or degradation of performance.
-  **Little Confidence:** Substantial doubt exists that the Offeror can successfully perform the proposed approach with little potential cause for disruption of schedule, increased cost or degradation of performance.
-  **No Confidence:** Extreme doubt exists that the Offeror can successfully perform the proposed approach with little potential cause for disruption of schedule, increased cost or degradation of performance.

Technical Evaluation Criteria – There are six technical evaluation criteria.

Failure by the Offeror to provide any of the information requested below will result in a lower assessment that will impact the Offeror's ability to be scored within the competitive range.

- 1. Primary Target Product Profile (TPP) Attributes (Sub-Factors for Evaluation): Breadth of Protection, Efficacy, Duration of Immunity, Priming Immunity, Safety**

Property/Vaccine	Desired Primary Characteristics
Breadth of Protection	<i>Protects against antigenically divergent influenza A viruses and viruses from both influenza B virus lineages</i>
Efficacy	<i>Shows 20% or greater above a licensed influenza vaccine comparator as measured by clinical endpoints or surrogate endpoints (e.g. seroprotection or seroconversion rates)</i>
Duration of Immunity	<i>Protects for two years or more against influenza A subtypes and influenza B lineages</i>
Priming Immunity	<i>Primes for baseline immunity such that a single dose of pandemic influenza vaccine will boost immune response to protective levels against the pandemic influenza virus</i>
Safety	<i>Comparable to licensed influenza vaccines</i>
	Desired Secondary Characteristics
Age Indication	<i>6 months (or younger) and above</i>
Route of Administration	<i>Intramuscular, intradermal, intranasal, transdermal, oral Preference given to route of administration most easily executed during an emergency</i>
Manufacture to Release	<i>12 weeks</i>

Offeror Instructions

- A. The technical proposal should describe each element of the TPP primary attributes for the proposed vaccine candidate separately with data supporting each attribute.
 - a. Clinical data will be weighted higher than non-clinical data.
 - b. Greater coverage against antigenically divergent viruses, for example, a candidate showing both cross-clade (homosubtypic) and cross-subtype (heterosubtypic) immunity will be weighted higher than candidates showing only cross-clade immunity.
 - c. Any experimental data in animal models or from clinical trials showing the candidate vaccine's ability to prime immunity for a pandemic influenza vaccine boost should also be provided.

- B. The technical proposal should provide a detailed description of the studies planned to be performed during the development process to confirm the TPP desired primary attributes.

Evaluation Instructions

The Offeror will be evaluated on data supplied supporting the desired primary attributes of the TPP for the proposed influenza vaccine candidate. Clinical data will be weighted higher than non-clinical data.

- a. Evaluation will be based on the degree to which the pre-clinical and clinical data support achievement of the TPP primary desired attributes.
- b. Evaluation will be based on experimental data in animal models or from clinical trials showing the candidate vaccine's ability to prime immunity for a pandemic influenza vaccine boost.
- c. Evaluation will be based on how well the existing body of evidence supports the proposed plan/studies to confirm the TPP primary desired attributes

2. Technical Methodology and Approach

Offeror Instructions

- A. The technical proposal should describe the cell substrate and other biological materials used to produce the candidate influenza vaccine. Describe and provide a rationale for the cell substrate selection; include details such as its origin, passage history, stability, results of adventitious agents testing. For additional information, please refer to FDA's 2010 Guidance to Industry "Characterization and Qualification of Cell Substrates and Other Biological Materials Used in the Production of Viral Vaccines for Infectious Disease Indications." Offeror should provide any prior regulatory evaluation or review by FDA or other regulatory agencies, and any other factors pertaining to its regulatory status or that may affect FDA licensure of a vaccine produced using the proposed cell substrate.
- B. The technical proposal should include a detailed summary of process development, analytical development, product stability, scale-up and clinical manufacturing plans and available results. Any detailed information regarding host cell protein/DNA levels as well as the capacity of the process to remove residual host cell protein/DNA and adventitious or extraneous agents should be incorporated as an appendix in the preliminary results section of the technical proposal. Viral inactivation information for any vaccine derived from viral seeds or viral vectors should be incorporated into the appendix as well.
- C. The technical proposal should include a detailed summary of all non-clinical proof-of-concept and preclinical toxicology/safety studies. Preclinical GLP toxicology final study report as well as records of consultation with CBER at FDA should be included as an appendix in the preliminary results section of the technical proposal.
- D. The technical proposal should include detailed results of all clinical testing such as clinical study reports (CSRs) that has been completed in the U.S. or internationally including protocol synopsis, vaccine description and end points (including records of consultation with independent safety monitor (ISM), Safety Monitoring Committee (SMC), or Data Safety Monitoring Board (DSMB) during clinical trial execution, as well as all communications between Offeror and CBER at FDA as an appendix). Clinical information should also include development status for analytical assays to determine immune response as well as preliminary results.

- E. The technical proposal should detail any data and plans to identify and explain the mechanism(s) of action, to support the identification of correlate(s) of protection, for the influenza vaccine candidate.

Many of these requirements can be satisfied by inclusion, in whole or part, of the Offeror's IND, CSRs and relevant supplements and referenced appropriately.

Evaluation Instructions

The Offeror will be evaluated on their proposed methodology and approach to the advanced development of their influenza vaccine candidate including:

- a. Sound rationale and quality of the selected cell substrate to support product development and licensure
- b. Adequacy and robustness of process development, analytical development (including in-process, release and potency assays), product stability, scale-up and clinical manufacturing of the proposed vaccine candidate
- c. Appropriateness and quality of supportive non-clinical proof-of-concept and preclinical toxicology/safety data along with FDA correspondence to understand the safety risks and potential efficacy of the candidate vaccine for advanced development and licensure
- d. Appropriateness and quality of clinical studies performed with the proposed candidate as well as status of immunological assays under development
- e. Appropriateness and adequacy of any plans to elucidate and explain the mechanism(s) of action for the influenza vaccine candidate to support the identification of correlate(s) of protection

3. Development Plan

Offeror Instructions

- A. The technical proposal should provide a Contractor's Work Plan (CWP) that describes the activities to be performed in response to the 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 government. The CWP and the corresponding Gantt chart shall be sufficiently detailed to facilitate management and execution of the contract by the successful Offeror(s).
- B. The technical proposal should describe, in detail, the Offeror's work plan to complete all activities identified in the Offeror's defined statement of work. This should include details of plans for the Offeror to meet all of the desired attributes, including age indication and route of administration. Discuss phasing and integration of research and development activities and, to the extent possible, relate such activities to experimental design, sample size and analytic strategy. Discuss anticipated and theoretical risks for execution of the development plan, as well as potential approaches to mitigate or resolve them. Critical path decision trees for candidate vaccine development in the areas of manufacturing, process development, product assay development, clinical evaluation, clinical assay development, and regulatory licensure plan should be provided.
- C. The technical proposal should 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 that the Offeror take all steps necessary to secure access to all intellectual

property, expertise and tangible materials. Accordingly, the U.S. Government requires written evidence that the Offeror has secured access to such intellectual property, expertise and tangible materials to the proposed influenza vaccine technology unencumbered by legal or patent constraints.

Evaluation Instructions

The Offeror will be evaluated on their proposed development plan for the advanced development of their influenza vaccine candidate including:

- a. Adequacy of the Contractor's Work Plan and Gantt charts
- b. Completeness of the work plan for the advanced development of the proposed vaccine candidate for all of the desired attributes including age indication and route of administration
- c. Access to all the intellectual property needed to fully develop the proposed more effective/universal influenza vaccine candidate(s)

4. Facilities

Offeror Instructions

- A. The technical proposal should describe any facilities, including U.S. facilities, to be used for development and manufacture of investigational lots of more effective/universal influenza vaccine candidate(s) suitable for clinical evaluation under an IND as specified in the proposal, including documentation of compliance with cGMP.
- B. The technical proposal should include information concerning 1) site selection criteria 2) facility regulatory compliance proposed biosafety and biocontainment levels (if applicable) 3) manufacturing processes 4) conceptual architectural and structural plans 5) process and building mechanical utilities conceptual plans 6) a proposed construction schedule 7) proposed master validation plan and 8) a description of the facility quality and regulatory program. Offeror shall provide evidence of domestic manufacturing capability, either alone or in partnership with other manufacturers, or plans for technology transfer to a domestic production site. Identify potential barriers to implementation of the facility strategy and approaches to overcome those barriers.
- C. The technical proposal should describe the Offeror's corporate strategy for production and release of the proposed influenza vaccine within 12 weeks of the declaration of a pandemic and with a surge capacity of 50 million doses within four (4) months of the declaration of a pandemic at a qualified, commercial-scale U.S.-based manufacturing facility.

Evaluation Instructions

The Offeror will be evaluated on their comprehensive approach to comply with cGMP and regulatory requirements commensurate with their product development status, as well as their domestic manufacturing capabilities including:

- a. Adequacy and appropriateness of the facilities for production of investigational lots of the proposed vaccine candidate and the cGMP compliance of these facilities

- b. Adequacy and appropriateness of the plans for: 1) site selection 2) facility regulatory compliance with proposed biosafety and biocontainment levels (if applicable) 3) manufacturing processes 4) architectural and structural concepts 5) process and building mechanical utilities concepts 6) construction schedule 7) master validation and 8) the facility quality and regulatory program
- c. Demonstrated evidence of domestic manufacturing capability, either alone or in partnership with other manufacturers, or plans for technology transfer to a domestic production site
- d. Feasibility of plans for domestic surge manufacturing of their candidate influenza vaccine with first doses released within 12 weeks and 50 million doses delivered within 4 months of a pandemic declaration

5. Organizational Experience

Offeror Instructions

The proposal should describe previous programs for vaccine development, evaluation, licensure, and production that document organizational capabilities to complete proposed activities, achieve regulatory approvals, and successfully produce a more effective/universal influenza vaccine.

Evaluation Instructions

The Offeror organization will be evaluated on prior experience in the advanced development of vaccine and biologics towards licensure in the US.

6. Personnel

Offeror Instructions

- A. The technical proposal should provide the name of the Principal Investigator (PI)/Project Director responsible for the overall implementation of the contract, co-investigators and key participants for technical aspects of the project. Describe the qualifications, experience, and accomplishments of the PI, co-investigators, and key participants. Include, in an attachment, curricula vitae of supervisors and key technical personnel, and the approximate percentage of time each will be available for this program.
- B. The technical proposal should describe the experience and qualifications of other personnel who will be assigned to work on this program. Using organizational charts, show the composition of task or work groups by project area. Document the general qualifications of work groups and recent experience with similar programs.
- C. The technical proposal should list names, titles, and proposed duties of additional personnel, if any, who will be required for full-time employment or on a subcontract or consultant basis. Indicate the technical areas, character, and extent of subcontract or consultant activities and anticipated sources. For all proposed personnel who are not currently members of Offeror's staff, provide a letter of commitment or other evidence of availability. The letter of commitment must at a minimum include (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 consultant and (4) how rights to publication and patents will be handled.

Evaluation Instructions

The Offeror will be evaluated on the following:

- a. The proposed personnel will be evaluated for individual training and contributions in previous vaccine/biologics development programs relevant to this statement of objectives. These include, but are not limited to experts in, product development, process development, process scale-up, technology transfer, analytical and assay development and validation, clinical trial design, clinical trial performance, quality management, data management, and regulatory science. In addition, the Contractor leadership will be evaluated on successful efforts of a similar magnitude and scope of this statement of objectives.
- b. Adequacy of the key personnel.

(4) PAST PERFORMANCE EVALUATION.

Past performance will be evaluated.

The Government's evaluation will include an analysis of the Offeror's description of relevant ongoing and previous USG and commercial contracts. This evaluation will include analysis of the Offeror's detailed discussion of corporate experience solving challenging problems similar to those anticipated on this effort; experience with USG regulations with respect to the requirements of this effort. If the Offeror has limited or no government contract experience, then the USG will evaluate the Offeror's description of similar contracts with commercial entities, local and/or state governments.

The USG will consider the currency and relevance of the information, source and context of the information, and general trends in the Offeror's performance. The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the Offeror. In this case, past performance will be noted as "No relevant past performance history identifiable".

Evaluators will only be assigned a merit rating related to the Offeror's past performance in completing task similar to the required elements as listed in the Statement of Objectives.

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

-  **Outstanding:** Based on the Offeror's performance record, no doubt exists that the Offeror will successfully perform the required effort. Sources of information are consistently firm in stating that the Offeror's performance was superior and that they would unhesitatingly do business with the Offeror again.
-  **Excellent:** Based on the Offeror's performance record, little doubt exists that the Offeror will successfully perform the required effort. Sources of information state that the Offeror's performance was good, better than average, etc., and that they would do business with the Offeror again.
-  **Acceptable:** Based on the Offeror's performance record, some doubt exists that the Offeror will successfully perform the required effort. Sources of information indicate that the Offeror's performance is average or that favorable reports are offset by unfavorable reports.

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

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

(5) EXTENT OF SMALL AND DISADVANTAGED BUSINESS (SDB) PARTICIPATION

SDB participation will not be scored, but the USG's conclusions about overall commitment and realism of the Contractor's SDB Participation targets will be used in determining the relative merits of the Contractor's proposal and in selecting the Contractor whose proposal is considered to offer the best value to the USG. The extent of the Contractor'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 Contractor's proposal. The USG is seeking to determine whether the Contractor has demonstrated a commitment to use SDB concerns for the work that it intends to perform. Offers will be evaluated on the following sub-factors:

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

(6) COST/PRICE EVALUATION CRITERIA

The Contractor's business proposal and proposed cost/pricing shall be evaluated separately and then the overall analysis of the business proposal will be evaluated to reach the best overall value to the Government. The proposed cost/prices will be evaluated to determine cost realism and reasonableness. The basis of evaluation may include the use of various cost/price realism analysis techniques to ensure a fair and reasonable price such as, but not limited to:

1. Comparison of proposed prices received in response to the solicitation.
2. Comparison of proposed prices with resources proposed.
3. Obtaining information/reports from DCAA or other outside agencies, and the Independent Government Cost Estimate.
4. Review and analysis of cost and pricing data as well as other cost and pricing data submitted.

Attachment 1: Past Performance Questionnaire

PAST PERFORMANCE QUESTIONNAIRE

Please complete the following questionnaire and return via e-mail to the attention of:

Matthew.McCord@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*):

CO 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

Past Performance Questionnaire

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

Past Performance Questionnaire

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

6. Liquidated damages assessed: Yes No (circle one)

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

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

Past Performance Questionnaire

Past Performance Rating Guidelines

	Quality of Product or Service	Cost Control	Timeliness of Performance	Business Relations
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
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
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
3 – Good	Minor inefficiencies/errors 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
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
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 2: Reserved

HHSAR 352.223-70 SAFETY AND HEALTH (JANUARY 2006)

- (a) To help ensure the protection of the life and health of all persons, and to help prevent damage to property, the Contractor shall comply with all Federal, State and local laws and regulations applicable to the work being performed under this contract. These laws are implemented and/or enforced by the Environmental Protection Agency, Occupational Safety and Health Administration and other agencies at the Federal, State and local levels (Federal, State and local regulatory/enforcement agencies).
1. In addition, the following regulations must be followed when developing and implementing health and safety operating procedures and practices for both personnel and facilities involving the use or handling of hazardous materials and the conduct of research, development, or test projects:
 - (1) 29 CFR 1910.1030, Bloodborne pathogens; 29 CFR 1910.1450, Occupational exposure to hazardous chemicals in laboratories; and other applicable occupational health and safety standards issued by the Occupational Health and Safety Administration (OSHA) and included in 29 CFR Part 1910. These regulations are available at: <http://www.osha.gov/comp-links.html>
 - (2) Nuclear Regulatory Commission Standards and Regulations, pursuant to the Energy Reorganization Act of 1974 (42 U.S.C. 5801 et seq.). Copies may be obtained from the U.S. Nuclear Regulatory Commission, Washington, DC 20555B0001.
 2. The following guidelines are recommended for use in developing and implementing health and safety operating procedures and practices for both personnel and facilities:
 - (1) Biosafety in Microbiological and Biomedical Laboratories, CDC and NIH, HHS. This publication is available at <http://www.cdc.gov/od/ohs/biosfty/bmb15/bmb15toc.htm>
 - (2) Prudent Practices for Safety in Laboratories (1995), National Research Council, National Academy Press, 500 Fifth Street, NW., Lockbox 285, Washington, DC 20055 (ISBN 0B309B05229B7). This publication can be obtained by telephoning 800B624B8373. It also is available at <http://www.nap.edu/catalog/4911.html>.
- (b) Further, the Contractor shall take or cause to be taken additional safety measures as the Contracting Officer, in conjunction with the project or other appropriate officers, determines to be reasonably necessary. If compliance with these additional safety measures results in an increase or decrease in the cost or time required for performance of any part of work under this contract, an equitable adjustment will be made in accordance with the applicable "Changes" clause set forth in this contract.
- (c) The Contractor shall maintain an accurate record of, and promptly report to the Contracting Officer, all accidents or incidents resulting in the exposure of persons to toxic substances, hazardous materials or hazardous operations; the injury or death of any person; and/or damage to property incidental to work performed under the contract and all violations for which the Contractor has been cited by any Federal, State or local regulatory/enforcement agency. The report shall include a copy of the notice of violation and the findings of any inquiry or inspection, and an analysis addressing the impact these violations may have on the work remaining to be performed. The report shall also state the required action(s), if any, to be taken to correct any violation(s) noted by the Federal, State or local regulatory/enforcement agency and the time frame allowed by the agency to accomplish the necessary corrective action.

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

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

(End of Clause)

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

This disclosure form shall be completed by the reporting entity, whether subawardee or 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 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 a covered Federal action. Use the SF-LLLA 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 change 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-LLLA Continuation Sheet(s) is attached.
16. The certifying official shall sign and date the form, print his/her name, title, and telephone number.

According to the Paperwork Reduction Act, as amended, no persons are required to respond to a collection of information unless it displays a valid OMB Control Number. The valid OMB control number for this information collection is OMB No. 0348-0046. 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, DC 20503.

REPORT OF GOVERNMENT OWNED, CONTRACTOR HELD PROPERTY							
CONTRACTOR:				CONTRACT NUMBER			
ADDRESS				REPORT DATE:			
				FISCAL YEAR:			
CLASSIFICATION	BEGINNING OF PERIOD		ADJUSTMENTS			END OF PERIOD	
	#ITEMS	VALUE	GFP ADDED	CAP ADDED	DELETIONS	#ITEMS	VALUE
LAND >=\$25K							
LAND <\$25K							
OTHER REAL >=\$25K							
OTHER REAL <\$25K							
PROPERTY UNDER CONST >=\$25K							
PROPERTY UNDER CONST <\$25K							
PLANT EQUIP >=\$25K							
PLANT EQUIP <\$25K							
SPECIAL TOOLING >= \$25K							
SPECIAL TOOLING <\$25K							
SPECIAL TEST EQUIP >=\$25K							
SPECIAL TEST EQUIP <\$25K							
AGENCY PECULIAR >=\$25K							
AGENCY PECULIAR <\$25K							
MATERIAL >=\$25K (CUMULATIVE)							
PROPERTY UNDER MFR >=\$25K							
PROPERTY UNDER MFR <\$25K							
SIGNED BY: (SIGNATURE) (NAME) PRINTED) (TITLE)				DATE SIGNED: _____ (TELEPHONE) _____			

The documents below can be found at the following websites:

Contract Performance Reports (EVM):

Format 1: Work Breakdown Structure,

<http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2734-1.pdf>

Format 2: Organizational Categories,

<http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2734-2.pdf>

Format 3: Baseline

<http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2734-3.pdf>

Format 4: Staffing

<http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2734-4.pdf>

Format 5: Explanations and Problem Analyses

<http://www.dtic.mil/whs/directives/infomgt/forms/eforms/dd2734-5.pdf>

Department of Health & Human Services
HHS
Office of the Assistant Secretary for Preparedness and Readiness
ASPR
Biomedical Advanced Research and Development Authority
BARDA

7 Principles of Earned Value Management Tier 2 System Implementation Intent Guide

01 October 2011



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OVERVIEW

Earned Value Management (EVM) is a program management tool, technique, and discipline that facilitates systematic planning for and monitoring of, high value, complex projects. It integrates a project's scope of work with the related budget and schedule to permit detailed assessment of overall performance during the life of the project.

Several government-wide guidance documents govern the definition and use of EVM systems. Guidelines outlining the qualities and characteristics of an EVM system are set forth in the American National Standards Institute/Electronic Industries Alliance (ANSI/EIA) Standard-748 (most current version). More detailed and specific guidance and direction is contained in OMB Circular A-11, *Preparation, Submission and Execution of the Budget*, specifically in Part 7 of that Circular A-11, *Planning, Budgeting, Acquisition, and Management of Capital Assets*, and its supplement, the Capital Programming Guide. Based on this collective OMB guidance, EVMS is intended to be used on those parts of acquisitions that will involve developmental effort. This would include not only those acquisitions designated by the agency as major systems but also those acquisitions that include significant developmental, modification, or upgrade during the operational or steady-state phase of a program.

The FAR rule on EVMS became effective on July 5, 2006. Its purpose is to implement EVMS policy in accordance with OMB Circular A-11. Because the new FAR coverage applies throughout the executive branch and to agencies with disparate definitions of and processes and procedures for major systems acquisitions, the FAR Council decided against a "one-size-fits all" approach and left several significant aspects of the detailed implementation up to the discretion of each covered agency.

The FAR and Health and Human Services Acquisition Regulations (HHSAR) language for EVMS will be utilized for all construction or Information Technology (IT) projects. Since most of the acquisitions at the Biomedical Advanced Research and Development Agency (BARDA) are unique in that most acquisitions are not Information Technology projects or construction projects, BARDA is developing EVM language that incorporates the 7 Principles of Earned Value Management. These principles allow flexibility to an EVM system structure but still meet the spirit of the ANSI/EIA Standard-748. It also incorporates discipline in implementation and operations and also provides the same reporting data outlined by OMB.

The Seven Principles of Earned Value Management are as follows:

1. Plan all work scope to completion
2. Break down the program work scope into finite pieces that can be assigned to a responsible person or organization for control of technical, schedule and cost objectives
3. Integrate program work scope, schedule, and cost objectives into a performance measurement baseline plan against which accomplishments can be measured. Control changes to the baseline.
4. Use actual costs incurred and recorded in accomplishing the work performed.
5. Objectively assess accomplishments at the work performance level.

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6. Analyze significant variances from the plan, forecast impacts, and prepare an estimate at completion based on performance to date and work to be performed.
7. Use earned value information in the company's management processes.

EVM IMPLEMENTATION TIERS

BARDA will be implementing a tiered approach to EVM based on the type of acquisition, size of the acquisition and the technical readiness level. There are three tiers and they are as follows:

TIER 1

For all construction contracts and IT contracts the ANSI/EIA-748 Standard for Earned Value Management Systems will apply and all relevant FAR/HHSAR clauses pertaining to EVMS will be incorporated in the contract. The National Defense Industrial Association (NDIA) Program Management Systems Committee (PMSC) ANSI/EIA-748 Standard for Earned Value Management Systems Intent Guide should be used as guidance.

TIER 2

For countermeasure research and development contracts that have a total acquisition costs greater than or equal to \$25 million and have a Technical Readiness Level (TRL) of less than 7 will apply EVM principles for tracking cost, schedule and technical performance that comply with the 7 Principles of EVM Implementation.

TIER 3

For countermeasure research and development contracts that have total acquisition costs less than \$25 million but greater than \$10 million will apply EVM principles for tracking cost, schedule and technical performance that are consistent with the 7 Principles of EVM Implementation.

This Guide is an explanation of the intent of what is expected for a Tier 3 system implementation of the 7 Principles of EVM.

SEVEN PRINCIPLES OF EVM

Principle 1: Plan all Work Scope

In a performance measurement system implementation the Statement of Work (SOW) should reflect all work that is to be performed. In a 7 Principles implementation a Work Breakdown Structure (WBS) shall be developed to include all elements of the SOW. The level of the WBS may not be as detailed as in a Tier 1 implementation. It would be developed at a higher level, such as level three or four, however, the government may expand specific technical legs to lower than level four and it may retract some non-technical legs to higher than 3. It is beneficial and required to develop a WBS dictionary that explains what work is going to be performed in each WBS in detail. This will ensure that the contractor has identified all work scope and left no major work undefined. It is recommended that the work packages descriptions are clear and detailed so that there is an understanding of the work that is to be performed in the work packages. For the 7 Principles implementation programs it would be acceptable for the WBS Dictionary be expanded to include information that would normally be kept on a Work Authorization Document, such as charge numbers associated with the work, period of performance, the manager who is responsible for the work, and budget associated with the WBS. The additional “WAD info” would only be added to the lowest level (i.e. level 3 or 4) of the WBS. The roll up level WBS would only include scope. By doing this documentation is limited to one document instead of two.

By developing a WBS and a WBS Dictionary/Work Authorization Document the work scope has been defined but the documentation is greatly reduced and the costs associated with developing and updating the documentation is reduced. The intent of the combination document is not to reduce the level of information provided to the government but to reduce the amount of documents that need to be produced. An example of a WBS dictionary and Work Authorization document and what is expected on the document(s) is provided.

In a Tier 3 implementation it is not necessary to provide a WBS Dictionary or a Work Authorization Document but it is important to develop a WBS and define a scope of work for each level of the WBS at the reporting level (usually level 3 or 2).

Principle 2: Break Work into Finite Pieces and Define Person/Organization Responsible for Work

In a 7 Principles Tier 2 implementation it is recommended that the work be broken into finite pieces in the schedule tool. It is recommended to plan the work by the lowest level WBS. The lowest level WBS (level 3 or 4) should be the control account and the activities would act as the work packages. Most of the normal functions accomplished when scheduling will be required on a 7 Principles Tier 3 implementation. These normal functions include, network scheduling, horizontal and vertical traceability, forecasting schedule start and completion dates, and running critical path analysis. As part of vertical traceability it is expected that all contract milestones will be listed on the schedule.

The schedule should include but is not limited to include the following fields:

- WBS number
- Control Account number
- Work package number
- Task name
- Duration

Baseline Start and Finish Dates
Actual Start and Finish Dates
Forecast Start and Finish Dates
Predecessor/Successors
Activity Percent Complete

All the work scheduled at the lowest level WBS should be identified by a single responsible manager. This manager, known as a Control Account Manager should be identified in the schedule tool and/or in a cost tool. In a 7 Principles implementation, only individuals at the lowest level WBS need be identified and there is no requirement for the costs to roll up by organization, although if it is not cost intensive or tool restricted then developing the OBS is recommended. In many cases, BARDA will provide the top three levels of the WBS for the contractor to use.

Principle 3a: Integrate Scope, Schedule and Budget into a Performance Measurement Baseline

This principle integrates the work scope, the schedule and the budget into a performance measurement baseline. Since we discussed work scope and schedule the focus of this principle is the incorporation of the budget in a time-phased manner. The budget must be integrated with the scope of work and the schedule into a Performance Measurement Baseline (PMB). The budget is made up of both direct and indirect dollars. An accepted way of incorporating the budget and integrating with the scope and schedule is to resource load the Microsoft Project (or other scheduling tool) schedule. This is done by loading the individual people and their loaded rate into the tool. This budget data will be input at the work package level with a rate that includes the indirect costs. The budget will have to have the capability to be rolled up to the control account level and will need to be reported in a way that provides the responsible manager (Control Account Manager) with information needed to manage the program. Resource loading of the schedule is not the only way to incorporate the budget. As long as the budget in the budget/EV tool is linked to the schedule activities and it is flexible to change when schedule baseline dates change, then loading the budget in the Budget/EV tool is an acceptable way to integrate the cost and schedule baselines. The budget information will be displayed on the time-phased Control Account Plan reports. These reports should have the flexibility to report the dollars both in total dollars, as well as, direct and indirect broken out separately. Also the report is generally required as a deliverable on most contracts and must have the capability to include earned value or Budgeted Cost of Work Performed (BCWP) and actual costs or Actual Costs of Work Performed (ACWP).

Budgeting of subcontractor effort will vary depending on whether or not the subcontractor is a cost plus or fixed price subcontract. If it is cost plus then the expectation is that there will be monthly billing of costs from the subcontractor to the prime contractor and therefore budget must be planned in accordance with the work completed and billed. If it is fixed price then the budget should be planned with work execution or milestones completed and budget should only be planned in those months where work is expected to be completed.

It is recommended that management reserve and undistributed budget be utilized in the budgeting process. Undistributed budget is budget that has not yet been distributed to a control account and it requires additional time to plan the work and distribute the budget to a control account. It is a

temporary holding account and budget should only stay in Undistributed Budget for one or two months. If the work scope is easily identified to all the control accounts then the use of Undistributed Budget may not be necessary.

Management Reserve is budget that is set aside, normally by the Program Manager, to be used to budget future but currently unknown tasks. It is associated with risk issues and is to be used to mitigate risk. It is not part of the Performance Measurement Baseline and it should not be used for out of scope work and to cover overruns.

Principle 3b: Control Changes to the Baseline

A properly controlled PMB is crucial to effective program management. The timely and accurate incorporation of contractual changes ensures that the information generated from the execution of the baseline plan provides an accurate picture of progress and facilitates correct management actions and decisions. The accurate and timely incorporation of authorized and negotiated changes into the PMB ensures that valid performance measurement information is generated for the new scope being executed. Near term new scope effort should be planned and have budget in control accounts. Far term new scope effort that cannot be reasonably planned in the near term can either be put in planning packages in the control account or left in Undistributed Budget if the control account has not been identified. The timely and accurate incorporation of authorized and negotiated changes into the PMB ensures that valid performance measurement information is generated for the new scope being executed. Budget revisions are made when work is added to the contract and are traceable from authorized contract target costs to the control account budgets or from management reserve. Management reserve may be used for future work when additional in-scope work has been identified.

Retroactive changes to the baseline may mask variance trends and prevent the use of performance data to project estimates of cost and schedule at completion. Controlling retroactive adjustments, which should only be made in the current period, if possible, is imperative because they could arbitrarily eliminate existing cost and schedule variances.

The use of program budget logs should be used to track and log all budget changes. The ability to track budget values for both the internal and external changes will help in the maintenance of the performance measurement baseline from program start to completion. Contractor is expected to utilize baseline change documentation facilitating the change. It should provide the rationale/justification, approval process, work scope additions or deletions, dollars, changes to schedules, estimate at completion, etc. It should also include contractual change documents for external changes, such as a contract modification, letter to proceed, not to exceed letter, change order, etc., that transmit and authorize the change or addition to work, budget, and schedule. Other documents that should change if a change of scope has been authorized are: Statement of Work, WBS (changes if applicable); WBS Dictionary (additions or deletions to scope); work authorization documents authorizing new scope, schedule and budget; schedules.

Principle 4: Use Actual Costs Incurred and Recorded in Accomplishing the Work Performed

Some of the new acquisitions at BARDA will be required to be compliant with the Cost Accounting Standards. For Tier 3 implementation contractors must utilize a work order/job order/task code charge number structure that uniquely identifies costs at the control account

level, which may be as high as the reporting level of the WBS. This will allow for accumulation and summarization of costs to higher levels of the work breakdown structure. Actual costs are accumulated in the formal accounting system in a manner consistent with the way the related work is planned and budgeted. Actual costs reported in the performance reports agrees with the costs recorded in the accounting system or can be explained as timing differences. The contractor will have to be able to incorporate and reconcile to the accounting system actual costs on their Contract Performance Reports (CPR) to the customer.

Depending on the amount of material and subcontractors on the program, it may be necessary for reporting purposes, to include accruals, or estimated actuals, for these costs. Since material and subcontractor invoices are not paid and recorded in the accounting system for up to several months after the work has been planned, performance data will be skewed. Accruing or estimating actual costs based on receipt (for material) and expended hours for subcontractors will alleviate this issue. The use of accrual/estimated actuals should be reviewed on a case by case basis depending on the size of program, the amount of material or subcontractor budget and costs. If the material and subcontract effort on the project is minimal (represents less than 5% of the project budget) then the time and effort needed to manage the accruals would outweigh the benefit of having the costs accrued since the performance data would only be minimally affected. Although actual costs are generally reported to the USG in total dollars the system must be able to differentiate and report direct costs and indirect costs if requested.

If the subcontractor has a fixed price contract the prime contractor, then the prime contractor must report actual costs in accordance with the work that is accomplished. This is achieved by recording the actual costs equal to the work that was performed in the EVM system and on the CPR. If the subcontractor is a cost plus contract it is imperative the costs the prime reports is in accordance with the costs incurred in that month. This is necessary to ensure that the data reported is not skewed. With this premise, fixed price subcontractors cost variances should not exist or be reported on the CPR whereas the cost reported for cost plus subcontractors should be based on what was incurred and not what has been invoiced to date, which may be months behind.

Principle 5: Objectively Assess Accomplishments at the Work Performance Level

In order to meet this Principle, the scheduling of the scope of work in work packages or activities need to incorporate measurable units or milestones in order to objectively assess accomplishments or obtain what we call “earned value”. These units or milestones are given a value based on labor resources needed to accomplish the work (which becomes the Budgeted Cost of Work Scheduled or BCWS). When they are accomplished (known as Budgeted Cost of Work Performed or BCWP) they receive the value associated with the budget which measures progress.

Schedule status to measure progress needs to be on at least on a monthly basis although it is preferred on a bi-weekly basis. As part of the status process progress dates, such as actual start/complete and forecast start/complete need to be updated.

Since Microsoft Project seems to be the schedule tool of choice by most contractors, there are four types of earned value methodologies utilized by Microsoft Project of which two assess progress by the completion of milestones and they are the 50/50 and 0/100 methodologies. In both cases, progress is reported for completion milestones and in the 50/50 methodology fifty percent of the value of the work package/activity is credited for starting the work. The other two earned value methodologies are assessed percent complete (also known as Supervisor's Estimate) and level of effort (LOE). All four methodologies are legitimate earned value measurement techniques.

Additional earned value methodologies, such as the weighted milestone methodology and percent complete with milestone gates may be utilized. The weighted milestone method allows value to be earned based on the resource value in each month, which eliminates artificial schedule variances.

For subcontractors that have a fixed price contract with the prime contractor, the expectation is that there will be no cost variance. The ACWP reported on the CPR will equal the BCWP earned, regardless of the payment schedule with subcontractor.

Principle 6a: Analyze Significant Variances From the Plan

The purpose of this principle is to ensure that the earned value data is analyzed by the contractor and reported to the customer. The 7 Principles programs should be able to calculate the cost variance (BCWP minus Actual Cost of Work Performed (ACWP) and the schedule variance (BCWP minus BCWS) at least on a cumulative basis. It is recommended that variances be calculated on a current month basis also. The EVM system should also provide both monthly and cumulative Cost Performance Index (BCWP divided by ACWP) and Schedule Performance Index (BCWP divided by the BCWS). This data should be provided at the control account level and at the roll up levels and it needs to be in a format for Control Account Managers and program management to be able to utilize in managing the work.

It is also recommended that the To-Complete Performance Index (TCPI) be included in the Control Account Manager Performance report. The TCPI is a valuable index that calculates the cost performance the control account needs to perform at in order to complete the work within the current reported EAC. When the TCPI is compared against the cumulative CPI it gives a good indication whether or not the current EAC is reasonable. For example, if a cumulative CPI is .85 and the TCPI calculates to equal 1.15 that is the performance factor that work would need to perform at in order to meet the current EAC. If the cumulative CPI is .85 then it can be determined that the current EAC might not be reasonable. It allows management and Project Controls the opportunity to question the Control Account Manager as to the validity of the current EAC. As a rule in thumb if the deviation between the CPI and the TCPI is greater than .2 then the CAM should reassess the control account EAC.

These reports, which should be provided monthly, should also include the current Budget at Completion (BAC) and the current Estimate at Completion (EAC). In addition, it would be a plus if the CAM could see a report with their time-phased spread of hours and dollars for their budget plan (BCWS), work accomplished (BCWP) and actual costs (ACWP).

For all variances that exceed the contractual variance threshold will include a description of what caused the variance, impact to the control account and the program, and a corrective action.

Principle 6b: Prepare an Estimate at Completion Based on Performance to Date and Work to be Performed

Providing an updated EAC is a prime concern of the customer and the contractor. Therefore a robust EAC process should be in place whether the program is ANSI compliant or not.

Based on the performance to date the Estimates at Completion can be updated on a monthly basis by the Control Account Manager in the scheduling tool during the status process or in the cost/EVM tool at the end of the month's process prior to submittal of the EVM report. The EAC is an element of the performance measurement system that needs to accurately reflect the contractor's best estimate of what it will cost to complete the project.

Program management should be able to validate control account manager's EACs by looking at performance indices, such as the To-Complete Performance Index, as well as independent statistical EACs.

Principle 7: Use EVMS Information in the Company's Management Processes

One of the key areas that concerns government Program Management Offices (PMO) is the level of importance that contractor's place on EVM as a management tool. During a site visit, such as conducting an Integrated Baseline Review, the PMO gauges what the interest, knowledge, and most importantly, the usage of the performance measurement data in managing the program. They want to know that the managers on the program, including the program manager, have received some earned value training. The level of involvement and use of the EVM data to manage their schedule, cost and technical issues is ascertained by questions. The PMO can also tell by how robust the EACs are and if the variance narratives are being written with impacts to the program and corrective actions being monitored by the contractor. It is important that the contractor's management team, including the Program Manager, utilize the data from the performance measurement system as a management tool. They should be knowledgeable and understand the data. They should know what is causing the variances and ensure that the variance narratives are written properly and answer what the issues, impacts and corrective actions are. They should be able to demonstrate that they use the information to assist them in the management decision process.

APPENDICES

The following appendices provide further support in understanding the meaning and intent of properly implementing the 7 Principles of EVM.

Appendix 1 is a glossary of the terms used in the Intent Guide.

Appendix 2 is supplemental guidance on EVM implementation. It provides some guidelines on what is expected in the implementation, required documents needed for the Performance Measurement Baseline Review, expected EVM implementation costs, EVM engines functionality needs, explains what is expected in the monthly EVM facilitation, discusses what EVM consultants need to know, and what the expected costs of EVM to BARDA.

Appendix 3 are examples of some of the EVM documents that are needed in an EVM system. There are three documents and they mostly apply to Tier 2 EVM implementations. These documents are samples and are not a reflection of the specific way the document must look. It's included to provide contractors with an understanding of the type of information that is expected on these forms.

APPENDIX 1: Glossary of Terms

Actual Cost of Work Performed (ACWP)	The costs actually applied and recorded in accomplishing the work performed within a specified period.
Actual Direct Cost	Those costs identified specifically with a contract, based upon the contractor's cost identification and accumulation system as accepted by the cognizant DCAA representatives. (See Direct Costs).
Advance Agreement (AA)	An agreement between the contractor and the Contract Administration Office concerning the application of an approved earned value management system to contracts within the affected facility.
Authorized Work	That effort which has been authorized and is on contract, or that for which authorized contract costs have not been agreed to but for which written authorization has been received.
Baseline	(See Performance Measurement Baseline).

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Budget at Completion (BAC)	The sum of all budgets (BCWS) allocated to the contract. Synonymous with the term Performance Measurement Baseline.
Budgeted Cost for Work Performed (BCWP)	The sum of the budgets for completed Work Packages and completed portions of open Work Packages, plus the appropriate portion of the budgets for level of effort and apportioned effort (Also see Earned Value).
Budgeted Cost for Work Scheduled (BCWS)	The sum of the budgets for completed Work Packages, planning packages, etc., scheduled to be accomplished (including in-process Work Packages), plus the amount of level of effort and apportioned effort scheduled to be accomplished within a given time period.
Change Order (CO)	A formal authorization by the Procuring Contracting Officer for a change of scope to an existing contract
Contract Modification	A written and binding authorization to proceed created after change proposal negotiations.
Contract Budget Base (CBB)	The negotiated contract cost plus the estimated cost of authorized unpriced work, where: (1) Negotiated Contract Cost is that cost on which contractual agreement has been reached. For an incentive contract, it is the definitized contract target cost plus/minus the value of changes which have been priced and incorporated into the contract through contract change order or supplemental agreement. For fixed-fee contracts, it is the negotiated estimated cost. Changes to the estimated cost will consist only of the formal contract modifications or change orders or change in the contract statement of work, not for cost growth, and

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(2) Estimated cost of authorized, unpriced work is the estimated cost (excluding fee or profit) for that work for which written authorization has been received, but for which definitized contract prices have not been incorporated into the contract through supplemental agreement.

Control Account

A management control point at which actual costs can be accumulated and compared to budgeted cost for work performed. A control account is a natural control point for cost/schedule planning and control since it represents the work assigned to one responsible organizational element on one contract work breakdown structure (CWBS) element.

Control Account Manager (CAM)

A member of a functional organization responsible for task performance detailed in a Control Account and for managing the resources authorized to accomplish the tasks.

Control Account Plan (CAP) Report

A CAP report is a timephased report which reflects all the work and effort to be performed in a control account. The CAP report will reflect the hours and dollars by element of cost (labor, subcontract, ODC, etc) and may also include milestone information.

Contract Performance Report (CPR)

The monthly report submitted to the customer showing the current, cumulative and at completion status, the performance measurement baseline, manpower loading, and a narrative explanation of significant program variances.

Contract Target Cost

The dollar value (excluding fee or profit) negotiated in the original contract plus the cumulative cost (excluding fee or profit) applicable to all definitized changes to the contract. It consists of the estimated cost negotiated for a cost plus

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	<p>fixed fee contract and the definitized target cost for an incentive contract. The contract target cost does not include the value of authorized/un-negotiated work, and is thus equal to the contract budget base only when all authorized work has been negotiated/definitized.</p>
Cost Performance Index (CPI)	<p>An efficiency rating reflecting a project's budget performance - either over or under. Measured as a ratio of the budgeted value of work accomplished versus the actual costs expended for a given project time period. The formula for CPI is $BCWP/ACWP$.</p>
Discrete Effort	<p>Program effort that has a measurable output, product or service.</p>
Direct Costs	<p>Those costs (labor, material, etc.) that can be reasonably and consistently related directly to service performed on a unit of work, and are charged directly to the contract, without distribution to an overhead unit.</p>
Earned Value	<p>See Budgeted Cost for Work Performed (BCWP)</p>
Earned Value Management System (EVMS)	<p>A project management system utilized for measuring project progress in an objective manner. Combines measurements of scope, schedule, and cost in a single integrated system.</p>
Estimate at Completion (EAC)	<p>A value (expressed in dollars and/or hours) developed to represent a realistic appraisal of the final cost of tasks when accomplished. It's the sum of direct & indirect costs to date plus the estimate of costs for all authorized Work remaining. The $EAC = ACWP + \text{the Estimate-to-Complete}$.</p>

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Estimate to Completion (ETC)	A value (expressed in dollar and/or hours) developed to represent a realistic appraisal of the cost of the work still required to be accomplished in completing a task.
Indirect Costs	Represents those costs, because they are incurred for common or joint objectives, are not readily subject to treatment as direct costs. (See overhead).
Integrated Baseline Review (IBR)	<p>An Integrated Baseline Review (IBR) also known as Performance Measurement Baseline Review (PMBR) is a formal review led by the Government Program Manager and Technical Support Staff. An IBR is conducted jointly with the Government and their Contractor counterparts.</p> <p>The purpose of an IBR is to: verify the technical content of the Performance Measurement Baseline (PMB); assess the accuracy of the related resources (budgets) and schedules; identify potential risks.</p>
Integrated Master Plan (IMP)	The overall program plan including the work definition, technical approach, performance criteria, and completion criteria.
Integrated Master Schedule (IMS)	The IMS expands the IMP to the work planning level. It defines the tasks, their durations, milestones, milestone dates which relate to the IMP completion criteria, and interdependencies required to complete the program. The IMP and IMS are used to track and execute the program.
Integrated Product Team (IPT)	A grouping of project personnel along project objective lines rather than along organizational lines. Integrated Product Teams are work teams that represent a transition from a functional organization structure to a multi-functional project objective arrangement.

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Internal Replanning	Replanning actions performed by the program for remaining effort within the recognized total allocated budget.
Level of Effort (LOE)	Work that does not result in a final product, e. g., liaison, coordination, follow-up, or other support activities, and which cannot be effectively associated with a definable end product process result. It is measured only in terms of resources actually consumed within a given time period.
Management Reserve (MR)	An amount of the total Contract Budget Base (CBB) withheld for management control purposes rather than designated for the accomplishment of a specific task or set of tasks. It is not a part of the Performance Measurement Baseline.
Negotiated Contract Target Cost	The estimated cost negotiated in a Cost Plus Award Fee (CPAF), Cost Plus Fixed Fee (CPFF), Cost Plus Incentive Fee (CPIF) or Fixed Price Incentive Fee (FPIF) contract.
Original Budget	The budget established at, or near, the time the contract was signed, based on the negotiated contract cost.
Overhead	Indirect labor and material, supplies and services costs and other charges, which cannot be consistently identified with individual programs.
Other Direct Costs	A group of accounting elements which can be isolated to specific tasks, other than labor and material. Included in ODC are such items as travel, computer time, and services

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Performance Measurement Baseline (PMB)	The time-phased budget plan against which contract performance is measured. It is formed by the budgets assigned to scheduled Control Accounts and the allocation of overhead costs. For future effort, not planned to the Control Account level, the performance measurement baseline also includes budgets assigned to higher level WBS elements, and undistributed budgets. It equals the total assigned budget less management reserve.
Performing Organization	A defined unit within the program organization structure, which applies the resources to performs the authorized scope of work.
Planning Package	A logical aggregation of far term work within a Control Account that can be identified and budgeted but not yet defined into Work Packages.
Reprogramming	Replanning of the effort remaining in the contract, resulting in a new budget allocation which exceeds the contract budget base. The resulting baseline is called an Over Target Baseline (OTB).
Responsible Organization	A defined unit within program's organization structure that is assigned responsibility for accomplishing specific tasks.
Risk Register	Is a tool commonly used in project planning and organizational risk assessments. It is often referred to as a Risk Log. It is used for identifying, analyzing and managing risks.
Schedule Performance Index (SPI)	An efficiency rating reflecting how quickly or slowly project work is progressing. Measured as a ratio of work accomplished versus work planned for a given period of time. The formula for SPI is $BCWP/BCWS$.

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Significant Variances	Those differences between planned and actual cost and schedule performance which require further review, analysis, or action. Appropriate thresholds are established as to the magnitude of variances which will require variance analysis.
Statistical Estimate at Completion	Is a single point estimate that can be quickly prepared and used to test the reasonableness of the current cost estimates and budget and to indicate when a comprehensive EAC should be prepared
Time-Phased S/P/A Report	Provides the timphased budget, performance (earned value) and actual costs at a specific level. It may be at the reporting level, control account, and/or work package level. In all cases the report will also provide the data at the total project level.
To-Complete Performance Index (TCPI)	An efficiency rating that provides a projection of the anticipated performance required to achieve the EAC. TCPI indicates the future required cost efficiency needed to achieve a target EAC (Estimate At Complete). Any significant difference between TCPI and the CPI needed to meet the EAC should be accounted for by management in their forecast of the final cost.
Total Allocated Budget (TAB)	The sum of all budgets allocated to the contract. Total allocated budget consists of the performance measurement baseline and all management reserve. The total allocated budget will reconcile directly to the Contract Budget Base (CBB). Any differences will be documented as to quantity and cause.
Undistributed Budget (UB)	Budget applicable to contract effort which has not yet been identified to WBS elements at or below the lowest level of reporting to the Government.

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Variance Analysis Report (VAR)	The internal report completed by the Control Account Manager and submitted, through the Intermediate Manager, to the program manager for those Control Accounts which have variances in excess of established thresholds.
Variances	(See Significant Variances).
Work Authorization Document (WAD)	A form used to formally authorize and budget work to the Control Account Manager. This document must include, as a minimum, the Control Account number, Statement of Work, scheduled start and finish dates, budget, and the identity of the CAM. It must be approved by Intermediate Manager, and be agreed to by the Control Account Manager.
Work Breakdown Structure (WBS)	<p>A product-oriented, family-tree composed of hardware, software, services, data and facilities which results from system engineering efforts. A work breakdown structure displays and defines the product(s) to be developed and/ or produced and relates the elements of work to be accomplished to each other and to the end product.</p> <p>(1) Program WBS. The work breakdown structure that covers the acquisition of a specific defense material item and is related to contractual effort. A program work breakdown structure includes all applicable elements consisting of at least the first three levels of the work breakdown structure and extended by the program manager and /or contractor(s). A program work</p>

breakdown structure has uniform element terminology, definition, and placement in the family tree structure.

(2) Contract WBS (CWBS) The complete WBS for a contract, developed and used by a contractor within the guidelines of MIL-Handbook 881 (latest revision) or NASA WBS Handbook (insert reference) or other customer guidelines and according to the contract work statement. It includes the approved work breakdown structure for reporting purposes and its discretionary extension to the lower levels by the contractor, in accordance with MIL-Handbook 881 and the contract work statement. It includes all the elements for the products (hardware, software, data, or services) which are the responsibility of the contractor.

Work Packages

Detailed short-span jobs, or material items, identified by the contractor for accomplishing work required to complete the contract. A Work Package has the following characteristics.

1. It represents units of work at levels where work is performed.
2. It is clearly distinguishable from all other work packages.
3. It is assignable to a single organizational element.
4. It has scheduled start and finish dates and, as applicable, interim milestones, all of which are representative of physical accomplishment.
5. It has a budget or assigned value expressed in terms of dollars, man-hours or other measurable units.
6. Its duration is limited to a relatively short span of time or it is subdivided by discrete value milestones to facilitate the objective measurement of work performed.
7. It is integrated with detailed engineering, manufacturing, or other schedules.

Work Package Budgets

Resources which are formally assigned by the CAM to accomplish a Work Package, expressed in dollars and/or hours.

Appendix 2 Supplemental EVM Implementation Guideline

Implementation of a 7 Principles of EVM system should be less expensive than if there was an ANSI/EIA-748. There is no need for the system to have to go through an EVM compliance review, plus the level of documentation should be streamlined.

The implementation should include:

- EVM Process flows that reflect how a company will build and maintain the EVM system. (EVM Procedures may also be included if the cost associated with them is reasonable)
- EVM engine tool and a schedule tool. It is not necessary to load the schedule tool, such as Microsoft Project, with resources. This adds an extra step, additional costs and little to no value. It is recommended that all resource information be loaded in the EVM engine and leave the schedule tool to what it does best, measure progress through time (duration).
- The EVM Engine needs to be integrated with the company's accounting system.

Documentation needed for the Performance Measurement Baseline Review (PMBR)

- WBS Dictionary/Control Account Work Authorization Documentation
- Integrated Master Schedule
- Responsibility Assignment Matrix
- Control Account Plans
- PMB Log
- Baseline Revision Documents
- Risk Register

EVM IMPLEMENTATION COSTS

The cost for an implementation depends on the size of the contract and the tier level of EVM.

Tier 2 (projects greater than \$25M)

Implementation costs should range \$75K-\$125K

Tier 3 (projects less than \$25M)

Implementation costs should range (\$50K - \$100K)

EVM ENGINES/TOOLS

Depending on the size of the contract would predicate the level of functionality that would be needed. For Tier 2 contracts a larger, more robust EVM engine would be needed. For the Tier 3 small contracts MS Project or the MSP wrap-around would probably suffice although the more robust EVM engines can be used also.

Tier 2

It is recommended that one of the larger and flexible EVM engines be utilized. The tool should have the flexibility to be able to download data from MS Project and be able to upload or input

budget data to provide time-phased budget information down to the work package level. It should be able to incorporate the companies Organization Breakdown Structure. It should be able to maintain baseline, actual costs, forecast and performance periodic data. It should be able to forecast Estimate to Complete with the ability to set up different rate tables if necessary. It should have the capability to use all earned value methodologies. It should be able to print many types of EVM reports that can provide information to the Control Account Managers (CAM) and Program Managers (PM), as well as, the Contract Performance Report (CPR) and the Control Account Plans (CAP) that are contract deliverables.

Tier 3

For Tier 3 projects, a company can certainly utilize an EVM engine as listed above or a less robust, less expensive EVM engine that provides the CPR and timephased S/P/A report. It may also use the Microsoft Project wrap-around tools of which there are several on the market. These tools also will provide the CPR and timephased S/P/A report for contract deliverable purposes.

EVM FACILITATION

EVM facilitation pertains to the monthly process to include:

- Schedule Status
- Integration of accounting data into EVM engine
- Run monthly reports for Control Account Managers (Tier 2 only)
- Prepare the monthly Contract Performance Report (CPR) Formats 1 and 5
- Run the monthly timephased S/P/A for both internal and external (contract requirement)
- PMB Change Control

Depending on the size of contract, a contractor should have an EVM/cost analyst and schedule analyst for a Tier 2 contract and one combined cost/schedule analyst for a Tier 3 contract. The costs for a schedule analyst on a yearly basis for an employee hire should be equal to or less than \$125K. For a cost analyst it should be equal to or less than \$110K. If a company is bringing in a contractor to provide staff implementation the costs should be up to \$125/hr for a schedule analyst and \$110/hr for an EVM/cost analyst.

EVM CONSULTANTS

There may be the need to bring in consultants to help set up your EVM system and perhaps provide EVM staff augmentation to provide the monthly facilitation. Make sure that you shop around and get several quotes. Also make sure that the consultants understand the statement of work pertaining to the BARDA EVM requirements. Most EVM consultants are used to working with companies that have a requirement to implement an ANSI/748 compliant EVM system per the DoD requirements and it is important that they have an understanding of what is required in a 7 Principles EVM implementation so that they don't propose much more complex

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EVM system than is needed. Please be advised that the government will only accept reasonable costs associated with implementing a 7 Principles of EVM system.

COST OF EVM

BARDA is working diligently to keep the costs of EVM implementation and facilitation at a reasonable level. Since the goal at BARDA is to provide an integrated, systematic approach to the development and purchase of the necessary vaccines, drugs, therapies, and diagnostic tools for public health medical emergencies, it is imperative that the funds for product development are used for that such purpose. BARDA expects the costs for implementation and facilitation of EVM to range 1%-2% of development budget. This is ratified by the white paper by Dr. Christenson titled "The Costs and Benefits of the Earned Value Management Process".

Appendix 3 Sample EVM Documents

WBS 1.4.1.x Cardiac (QTc) Safety

Description

Study Title: “A Phase 1 study to assess the cardiovascular safety of intravenous (IV) Panaceomycin in volunteers” (Thorough QT Study)

We will conduct a thorough evaluation of the cardiac effect of Panaceomycin Injection via a randomized, double-blind crossover study. A total of 100 participants (18-22 per arm) will randomize to one of five study arms to receive in a double-blind fashion a single IV infusion of either Panaceomycin Injection 10 mg/kg, Panaceomycin Injection at a supra-therapeutic dose, ciprofloxacin (positive control), or placebo. 12-Lead digital ECGs will be collected in triplicate via Holter monitor from each participant during dosing. Seven days after dosing, participants will be re-randomized to receive another treatment. ECGs will be collected and analyzed. A full statistical analysis and expert ECG report will be generated. Serum PK samples will also be collected at ECG collection time points and analyzed to confirm exposure.

Sample WBS Scope Description

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CAP: 1.1.1 Drug Production		Month End: 3/31/2011													
Control Account Performance		Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12	Total	
BCWS		200	30	30	40	60	80	60	80	15	25	30	25	675	
BCWP		10	190	60											
ACWP		12	190	60											
SV		-190	160	30											
CV		-2	0	0											
Resource Summary		Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12	Total	
Labor		10	10	10	10	10	10	10	10	10	10	10	10	120	
Sub DB			20	20	30									70	
Sub DP						50	70	50	70					240	
Sub Pack										5	20	15		40	
Material		190												190	
ODC										5	10			15	
BCWS		200	30	30	40	60	80	60	80	15	25	30	25	675	
Work Package Summary		EVM	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7	Month 8	Month 9	Month 10	Month 11	Month 12	Total
Sub Contract Management	LOE		10	10	10	10	10	10	10	10	10	10	10	10	120
Purchase Materials	0/100		190												190
Manufacture Drug Substanc	MS			20	20	30									70
Manufacture Drug Product	MS						50	70	50	70					240
Ship	Units									5	10				15
Package & Store	Units										5	20	15		40
BCWS			200	30	30	40	60	80	60	80	15	25	30	25	675

Sample Timephased S/P/A Report