

2 CONTRACT (Proc. Inst. Ident.) NO HHS0100201600031C 3. EFFECTIVE DATE See Block 20C 4. REQUISITION/PURCHASE REQUEST/PROJECT NO. DS182642

5 ISSUED BY CODE ASPR-BARDA 6 ADMINISTERED BY (If other than Item 5) CODE ASPR-BARDA01
 ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201
 ASPR-BARDA 330 Independence Ave, SW, Rm G644 Washington DC 20201

7 NAME AND ADDRESS OF CONTRACTOR (No., Street, City, Country, State and ZIP Code) BIOPROTECTION SYSTEMS CORPORATION 1455640 CARL LANGREN ;2503 SOUTH LOOP DRIVE 2503 SOUTH LOOP DRIVE AMES IA 500108646
 8. DELIVERY FOB ORIGIN OTHER (See below)
 9 DISCOUNT FOR PROMPT PAYMENT
 10 SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN ITEM See G.5

CODE 1455640 FACILITY CODE
 11. SHIP TO/MARK FOR CODE HHS 12. PAYMENT WILL BE MADE BY CODE PSC
 HHS 200 Independence Avenue, SW Washington DC 20201
 PSC Program Support Center 5600 Fishers Lane Room 17-21 Rockville MD 20852

13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION 10 U.S.C. 2304 (c) 41 U.S.C. 253 (c) 14. ACCOUNTING AND APPROPRIATION DATA 2016.1990503.25103

15A. ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
Continued					

15G. TOTAL AMOUNT OF CONTRACT \$24,752,733.00

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CONTRACTING OFFICER WILL COMPLETE ITEM 17 (SEALED-BID OR NEGOTIATED PROCUREMENT) OR 18 (SEALED-BID PROCUREMENT) AS APPLICABLE

17. CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return 1 copies to issuing office.) Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. (Attachments are listed herein.)
 18. SEALED-BID AWARD (Contractor is not required to sign this document.) Your bid on Solicitation Number including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)

19A. NAME OF CONTRACTING OFFICER (b) (6)
 19B. UNITED STATES OF AMERICA (b) (6)
 19C. DATE SIGNED 9/29/16
 19D. SIGNATURE OF THE CONTRACTING OFFICER (b) (6)
 20C. DATE SIGNED 9/29/16

CONTINUATION SHEET

REFERENCE NO. OF DOCUMENT BEING CONTINUED
HHSO100201600031C

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NAME OF OFFEROR OR CONTRACTOR

BIOPROTECTION SYSTEMS CORPORATION 1455640

ITEM NO. (A)	SUPPL ES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Tax ID Number: (b) (4) DUNS Number: 606727076 Advance the development of V920, a vaccine against Ebola virus using a recombinant Vesicular Stomatitis Virus vector. Appr. Yr.: 2016 CAN: 1990503 Object Class: 25103 FOB: Destination				
1	Facility, Site, Process Performance Qualification (PPQ) Readiness Activities Obligated Amount: \$24,752,733.00				24,752,733.00
2	Option 1 - Manufacturing and Testing of PPQ Lots, BLA Preparation, and Pre-PAI Activities Amount: (b) (4) (Option Line Item)				0.00
3	Option 2 - Pediatric Clinical Trial Amount: (b) (4) (Option Line Item)				0.00
4	Option 3 - Additional Process Simulations and Manufacturing of PPQ Lots Amount: (b) (4) (Option Line Item)				0.00

PART I – THE SCHEDULE

SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

There are currently no medical countermeasures available for the prophylaxis or treatment of infection with Ebola virus, a high priority agent for the Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Implementation Plan.

The objective of this contract is to advance the development of V920, a vaccine against Ebola virus using a recombinant Vesicular Stomatitis Virus vector. The scope of work for this contract includes non-clinical, clinical, regulatory, and manufacturing development activities that fall into the following areas: non-clinical toxicology studies; clinical activities; manufacturing activities; and all associated regulatory, quality assurance, program management, and administrative activities. The Research and Development (R&D) effort for V920 will progress in specific stages that cover one base performance segments and three (3) option segments as specified in this contract. The Contractor must complete specific tasks required in each of the four (4) discrete work segments. The scope of work has been broken into the following base period and three options which are discrete work segments:

Base Period: Facility, Site, Process Performance Qualification (PPQ) Readiness Activities

Option 1: Manufacturing and Testing of PPQ Lots, BLA Preparation, and Pre-PAI Activities

Option 2: Pediatric Clinical Trial

Option 3: Additional Process Simulations and Manufacturing of PPQ Lots

Work performed during the base segments and during each option segment constitutes an independent, non-severable discrete work segment that cannot be subdivided for separate performance and is necessary to support R&D tasks related to the platform. Each non-severable, work segment constitutes an entire job (discrete requirement) which shall contain multiple R&D activities that when reviewed in total shall satisfy a defined end-product. There are technical and programmatic deliverables and milestones within a work segment that may trigger the execution of option(s). The non-severable work segment will be fully funded from an appropriation source that will be current at the time the work is authorized to begin. See the Statement of Work, Attachment #1.

The Government has determined a *Bona Fide Need* for each non-severable discrete work segment which will conclude upon the completion of a defined task(s) that provides independent merit and value to the Government. The Contractor must achieve defined deliverables and/or milestone(s), as outlined in the SOW of this contract, before the Government will consider exercising any of the follow-on option segment(s). The Contractor's success in completing the required tasks under

each work segment must be demonstrated through the Deliverables and Milestones specified under Section F of this contract. Those deliverables will support the GO/NO GO Contract Milestones and Decision Gates specified therein. The GO/NO GO Contract Milestones and Decision Gates will constitute the basis for the Government's decision, at its sole discretion, to exercise any follow-on option segment(s).

The base and option segments under Contract Line Items (CLINs) 0001 through 0004 are event driven work segments rather than time driven CLINs. The funds for each independent, non-severable discrete work segment (requirement), regardless of duration, are separated by CLIN, and shall only be used for the scope of work covered in each discrete work segment. The periods of performance listed under each of the CLINs under Article B.2 and Article B.3 below are estimated time periods. Those individual time periods may be extended by mutual agreement of the parties to complete the tasks required under each work segment. It is possible that more than one independent, non-severable discrete work segment (requirement), may be awarded at one time and that individual CLINs may overlap and/or proceed concurrently.

ARTICLE B.2. ESTIMATED COST

1. The total estimated cost of this contract is (b) (4).
2. CLIN 0001, is the base performance segments, and CLINs 0002 through 0004 are the option periods, with all being cost-reimbursement CLINs.
3. The Government shall provide monies for the base performance segment (CLIN 0001) in an amount not to exceed \$24,752,733. The total amount obligated by the Government for the base segment of the contract shall not exceed the Total Estimated Cost of \$24,752,733. and the Government will not be responsible for any Contractor incurred costs that exceed this amount unless a modification to the contract is signed by the Contracting officer which expressly increases this amount.
4. The Contractor shall maintain records of all contract costs and such records shall be subject to the Audit and Records-Negotiation and Final Decisions on Audit Findings clauses of the General Clauses.
5. Costs contributed by the Contractor shall not be charged to the Government under any other contract, grant, or cooperative agreement (including allocation to other grants, contracts, or cooperative agreements as part of an independent research and development program).
6. Consistent with FAR 52.216-8, Fixed-Fee (Jun 2011), any fixed fees payable in the base or option periods may be invoiced, and will be paid, in an amount proportionate to the percentage of total estimated costs for each applicable option period that the Contractor is estimated to have incurred at the time at which an invoice is submitted. Amounts paid under this provision will not

exceed the total fixed fee identified in Article B.2. and B.3 for each option period, and the Contracting Officer may withhold a portion of the total fixed fee for each option period in an amount not to exceed 15 percent of the fixed fee or \$100,000, whichever is less, consistent with FAR 52.216-8, Fixed Fee (Jun 2011).

7. It is estimated that the amount currently allotted will cover performance of the contract through 31 May 2020 for the base period.

BASE PERIOD

CLIN	Estimated Period of Performance	Supplies/Services	Estimated USG Cost	Fee/profit	Total Estimated Cost
0001	9/1/2016 Through 5/31/2020	Facility, Site, Process Performance Qualification (PPQ) Readiness Activities	(b) (4)	(b) (4)	\$24,752,733
		TOTAL	(b) (4)	(b) (4)	\$24,752,733

ARTICLE B. 3. OPTION PRICES

- a. Unless the government exercises its option pursuant to the option clause contained in ARTICLE I.2, the contract consists only of the Base Period Work segment (CLIN 0001) specified in the Statement of Work as defined in Attachment 1, for the price set forth in ARTICLE B.2 of the contract.
- b. Pursuant to FAR Clause 52.217-9 (Option to Extend the Term of the Contract), the Government may, by unilateral contract modification, require the Contractor to perform the Option Work Segments specified in the Statement of Work as defined in Attachment 1 of this contract. If the Government decides to exercise an option(s), the Government will provide the Contractor a preliminary written notice of its intent as referenced in the clause. Specific information regarding the time frame for this notice is set forth in the OPTION CLAUSE Article in SECTION G of this contract. The amount obligated to the contract will be increased as set forth below:

OPTIONS

Option 1 (CLIN 0002) thru Option 3 (CLIN 0004)

CLIN	Option Period	Estimated Period of	Supplies/Services	Estimated	Fee/Profit	Total Estimated
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		Performance		USG Cost		Cost
0002	0001	(b) (4) ██████████ ██████████	Manufacturing and Testing of PPQ Lots, BLA Preparation, and Pre-PAI Activities	(b) (4) ██████████	██████████	██████████
0003	0002	(b) (4) ██████████ ██████████	Pediatric Clinical Trial	(b) (4) ██████████	██████████	██████████
0004	0003	(b) (4) ██████████ ██████████	Additional Process Simulations and Manufacturing of PPQ Lots	(b) (4) ██████████	██████████	██████████

ARTICLE B. 4. LIMITATIONS APPLICABLE TO DIRECT COSTS

a. Items Unallowable Unless Otherwise Provided

Notwithstanding other clauses and unless authorized in writing by the Contracting Officer, the cost of the following items or activities shall be unallowable as direct costs:

- 1) Acquisition, by purchase or lease, of any interest in real property;
- 2) Special rearrangement or alteration of facilities;
- 3) Accountable Government Property (*see* the HHS Contracting Guide for Control for Government Property incorporated by ARTICLE G.10. of this contract);

Note: this includes the lease or purchase of any item of general purpose office furniture or office equipment regardless of dollar value.

- 4) Purchase or lease scientific instruments or equipment over \$1,500;
- 5) Travel to attend general scientific meetings/conferences;
- 6) Printing Costs (as defined in the Government Printing and Binding Regulations);
- 7) Overtime (premium) compensation

-
- 8) Entering into certain types subcontract of arrangements (See Article B.5(c) for specific obligations). Note that most consulting agreements require CO's written consent.
 - 9) Foreign Travel (see Subparagraph b.3);
 - 10) Patient care costs (see Attachment 6);
 - 11) Light Refreshment and Meal Expenditures - Requests to use contract funds to provide light refreshments and/or meals to either federal or nonfederal employees must be submitted to the Contracting Officer's Representative (COR), with a copy to the Contracting Officer, at least six (6) weeks in advance of the event and are subject to "HHS Policy on Promoting Efficient Spending: Use of Appropriate Funding for Conferences and Meetings, Food and Promotional Items and Printing and Publications." The request shall contain the following information: (a) name, date, and location of the event at which the light refreshments and/or meals will be provided; (b) a brief description of the purpose of the event; (c) a cost breakdown of the estimated light refreshments and/or meals costs; (d) the number of nonfederal and federal attendees receiving light refreshments and/or meals; and (e) confirmation of whether if the event will be held at a government facility.

b. Travel Costs

1. Total expenditures for travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this contract during the base segment (CLIN 0001) shall not exceed (b) (4) without the prior written approval of the Contracting Officer. The Contractor shall notify the Contracting Officer in writing when travel expenditures have exceeded (b) (4) of the base segment travel expenses. Cost must be consistent with Federal Acquisition Regulations (FAR) 52.247-63 – Preference for U.S. Air Flag carriers. Costs incurred for lodging, meals, and incidental expenses shall be considered reasonable and allowable to the extent that they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulation (FTR).
2. Subject to the annual dollar limitation specified under B.4.b.1. 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.
3. If foreign travel is necessary, a Contracting Officer Authorization (COA) will be required. Expenditures for foreign travel (transportation, lodging, subsistence, and incidental expenses) incurred in direct performance of this contract shall not

exceed the amount specified in each approved COA, without the prior written approval of the Contracting Officer.

Requests for foreign travel must be submitted at least four weeks in advance and shall contain the following:

- (a) meeting(s) and place(s) to be visited, with costs and dates;
- (b) name(s) and title(s) of Contractor personnel to travel and their functions in the contract project;
- (c) contract purposes to be served by the travel;
- (d) how travel of Contractor personnel will benefit and contribute to accomplishing the contract project, or will otherwise justify the expenditure of ASPR contract funds;
- (e) how such advantages justify the costs for travel and absence from the project of more than one person if such are suggested; and
- (f) what additional functions may be performed by the travelers to accomplish other purposes of the contract and thus further benefit the project.

ARTICLE B.5. ADVANCE UNDERSTANDINGS

a. Person-in-Plant

With seven (7) days advance notice to the Contractor in writing from the Contracting Officer, the Government may place one (1) person-in-plant in the Contractor's facility or performance sites (to include subcontracts) for the sole purpose of monitoring activities directly related to performance of this contract during normal business hours, who shall be subject to the Contractor's policies and procedures regarding security, facility access, and training 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 coming to him in the course of employment or official duties, while stationed in a contractor plant.

b. Security

A Security Plan is required for this effort. A security waiver may be requested. In the event a security waiver cannot successfully be attained, the Government will notify the Contractor who will subsequently will be required to deliver a security plan to the Government, conforming with the following paragraphs.

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 request submission of a Draft Security Plan for Merck's (b) (4) within) within

ninety (90) days of contract award and review the Draft Security Plan in detail and submit comments within ten (10) business days to the 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 CO and Contracting Officer's Representative (COR) 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 considered as part of the Contractor's Technical Proposal. 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 offsite); 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.

Security Reporting Requirement - Violations of established security protocols shall be reported to the CO and COR within 24 hours of the contractor's discovery 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 CO 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.

c. **Subcontracts**

Prior written consent from the Contracting Officer in the form of Contracting Officer Authorization (COA) is required for any subcontract that:

- Is of the cost-reimbursement type; or
- Is Fixed-Price and exceeds \$150,000 or 5% of the total estimated cost of the Contract, whichever value is greater.

The Contracting Officer shall request appropriate supporting documentation in order to review and determine authorization, pursuant with FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, the Contractor shall provide a copy of the signed, executed subcontract and consulting agreement to the Contracting Officer.

Note: Consulting services are treated as subcontracts and subject to the 'consent to subcontract' provisions set forth in this Article.

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 352.224-71).

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 at or prior to the time

of its disclosure 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. **Sharing of contract deliverables within United States Government (USG)**

In an effort to build a robust medical countermeasure pipeline through increased collaboration, BARDA may share technical deliverables set forth in Article F.2 with Government entities responsible for Medical Countermeasure Development to the extent permitted by and with restrictions required under FAR 52.227-14, Alternate II. This provision applies to all deliverables and data developed during performance. This advance understanding does not authorize BARDA to share financial information outside HHS. The Contractor is advised to review the terms of FAR Clause 52.227-14 regarding the Government's rights to deliverables submitted during performance as well as the Government's rights to data contained within those deliverables.

f. **Overtime Compensation**

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

g. (b) (4) [REDACTED]

[REDACTED]

h. Disclosure by Contractor

Notwithstanding any other provision in this contract, Contractor may disclose any information relating to this Agreement to its affiliates, subcontractors, or third parties that have an interest in V920, subject to any restrictions on further use or disclosure that may apply to Contractor under this contract. If authorized by Contractor, recipients of information under this provision will have the same rights as Contractor to use, release to others, reproduce, distribute, or publish such information.

- i. All cost for insurance must be reviewed and approved by the CO in advance and cannot exceed authorized funding amounts.

SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF WORK

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 Work attached to this contract as Attachment 1 (SECTION J-List of Attachments).

ARTICLE C.2. REPORTING REQUIREMENTS

Refer to ARTICLE F.2. for specific instructions regarding Reporting Requirements.

ARTICLE C.3. EARNED VALUE MANAGEMENT SYSTEM (EVMS) IMPLEMENTATION REQUIREMENTS

The Contractor and the Government 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 Attachment 9 (See SECTION J-List of Attachments) to the contract. Attachment 9 is provided as an example of a Contract Performance Report and is not binding. . 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.

Refer to ARTICLE F.2. for specifics on EVMS deliverables.

ARTICLE C.4. PROJECT MEETING CONFERENCE CALLS

A teleconference call between the Contracting Officer, Contracting Officer's Representative and the Contractor's Program Manager shall occur bi-weekly (every two weeks), or at the discretion of the Government. During this call, the Program Manager will discuss the activities during the reporting period, any problems that have arisen, and the activities planned for the ensuing reporting period. The Contractor's Program Manager may choose to include other key personnel on the conference call to give detailed updates on specific projects or this may be requested by the Contracting Officer's Representative.

Contractor will be responsible for preparing an agenda for the conference call and providing it to the Government no later than 2 business days prior to the scheduled conference call.

ARTICLE C.5. PROJECT MEETINGS

The Contractor shall participate in Project Meetings to coordinate the performance of the contract, as requested by the Contracting Officer's Representative. These meetings may include face-to-face meetings with BARDA/AMCG in Washington, D.C. and at work sites of the Contractor and its subcontractors. Such meetings may include, but are not limited to, meetings of the Contractor (and subcontractors invited by the Contractor) to discuss study designs, site visits to the Contractor's and subcontractor's facilities, and meetings with the Contractor and HHS officials to discuss the technical, regulatory, and ethical aspects of the program. The Contractor must provide data, reports, and presentations to groups of outside experts (subject to appropriate protections for Contractor confidential or proprietary data) and USG

personnel as required by the Contracting Officer's Representative in order to facilitate review of contract activities.

a. Kickoff Meeting

The Contractor shall complete a Kickoff meeting within 30 days after contract award. Contractor shall provide an itinerary/agenda no later than 5 business days before meeting.

b. Ad-Hoc Meetings

At the discretion of the Contracting Officer and/or Contracting Officer's Representative, the Contractor shall participate in Project Meetings to coordinate the performance of the contract. These meetings may include teleconferences or face-to-face meetings with BARDA/AMCG in Washington, D.C. or at work sites of the Contractor and its subcontractors. Such meetings may include, but are not limited to, meetings of the Contractor (and subcontractors invited by the Contractor) to discuss study designs, site visits to the Contractor's and subcontractor's facilities, and meetings with the Contractor and HHS officials to discuss the technical, regulatory, and ethical aspects of the program. The Contractor must provide data, reports, and presentations to groups of outside experts (subject to appropriate protections for Contractor's confidential or proprietary data) and Government personnel as required by the Contracting Officer's Representative, giving reasonable prior notice of such requirement to Contractor, in order to facilitate review of contract activities.

Contractor shall provide itinerary/agenda at least 5 business days in advance of face-to-face meeting.

c. Face-to-Face Project Review Meetings

The Contractor shall, at a time to be determined later, present a comprehensive review of contract progress to date in a face-to-face meeting in Washington, DC. The Contractor will be responsible for updating BARDA program on technical progress under the Statement of Work. Presentation must be delivered seven (7) business days prior to the scheduled meeting.

SECTION D – PACKAGING, MARKING, AND SHIPPING

All deliverables required under this contract shall be packaged, marked and shipped in accordance with Section F. 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, delivery of reports to be furnished to the USG under this contract (including invoices) shall be delivered to

AMCG and BARDA electronically along with a concurrent email notification to the Contracting Officer, Contract Specialist, and COR (as defined in SECTION F.3. ELECTRONIC SUBMISSION) summarizing the electronic delivery.

SECTION E – INSPECTION AND ACCEPTANCE

ARTICLE E.1. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE (FEBRUARY 1998)

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

FAR Clause	Title and Date
52.242-15	Stop Work Order (Aug 1989)
52.246-8	Inspection of Research and Development - Cost-Reimbursement (May 2001)

ARTICLE E.2. DESIGNATION OF GOVERNMENT PERSONNEL

For the purpose of this SECTION E, the designated Contracting Officer’s Representative (COR) is the authorized representative of the Contracting Officer. The COR will assist in resolving technical issues that arise during performance. The COR however is not authorized to change any contract terms or authorize any changes in the Statement of Work or modify or extend the period of performance, or authorize reimbursement of any costs incurred during performance.

ARTICLE E.3. INSPECTION, ACCEPTANCE AND CONTRACT MONITORING

Inspection and acceptance of the materials services and documentation called for herein shall be accomplished by the Contracting Officer or a duly authorized representative.

Inspection and acceptance for report deliverables will be performed at:

Office of Acquisitions Management, Contracts, and Grants (AMCG) Office of the
Assistant Secretary for Preparedness and Response
U.S. Department of Health and Human Services 330 Independence Avenue, S.W.,
Room G644 Washington, D.C. 20201

Inspection and acceptance for non-report deliverables will be performed at the Contractor's or its subcontractor's facilities.

a. Site Visits and Inspections

At the discretion of the USG and independent of activities conducted by the Contractor, with 5 business days' notice to the Contractor, the USG reserves the right to conduct site visits and inspections on an as needed basis, including collection of product samples and intermediates held at the location of the contractor, or subcontractor. Such site visits and inspections shall be limited to facilities or parts of facilities directly related to the performance of this contract and for purposes directly related to this contract. All costs reasonably incurred by the Contractor and subcontractor for such visit and/or inspection shall be allowable costs subject to the Allowable cost requirements in FAR Subpart 31.2. The Contractor shall coordinate these visits and shall have the opportunity to accompany the USG on any such visits. Under time-sensitive or critical situations, the USG reserves the right to suspend the 48 hour notice to the Contractor. The areas included under the site visit could include, but are not limited to: security, regulatory and quality systems, manufacturing processes and cGMP/GLP/GCP compliance.

If the USG, Contractor, or any other interested party identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the USG for review and acceptance.

- If issues are identified during the audit, the Contractor shall submit a report to the CO and COR within ten (10) business days detailing the finding and proposed corrective action(s) of the audit.
- COR and CO will review the report and provide a response to the Contractor within ten (10) business days.
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

SECTION F – DELIVERIES OR PERFORMANCE

ARTICLE F.1. ESTIMATED PERIOD OF PERFORMANCE

The estimated period of performance for this contract shall be consistent with the dates set forth in the base period CLIN 0001 set forth in ARTICLE B.2. If the Government

exercises its Option(s) pursuant to the Option Clause of the contract, the period of performance shall be increased as shown in the table in Article B.3.

ARTICLE F.2. DELIVERABLES

Successful performance of the final contract shall be deemed to occur upon completion of performance of the work set forth in Attachment 1, the Statement of Work dated 12 September 2016, set forth in SECTION J - List of Attachments of this contract and upon delivery and acceptance, as required by the Statement of Work, by the Contracting Officer, of each of the deliverables described in SECTION F and SECTION J.

All deliverables and reporting documents listed within this section shall be delivered electronically (as defined in SECTION F.3. ELECTRONIC SUBMISSION) to the CO, CS, and the COR unless otherwise specified by the Contracting Officer.

Summary of Contract Deliverables

Unless otherwise specified by the Contracting Officer, the deliverables identified in this SECTION F shall also be delivered electronically to the designated eRoom along with a concurrent email notification sent to the Contracting Officer, Contract Specialist, COR, and Alternate COR, if designated stating delivery has been made.

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). Hard copies of deliverables and reports furnished to the USG under the resultant Contract (including invoices) shall be addressed as follows:

HHS/ASPR/AMCG

ATTN: (b) (6), Contracting Officer (CO)
330 Independence Avenue, S.W., Room G640 Washington, DC 20201
Email : (b) (6)

HHS/ASPR/BARDA

ATTN: (b) (6),
Contracting Officer's Representative (COR)
330 Independence Avenue, S.W.,
Washington, DC 20201
Email: (b) (6)

1. Summary of Contract Deliverables - Unless otherwise stated, each deliverable in the table below shall be provided as one (1) electronic copy to the COR, CS, and CO as set forth in SECTION D.

TECHNICAL DELIVERABLES

Item #	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
01	Kickoff Meeting	The Contractor shall complete a Kickoff meeting after contract award	<ul style="list-style-type: none"> • Within a 30 days of contract award. • Contractor shall provide itinerary and agenda at least 5 business days in advance of site visit. • CO approves and distributes itinerary and agenda within 3 business days. • Contractor provides meeting minutes to COR within 5 business days after the meeting. • CO and COR reviews, comments, and approves minutes within 10 business days.
02	Biweekly Teleconference Meetings	The Contractor shall participate in teleconferences every two weeks with the Government to discuss the performance of the contract.	<ul style="list-style-type: none"> • Contractor provides agenda to CO and COR no later than 2 business days in advance of meeting. • COR approves and distributes agenda prior to meeting. • Contractor provides meeting minutes to CO and COR within 5 business days following the meeting. • COR reviews, comments, and approves minutes within 10 business days following the meeting.
03 (Monthly) 05 (Annually)	Monthly & Annual Technical Progress Reports	<p>The Monthly and Annual Technical Progress report shall address each of the below items and be cross-referenced to the Work Breakdown Structure (WBS), Statement of Work (SOW), Integrated Master Schedule (IMS), Performance Measurement Baseline Review report (PMBR), Earned Value Management (EVM), and Contract Performance Report (CPR).</p> <p>1. An Executive Summary highlighting the progress, issues and relevant manufacturing, non-clinical, clinical and regulatory</p>	<ul style="list-style-type: none"> • Monthly Reports shall be submitted on the 20th day of the month after the end of each month with an Annual Report submitted on the 30th calendar day of the final month of each contract year for the previous twelve calendar months. Monthly progress reports are not required for the periods when the Annual Report(s) and Final Report are due. The COR and CO will review the monthly reports with the Contractor and provide feedback.

Item #	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<p>activities. The Executive Summary should highlight only critical issues for that reporting period and resolution approach; limited to 2-3 pages.</p> <p>2. Progress in meeting contract milestones – broken out by subtasks within each milestone, overall project assessment, problems encountered and recommended solutions. The reports shall detail the planned and actual progress during the period covered, explaining occurrences of any differences between the two and the corrective steps.</p> <p>3. The reports shall also include a three-month rolling forecast of the key planned activities, referencing the WBS/IMS.</p> <p>4. A tracking log of progress on regulatory submissions with the FDA number, description of submission, date of submission, status of submission and next steps.</p> <p>5. Provide updated EVM/CPR.</p> <p>6. Estimated and Actual Expenses.</p> <p>7. This report shall also contain a narrative or table detailing whether</p>	

Item #	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<p>there is a significant discrepancy (>10%) at this time between the % of work completed and the cumulative costs incurred to date. Monthly and actual expenses should be broken down to the appropriate WBS level. This section of the report should also contain estimates for the Subcontractors' expenses from the previous month if the Subcontractor did not submit a bill in the previous month. If the subcontractor(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subcontractors.</p>	
04	<p>Earned Value Management (EVM) / Contract Performance Report (CPR)</p>	<p>Contractor will provide a monthly Contract Performance Report (CPR) Format 1 at an agreed upon reporting level using the BARDA provided WBS and a Variance Analysis Report (Format 5).</p> <p>The supplemental monthly CAP report shall contain, at the work package level, time phased budget (budgeted cost of work scheduled), earned value (budgeted cost of work</p>	<ul style="list-style-type: none"> • Contractor shall provide EVM/CPR as part of the Monthly Progress Report on the 20th day of the month after the end of each month (this requirement begins only as set forth in the Contract Milestones & Related Deliverables table to the CO and COR.. • Contractor shall provide top level or key changes in baseline cost as a result of anticipated cost savings or risks to the CO and COR. • The Government may request, on a monthly or ad hoc basis that the Contractor provide raw data at a reporting level or lower level as COR deems necessary. • The COR or CO may raise, in writing, concerns for Contractor to address; Contractor must address, in writing, all concerns raised by COR. • Reporting will commence after the EVM system has been implemented but no later than 3 months after

Item #	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		performed), and actual costs of work performed as captured in Contractor's EVM systems. The Contractor shall provide a rationale in the package of its use of % complete as EVMS methodology or identity whether any other EVMS methodology is being used.	start of base period.
05	Performance Measurement Baseline Review (PMBR)	<p>PMBR Report shall address each of the items listed below and be cross-referenced to the IMP, WBS, SOW, and Risk Management Plan.</p> <ol style="list-style-type: none"> 1. Contractor provided baseline proposal. 2. Responsibility Assignment Matrix. 3. A description of the work scope through control account Work Authorization Documents and/or WBS Dictionary down to the control account level. 4. Template for work packages. 5. IMS with the inclusion of agreed major milestones and control account plans for all control accounts. 6. Baseline revision documentation and program log(s) risk management plan. 	<ul style="list-style-type: none"> • Due within 180 days of contract award. • Contractor shall provide baseline proposal .ppt briefing 10 business days prior to meeting to the CO and COR. • Contractor provides agenda to CO and COR 2 business days in advance of meeting. • COR approves (with CO concurrence) and distributes agenda no later than 2 business days in advance of meeting. • COR approves (with CO concurrence) all meeting material no later than 2 business days in advance of meeting. • Contactor provides minutes within 5 business days of the meeting to the CO and COR. • COR reviews and approves (with CO concurrence) minutes. • COR will review documentation and provide written comments and questions to CO which provide them to the Contractor. • Contractor shall address COR's comments and resubmit PMBR report for COR and CO approval within 10 business days.
06	Risk Management Plan	The Contractor shall provide a Risk Management Plan that outlines the impacts of	<ul style="list-style-type: none"> • Due within 90 days of contract award. • Contractor provides updated Risk Management Plan in Monthly Progress Report. • COR shall provide Contractor with a written list of

Item #	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<p>each risk in relation to the cost, schedule, and performance objectives. The plan shall include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule and performance.</p>	<p>concerns in response plan submitted.</p> <ul style="list-style-type: none"> Contractor must address, in writing, all concerns raised by the COR within 20 business days of Contractor's receipt of the COR's concerns.
07	<p>Deviation Notification and Mitigation Strategy</p>	<p>Process for changing IMS activities associated with cost and schedule as baselined at the PMBR. Contractor shall notify the COR and CO of significant changes the IMS defined as increases in cost above 5% or schedule slippage of more than 30 days, which would require a PoP extension. Contractor shall provide a high level management strategy for risk mitigation.</p>	<ul style="list-style-type: none"> Due as needed.
08	<p>Go/No-Go Decision Gate Presentation</p>	<p>Contractor shall provide a presentation detailing technical progress made towards completion of Go/No-Go decision gate milestones following a prescribed template provided by the CO or COR prior to the IPR.</p>	<ul style="list-style-type: none"> Contractor shall provide presentation in .ppt format 10 business days prior to the In-Process Review (IPR). Contractor shall submit written justification of progress towards satisfying Go/No-Go criteria. After reviewing, COR and CO will provide a written response.
09	<p>Incident Report</p>	<p>Contractor shall communicate and document all critical programmatic concerns, risks, or potential risks with the COR.</p>	<ul style="list-style-type: none"> Due within 48 hours of activity or incident or within 24 hours for a security activity or incident. Email or telephone with written follow-up to COR and CO. Additional updates due to COR and CO within 48 hours of additional developments. Contractor shall submit within 5 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues.

Item #	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
			<ul style="list-style-type: none"> If corrective action is deemed necessary, Contractor must address in writing, its consideration of concerns raised by COR within 5 business days of receiving such concerns in writing.
10	Draft and Final Reports for Clinical and Non-Clinical Studies	Contractor shall provide Draft and Final Clinical/Non-Clinical Study Reports to the COR and CO for review and comment.	<ul style="list-style-type: none"> Draft report due within 45 calendar days after completion of analysis and at least 15 business days prior to submission to FDA. Subcontractor prepared reports received by the Contractor shall be submitted to the Contracting Officer's Representative and Contracting Officer (CO) for review and comment no later than 5 business days after receipt by Contractor. The Government shall provide written comments to the Draft Final Report for Clinical and Non-Clinical Studies within 15 business days after the submission. Final report due 30 calendar days after receiving comments on the Draft Final Report for Clinical and Non-Clinical Studies. If corrective action is recommended, Contractor must address, in writing, all concerns raised by the COR in writing. Contractor shall consider revising reports to address COR's recommendations prior to FDA submission. Final FDA submissions shall be provided to COR concurrently or no later than 1 business day after submission to the FDA.
11	Standard Operating Procedures	The Contractor shall make internal and, to the extent possible, subcontractor Standard Operating Procedures (SOPs) related to the performance of this contract, available for review electronically.	<ul style="list-style-type: none"> Upon request from the COR/Contracting Officer.
12	Manufacturing Campaign Reports	<p>Contractor shall provide Manufacturing Campaign Reports to COR for review and comment prior to submission to FDA.</p> <p>The COR and CO reserve the right to request within the PoP an unredacted Manufacturing Campaign</p>	<ul style="list-style-type: none"> Contractor will submit Manufacturing Campaign Reports at least 15 business days prior to FDA submission. If corrective action is recommended, Contractor must address, in writing, all concerns raised by BARDA in writing. Contractor shall consider revising reports to address COR's concerns and/or recommendations prior to FDA submission. Final FDA submission shall be submitted to COR

Item #	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		Report-for distribution within the USG.	concurrently or no later than 1 business day after submission to the FDA.
13	FDA Correspondence	The Contractor shall memorialize any correspondence between Contractor and FDA and submit to COR. All documents shall be duly marked as either "Draft" or "Final".	<ul style="list-style-type: none"> Contractor shall provide written summary of any FDA correspondence within 5 business days of correspondence.
14	FDA Meetings	The Contractor shall forward the dates and times of any meeting with the FDA to the CO and COR and make arrangements for appropriate BARDA staff to attend the FDA meetings. BARDA staff shall include up to a maximum of four people (COR, CO and up to 2 subject matter experts).	<ul style="list-style-type: none"> Contractor shall notify COR of upcoming FDA meeting within 24 hours of scheduling Type A, B or C meetings OR within 24 hours of meeting occurrence for ad hoc meetings. The Contractor shall forward initial Contractor and FDA-issued draft minutes and final minutes of any meeting with the FDA to COR within 5 business days of receipt. All documents shall be duly marked as either "Draft" or "Final".
15	FDA Submissions	The Contractor shall provide the COR the opportunity to review and comment upon all draft submissions directly related to this contract before submission to the FDA. Contractor shall provide the COR with an electronic copy of the final FDA submission. All documents shall be duly marked as either "Draft" or "Final".	<ul style="list-style-type: none"> Contractor shall submit draft FDA submissions to COR and CO at least 15 business days prior to FDA submission. COR will provide feedback to the Contractor within 5 business days after receipt, provided that COR reserves the right to request more than 5 business days for review of any regulatory submission that is of significant length. The Contractor shall inform COR of the anticipated submission length so COR can make a determination on required time for review." If corrective action is recommended, the Contractor must address, in writing, its consideration of all concerns raised by the COR. The Contractor shall consider revising their documents to address COR's concerns and/or recommendations prior to FDA submission. Final FDA submissions shall be submitted to the COR concurrently or no later than 3 calendar day of its submission to FDA.
16	FDA Audits	In the event of an FDA	<ul style="list-style-type: none"> Contractor shall notify CO and COR within 10

Item #	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<p>inspection which occurs as a result of this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for BARDA representative(s) to be present during the final debrief by the regulatory inspector.</p>	<p>business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if the FDA does not provide advanced notice.</p> <ul style="list-style-type: none"> • Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within 5 business days of receiving correspondence from the FDA or third party. • Within 10 business days of audit report, Contractor shall provide CO with a plan for addressing areas of nonconformance, if any are identified.
17	QA Audit Reports	<p>The Government reserves the right to participate in QA audits. Upon completion of the audit/site visit the</p>	<ul style="list-style-type: none"> • Contractor shall notify CO and COR 10 business days in advance of upcoming, ongoing, or recent audits/site visits of subcontractors as part of bi-weekly communications. • Contractor shall notify the COR and CO within 5

Item #	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		Contractor shall provide a summary report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of a subcontractor, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to the CO and COR. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.	business days of report completion.
18	BARDA Audit	Contractor shall accommodate periodic or ad hoc site visits by the Government. If the Government, the Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to CO and COR.	<ul style="list-style-type: none"> • If issues are identified during the audit, Contractor shall submit a report to the CO and COR detailing the finding and proposed corrective action(s) within 10 business days of the audit. • COR and CO will review the report and provide a response to the Contractor with 10 business days. • Once corrective action is completed, the Contractor will provide a final report to COR and CO.
19	Technical Documents	Upon request, Contractor shall provide CO and COR with deliverables from the following contract funded activities: process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records,	<ul style="list-style-type: none"> • Contractor shall provide technical document within 10 business days of CO or COR request. Contractor can request additional time on an as needed basis. • If corrective action is recommended, the Contractor must address, in writing, concerns raised by COR and CO in writing.

Item #	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		SOPs, Master Production Records, Certificate of Analysis, Clinical Studies Data or Reports. The CO and COR reserve the right to request within the PoP an unredacted technical document for distribution within the Government.	
20	Animal Model or Other Technology Transfer Package	Contractor shall provide Animal Model or Other Technology Transfer Package relevant data.	<ul style="list-style-type: none"> Contractor shall provide data within 10 business days of COR or CO request.
21	Raw Data or Data Analysis	Contractor shall provide raw data or data analysis to the Government upon request.	<ul style="list-style-type: none"> Contractor shall provide data or data analysis to CO and COR within 20 business days of request.
22	Publications	Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted to COR and CO for review prior to submission.	<ul style="list-style-type: none"> Contractor must submit all manuscript or scientific meeting abstract to COR and CO no later than 30 business days prior to submission for publication for manuscripts and 15 business days for abstracts. Contractor must address in writing all concerns raised by the COR in writing. Final submissions shall be submitted to the COR and CO concurrently or no later than one (1) calendar day of its submission.
23	Press Releases	Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases.	<ul style="list-style-type: none"> With the exception of ad-hoc press releases required by applicable law or regulations, Contractor shall ensure that the CO has received and approved an advanced copy of any press release to this contract not less than 5 business days prior to the issuance of the press release. If corrective action is required, the Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. Any final press releases shall be submitted to COR and CO no later than 1 (one) calendar day prior to its release.
24	Integrated Master Plan (IMP)	The Contractor shall provide an IMP including WBS, critical path	<ul style="list-style-type: none"> Contractor shall provide the draft IMP within 90 days of contract award with final due 8 months after award and updated monthly as part of the Monthly Progress

Item #	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		milestones, and Earned Value Management Plan.	<p>Report.</p> <ul style="list-style-type: none"> Contractor must address, in writing, all concerns raised by COR in writing.
25	Draft Final and Final Reports	<p>A Draft Final Report containing a summation of the work performed and the results obtained for the entire contract PoP. The draft report shall be duly marked as 'Draft'.</p> <p>The Final Technical Progress Report incorporating feedback received from the COR and CO and containing a summation of the work performed and the results obtained for the entire contract PoP. The final report shall document the results of the entire contract. This report shall be in sufficient detail to fully describe the progress achieved under all milestones. The final report shall be duly marked as 'Final'.</p>	<ul style="list-style-type: none"> Contractor shall provide a draft Technical Progress Report 75 calendar days before the end of the PoP and the Final Technical Progress Report on or before the completion date of the PoP. Subcontractor prepared reports received by the Contractor shall be submitted to the COR and CO for review and comment no later than 5 business days after receipt by the Contractor. COR shall provide feedback on draft report within 15 calendar days of receipt, which the Contractor shall consider incorporating into the Final Report. Contractor shall submit, with the Final Technical Progress Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.
26	Draft and Final Study Protocols	Contractor shall provide all Draft and Final Study Protocols to the Government for evaluation. (The CO and PO reserves the right to request within the period of performance an unredacted Study Protocol for distribution within the United States Government (USG))	<ul style="list-style-type: none"> The Contractor will submit all proposed protocols to COR and CO at least 10 business days prior to study start. If corrective action is required, the Contractor must address in writing all concerns raised by the Government to the satisfaction of the Government before study execution and provide BARDA a revised draft protocol that addresses the Government's comments and requested changes. After receiving the revised Study Protocol that satisfies the Government, the CO and COR will approve the revised Study Protocol and will provide a written approval to the Contractor that provides authorization to the Contractor to execute the specific study. Contractor shall not proceed with any study protocol until COR and CO gives its approval and the

Item #	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
			Contractor has provided BARDA with a final and approved Study Protocol.
27	Clinical Study Status Update	Contractor shall provide PO with a status update of clinical studies that are actively enrolling patients to include by study site: cumulative enrollment; new enrollments; screen failures; patients dropped from study; AE and SAEs; activation or inactivation of study sites; investigator appointments or changes; and status of IRB/IEC review/approval/renewal. Contractor will provide proposed format for COR review and approval.	<ul style="list-style-type: none"> • Update will be submitted by e-mail or other electronic format to be provided by CO and COR by the end of the 5th business day of each new month. • Updates, to the extent they are available, will be presented during biweekly teleconferences. • If no changes have occurred since the prior update only a simple statement that there is no new data is required.
28			<ul style="list-style-type: none"> • Contractor must submit samples of vaccine material within 20 business days of request by CO/COR. • The Contractor will be advised by the CO how samples are to be packaged and where samples are to be shipped. • The Government will not use, and will restrict others from using, for any use without the Contractor's consent, any samples or other physical materials developed or provided under this contract during the period of performance for this contract.

NOTE: Pursuant to federal law, no Government personnel shall publish, divulge, disclose, or otherwise make known to any non-government entity any Contractor data marked according to FAR 52.227-14, Alternate II, unless permitted to do so by law or regulation.

2. Detailed Description of Select Contract Deliverables

A. Monthly and Annual Progress 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 this Article F of this contract, and in the Statement of Work, attached to this contract as Attachment 1 (SECTION J-List of Attachments).

i. **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 the summary table (“Summary of Contract Deliverables”) under this article. The progress report shall conform to the requirements set forth in the DELIVERABLES Article in SECTION F 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;
- SECTION I – EXECUTIVE SUMMARY
- 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: Estimated and Actual Expenses.
 - a. This section of the report shall contain a narrative or table detailing whether there is a significant discrepancy (>10%) at this time between the % of work completed and the cumulative costs incurred to date. Monthly and actual expenses should be broken down to the appropriate WBS level.
 - b. This section of the report should also contain estimates for the Subcontractors' expenses from the previous month if the Subcontractor did not submit a bill in the previous month. If the subcontractor(s) was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subcontractors.
- SECTION IV: Earned Value Management Reporting: Contractor will provide a monthly Contract Performance Report (CPR) at an agreed upon reporting level (WBS level 3) using the AMCG provided WBS and a Variance Analysis Report. EVMS shall be applied to all 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. The Government may request additional data at a reporting level or at lower levels, as the Government deems necessary.

A Monthly Progress Report will not be required in the same month that the Annual Progress Report is submitted.

ii. **Annual Progress Report**

This report shall include a summation of the results of the entire contract work for the period covered. Monthly Progress Reports shall not be submitted in the same month when an Annual Progress Report is due. Furthermore, an Annual Progress Report will not be required for the period when the Final Report is due.

The first Annual Progress Report shall be submitted in accordance with the date set forth in the table ("Summary of Contract Deliverables") under ARTICLE F.2. of this contract. The progress report shall conform to the

requirements set forth in the DELIVERABLES Article in SECTION F of this contract.

Each Annual Progress Report shall 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 email address; and the date of submission;
- SECTION I: EXECUTIVE SUMMARY - A brief overview of the work completed, and the major accomplishments achieved during the reporting period.
- SECTION II: PROGRESS
- SECTION II Part A: OVERALL PROGRESS - A description of overall progress.
- SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE - A high level summary of critical meetings, etc. that have taken place during the reporting period. Include progress on administration and management to critical factors of the project (e.g. regulatory compliance audits and key personnel changes).
- SECTION II Part C: TECHNICAL PROGRESS - A detailed description of the work performed structured to follow the activities and decision gates outlined at the Integrated Baseline Review and as described in the Integrated Master Plan. The Report should include a description of any problems (technical or financial) that occurred or were identified during the reporting period, and how these problems were resolved.
- SECTION II Part D: PROPOSED WORK - A summary of work proposed for the next year period to include an updated Gantt Chart.
- SECTION III: Estimated and Actual Expenses.
 - a. This section of the report shall contain a narrative or table detailing whether there were discrepancies between estimated and actual expenses over the past year. Actual expenses should be broken down to the appropriate WBS level. This section of the report should also contain estimates for outstanding costs for the previous year which may have been incurred, but not yet billed.
- SECTION IV: EARNED VALUE MANAGEMENT REPORTING - Contractor will provide a quarterly Contract Performance Report (CPR) at an agreed upon (WBS level 3)

reporting level using the AMCG provided WBS and a Variance Analysis Report. EVMS shall be applied to all Cost 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, the COR may request, on a quarterly or ad hoc basis, that the Contractor provide raw data. The COR or CO may request additional data at a reporting level or at lower levels, as BARDA deems necessary.

Contractor also should include the following in the Annual Progress Report:

1. Copies of manuscripts (published and unpublished), abstracts, and any protocols or methods developed specifically under the contract during the reporting period; and
2. A summary of any Subject Inventions per the requirements under FAR Clause 52.227-11.

iii. Draft Final Report and Final 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 DELIVERABLES Article in SECTION F of the contract. An Annual Progress Report will not be required for the period when the Final Report is due. The Draft Final Report and the Final Report shall be submitted in accordance with the dates set forth in the table (“Summary of Contract Deliverables”) under 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 WBS and 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 Final Report: The Contractor is required to submit the Draft Final Report to the Contracting Officer's Representative and Contracting Officer. The Contracting Officer's Representative and Contracting Officer will review the Draft Final Report and provide the Contractor with comments in accordance with the dates set forth in ARTICLE F.2. of this contract.

Final Report: The Contractor will deliver the final version of the Final Report on or before the completion date of the contract. The final version shall include or address the COR's and CO's written comments on the draft report. Final Report shall be submitted on or before the completion date of the contract.

iv. **Summary of Salient Results**

The Contractor shall submit, with the Final Report, a summary (not to exceed 200 words) of salient results achieved during the performance of the contract.

v. **Audit Reports**

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

vi. **Other Technical Reports**

1. Draft Report for Clinical and Non-Clinical Studies and Final Report for Clinical and Non-Clinical Studies

- The clinical trial reports shall follow the format of International Conference on Harmonization document ICH E3 "Guideline for Industry on Structure and Content of Clinical Study Reports"
 - Draft Final Report for Clinical and Non-Clinical Studies funded by this contract will be submitted to the Contracting Officer's Representative and Contracting Officer (CO) for review and

comment within the time frames set forth in the table (“Summary of Contract Deliverables”) under ARTICLE F.2.

- Subcontractor prepared reports received by the Contractor shall be submitted to the Contracting Officer’s Representative and Contracting Officer (CO) for review and comment as set forth by the table in this Article. Contractor shall consider revising reports to address BARDA’s recommendations prior to FDA submission.
- The Government shall provide written comments to the Draft Final Report for Clinical and Non-Clinical Studies in accordance with the dates set forth by the table in this Article.
- The comprehensive Final Report for Clinical and Non-Clinical Studies will be submitted to the Contracting Officer and the Contracting Officer’s Representative set forth by the table in this Article.

2. Supplemental Technical Documents

Upon request, Contractor shall provide CO and COR with the following contract funded documents as specified below but not limited to: Process Development Reports; Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, Contractor/Subcontractor Standard Operating Procedures (SOP’s), Master Production Records, Certificate of Analysis, Clinical Studies Data or Reports. The COR and CO reserve the right to request within the period of performance an unredacted technical document for distribution within the USG. Contractor shall provide technical document within 10 business days of CO or COR request. Contractor can request additional time on an as needed basis. If edits are recommended, the Contractor must address, in writing, concerns raised by COR and CO in writing.

A. Deliverables Arising from FDA Correspondence

i. FDA Meetings

The Contractor shall forward the dates and times of any meeting with the FDA to COR and make arrangements for appropriate Government staff to attend the FDA meetings. The Government staff shall include up to a maximum of four people (COR, CO and up to 2 subject matter experts).

- Contractor shall notify COR of upcoming FDA meeting within 24 hours of scheduling Type A, B or C meetings OR within 24 hours of meeting occurrence for ad hoc meetings.
- The Contractor shall forward initial Contractor and FDA-issued draft minutes and final minutes of any meeting with the FDA to COR within 5

business days of receipt. All documents shall be duly marked as either “Draft” or “Final.”

ii. FDA Submissions

The Contractor shall provide COR all documents submitted to the FDA directly related to this contract.

Contractor shall provide COR with an electronic copy of the final FDA submission. All documents shall be duly marked as either “Draft” or “Final.”

- If draft documents are submitted for COR review, COR will provide feedback to the Contractor within 5 business days after receipt, provided that COR reserves the right to request more than 5 business days for review of any regulatory submission that is of significant length. The Contractor shall inform COR of the anticipated submission length so COR can make a determination on required time for review..
- If COR reviews draft documents, the Contractor shall consider revising their documents to address COR’s written concerns and/or recommendations prior to FDA submission.
- Final FDA submissions shall be submitted to COR concurrently or no later than 3 calendar days of their submission to FDA.

iii. FDA Audits

In the event of an FDA inspection which occurs as a result of this contract and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this contract, the Contractor shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR) within five (5) business days after the Contractors receipt of those documents. The Contractor shall provide the COR and CO with copies of the plan for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the audit report, status updates during the plans execution and a copy of all final responses to the FDA. The Contractor shall also provide redacted copies of any FDA audits received from subcontractors that occur as a result of this contract or for this product. The Contractor shall make arrangements for the Government representative(s) to be present during the final debrief by the regulatory inspector.

- Contractor shall notify CO and COR within 10 business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if the FDA does not provide advanced notice.

-
- Contractor shall provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within 5 business days of receiving correspondence from the FDA, Subcontractor, or third party.
 - Within 10 business days of audit report, Contractor shall provide CO with a plan for addressing areas of nonconformance, if any are identified.

iv. **Manufacturing Campaign Reports**

Contractor shall provide Manufacturing Campaign Reports to COR for review and comment prior to submission to FDA.

The COR and CO reserve the right to request within the Period of Performance (PoP) an unredacted Manufacturing Campaign Report for distribution within the USG.

- Contractor will submit Manufacturing Campaign Reports at least 15 business days prior to FDA submission.
- If corrective action is recommended, Contractor must address, in writing, all concerns raised by COR.
- Contractor shall consider revising the reports to address COR's concerns and/or recommendations prior to FDA submission.
- Final FDA submission shall be submitted to COR concurrently or no later than 1 business day after submission to the FDA.

v. **Other FDA Correspondence**

The Contractor shall memorialize any correspondence between Contractor and FDA and submit to BARDA. All documents shall be duly marked as either "Draft" or "Final." Contractor shall provide written summary of any FDA correspondence within 5 business days of correspondence.

C. Earned Value Management (EVM) Deliverables

i. **Earned Value Management (EVM) / Contract Performance Report (CPR)**

Contractor will provide a monthly CPR at an agreed upon reporting level using WBS and Variance Analysis report formats agreed upon by COR and CO.

The supplemental monthly Control Account Plan (CAP) report shall contain, at the work package level, time phased budget (budgeted cost of

work scheduled), earned value (budgeted cost of work performed), and actual costs of work performed as captured in Contractor's EVM systems. The Contractor shall provide a rationale in the package of its use of % complete as EVMS methodology, or identify if any other EVMS methodology is being used.

- Contractor shall provide EVM/CPR as part of the Monthly Progress Report (this requirement begins only as set forth in the Contract Milestones & Related Deliverables table)
- Contractor shall provide top level or key changes in baseline cost as a result of anticipated cost savings or risks
- The COR may request, on a monthly or ad hoc basis that the Contractor provide raw data at a reporting level or lower level as COR deems necessary.
- Contractor must address, in writing, all concerns raised by the Government.
- Reporting will commence after the EVM system has been implemented but no later than 90 days after start of base period and each exercised option period.

ii. **Integrated Master Plan (IMP)**

The Contractor shall provide an IMP including WBS, critical path milestones, and Earned Value Management Plan

- Contractor shall provide the draft IMP within 180 days of contract award with final due 8 months after award and updated monthly as part of the Monthly Progress Report
- Contractor must address, in writing, all concerns raised by the Government.

iii. **Performance Measurement Baseline Review (PMBR)**

PMBR Report shall address each of the items listed below and be cross-referenced to the IMP, WBS, SOW, and Risk Management Plan.

1. Contractor provided baseline proposal
2. Responsibility Assignment Matrix
3. A description of the work scope through control account Work Authorization Documents and/or WBS Dictionary down to the agreed upon control account level.

-
4. Template for work packages
 5. Integrated Master Schedule (IMS) with the inclusion of agreed major milestones and control account plans for all control accounts
 6. Baseline revision documentation and program log(s) risk management plan
- PMBR is due within 90 days of contract award
 - Contractor shall provide baseline proposal .ppt briefing 10 business days prior to meeting
 - Contractor provides agenda to COR 2 business days in advance of meeting
 - COR approves (with CO concurrence) and distributes agenda
 - COR approves (with CO concurrence) all meeting material
 - Contractor provides minutes with 5 business days of the meeting
 - COR reviews and approves (with CO concurrence) minutes
 - The Government will review documentation and provide written comments and questions to Contractor
 - Contractor shall address the Government's comments and resubmit PMBR report for COR approval within 10 business days.

iv. **Risk Management Plan**

The Contractor shall provide a Risk Management Plan that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan shall include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule and performance.

- Due within 90 days of contract award
- Contractor provides updated Risk Management Plan in Monthly Progress Report
- The CO or COR shall provide Contractor with a written list of concerns in response plan submitted
- Contractor must address, in writing, all concerns raised by the Government within 20 business days of Contractor's receipt of the Government's concerns.

v. **Requirement for Notification of Deviation and Mitigation Strategy**

Process for changing IMS activities associated with cost and schedule as baselined at the PMBR. Contractor shall notify BARDA of significant

changes the IMS defined as increases in cost above 5% or schedule slippage of more than 30 days, which would require an extension to the period of performance. Contractor shall provide a high level management strategy for risk mitigation. Notice due as needed.

ARTICLE F.3. ELECTRONIC SUBMISSION

For electronic delivery, the Contractor shall upload documents to the appropriate folder on <https://eroom.bardatools.hhs.gov/eRoom> (“eRoom”) which is the designated USG file sharing system. The USG shall provide two contractor representatives authorized log in access to the file share program. Each representative must complete a mandatory training provided by the USG prior to gaining user access. A notification email should be sent to the CO and COR upon electronic delivery of any documents.

ARTICLE F.4. SUBJECT 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, one copy of an annual utilization report, and a copy of the final invention statement, shall be submitted to the Contracting Officer. A final invention statement (see FAR 27.303 (b)(2)(ii)) shall be submitted to the Contracting Officer on the expiration date of the contract.

Reports and documentation submitted to the Contracting Officer shall be sent to the address set forth in SECTION G – CONTRACT ADMINISTRATION DATA.

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.

WBS	Milestone	Deliverable	Success Criteria	Go/No-Go for initiation
BASE: Facility, Site, and Process Performance Qualification (PPQ) Readiness Activities and the Manufacture and Testing of Process Simulations				
1.1	Program Management	See below	See below	
1.1.1	Overall management, integration and coordination of all contract activities, including technical and administrative infrastructure	On-going	Milestones Met	Contract execution
1.1.2	Principal Investigator (PI) responsible for program management, communication, tracking, monitoring and reporting on status and progress, and modification to the project	Program PI	Milestones Met	Contract execution

WBS	Milestone	Deliverable	Success Criteria	Go/No-Go for initiation
	requirements and timelines, including projects undertaken by subcontractors			
1.1.3	Project Manager(s) with responsibility for monitoring and tracking day-to-day progress and timelines, coordinating communication and project activities; cost incurred and; program management	Program PM	Milestones Met	Contract execution
1.1.4	BARDA Liaison with responsibility for effective communication with the Project officer and Contracting Officer	Liaison	Effective Communication with BARDA	Contract execution
1.1.5	(b) (4) [REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
1.1.6	Administrative staff with responsibility for financial management and reporting on all activities conducted by the Contractor and any subcontractor	Administrative & Financial Management	Timely Reporting	Contract execution
1.1.7	Contract Review Meeting	See Below	See Below	
1.1.7.1	Program Review Meetings	Regularly scheduled meetings with subcontractors to discuss program progress and updates	Meeting conducted	Contract Execution
1.1.7.2	Bi-weekly Teleconferences	Teleconferences with BARDA on a bi-weekly basis	Meetings conducted	Contract Execution
1.1.8	Submit Updated Integrated Master Schedule (IMS)	Updated IMS Submitted	IMS Accepted	Contract Execution
1.1.9	Submit Updated Integrated Master Plan (IMP)	Updated IMP Submitted	IMP Accepted	Contract Execution
1.1.10	Submit and Maintain Program Management Plan	Updated Program Management Plan	Acceptance of PMP	Contract Execution
1.1.11	Submit and Maintain Product Development Plan	IPDP input provided	IPDP input accepted	Contract Execution
1.1.12	Subcontractor Management	Subcontractor management plan	Documentation/reporting on-time	Contract Execution

WBS	Milestone	Deliverable	Success Criteria	Go/No-Go for initiation
	(b) (4) [Redacted]	[Redacted]	[Redacted]	[Redacted]
	[Redacted]	[Redacted]	[Redacted]	[Redacted]
	[Redacted]	[Redacted]	[Redacted]	[Redacted]
1.3	Facility and Site Readiness Activities	See below	See below	
	(b) (4) [Redacted]	[Redacted]	[Redacted]	[Redacted]
	[Redacted]	[Redacted]	[Redacted]	[Redacted]
	[Redacted]	[Redacted]	[Redacted]	[Redacted]
	[Redacted]	[Redacted]	[Redacted]	[Redacted]
1.4	Manufacture and Testing of Process Simulations	See below	See below	
	(b) (4) [Redacted]	[Redacted]	[Redacted]	[Redacted]
	[Redacted]	[Redacted]	[Redacted]	[Redacted]

WBS	Milestone	Deliverable	Success Criteria	Go/No-Go for initiation
		(b) (4)		
	(b) (4)			
1.5	Regulatory (Type C Meeting)	Meeting minutes	Minutes accepted	Type C meeting package prepared and available
1.6	Nonclinical Reproductive Toxicology Studies			
1.6.1	Embryo-fetal Development (EFD) Study in Pregnant Female Rats	See below	See below	
	Study document development and approval	Finalized protocol	Protocol approved	Favorable rat viremia and immunogenicity study data
	Study execution	Vaccination, monitoring, procedures, and blood collection as defined in the protocol	Study complete	Approved protocol
	Draft and Final Report generated	Un-audited draft report and final report	Final report complete	Study Complete
1.6.2	Pre- and Post-natal Development Study in Rats (may be conducted as combination study with EFD)	See below	See below	
	Study document development and approval	Finalized protocol	Protocol approved	Favorable rat viremia and immunogenicity study data
	Study execution	Vaccination, monitoring, procedures, and blood collection as defined in the protocol	Study complete	Approved protocol
	Draft and Final Report generated	Un-audited draft report and final report	Final report complete	Study Complete
1.6.3	Testing of Rat Specimens in Qualified RT-PCR Assays at Focus Diagnostics	See below	See below	

WBS	Milestone	Deliverable	Success Criteria	Go/No-Go for initiation
	RT-PCR and ELISA developed and qualified for rat specimens	Qualified assay	Assay qualified	Study complete
	Assay testing for three preclinical studies (listed above)	Test performed in the rat IgG ELISA and RT-PCR	Immunology results	Qualified Assay
1.7	Immunogenicity for PREVAIL and PREPARE Studies	See below	See below	
1.7.1	(b) (4)			
Option 1: Manufacturing and Testing of PPQ lots, BLA Preparation and Pre-PAI Activities				
2.1	Program Management	See 1.1 Above	See 1.1 Above	Option exercised
2.2	Manufacturing and Testing of Process Performance Qualification (PPQ) Lots	See below	See below	
	(b) (4)			

WBS	Milestone	Deliverable	Success Criteria	Go/No-Go for initiation
	(b) (4) [Redacted]	[Redacted]	[Redacted]	[Redacted]
	(b) (4) [Redacted]	[Redacted]	[Redacted]	[Redacted]
	[Redacted]	[Redacted]	[Redacted]	[Redacted]
	[Redacted]	[Redacted]	[Redacted]	[Redacted]
	[Redacted]	[Redacted]	[Redacted]	[Redacted]
	[Redacted]	[Redacted]	[Redacted]	[Redacted]
	[Redacted]	[Redacted]	[Redacted]	[Redacted]

WBS	Milestone	Deliverable	Success Criteria	Go/No-Go for initiation
	(b) (4)			
Option 3: Additional Process Simulations and Manufacturing of PPQ lots				
4.1	Program Management	See 1.1 Above	See 1.1 Above	Option exercised
(b) (4)				

SECTION G - CONTRACT ADMINISTRATION DATA

ARTICLE G.1. CONTRACTING OFFICER

The following Contracting Officers (CO) will represent the USG for the purpose of this contract:

(b) (6)
Contracting Officer
DHHS/OS/ASPR/AMCG
330 Independence Avenue, S.W. Room G640 Washington, D.C. 20201

(b) (6)

(b) (6)

(b) (6)
Contract Specialist
HHS/ASPR/AMCG
330 Independence Ave., S.W., Room G640
Washington, DC 20201

(b) (6)

(b) (6)

- 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 other than that which may be contained in an authorized modification to this contract, duly issued by the Contracting Officer, which may be received from any person employed by the US Government, other otherwise, shall be considered grounds for deviation from any stipulation of this contract.
- 4) The Government may unilaterally change its CO designation, after which it will notify Contractor in writing of such change.

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:

ATTN: (b) (6), PhD

Contracting Officer's Representative (COR)
Biomedical Advanced Research and Development Authority (BARDA)
Office of the Assistant Secretary for Preparedness and Response
Office of the Assistant Secretary for Preparedness and Response
Department of Health and Human Services

Mailing Address:
330 Independence Avenue, S.W.
Room G644
Washington, D.C. 20201
(b) (6) (work)
(b) (6)

Alternate COR:

ATTN: (b) (6),
Contracting Officer's Representative (COR)
Biomedical Advanced Research and Development Authority (BARDA)
Office of the Assistant Secretary for Preparedness and Response
Department of Health and Human Services

Mailing Address:
330 Independence Avenue, S.W.
Room G644
Washington, D.C. 20201
(b) (6)
Email: (b) (6)

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 may unilaterally change its COR designation, after which it will notify Contractor in writing of such change.

ARTICLE G.3. KEY PERSONNEL

Pursuant to the Key Personnel clause incorporated in Section I of this contract, the following individuals are considered to be essential to the work being performed hereunder:

#	Name	Function
1	(b) (4), (b) (6)	
2		(b) (4), (b) (6)
3	(b) (4), (b) (6)	
4	(b) (4),	

The key personnel specified in this contract are considered to be essential to work performance. At least thirty (30) business days prior to diverting any of the specified individuals to other programs or contracts, including, where practicable, an instance when an individual must be replaced 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) 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.

ARTICLE G.4. CONTRACT FINANCIAL REPORT

- a. Financial reports on the attached Financial Report of Individual Project/Contract shall be submitted by the Contractor to the CO with a copy to the COR in accordance with the instructions for completing this form, which accompany the form, in an original and one electronic copy, not later than the 30th business day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories), which shall be reported within the total contract, are discussed in paragraph e., below. Subsequent changes and/or additions in the line entries shall be made in writing.
- b. Unless otherwise stated in the instructions for completing this form, all columns A through J, shall be completed for each report submitted.
- c. The first financial report shall cover the period consisting of the first full three calendar months following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a quarterly basis.
- d. The Contracting Officer may require the Contractor to submit detailed support for costs contained in one or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.
- e. The listing of expenditure categories to be reported is incorporated as a part of this contract and can be found under SECTION J Attachment 4 entitled, "Instructions for Completing Financial Report of Individual Project/Contract".

- f. The USG may unilaterally revise the “Financial Report of Individual Project/Contract” to reflect the allotment of additional funds.

ARTICLE G.5. INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORTING

Include Program Support Center (PSC) in Receipt of Invoices:

Documents shall be delivered electronically to the Contracting Officer (CO), the Contracting Specialist (CS), the Contracting Officer’s Representative (COR) and PSC. Unless otherwise specified by the Contracting Officer all deliverables and reports furnished to the Government under the resultant contract (including invoices) shall be addressed as follows:

<p>(b) (6) [Redacted] Contracting Officer HHS/ASPR/AMCG 330 Independence Ave., S.W., Room G640 Washington, DC 20201 Email: (b) (6) [Redacted] [Redacted]</p>	<p>(b) (6) [Redacted] Contract Specialist HHS/ASPR/AMCG 330 Independence Ave., S.W., Room G640 Washington, DC 20201 Email: (b) (6) [Redacted] [Redacted]</p>	<p>(b) (6) [Redacted] Contracting Officer Representative HHS/ASPR/AMCG 330 Independence Ave., S.W., Washington, DC 20201 Email: (b) (6) [Redacted] [Redacted]</p>	<p>PSC Invoices @psc.hhs.gov</p>
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- a. Contractor invoices/financial reports shall conform to the form, format, and content requirements of the instructions for Invoice/Financing requests and Contract Financial Reporting.
- b. Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the USG.
- c. The Contractor agrees to immediately notify the CO in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10 percent) of the estimated costs for the base period or any option period(s) (See estimated costs under Articles B.2) and the reasons for the variance. These requirements are in addition to the specified requirements of FAR Clause 52.232-20, Limitation of Cost that is incorporated by reference under Article I.1 which states;

Limitation of Cost (Apr 1984)

- (a) The parties estimate that performance of this contract, exclusive of any fee, will not cost the Government more than (1) the estimated cost specified in the

Schedule or, (2) if this is a cost-sharing contract, the Government's share of the estimated cost specified in the Schedule. The Contractor agrees to use its best efforts to perform the work specified in the Schedule and all obligations under this contract within the estimated cost, which, if this is a cost-sharing contract, includes both the Government's and the Contractor's share of the cost.

(b) The Contractor shall notify the Contracting Officer in writing whenever it has reason to believe that—

(1) The costs the Contractor expects to incur under this contract in the next 60 days, when added to all costs previously incurred, will exceed 75 percent of the estimated cost specified in the Schedule; or

(2) The total cost for the performance of this contract, exclusive of any fee, will be either greater or substantially less than had been previously estimated.

(c) As part of the notification, the Contractor shall provide the Contracting Officer a revised estimate of the total cost of performing this contract.

(d) Except as required by other provisions of this contract, specifically citing and stated to be an exception to this clause—

(1) The Government is not obligated to reimburse the Contractor for costs incurred in excess of (i) the estimated cost specified in the Schedule or, (ii) if this is a cost-sharing contract, the estimated cost to the Government specified in the Schedule; and

(2) The Contractor is not obligated to continue performance under this contract (including actions under the Termination clause of this contract) or otherwise incur costs in excess of the estimated cost specified in the Schedule, until the Contracting Officer (i) notifies the Contractor in writing that the estimated cost has been increased and (ii) provides a revised estimated total cost of performing this contract. If this is a cost-sharing contract, the increase shall be allocated in accordance with the formula specified in the Schedule.

(e) No notice, communication, or representation in any form other than that specified in paragraph (d)(2) of this clause, or from any person other than the Contracting Officer, shall affect this contract's estimated cost to the Government. In the absence of the specified notice, the Government is not obligated to reimburse the Contractor for any costs in excess of the estimated cost or, if this is a cost-sharing contract, for any costs in excess of the estimated cost to the Government specified in the Schedule, whether those excess costs

were incurred during the course of the contract or as a result of termination.

(f) If the estimated cost specified in the Schedule is increased, any costs the Contractor incurs before the increase that are in excess of the previously estimated cost shall be allowable to the same extent as if incurred afterward, unless the Contracting Officer issues a termination or other notice directing that the increase is solely to cover termination or other specified expenses.

(g) Change orders shall not be considered an authorization to exceed the estimated cost to the Government specified in the Schedule, unless they contain a statement increasing the estimated cost.

(h) If this contract is terminated or the estimated cost is not increased, the Government and the Contractor shall negotiate an equitable distribution of all property produced or purchased under the contract, based upon the share of costs incurred by each.

- d. The Contractor shall submit an electronic copy of the payment request to the approving official instead of a paper copy. 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.
- e. An electronic copy of the payment request shall be uploaded into the designated eRoom (as defined in SECTION F.3 ELECTRONIC SUBMISSION) and an e-mail notification of the upload will be provided to the CO and COR.
- f. All invoice submissions shall be in accordance with FAR Clause 52.232-25, Prompt Payment (Jul 2013), Alt I.
- g. 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), 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 over \$1,500.

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- e. Travel - Identify travelers, dates, destination, purpose of trip, and total breaking out amounts for transportation (plane, car etc), lodging, M&IE. Cite COA, if appropriate. List separately, domestic travel, general scientific meeting travel, and foreign travel.
 - f. Consultant Fees - Identify individuals, amounts and activities. Cite appropriate COA
 - g. Subcontracts - Attach subcontractor invoice(s). Cite appropriate COA
 - h. Equipment - Cite authorization and amount. Cite appropriate COA
 - i. Other Direct Costs - Include detailed breakdown when total amount is over \$1,500.
 - j. G&A - Cite rate and amount.
 - k. Total Cost
 - l. Fee
 - m. Total Cost Plus Fixed Fee

Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the USG. Nothing in this section discharges the contractor's responsibility to comply with any applicable FAR Parts 30 or 31 clauses' relating to cost reimbursement subcontracts. In order to verify allowability, further breakdown of costs may be requested at the USG's discretion. The Contractor shall subcontract with Firm Fixed Price Contracts to the maximum extent practicable.

Additional instructions and an invoice template are provided in Attachment 2, Invoice/Financing Request Instructions and Contract Financial Reporting Instructions for AMCG Cost-Reimbursement Contracts. All invoices must be signed by a representative of the contractor authorized to certify listed charges are accurate and comply with government regulations. Invoices should be submitted electronically (in accordance with ARTICLE F.3., (ELECTRONIC SUBMISSION) Only with signature.

If applicable, the Contractor shall convert any foreign currency amount(s) in the monthly invoice to U.S. dollars each month, on the 1st of the month, using the foreign exchange rate index published on www.federalreserve.gov. Payment of invoices is subject to the U.S. dollar limits within the Total Estimated Cost, the Total Fixed Fee and the Total Estimated Cost of each active CLIN(s) in Section B under the contract.

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 FAR Clause 52.216-7, Allowable Cost and Payment incorporated by reference in Section I, Contract Clauses, of this contract, and FAR Subpart 31.2. Examples of allowable costs include, but are not limited to, the following:

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- a) All direct materials and supplies that are used in performing 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 coach-class which may also be referred to by airlines as “tourist class,” “economy class,” or as “single class” when the airline offers only one class of accommodations to all travelers. Government and contractor travelers are required to exercise the same care in incurring expenses that a prudent person would exercise if traveling on personal business when making official travel arrangements, and therefore, should consider the least expensive class of travel that meets their needs. You may use the lowest other than coach-class airline accommodations only when the agency specifically authorizes/approves such use (per the Federal Travel Regulation @ <http://www.gsa.gov/graphics/ogp/FTR2011-02Complete.pdf>)
 - (ii) You must use coach-class accommodations for all train travel, except when your agency authorizes other than coach-class service in a written statement.
 - (iii) Costs incurred for lodging, meals, and incidental expenses shall be considered reasonable and allowable to the extent that they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulation (FTR).
 - (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. INDIRECT COST RATE

The following contractor established provisional billing rates are incorporated into the contract, and will be utilized for billing purposes during both the base and contract option

periods pending the establishment of final indirect cost rates for each fiscal year or until revised by the contracting officer in accordance with the provisions of FAR 42.705-1. See FAR Clause 52.216-7.

Rate Type	Rate	Allocation Base
(b) (4)		

Use of the above provisional rates does not change any cost ceilings, contract obligations, or specific allowance or disallowance provided for in the contract. Contractor must notify the contracting officer promptly for an adjustment of the provisional rates if it becomes evident that the rates would cause substantial overpayment or underpayment of indirect expenses to BioProtection Systems.

The final billing rates for each fiscal year will be based on the incurred cost submission subject to Government audit determination. Indirect costs rate proposals must be submitted to the cognizant agency’s Contracting Officer within 6 months subsequent to each of the contractor’s fiscal year ends. (See also FAR Clause 52.216-7(d) (2) incorporated herein). Copies of the indirect cost submission for each fiscal year must also be submitted to the AMCG contracting officer, and the AMCG auditor identified.

ARTICLE G.8. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

1. Contractor Performance Evaluations

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

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

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

2. Electronic Access to Contractor Performance Evaluations

Contractors that have Internet capability may access evaluations through a secure Web site for review and comment by completing the registration form that can be obtained at the following address:

<http://www.cpars.csd.disa.mil/cparsmain.htm>

The registration process requires the Contractor to identify an individual that will serve as a primary contact and who will be authorized access to the evaluation for review and comment. In addition, the Contractor will be required to identify an alternate contact that will be responsible for notifying the cognizant contracting official in the event the primary contact is unavailable to process the evaluation within the required 14-day time frame.

ARTICLE G.9. CONTRACT COMMUNICATIONS/CORRESPONDENCE

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

ARTICLE G.10. GOVERNMENT PROPERTY

a. In addition to the requirements of the FAR Clause 52.245-1, GOVERNMENT PROPERTY, incorporated in SECTION I of the contract, the Contractor shall comply with the provisions of HHS Publication, "HHS Contracting Guide for Contract of Government Property," which is incorporated into the contract by reference. This document can be accessed at: http://ncioa.cancer.gov/oa-internet/reference/Appendix_Q_HHS_Contracting_Guide-508.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.](#)

- b. [Notwithstanding the provisions outlined in the HHS Publication, "HHS Contracting Guide for Contract of Government Property," which is incorporated in the 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.](#)
- c. [Title will vest in the USG for equipment purchased as a direct cost.](#)

ARTICLE G.11. EXERCISE OF OPTIONS

Unless the Government exercises its option pursuant to the Option Clause set forth in Section I, Article I.2, the contract will consist only of CLIN 0001 of the Statement of Work, Deliverables and Requirements as defined in Sections C, F and J of the contract. Pursuant to FAR Clause 52.217-9 (Option to Extend the Term of the Contract) set forth in Section I of this contract, under Article I.2, the Government may, by unilateral contract modification, require the Contractor to perform the additional CLINs listed in Section B, Article B.3., and as also defined in Sections C, F and J of this contract. If the Government exercises an option, written notice must be given to the Contractor within 30 days after the Government has completed its analysis of the deliverables associated with the applicable in-process programmatic review; and the Government must give the Contractor a preliminary written notice of its intent to exercise the option at least 30 days before the contract expires. The amount obligated to the contract may then be increased as set forth in Section B, Article B.3 provided that Government funds are available.

SECTION H - SPECIAL CONTRACT REQUIREMENTS

The Contractor, depending upon the nature of the work, is responsible for following the provisions below in conducting its own work under this contract. The Contractor also is responsible for incorporating these provisions into any subcontract awarded, if applicable to the specific nature of the work in the subcontract. Accordingly, those provisions shall be flowed-down as applicable.

ARTICLE H.1 CLINICAL AND NON-CLINICAL TERMS OF AWARD

BARDA has a responsibility to obtain documentation concerning mechanisms and procedures that are in place to protect the safety of participants and animals in BARDA funded clinical trials and non-clinical studies. Therefore, the Contractor shall develop a protocol for each clinical trial *and* non-clinical study funded under this contract and submit all such protocols and protocol amendments to the Contracting Officer's Representative (COR) for evaluation and comment.

Approval by the COR is required before work under a protocol may begin. The COR comments will be forwarded to the Contractor within eight (8) business days. The Contractor must address, in writing, all concerns (*e.g.* study design, safety, regulatory, ethical, and conflict of interest) noted by the COR.

If the draft protocols are to be submitted to the FDA, COR review shall occur before submission, pursuant to the terms set forth by ARTICLE F.2 of this contract. The Contractor shall consider revising their protocols to address COR's concerns and recommendations prior to FDA submission. The Contractor must provide COR with a copy of FDA submissions, within the time frame set forth by ARTICLE F.2 of this contract.

Execution of clinical and non-clinical studies requires written authorization from the Government. The USG will provide written authorization to the Contractor upon either 1)

receiving documentation in which all COR comments have been satisfactorily addressed; or 2) receiving documentation that the FDA has reviewed and commented on the protocol.

The Government shall have rights to all protocols, data resulting from execution of these protocols, and final reports funded by BARDA under this contract, as set forth in the FAR clauses referenced in PART II of this contract. 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.

Important information regarding performing human subject research is available at <http://www3.niaid.nih.gov/healthscience/clinicalstudies/>
<https://humansubjects.nih.gov/>

Any updates to technical reports are to be addressed in the Monthly and Annual Progress Reports. The Contractor shall advise the Contracting Officer's Representative or designee in writing and via electronic communication in a timely manner of any issues potentially affecting contract performance.

1. Non-Clinical Terms of Award

These Non-Clinical Terms of Award detail an agreement between the Biomedical Advanced Research and Development Authority (BARDA) and the Contractor; they apply to all grants and contracts that involve non-clinical research.

a. Safety and Monitoring Issues

i. PHS Policy on Humane Care and use of Laboratory Animals

Before award and then with the annual progress report, the Contractor must submit to the COR a copy of the current Institutional Animal Care and Use Committees (IACUC) documentation of continuing review and approval and the Office of Laboratory Animal Welfare (OLAW) federal wide assurance number for the institution or site.

If other institutions are involved in the research (e.g., a multicenter trial or study), each institution's IACUC must review and approve the protocol.

They must also provide COR initial and annual documentation of continuing review and approval and federal wide assurance number.

The Contractor must ensure that the application, as well as all protocols, are reviewed by the performing institution's IACUC.

To help ensure the safety of animals used in BARDA-funded studies, the Contractor must provide COR copies of documents related to all

major changes in the status of ongoing protocols, including the following:

- All amendments or changes to the protocol, identified by protocol version number, date, or both and date it is valid.
- All material changes in IACUC policies and procedures, identified by version number, date, and all required signatories (if applicable).
- Termination or temporary suspension of the study(ies) for regulatory issues.
- Termination or temporary suspension of the protocol.
- Any change that is made in the specific IACUC approval for the indicated study(ies).
- Any other problems or issues that could affect the scientific integrity of the study(ies), i.e., fraud, misrepresentation, misappropriation of funds, etc.

Contractor must notify COR of any of the above changes within five (5) working days from the time the Contractor becomes aware of such changes by email or fax, followed by a letter signed by the institutional business official, detailing notification of the change of status to the local IACUC and a copy of any responses from the IACUC.

If a non-clinical protocol has been reviewed by an institutional biosafety 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.

ii. Non-Clinical Data and Safety Monitoring Requirements

The Government strongly recommends continued safety monitoring for all non-clinical studies of investigational drugs, devices, or biologics. FDA expects non-clinical studies to include safety in addition to efficacy. The Contractor should consider evaluation of clinical relevant safety markers in the pivotal and non-pivotal, non-clinical studies. In preparation for clinical trials of licensed or not yet licensed products, it is imperative that BARDA-sponsored studies of any type measure the risk and safety parameters that are elicited and provide a safety profile from the studies for future human risk assessment.

A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For example, the risk of drawing a small amount of blood from a healthy subject for research purposes is no greater than the risk of doing so as part of a routine physical examination (45 CFR 46.102(i)).

BARDA will work with the Contractor on decisions regarding the type and extent of safety data accrual to be employed before the start of efficacy or safety studies.

The Contractor shall inform COR of any upcoming site visits and/or audits of CRO facilities funded under this effort. The Government reserves the right to accompany the Contractor on site visits and/or audits of CRO's as COR deems necessary.

b. BARDA Review Process before Non-Clinical study Execution Begins

BARDA is under the same policy-driven assurances as NIH in that it has a responsibility to ensure that mechanisms and procedures are in place to protect the safety and welfare of animals used in BARDA-funded non-clinical trials. Therefore, before study execution, the Contractor must provide the following (as applicable) for review and comment by COR:

- IACUC approved (signed) non-clinical research protocol identified by version number, date, or both, including details of study design, euthanasia criteria, proposed interventions, and exclusion criteria.
- For non-pivotal mouse studies, the Contractor will provide an annual animal care and use protocol.
- Documentation of IACUC approval, including OLAW federal wide number, IACUC registration number, and IACUC name.
- Contractor should reduce the number of animals required for a study using statistical power.
- Plans for the management of side effects, rules for interventions and euthanasia criteria.
- Procedures for assessing and collecting safety data.
- If a study is contracted through Contract Research Organizations (CROs), work orders and service agreements the Contractor shall assure an integrated safety documentation plan is in place for the study site,

pharmacy service records on the dosing material to be used and excipients, and laboratory services (including histopathology).

- Documentation that the Contractor and all required staff responsible for the conduct of the research have received training in the protection and handling of animals, or that the CRO has the required documentation.
- Purchasing of animals and/or other supplies for non-clinical studies funded in part or in whole by BARDA requires written approval by the Contracting Officer in accordance with the contract. The Contractor must have the ability to return/re-sell animals, at purchase price, to distributor or a third part, in the event that the Contracting Officer Authorization is not granted.
- Provide justification for whether studies require good laboratory practice (GLP) conditions.
- Provide justification for whether studies will be classified as non-pivotal or pivotal studies.

Documentation of each of the above items shall be submitted to COR for evaluation and comment in conjunction with the protocol. Execution of non-clinical studies requires written authorization from the Contracting Officer in accordance with this section of the contract.

c. References

Public Health Service Policy on Humane Care and Use of Laboratory Animals:

<http://grants.nih.gov/grants/olaw/InvestigatorsNeed2Know.pdf>

USDA Animal Welfare Act:

https://www.aphis.usda.gov/aphis/ourfocus/animalwelfare/sa_awa/ct_awa_program_information!/ut/p/z1/tVJNc4IwEP0tPXhkNnwoeARLxY60UxX5uGTCd1oIiCi1v75BD51pp1IPzWVnk337dt8LBOBBwMiRZqSIFSMFz_1ggpfPykw01ohH00C6uVJt01xISFXAvVogyhDcht9aE16wcTZPmmsgptLf8OiXo6Mh_BYCCCLW1m0OPqlzsdRxdqEtbigYUOa0wjtCa4ODU6r6LA_Z4TRkhS4S4qUNMnlqiMjFLV9xHVTZQ0pMWVp1ZRnKXuWOqIx-GM51FAspYIco6mgxIoihKEaCbGcSJI8TcVIJgOq8rGD60u7Pd-AL98Kfgo_ROLzIdWvDvP7-QPSHVG0xrYpI2UM7pEmHTisF6GA9Y0aWAgeh9zj35O-7naBzj3sXXtwftHEzmd1NgzO-OLkDYX-jfwLkDwrgD5IIIRhVwF1wBf6Xbpiw516ThOqckn4W2ldZs0L45L62Nx9wkRThTc/dz/d5/L2dBISEvZ0FBIS9nQSEh/?urile=wcm%3Apath%3A%2Faphis_content_library%2Fsa_our_focus%2Fsa_animal_welfare%2Fsa_awa%2Fct_awa_program_information

2. Clinical Terms of Award

These Clinical Terms of Award detail an agreement between the Government and the Contractor; they apply to all grants and contracts that involve clinical research.

Draft protocols for each clinical study will be submitted to COR for evaluation and comment. COR comments will be addressed and/or incorporated into the draft protocol prior to submission to the FDA for comment, if required.

The Government shall have unlimited rights to all protocols, data generated from the execution of these protocols, and final reports, funded by BARDA under this contract, as defined in Rights in Data Clause in FAR 52.227-14, Alternate II. The Government reserves the right to request that the Contractor provide any contract deliverable in a without any restrictive legends to ensure the COR has the ability to review and distribute the deliverables, as COR deems necessary.

a. Safety and Monitoring Issues

i. Institutional Review Board or Independent Ethics Committee Approval

Before award and then with the annual progress report, the Contractor must submit to the COR a copy of the current IRB-or IEC-approved informed consent document, documentation of continuing review and approval and the OHRP federal wide assurance 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 COR initial and annual documentation of continuing review and approval, including the current approved informed consent document and federal wide number.

The Contractor must ensure that the application 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 COR copies of documents related to all major changes in the status of ongoing protocols, including the following:

- All amendments or changes to the protocol, identified by protocol version number, date, or both and dates it is valid.
- All changes in informed consent documents, identified by version number, dates, or both and dates it is valid.

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- Termination or temporary suspension of patient accrual.
 - Termination or temporary suspension of the protocol.
 - Any change in IRB approval.
 - Any other problems or issues that could affect the participants in the studies.

The Contractor must notify the Government through the COR and CO of any of the above changes within five (5) working days electronically, 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 biosafety 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.

ii. Data and Safety Monitoring Requirements

The Government strongly recommends independent safety monitoring for clinical trials of investigational drugs, devices, or biologics; clinical trial 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 be reviewed by an independent data and safety monitoring board (DSMB); other trials may require DSMB oversight as well. The Contractor shall inform the COR of any upcoming site visits and/or audits of CRO facilities funded under this effort.

The Government reserves the right to accompany the Contractor on site visits and/or audits of CROs as COR deems necessary.

A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research and not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. For examples, the risk of drawing a small amount of blood from a healthy individual for research purposes is no greater than the risk of doing so as part of a routine physical examination (45 CFR 46.102(i)).

Final decisions regarding the type of monitoring to be used must be made jointly by the Government and the Contractor before enrollment starts. Discussions with the responsible Contracting Officer's Representative regarding appropriate safety monitoring and approval of the final monitoring plan by the COR must occur before patient enrollment begins and may include discussions about the appointment of one of the following. . BARDA will have one non-voting observer as a representative on any Data and Safety Monitoring board or other similar oversight board.

- **Independent Safety Monitor** – 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.
- **Independent Monitoring Committee (IMC) or Safety Monitoring Committee (SMC)** – a small group of independent investigators and biostatisticians who review data from a particular study.
- **Data and Safety Monitoring Board** – 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

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 COR before enrollment starts. The Contractor will also ensure that the monitors and board members report any conflicts of interest and the Contractor will maintain a record of this. The Contractor will share conflict of interest reports with COR and CO. Additionally, the Contractor must submit written summaries of all reviews conducted by the monitoring group to the COR within thirty (30) days of reviews or meetings.

iii. **BARDA Protocol Review Process Before Patient Enrollment Begins**

The Government 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 ensure the following (as applicable) are in place at each participating institution, prior to patient accrual or enrollment:

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- 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.
 - Documentation of IRB or IEC approval, including OHRP federal wide number, IRB or IEC registration number, and IRB and IEC name.
 - IRB- or IEC- approved informed consent document, identified by version number, date, or both and dates it is valid.
 - Plans for the management of side effects.
 - Procedures for assessing and reporting adverse events.
 - Plans for data and safety monitoring (see above) and monitoring of the clinical study site, pharmacy, and laboratory.
 - Documentation that the Contractor and all study staff responsible for the design or conduct of the research have received training in the protection of human subjects.

Documentation to demonstrate that each of the above items are in place shall be submitted to the COR) for evaluation and comment in conjunction with the protocol. Execution of clinical studies requires written authorization from the COR in accordance with this section of this contract.

iv. Investigational New drug or Investigational Device Exemption Requirements

Consistent with federal regulations, clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under a research protocol must be performed under a Food and Drug Administration (FDA) investigational new drug (IND) or investigational device exemption (IDE).

Exceptions must be granted in writing by FDA. If the proposed clinical trial will be performed under an IND or IDE, the Contractor must provide the COR with the name and institution of the IND or IDE sponsor, the date the IND or IDE was filed with FDA, the FDA IND or IDE number, any written comments from FDA, and the written responses to those comments.

Unless FDA notifies Contractor otherwise, The Contractor must wait thirty (30) calendar days from FDA receipt of an initial IND or IDE application before initiating a clinical trial.

The Contractor must notify the COR if the FDA places the study on clinical hold and provide the COR any written comments from FDA, written responses to the comments, and documentation in writing that the hold has been lifted. The Contractor must not use grant or contract funds during a clinical hold to fund clinical studies that are on hold. The Contractor must not enter into any new financial obligations related to clinical activities for the clinical trial on clinical hold.

v. Required Time-Sensitive Notification

Under an IND or IDE, the sponsor must provide FDA safety reports of serious adverse events. Under these Clinical Terms of Award, the Contractor must submit copies to the responsible Contracting Officer's Representative (COR) as follows:

- i. 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 (7) days after the IND sponsor's receipt of the information, must be submitted to the COR within 24 hours of FDA notification.

- ii. 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 day after the IND sponsor's receipt of the information, must be submitted to the COR within 24 hours of FDA notification.

- iii. 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 COR within 24 hours of FDA notification.

- iv. Expedited safety reports:

Sent to the COR concurrently with the report to FDA.

- v. Other adverse events documented during the course of the trial should be included in the annual IND or IDE report and reported to the COR annually.

In case of problems or issues, the Contracting Officer's Representative will contact the Contractor within ten (10) working days by email or fax, followed within thirty (30) calendar days by an official letter to the Contractor's Project Manager, with a copy to the

institutions' office of sponsored programs, listing issues and appropriate actions to be discussed.

vi. Safety reporting for research not performed under an IND or IDE.

Final decisions regarding ongoing safety reporting requirements for research not performed under an IND or IDE must be made jointly by the Contracting Officer's Representative and the Contractor.

**ARTICLE H.2. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4(b)
(December 18, 2015)**

- 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 Federal-wide Assurance (FWA) 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. Nothing in this contract shall create an agency or employee relationship between the Government and the Contractor, or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever. 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 creating liability on the part of the Government for the acts of the Contractor or its employees.
- c. Contractors involving other agencies or institutions in activities considered to be engaged in research involving human subjects must ensure that such other agencies or institutions obtain their own FWA if they are routinely engaged in research involving human subjects or ensure that such agencies or institutions are covered by the Contractors' FWA via designation as agents of the institution or via individual investigator agreements (see OHRP website at: <http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.pdf>).
- d. If at any time during the performance of this contract 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.

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

The acquisition and supply of all human specimen material (including fetal material) used under this contract shall be obtained by the Contractor in full compliance with applicable Federal, 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. RESEARCH INVOLVING HUMAN FETAL TISSUE

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

The Contractor shall make available, for audit by the Secretary, HHS, the physician statements and informed consents required by 42 USC 289g-1(b) and (c), or ensure HHS access to those records, if maintained by an entity other than the Contractor.

ARTICLE H.5. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5b (December 18, 2015)

- 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 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.6. 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. This policy may be accessed at:

<http://grants1.nih.gov/grants/olaw/references/phspol.htm>

ARTICLE H.7. INFORMATION ON COMPLIANCE WITH ANIMAL CARE REQUIREMENTS

Registration with the U. S. Dept. of Agriculture (USDA) is required to use regulated species of animals for biomedical purposes. USDA is responsible for the enforcement of the Animal Welfare Act (7 U.S.C. 2131 et. seq.), <https://awic.nal.usda.gov/>

The Public Health Service (PHS) Policy is administered by the Office of Laboratory Animal Welfare (OLAW) <http://grants2.nih.gov/grants/olaw/olaw.htm>. An essential requirement of the PHS Policy <http://grants2.nih.gov/grants/olaw/references/phspol.htm> is that every institution using live vertebrate animals must obtain an approved assurance from OLAW before they can receive funding from any component of the U. S. Public Health Service.

The PHS Policy requires that Assured institutions base their programs of animal care and use on the Guide for the Care and Use of Laboratory Animals <http://www.nap.edu/readingroom/books/labrats/> and that they comply with the regulations (9 CFR, Subchapter A) <https://awic.nal.usda.gov/final-rules-animal-welfare-9-cfr-parts-1-2-and-3> issued by the U.S. Department of Agriculture (USDA) under the Animal Welfare Act. The Guide may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of this Policy.

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

ARTICLE H.8. Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (January 2006)

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (PHS Policy) establishes a number of requirements for research activities involving animals. Before award may be made to an applicant organization, the organization shall file, with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), a written Animal Welfare Assurance (Assurance) which commits the organization to comply with the provisions of the PHS Policy, the Animal Welfare Act, and the Guide for the Care and Use of Laboratory Animals (National Academy Press,

Washington, DC). In accordance with the PHS Policy, applicant organizations must establish an Institutional Animal Care & Use Committee (IACUC), qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities and procedures. Applicant organizations are required to provide verification of IACUC approval prior to release of an award involving live vertebrate animals. No award involving the use of animals shall be made unless OLAW approves the Assurance and verification of IACUC approval for the proposed animal activities has been provided to the Contracting Officer. Prior to award, the Contracting Officer will notify Contractor(s) selected for projects that involve live vertebrate animals that an Assurance and verification of IACUC approval are required. The Contracting Officer will request that OLAW negotiate an acceptable Assurance with those Contractor(s) and request verification of IACUC approval. For further information, contact OLAW at NIH, 6705 Rockledge Drive, RKL1, Suite 360, MSC 7982 Bethesda, Maryland 20892-7982 (E-mail: olaw@od.nih.gov; Phone: 301-496-7163).

No PHS supported work for research involving vertebrate animals will be conducted by an organization, unless that organization is operating in accordance with an approved Animal Welfare Assurance and provides verification that the Institutional Animal Care and Use Committee (IACUC) has reviewed and approved the proposed activity in accordance with the PHS policy. Applications may be referred by the PHS back to the institution for further review in the case of apparent or potential violations of the PHS Policy. No award to an individual will be made unless that individual is affiliated with an assured organization that accepts responsibility for compliance with the PHS Policy. Foreign applicant organizations applying for PHS awards for activities involving vertebrate animals are required to comply with PHS Policy or provide evidence that acceptable standards for the humane care and use of animals will be met. Foreign applicant organizations are not required to submit IACUC approval, but should provide information that is satisfactory to the USG to provide assurances for the humane care of such animals.

ARTICLE H.9. APPROVAL OF REQUIRED ASSURANCE BY OLAW

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

ARTICLE H.10. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

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

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

ARTICLE H.11. 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.12. IDENTIFICATION AND DISPOSITION OF DATA

The Contractor will be required to provide certain data generated under this contract to the Department of Health and Human Services (DHHS). DHHS reserves the right to review any other data determined by DHHS to be relevant to this contract in accordance with FAR 52.227-14, Alternate II. The Contractor shall keep copies of all data required by the Food and Drug Administration (FDA) relevant to this contract for the time specified by the FDA.

ARTICLE H.13. EXPORT CONTROL NOTIFICATION

Contractors are responsible for ensuring compliance with all export control laws and regulations that may be applicable to the export of and foreign access to their proposed technologies.

Contractors may consult with the Department of State with any questions regarding the International Traffic in Arms Regulation (ITAR) (22 C.F.R. Parts 120-130) and/or the Department of Commerce regarding the Export Administration Regulations (15 C.F.R. Parts 730-774).

ARTICLE H.14. CONFLICT OF INTEREST

The Contractor represents and warrants that, to the best of the Contractor's knowledge and belief, there are no relevant facts or circumstances which could give rise to an organizational conflict of interest, as defined in FAR 2.101 and Subpart 9.5, or that the Contractor has disclosed all such relevant information. Prior to commencement of any work, the Contractor agrees to notify the Contracting Officer promptly that, to the best of its knowledge and belief, no actual or potential conflict of interest exists or to identify to the Contracting Officer any actual or potential conflict of interest the firm may have. In emergency situations, however, work may begin but notification shall be made within five (5) working days. The Contractor agrees that if an actual or potential organizational conflict of interest is identified during performance, the Contractor shall promptly make a full disclosure in writing to the Contracting Officer. This disclosure shall include a description of actions which the Contractor has taken or proposes to take, after consultation with the Contracting Officer, to avoid, mitigate, or neutralize the actual or potential conflict of interest. The Contractor shall continue performance until notified by the Contracting Officer of any contrary action to be taken. Remedies include termination of this contract for convenience, in whole or in part, if the Contracting Officer deems such termination necessary to avoid an organizational conflict of interest. If the Contractor was aware of a potential organizational conflict of interest prior to award or discovered an actual or potential conflict after award and did not disclose it or misrepresented relevant information to the Contracting Officer, the USG may terminate the contract for default, debar the Contractor from USG contracting, or pursue such other remedies as may be permitted by law or this contract.

ARTICLE H.15. INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR FINANCIAL CONFLICTS OF INTEREST

The Contractor 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 BARDA 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.

If the failure of an Investigator 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 BARDA-funded research, the Contractor 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 Contractor for further action, which may include directions to the Contractor on how to maintain appropriate objectivity in the BARDA-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 Contractor's review of, and response to, such disclosure, regardless of whether the disclosure resulted in the

Contractor'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 BARDA-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 45 C F R Part 94. 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 BARDA-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 not disclosed managed or reported the Contractor 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.16. NEEDLE DISTRIBUTION/EXCHANGE HHSAR 352.270-12 (Dec 2015)

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.17. CONTINUED BAN on FUNDING ABORTION AND CONTINUED BAN OF FUNDING HUMAN EMBRYO RESEARCH HHSAR 352.270-13 (Dec 2015)

- (a) The Contractor shall not use any funds obligated under this contract for any abortion.
- (b) The Contractor shall not use any funds obligated under this contract for the following:
 - (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 of death greater than that allowed for research on fetuses in utero under 45 CFR Part 46 and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).
- (c) The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR Part 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 of human diploid cells.
- (d) The Contractor shall not use any Federal funds for the cloning of human beings.

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

ARTICLE H.18. 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.19. CONFIDENTIALITY OF INFORMATION

- a. Confidential information, as used in this article, means information or data of a personal nature about an individual, or proprietary information or data submitted by or pertaining to an institution or organization.
- b. The Contracting Officer and the Contractor may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the USG will furnish to the Contractor or that the Contractor is expected to generate which is confidential and providing further that the Government is not entitled to unlimited rights to that information pursuant to FAR 52.227-14, Alternate II. Similarly, the Contracting Officer and the Contractor may, by mutual consent, identify such confidential information from time to time during the performance of the contract. Failure to agree will be settled pursuant to the "Disputes" clause.
- c. If it is established elsewhere in this contract that information to be utilized under this contract, or a portion thereof, is subject to the Privacy Act, the Contractor will follow the rules and procedures of disclosure set forth in the Privacy Act of 1974, 5 U.S.C. 552a, and implementing regulations and policies, with respect to systems of records determined to be subject to the Privacy Act.
- d. Confidential information, as defined in paragraph (a) of this article, shall not be disclosed without the prior written consent of the individual, institution, or organization.
- e. Whenever the Contractor is uncertain with regard to the proper handling of material under the contract, or if the material in question is subject to the Privacy Act or is confidential information subject to the provisions of this article, the Contractor should obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.
- f. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

ARTICLE H.20. ACCESS TO DOCUMENTATION/DATA

The USG shall have physical and electronic access to all documentation and data generated under this contract, including: all data documenting Contractor performance; all data generated; all communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, milestone completion

documents, and all Offeror commitments and responses. Contractor shall provide the USG with an electronic copy of all correspondence and submissions to the FDA within 5 business days of receipt. The USG shall acquire unlimited rights to all data funded under this contract in accordance with FAR Subpart 27.4 and FAR Clause 52.227-14, Alternate II.

ARTICLE H.21. 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 USG 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.22. ACKNOWLEDGMENT OF FEDERAL FUNDING

Section 507 of P.L. 104-208 mandates that Contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. This requirement is in addition to the continuing requirement to provide an acknowledgment of support and disclaimer on any publication reporting the results of a contract funded activity.

A. Publication and Publicity

No information related to data obtained under this contract shall be released or publicized without providing the COR with at least thirty (30) days advanced notice and an opportunity to review the proposed release or publication.

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, Section 507 of P.L. 104-208 mandates that Contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. Contractors are required to state: (1) the percentage and dollar amounts of the total program or project costs financed with Federal money and; (2) the percentage and dollar amount of the total costs financed by nongovernmental sources. For purposes of this contract "publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of

information, including any manuscript or scientific meeting abstract. Any publication containing data generated under this contract must be submitted for the COR review no less than thirty (30) calendar days for manuscripts and fifteen (15) calendar days for abstracts before submission for public presentation or publication. Contract support shall be acknowledged in all such publications substantially as follows:

"This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. HHSO100201600031C.

B. Press Releases

Misrepresenting contract results or releasing information that is injurious to the integrity of the Government 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. With the exception of ad-hoc press releases required by applicable law or regulations, the Contractor shall ensure that the COR has received an advance copy of any press release related to the contract not less than five (5) business days prior to the issuance of the press release.

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 Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority, under Contract No. HHSO100201600031C.

ARTICLE H.23. PROHIBITION ON THE USE OF APPROPRIATED FUNDS FOR LOBBYING ACTIVITIES AND HHSAR 352.203-70 ANTI-LOBBYING (December 18, 2015)

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

Section 1352 of Title 31, United States Code (Public Law 101-121, effective 12/23/89), among other things, prohibits a recipient (and their subcontractors) of a Federal contract, grant, loan, or cooperative agreement from using appropriated funds (other than profits from a federal contract) to pay any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with any of the following covered Federal actions; the awarding of any Federal contract; the making of any Federal grant; the making of any Federal loan; the entering

into of any cooperative agreement; or the modification of any Federal contract, grant, loan, or cooperative agreement. For additional information of prohibitions against lobbying activities, see FAR Subpart 3.8 and FAR Clause 52.203-12.

In addition, as set forth in HHSAR 352.203-70 “Anti-Lobbying” (December 18, 2015), the current Department of Health and Human Services Appropriations Act provides that no part of any appropriation contained in this Act shall be used, other than for normal and recognized executive- legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support, or defeat legislation pending before the Congress, or any State or Local legislature except in presentation to the Congress, or any State or Local legislative body itself.

The current Department of Health and Human Services Appropriations Act also provides that no part of any appropriation contained in this Act shall be used to pay the salary or expenses of any contract or grant recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress, or any State or Local legislature.

ARTICLE H.24. PRIVACY ACT APPLICABILITY

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 USG. 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 <https://www.law.cornell.edu/cfr/text/45/part-5b>

The Project Officer is hereby designated as the official who is responsible for monitoring contractor compliance with the Privacy Act.

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.25. LABORATORY LICENSE REQUIREMENTS

The Contractor shall comply with all applicable requirements of Section 353 of the Public Health Service Act (Clinical Laboratory Improvement Act as amended) (42 U.S.C. 263a and 42 CFR Part 493). This requirement shall also be included in any subcontract for services under the contract.

ARTICLE H.26. QUALITY ASSURANCE (QA) AUDIT REPORTS

The Government reserves the right to participate in QA audits. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and

next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to the COR. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.

- Contractor shall notify CO and COR of upcoming, ongoing, or recent audits/site visits of subcontractors as part of weekly communications.
- Contractor shall notify the COR and CO within five (5) business days of report completion.

ARTICLE H.27. TECHNICAL AUDITS

Contractor shall accommodate periodic or ad hoc site visits by the USG with forty-eight (48) hours advance notice. If the USG, the Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the USG.

- If issues are identified during the audit, Contractor shall submit a report to the CO and COR detailing the finding and proposed corrective action(s) within 10 business days of the audit.
- COR and CO will review the report and provide a response to the Contractor with ten (10) business days.
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

ARTICLE H.28. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

The Contractor shall not use contract funds to employ workers described in section 274A (h)(3) of the Immigration and Nationality Act, which reads as follows:

“(3) Definition of unauthorized alien – As used in this section, the term ‘unauthorized alien’ with respect to the employment of an alien at a particular time, that the alien is not at that time either an alien lawfully admitted for permanent residence, or (B) authorized to be so employed by this Act or by the Attorney General.”

ARTICLE H.29. NOTIFICATION OF CRITICAL PROGRAMMATIC CONCERNS, RISKS, OR POTENTIAL RISKS

If any action occurs that creates a cause for critical programmatic concern, risk, or potential risk to the Government or the Contractor and Incident Report shall be delivered to the CO and COR.

- Within 48 hours of activity or incident or within 24 hours for a security related activity or incident, Contractor must notify the CO and COR.
- Additional updates due to COR and CO within 48 hours of additional developments.

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- Contractor shall submit within 5 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues.

If corrective action is deemed necessary, Contractor must address in writing, its consideration of concerns raised by the CO or COR within 5 business days.

ARTICLE H.30. PROTECTION OF PERSONNEL WHO WORK WITH NONHUMAN PRIMATES

All Contractor personnel who work with nonhuman primates or enter rooms or areas containing nonhuman primates shall comply with the procedures set forth in NIH Policy Manual 3044-2, entitled, "Protection of NIH Personnel Who Work with Nonhuman Primates," located at the following URL:

<http://www1.od.nih.gov/oma/manualchapters/intramural/3044-2/>

ARTICLE H.31. DISSEMINATION OF INFORMATION

Other than scientific and technical articles for which the contractor can assert a copyright under FAR Clause 52.227-14 (c) no information related to data obtained under this contract shall be released or publicized without the prior written consent of the Contracting Officer. In the event that the contractor seeks to publicize data through a scientific or technical article, the contractor shall provide the Government, through the COR, with a minimum of thirty (30) business days to review the article prior to publication.

ARTICLE H.32. REGISTRATION WITH THE SELECT AGENT PROGRAM FOR WORK INVOLVING THE POSSESSION, USE, AND/OR TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

Work involving select biological agents or toxins shall not be conducted under this contract until the Contractor and any affected subcontractor(s) are granted a certificate of registration or are authorized to work with the applicable select agents.

For prime or subcontract awards to domestic institutions who possess, use, and/or transfer Select Agents under this contract, the institution must complete registration with the Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (DHHS) or the Animal and Plant Health Inspection Services (APHIS), U.S. Department of Agriculture (USDA), as applicable, before performing work involving Select Agents, in accordance with 42 CFR 73. No Government funds can be used for work involving Select Agents, as defined in 42 CFR 73, if the final registration certificate is denied.

For prime or subcontract awards to foreign institutions who possess, use, and/or transfer Select Agents under this contract, the institution must provide information satisfactory to the Government that a process equivalent to that described in 42 CFR 73 (<http://www.selectagents.gov/Regulations.html>) for U.S. institutions is in place and will

be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. The Contractor must provide information addressing the following key elements appropriate for the foreign institution: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations and policies equivalent to [42 CFR 73](#). The Government will assess the policies and procedures for comparability to the U.S. requirements described in [42 CFR Part 73](#). When requested by the contracting officer, the Contractor shall provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes summaries of safety, security, and training plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, the Contractor must provide the names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals have access to Select Agents under the contract.

Listings of HHS select agents and toxins, biologic agents and toxins, and overlap agents or toxins as well as information about the registration process, can be obtained on the Select Agent Program Web site at <http://www.selectagents.gov>

ARTICLE H.33. MANUFACTURING STANDARDS

The Good Manufacturing Practice Regulations (GMP)(21 CFR Parts 210-211) will be the standard to be applied for manufacturing, processing, packaging, storage and delivery of this product.

If at any time during the life of the contract, the Contractor fails to comply with GMP in the manufacturing, processing, packaging, storage, stability and other testing of the manufactured drug substance or product and delivery of this product and such failure results in a material adverse effect on the safety, purity or potency of the product (a material failure) as identified by the FDA, the Contractor shall have thirty (30) calendar days from the time such material failure is identified to cure such material failure. If, within the thirty (30) calendar day period, the Contractor fails to take such an action to the satisfaction of the USG Project Officer, or fails to provide a remediation plan that is acceptable to the COR, then the contract may be terminated.

ARTICLE H.34. IN-PROCESS REVIEW

In Process Reviews (IPR) will be conducted at the discretion of the USG to discuss the progression of the milestones. The USG reserves the right to revise the milestones and budget pending the development of the project. Deliverables such as an overall project summary report and/or slides will be required when the IPRs are conducted. The Contractor's success in completing the required tasks under each work segment must be demonstrated through the Deliverables and Milestones specified under SECTION F. Those deliverables will constitute the basis for the USG's decision, at its sole discretion, to proceed with the work segment, or institute changes to the work segment, or terminate the work segment as otherwise permitted by this contract.

IPRs may be scheduled at the discretion of the USG to discuss progression of the contract. The Contractor shall provide a presentation following a prescribed template which will be provided by the USG at least 30 business days prior to the IPR. Subsequently, the contractor will be requested to provide a revised/final presentation to the Contracting Officer at least 10 business days prior to the IPR.

H.35. PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM ASPR FUNDED RESEARCH

All ASPR-funded investigators shall submit to the NIH National Library of Medicine's (NLM) PubMed Central (PMC) an electronic version of the author's final manuscript, upon acceptance for publication, of any peer-reviewed scientific publications resulting from research supported in whole or in part with Federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response. ASPR defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and ASPR. The Policy directs electronic submissions to the NIH/NLM/PMC: <http://www.pubmedcentral.nih.gov>.

Additional information is available at <http://www.phe.gov/Preparedness/planning/science/Pages/AccessPlan.aspx>

(b) (4)

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PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

**ARTICLE I.1. FAR 52.252-2, CLAUSES INCORPORATED BY REFERENCE
(FEBRUARY 1998)**

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

Clauses for Cost-Reimbursement Research and Development Contract

- 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 (Over \$150,000)
52.203-13	Oct 2015	Contractor Code of Business Ethics and Conduct
52.203-14	Oct 2015	Display of Hotline Poster(s)
52.203-17	Apr 2014	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights.
52.204-4	May 2011	Printed or Copied Double-Sided on Recycled Paper
52.204-7	Jul 2013	System for Award Management
52.204-10	Oct 2015	Reporting Executive Compensation and First-Tier Subcontract Awards
52.204-13	Jul 2013	System for Award Management Maintenance
52.204-19	Dec 2014	Incorporation by Reference of Representations and Certifications
52.209-6	Oct 2015	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment (Over \$30,000)
52.209-9	Jul 2013	Updates of Publicly Available Information Regarding Responsibility Matters

<u>FAR CLAUSE NO.</u>	<u>DATE</u>	<u>TITLE</u>
52.209-10	Nov 2015	Prohibition on Contracting With Inverted Domestic Corporations
52.210-1	Apr 2011	Market Research
52.215-2	Oct 2010	Audit and Records – Negotiation
52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
52.215-10	Aug 2011	Price Reduction for Defective Cost or Pricing Data
52.215-11	Aug 2011	Price Reduction for Defective Certified Cost or Pricing Data—Modifications.
52.215-12	Oct 2010	Subcontractor Cost or Pricing Data
52.215-13	(Oct 2010)	Subcontractor Certified Cost or Pricing Data—Modifications.
52.215-15	Oct 2010	Pension Adjustments and Asset Reversions
52.215-17	Oct 1997	Waiver of Facilities Capital Cost of Money
52.215-18	Jul 2005	Reversion or Adjustment of Plans for Post-Retirement Benefits (PRB) other than Pensions
52.215-19	Oct 1997	Notification of Ownership Changes
52.215-21	Oct 2010	Requirements for Cost or Pricing Data or Information Other Than Cost or Pricing Data - Modifications
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 Alternate I
52.215-23	Oct 2009	Limitations on Pass-Through Charges (Over the Simplified Acquisition threshold)
52.216-7	Jun 2013	Allowable Cost and Payment
52.216-8	Jun 2011	Fixed Fee
52.219-8	Oct 2014	Utilization of Small Business Concerns
52.222-2	Jul 1990	Payment for Overtime Premiums
52.222-3	Jun 2003	Convict Labor
52.222-21	Apr 2015	Prohibition of Segregated Facilities
52.222-26	Apr 2015	Equal Opportunity
52.222-35	Oct 2015	Equal Opportunity for Veterans
52.222-36	Jul 2014	Equal Opportunity for Workers With Disabilities
52.222-37	Feb 2016	Employment Reports on Veterans.
52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act
52.222-50	Mar 2015	Combating Trafficking in Persons
52.222-54	Oct 2015	Employment Eligibility Verification
52.223-18	Aug 2011	Encouraging Contractor Policy to Ban Text Messaging While Driving
52.224-1	April 1984	Privacy Act Notification
52.224-2	April 1984	Privacy Act

<u>FAR CLAUSE NO.</u>	<u>DATE</u>	<u>TITLE</u>
52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
52.225-25	Oct 2015	Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran— Representation and Certifications
52.227-1	Dec 2007	Authorization and Consent, Alternate I (Apr 1984)
52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
52.227-11	May 2014	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.
52.227-14	May 2014	Rights in Data-General
52.227-14 – Alternate II	May 2014	<p>Rights in Data – General, Alternate II.</p> <p>Completed portion as follows:</p> <p>Limited Rights Notice (Dec 2007)</p> <p>(a) These data are submitted with limited rights under Government Contract No HHSO100201600031C. These data may be reproduced and used by the Government with the express limitation that they will not, without written permission of the Contractor, be used for purposes of manufacture nor disclosed outside the Government; except that the Government may disclose these data outside the Government for the following purposes, provided that the Government makes such disclosure subject to prohibition against further use and disclosure:</p> <p style="padding-left: 40px;">(i) Use (except for manufacture) by support service contractors.</p> <p style="padding-left: 40px;">(ii) Evaluation by nongovernment evaluators.</p> <p>(b) This Notice shall be marked on any reproduction of these data, in whole or in part.</p>

<u>FAR CLAUSE NO.</u>	<u>DATE</u>	<u>TITLE</u>
52.227-14 – Alternate IV	Dec 2007	Copyright—(1) Data first produced in the performance of the contract. Except as otherwise specifically provided in this contract, the Contractor may assert copyright in any data first produced in the performance of this contract. When asserting copyright, the Contractor shall affix the applicable copyright notice of 17 U.S.C. 401 or 402, and an acknowledgment of Government sponsorship (including contract number), to the data when such data are delivered to the Government, as well as when the data are published or deposited for registration as a published work in the U.S. Copyright Office. For data other than computer software, the Contractor grants to the Government, and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license for all such data to reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, by or on behalf of the Government. For computer software, the Contractor grants to the Government and others acting on its behalf, a paid-up, nonexclusive, irrevocable, worldwide license for all such computer software to reproduce, prepare derivative works, and perform publicly and display publicly (but not to distribute copies to the public), by or on behalf of the Government.
52.227-16	Jun 1987	Additional Data Requirements
52.228-7	Mar 1996	Insurance -- Liability to Third Persons
52.230-6	June 2010	Administration of Cost Accounting Standards
52.232-9	Apr 1984	Limitation on Withholding of Payments
52.232-17	May 2014	Interest
52.232-20	Apr 1984	Limitation of Cost
52.232-23	May 2014	Assignment of Claims
52.232-25	Jul 2013	Prompt Payment, Alternate I (Feb 2002)
52.232-33	Jul 2013	Payment by Electronic Funds Transfer-- System for Award Management
52.232-39	Jun 2013	Unenforceability of Unauthorized Obligations.
52.233-1	May 2014	Disputes
52.233-2	Sept 2006	Service of Protest.
52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
52.234-4	May 2014	Earned Value Management System
52.242-1	Apr 1984	Notice of Intent to Disallow Costs

<u>FAR CLAUSE NO.</u>	<u>DATE</u>	<u>TITLE</u>
52.242-3	May 2014	Penalties for Unallowable Costs
52.242-4	Jan 1997	Certification of Final Indirect Costs
52.242-13	Jul 1995	Bankruptcy
52.243-2	Aug 1987	Changes - Cost Reimbursement, Alternate V (Apr 1984)
52.244-2	Oct 2010	Subcontracts, Alternate I (June 2007)
52.244-5	Dec 1996	Competition in Subcontracting
52.244-6	Feb 2016	Subcontracts for Commercial Items
52.245-1 Alt. II	Apr 2012	Government Property, Alternate II (Apr 2012)
52.245-9	Apr 2012	Use and Charges
52.246-8	May 2001	Inspection of Research and Development – Cost-Reimbursement
52.246-23	Feb 1997	Limitation of Liability
52.246-25	Feb 1997	Limitation of Liability -- Services
52.247-63	Jun 2003	Preference for U.S.-Flag Air Carriers
52.249-6	May 2004	Termination (Cost-Reimbursement)
52.249-14	Apr 1984	Excusable Delays
52.251-1	Apr 2012	Government Supply Sources
52.253-1	Jan 1991	Computer Generated Forms

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>
352.211-3	Dec 2015	Paperwork Reduction Act
352.203-70	Dec 2015	Anti-Lobbying
352.222-70	Dec 2015	Contractor Cooperation in Equal Employment Opportunity Investigations
352.223-70	Dec 2015	Safety and Health
352.224-70	Dec 2015	Privacy Act
352.227-70	Dec 2015	Publications and Publicity
352.231-70	Dec 2015	Salary Rate Limitation
352.233-71	Dec 2015	Litigation and Claims
352.237-75	Dec 2015	Key Personnel
352.270-6	Dec 2015	Restriction on use of Human Subjects

[End of GENERAL CLAUSES FOR A NEGOTIATED COST-REIMBURSEMENT RESEARCH AND DEVELOPMENT CONTRACT-Rev. 12/2011].

ARTICLE I.2. 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:

a. FAR Clause 52.217-8, Option to Extend Services (Nov 1999)

The Government may require continued performance of any services within the limits and at the rates specified in the contract. These rates may be adjusted only as a result of revisions to prevailing labor rates provided by the Secretary of Labor. The option provision may be exercised more than once, but the total extension of performance hereunder shall not exceed 6 months. The Contracting Officer may exercise the option by written notice to the Contractor within 30 days before the contract expires.

(End of Clause)

b. FAR Clause 52.217-9, Option to Extend the Term of the Contract (Mar 2000)

(a) The Government may extend the term of this contract by written notice to the Contractor within 30 days after the Government has completed its analysis of the deliverables associated with all milestones required for the exercise of a particular option unless the Parties mutually agree to an earlier exercise of the option. The Government will provide the Contractor a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension.

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

(c) The total duration of this contract, including the exercise of any options under this clause, shall not exceed 10 years.

b. FAR Clause 52.219-28, Post-Award Small Business Program Representation (July 2013).

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

Long-term contract means a contract of more than five years in duration, including options. However, the term does not include contracts that exceed five years in duration because the period of performance has been extended for a cumulative period not to exceed six months under the clause at 52.217-9, Option to Extend the Term of the Contract, or other appropriate authority.

Small business concern means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (c) of this clause. Such a concern is "not dominant in its field of operation" when it does not exercise a controlling or major influence on a national basis in a kind of business activity in which a number of business concerns are primarily engaged. In determining whether dominance exists, consideration shall be given to all appropriate factors, including volume of business, number of employees, financial resources, competitive status or position, ownership or control of materials, processes, patents, license agreements, facilities, sales territory, and nature of business activity.

(b) If the Contractor represented that it was a small business concern prior to award of this contract, the Contractor shall represent its size status according to paragraph (e) of this clause or, if applicable, paragraph (g) of this clause, upon the occurrence of any of the following:

(1) Within 30 days after execution of a novation agreement or within 30 days after modification of the contract to include this clause, if the novation agreement was executed prior to inclusion of this clause in the contract.

(2) Within 30 days after a merger or acquisition that does not require a novation or within 30 days after modification of the contract to include this clause, if the merger or acquisition occurred prior to inclusion of this clause in the contract.

(3) For long-term contracts--

(i) Within 60 to 120 days prior to the end of the fifth year of the contract; and

(ii) Within 60 to 120 days prior to the date specified in the contract for exercising any option thereafter.

(c) The Contractor shall represent its size status in accordance with the size standard in effect at the time of this representation that corresponds to the North American Industry Classification System (NAICS) code assigned to this contract. The small business size standard corresponding to this NAICS code can be found at <https://www.sba.gov/contracting/getting-started-contractor/make-sure-you-meet-sba-size-standards/table-small-business-size-standards>.

(d) The small business size standard for a Contractor providing a product which it does not manufacture itself, for a contract other than a construction or service contract, is 500 employees.

(e) Except as provided in paragraph (g) of this clause, the Contractor shall make the representation required by paragraph (b) of this clause by validating or updating all its representations in the Online Representations and Certifications Application and its data in the Central Contractor Registration, as necessary, to ensure that they reflect the Contractor's current status. The Contractor shall notify the contracting office in writing within the timeframes specified in paragraph (b) of this clause that the data have been validated or updated, and provide the date of the validation or update.

(f) If the Contractor represented that it was other than a small business concern prior to award of this contract, the Contractor may, but is not required to, take the actions required by paragraphs (e) or (g) of this clause.

(g) If the Contractor does not have representations and certifications in ORCA, or does not have a representation in ORCA for the NAICS code applicable to this contract, the Contractor is required to complete the following representation and submit it to the contracting office, along with the contract number and the date on which the representation was completed:

The Contractor represents that it is, is not a small business concern under NAICS Code 541711 assigned to contract number HHSO100201600031C.

FAR 52.232-40 Providing Accelerated Payments to Small Business Subcontractors.

**PROVIDING ACCELERATED PAYMENTS TO SMALL BUSINESS
SUBCONTRACTORS (DEC 2013)**

(a) Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.

(b) The acceleration of payments under this clause does not provide any new rights under the Prompt Payment Act.

(c) Include the substance of this clause, including this paragraph (c), in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

(End of clause)

PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. Statement of Work, dated 12 September 2016, 19 pages
2. Contract WBS Milestones/Deliverables and Technical Deliverables (see inside contract)
3. Invoice/Financing Request Instructions and Contract Financial Reporting Instructions for AMCG Cost-Reimbursement Type Contracts, 6 pages
4. Financial Report of Individual Project/Contract, 1 page
5. Instructions for Completing Financial Report of Individual Project/Contract, 3 pages
6. Inclusion Enrollment Report, 5/01 (Modified OAMP: 10/01), 1 page.
7. Research Patient Care Costs, 2 page
8. Disclosure of Lobbying Activities, 2 pages
9. Earned Value Management (EVM) Data Item Description (DID) Sample, 16 pages.
10. 7 Principles of Earned Value Management Tier 2 System Implementation Guide, 30 pages.
11. Listing of Project-Relevant Background Inventions
12. Data Rights Assertion Table

PART IV - REPRESENTATIONS AND INSTRUCTIONS

SECTION K - REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

The following documents are incorporated by reference in this contract:

- 1) Human Subjects Assurance Identification Numbers: To be provided prior to study execution
- 2) Animal Welfare Assurance Numbers (OLAW/PHS): To be provided prior to study execution

**BARDA Broad Agency Announcement (BAA)
(Solicitation # CBRN-BAA-13-100-SOL-00013)**

Advanced Research and Development of Chemical, Biological, Radiological and Nuclear
Medical Countermeasures

Topic Area of Interest No. (#1), Vaccines

MANUFACTURING AND LICENSURE OF BPSC1001/V920 (rVSVΔG-ZEBOV-GP)

Statement of Work

PREAMBLE

Independently and not as an agency of the Government, the Contractor shall be required to furnish all the necessary services, qualified personnel, material, equipment, and facilities, not otherwise provided by the Government, as needed to perform the Statement of Work submitted in response to the BARDA Broad Agency Announcement (BAA) BARDA CBRN BAA-13-100-SOL-00013.

The Government reserves the right to modify the milestones, progress, schedule, budget, or deliverables to add or delete deliverables, process, or schedules if the need arises. Because of the nature of this research and development (R&D) contract and the complexities inherent in this and prior programs, at designated milestones the Government will evaluate whether work should be redirected, removed, or whether schedule or budget adjustments should be made. The Government reserves the right to change the product, process, schedule, or events to add or delete part or all of these elements as the need arises, and upon reaching agreement with the Contractor regarding any required change.

(b) (4) [Redacted]

[Redacted]



(b) (4) [Redacted text block]

[Redacted text block]

[Redacted text block]

Statement of Work and Work Breakdown Structure

1. Base: Facility, Site, Process Performance Qualification (PPQ) Readiness Activities, Manufacturing and Testing of Process Simulations

The BASE contract will support the necessary activities at the final commercial manufacturing facility at the expected commercial process scale (400RB process).

The proposal thus includes:

(b) (4) [Redacted text block]



(b) (4)

[Redacted text block containing multiple paragraphs of blacked-out content]

1.1. Program Management (WBS1.1)

The Contractor [BioProtection Systems Inc. (BPS)] shall provide for the following as outlined below and in the contract deliverables list (Article F.2):

- 1.1.1. The overall management, integration and coordination of all contract activities, including a technical and administrative infrastructure to ensure the efficient planning, initiation, implementation, and direction of all contract activities;
- 1.1.2. Principal Investigator (PI) responsible for project management, communication, tracking, monitoring and reporting on status and progress, and modification to the project requirements and timelines, including projects undertaken by subcontractors; The contract



deliverables list (reference), identifies all contract deliverables and reporting requirements for this contract.

- 1.1.3. Project Manager(s) with responsibility for monitoring and tracking day-to-day progress and timelines, coordinating communication and project activities; costs incurred; and program management; The contract deliverables list (reference), identifies all contract deliverables and reporting requirements for this contract.
- 1.1.4. BARDA Liaison with responsibility for effective communication with the Project Officer and Contracting Officer. May be the PI or Project Manager.
- 1.1.5. Administrative and legal staff to provide development of compliant subcontracts, consulting, and other legal agreements, and to ensure timely acquisition of all proprietary rights, including IP rights, and reporting all inventions made in the performance of the project.
- 1.1.6. Administrative staff with responsibility for financial management and reporting on all activities conducted by the Contractor and any subcontractors.
- 1.1.7. Contract Review Meetings**
 - 1.1.7.1 The Contractor shall participate in regular meetings to coordinate and oversee the contract effort as directed by the Contracting and Project Officers. Such meetings may include, but are not limited to, meeting of the Contractors and subcontractors to discuss manufacturing progress, product development, product assay development, scale up manufacturing development, clinical sample assays development, preclinical/clinical study designs and regulatory issues; meetings with individual contractors and other HHS officials to discuss the technical, regulatory, and ethical aspects of the program; and meeting with technical consultants to discuss technical data provided by the Contractor.
 - 1.1.7.2 The Contractor shall participate in teleconferences every two weeks between the Contractor and subcontractors (as required) and BARDA to review technical progress. Teleconferences or additional face-to-face meetings shall be more frequent at the request of BARDA.
- 1.1.8. Integrated Master Schedule**

Within 30 calendar days of the effective date of the contract, the Contractor shall submit a first draft of an updated Integrated Master Schedule in a format agreed upon by BARDA to the Project Officer and



the Contracting Officer for review and comment. The Integrated Master Schedule shall be incorporated into the contract, and will be used to monitor performance of the contract. Contractor shall include the key milestones and Go/No Go decision gates. The IMS for the period of performance will be accepted by BARDA at the PMBR.

1.1.9. Integrated Master Plan

Work Breakdown Structure

The Contractor shall utilize a WBS template agreed upon by BARDA for reporting on the contract. The Contractor shall expand and delineate the Contract Work Breakdown Structure (CWBS) to a level agreed upon by BARDA as part of their Integrated Master Plan for contract reporting. The CWBS shall be discernable and consistent. BARDA may require Contractor to furnish WBS data at the work package level or at a lower level if there is significant complexity and risk associated with the task.

GO/ NO-GO Decision Gates:

The Integrated Master Plan outlines key milestones with “Go/No Go” decision criteria (entrance and exit criteria for each phase of the project). The project plan should include, but not be limited to, milestones in manufacturing, non-clinical and clinical studies, and regulatory submissions. Specific milestones will be defined that will be used to trigger subsequent Option Periods.

1.1.10. Program Management Plan

Within 3 months of contract award, the Contractor will develop, and submit to BARDA for approval, a revised version of the Program Management Plan (PMP) that was initially submitted to HHS under contract No. HSSO100201500002C. The revised plan will detail the tools and techniques that BPS intends to employ in its management of the proposed work.

This plan is intended to be a living document and changes to any of the individual sub-plans as well as the addition or subtraction of sub-plans will be documented and must be approved by the Program Manager and Principal Investigator. Changes to the PMP will be tracked by version number and date, and assuming changes have been made, will be submitted to BARDA for review and approval.

The Program Management Plan will update the following individual sub-plans:



- Scope/Schedule Management Plan
- Costs Management Plan
- Communications Management Plan
- Stakeholder Management Plan
- Change Management Plan
- Quality Management Plan
- Human Resources/Staffing Plan

1.1.11. Product Development Plan

Within 3 months of the effective date of subcontract award, the Contractor will submit a revised version of the Integrated Product Development Plan (IPDP) that was initially submitted to HHS under contract No. HSSO100201500002C. Ultimately, this plan will require approval by BARDA’s Contracting Officer's Representative and the Contracting Officer prior to initiation of any activities related to their implementation. This plan will be updated, as required.

1.1.12. Subcontractor Management

The Contractor will manage all subcontractors to oversee effective and timely execution of deliverables in the scope of work and to meet reporting requirements under this contract.

(b) (4)
[Redacted text block]

1.1.13. Financial Management, Accounting and Reporting

The Contractor will engage a subcontractor to provide specific services in Contracts and Subcontracts Management to help ensure compliance with contracts clauses and requirements, Federal Acquisition Regulations; and purchasing. Specific services will include:

- Subcontract Requests for Proposal
- Contracts reporting and monitoring
- Contracting Office Consent to Subcontract
- Price Reasonableness analysis
- Internal Controls



To the extent required by the contract, the Contractor will develop, implement, and provide ongoing support to the contract Earned Value Management (EVM) reporting. This will include the design and implementation of processes, documentation, control account plans, and the Performance Measurement Baseline (PMB) enabling the implementation of a software solution. Further, the Contractor and/or its subcontractor will support the monthly EVM processing and reporting and format 5 variance reporting

The Contractor and/or its subcontractor will provide Project Accounting and Finance Management to help ensure compliance with contracts clauses and requirements, Federal Acquisition Regulations; and cost accounting and billing. Specific services will include:

- Monthly Job Cost reporting and billing
- Time Reporting
- Indirect Rate calculations
- Internal Controls and training
- QA/QC Plans and Ongoing activity

Elements of EVMS shall be applied to all CLINs as part of the Integrated Master Project Plan, the Contractor shall submit a written summary of the management procedures that it will establish, maintain and use to comply with EVMS requirements. This summary is provided as an Attachment to this proposal.

1.1.14. Decision Gate Reporting

On completion of a stage of the product development, as defined in the agreed upon Integrated Master Schedule and Integrated Master Plan, the Contractor shall prepare and submit to the Project Officer and the Contracting Officer a Decision Gate Report that contains (i) sufficient detail, documentation and analysis to support successful completion of the stage according to the predetermined qualitative and quantitative criteria that were established for Go/No Go decision making; and (ii) a description of the next stage of product development to be initiated and a request for approval to proceed to the next stage of product development.

1.1.15. Risk Management Plan

The Contractor shall develop a risk management plan within 90 days of contract award highlighting potential problems and/or issues that may arise during the life of the contract, their impact on cost, schedule and performance, and appropriate remediation plans. This plan should



reference relevant WBS elements where appropriate. Updates to this plan shall be included every three months (quarterly) in the monthly Project Status Report.

1.1.16. Quality Management Plan

Within 3 months of contract award, the Contractor will update, and submit to BARDA for approval, a revised quality plan for the program to ensure compliance with specified requirements, guidance documents and GCP/GMP/GLP regulations; and to ensure continual improvement. The quality plan will:

- Describe the quality planning process;
- Establish quality objectives;
- Identify quality system changes in alignment with compliance requirements, contractual requirements and operational requirements; and
- Ensure comprehensive quality oversight of the subcontractors through documentation reviews and quality system compliance audits.

This quality plan will be maintained by the BPS quality lead who will be responsible for assuring that all quality objectives are appropriately documented and accomplished. This quality plan may be supplemented with additional, separate implementation plans and schedules.

The Contractor will manage the program's quality activities according to the approved quality plan.

1.1.17. Performance Measurement Baseline Review (PMBR):

The Contractor shall submit a plan for a PMBR to occur within 180 days of contract award. At the PMBR, the Contractor and BARDA shall mutually agree upon the budget, schedule and technical plan baselines (Performance Measurement Baseline). These baselines shall be the basis for monitoring and reporting progress throughout the life of the contract. The PMBR is conducted to achieve confidence that the baselines accurately capture the entire technical scope of work, are consistent with contract schedule requirements, are reasonably and logically planned, and have adequate resources assigned. The goals of the PMBR are as follows:

- Jointly assess areas such as the Contractor's planning for complete coverage of the SOW, logical scheduling of the work activities, adequate resources, and identification of inherent risks



- Confirm the integrity of the Performance Measurement Baseline (PMB)
- Foster the use of EVM as a means of communication
- Provide confidence in the validity of Contractor reporting
- Identify risks associated with the PMB
- Present any revised PMBs for mutual agreement
- Present an Integrated Master Schedule: The Contractor shall deliver an initial program level Integrated Master Schedule (IMS) that rolls up all time-phased WBS elements down to the activity level. This IMS shall include the dependencies that exist between tasks. This IMS will be agreed to and finalized at the PMBR. DI-MGMT-81650 may be referenced as guidance in creation of the IMS (see <http://www.acq.osd.mil/pm/>).
- Present the Risk Management Plan

1.1.18. Deviation Request:

During the course of contract performance, in response to a need to change IMS activities as baselined at the PMBR, the Contractor shall submit a Deviation Report. This report shall request a change in the agreed-upon IMS and timelines. This report shall include: (i) discussion of the justification/rationale for the proposed change; (ii) options for addressing the needed changes from the agreed upon timelines, including a cost-benefit analysis of each option; and (iii) recommendations for the preferred option that includes a full analysis and discussion of the effect of the change on the entire product development program, timelines, and budget.

1.1.19. Monthly and Annual Reports

The Contractor shall deliver Project Status Reports on a monthly basis. The reports shall address the items below cross referenced to the WBS, SOW, IMS, and EVM:

- Executive summary highlighting the progress, issues, and relevant activities in manufacturing, non-clinical, clinical, and regulatory;
- Progress in meeting contract milestones, detailing the planned progress and actual progress during the reporting period, explaining any differences between the two and corrective steps;
- Updated IMS;
- Updated EVM;



- Updated Risk Management Plan (Every 3 months);
- Three month rolling forecast of planned activities;
- Progress of regulatory submissions;
- Estimated and actual expenses;

1.1.20. Data Management

The Contractor shall develop and implement appropriate data management and quality control systems/procedures, including transmission, storage, confidentiality, and retrieval of all contract data;

Provide for the statistical design and analysis of data resulting from the research;

1.1.21. Long-term Stability Testing, 90 Roller Bottle Drug Product Lots Produced Under Contract HHS0100201500002C

(b) (4)

[Redacted text block]

1.1.22. Long-term Storage Testing, 90 Roller Bottle Drug Product Lots Produced Under Contract Modification HHS0100201500002C

(b) (4)

[Redacted text block]



(b) (4)
[Redacted]

1.2. Process Performance Qualification (PPQ) Readiness Activities (WBS 1.2)

The contractor and/or its subcontractor(s) will conduct PPQ readiness activities to generate necessary documents and data to support process validation and to support a Biological License Application (BLA) for BPSC1001/V920 (rVSVΔG-ZEBOV-GP manufacturing).

This shall include:

- (b) (4)
[Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

1.3. Facility and Site Readiness Activities (WBS 1.3)

The contractor and/or its subcontractor(s) shall complete the necessary facility upgrades and implementation of quality systems to support cGMP production of the Ebola Zaire Vaccine BPSC1001/V920 (rVSVΔG-ZEBOV-GP). The scope of this WBS shall include:

- (b) (4)
[Redacted]



- (b) (4) [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

1.4. Manufacture and Testing of Process Simulations (WBS 1.4)

Complete the necessary three consecutive end-to-end Process Simulations for DS and DP product with the expected commercial process.

Activities include:

- (b) (4) [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

1.5. Regulatory (WBS 1.5)

This activity will largely be performed pre-award and no costs are assigned to the work.

Engage CBER in formal Type C meeting to discuss following topics:

- (b) (4) [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]



- (b) (4) [Redacted]
- [Redacted]
- [Redacted]

1.6. Non-Clinical: Reproductive Toxicology Studies (WBS 1.6)

1.6.1. Embryo-fetal Development Study in Pregnant Female Rats (WBS 1.6.2)

The contractor and/or its subcontractor(s) will conduct a GLP embryofetal development study to evaluate the potential developmental toxicity profile for BPSC1001/V920 (rVSVΔG-ZEBOV-GP). The study design (either single or multiple doses) will be based upon the results of an exploratory immunogenicity study (funded outside of this proposal) using the dosing regimen that produces the greatest viremia in rats.

Activities include GLP protocol development, study conduct, generation of an un-audited report, and completion of the final study report. An initial study design has been discussed with FDA and deemed to be appropriate.

1.6.2. Pre- and Post-natal Development Study in Rats (WBS 1.6.3)

The contractor and/or its subcontractor(s) will conduct a pre- and post-natal development study to evaluate the potential effects of BPSC1001/V920 (rVSVΔG-ZEBOV-GP) on development, growth, behavior, and reproductive performance of the F1 generation. The study design (either single or multiple doses) will be based upon the results of an exploratory immunogenicity study using the dosing regimen that produces the greatest viremia. Activities include GLP protocol development, study conduct, generation of an un-audited report, and completion of the final study report. An initial study design has been discussed with FDA and deemed to be appropriate.

1.6.3. Testing of Rat Specimens in Qualified RT-PCR Assays (WBS 1.6.4)

Samples from these studies will be tested in the immunogenicity assay as well as the qualified BPSC1001/V920 (rVSVΔG-ZEBOV-GP) real-time RT-PCR assay to detect potential viremia of the vaccine virus in the sera collected at different time points post vaccination.

1.7. Immunogenicity for PREVAIL and PREPARE Studies (WBS 1.7)



(b) (4)

[Redacted text block consisting of multiple lines of blacked-out content]

2. Option 1: Manufacturing and Testing of PPQ Lots, BLA Preparation and Pre-PAI Activities

Go/No Go Decision Criteria: Option 1. Go/No Go Decision Criteria: Completion of construction of the Drug Substance (DS) production facility. Finalization of the Validation Master Plan. Finalization of the DS Process Simulation protocol and Initiation of the DS Process Simulations. The decision gate may include a site visit by BARDA to the manufacturing facility .

The Contractor and/or its subcontractor(s) shall carry out the following tasks and subtasks and in accordance with the agreed upon Integrated Master Schedule and Integrated Master Plan (defined in 4.1.1.2 and 4.1.1.3) which shall further detail the conduct of the specific tasks and subtasks.

2.1 Program Management (consistent with section 1.1.1) (WBS 2.1)

Program management scope in BASE year is consistent with program management scope in each option year.

2.2 Manufacturing and Testing of Process Performance Qualification (PPQ) Lots (WBS 2.2)

These activities will provide the necessary information to show the commercial process is robust and reproducible.

These lots are necessary for BLA Submission. The Contractor and/or its subcontractor(s) will perform the following activities:



- (b) (4) [Redacted]
- [Redacted]
- [Redacted]

2.3 BLA Preparation and Pre-PAI Activities (WBS 2.3)

Following completion of Process Performance Qualification lots, the contractor and/or its subcontractor(s) shall complete the necessary activities and documentation to support BLA licensure for the Ebola Vaccine BPSC1001/V920 (rVSVΔG-ZEBOV-GP). These shall include:

- (b) (4) [Redacted]
- [Redacted]
- [Redacted]

3. Option 2: Pediatric Clinical Trial

(b) (4) [Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

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[Redacted]

[Redacted]

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[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]

[Redacted]



(b) (4) [Redacted text block]

3.1 Program Management (Consistent with section 4.1.1.1) (WBS 4.1)

Program management scope in BASE year is consistent with program management scope in each option year.

(b) (4) [Redacted text block]

- [Redacted list item]
- [Redacted list item]
- [Redacted list item]
- [Redacted list item]
- [Redacted list item]
- [Redacted list item]
- [Redacted list item]
- [Redacted list item]

(b) (4) [Redacted text block]

- [Redacted list item]
- [Redacted list item]
- [Redacted list item]
- [Redacted list item]



- (b) (4) [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]

4. Option 3: Additional Process Simulations and Manufacturing of PPQ Lots

Go/No Go Decision Criteria: Option 3 will be considered if additional process simulation and/or Process Performance Qualification Lots are needed. This decision will be considered after completion of all milestones under WBS 1.4, and again after all milestones under WBS 2.2 (if Option 2 should be exercised).

The contractor and/or its subcontractor(s) shall carry out the following tasks and subtasks and in accordance with an agreed upon Integrated Master Schedule and Integrated Master Plan (defined in 4.1.1.2 and 4.1.1.3) which shall further detail the conduct of the specific tasks and subtasks.

4.1 Program Management (Consistent with section 1.1.1) (WBS 6.1)

Program management scope in BASE year is consistent with program management scope in each option year.

- (b) (4) [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]
- [Redacted]



- (b) (4) [Redacted]
 - | [Redacted]
 - | [Redacted]
 - | [Redacted]
- [Redacted]
- [Redacted]
- | [Redacted]
 - | [Redacted]
- | [Redacted]
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 - | [Redacted]
- | [Redacted]



BioProtection Systems



ATTACHMENT 3

INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORTING INSTRUCTIONS FOR COST-REIMBURSEMENT TYPE CONTRACTS

Format: Payment requests shall be submitted on the Contractor's self-generated form in the manner and format prescribed herein and as illustrated in the Sample Invoice/Financing Request. Standard Form 1034, Public Voucher for Purchases and Services Other Than Personal, may be used in lieu of the Contractor's self-generated form provided it contains all of the information shown on the Sample Invoice/Financing Request. DO NOT include a cover letter with the payment request.

Number of Copies: Payment requests shall be submitted in the quantity specified in the Invoice Submission Instructions in Section B of the Contract.

Frequency: Payment requests should not be submitted more frequently than once every two weeks in accordance with the Allowable Cost and Payment Clause incorporated into this contract unless otherwise instructed by the Contract Officer. Small business concerns may submit invoices/financing requests more frequently than every two weeks when authorized by the Contracting Officer.

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

Billing of Costs Incurred: If billed costs include (1) costs of a prior billing period, but not previously billed, or (2) costs incurred during the contract period and claimed after the contract period has expired, the Contractor shall cite the amount(s) and month(s) in which it incurred such costs.

Contractor's Fiscal Year: Payment requests shall be prepared in such a manner that the Government can identify costs claimed with the Contractor's fiscal year.

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

Costs Requiring Prior Approval: Costs requiring the Contracting Officer's approval, which are not set forth in an Advance Understanding in the contract, shall be identified and reference the Contracting Officer's Authorization (COA) Number. In addition, the Contractor shall show any cost set forth in an Advance Understanding as a separate line item on the payment request.

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

- (a) **Interim Invoice/Contract Financing Request:** These are interim payment requests submitted during the contract performance period.
- (b) **Completion Invoice:** The completion invoice shall be submitted promptly upon completion of the work, but no later than one year from the contract completion date, or within 120 days after settlement of the final indirect cost rates covering the year in which the contract is physically complete (whichever date is later). The Contractor shall submit the completion invoice when all costs have been assigned to the contract and it completes all performance provisions.
- (c) **Final Invoice:** A final invoice may be required after the amounts owed have been settled between the Government and the Contractor (e.g., resolution of all suspensions and audit exceptions).

Preparation and Itemization of the Invoice/Financing Request: The Contractor shall furnish the information set forth in the instructions below. The instructions are keyed to the entries on the Sample Invoice/Financing Request.

- (a) **Designated Billing Office Name and Address:** Enter the designated billing office name and address, as identified in the Invoice Submission Instructions in Section B and F of the Contract Schedule.
- (b) **Contractor's Name, Address, Point of Contact, VIN, and DUNS or DUNS+4 Number:** Show the Contractor's name and address exactly as they appear in the contract, along with the name, title, phone number, and e-mail address of the

person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent. Provide the Contractor's Vendor Identification Number (VIN), and Data Universal Numbering System (DUNS) number or DUNS+4. The DUNS number must identify the Contractor's name and address exactly as stated on the face page of the contract. When an approved assignment has been made by the Contractor, or a different payee has been designated, provide the same information for the payee as is required for the Contractor (i.e., name, address, point of contact, VIN, and DUNS).

- (c) **Invoice/Financing Request Number:** Insert the appropriate serial number of the payment request.
- (d) **Date Invoice/Financing Request Prepared:** Insert the date the payment request is prepared.
- (e) **Contract Number and Order Number (if applicable):** Insert the contract number and order number (if applicable).
- (f) **Effective Date:** Insert the effective date of the contract or if billing under an order, the effective date of the order.
- (g) **Total Estimated Cost of Contract/Order:** Insert the total estimated cost of the contract, exclusive of fixed-fee. If billing under an order, insert the total estimated cost of the order, exclusive of fixed-fee.
- (h) **Total Fixed-Fee:** Insert the total fixed-fee (where applicable).
- (i) **Two-Way/Three-Way Match:** Identify payment to be made using a three-way match.
- (j) **Office of Acquisitions:** Insert the name of the Office of Acquisitions, as identified in Section G of the Contract Schedule.
- (k) **Central Point of Distribution:** Insert the Central Point of Distribution, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.
- (l) **Billing Period:** Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.
- (m) **Amount Billed - Current Period:** Insert the amount claimed for the current billing period by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.
- (n) **Amount Billed - Cumulative:** Insert the cumulative amounts claimed by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.
- (o) **Direct Costs:** Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.
 - (1)
 - (2) **Direct Labor:** Include salaries and wages paid (or accrued) for direct performance of the contract.

For Level of Effort contracts only, the Contractor shall provide the following information on a separate sheet of paper attached to the payment request:

- hours or percentage of effort and cost by labor category (as specified in the Level of Effort Article in Section F of the contract) for the current billing period, and

- hours or percentage of effort and cost by labor category from contract inception through the current billing period. (NOTE: The Contracting Officer may require the Contractor to provide additional breakdown for direct labor, such as position title, employee name, and salary or hourly rate.)

- (3) **Fringe Benefits:** List any fringe benefits applicable to direct labor and billed as a direct cost. Do not include in this category fringe benefits that are included in indirect costs.
- (4) **Accountable Personal Property:** Include permanent research equipment and general purpose equipment having a unit acquisition cost of \$1,000 or more, with a life expectancy of more than two years, and sensitive property regardless of cost (see the HHS *Contractor's Guide for Control of Government Property*). Show permanent research equipment separate from general purpose equipment.

On a separate sheet of paper attached to the payment request, list each item for which reimbursement is requested. An asterisk (*) shall precede the item if the equipment is below the \$1,000 approval level. Include reference to the following (as applicable):

- item number for the specific piece of equipment listed in the Property Schedule, and
- COA number, if the equipment is not covered by the Property Schedule.

The Contracting Officer may require the Contractor to provide further itemization of property having specific limitations set forth in the contract.

- (5) **Materials and Supplies:** Include equipment with unit costs of less than \$1,000 or an expected service life of two years or less, and consumable material and supplies regardless of amount.
 - (6) **Premium Pay:** List remuneration in excess of the basic hourly rate.
 - (7) **Consultant Fee:** List fees paid to consultants. Identify consultant by name or category as set forth in the contract or COA, as well as the effort (i.e., number of hours, days, etc.) and rate billed.
 - (8) **Travel:** Include domestic and foreign travel. Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside Canada, the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel.
 - (9) **Subcontract Costs:** List subcontractor(s) by name and amount billed. Cite applicable COA or notification.
 - (10) **Other:** List all other direct costs in total unless exceeding \$1,000 in amount. If over \$1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.
- (p) **Cost of Money (COM):** Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed.
 - (q) **Indirect Costs:** Identify the indirect cost base (IDC), indirect cost rate, and amount billed for each indirect cost category.
 - (r) **Fixed-Fee:** Cite the formula or method of computation for fixed-fee, if applicable. The fixed-fee must be claimed as provided for by the contract.
 - (s) **Total Amounts Claimed:** Insert the total amounts claimed for the current and cumulative periods.
 - (t) **Adjustments:** Include amounts conceded by the Contractor, outstanding suspensions, and/or disapprovals subject to appeal.
 - (u) **Grand Totals**
 - (v) **Certification of Salary Rate Limitation:** If required by the contract (see Invoice Submission Instructions in Section G of the Contract Schedule), the Contractor shall include the following certification at the bottom of the payment request:

"I hereby certify that the salaries billed in this payment request are in compliance with the Salary Rate Limitation Provisions in Section H of the contract."
 - (w) **Signature**

The Contracting Officer may require the Contractor to submit detailed support for costs claimed on one or more interim payment requests.

FINANCIAL REPORTING INSTRUCTIONS:

These instructions are keyed to the Columns on the sample invoice/financing request.

Column A - Expenditure Category: Enter the expenditure categories required by the contract.

Column B - Cumulative Percentage of Effort/Hrs. - Negotiated: Enter the percentage of effort or number of hours agreed to for each employee or labor category listed in Column A.

Column C - Cumulative Percentage of Effort/Hrs. - Actual: Enter the percentage of effort or number of hours worked by each employee or labor category listed in Column A.

Column D - Amount Billed - Current: Enter amounts billed during the current period.

Column E - Amount Billed - Cumulative: Enter the cumulative amounts to date.

Column F - Cost at Completion: Enter data only when the Contractor estimates that a particular expenditure category will vary from the amount negotiated. Realistic estimates are essential.

Column G - Contract Amount: Enter the costs agreed to for all expenditure categories listed in Column A.

Column H - Variance (Over or Under): Show the difference between the estimated costs at completion (Column F) and negotiated costs (Column G) when entries have been made in Column F. This column need not be filled in when Column F is blank. When a line item varies by plus or minus 10 percent, i.e., the percentage arrived at by dividing Column F by Column G, an explanation of the variance should be submitted. In the case of an overrun (net negative variance), this submission shall not be deemed as notice under the Limitation of Cost (Funds) Clause of the contract.

Modifications: Any modification in the amount negotiated for an item since the preceding report should be listed in the appropriate cost category.

Expenditures Not Negotiated: An expenditure for an item for which no amount was negotiated (e.g., at the discretion of the Contractor in performance of its contract) should be listed in the appropriate cost category and all columns filled in, except for G. Column H will of course show a 100 percent variance and will be explained along with those identified under H above.

SAMPLE INVOICE/FINANCING REQUEST AND CONTRACT FINANCIAL REPORT

<p>(a) Designated Billing Office Name and Address:</p> <p style="margin-left: 20px;">DHHS/OS/ASPR/BARDA Attn: Contracting Officer 330 Independence Ave., S.W. Room G644 Washington, D.C. 20201</p> <p>(b) Contractor's Name, Address, Point of Contact, VIN <input type="checkbox"/> and DUNS or DUNS+4 Number: <input checked="" type="checkbox"/></p> <p style="margin-left: 20px;">ABC CORPORATION 100 Main Street Anywhere, USA Zip Code</p> <p style="margin-left: 20px;">Name, Title, Phone Number, and E-mail Address of person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent.</p> <p style="margin-left: 20px;">VIN: DUNS or DUNS+4:</p>	<p>(c) Invoice/Financing Request No.:</p> <p>(d) Date Invoice Prepared:</p> <p>(e) Contract No. and Order No. (if applicable): _____</p> <p>(f) Effective Date:</p> <p>(g) Total Estimated Cost of Contract/Order:</p> <p>(h) Total Fixed-Fee (if applicable):</p> <p style="margin-left: 20px;">(i) Two-Way Match: Three-Way Match:</p> <p>(j) Office of Acquisitions:</p> <p>(k) Central Point of Distribution:</p>
---	---

(l) This invoice/financing request represents reimbursable costs for the period from _____ to _____

Expenditure Category* A	Cumulative Percentage of Effort/Hrs.		Amount Billed		Cost at Completion F	Contract Amount G	Variance H
	Negotiated B	Actual C	(m) Current D	(n) Cumulative E			
(o) Direct Costs:							
(1) Direct Labor							
(2) Fringe Benefits							
(3) Accountable Property							
(4) Materials & Supplies							
(5) Premium Pay							
(6) Consultant Fees							
(7) Travel							
(8) Subcontracts							
(9) Other							
Total Direct Costs							
(p) Cost of Money							
(q) Indirect Costs							
(r) Fixed Fee							
(s) Total Amount Claimed							
(t) Adjustments							
(u) Grand Totals							

I certify that all payments are for appropriate purposes and in accordance with the contract.

(Name of Official)

(Title)

* Attach details as specified in the contract

Attachment 3

FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT Note: Complete this Form in Accordance with Accompanying Instructions.	Project Task:	Contract No.:	Date of Report:	0990-0134 0990-0131
Reporting Period:		Contractor Name and Address:		

Expenditure Category	Percentage of Effort/Hours		Cumulative Incurred Cost at End of Prior Period	Incurred Cost-Current Period	Cumulative Cost to Date (D + E)	Estimated Cost to Complete	Estimated Cost at Completion (F + G)	Negotiated Contract Amount	Variance (Over or Under) (I - H)
	Negotiated	Actual							
A	B	C	D	E	F	G	H	I	J

Attachment 4
INSTRUCTIONS FOR COMPLETING
"FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT"

GENERAL INFORMATION

Purpose. This Quarterly Financial Report is designed to: (1) provide a management tool for use by BARDA in monitoring the application of financial and personnel resources to the BARDA contracts; (2) provide contractors with financial and personnel management data which is usable in their management processes; (3) promptly indicate potential areas of contract underruns or overruns by making possible comparisons of actual performance and projections with prior estimates on individual elements of cost and personnel; and (4) obtain contractor's analyses of cause and effect of significant variations between actual and prior estimates of financial and personnel performance.

REPORTING REQUIREMENTS

Scope. The specific cost and personnel elements to be reported shall be established by mutual agreement prior to award. The Government may require the contractor to provide detailed documentation to support any element(s) on one or more financial reports.

Number of Copies and Mailing Address. An original and two (2) copies of the report(s) shall be sent to the contracting officer at the address shown on the face page of the contract, no later than 30 working days after the end of the period reported. However, the contract may provide for one of the copies to be sent directly to the Contracting Officer's Technical Representative.

REPORTING STATISTICS

A modification which extends the period of performance of an existing contract will not require reporting on a separate quarterly report, except where it is determined by the contracting officer that separate reporting is necessary. Furthermore, when incrementally funded contracts are involved, each separate allotment is not considered a separate contract entity (only a funding action). Therefore, the statistics under incrementally funded contracts should be reported cumulatively from the inception of the contract through completion.

Definitions and Instructions for Completing the Quarterly Report. For the purpose of establishing expenditure categories in Column A, the following definitions and instructions will be utilized. Each contract will specify the categories to be reported.

- (1) **Key Personnel.** Include key personnel regardless of annual salary rates. All such individuals should be listed by names and job titles on a separate line including those whose salary is not directly charged to the contract but whose effort is directly associated with the contract. The listing must be kept up to date.
- (2) **Personnel--Other.** List as one amount unless otherwise required by the contract.

- (3) **Fringe Benefits.** Include allowances and services provided by the contractor to employees as compensation in addition to regular salaries and wages. If a fringe benefit rate(s) has been established, identify the base, rate, and amount billed for each category. If a rate has not been established, the various fringe benefit costs may be required to be shown separately. Fringe benefits which are included in the indirect cost rate should not be shown here.
- (4) **Accountable Personal Property.** Include nonexpendable personal property with an acquisition cost of \$1,000 or more and with an expected useful life of two or more years, and sensitive items regardless of cost. Form HHS 565, "Report of Accountable Property," must accompany the contractor's public voucher (SF 1034/SF 1035) or this report if not previously submitted. See "Contractor's Guide for Control of Government Property."
- (5) **Supplies.** Include the cost of supplies and material and equipment charged directly to the contract, but excludes the cost of nonexpendable equipment as defined in (4) above.
- (6) **Inpatient Care.** Include costs associated with a subject while occupying a bed in a patient care setting. It normally includes both routine and ancillary costs.
- (7) **Outpatient Care.** Include costs associated with a subject while not occupying a bed. It normally includes ancillary costs only.
- (8) **Travel.** Include all direct costs of travel, including transportation, subsistence and miscellaneous expenses. Travel for staff and consultants shall be shown separately. Identify foreign and domestic travel separately. If required by the contract, the following information shall be submitted: (i) Name of traveler and purpose of trip; (ii) Place of departure, destination and return, including time and dates; and (iii) Total cost of trip.
- (9) **Consultant Fee.** Include fees paid to consultant(s). Identify each consultant with effort expended, billing rate, and amount billed.
- (10) **Premium Pay.** Include the amount of salaries and wages over and above the basic rate of pay.
- (11) **Subcontracts.** List each subcontract by name and amount billed.
- (12) **Other Costs.** Include any expenditure categories for which the Government does not require individual line item reporting. It may include some of the above categories.
- (13) **Overhead/Indirect Costs.** Identify the cost base, indirect cost rate, and amount billed for each indirect cost category.
- (14) **General and Administrative Expense.** Cite the rate and the base. In the case of nonprofit organizations, this item will usually be included in the indirect cost.
- (15) **Fee.** Cite the fee earned, if any.
- (16) **Total Costs to the Government.**

PREPARATION INSTRUCTIONS

These instructions are keyed to the Columns on the Quarterly Report.

Column A--Expenditure Category. Enter the expenditure categories required by the contract.

Column B--Percentage of Effort/Hours Negotiated. Enter the percentage of effort or number of hours agreed to during contract negotiations for each labor category listed in Column A.

Column C--Percentage of Effort/Hours-Actual. Enter the cumulative percentage of effort or number of hours worked by each employee or group of employees listed in Column A.

Column D--Cumulative Incurred Cost at End of Prior Period. Enter the cumulative incurred costs up to the end of the prior reporting period. This column will be blank at the time of the submission of the initial report.

Column E--Incurred Cost-Current Period. Enter the costs which were incurred during the current period.

Column F--Cumulative Incurred Cost to Date. Enter the combined total of Columns D and E.

Column G--Estimated Cost to Complete. Make entries only when the contractor estimates that a particular expenditure category will vary from the amount negotiated. Realistic estimates are essential.

Column H--Estimated Costs at Completion. Complete only if an entry is made in Column G.

Column I--Negotiated Contract Amount. Enter in this column the costs agreed to during contract negotiations for all expenditure categories listed in Column A.

Column J--Variance (Over or Under). Complete only if an entry is made in Column H. When entries have been made in Column H, this column should show the difference between the estimated costs at completion (Column H) and negotiated costs (Column I). When a line item varies by plus or minus 10 percent, i.e., the percentage arrived at by dividing Column J by Column I, an explanation of the variance should be submitted. In the case of an overrun (net negative variance), this submission shall not be deemed as notice under the Limitation of Cost (Funds) Clause of the contract.

Modifications. List any modification in the amount negotiated for an item since the preceding report in the appropriate cost category.

Expenditures Not Negotiated. List any expenditure for an item for which no amount was negotiated (e.g., at the discretion of the contractor in performance of its contract) in the appropriate cost category and complete all columns except for I. Column J will of course show a 100 percent variance and will be explained along with those identified under J above.

Program Director/Principal Investigator (Last, First, Middle):

Inclusion Enrollment Report

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

Study Title: _____
Total Enrollment: _____ Protocol Number: _____
Grant Number: _____

PART A. TOTAL ENROLLMENT REPORT: Number of Subjects Enrolled to Date (Cumulative) by Ethnicity and Race				
Ethnic Category	Females	Males	Sex/Gender Unknown or Not Reported	Total
Hispanic or Latino				**
Not Hispanic or Latino				
Unknown (individuals not reporting ethnicity)				
Ethnic Category: Total of All Subjects*				*
Racial Categories				
American Indian/Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of All Subjects*				*
PART B. HISPANIC ENROLLMENT REPORT: Number of Hispanics or Latinos Enrolled to Date (Cumulative)				
Racial Categories	Females	Males	Sex/Gender Unknown or Not Reported	Total
American Indian or Alaska Native				
Asian				
Native Hawaiian or Other Pacific Islander				
Black or African American				
White				
More Than One Race				
Unknown or Not Reported				
Racial Categories: Total of Hispanics or Latinos**				**

* These totals must agree.

** These totals must agree.

Attachment 7

Research Patient Care Costs

- (a) Research patient care costs are the costs of routine and ancillary services provided to patients participating in research programs described in this contract.
- (b) Research patient care costs shall be computed in a manner consistent with the principles and procedures used by the Medicare Program for determining the part of Medicare reimbursement based on reasonable costs. The Diagnostic Related Group (DRG) prospective reimbursement method used to determine the remaining portion of Medicare reimbursement shall not be used to determine research patient care costs. Research patient care rates or amounts shall be established by the Secretary of HHS or his/her duly authorized representative.
- (c) Prior to submitting an invoice for research patient care costs under this contract, the contractor must make every reasonable effort to obtain third party payment, where third party payors (including Government agencies) are authorized or are under a legal obligation to pay all or a portion of the charges incurred under this contract for research patient care.
- (d) The contractor must maintain adequate procedures to identify those research patients participating in this contract who are eligible for third party reimbursement.
- (e) Only those charges not recoverable from third party payors or patients and which are consistent with the terms and conditions of the contract are chargeable to this contract.

DISCLOSURE OF LOBBYING ACTIVITIES

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

(See reverse for public burden disclosure.)

1. Type of Federal Action: <input type="checkbox"/> a. contract <input type="checkbox"/> b. grant <input type="checkbox"/> c. cooperative agreement <input type="checkbox"/> d. loan <input type="checkbox"/> e. loan guarantee <input type="checkbox"/> f. loan insurance	2. Status of Federal Action: <input type="checkbox"/> a. bid/offer/application <input type="checkbox"/> b. initial award <input type="checkbox"/> c. post-award	3. Report Type: <input type="checkbox"/> a. initial filing <input type="checkbox"/> b. material change For Material Change Only: year _____ quarter _____ date of last report _ _
4. Name and Address of Reporting Entity: <input type="checkbox"/> Prime <input type="checkbox"/> Subawardee Tier _____, <i>if known:</i> Congressional District, <i>if known:</i> 4c	5. If Reporting Entity in No. 4 is a Subawardee, Enter Name and Address of Prime: Congressional District, <i>if known:</i>	
6. Federal Department/Agency:	7. Federal Program Name/Description: CFDA Number, <i>if applicable:</i> _____	
8. Federal Action Number, if known:	9. Award Amount, if known: \$	
10. a. Name and Address of Lobbying Registrant <i>(if individual, last name, first name, MI):</i>	b. Individuals Performing Services <i>(including address if different from No. 10a)</i> <i>(last name, first name, MI):</i>	
11. Information requested through this form is authorized by title 31 U.S.C. section 1352. This disclosure of lobbying activities is a material representation of fact upon which reliance was placed by the tier above when this transaction was made or entered into. This disclosure is required pursuant to 31 U.S.C. 1352. This information will be available for public inspection. Any person who fails to file the required disclosure shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.	Signature: _____ Print Name: _____ Title: _____ Telephone No.: _____ Date: _____	
Federal Use Only:		Authorized for Local Reproduction Standard Form LLL (Rev. 7-97)



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. 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 followup 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 registrant under the Lobbying Disclosure Act of 1995 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. 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 10 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.

DATA ITEM DESCRIPTION

TITLE: CONTRACT PERFORMANCE REPORT (CPR)
NUMBER: DI-MGMT-81466A **APPROVAL DATE:** 20050330
AMSC NUMBER: D7549 **LIMITATION:**
DTIC APPLICABLE: **GIDEP APPLICABLE:**
PREPARING ACTIVITY: OUSD(AT&L)ARA/AM(SO)

APPLICABLE FORMS: DD Forms are available and shall be used to submit required formats as follows:

<u>CPR Format</u>	<u>DD Form Number</u>	<u>Sample Format No.</u>
Work Breakdown Structure	2734/1	1
Organizational Categories	2734/2	2
Baseline	2734/3	3
Staffing	2734/4	4
Explanations and Problem Analyses	2734/5	5

USE/RELATIONSHIP: This report consists of five formats containing data for measuring contractors' cost and schedule performance on Department of Defense (DoD) acquisition contracts. Format 1 (Sample Format 1) provides data to measure cost and schedule performance by product-oriented Work Breakdown Structure (WBS) elements, the hardware, software, and services the Government is buying. Format 2 (Sample Format 2) provides the same data by the contractor's organization (functional or Integrated Product Team (IPT) structure). Format 3 (Sample Format 3) provides the budget baseline plan against which performance is measured. Format 4 (Sample Format 4) provides staffing forecasts for correlation with the budget plan and cost estimates. Format 5 (Sample Format 5) is a narrative report used to explain significant cost and schedule variances and other identified contract problems and topics.

CPR data shall be used by DoD system managers to: (1) integrate cost and schedule performance data with technical performance measures, (2) identify the magnitude and impact of actual and potential problem areas causing significant cost and schedule variances, and (3) provide valid, timely program status information to higher management.

The CPR is a management report. It provides timely, reliable summary-level data with which to assess current and projected contract performance. The CPR's primary value to the Government is its ability to reflect current contract status and reasonably project future program performance. It is important that the CPR be as accurate as possible so it may be used for its intended purpose, which is to facilitate informed, timely decisions. It will be used by the DoD component staff, including program managers, engineers, cost estimators, and financial management personnel, to confirm, quantify, and track known or emerging contract problems and serve as a basis for communicating with the contractor. The CPR data shall accurately reflect how work is being planned, performed, and measured and shall be consistent with the actual contract status.

a. This Data Item Description (DID) contains the format and content preparation instructions for the data product generated by the specific and discrete task requirements as delineated in the contract.

b. This DID shall be used in conjunction with the Integrated Master Schedule (IMS) DID, DI-MGMT-81650. This DID may be used in conjunction with the Contract Funds Status Report (CFSR) DID, DI-MGMT-81468, the Contract Work Breakdown Structure (CWBS) DID, DI-MGMT-81334A, the Cost Data Summary Report DID, DI-FNCL-81565A, and the Functional Cost-Hour and Progress Curve Report

DI-MGMT-81466A

DID, DI-FNCL-81566A. The same WBS shall be utilized for the Integrated Master Plan (IMP), IMS, CPR, and Contractor Cost Data Report (CCDR) as applicable.

c. The CPR shall be used to obtain cost and schedule performance information on contracts requiring compliance with the American National Standards Institute/Electronic Industries Alliance Standard 748 (ANSI/EIA-748), Earned Value Management Systems (EVMS) (current version in effect at time of contract award). Refer to the Federal Acquisition Regulation (FAR) or Defense Federal Acquisition Regulation Supplement (DFARS) clause on contract. The CPR data elements shall reflect the output of the contractor's ANSI/EIA-748 compliant integrated management system.

d. The CPR shall be required no less frequently than monthly. All formats shall be submitted to the procuring activity no later than 12 working days following the contractor's accounting period cutoff date. This requirement may be tailored through contract negotiations to allow submission as late as 17 working days, provided that the contractor and Government agree that program complexity and integration of subcontractor and vendor performance data warrant additional time and will yield more accurate performance. Reports may reflect data either as of the end of the calendar month or as of the contractor's accounting period cutoff date, provided it is consistent with the IMS. Formats 2, 3, and 4 may be submitted on a less frequent basis in some cases. Refer to the Earned Value Management Implementation Guide (EVMIG) for guidance on tailoring reporting. (Note: Contractors may elect to attach subcontractor Format 5 reporting and cross reference this analysis in the Format 5 reporting submitted to the Government to gain time efficiencies and meet submission dates.)

e. Unless otherwise provided in the contract, data reported in the CPR shall pertain to all authorized contract work, including both priced and unpriced effort. Refer to the EVMIG for guidance on tailoring reporting.

f. Submission of Format 1 using a product-oriented WBS in accordance with the WBS Handbook, MIL-HDBK-881, and the CWBS DID, DI-MGMT-81334A, is mandatory. (Note: For contracts that require CCDRs, the CWBS shall be developed, approved, and maintained in accordance with DoD 5000.4-M-1, Cost and Software Data Reporting Manual, and the CWBS DID.) Certain aspects of the report are subject to negotiation between the Government and the contractor, such as:

f.1 The level of detail to be reported in Format 1 normally will be at level three of the CWBS, but lower levels may be specified for high-cost or high-risk items. The Government and the contractor shall periodically review and adjust as necessary CWBS reporting levels on Format 1 to ensure they continue to provide appropriate visibility without requiring excessive information. If there is a significant problem at a lower level, detailed reporting for that CWBS element may be required until the problem is resolved.

f.2 Formats 1 and 5 are mandatory in all cases. Formats 2, 3, and 4 are optional in some cases. Refer to the EVMIG for guidance on tailoring reporting.

f.3 Variance analysis thresholds which, if exceeded, require problem analysis and narrative explanations in Format 5. If the contract does not specify variance analysis thresholds, the contractor shall provide appropriate variance analyses. (See 2.6.3 below.) Variance analysis thresholds shall be reviewed periodically and adjusted as necessary to ensure they continue to provide appropriate visibility.

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f.4 If the organizational categories for Format 4 are different from Format 2, the Government may request that different organizational categories be used for reporting staffing in Format 4 instead of those used in Format 2. If so, the Government and the contractor shall negotiate the Format 4 categories. If required, the Format 2 categories shall reflect the contractor's internal organization being used to execute the contract.

g. Subject to f., the CPR Contract Data Requirements List (CDRL) is subject to tailoring. Requiring more information in the CPR CDRL than specified in this DID is contrary to DoD policy. All negotiated reporting provisions shall be specified in the contract. Refer to the EVMIG for guidance on tailoring reporting.

REQUIREMENTS:

1. Format. Use the relevant DD Forms as listed above. All formats shall be submitted electronically in accordance with the following requirements. All formats shall be in a readable digital format (e.g., pdf files are not acceptable). The American National Standards Institute (ANSI) X12 standard (839 transaction set), the United Nations Electronic Data Interchange for Administration, Commerce and Transport (UN/EDIFACT) standard (PROCST message), or the XML equivalent shall be used to submit data electronically to the procuring activity. Contractor formats may be substituted whenever they contain all of the required data elements at the specified reporting levels and are compliant with the X12 standard, XML schema, or equivalent. On-line access to the data may be provided to augment formal CPR submission. (Note: Until the ANSI X12/XML standards are redefined to incorporate the changes to the forms, the new data elements shall be reported in Format 5.)

2. Content. The CPR shall contain the following:

2.1 Heading Information - Formats 1 - 5. Preparation instructions for Heading Information (Blocks 1 through 4) apply to Formats 1 through 5.

2.1.1 Contractor. Enter in Block 1.a the contractor's name and division (if applicable). Enter in Block 1.b the facility location and mailing address of the reporting contractor.

2.1.2 Contract. Enter the contract name in Block 2.a, the contract number (and the applicable Contract Line Item Number(s) (CLIN(s)) in Block 2.b, the contract type in Block 2.c, and the contract share ratio (if applicable) in Block 2.d.

2.1.3 Program. Enter in Block 3.a the program name, number, acronym, type, model, and series, or other designation of the prime item(s) purchased under the contract. Indicate the program phase (development, production, etc.) in Block 3.b. Indicate whether the contractor's EVMS has been accepted by the Government and the date of the acceptance.

2.1.4 Report Period. Enter the beginning date in Block 4.a and the ending date in Block 4.b of the period covered by the report.

2.1.5 Security Classification. Enter the appropriate security classification at the top and bottom of each page.

2.1.6 Dollars in _____. If reported dollar amounts are in thousands, millions, or billions, enter the factor at the top of each page.

2.2 Format 1 - Work Breakdown Structure.

2.2.1 Contract Data.

2.2.1.1 Quantity. Enter in Block 5.a the number of principal items to be procured on this contract.

2.2.1.2 Negotiated Cost. Enter in Block 5.b the dollar value (excluding fee or profit) on which contractual agreement has been reached as of the cutoff date of the report. For an incentive contract, enter the definitized contract target cost. Amounts for changes shall not be included in this item until they have been priced and incorporated in the contract through contract change order or supplemental agreement. For a cost plus fixed fee, award fee, or incentive fee contract, enter the estimated cost negotiated. Changes to the estimated cost shall consist only of estimated amounts for changes in the contract scope of work, not for cost growth ("overrun") above the original estimated cost.

2.2.1.3 Estimated Cost of Authorized, Unpriced Work. Enter in Block 5.c the amount (excluding fee or profit) estimated for that work for which written authorization has been received, but for which definitized contract prices have not been incorporated in the contract through contract change order or supplemental agreement.

2.2.1.4 Target Profit/Fee. Enter in Block 5.d the fee or percentage of profit that shall apply if the negotiated cost of the contract is met. (See 2.2.1.2 above.)

2.2.1.5 Target Price. Enter in Block 5.e the target price (negotiated contract cost plus profit/fee) applicable to the definitized contract effort.

2.2.1.6 Estimated Price. Based on the most likely estimate of cost at completion for all authorized contract work and the appropriate profit/fee, incentive, and cost sharing provisions, enter in Block 5.f the estimated final contract price (total estimated cost to the Government). This number shall be based on the most likely management EAC in Block 6.c.1 and normally will change whenever the management estimate or the contract is revised.

2.2.1.7 Contract Ceiling. Enter in Block 5.g the contract ceiling price applicable to the definitized effort.

2.2.1.8 Estimated Contract Ceiling. Enter in Block 5.h the estimated ceiling price applicable to all authorized contract effort including both definitized and undefinitized effort.

2.2.1.9 Over Target Baseline/Over Target Schedule. Enter in Block 5.i the date the last over target baseline or over target schedule was implemented (if applicable).

2.2.2 Estimated Cost at Completion. These blocks shall present the contractor's range of estimated costs at completion. The range of estimates is intended to allow contractor management flexibility to express possible cost outcomes. Contractors shall provide the most accurate Estimates at Completion (EACs) possible through program-level assessments of factors that may affect the cost, schedule, or technical outcome of the contract. Such program-level assessments shall include consideration of known or anticipated risk areas, and planned risk reductions or cost containment measures. EACs shall be reported without regard to contract ceiling.

2.2.2.1 Management Estimate at Completion - Best Case. Enter in Block 6.a.1 the contractor's best case EAC. The best case estimate is the one that results in the lowest cost to the Government. This estimate shall be based on the outcome of the most favorable set of circumstances. If this estimate is different from the most likely EAC (Block 6.c.1), the assumptions, conditions, and methodology underlying this estimate shall be explained briefly in Format 5. This estimate is for informational purposes only; it is not an official company estimate. There is no requirement for the contractor to prepare and maintain backup data beyond the explanation provided in Format 5.

2.2.2.2 Management Estimate at Completion - Worst Case. Enter in Block 6.b.1 the contractor's worst case EAC. The worst case estimate is the one that results in the highest cost to the Government. This estimate shall be based on the outcome of the least favorable set of circumstances. If this estimate is different from the most likely EAC (Block 6.c.1), the assumptions, conditions, and methodology underlying this estimate shall be explained briefly in Format 5. This estimate is for informational purposes only; it is not an official company estimate. There is no requirement for the contractor to prepare and maintain backup data beyond the explanation provided in Format 5.

2.2.2.3 Management Estimate at Completion - Most Likely. Enter in Block 6.c.1 the contractor's most likely EAC. This estimate is the contractor's official contract EAC and, as such, takes precedence over the estimates presented in Column (15) of Formats 1 and 2 and Blocks 6.a.1 and 6.b.1. This EAC is the value that the contractor's management believes is the most likely outcome based on a knowledgeable estimate of all authorized work, known risks, and probable future conditions. This value need not agree with the total of Column (15) (Block 8.e). However, any difference shall be explained in Format 5 in such terms as risk, use of Management Reserve (MR), or higher management knowledge of current or future contract conditions. The assumptions, conditions, and methodology underlying this estimate shall be explained briefly in Format 5. This EAC need not agree with EACs contained in the contractor's internal data, but must be reconcilable to them. The most likely EAC shall also be reconcilable to the contractor's latest statement of funds required as reported in the CFSR, or its equivalent, if this report is a contractual requirement.

2.2.2.4 Contract Budget Base. Enter in Block 6.c.2 the total of negotiated cost (Block 5.b) and estimated cost of authorized, unpriced work (Block 5.c).

2.2.2.5 Variance. Enter in Block 6.c.3 the Contract Budget Base (Block 6.c.2) minus the most likely estimate at complete (Block 6.c.1). This value shall be explained in Format 5 according to applicable contractual requirements.

2.2.3 Authorized Contractor Representative. Enter in Block 7.a the name of the authorized person (program manager or designee) signing the report. Enter that person's title in Block 7.b. The authorized person shall sign in Block 7.c. Enter the date signed in Block 7.d. Electronic signatures are encouraged.

2.2.4 Performance Data.

2.2.4.1 Column (1) - Work Breakdown Structure Element. Enter in Column (1) of Block 8.a the noun description of the CWBS items for which cost information is being reported. CWBS elements and levels reported shall be those specified in the contract. (See f.1 above.)

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2.2.4.2 Cost of Money. Enter in Columns (2) through (16) of Block 8.b the Facilities Capital Cost of Money applicable to the contract.

2.2.4.3 General and Administrative. Enter in Columns (2) through (16) of Block 8.c the appropriate General and Administrative (G&A) costs. If G&A costs have not been included in the CWBS costs reported in Block 8.a above, G&A shall be shown as an add entry in Block 8.a. If G&A costs have been included in the CWBS costs reported in Block 8.a above, G&A shall be shown as a non-add entry in Block 8.c with an appropriate notation to that effect. For contracts that require CCDRs, contractors may also have to submit separate costs without G&A for the CWBS elements reported in Block 8.a on an exception basis if the Government specifies such a requirement in the CDRL. If a G&A classification is not used, no entry shall be made other than an appropriate notation to that effect.

2.2.4.4 Undistributed Budget. Enter the amount of budget applicable to contract effort that has not yet been identified to CWBS elements at or below the reporting level. For example, if contract changes were authorized late in the reporting period, they should have received a total budget; however, assignment of work and allocation of budgets to individual CWBS elements may not have been accomplished as of the contractor's accounting period cutoff date. Budgets that can be identified to CWBS elements at or below the specified reporting level shall be included in the total budgets shown for the CWBS elements in Block 8.a and shall not be shown as Undistributed Budget (UB). Enter in Column (15) of Block 8.d the EAC for the scope of work represented by the UB in Column (14) of Block 8.d. Enter in Column (16) of Block 8.d the variance, if any, and fully explain it in Format 5. The reason(s) for UB shall be fully explained in Format 5.

2.2.4.4.1 Use of Undistributed Budget. UB is used to accommodate temporary situations where time constraints prevent adequate budget planning or where contract effort can only be defined in very general terms. UB shall not be used as a substitute for adequate contract planning. Formal budgets shall be allocated to contract effort and responsible organizations at the earliest possible time, preferably within the next reporting period.

2.2.4.5 Subtotal (Performance Measurement Baseline). In Columns (2) through (16) of Blocks 8.a through 8.e, enter the sum of the costs and budgets for direct, indirect, cost of money, and G&A. This subtotal represents the dollars in the allocated budget (less MR), which is the Performance Measurement Baseline (PMB) against which performance is measured.

2.2.4.6 Management Reserve. MR is an amount of the overall contract budget withheld for management control purposes and is held for program unknowns (realized risks on authorized work scope). Reserve is held for future needs and shall not be used to offset cumulative cost variances. It shall not be eliminated from contract prices by the Government during subsequent negotiations nor used to absorb the cost of contract changes. In Column (14) of Block 8.f enter the total amount of budget identified as MR as of the end of the current reporting period. The amounts shown as MR in Formats 1, 2, and 3 should agree. Amounts of MR applied to CWBS elements during the reporting period shall be listed in Block 6.b of Format 3 and explained in Format 5.

2.2.4.6.1 Negative Management Reserve. Negative entries shall not be made in Management Reserve (Column (14) of Block 8.f). There is no such thing as "negative MR." If the contract is budgeted in excess of the Contract Budget Base (the negotiated contract cost plus the estimated cost for authorized, unpriced work), the provisions applicable to formal reprogramming and the instructions in paragraphs 2.2.5.1, 2.2.6.6, 2.2.6.7, and 2.4.1.7 apply.

2.2.4.7 Total. Enter the sum of all direct, indirect, cost of money, and G&A costs, and UB and MR (if applicable) in Columns (2) through (14) of Block 8.g. The Total lines of Format 1 (Block 8.g) and Format 2 (Block 5.g) should agree. The total of Column (14), Block 8.g, should equal the Total Allocated Budget shown in Block 5.f on Format 3.

2.2.5 Reconciliation to Contract Budget Base.

2.2.5.1 Formal Reprogramming. In exceptional cases, the contractor may establish performance measurement budgets that exceed the Contract Budget Base. Acceptance of the new baseline in excess of the Contract Budget Base will be predicated on Government approval. This process is called formal reprogramming. The contractor and the Government shall agree on how the results of a formal reprogramming will be reported in the CPR before the formal reprogramming is initiated. This agreement and any other pertinent details on the reporting of the formal reprogramming shall be included in Format 5. Blocks 9.a and 9.b are used to reconcile the higher performance measurement budgets, also called an "over target baseline," to the Contract Budget Base. (See 2.2.6.6, 2.2.6.7, 2.4.1.7, and 2.6.5 below for more information on reporting over target baselines (Formal Reprogramming).)

2.2.5.2 Variance Adjustment. In a formal reprogramming (over target baseline), the contractor may: (1) apply the additional budget to completed work, thereby eliminating some or all of the existing cost or schedule variances, (2) apply the additional budget to remaining work, (3) apply some of the additional budget to completed work and some to remaining work, and/or (4) apply some of the additional budget to MR. If the contractor uses a portion of the additional budget to eliminate variances applicable to completed work, the total adjustments made to the cost and schedule variances shall be shown in Columns (10) and (11) of Block 9.a. The total cost variance adjustment entered in Column (11) of Block 9.a should be the sum of the individual cost variance adjustments shown in Column (12) of Block 8.g.

2.2.5.3 Total Contract Variance. In Columns (10) and (11) of Block 9.b, enter the sum of the cost and schedule variances shown on the Total line (Block 8.g) and on the Variance Adjustment line (Block 9.a). In Column (14) enter the Contract Budget Base from Block 6.c.2. In Column (15) enter the management EAC from Block 6.c.1. In Column (16) of Block 9.b enter the difference between Columns (14) and (15) of Block 9.b.

2.2.6 Columns (2) Through (16). When compliance with the ANSI/EIA-748 (current version in effect at time of contract award) is contractually required, the data in Columns (2) through (16) shall reflect the output of the contractor's ANSI/EIA-748 compliant integrated management system.

2.2.6.1 Column (2) and Column (7) - Budgeted Cost - Work Scheduled. For the time period indicated, enter the Budgeted Cost for Work Scheduled (BCWS) in these columns.

2.2.6.2 Column (3) and Column (8) - Budgeted Cost - Work Performed. For the time period indicated, enter the Budgeted Cost for Work Performed (BCWP) in these columns.

2.2.6.3 Column (4) and Column (9) - Actual Cost - Work Performed. For the time period indicated, enter the Actual Cost of Work Performed (ACWP) without regard to ceiling. In all cases, costs and budgets shall be reported on a comparable basis.

2.2.6.4 Column (5) and Column (10) - Variance - Schedule (i.e., accomplishment). For the time period indicated, these columns reflect the differences between BCWS and BCWP. For the current period column, Column (5) (schedule variance) is derived by subtracting Column (2) (BCWS) from Column (3) (BCWP). For the cumulative to date column, Column (10) (schedule variance) is derived by subtracting Column (7) (BCWS) from Column (8) (BCWP). A positive number in Column (5) and Column (10) indicates a favorable variance. A negative number (indicated by parentheses) indicates an unfavorable variance. Significant variances as specified in the contract shall be fully explained in Format 5. If the contract does not specify variance analysis thresholds, the contractor shall provide appropriate variance analyses. (See 2.6.3 below.)

2.2.6.5 Column (6) and Column (11) - Variance - Cost. For the time period indicated, these columns reflect the difference between BCWP and ACWP. For the current period column, Column (6) (cost variance) is derived by subtracting Column (4) (ACWP) from Column (3) (BCWP). For the cumulative to date column, Column (11) (cost variance) is derived by subtracting Column (9) (ACWP) from Column (8) (BCWP). A positive value indicates a favorable variance. A negative value (indicated by parentheses) indicates an unfavorable variance. Significant variances as specified in the contract shall be fully explained in Format 5. If the contract does not specify variance analysis thresholds, the contractor shall provide appropriate variance analyses. (See 2.6.3 below.)

2.2.6.6 Column (12a) and Column (12b) Reprogramming Adjustments - Cost Variance and Schedule Variance. Formal reprogramming (over target baseline) results in budget allocations in excess of the Contract Budget Base and, in some instances, adjustments to previously reported variances. If previously reported variances are being adjusted, the adjustment applicable to each reporting line item affected shall be entered in Column (12a) if for a cost variance and Column (12b) if for a schedule variance. The total of Column (12a) and Column (12b) should equal the amount shown on the Variance Adjustment line (Block 9.a) in Column (10) and Column (11).

2.2.6.7 Column (13) Reprogramming Adjustments - Budget. Enter the total amounts added to the budget for each reporting line item as the result of formal reprogramming (over target baseline). The amounts shown shall consist of the sum of the budgets used to adjust cost variances (Column (12)) plus the additional budget added to the CWBS element for remaining work. Enter the amount of budget added to MR in the space provided on the Management Reserve line (Block 8.f of Column (13)). The total of Column (13) should equal the budget amount by which the Total Allocated Budget exceeds the Contract Budget Base as shown in Block 5.g of Format 3. An explanation of the reprogramming shall be provided in Format 5.

2.2.6.7.1 Formal Reprogramming Reporting. Columns (12) and (13) are intended for use only in situations involving formal reprogramming (over target baseline). Internal replanning actions within the Contract Budget Base do not require entries in these columns. Where contractors are submitting CPR data directly from automated systems, the addition of Columns (12) and (13) as shown may not be practical due to computer reprogramming problems or space limitations. In such cases, the information shall be provided in Format 5. Contractors shall not be required to abandon or modify existing automated reporting systems to include Columns (12) and (13) if significant costs will be associated with such change. Nor shall contractors be required to prepare the report manually solely to include this information.

2.2.6.7.2. Formal Reprogramming Timeliness. Formal reprogramming (over target baseline) can be a significant undertaking that may require more than a month to implement. To preclude a disruption of management visibility caused by a reporting hiatus, formal reprogramming shall be implemented expeditiously. If a reporting hiatus is needed, the contractor and the Government shall agree on the date and duration of the hiatus before the formal reprogramming is initiated.

2.2.6.8 Column (14) - At Completion - Budgeted. Enter the budgeted cost at completion for the items listed in Column (1). This entry shall consist of the sum of the original budgets plus or minus budget changes resulting from contract changes, internal replanning, and application of MR. The total (Block 8.g) should equal the Total Allocated Budget shown in Block 5.f on Format 3.

2.2.6.9 Column (15) - At Completion - Estimated. Enter the latest revised estimate of cost at completion including estimated overrun/underrun for all authorized work. If the subtotal (Block 8.e) does not agree with the most likely management EAC (Block 6.c.1), the difference shall be explained in Format 5. (See 2.2.2.3 above.)

2.2.6.10 Column (16) - At Completion - Variance. Enter the difference between the Budgeted - At Completion (Column (14)) and the Estimated - At Completion (Column (15)) by subtracting Column (15) from Column (14). A negative value (indicated by parentheses) reflects an unfavorable variance. Significant variances as specified in the contract shall be fully explained in Format 5. If the contract does not specify variance analysis thresholds, the contractor shall provide appropriate variance analyses. (See 2.6.3 below.)

2.3 Format 2 - Organizational Categories.

2.3.1 Performance Data.

2.3.1.1 Column (1) - Organizational Category. In Block 5.a list the organizational categories that reflect the contractor's internal management structure. This format shall be used to collect organizational cost information at the total contract level for organizational elements rather than for individual CWBS elements. This column shall also identify each major subcontractor as defined in the contract. The individual subcontractor line shall reconcile with the cost to the prime (includes subcontractor fee, MR, UB, G&A, cost of money, etc.) or shall track directly with the subcontractor submittal consistent with the company/program documented process for subcontract integration. The process for subcontract integration shall be explained in Format 5. This column shall also identify each major subcontractor and each major vendor separately as an add item. (Note: The separation of subcontractor efforts is for reporting purposes and not intended to impact how contracts are managed.) Except for material included in the add item for each major subcontractor or major vendor, the column shall also identify material separately as an add item. The level of detail to be reported normally will be limited to the organizational level immediately under the operating head of the facility. The contractor may report this information according to its own internal management structure. If the contractor is organized by product teams, this format may not be needed because it may resemble Format 1.

2.3.1.2 Cost of Money. Enter in Columns (2) through (16) of Block 5.b the Facilities Capital Cost of Money applicable to the contract.

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2.3.1.3 General and Administrative. Enter in Columns (2) through (16) of Block 5.c the appropriate G&A costs. If G&A costs have not been included in the CWBS costs reported in Block 5.a above, G&A shall be shown as an add entry in Block 5.a. If G&A costs have been included in the CWBS costs reported in Block 5.a above, G&A shall be shown as a non-add entry in Block 5.c with an appropriate notation to that effect. If a G&A classification is not used, no entry shall be made other than an appropriate notation to that effect. (See 2.2.4.3 above.)

2.3.1.4 Undistributed Budget. Enter in Column (14) of Block 5.d the budget applicable to contract effort that cannot be planned in sufficient detail to be assigned to a responsible organizational area at the reporting level. The amount shown on this format may exceed the amount shown as UB on Format 1 if budget is identified to a task at or below the CWBS reporting level but organizational identification has not been made; or may be less than the amount on Format 1 where budgets have been assigned to organizations but not to CWBS elements. Enter in Column (15) of Block 5.d the EAC for the scope of work represented by the UB in Column (14) of Block 5.d. Enter in Column (16) of Block 5.d the variance, if any, and fully explain it in Format 5. (See 2.2.4.4 above.)

2.3.1.5 Subtotal (Performance Measurement Baseline). Enter the sum of the direct, indirect, cost of money, and G&A costs and budgets in Columns (2) through (16) of Blocks 5.a through 5.e. (See 2.2.4.5 above.)

2.3.1.6 Management Reserve. In Column (14) of Block 5.f enter the amount of budget identified as MR. The Management Reserve entry should agree with the amounts shown in Formats 1 and 3. (See 2.2.4.6 above.)

2.3.1.7 Total. Enter the sum of all direct, indirect, cost of money, and G&A costs and budgets, UB, and MR (if applicable) in Columns (2) through (14) of Block 5.g. The totals on this page should equal the Total line on Format 1. The total of Column (14) should equal the Total Allocated Budget shown in Block 5.f on Format 3.

2.3.2 Columns (2) Through (16). The instructions applicable to these columns are the same as the instructions for corresponding columns on Format 1. (See 2.2.6 and 2.2.6.1 through 2.2.6.10 above.)

2.4 Format 3 - Baseline.

2.4.1 Contract Data.

2.4.1.1 Original Negotiated Cost. Enter in Block 5.a the dollar value (excluding fee or profit) negotiated in the original contract. For a cost plus fixed fee, incentive, or award fee contract, enter the estimated cost negotiated. For an incentive contract, enter the definitized contract target cost.

2.4.1.2 Negotiated Contract Changes. Enter in Block 5.b the cumulative cost (excluding fee or profit) applicable to definitized contract changes that have occurred since the beginning of the contract.

2.4.1.3 Current Negotiated Cost. Enter in Block 5.c the sum of Blocks 5.a and 5.b. The amount shown should equal the current dollar value (excluding fee or profit) on which contractual agreement has been reached and should be the same as the amount in Negotiated Cost (Block 5.b) on Format 1.

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2.4.1.4 Estimated Cost of Authorized, Unpriced Work. Enter in Block 5.d the estimated cost (excluding fee or profit) for contract changes for which authorization has been received from the contracting officer, but for which contract prices have not been incorporated in the contract, as shown in Block 5.c of Format 1.

2.4.1.5 Contract Budget Base. Enter in Block 5.e the sum of Blocks 5.c and 5.d.

2.4.1.6 Total Allocated Budget. Enter in Block 5.f the sum of all budgets allocated to the performance of the contractual effort. The amount shown shall include all MR and UB. This amount should be the same as that shown on the Total line in Column (14) on Format 1 (Block 8.g) and Format 2 (Block 5.g).

2.4.1.7 Difference. Enter in Block 5.g the difference between Blocks 5.e and 5.f. In most cases, the amounts shown in Blocks 5.e and 5.f will be identical. If the amount shown in Block 5.f exceeds that shown in Block 5.e, it usually is an indication of a formal reprogramming (over target baseline). The difference shall be explained in Format 5 at the time the negative value appears and subsequently for any changes in the difference between Contract Budget Base and the Total Allocated Budget.

2.4.1.8 Contract Start Date. Enter in Block 5.h the date the contractor was authorized to start work on the contract, regardless of the date of contract definitization. (Note: Long-lead procurement efforts authorized under prior contracts are not to be considered.)

2.4.1.9 Contract Definitization Date. Enter in Block 5.i the date the contract was definitized.

2.4.1.10 Planned Completion Date. Enter in Block 5.j the completion date to which the budgets allocated in the PMB have been planned. This date represents the planned completion of all significant effort on the contract. The cost associated with the schedule from which this date is taken is the Total Allocated Budget (Block 5.f of Format 3).

2.4.1.10.1 Performance Measurement Schedule Inconsistent With Contractual Schedule. In exceptional cases, the contractor may determine that the existing contract schedule cannot be achieved and no longer represents a reasonable basis for management control. With Government approval, the contractor may rephrase its performance measurement schedule to new dates that exceed the contractual milestones, a condition known as "over target schedule." These new dates are for performance measurement purposes only and do not represent an agreement to modify the contract terms and conditions.

2.4.1.10.2 Over Target Schedule Agreement. The Government and the contractor shall agree on the new performance measurement schedule prior to reporting it in the CPR. The contractor shall provide pertinent information in Format 5 on any schedule milestones that are inconsistent with contractual milestones, beginning the month the schedule is implemented and each month thereafter.

2.4.1.10.3 Indicators of a Performance Measurement Schedule Inconsistent With the Contractual Schedule. Formal reprogramming or internal replanning may result in performance measurement milestones that are inconsistent with the contractual milestones (Over Target Schedule). A difference between the planned completion date (Block 5.j) and the contract completion date (Block 5.k) usually indicates that some or all of the performance measurement milestones are inconsistent with the contractual milestones.

2.4.1.11 Contract Completion Date. Enter in Block 5.k the contract scheduled completion date in accordance with the latest contract modification. The cost associated with the schedule from which this date is taken is the Contract Budget Base (Block 5.e of Format 3).

2.4.1.12 Estimated Completion Date. Enter in Block 5.l the contractor's latest revised estimated completion date. This date represents the estimated completion of all significant effort on the contract. The cost associated with the schedule from which this date is taken is the "most likely" management EAC (Block 6.c.1 of Format 1).

2.4.2 Performance Data.

2.4.2.1 Column (1) - Performance Measurement Baseline (Beginning of Period). Enter in Block 6.a the time-phased PMB (including G&A) that existed at the beginning of the current reporting period. Most of the entries on this line (e.g., for Columns (4) through (9)) are taken directly from the PMB (End of Period) line on the previous report. For example, the number in Column (4) on the PMB (End of Period) line from the last report becomes the number in Column (3) on the PMB (Beginning of Period) line on this report. The number in Column (5) (End of Period) last report becomes Column (4) (Beginning of Period) on this report, etc. (if each of the two columns covers the same length of time).

2.4.2.2 Baseline Changes. In Block 6.b, list all significant baseline changes that have occurred during the reporting period. This listing shall include the contract changes and supplemental agreements authorized during the reporting period, allocations from MR and UB, and any significant rephasing of budgets. All significant authorized baseline changes shall be listed whether priced or unpriced.

2.4.2.3 Performance Measurement Baseline (End of Period). Enter in Block 6.c the time-phased PMB as it exists at the end of the reporting period. The difference between this line and the PMB (Beginning of Period) represents the effects of all significant changes, including the authorized changes, allocations of MR made during the period, and changes to time phasing due to internal replanning or formal reprogramming. The reasons for these changes shall be explained in Format 5.

2.4.2.4 Management Reserve. Enter in Block 7 the total amount of MR remaining as of the end of the reporting period. This value should agree with the amounts shown as MR in Formats 1 and 2.

2.4.2.5 Total. Enter in Column (16) of Block 8 the sum of Column (16) of Block 6.c (PMB (End of Period)) and Column (16) of Block 7 (Management Reserve). This amount should be the same as that shown on the Total line (Block 8.g) in Column (14) on Format 1.

2.4.3 Column (2) - BCWS - Cumulative To Date. On the PMB (Beginning of Period) line (Block 6.a), enter the cumulative BCWS as of the first day of the reporting period. This should be the same number reported as BCWS - Cumulative To Date on the Total line (Column (7) of Block 8.g) of Format 1 of the previous CPR. On the PMB (End of Period) line (Block 6.c), enter the cumulative BCWS as of the last day of the reporting period. This should be the same number reported as BCWS - Cumulative to Date on the Total line (Column (7) of Block 8.g) of Format 1 for this CPR.

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2.4.4 Column (3) - BCWS For Report Period. On the PMB (Beginning of Period) line (Block 6.a), enter the BCWS planned for the reporting period. This should be the number in Column (4) on the PMB (End of Period) line (Block 6.c) on the previous CPR.

2.4.5 Columns (4) Through (14). Enter the names of each month for the contract period of performance in the headings of each of the Columns (4) through (9), and the names of the appropriate periods in the headings of each of the Columns (10) through (14) of Block 6. Columns beyond (14) may be added when necessary or desirable. In the PMB (Beginning of Period) line (Block 6.a), enter the BCWS projection reported in Format 3 of the previous CPR as PMB (End of Period) (Block 6.c). In the PMB (End of Period) line (Block 6.c) of this report, enter the projected BCWS by month for the next six months and for periodic increments (monthly, quarterly, or annually) thereafter for the remainder of the contract. The time phasing of each item listed in Column (1) of Block 6.b need not be shown in Columns (4) through (14). It is useful to show the time phasing of any baseline changes. (Note: For the purposes of illustration, Sample Format 3 has Columns (4) through (14) for reporting BCWS. The actual number of columns will vary from contract to contract.)

2.4.6 Column (15) - Undistributed Budget. On the PMB (Beginning of Period) line (Block 6.a), enter the number from Column (15) on the PMB (End of Period) line (Block 6.c) from the previous CPR. On the PMB (End of Period) line, enter the UB shown in Column (14) of Block 8.d on Format 1 of this report.

2.4.7 Column (16) - Total Budget. On the PMB (Beginning of Period) line (Block 6.a) enter the number from Column (16) on the PMB (End of Period) line (Block 6.c) from the previous CPR. In the section where baseline changes that occurred during the period are listed (Column (1) of Block 6.b), enter the amount of each of the changes listed. On the PMB (End of Period) line (Block 6.c), enter the sum of the amounts in the preceding columns on this line. On the Management Reserve line (Block 7), enter the amount of MR available at the end of the period. On the Total line (Block 8) enter the sum of the amounts in this column on the PMB (End of Period) line and the Management Reserve line. (Note: This should equal the amount in Block 5.f on this format and also the amount of the Total line in Column (14), Block 8.g, of Format 1.)

2.5 Format 4 - Staffing.

2.5.1 Performance Data. For those organizational categories shown in Column (1) of Block 5, equivalent months shall be indicated for the current reporting period (Column (2)), cumulative through the current period (Column (3)), forecast to completion (Columns (4) through (14)), and at completion (Column (15)). Direct equivalent months shall be shown for each organizational category for the contract. An equivalent month is defined as the effort equal to that of one person for one month. Values shall be reported in whole numbers. (Note: Partial months, .5 and above, shall be rounded to 1; below .5 to 0.) When the Government and the contractor agree, staffing may be reported in equivalent days or hours.

2.5.1.1 Column (1) - Organizational Category. In Block 5, list the organizational categories that reflect the contractor's internal management structure. Format 4 categories may differ from those reported in Format 2. If the Government needs different categories in Formats 2 and 4, the Format 4 categories shall be addressed during negotiations. (See f.4 above.)

2.5.1.2 Total Direct. In Block 6, Columns (2) through (15), enter the sum of all direct equivalent months for the organizational categories shown in Column (1).

2.5.2 Column (2) - Actual - Current Period. Enter the actual equivalent months incurred during the current reporting period.

2.5.3 Column (3) - Actual End of Current Period (Cumulative). Enter the actual equivalent months incurred to date (cumulative) as of the end of the reporting period.

2.5.4 Columns (4) Through (14) - Forecast (Non-Cumulative). Enter the names of each month for the contract period of performance in the headings of each of the Columns (4) through (9), and the names of the appropriate periods in the headings of each of the Columns (10) through (14) of Block 5. Enter a staffing forecast by month for the next six months and for periodic increments (monthly, quarterly, or annually) thereafter for the remainder of the contract. The staffing forecast shall be updated as part of the formal EAC process followed by the contractor. The staffing forecast shall reflect the same staffing estimate used as the basis for the EAC in Column (15) on both Format 1 and Format 2. (Note: For the purposes of illustration, Sample Format 4 has Columns (4) through (14) for reporting staffing forecast. The actual number of columns will vary from contract to contract.)

2.5.5 Column (15) - Forecast at Completion. Enter the estimate of equivalent months necessary for the total contract in Column (15) by organizational category. This estimate shall be consistent with the "most likely" management EAC shown in Column (15) of Block 8.e of Format 1. Any significant change in the total number of equivalent months at completion of the contract (i.e., Column (15) Total) shall be explained in Format 5.

2.6 Format 5 - Explanations and Problem Analyses.

2.6.1 General. Format 5, Explanations and Problem Analyses, is a narrative report prepared to amplify and explain data in the other CPR formats. Format 5 shall normally address the following: (1) contractually required cost, schedule, and EAC variance analyses, (2) MR changes and usage, (3) UB contents, (4) differences between the best case, worst case, and most likely management EAC, if any, (5) the difference between the most likely management EAC and the estimate in Block 8.e of Column (15), if any, (6) significant differences between beginning of period PMB time phasing and end of period PMB time phasing in Format 3, (7) performance measurement milestones that are inconsistent with contractual milestones (Over Target Schedule), (8) formal reprogramming (over target baseline) implementation details, and (9) significant staffing estimate changes in Format 4. Any other topic relevant to contract cost, schedule, or technical performance may be addressed in this format. The date(s) of the Integrated Baseline Review(s) may also be addressed in this format. Contractors may elect to attach subcontractor Format 5 reporting and cross reference this analysis in the Format 5 reporting submitted to the Government to gain time efficiencies and meet submission dates.

2.6.2 Total Contract. Provide a summary analysis that identifies significant problems affecting performance. Indicate corrective actions required, including Government action where applicable. Significant changes since the previous report shall be highlighted. Discuss any other issues affecting successful attainment of contract cost, schedule, or technical objectives that the contractor deems significant or noteworthy. This section is brief, normally one page.

2.6.3 Cost and Schedule Variances. Explain all variances that exceed specified variance thresholds. Explanations of variances shall clearly

identify the nature of the problem, significant reasons for cost or schedule variance, effect on the immediate task, impact on the total contract, and the corrective action taken or planned. Explanations of cost variances shall identify amounts attributable to rate changes separately from amounts applicable to hours worked; amounts attributable to material price changes separately from amounts applicable to material usage; and amounts attributable to overhead rate changes separately from amounts applicable to overhead base changes or changes in the overhead allocation basis. To reduce the volume of variance analysis explanations, the contractor may refer to a prior CPR's variance analysis explanations if the explanation for the current CPR's variance has not changed significantly. Explanations of schedule variances and the impact on the contract shall be performed in parallel with the schedule analysis called out by the IMS DID. Accordingly, there is a requirement in b. above for the IMS DID, DI-MGMT-81650, to be used in conjunction with this DID. (See 2.2.6.4 and 2.2.6.5 above.)

2.6.3.1 Setting Variance Analysis Thresholds. In Format 5, the Government will require only that amount of variance analysis that satisfies its management information needs. Excessive variance analysis is burdensome and costly, and detracts from the CPR's usefulness, while too little information is equally undesirable.

2.6.4 Other Analyses. In addition to variance explanations, the following analyses are mandatory:

2.6.4.1. Management Estimate at Completion. If the best or worst case management EACs differ from the most likely estimate (Column (1) of Block 6 of Format 1), a brief explanation of the difference shall be provided. Also, if the most likely management EAC differs from the total entered in Column (15) of Format 1 or 2, the difference shall be explained. The explanations shall focus on such areas as a knowledgeable, realistic risk assessment; projected use of MR; estimate for UB; and higher management's knowledge of current or future contract conditions. The assumptions, conditions, and methodology underlying all management EACs shall be explained. (See 2.2.2 to 2.2.2.3, 2.2.2.5, 2.2.6.9, and 2.2.6.10 above.)

2.6.4.2 Undistributed Budget. Identify the effort to which the UB applies. Also, explain any variance between the UB and the estimate for UB in Formats 1 and 2. (See 2.2.4.4 and 2.3.1.4 above.)

2.6.4.3 Management Reserve Changes. Identify the sources and uses of MR changes during the reporting period. Identify the CWBS and organizational elements to which MR is applied, and the reasons for its application. (See 2.2.4.6 above.)

2.6.4.4 Baseline Changes. Explain reasons for significant shifts in time phasing of the PMB shown on Format 3. (See 2.4.2.3 above.)

2.6.4.5 Staffing Level Changes. Explain significant changes in the total staffing EAC shown on Format 4. Also, explain reasons for significant shifts in time phasing of planned staffing. (See 2.5.5 above.)

2.6.5 Formal Reprogramming (Over Target Baseline). If the difference shown in Block 5.g on Format 3 becomes a negative value or changes in value, provide information on the following:

2.6.5.1 Authorization. Procuring activity authorization for the baseline change that resulted in negative value or change.

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2.6.5.2 Reason. A discussion of the reason(s) for the change.

2.6.5.3 CPR Reporting. A discussion of how the change affected CPR reporting (i.e., amount allocated to MR, adjustments to cost or schedule variances, etc.). (See 2.4.1.7, 2.2.5.1, and 2.2.6.7 above.)

2.6.5.4 Schedule. Indicate whether the contract schedule was retained for performance measurement or was replaced with a schedule that exceeds the contractual schedule (Over Target Schedule).

2.6.6 Over Target Schedule. If a performance measurement schedule exceeding the contractual schedule (Over Target Schedule) has been implemented, provide a discussion of the pertinent information, such as authorization, reasons, and significant dates. (See 2.4.1.10.1 above.)

END OF DI-MGMT-81466A

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

21 December 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.

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5. Objectively assess accomplishments at the work performance level.
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 2 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.

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. For Tier 2 programs that are of larger value (greater than \$25M) the expectation is that the control account will be at least at level 4 and potentially level 5. Most of the normal functions accomplished when scheduling will be required on a 7 Principles Tier 2 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 is: 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 7 Principles implementation contractors must utilize a work order/job order/task code charge number structure that uniquely identifies costs at the control account level. 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 its 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.

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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 know as Supervisor's Estimate) and level of effort (LOE). All four methodologies are legitimate earned value measurement techniques but the assessed percent complete based or supervisor's estimates are highly discouraged. The reason is that it is highly subjective and is not based on any quantifiable criteria. BARDA will not accept these earned value methodologies unless approved as an exception on a case by case basis. If percent complete on work packages is used with objective measurable activities, the contractor must show distinct relationship between the budget planned at the work package level and the value earned at the activity level. If this is done properly then the measurement will be objective and the schedule variance will be clearly understood and easy to explain. If this is not done properly then schedule activities are not aligned with the budget in the performance measurement baseline and schedule variances will not be easy to understand. If the latter is the case, BARDA will not accept that as an acceptable earned value methodology.

There are built in weaknesses with the 0/100 and 50/50 methodologies also. If the responsible manager is being asked to plan their work in monthly increments in order to utilize the 0/100 methodology then they may be asked to break the work up in pieces that don't make logical sense or represent the natural ending of the work. Also the 50/50 methodology, which is usually used for a two month work package, will provide skewed monthly data if the resources in the work package are not loaded equally for each month. It will give an artificial positive or negative schedule variance the first month and vice versa the next month.

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 all discrete measurable work packages or control accounts, there must be an activity in each month to measure. Gaps, in which there is nothing to measure in a month or months is not acceptable.

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

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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. They should hold their Control Account Managers accountable to use the data and write clear proper variance analysis report (VAR). If the Control Account Manager does not write a proper VAR then Project Controls needs to help instruct them how to do it. It is recommended that prior to the Earned Value report be sent to the government that the Program Manager has a meeting with the Control Account Managers and Project Control and review the data and ensure that the variance analysis is complete and that the Program Manager agrees with it. This review is also used to ensure that the EACs are acceptable to the Program Manager, who is ultimately responsible for the program EAC. This is an efficient and quick way to make any adjustments to the earned value report since all the key personnel are in one room. If the data appears to be unreliable then the PM needs to hold Project Controls accountable to ensure that they are using discipline in changing baselines, assessing process properly, and capturing actual costs to ensure that the data that is reported is accurate.

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.

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Baseline	(See Performance Measurement Baseline).
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)	<p>The negotiated contract cost plus the estimated cost of authorized unpriced work, where:</p> <p>(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</p>

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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).

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 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.

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Cost Performance Index (CPI)	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 $BCWP/ACWP$.
Discrete Effort	Program effort that has a measurable output, product or service.
Direct Costs	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.
Earned Value	See Budgeted Cost for Work Performed (BCWP)
Earned Value Management System (EVMS)	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.
Estimate at Completion (EAC)	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 $EAC = ACWP + \text{the Estimate-to-Complete}$.
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

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treatment as direct costs. (See overhead).

Integrated Baseline Review (IBR)

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.

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.

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.

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

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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
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

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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 $BCWP/BCWS$.
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

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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.
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)

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.

(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 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.

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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-\$150K

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

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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 Control Account Plans 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 \$135K. For a cost analyst it should be equal to or less than \$120K. If a company is bringing in a contractor to provide staff implementation the costs should be up to \$135/hr for a schedule analyst and \$120/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 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 monthly 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.

Targeted Outcome: No evidence of delay in cardiac repolarization induced by Panaceomycin as shown by analysis of the QT interval.

Subcontractors

Vendor	Area of Responsibility
Phase Research	<ul style="list-style-type: none"> ○ Study Documentation Design and Development ○ Clinical Monitoring: Includes site initiation, interim, and close-out monitoring visits, ○ Pharmacovigilance ○ Data Management: Includes build and maintenance of electronic case report forms (eCRFs); data query generation and resolution ○ Biostatistics ○ Medical Writing: ○ Project Management: The Project Manager will actively facilitate Phase Research's interaction with the research site and provide close monitoring oversight in conjunction with the assigned CRA. Project Management will also assist in the finalization of all applicable study documents and provide coordination between study vendors. ○ Pass-through Expenses <ul style="list-style-type: none"> Travel for CRA monitoring visits to clinical sites, shipping and printing costs ○ Investigator Grants
Energetics	Core Cardiac Lab
TBD	Clinical study site(s)
Pulse Tech	To provide Central Lab services
Analyx	To perform PK analyses
Claritron	To write the PK report
Obelisk	To label and distribute study drug product

Consultants

Joe Josephs	Internal Medical Monitor: Sponsor medical oversight
Rolf Xerd	Pharmacologist: Design and analysis consultation for PK parameters and analysis
Julie Simms	Clinical Trials Manager

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Phil Thomas	Medical Writer
Claire Cools	SAS Programmer
Mary Doe	Clinical Contracts
Jim Dodds	Supply Chain Manager

Milestones, EV at Milestones

Consultants and Phase Project Management will earn value as Level of Effort activities. All other costs will earn value according to the schedule below.

Signed Study Protocol	10 %
First participant dosed	20 %
40 % Enrollment	35%
70% Enrollment	50%
Last participant procedure (Treatment phase)	60 %
Last participant follow-up	70 %
Database lock	80 %
Clinical Study Report	90 %
Transferred Trial Master File	100 %

Deliverables

1. Signed Study Protocol
2. Top-line data
3. Signed Clinical Study Report

External Dependencies

1. Top-line Data from an External Clinical Study Identifying Panaceomycin Maximum Tolerated Dose as a single dose in Humans. The Maximum Tolerable Dose will be defined in a study not included in the BARDA contract. This dose will be used in selecting the Supra-therapeutic dose in this Thorough QT Study.
2. Successful production of cGMP lot of Panaceomycin.
3. Enrollment and retention of study participants.

Sample WBS Dictionary

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Work Authorization					
Project/Contract	BARDA	WBS #	1.1.6.2		
WBS description	Program Management, Meetings and Control				
Authorization version #	1	Scheduled Start	Oct 2010	Scheduled Finish	Sep 2012
Work Description					
<p>██████████ staff will manage the integration and performance control of the program.</p> <p>For further detail, see description of scope for WBS 1.1.6.2</p>					
Budget					
Labor	\$ 250,000				
Subcontractors	\$				
Consultants	\$				
Materials	\$				
Travel	\$				
Total	\$ 250,000				
Approvals					
Control Account Manager	Name: Benjamin Gay	Signature:	Date:		
Project Manager	Name: Ronald Smith	Signature:	Date:		
Finance	Name: Denise Blessi	Signature:	Date:		

Sample Work Authorization Document

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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	O/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 Control Account Plan

Attachment 11

Listing of Project-Relevant Background Inventions

(b) (4) [Redacted]

(b) [Redacted]	[Redacted]	[Redacted]	[Redacted]
(4) [Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]

Attachment 12

Data Rights Assertion Table

Data Rights Assertion Table

Identification and Assertion of Restrictions on the Government's Use, Release, or Disclosure of Technical Data or Computer Software.

The Contractor asserts for itself, or the persons identified below, that the Government's rights to use, release, or disclose the following technical data or computer software should be restricted:

Technical data or computer software to be furnished with restrictions*	Basis for assertion**	Asserted rights category***	Name of person asserting restrictions****
(LIST)*****	(LIST)	(LIST)	(LIST)
(b) (4) [Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]

(b) (4) [Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]
[Redacted]	[Redacted]	[Redacted]	[Redacted]

*For technical data (other than computer software documentation) pertaining to items, components, or processes developed at private expense, identify both the deliverable technical data and each such item, component, or process. For computer software or computer software documentation identify the software or documentation.

**Generally, development at private expense, either exclusively or partially, is the only basis for asserting restrictions. For technical data, other than computer software documentation, development refers to development of the item, component, or process to which the data pertain. The Government's rights in computer software documentation generally may not be restricted. For computer software, development refers to the software. Indicate whether development was accomplished exclusively or partially at private expense. If development was not accomplished at private expense, or for computer software documentation, enter the specific basis for asserting restrictions.

***Enter asserted rights category (e.g., government purpose license rights from a prior contract, rights in SBIR data generated under another contract, limited, restricted, or government purpose rights under this or a prior contract, or specially negotiated licenses).

***Corporation, individual, or other person, as appropriate.
***Enter "none" when all data or software will be submitted without restrictions.