



Case No. 2020-01158-FOIA-OS

July 31, 2020

Mr. Austin R Evers
Executive Director
American Oversight
1030 15th Street, N.W., Suite B255
Washington, DC 20005
Sent via email: foia@americanoversight.org

Dear Mr. Evers:

This letter is the final response to your May 06, 2020, Freedom of Information Act (FOIA) request. Specifically, you requested the following records:

- “1. A complete copy of the contract, amendment, memorandum of understanding, or other written agreement between (a) the Office of the Assistant Secretary for Preparedness and Response (ASPR) and/or the Biomedical Advanced Research and Development Authority (BARDA), and (b) Moderna, Inc. regarding the development of a coronavirus vaccine, as announced by HHS on March 30, 2020.
2. A copy of the \$483 million “award” by BARDA to Moderna, Inc., to accelerate development of Moderna’s mRNA vaccine candidate (mRNA-1273), entered into on or before April 16, 2020, including any attachments thereto. (Date Range for Record Search: From 2/1/2020 To 4/23/2020).”

The Assistant Secretary for Preparedness and Response (ASPR) conducted a search and located **112 pages** of responsive records. After a careful review of these pages, I have determined to release **90 pages** to you in their entirety, and I am further releasing **22 pages** in part, with portions redacted, pursuant to Exemption 4 and Exemption 6 of the FOIA (5 U.S.C. §552 (b)(4) (b)(6)).

FOIA exemption (b)(4) permits the withholding of trade secrets and commercial or financial information that is privileged or confidential.

FOIA exemption (b)(6) permits a Federal agency to withhold information and records about individuals in “personnel and medical files and similar files, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.” The definition of “similar files” has historically been broadly interpreted to include a wide variety of files, and the United States Supreme Court has held that Congress intended the term “similar files” to be interpreted broadly, rather than narrowly. I have analyzed these records and find they meet the threshold requirement of this exemption. Additionally, I have reviewed and weighed the public interest in disclosure of this information against the privacy interest in nondisclosure, and found that the privacy interest outweighs the public’s interest in disclosure.

If you believe the information withheld should not be exempt from disclosure, or this response constitutes an adverse determination, you may appeal. By filing an appeal, you preserve your rights under FOIA and give the agency a chance to review and reconsider your request and the agency's decision.

Your appeal must be mailed within 90 days from the date of receipt of this letter, to:

Ms. Kim Hutchinson
Deputy Agency Chief FOIA Officer
U.S. Department of Health and Human Services
Office of the Assistant Secretary for Public Affairs
Room 729H
200 Independence Avenue, S.W.
Washington, DC 20201

Please clearly mark both the envelope and your letter "Freedom of Information Act Appeal."
You may also e-mail your appeal to: HHS.ACFO@hhs.gov.

If you would like to discuss our response before filing an appeal to attempt to resolve your dispute without going through the appeals process, you may contact the HHS FOIA Public Liaison for assistance at:

HHS FOIA/PA Public Liaison
FOI/Privacy Acts Division
Assistant Secretary for Public Affairs (ASPA)
Office of the Secretary (OS)
U.S. Department of Health and Human Services (HHS)
200 Independence Avenue, SW, Suite 729H
Washington, DC 20201

Telephone: (202) 690-7453
Fax: (202) 690-8320
E-mail: [HHS FOIA Public Liaison@hhs.gov](mailto:HHS_FOIA_Public_Liaison@hhs.gov)

If you are unable to resolve your FOIA dispute through our FOIA Public Liaison, the Office of Government Information Services (OGIS), the Federal FOIA Ombudsman's office, offers mediation services to help resolve disputes between FOIA requesters and Federal agencies. The contact information for OGIS is:

Office of Government Information Services
National Archives and Records Administration
8601 Adelphi Road—OGIS
College Park, MD 20740-6001

Telephone: 202-741-5770
Toll-Free: 1-877-684-6448
E-mail: ogis@nara.gov
Fax: 202-741-5769

There are no charges in this instance because the billable costs are less than our threshold of \$25.

Sincerely yours,

Wakema Williams for

Brandon J. Gaylord

Director

FOI/Privacy Acts Division

Enclosure(s)

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE OF PAGES 1 112
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2. CONTRACT (Proc. Inst. Ident.) NO. 75A50120C00034	3. EFFECTIVE DATE See Block 20C	4. REQUISITION/PURCHASE REQUEST/PROJECT NO. OS256972
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5. ISSUED BY CODE ASPR-BARDA ASPR-BARDA 200 Independence Ave., S.W. Room 640-G Washington DC 20201	6. ADMINISTERED BY (If other than Item 5) CODE ASPR-BARDA02 US DEPT OF HEALTH & HUMAN SERVICES ASST SEC OF PREPAREDNESS & RESPONSE ACQ MANAGEMENT, CONTRACTS, & GRANTS O'NEILL HOUSE OFFICE BUILDING Washington DC 20515
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7. NAME AND ADDRESS OF CONTRACTOR (No., street, country, State and ZIP Code) MODERNATX, INC (b)(4) (b)(6) MODERNATX, INC. 200 TECHNOLOGY 200 TECHNOLOGY SQ CAMBRIDGE MA 021393578	8. DELIVERY <input type="checkbox"/> FOB ORIGIN <input checked="" type="checkbox"/> OTHER (See below)
	9. DISCOUNT FOR PROMPT PAYMENT
	10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN ITEM

CODE 1492235	FACILITY CODE	11. SHIP TO/MARK FOR CODE HHS HHS 200 Independence Avenue, SW Washington DC 20201	12. PAYMENT WILL BE MADE BY CODE PSC PSC Program Support Center 7700 Wisconsin Ave Bethesda MD 20814
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13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION: <input type="checkbox"/> 10 U.S.C. 2304 (c) () <input checked="" type="checkbox"/> 41 U.S.C. 3304 (a) ()	14. ACCOUNTING AND APPROPRIATION DATA (b)(4)
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15A. ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
Continued					

15G. TOTAL AMOUNT OF CONTRACT \$430,298,520.00

16. TABLE OF CONTENTS							
(X)	SEC.	DESCRIPTION	PAGE(S)	(X)	SEC.	DESCRIPTION	PAGE(S)
PART I - THE SCHEDULE				PART II - CONTRACT CLAUSES			
	A	SOLICITATION/CONTRACT FORM		X	I	CONTRACT CLAUSES	61
X	B	SUPPLIES OR SERVICES AND PRICES/COSTS	2	PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACH.			
X	C	DESCRIPTION/SPECS./WORK STATEMENT	10	X	J	LIST OF ATTACHMENTS	67
X	D	PACKAGING AND MARKING	20	PART IV - REPRESENTATIONS AND INSTRUCTIONS			
X	E	INSPECTION AND ACCEPTANCE	20		K	REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS	
X	F	DELIVERIES OR PERFORMANCE	21		L	INSTRS., CONDS., AND NOTICES TO OFFERORS	
X	G	CONTRACT ADMINISTRATION DATA	47		M	EVALUATION FACTORS FOR AWARD	
X	H	SPECIAL CONTRACT REQUIREMENTS	52				

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

17. <input checked="" type="checkbox"/> CONTRACTOR'S NEGOTIATED AGREEMENT (Contractor is required to sign this document and return _____ 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. <input type="checkbox"/> 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.)
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19A. NAME AND TITLE OF SIGNER (Type or print) (b)(6)	19B. NAME OF CONTRACTOR (b)(6)	19C. DATE SIGNED 4/16/2020	20B. UNITED STATES OF AMERICA Wendell Conyers -S Digitally signed by Wendell Conyers -S Date: 2020.04.16 12:21:10 -04'00' <i>(Signature of the Contracting Officer)</i>	20A. NAME OF CONTRACTING OFFICER WENDELL CONYERS	20C. DATE SIGNED April 16, 2020
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CONTINUATION SHEET

REFERENCE NO. OF DOCUMENT BEING CONTINUED
75A50120C00034

PAGE OF
2 112

NAME OF OFFEROR OR CONTRACTOR

MODERNATX, INC (b)(4)

ITEM NO. (A)	SUPPLIES/SERVICES (B)	QUANTITY (C)	UNIT (D)	UNIT PRICE (E)	AMOUNT (F)
	Tax ID Number: (b)(4) DUNS Number: (b)(4) Appr. Yr.: 2020 CAN: 199COV1 Object Class: 25103				
1	Pre-Award Cost				
2	Base CLIN 0002 - Development of mRNA vaccine to BLA				
3	Option 1 Kit Build-Out				
	Amount: (b)(4)				

(b)(4)

Table of Contents

PART I – THE SCHEDULE.....	4
B. SUPPLIES/SERVICES AND COST/PRICE.....	4
C. DESCRIPTION / SPECIFICATIONS / WORK STATEMENT	9
D. PACKAGING AND MARKING (if applicable).....	16
E. INSPECTION AND ACCEPTANCE.....	16
F. DELIVERABLES / PERFORMANCE	17
G. CONTRACT ADMINISTRATION.....	36
H. SPECIAL CONTRACT REQUIREMENTS	41
PART II – CONTRACT CLAUSES	49
I. CONTRACT CLAUSES.....	49
PART III – LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS	53
J. LIST OF ATTACHMENTS	53

PART I – THE SCHEDULE

B. SUPPLIES/SERVICES AND COST/PRICE

B.1 Brief Description of Supplies/Services

The Department of Health and Human Services (HHS), Office of the Assistant Secretary for Preparedness and Response (ASPR), Biomedical Advanced Research and Development Authority (BARDA) requires the contractor(s) to develop a mRNA vaccine to licensure for the prevention of COVID-19. The project will entail pre-clinical and Phase 2 and Phase 3 clinical studies sufficient to demonstrate the safety and efficacy of the proposed vaccine(s); CMC development, scale-up, scale-out and validation of manufacturing capacities, including bulk drug substance and fill and finished drug product, with a capacity of 100 million doses by 2021 and all program management and regulatory activities necessary to achieve FDA licensure of the vaccine. The project shall be accomplished on an accelerated timeline, with parallel activity WBS, aggressive manufacturing scale-up, risk management, and taking advantage of any regulatory flexibilities. Contract terms include a requirement for domestic production of vaccine and assurance of material sourcing for vaccine production during execution of the project.

B.2 Price/Cost

This contract contains the price/cost provisions agreed upon by the Government and the Contractor.

B.2.1 Contract Budget Ceiling

The contract has a cost/price ceiling that the Contractor exceeds at its own risk. The Contractor is responsible for managing its performance in accordance with the final scope of work and costs/prices incorporated into the contract. The Government is not obligated to reimburse the Contractor for costs incurred in excess of costs/prices agreed upon at time of award. The contract ceiling is \$483,298,520.00.

B.2.2 Contract Periods

This contract consists of pre-award cost (CLIN 0001), a base period for the Development of mRNA vaccine to BLA (CLIN 0002) and one (1) option period for the Domestic Manufacturing Scale-Out (CLIN 0003).

B.3 Contract Line Item Numbers (CLINs) Schedule

This is a Cost-Plus-Fixed-Fee (CPFF), contract.

B.3.1 Base Period of Performance

The base period of performance (POP) includes pre-award cost (CLIN 0001) and the Development of mRNA vaccine to BLA (CLIN 0002).

- a. CLIN 0001 costs shall be pre-award cost incurred by Moderna, with a do not exceed cost of (b)(4)
- b. CLIN 0002 costs shall cover the base period statement of work that consists of the development of mRNA vaccine to BLA.
- c. These are cost-plus-fixed-fee CLINs with a CPFF structure, (b)(4)
- d. Monies shall be provided for the total cost of performance from the Department of Health and Human Services.
- e. The Contractor shall maintain records of all contract costs and such records shall be subject to the Audit and Records-Negotiation clause.
- f. It is estimated that the amount currently allotted will cover performance of the contract through (b)(4) for the base period.

Pre-Award Period of Performance: (b)(4)

Table 1

CLIN	Estimated Period of Performance	Supplies/Services	Estimated USG Cost	Management Fee (Profit)	Total
0001		Pre-Award Cost	(b)(4)		

Base Period of Performance: (b)(4)

Table 2

CLIN	Estimated Period of Performance	Supplies/Services	Estimated USG Cost	Management Fee (Profit)	Total
0002		Development of mRNA vaccine to BLA	(b)(4)		

B.3.2 Option Period 1

This option period includes all Kit Build-Out activities for the facility under CLIN 0003, and may overlap with the base period.

CLIN 0003 is under a CPFF structure, (b)(4)

CLIN	Estimated Period of Performance	Supplies/Services	Estimated USG Cost	Management Fee (Profit)	Total
0003		Domestic Manufacturing Scale-Out	(b)(4)		

B.3.3 Total Contract Value

The total potential value of this contract, including all CLINs 0001, 0002 and option CLIN 0003 is \$483,298,520.00.

B.4 Advanced Understandings

This contract contains advanced understandings between the Government and the Contractor. Specific elements of cost, which normally require prior written approval of the Contracting Officer before incurrence of the cost, will be included in this Section if the Contracting Officer has granted approval prior to contract award.

B.4.1 Rights of first refusal – mRNA Vaccines

(b)(4)

B.4.2 HHS reserves the right to exercise priorities and allocations authority with respect to this contract, to include rating this order in accordance with 45 CFR Part 101, Subpart A—Health Resources Priorities and Allocations System

B.4.3 Earned Value Management (EVM) Lite Requirements

The Contractor shall use an Earned Value Management (EVM) System for all retrofit and development activities of the anticipated requirement, that is consistent with the “7 Principles of Earned Value Management Tier 2 System Implantation Intent Guide” attached to this contract. Alternative systems may be submitted to the Contracting Officer for consideration and approval.

B.4.4 Public Readiness and Emergency Preparedness Act (“PREP ACT”) Coverage

The Federal Government may not use, or authorize the use of, any products or materials provided under either this agreement or any future purchase from Recipient's domestic manufacturing capacity unless such use occurs in the United States and is protected from liability under a declaration issued under the Public Readiness and Emergency Preparedness Act, 42 U.S.C. § 247d-6d.

B.4.5 Provisions to Applicable Costs

This section prohibits or restricts the use of contract funds which includes the following items (costs unallowable unless otherwise approved by the Contracting Officer):

- a. Acquisition, by purchase or lease, of any interest in real property;
- b. Purchase or lease of any item of general purpose office furniture or office equipment regardless of dollar value;
- c. Accountable Government Property (as defined by HHS Government property policies)
- d. Overtime;
- e. General scientific meetings/conferences;
- f. Travel costs including foreign travel;
- g. Costs incurred in the performance of any cost-reimbursement type subcontract (including consulting agreements);
- h. Costs to be paid for the performance of a fixed-price subcontract that exceeds \$250,000.00 (for equipment purchases, \$25,000.00 per unit);
- i. Refreshments and Meal Expenditures;
- j. Promotional Items Printing;
- k. Payment of regulatory submission fees to the FDA or other U.S. regulatory agency;
- l. BLA licensing or renewal fees;
- m. Pre-contract costs (other than those expressly set forth herein).

B.4.6 Facility, Equipment and Product Ownership

In the event the USG terminates this contract for other than default, all Contractor-acquired Government Furnished Property (GFP) [as defined by 52.245-1], to include process equipment, is to be assessed by a reputable third party firm that specializes in assigning fair market value of biopharmaceutical materials, supplies and equipment for the resale market. The USG will use this fair market value assessment in settlement, around the disposition of the GFP.

Ownership and applicable usage rights of all materials/product (e.g. vaccines, validated lots) manufactured and/or acquired with Government funds, throughout the Contract's entire period of performance, shall be retained by the USG. The Contracting Officer will direct the Contractor on the disposition (i.e. storage, transfer, disposal, etc.) of all Contractor-acquired/manufactured USG materials/product.

B.4.7 [reserved]

B.4.8 Advanced Understanding: Milestone Review: the development of a COVID-19 vaccine is an accelerated program. Progress for vaccine development will be continually assessed for go/no go decisions so that funding is properly allocated across the MCM development effort to those candidates most likely to be available in time to impact the COVID-19 public health emergency. Formal ‘go/no go’ assessments will be made at multiple points, including:

(b)(4)



B.4.9 Contractor Responsibility for Major Site Service & Utility System

BARDA acknowledges that Moderna is offering to undergo potential upgrades to its manufacturing processes as outlined in the Technical Proposal. A preliminary assessment of major site service and utility systems of Contractor's existing facility has deemed them adequate in supply and fitness to meet stated scope. However, if, during the course of executing this contract, Moderna discovers that major site service or utility replacement/upgrades at such facility are required to accomplish the scope of work, then the costs for said replacement/upgrades shall be covered by Moderna. As with any significant renovation Moderna has implied duty to disclose superior knowledge of site conditions. As contract work is performed, Moderna will ensure that the BARDA Contracting Officer's Representative (COR) is fully informed of all issues that could affect cost or schedule. BARDA commits to work with Moderna to assess specific complex situations.

Examples of major site-wide service/utility systems outside the envelope of Buildings to be warranted by Moderna:

- Plant steam supply;
- Potable water/ Non-potable water supply (depending on the site, non-potable water could be fire hydrants);
- Sewer line\Sanitation line (post inactivation/ treatment) ;
- Site chiller/ chilled water supply;
- High and Low voltage Electrical feed(s) ;
- Network Infrastructure;
- Site-wide automation capacity;
- Perimeter fencing/ site security;
- Storm water;
- Gas (natural gas, site gas feeds);
- Fuel (generator fuel piping, this may be out of scope);
- Earthwork required to relocate, improve, or maintain site infrastructure such as manholes, duct banks, etc.

All NEPA, state and local government environmental requirements are met for this project; any concerning issues have been disclosed to the USG before award.

B.4.10 Evaluating the Expansion of Surge Vaccine Manufacturing Capacity

The parties agree to develop and evaluate plans to further expand and diversify US-based domestic vaccine manufacturing capacity to respond to the pandemic. A draft framework will be completed within 60 days. This CMC domestic build-out/scale-out will further ensure that the United States has sufficient manufacturing capacity in response to the pandemic.

B.4.11 Subcontracts

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

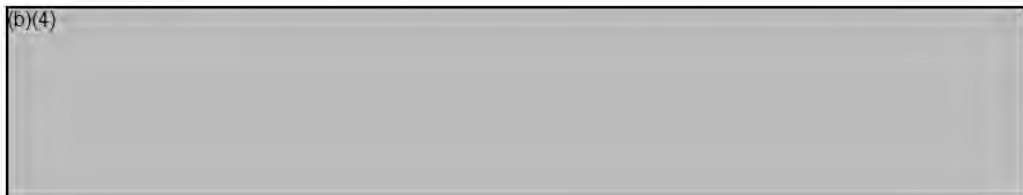
- Is of the cost-reimbursement type; or
- Is Fixed-Price and exceeds \$250,000 or 5% of the total estimated cost of the Contract, whichever value is greater.

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.

On March 13, 2020, the U.S. President declared a national emergency due to the outbreak of the coronavirus. The subcontractors and consultants listed below are currently engaged in the mRNA-1273 development program and are tentatively approved to continue work. These subcontractors must complete the COA process per FAR Clause 52.244-2 within 90 days. New vendors initiating work within the first 60 days of the contract will be allowed to start, and COA requests will be submitted within 90 days.

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

(b)(4)

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(b)(4)

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B.4.12 Performance Standard

The contractor will not be in default under this agreement to the extent that it makes reasonable efforts to perform the services and produce and provide the items described in this contract.

B.4.13 Limited Rights Data

Notwithstanding any contrary representation by the Contractor on the System for Award Management or any contrary provision in this contract, the following categories of information developed at private expense will, if provided to the Government, be considered limited rights data subject to the restrictions specified in FAR 52.227-14, Alternate II. These restrictions apply to any component of information covered by this provision, regardless of whether a component is included in a contract deliverable. The Government will not reverse engineer or otherwise evaluate materials provided under this Contract to reproduce the type of information described below without Moderna's prior written consent.

(b)(4)

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C. DESCRIPTION / SPECIFICATIONS / WORK STATEMENT**C.1 Background**

Coronaviruses are potential epidemic threats and have been recognized on the World Health Organization's list of top emerging diseases likely to cause major epidemics and Coalition for Epidemic Preparedness Innovations priority pathogens list. No vaccines to prevent Coronavirus infection are currently available. The emergence of the SARS-CoV-2 virus creates an urgent need to rapidly develop vaccines to prevent COVID-19 disease. Developing and delivering a vaccine for highly transmissible, emerging diseases such as the SAR-CoV-2 virus requires breaking from traditional approaches. It requires parallel development activities, aggressive manufacturing scale-up, risk management and implementation of regulatory flexibilities. Many of these requirements are met by manufacturing 'platforms' that are capable of producing vaccines against different agents using essentially the same manufacturing systems. Suitable platforms are constituted by defined product production processes that allow significant planning for manufacturing scale and time to vaccine availability and will be supported by human safety and immunogenicity data targeting an one or more infectious agents. To meet the purposes of this contract, it is critical that the vaccine be produced in the United States. Domestic production of the vaccine is the only assurance that Americans will have access to the finished product.

Moderna's mRNA-based vaccine platform has been used to rapidly prepare vaccine candidates against Cytomegalovirus, Zika, Respiratory Syncytial Virus, Influenza, Human Metapneumovirus and Parainfluenza virus. Four of these candidates have been evaluated in Phase 1 clinical studies and shown to be safe and immunogenic. Moderna collaborated with the Vaccine Research Center, NIAID ("VRC/NIAID") to design a lead SARS-CoV-2 vaccine candidate encoding a stabilized pre-fusion SARS-CoV-2 Spike protein, which is more immunogenic than wild-type or subunit proteins. Moderna's mRNA vaccine is currently being evaluated in pre-clinical studies and Phase 1 trials sponsored by the NIAID. For the purposes of this contract, Moderna will perform all work required to support the advanced development, scale-up manufacturing and FDA licensure of their lead SARS-CoV-2 vaccine candidate(s). This work includes preclinical development of mRNA vaccines to demonstrate safety and efficacy against COVID-19, mRNA vaccine process and manufacturing scale-up development, product lot release assay development and process validation, production of clinical material and consistency lots clinical evaluation studies for safety, immunogenicity and efficacy; and fill/finish capacity evaluation, expansion, and validation.

The Governments 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 a defined end-point required in each discrete work segment, as outlined in Section F 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 B and 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 0003 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 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

C.2 Statement of Work

Independently, and not as an agent of the United States Government, the contractor shall furnish all necessary services, qualified professional, technical, and administrative personnel, material, equipment and facilities, not otherwise provided by the Government under the terms of this contract, as needed to perform the tasks set forth below.

mRNA Vaccine Development (WBS 1.0)

The Contractor, Moderna, Inc. ("Moderna") shall execute the preclinical, clinical, and chemistry, manufacturing and controls (CMC) activities required to license a vaccine against the SARS-CoV-2 virus (herein referred to as "mRNA vaccine"). Building upon early clinical development already underway, this proposal will support the late stage development, including the demonstration of clinical efficacy and generation of a dataset supportive of licensure. Moderna will additionally evaluate the platform manufacturing capabilities relative to the needs for supply in response to a pandemic.

Program Management (WBS 1.1)**mRNA Program Management (WBS 1.1.1)**

Moderna's mRNA program team is composed of a multidisciplinary, highly matrixed, group of functional leads with experience in, and responsibility for, integrating plans and operationalizing strategies across Research, Toxicology, CMC, Regulatory Affairs,

Clinical Development and Quality. Collectively, the team has advanced ten programs to first-in-human studies within five years. The group will be led by a program lead (PL) who will oversee and coordinate the activities necessary to meet program objectives. The PL will be the point of accountability for the development of mRNA vaccine. The Principal Investigator will set the strategic objectives for the program and ensure that Moderna is prepared to license a vaccine (b)(4)

(b)(4). A program management office (PMO) will be responsible for managing the cost and schedule constraints of the contract via an integrated master schedule and corresponding budget, identifying and managing program risk, and ensuring contract compliance. With the input from the mRNA project team, the PMO will be responsible for coordinating the drafting of and management to an integrated development plan. Upon execution of the contract, weekly meetings with BARDA will be held to monitor program performance and monthly and annual reports will be will delivered to BARDA for the record.

Nonclinical Toxicology (WBS 1.2)

Development and Reproductive Toxicology of mRNA (WBS 1.2.2.1)

To assess the risk of administering the vaccine to pregnant women, a complete GLP rat developmental and reproductive toxicology (DART) study is planned. Female Sprague Dawley rats will be dosed at the highest anticipated clinical dose level and include a control arm of phosphate-buffered saline (PBS). As is typical for DART evaluations for vaccines, the animals will be immunized three times prior to mating and two times during gestation. Each group will have two cohorts (one group will undergo Cesarean section with examination of the uteri and embryos; the other group will have natural delivery and will be terminated at weaning).

Nonclinical (WBS 1.3)

For the purposes of this proposal it is assumed that the VRC continues to support nonclinical activities to develop murine and non-human primate efficacy studies, and animal models to assess the potential of vaccine-enhanced disease. The scope of work below will execute additional robustness experiments in these developed models.

Assess Disease Enhancement (WBS 1.3.3.1)

(b)(4)

We plan to perform studies in mouse and NHPs to assess the theoretical risk of vaccine induced disease enhancement triggered by CoV infection following vaccination with imRNA vaccine. (b)(4)

(b)(4)

(b)(4)

(b)(4)

Establish a Surrogate of Protection (WBS 1.3.3.2)

The primary endpoint for accelerated approval of a SARS-CoV-2 vaccine would be a neutralization assay. This endpoint must be supported with a body of pre-clinical work that demonstrates a correlation between neutralizing titers and efficacy and that quantifies a protective serologic threshold titer using the same neutralization assay. Murine and NHP efficacy models are being developed in parallel to the Phase 1 clinical study. Building on data from these preliminary models and studies, Moderna will conduct NHP efficacy and murine passive transfer studies to confirm and refine the surrogate of protection.

Clinical (WBS 1.4)

(b)(4)

Phase 2 Safety and Immunogenicity Study (WBS 1.4.2.1)

(b)(4)

Phase 3 Pivotal Study:(WBS 1.4.3.1)

I. Scenario in which SARS-CoV-2 virus is circulating: In this scenario a randomized controlled trial with prevention of disease endpoint would serve to demonstrate effectiveness of the vaccine.

(b)(4)

(b)(4)

II. Scenario in the absence of SARS-CoV-2 virus: In this scenario an efficacy study becomes infeasible.

(b)(4)

Lot to Lot Consistency (WBS 1.4.3.2)

(b)(4)

Pediatrics (WBS 1.4.3.3)

(b)(4)

Regulatory (WBS 1.5)

IND Preparation and Filing (WBS 1.5.1.1)

Moderna's Regulatory Affairs group, in close collaboration with BARDA, will work to draft a comprehensive regulatory master plan to guide the preclinical, CMC and clinical development of mRNA within the first 90 days of the contract. An original investigational new drug application (IND) will be filed with the United States Food and Drug Administration (FDA) to support the clinical development of the Moderna product from Phase 2 onwards.

IND Maintenance (WBS 1.5.1.2)

The Moderna-owned IND will be maintained to support the desired clinical development plan. As needed, meetings will be conducted to receive feedback and gain concurrence on the specifics of the development activities with the FDA.

BLA Submission (WBS 1.5.2.1)

Moderna will submit a Biologics License Application (BLA) and seek approval for the mRNA vaccine.

CMC (WBS 1.6)

CTM Manufacture for Phase 2 (WBS 1.6.3.2)

(b)(4)

(b)(4)

Process Development for Late Stage Clinical Supply (WBS 1.6.3.3)

mRNA Process Development

Technical Development will confirm and optimize the process parameters for mRNA manufacture. (b)(4)

(b)(4)

(b)(4)

(b)(4)

BLA Readiness (WBS 1.6.3.8)

In support of the Biologics License Application (BLA) due to the nature of the proposed timeline, it is likely that Moderna will need to complete some of process validation activities, primarily process characterization, after the completion of process performance qualification and before BLA filing. Moderna intends to rapidly develop a robust process for clinical manufacturing and PPQ, and then fully describe the acceptable design space for the process prior to BLA filing. Other activities to support this BLA filing, such as completing raw material qualification activities; if not included in the BLA submission, will require a supplement to the initial BLA. In the initial BLA filing Moderna will describe its control strategy to cover the gap between initial BLA filing and the BLA supplement.

Process Development for Full Commercial Scale (WBS 1.6.4.1)

The following section outlines the process development activities (b)(4)

(b)(4) The goal of this work is to demonstrate the capability to produce mRNA at a scale that can support clinical demand.

(b)(4)

(b)(4)

Analytical Method Development and Validation (WBS 1.6.5.2)

(b)(4)

(b)(4)

Characterization Assay Development and Implementation (WBS 1.6.5.3)

(b)(4)

Stability Studies (WBS 1.6.5.4)

Throughout the program, many studies will be undertaken (b)(4)

(b)(4) This includes studies using development bench scale material, engineering lot material, and GMP material. This body of data will be used to apply interim and long-term shelf life to the drug product and process intermediates.

1. Intellectual Property

The parties agree that that data generated prior to entering into or outside the scope of the agreement will, when delivered to the USG, be considered to be limited rights data subject to the restrictions covered under FAR Clause 52.227-14 Alt II paragraph (g)(3). The government will obtain unlimited rights to data funded under this contract pursuant to FAR Clause 52.227-14. The parties rights to subject inventions developed during performance of this contract will be governed by the terms of FAR Clause 52.227-11

2. Use of Select Agents

As Moderna selects programs for demonstration of the platform, Moderna will defer to an HHS chaired committee of contracting, security, safety and scientific program management to assess the applicability of the facilities, regulations, policies, and procedures for meeting the U.S. requirements described in 42 CFR part 73, 7 CFR part 331, and/or 9 CFR part 121.

3. Laboratory Licenses Requirements

Moderna will comply with all applicable requirements of Section 353 of the Public Health Service Act (CLIA, as amended). This requirement shall also be included in any relevant subcontract for services under the contract.

4. Target Product Profile

(b)(4)

(b)(4)

D. PACKAGING AND MARKING (if applicable)

Unless otherwise specified by the Contracting Officer, all deliverable items to be furnished to the Government under this contract (including invoices) shall be made by first class mail, overnight carrier, or email, as described in Section F.

All physical deliverables shall be preserved, packaged, and marked in accordance with normal commercial practices to meet the packaging requirements of the carrier, including that which is necessary to prevent deterioration and damages due to the hazard of shipping, handling, and storing. The Contractor shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

E. INSPECTION AND ACCEPTANCE

E.1 Federal Acquisition Regulation Clauses Incorporated by Reference

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

The following FAR clauses, pertinent to Section E, are hereby incorporated by reference:

FAR Clause	Title	Date
52.246-2	Inspection of Supplies – Fixed Price	Aug 1996
52.246-5	Inspection of Services – Cost Reimbursement	Apr 1984
52.246-9	Inspection of Research and Development	May 2001

All work under this contract may be subject to inspection and final acceptance by the Contracting Officer or the duly authorized representative of the Government. The Contracting Officer’s Representative (COR) is a duly authorized representative of the Government and is responsible for the inspection and acceptance of all items/activities to be delivered and or completed under this contract.

F. DELIVERABLES / PERFORMANCE

F.1 Federal Acquisition Regulation Clauses Incorporated by Reference

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

The following FAR clause, pertinent to Section F, is hereby incorporated by reference:

FAR Clause	Title	Date
52.242-15	Stop-Work Order, Alternate I (Apr 1984)	Aug 1989

F.1.1 A pandemic facility and/or operational management plan including change procedures from normal to pandemic operations. Prepare an operational plan to continue operations in the event of a declared pandemic emergency (Draft within 15 days of award, Final within 30 days of award).

F.1.2 Data Management Plan

The Contractor shall develop and implement 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; provide raw data or specific analyses of data generated with contract funding to the Project Officer, upon request.

F.1.3 Standard Operating Procedures

The Contractor shall make internal and, to the extent possible, Subcontractor Standard Operating Procedures (SOPs) available for review by the Government on-site at Contractor’s facility, upon request from the COR or CO. At Contractor’s election, SOPs may be provided electronically.

F.1.4 Evaluation of Fill Finish Alternatives

The Contractor shall submit a Draft Final and Final Report describing the fill finish alternatives evaluated, the evaluation method and criteria used, cost comparison, and recommendation for which fill finish alternative to move forward. The draft report shall be due within thirty (30) days after completion of analysis. Subcontractor-prepared reports, on behalf of the Contractor, shall be submitted to the COR and CO for review and comment, no later than five (5) business days after receipt by the Contractor. BARDA shall provide written comments to the Draft Final Report within fifteen (15) days after the submission. The Final Report shall be due thirty (30) days after receiving comments on the Draft Final Report from BARDA. If corrective action is recommended, the Contractor must address, in written, all concerns raised by the Government.

F.1.5 Supply Chain Resiliency Plan

The partner contractor shall have a comprehensive Supply Chain Resiliency Program that provides for identification and reporting of critical components associated with the secure supply of drug substance, drug product, and work-in-process through to finished goods. A critical component is any material that is essential to the product or the manufacturing process associated with that product. Included in the definition are consumables and disposables associated with manufacturing. NOT included in the definition are facility and capital equipment.

Consideration of critical components includes the evaluation and potential impact of raw materials, excipients, active ingredients, substances, pieces, parts, software, firmware, labeling, assembly, testing, analytical and environmental componentry, reagents, or utility materials which are used in the manufacturing of a drug, cell banks, seed stocks, devices and key processing components and equipment. A clear example of a critical component is one where a sole supplier is utilized.

Identification of key equipment suppliers and their locations, local resources and the associated planning and control processes at the time of award is important to the security of the medical countermeasure supply chain. These processes shall address planning and scheduling for active pharmaceutical ingredients, upstream, downstream, component assembly, finished drug product and delivery events as necessary for the delivery of product. Where multi-site manufacturing is integral to the delivery of contractual materials, it should be included as part of the planning and scheduling process. Communication for these requirements shall be updated as part of an annual review, or as necessary, as part of regular contractual communications.

The focus on the aspects of resiliency shall be on critical components and aspects of complying with the contractual delivery schedule. Delivery methods shall be addressed, inclusive of items that are foreign-sourced, both high and low volume, which would significantly affect throughput and adherence to the contractually agreed deliveries.

For upstream and downstream processing, both single-use and re-usable in-place processing equipment, and manufacturing disposables also shall be addressed. For finished goods, the inspection, labeling, packaging, and associated machinery shall be addressed taking into account capacity capabilities.

The partner contractor shall communicate the methodology for inventory control, production planning, scheduling processes and ordering mechanisms, as part of those agreed deliveries. For critical items these processes should provide visibility for key items over an adequate planning horizon that ensures effective control of the established supply chain for contractual deliveries. Production rates and lead times shall be understood and communicated to the HHS/ASPR/BARDA Contracting Officer or the Contracting Officer’s Representative as necessary.

Production throughput critical constraints should be well understood by activity and by design, and communicated to contractual personnel. As necessary, communication should focus on identification, exploitation, elevation, and secondary constraints of throughput, as appropriate.

Reports for critical items may be summarized with the following template:

Critical Material Name	Vendor	Supplier, Manufacturing / Distribution Location	Supplier Lead Time	Shelf Life	Transportation / Shipping restrictions
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The CO and COR reserve the right to request unredacted copies of technical documents, during the period of performance, for distribution within the Government, and Contractor will reasonably consider any such requests. Documents shall be provided within ten (10) days after CO issues the request. The Contractor may arrange for additional time if deemed necessary, and agreed to by the CO.

F.2 Deliverables Schedule

Successful performance of the final contract shall be deemed to occur upon performance of the work set forth in the Statement of Work attached to this contract as Attachment 1 (SECTION J-List of Attachments), and upon delivery and acceptance, as required by the Statement of Work, by the Contracting Officer, or the duly authorized representative pursuant to SECTION E-Inspection and Acceptance, of the following items listed below under heading 1 “Summary of Contract Deliverables” in accordance with the stated delivery schedule.

The items specified below under heading 1 “Summary of Contract Deliverables”, as described in the Statement of Work which is Attachment 1 to this contract will be required to be delivered by the date(s) specified below and in accordance with any specifications stated in SECTION D- PACKAGING, MARKING AND SHIPPING, of this contract. All reports identified below relate solely to the development activity funded under this contract:

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.

In addition to or in replacement of electronic copies, the CO may direct the Contractor to submit the below deliverables via BARDA Digital Resources Portal in machine readable format.

Table 5

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
01	Meetings		
01.1	Post Award Teleconference	The contractor shall complete an initial teleconference after contract award 1. Outline activities for the next 30 days 2. Discuss agenda items for the post-award Kickoff Meeting (01.2)	<ul style="list-style-type: none"> • Within one week of contract award • Contractor shall provide agenda and establish a teleconference number at least 3 business days in advance of the teleconference unless notified that BARDA will supply one • COR edits/approves and instructs contractor to distribute agenda prior to meeting by at least 2 business days • Contractor provides meeting minutes to COR within 3 business days after the meeting • COR reviews, comments and approves minutes within 10 business days
01.2	Kickoff Meeting	The Contractor shall complete a Kickoff meeting after contract award	<ul style="list-style-type: none"> • Within a month of contract award, pending concurrence by the contracting officer • Contractor shall provide itinerary and agenda at least 5 business days in advance of site visit or virtual meeting • COR edits/approves and instructs contractor to distribute agenda prior to meeting by at least 3 business days • Contractor provides meeting minutes to COR within 3 business days after the meeting • COR reviews, comments, and approves minutes within 10 business days
01.3	Every 2 weeks Teleconference	The Contractor shall participate in teleconferences every 2 weeks, with BARDA to discuss the performance on the contract. Meeting frequency can be increased as needed during the course of the project	<ul style="list-style-type: none"> • Contractor provides agenda to COR no later than 2 business days in advance of meeting • COR edits/approves and instructs contractor to distribute agenda prior to meeting • Contractor distributes agenda and presentation materials at least 24 hours in advance • Contractor provides meeting minutes to COR within 3 business days of the meeting • COR reviews, comments, and approves minutes within 6 business days
01.4	Quarterly Meetings	At the discretion of the government the Contractor shall hold recurring teleconference or face-to-face Project Review Meetings up to four per year either in Washington D.C or at work sites of the Contractor or sub-contractors. Face-to-face meetings shall alternate between Washington DC and Contractor, sub-contractor sites. The meetings will be used to discuss contract progress in relation to the Program Management deliverables described below as well as study designs, technical, regulatory, and ethical aspects of the program.	<ul style="list-style-type: none"> • Contractor shall provide itinerary and agenda at least 5 business days, and presentation materials at least 3 business days in advance of site visit • COR edits/approves and instructs contractor to distribute agenda prior to meeting by at least 3 business days • Contractor provides meeting minutes to COR within 3 business days after the meeting • COR reviews, comments, and approves minutes within 10 business days
01.5	FDA Meetings	The Contractor shall forward the dates and times of any meeting with the	<ul style="list-style-type: none"> • Contractor shall notify BARDA of upcoming FDA meeting within 24 hours of scheduling

CDRL#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<p>FDA to BARDA and make arrangements for appropriate BARDA staff to attend the FDA meetings. BARDA staff shall include up to a maximum of four people (typically COR and up to 3 subject matter experts)</p>	<p>Type A, B or C meetings OR within 24 hours of meeting occurrence for ad hoc meetings</p> <ul style="list-style-type: none"> •The Contractor shall forward initial Contractor and FDA-issued draft minutes and final minutes of any meeting with the FDA to BARDA within 2 business days of receipt
01.6	<p>Daily check in with project staff for COVID-19 Contract</p>	<p>Upon request of the Government, the Contractor shall participate in a daily check-in update with the project staff (via teleconference or email).</p> <p>The updates will address key cost, schedule and technical updates. Daily updates may be shared with senior Government leaders during the COVID- 19 response and should be provided on a non-confidential basis, unless the update includes confidential information in which case Contractor shall provide the update in both confidential and non-confidential formats.</p> <p>Daily check-ins may occur on weekdays, excluding federal holidays. Upon request of the Government, check-ins may also occur on weekends and on federal holidays, provided at least 24 hours' notice.</p>	<ul style="list-style-type: none"> •No agenda will be required for the meeting •No meeting minutes are required •Contractor will provide bulleted email updates following any call or in lieu of a call by 2PM for that day

02	Technical Reporting		
<p>02.1 (Monthly)</p> <p>02.2 (Annual)</p>	<p>Monthly & Annual Technical Progress Reports/Annual Meeting</p>	<ol style="list-style-type: none"> 1. The Integrated Program Management Report (IPMR) is a contractually required report prepared by the contractor. IPMR Formats 1, 3, 5, and 6 are required. These formats will contain performance data and information derived from the contractor's internal Earned Value Management System (EVMS) and Integrated Master Schedule (IMS). The Contractor's EVMS shall comply with Earned Value Management's Seven (7) Principles. 2. An Executive Summary highlighting the progress, issues and relevant manufacturing, non-clinical, clinical and regulatory activities. The Executive Summary should highlight only critical issues for that reporting period and resolution approach; limited to 2 pages 3. BARDA Contractor Clinical Trials Information Sheet – covering ongoing BARDA-sponsored clinical studies. This form shall provide data on relevant activities during the period covered, by study site, including: 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 4. Progress in meeting contract milestones organized by WBS, overall project assessment, problems encountered and recommended solutions. The reports shall detail the planned and actual progress during the period covered, explaining any differences between the two and the corrective steps 5. A three-month rolling forecast of the key planned activities, referencing the WBS/IMS 6. A tracking log of progress on regulatory submissions with the FDA number, description of submission, date of submission, status of submission and next steps 7. Estimated and Actual Expenses <ol style="list-style-type: none"> a. This report shall also contain a narrative or table detailing whether there is a significant discrepancy (>10%) at this time between the % 	<ul style="list-style-type: none"> • Monthly Reports shall be submitted on the 20th day of the month covering the preceding month; Annual Reports submitted on the 30th calendar day of the month after each contract anniversary. Monthly progress reports are not required for the months when the Annual Report(s) are due, and Monthly/Annual Report(s) are not due during a month when the Final Report (final version, not draft) is due (see deliverable 02.4). The COR and CO will review the monthly reports with the Contractor and provide feedback • Contractor shall provide FINAL versions of reports within 10 business days after receiving BARDA comments/edits • Integrated Performance Management Report (IPMR) shall be developed according to the instructions of Data Item Description (DiD) #81861A • The CPR shall be provided on the 20th day of the month covering the preceding month, including the same month as the Annual Report(s) is due • The IPMR required formats for this Contract shall be Formats 1 (WBS), 3 (Performance Measurement Baseline Changes and Reconciliation), 5 (Variance Analysis Report – Narrative Form), and 6 (Integrated Master Schedule)

		<p>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. If the COR and CO are satisfied that the contractor's reporting is sufficient to convey this information, this section may be waived.</p>	
<p>02.3 (Draft) 02.4 (Final)</p>	<p>Draft and Final Technical Progress Report</p>	<p>A draft Final Technical Progress Report containing a summation of the work performed and the results obtained over the entire contract. This report shall be in sufficient detail to fully describe the progress achieved under all milestones. Report should contain a timeline of originally planned and baselined activities and milestones overlaid with actual progress attained during the contract. Descriptions and rationale for activities and milestones that were not completed as planned should be provided. The draft report shall be duly marked as 'Draft'</p> <p>The Final Technical Progress Report incorporating feedback received from BARDA 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. The final report shall be duly marked as 'Final'. A cover letter with the report will contain a summary (not to exceed 200 words) of salient results achieved during the performance of the contract</p>	<ul style="list-style-type: none"> •The Draft Technical Progress Report shall be submitted 75 calendar days before the end of the PoP and the Final Technical Progress Report on or before the completion date of the PoP •COR will provide feedback on draft report within 15 calendar days of receipt, which the Contractor shall consider incorporating into the Final Report
<p>02.5 (Draft) 02.6 (Final)</p>	<p>Draft and Final Study Reports, Clinical and Non-Clinical</p>	<p>Contractor shall provide Draft and Final Clinical/Non-Clinical Study Reports to BARDA for review and comment.</p>	<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 COR and CO for review and comment no later than 5 business days after receipt by Contractor •The Government will provide written comments to the Draft Report for Clinical / Non-Clinical Study reports within 15 business days after the submission •Final report due 30 calendar days after receiving comments on the Draft Final

			<p>Report for Clinical and Non-Clinical Studies: If corrective action is recommended, Contractor must address all concerns raised by BARDA in writing</p> <ul style="list-style-type: none"> •Contractor shall consider revising reports to address BARDA’s recommendations prior to FDA submission
02.7	FDA Manufacturing Reports	<p>At BARDA’s request, Contractor shall provide Manufacturing Reports to BARDA for review and comment prior to submission to FDA</p> <p>The COR and CO reserve the right to request within the PoP a non-proprietary Manufacturing Report for distribution within the USG</p>	<ul style="list-style-type: none"> •Contractor will submit Manufacturing Reports at least 15 business days prior to FDA submission •The Government will provide written comments to the manufacturing report within 15 business days after the submission •If corrective action is recommended, Contractor must address all concerns raised by BARDA in writing •Contractor shall consider revising reports to address BARDA’s concerns and/or recommendations prior to FDA submission
02.8	Product Development Source Material and Manufacturing Report	<p>The Contractor shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing sites; and location and nature of non-clinical and clinical study sites.</p>	<ul style="list-style-type: none"> •Contractor will submit Product Development Source Material Report <ul style="list-style-type: none"> ○ Within month of contract award ○ Within 30 days of substantive changes are made to sources and/or materials ○ Or on the 6th month contract anniversary. •The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days after the submission •If corrective action is recommended, Contractor must address all concerns raised by BARDA in writing
02.9	Contractor Locations	<p>The contractor shall submit detailed data regarding locations where work will be performed under this contract, including addresses, points of contact, and work performed per location, to include sub-contractors.</p>	<p>Contractor will submit Work Locations Report:</p> <ul style="list-style-type: none"> •Within 5 business days of contract award •Within 30 business days after a substantive location or capabilities change •Within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a threat that has been declared a Public Health Emergency by the HHS Secretary or a Public Health Emergency of International Concern (PHEIC) by the WHO
02.10	Clinical Report during Active Enrollment Periods	<p>The contractor shall submit detailed clinical reports during active clinical trial enrollment to include at a minimum number of subjects screened and enrolled, site activation status, safety reporting (SAEs), deviation reports and database management. Exact format TBD by COR and contractor.</p>	<p>Contractor shall submit Clinical Reports on a weekly basis starting when first patient is enrolled and ending when last patient is enrolled.</p>

02.11	Study Protocols	The contractor shall submit draft and final nonclinical and clinical study protocols to CO and COR	<p>Draft study protocols will be submitted to COR electronically prior to finalization.</p> <ul style="list-style-type: none"> ○ BARDA will provide comments within 10 days of receipt of draft protocol ○ Contractor shall respond in writing to BARDA comments and recommendations prior to finalization of protocol. <p>Final study protocols will be submitted to COR electronically no later than 10 business days prior to FDA submission</p>
02.12	Final Data Submission Package	<p>Contractor must submit a data package consisting of all raw data produced under this contract. Data may be used by BARDA for analysis, evaluation, shared with other agencies, or shared outside of the government consistent with FAR 52.227-14. This submission package must be delivered in a non-proprietary format.</p> <p>If clinical trial data is included, that data must be provided consistent with applicable privacy laws to protect personally identifiable information (PII).</p>	Contractor will submit at least 15 days prior to contract end date. Partial data-sets may also be requested for delivery prior to submission of the Final Data Submission Package.
02.13	Supplemental Technical Documents, Raw Data, or Data Analysis	Upon request and also as part of deliverables the Contractor shall provide raw data, data analysis, or data report to BARDA.	Contractor shall provide the Technical Documents upon request from the CO or COR
03	Audits		
03.1	BARDA Audit	Contractor shall accommodate periodic or ad hoc site visits by BARDA. If BARDA, 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 BARDA	<ul style="list-style-type: none"> •If issues are identified during the audit, Contractor shall submit a report to BARDA detailing the finding and 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 BARDA
03.2	FDA Audits	In the event of an FDA inspection that occurs in relation to 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	<ul style="list-style-type: none"> •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 1 business day of receiving correspondence from the FDA or third party •Within 10 business days of audit report, Contractor shall provide CO with a plan for

		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	addressing areas of nonconformance, if any are identified
03.3	QA Audits	BARDA reserves the right to participate in QA audits performed by the contractor. 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 BARDA. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action	<ul style="list-style-type: none"> •Contractor shall notify CO and COR a minimum of 10 business days in advance of upcoming, audits/site visits of subcontractors •Contractor shall notify the COR and CO within 5 business days of report completion. •COR and CO will review the report and provide a response to the Contractor with 10 business days
03.4	Risk Management Plan (RMP)	The Contractor shall provide an RMP 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	<ul style="list-style-type: none"> •A Draft is due 90 business days within contract award; updates to the RMP are due concurrent with Monthly Technical Progress Reports. The contractor may choose to notify the government up to two times every three months if there are no changes from the prior submission, and not submit an update •BARDA will provide Contractor with a list of concerns in response plan submitted •Contractor must address, in writing, all concerns raised by BARDA within 20 business days of Contractor's receipt of BARDA's concerns
03.5	Integrated Master Schedule (IMS)	The contractor shall provide an IMS that illustrates project tasks, dependencies, durations throughout the period of performance, and milestones (GO/NO-GO). The IMS must map to the WBS, and provide baseline, and actual or forecast dates for completion of tasks	<ul style="list-style-type: none"> •The IMS is to be submitted in both PDF and Microsoft Project Form to the COR •The first Draft of the IMS is due 30 business within contract award •The Government will request revisions within 10 business days, at which point the schedule baseline for the period of performance will be set •Thereafter an updated IMS is due concurrent with Monthly Technical Progress Reports
03.6	Deviation Notification and Mitigation Strategy	Process for changing IMS activities associated with cost and schedule as baselined. Contractor shall notify BARDA of significant proposed 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	<ul style="list-style-type: none"> •Due at least 10 business days prior to the Contractor anticipating the need to implement changes

		shall provide a high level management strategy for risk mitigation	
03.7	Incident Report	Contractor shall communicate to BARDA and document all critical programmatic concerns, issues, or probable risks that have or are likely to significantly impact project schedule and/or cost and/or performance. "Significant" is frequently defined as a 10% or greater cost or schedule variance within a control account, but should be confirmed in consultation with the COR. Incidents that present liability to the project even without cost/schedule impact, such as breach of GCP during a clinical study, must also be reported	<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 • If corrective action is deemed necessary, Contractor must address in writing, its consideration of concerns raised by BARDA within 5 business days of receiving such concerns
09	Advanced R&D Products		
09.1	Technical Documents	Upon request, Contractor shall provide CO and COR with deliverables from the following contract funded activities: quality agreements between contractors and sub-contractors, process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, Certificate of Analysis, Clinical Studies Data or Reports. The CO and COR reserve the right to request within the PoP a non-proprietary technical document for distribution within the Government	<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 BARDA in writing
09.2	Animal Model or Other Technology Transfer Package	Contractor shall provide Animal Model or Other Technology Transfer Package containing relevant methodology and data sufficient to enable other practitioners in the field to successfully replicate experimental conditions developed and tested with BARDA support	<ul style="list-style-type: none"> • Contractor shall provide a draft package within 20 business days of COR or CO request • Contractor shall revise the package to address BARDA's concerns, recommendations and/or requests for additional detail
09.3	Raw Data or Data Analysis	Contractor shall provide raw data or data analysis to BARDA upon request	<ul style="list-style-type: none"> • Contractor shall provide raw data or data analysis to CO and COR within 20 business days of request
09.4	Publications	Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted to BARDA for review prior to submission. Acknowledgment of BARDA funding must be included as noted in contract articles H.9 and H.24	<ul style="list-style-type: none"> • Contractor must submit all manuscript or scientific meeting abstract to PO and CO prior to submission/presentation by 30 business days for manuscripts and 15 business days for abstracts or posters • Contractor must address in writing all concerns raised by BARDA in writing • Final submissions shall be submitted to BARDA concurrently or no later than one (1) calendar day of its submission
10	Regulatory Documents		

10.1	FDA Correspondence	The Contractor shall memorialize any correspondence between Contractor and FDA and submit to BARDA	<ul style="list-style-type: none"> • Contractor shall provide copies of any FDA correspondence within 2 business days of correspondence
10.2	FDA Submissions	The Contractor shall provide BARDA the opportunity to review and comment upon all draft submissions before submission to the FDA. Contractor shall provide BARDA 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 BARDA at least 15 business days prior to FDA submission • BARDA will provide feedback to Contractor within 10 business days of receipt • The Contractor must address, in writing, its consideration of all concerns raised by BARDA prior to FDA submission • Final FDA submissions shall be submitted to BARDA concurrently or no later than 1 calendar day of submission
11	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"> • 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 BARDA no later than one (1) calendar day prior to its release

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 DELIVERIES 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.

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 DELIVERIES 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.

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 DELIVERIES 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 CO and COR reserve the right to request within the Period of Performance a non-proprietary 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 BARDA.

B. Deliverables Arising from FDA Correspondence

i. FDA Meetings

The Contractor shall forward the dates and times of any meeting with the FDA to BARDA and make arrangements for appropriate BARDA staff to attend the FDA meetings. BARDA staff shall include up to a maximum of four people.

- Contractor shall notify BARDA 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 BARDA within 5 business days of receipt. All documents shall be duly marked as either "Draft" or "Final."

ii. FDA Submissions

The Contractor shall provide BARDA all documents submitted to the FDA.

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

- When draft documents are submitted for BARDA review, BARDA will provide feedback to Contractor within 3 business days of receipt.
- When BARDA reviews draft documents, the Contractor shall revise their documents to address BARDA's written concerns and/or recommendations prior to FDA submission.
- Final FDA submissions shall be submitted to BARDA concurrently or no later than 1 calendar day 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 Contractor's receipt of those documents. The Contractor shall provide the CO and COR 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 plan's 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.

- 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 BARDA for review and comment prior to submission to FDA.

The CO and COR reserve the right to request within the Period of Performance (PoP) a non-proprietary 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 shall address, in writing, the concerns raised by BARDA.
- Contractor shall revise the reports to address BARDA's concerns and/or recommendations prior to FDA submission.
- Final FDA submission shall be submitted to BARDA 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.

i. **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
- BARDA shall provide Contractor with a written list of concerns in response plan submitted
- Contractor must address, in writing, all concerns raised by BARDA within 20 business days of Contractor's receipt of BARDA's concerns.

3. Contract WBS Milestones/Deliverables and Technical Deliverables

Work Breakdown Structure (WBS), Go/No Go Program Stage Gates Gantt Chart, Integrated Master Schedule (IMS)



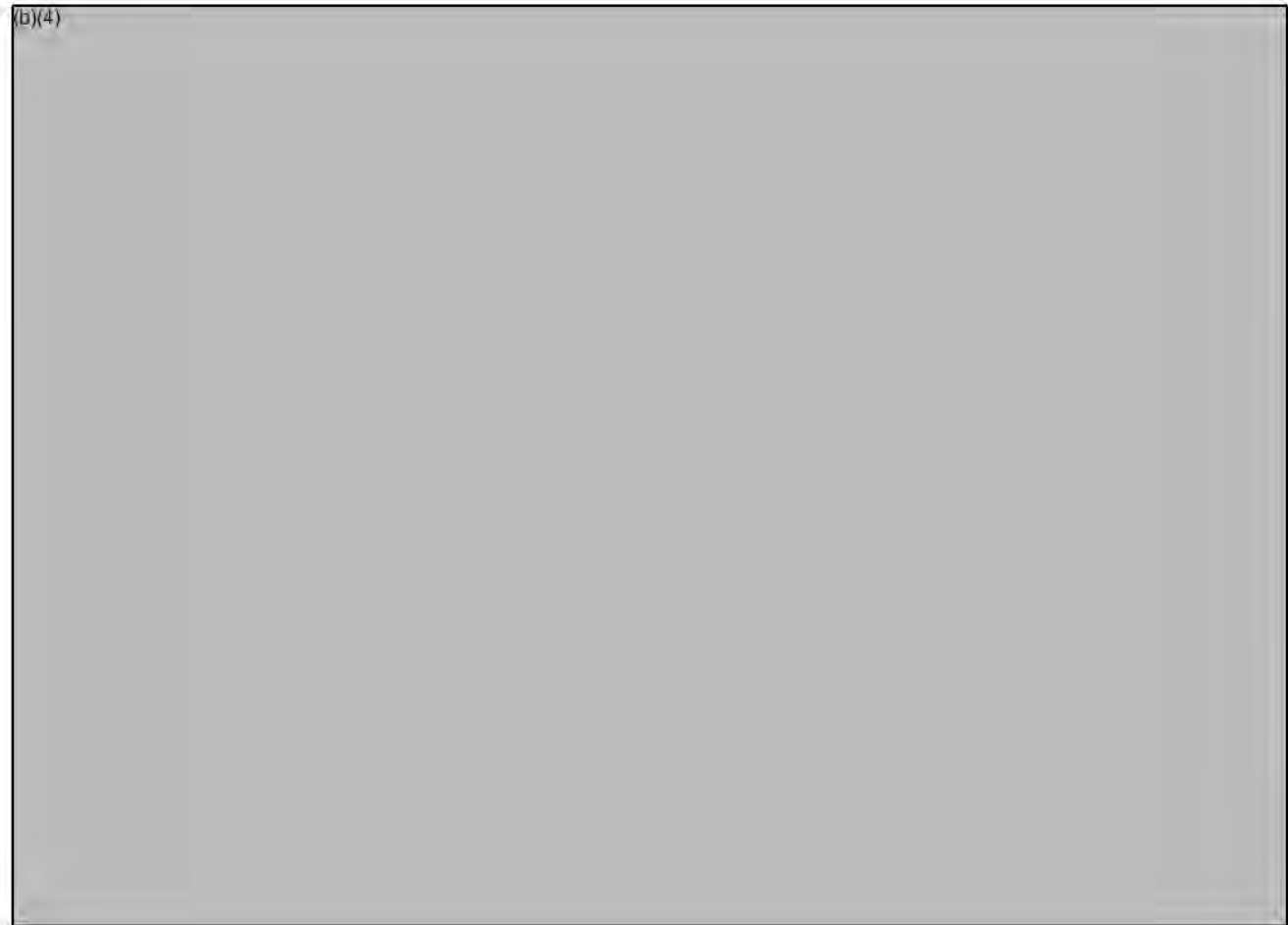
(b)(4)



Integrated Program Gantt Chart

Gantt Chart of Moderna's Proposal "Development of an mRNA Vaccine mRNA vaccine"

(b)(4)



Deliverables

The primary deliverable of this proposal is a licensed mRNA vaccine. In addition, the team, in partnership with BARDA, will also design a plan to enhance Moderna’s ability to rapidly respond to a Coronavirus pandemic by leveraging our mRNA platform. Interim deliverables are presented below.

WBS	Title	Deliverable	(b)(4)
1	mRNA Vaccine Development		
1.1	Program Management		
1.1.1	Program and Alliance Management	-Management Plans; Routine Reporting Deliverables	
1.2	Nonclinical Toxicology		
1.2.2	Safety		
1.2.2.1	Development and Reproductive Toxicology	- Final Study Report	
1.3	Nonclinical		
1.3.1	Model Development (reserved)		
1.3.1.2	NHP Efficacy Study	- Final Study Report	
1.3.1.3	Mouse Efficacy Study	- Final Study Report	
1.4	Clinical		
1.4.2	Phase 2		
1.4.2.1	Phase 2 Safety and Immunogenicity Study	- Clinical Study Protocol - Final Clinical Study Report	
1.4.3	Phase 3		
1.4.3.1	Phase 3 Efficacy or Safety and Immunogenicity	- Clinical Study Protocol - Final Clinical Study Report	
1.4.3.2	Phase 3 Lot-to-Lot	- Clinical Study Protocol - Final Clinical Study Report	
1.4.3.3	Phase 3 Adolescents	- Clinical Study Protocol - Final Clinical Study Report	
1.5	Regulatory		
1.5.1	IND		
1.5.1.1	IND Filing	- NA	
1.5.1.2	IND Maintenance	- Record of FDA Communications	
1.5.2	BLA		
1.5.2.1	BLA Submission	- NA	
1.6	CMC		
1.6.3	Pilot Scale Manufacturing		
1.6.3.2	CTM Manufacture for P201	- CoA for Clinical Lots	
1.6.3.4	CTM Manufacture for P301	- CoA for Clinical Lots	
1.6.3.6	CTM Manufacture for P302/P303	- CoA for Clinical Lots	

(b)(4)



G. CONTRACT ADMINISTRATION

G.1 Contracting Officer

The Contracting Officer (CO) 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.

The Contracting Officer is the only individual with authority to act as agent of the Government under this Contract, with authority to (1) direct or negotiate any changes in the statement of work, (2) modify or extend the period of performance, (3) authorize reimbursement to the Contractor for any costs incurred during the performance of this Contract and/or (5) otherwise change any terms and conditions of this Contract.

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

Wendell Conyers – (202) 692-4784 – wendell.conyers@hhs.gov – Office No. 21K13
Supervisory Contract Specialist Division of Contracts Management & Acquisition (CMA)
Biomedical Advanced Research & Development Authority (BARDA)

G.2 Contracting Officer’s Representative

As delegated by the CO, the Contracting Officer’s Representative (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 CO in interpreting the statement of work and any other technical performance requirements; (3) performing technical evaluation as required; (4) performing technical inspections required by this contract; and (5) assisting in the resolution of technical problems encountered during performance.

Chuong Huynh – (202) 260-2177 – chuong.huynh@hhs.gov – Office No.
Project Officer / COR for Development Activities
Influenza and Emerging Infectious Diseases Division
Biomedical Advanced Research & Development Authority (BARDA)

G.3 Deliveries

All deliveries of physical documents, shall be addressed in the following format:

UPS/FedEx/USPS
U.S. Department of Health & Human Services <i>Insert Recipient’s Name</i> HHS/ASPR/BARDA <i>Insert Office Number</i> – O’Neill House Office Building, 2 nd Floor Washington, DC 20515 <i>Insert Recipient’s Telephone Number</i>

G.4 Invoicing Instructions

Invoices for payment shall be submitted to the Contracting Officer and Contracting Officer’s Representative, as one (1) hard copy and one (1) electronic copy addressed in the format indicated in G.3, shall follow the detailed invoicing instructions listed in Section J, and include an SF-1034.

CO	COR	Alternate COR	PSC
Wendell Conyers (Contracting Officer) HHS/ASPR/BARDA/CMA O’Neill House Office Building Room Number 21C06 Washington, DC 20515 Email: wnedell.conyers@hhs.gov	Chuong Huynh (COR) HHS/ASPR/BARDA O’Neill House Office Building Room Number 24K24 Washington, DC 20515 <u>TBD</u>	TBD Alt COR HHS/ASPR/BARDA O’Neill House Office Building Room Number 24K13 Washington, D.C.20515 <u>TBD</u>	PSC_Invoices@psc.hhs.gov y & “HHS e-Room” (shared access may be provided to

			the Contractor after award).
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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 Government.
- 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%) of the estimated costs for the base period or any option period(s) (See estimated costs under Section B) and the reasons for the variance. These requirements are in addition to the specified requirements of FAR 52.232-20, Limitation of Cost that is incorporated by reference under Section I.I which states:

Limitation of Cost (Apr 1984)

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.

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

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

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.

As part of the notification, the Contractor shall provide the Contracting Officer a revised estimate of the total cost of performing this contract. Except as required by other provisions of this contract, specifically citing and stated to be an exception to this clause—

- 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
- 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.
- 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.
- 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.
- 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.
- 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 52.232-25, Prompt Payment (Oct 2008).
- g. Invoices - Cost and Personnel Reporting, and Variances from the Negotiated Budget.
- h. 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:

- 1. Direct Labor - List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or % of effort), and amount claimed.
- 2. Fringe Benefits - Cite rate and amount
- 3. Overhead - Cite rate and amount
- 4. Materials & Supplies - Include detailed breakdown when total amount is over \$100,000
- 5. 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.
- 6. Consultant Fees - Identify individuals, amounts and activities. Cite appropriate COA
- 7. Subcontracts - Attach subcontractor invoice(s). Cite appropriate COA
- 8. Equipment - Cite authorization and amount. Cite appropriate COA
- 9. Other Direct Costs - Include detailed breakdown when total amount is over \$100,000.
- 10. G&A - Cite rate and amount.
- 11. Total Cost (and applicable cost-shared ratio)
- 12. Fixed Fee (if applicable)
- 13. 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 Section J-List of Attachments, Invoice/Financing Request Instructions and Contract Financial Reporting Instructions for 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 shall be signed and submitted electronically (in accordance with Section F.3 Electronic Submission).

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 Costs of CLIN 0001 and 0002 in Section B of the contract.

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

The electronic version of the invoice can be submitted via e-mail or uploaded through HHS' eRoom (shared access may be provided to the Contractor after award).

The Government may request additional information (timecards, receipts, etc.) to support costs claimed in the Contractor's invoices. Incomplete invoices may be suspended by the Contracting Officer if the Contractor's claimed costs cannot be substantiated.

G.5 REIMBURSEMENT OF COST

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 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:

- 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.

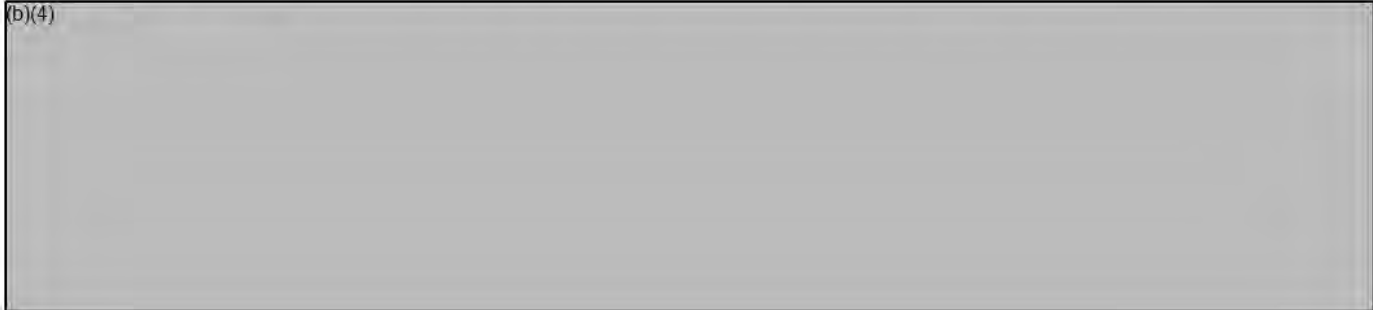
- c) All other items of cost budgeted for and accepted in the negotiation of this basic contract or modifications thereto.
- d) Travel costs including per diem or actual subsistence for personnel while in an actual travel status in direct performance of the work and services required under this contract subject to the following:
 - (i) Air travel shall be by the most direct route using "air coach" or "air tourist" (less than first class or business class) unless it is clearly unreasonable or impractical (e.g., not available for reasons other than avoidable delay in making reservations, would require circuitous routing or entail additional expense offsetting the savings on fare, or would not make necessary connections).
 - (ii) Rail travel shall be by the most direct route, first class with lower berth or nearest equivalent.
 - (iii) Costs incurred for lodging, meals, and incidental expenses shall be considered reasonable and allowable to the extent that they 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.

G.6 Providing Accelerated Payment to Small Business Subcontractors, FAR 52.232-40 (Dec. 2013)

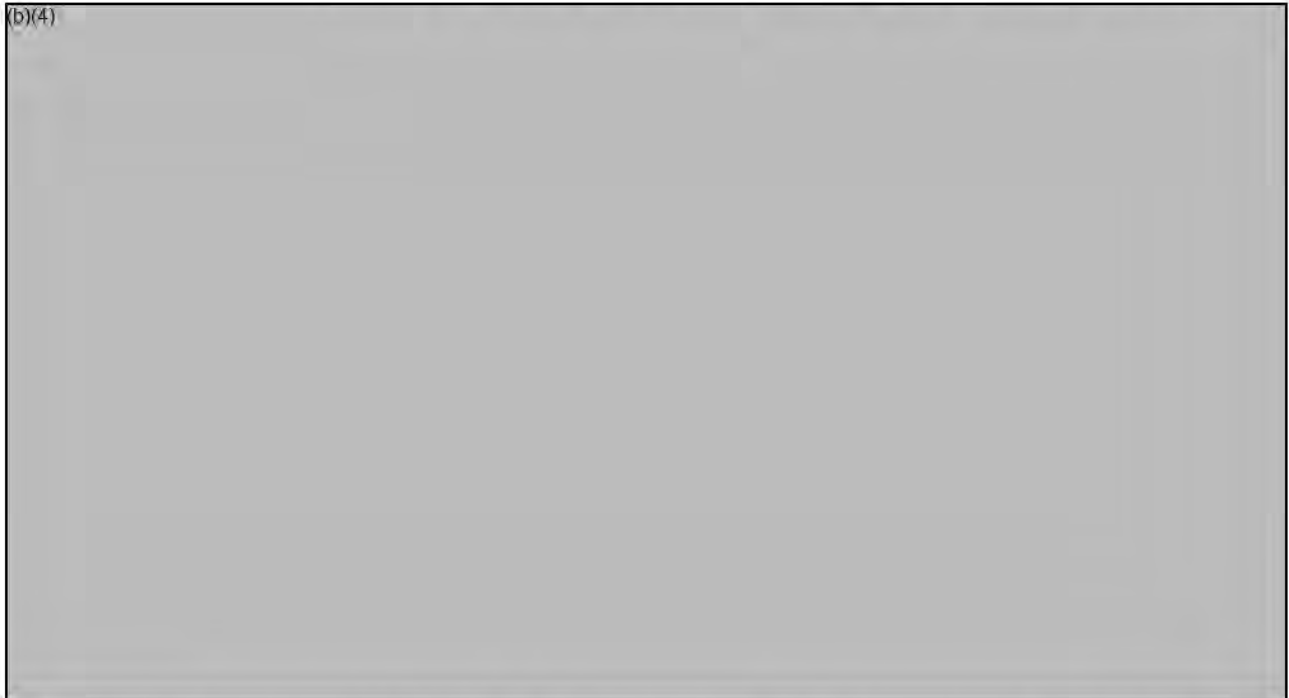
- (a) Upon receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, 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, include this paragraph c, in all subcontracts with small business concerns, including subcontracts with small business concerns for the acquisition of commercial items.

G.7 Contract Communication/Correspondence

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



(b)(4)



3. In accordance with FAR Part 5.216-7(d), the contractor shall submit an adequate final indirect cost rates proposal to the contracting officer within the 6-months period following the end of its fiscal years during the period of contract performance

G.9 Post-Award Evaluation of Contractor Performance

- (a) *Purpose:* In accordance with FAR 42.1502(a), past performance evaluations shall be prepared at least annually and at the time the work under a contract or order is completed, via CPARS, the Government-wide evaluation tool (www.cpars.gov).
- (b) *Evaluators:* The performance evaluation will be completed jointly by the Contracting Officer's Representative and the Contracting Officer.
- (c) *Performance Evaluation Factors:* Per FAR 42.1503(b)(2), evaluation factors for each assessment shall include, at a minimum: technical (quality of product or service); cost control; schedule/timeliness; management and business relations; small business subcontracting; other (as applicable).
- (d) *Contractor Review:* A copy of the evaluation will be electronically sent to the Contractor as soon as practicable after completion of the evaluation. The Contractor shall submit comments, rebutting statements, or additional information to the Contracting Officer within 14 calendar days after receipt of the evaluation.
- (e) *Resolving Disagreements between the Government and the Contractor:* Disagreements between the parties regarding the evaluation will be reviewed at a level above the Contracting Officer. The ultimate conclusion on the performance evaluation is a decision of the contracting agency. Copies of the evaluation, Contractor's response, and review comments, if any, will be retained as part of the evaluation.
- (f) *Release of Contractor Performance Evaluation Information:* The completed evaluation will not be released to other than Government personnel and the Contractor whose performance is being evaluated. Disclosure of such information could cause harm both to the commercial interest of the Government and to the competitive position of the Contractor being evaluated, as well as impede the efficiency of Government operations.
- (g) *Source Selection Information:* Departments and agencies may share past performance information with other Government departments and agencies when requested to support future award decisions. The information may be provided through interview and/or by sending the evaluation and comment document to the requesting source selection official.
- (h) *Retention Period:* The agency will retain past performance information for a maximum period of 3 years after completion of contract performance for the purpose of providing source selection information for future contract awards.

H. SPECIAL CONTRACT REQUIREMENTS

H.1 Access and Disposition of Data

The Government shall have physical and electronic access to all documentation and data generated under this contract, including: all Contractor efforts; Subcontractor efforts; communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, meeting minutes, and all Contractor commitments and responses.

H.2 Interactions with the Food and Drug Administration (FDA)

The Contractor shall memorialize any interactions between the Contractor and the FDA, and submit documentation to the COR and CO. All documents shall be duly marked as either "Draft" or "Final."

H.2.1 FDA Correspondence

Contractor shall provide written summary of any FDA correspondence within five (5) business days of correspondence.

H.2.2 FDA Meetings

The Contractor shall forward the dates and times of any meeting with the FDA to the COR and CO, 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).

- (1) Contractor shall notify the COR and CO 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.
- (2) The Contractor shall forward initial Contractor and FDA-issued draft and final minutes of any meeting with the FDA, to the COR and CO, within 2 business days of receipt. All documents shall be duly marked as either "Draft" or "Final."

H.2.3 FDA Pre-Submissions, Submissions, and Other Related Correspondence

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

- (1) Contractor shall submit draft FDA submissions to the COR and CO at least 15 business days prior to FDA submission.
- (2) The COR and CO will provide feedback to Contractor within 5 business days of receipt.
- (3) If corrective action is recommended, the Contractor must address, in writing, its consideration of all concerns raised by the COR and CO.
- (4) The Contractor shall consider revising their documents to address the COR and CO's concerns and/or recommendations prior to FDA submission.
- (5) Final FDA submissions shall be submitted to the COR and CO concurrently or no later than 1 calendar day of its submission to FDA

H.2.4 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). 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.

- (1) 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.
- (2) 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.
- (3) Within 10 business days of audit report, Contractor shall provide CO and COR with a plan for addressing areas of nonconformance, if any are identified.

H.3 Key Personnel

Pursuant to HHSAR 352.237-75 (Dec 2015), Key Personnel, any key personnel specified in this contract are considered to be essential to work performance. At least thirty (30) calendar days prior to the Contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the

replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the Contractor is terminated for cause or separates from the Contractor voluntarily with less than thirty (30) calendar-day notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties. The following individuals are determined to be key personnel:

(b)(4)



H.3.1 Personnel Qualifications

The Contractor shall provide curriculum vitae (CV) for each individual identified as key personnel. The CV shall clearly describe the individual's knowledge, work experiences, registrations, and certifications, and applicable experience. The CV shall include a summary describing the individual's involvement in similar work.

H.4 Substitution of Key Personnel

- a. The Contractor agrees to assign to the contract those persons whose resumes/CVs were submitted with the proposal who are necessary to fill the requirements of the contract. No substitutions shall be made except in accordance with this clause.
- b. All requests for substitution must provide a detailed explanation of the circumstance necessitating the proposed substitution, a complete resume for the proposed substitute and any other information requested by the contracting officer to approve or disapprove the proposed substitution. All proposed substitutes must have qualifications that are equal to or higher than the qualifications of the person to be replaced. The contracting officer or authorized representative will evaluate such requests and promptly notify the contractor of his approval or disapproval thereof.
- c. The contractor further agrees to include the substance of this clause in any subcontract, which may be awarded under this contract.

H.5 Contracting Officer's Authorization (COA) for Subcontracting

The Contractor shall submit a Contracting Officer's Authorization (COA) approval request, to the Contracting Officer, for all subcontractors, consultants and equipment purchases proposed during the course of this contract. COAs for subcontractors and consultant agreements shall be submitting when the potential subcontract is expected to exceed \$150,000; for equipment purchases, when the unit price per item is expected to exceed \$25,000. Sufficient time shall be provided for the Government to fully assess the transaction proposed. The supporting documents shall include, but not be limited to:

1. Competition activities, as well as technical and cost/price evaluation activities performed, in the selection of the subcontractor(s);
2. The subcontractor's qualifications/capabilities statement as they pertain to the activities included in the proposed subcontract;
3. The subcontractor's willingness to perform under the Contractor (i.e. commitment letters/preliminary agreements), with a list of specific duties included in the proposed subcontract;
4. A complete subcontractor cost proposal or quote, in similar format as the Contractor's cost proposal.

H.6 No Personal Services or Inherently Governmental Function

Pursuant to FAR 37.1, no personal services shall be performed under this contract. All work requirements shall flow only from the COR to the Contractor's Project Manager. No Contractor employee will be directly supervised by the Government. All employee assignments, and daily work direction, shall be given by the applicable Contractor supervisor. If the Contractor believes any Government action or communication has been given that would create a personal services relationship between the Government and any Contractor employee, the Contractor shall promptly notify the Contracting Officer of this communication or action.

Pursuant to FAR 7.5, the Contractor shall not perform any inherently governmental actions under this contract. No Contractor employee shall hold him or herself out to be a Government employee, agent, or representative. No Contractor employee shall state orally or in writing at any time that he or she is acting on behalf of the Government. In all communications with third parties in connection with this contract, Contractor employees shall identify themselves as Contractor employees and specify the name of the company for which they work. In all communications with other Government Contractors in connection with this contract, the Contractor employee shall state that they have no authority to in any way change this contract and that if the other Contractor believes this communication to be a direction to change their contract, they shall notify the Contracting Officer for that contract and not carry out the direction until a clarification has been issued by the Contracting Officer.

The Contractor shall ensure that all of its employees working on this contract are informed of the substance of this article. Nothing in this article shall limit the Government's rights in any way under the other provisions of this contract, including those related to the Government's right to inspect and accept the services to be performed under this contract. The substance of this article shall be included in all subcontracts at any tier.

H.7 Acknowledgement of Federal Funding – Publication and Publicity

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

"This project has been funded in whole or in part with Federal funds from the Office of the Assistant Secretary for Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. 75A50120C00034."

Press Releases:

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

H.8 352.270-4b, Protection of Human Subjects (Dec 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.

(End of clause)

H.9 HHSAR 352.270-5a, Notice to Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (Dec 2015)

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 awarding a contract to an offeror, 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, offerors must establish an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members, to oversee the institution's animal program, facilities, and procedures. Offerors must provide verification of IACUC approval prior to receiving 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 involving live vertebrate animals of the Assurance and verification of IACUC approval requirement. 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).

(End of provision)

H.10 HHSAR 352.270-5b, Care of Life Vertebrate Animals (Dec 2015)

(a) Before undertaking performance of any contract involving animal-related activities where the species is regulated by the United States Department of Agriculture (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 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 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 Animal Welfare 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 (Email: ace@aphis.usda.gov; Web site: <http://www.aphis.usda.gov/wps/portal/aphis/ourfocus/animalwelfare>)

(End of clause)

H.11 Animal Welfare

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

H.12 Dissemination of False or Deliberately Misleading Information

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

H.13 Electronic Information and Technology Accessibility Notice

- a. Section 508 of the Rehabilitation Act of 1973 (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 and the Architectural and Transportation Barriers Compliance Board Electronic and Information (EIT) Accessibility Standards (36 CFR part 1194), require that when Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.
- b. Accordingly, any Offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at <http://www.hhs.gov/web/508>. The complete text of the Section 508 Final Provisions can be accessed at <http://www.access-board.gov/sec508/standards.htm>.
- c. The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-74, Electronic and Information Technology Accessibility.

In order to facilitate the Government's determination whether proposed EIT supplies meet applicable Section 508 accessibility standards, Offerors must submit an HHS Section 508 Product Assessment Template, in accordance with its completion instructions. The purpose of the template is to assist HHS acquisition and program officials in determining whether proposed EIT supplies conform to applicable Section 508 accessibility standards. The template allows Offerors or developers to self-evaluate their supplies and document--in detail--whether they conform to a specific Section 508 accessibility standard, and any underway remediation efforts addressing conformance issues. Instructions for preparing the HHS Section 508 Evaluation Template are available under Section 508 policy on the HHS Web site <http://hhs.gov/web/508>.

In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, Offerors must provide enough information to assist the Government in determining that the EIT services conform to Section 508 accessibility standards, including any underway remediation efforts addressing conformance issues.

- d. Respondents to this solicitation must identify any exception to Section 508 requirements. If a Offeror claims its supplies or services meet applicable Section 508 accessibility standards, and it is later determined by the Government, i.e., after award of a contract or order, that supplies or services delivered do not conform to the described accessibility standards, remediation of the supplies or services to the level of conformance specified in the contract will be the responsibility of the Contractor at its expense.
(End of provision)

H.14 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 Government will furnish to the Contractor or that the Contractor is expected to generate which is confidential. 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 shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.
- f. Contracting Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.
- g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, State or local laws.

H.15 Institutional Responsibility Regarding Investigator Conflicts of Interest

The Institution (includes any Contractor, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Contractors, which promotes objectivity in research by establishing standards to ensure that Investigators (defined as the project director or principal Investigator and any other person, regardless of title or position,

who is responsible for the design, conduct, or reporting of research funded under 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. 45 CFR Part 94 is available at the following Web site: <http://www.ecfr.gov/cgi-bin/textidx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45>

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

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

Significant financial interests do not include the following:

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

- h. Maintain records relating to all Investigator disclosures of financial interests and the Institution's review of, and response to, such disclosures, and all actions under the Institution's policy or retrospective review, if applicable, for at least 3 years from the date of final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.
- i. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.
- j. Complete the certification in Section K - Representations, Certifications, and Other Statements of Contractors titled "Certification of Institutional Policy on Financial Conflicts of Interest".

If the failure of an Institution to comply with an Institution's financial conflicts of interest policy or a financial conflict of interest management plan appears to have biased the design, conduct, or reporting of the BARDA funded research, the Institution must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will consider the situation and, as necessary, take appropriate action or refer the matter to the Institution for further action, which may include directions to the Institution on how to maintain appropriate objectivity in the 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 Institution's review of, and response to, such disclosure, regardless of whether the disclosure resulted in the Institution's determination of a financial conflict of interests. The Contracting Officer may require submission of the records or review them on site. On the basis of this review of records or other information that may be available, the Contracting Officer may decide that a particular financial conflict of interest will bias the objectivity of the 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 Part 94.6(b). The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that 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 managed or reported by the Institution, the Institution 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.

H.16 Reporting Matters Involving Fraud, Waste and Abuse

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

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

H.17 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 Pub. 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.

H.18 FAR 52.227-14, Rights in Data – General (May 2014), Alternate II (December 2007)

As prescribed in FAR 27.409(b)(3), the following paragraph is inserted into (g)(3) of the basic clause:

(g)(3) Notwithstanding paragraph (g)(1) of this clause, the contract may identify and specify the delivery of limited rights data, or the Contracting Officer may require by written request the delivery of limited rights data that has been withheld or would otherwise be entitled to be withheld. If delivery of that data is required, the Contractor shall affix the following "Limited Rights Notice" to the data and the Government will treat the data, subject to the provisions of paragraphs (e) and (f) of this clause, in accordance with the notice:

Limited Rights Notice (Dec 2007)

(a) These data are submitted with limited rights under Government Contract No. 75A50120C00034 and subcontracts. 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, if any; provided that the Government makes such disclosure subject to prohibition against further use and disclosure:

- (i) Use (except for manufacture) by support service.
- (b) This notice shall be marked on any reproduction of these data, in whole or in part.

(End of notice)

PART II – CONTRACT CLAUSES

I. CONTRACT CLAUSES

I.1 52.252-2 Clauses Incorporated by Reference (Feb 1998)

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

The following FAR clauses, pertinent to Section I, are hereby incorporated by reference:

FAR Clause	Title	Date
52.202-1	Definitions	Nov 2013
52.203-3	Gratuities	Apr 1984
52.203-5	Covenant Against Contingent Fees	May 2014
52.203-6	Restrictions on Subcontractor Sales to the Government	Sep 2006
52.203-7	Anti-Kickback Procedures	May 2014
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity	May 2014
52.203-10	Price or Fee Adjustment for Illegal or Improper Activity	May 2014
52.203-12	Limitation on Payments to Influence Certain Federal Transactions	Oct 2010
52.203-13	Contractor Code of Business Ethics and Conduct	Oct 2015
52.203-14	Display of Hotline Poster(s)	Oct 2015
52.203-17	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights	Apr 2014
52.203-19	Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements	Jan 2017
52.204-1	Administrative Matters Provisions and Clauses	Dec 1989
52.204-4	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper	May 2011
52.204-7	System for Award Management	Oct 2018
52.204-10	Reporting Executive Compensation and First-Tier Subcontract Awards	Oct 2018
52.204-13	System for Award Management Maintenance	Oct 2018
52.204-16	Commercial and Government Entity Code Reporting	Jul 2016
52.204-17	Ownership of Control or Offeror	Jul 2016
52.204-18	Commercial and Government Entity Code Maintenance	Jul 2016
52.204-19	Incorporation by Reference of Representations and Certifications	Dec 2014
52.204-23	Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities	Jul 2018
52.209-5	Certification Regarding Responsibility Matters	Oct 2015
52.209-6	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment	Oct 2015
52.209-9	Updates of Publicly Available Information Regarding Responsibility Matters	Oct 2018
52.209-10	Prohibition on Contracting with Inverted Domestic Corporations	Nov 2015
52.210-1	Market Research	Apr 2011
52.215-2	Audit and Records – Negotiation	Oct 2010
52.215-8	Order of Precedence - Uniform Contract Format	Oct 1997
52.215-10	Price Reduction for Defective Cost or Pricing Data	Aug 2011
52.215-11	Price Reduction for Defective Certified Cost or Pricing Data—Modifications.	Aug 2011
52.215-12	Subcontractor Certified Cost or Pricing Data	Oct 2010

Contract No. 75A50120C00034 Development of an mRNA Vaccine for SARS-CoV-2

52.215-13	Subcontractor Certified Cost or Pricing Data—Modifications	Oct 2010
52.215-14	Integrity of Unit Prices (Over SAT)	Oct 2010
52.215-15	Pension Adjustments and Asset Reversions	Oct 2010
52.215-18	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) other than Pensions	Jul 2005
52.215-19	Notification of Ownership Changes	Oct 1997
52.215-20	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data)	Oct 2010
52.215-21	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data -Modifications	Oct 2010
52.215-22	Limitations on Pass-Through Charges—Identification of Subcontract Effort	Oct 2009
52.215-23	Limitations on Pass-Through Charges	Oct 2009
52.216-7	Allowable Cost and Payment	Aug 2018
52.216-8	Fixed Fee	Jun 2011
52.217-8	Option to Extend Services [<i>within thirty (30) calendar days from contract expiration.</i>]	Nov 1999
52.219-8	Utilization of Small Business Concerns	Oct 2018
52.219-28	Post-Award Small Business Program Representation	July 2013
52.222-1	Notice to the Government of Labor Disputes	Feb 1997
52.222-2	Payment for Overtime Premiums [<i>*\$0.00</i>]	July 1990
52.222-3	Convict Labor	Jun2003
52.222-21	Prohibition of Segregated Facilities	Apr 2015
52.222-24	Pre-award On-Site Equal Opportunity Compliance Evaluation	Feb 1999
52.222-26	Equal Opportunity	Sept 2016
52.222-35	Equal Opportunity for Veterans (\$150,000 or more)	Oct 2015
52.222-36	Equal Opportunity for Workers with Disabilities	Jul 2014
52.222-37	Employment Reports on Veterans	Feb 2016
52.222-38	Compliance with Veterans' Employment Reporting Requirements	Feb 2016
52.222-40	Notification of Employee Rights Under the National Labor Relations Act	Dec 2010
52.222-50	Combating Trafficking in Persons	Jan 2019
52.222-54	Employment Eligibility Verification	Oct 2015
52.223-6	Drug-Free Workplace	May 2001
52.223-18	Encouraging Contractor Policy to Ban Text Messaging While Driving	Aug 2011
52.224-1	Privacy Act Notification	April 1984
52.224-2	Privacy Act	April 1984
52.224-3	Privacy Training	Jan 2017
52.225-13	Restrictions on Certain Foreign Purchases	Jun 2008
52.225-25	Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran—Representation and Certifications	Aug 2018
52.227-1	Authorization and Consent	Dec 2007
52.227-2	Notice and Assistance Regarding Patent and Copyright Infringement	Dec 2007
52.227-11	Patent Rights-Ownership by the Contractor	May 2014
52.227-14	Rights in Data – General	May 2014
52.227-14	Rights in Data – General, Alternate II (Dec 2007)	May 2014
52.228-7	Insurance – Liability to Third Persons	Mar 1996
52.232-9	Limitation on Withholding of Payments	Apr 1984

52.232-17	Interest	May 2014
52.232-20	Limitation of Cost	Apr 1984
52.232-23	Assignment of Claims	May 2014
52.232-25	Prompt Payment Alt I	Jan 2017
52.232-33	Payment by Electronic Funds Transfer--System for Award Management	Oct 2018
52.232-39	Unenforceability of Unauthorized Obligations	Jun 2013
52.232-40	Providing Accelerated Payments to Small Business Subcontractors	Dec 2013
52.233-1	Disputes	May 2014
52.233-3	Protest After Award, Alternate I (Jun 1985)	Aug 1996
52.233-4	Applicable Law for Breach of Contract Claim	Oct 2004
52.242-1	Notice of Intent to Disallow Costs	Apr 1984
52.242-3	Penalties for Unallowable Costs	May 2014
52.242-4	Certification of Final Indirect Costs	Jan 1997
52.242-13	Bankruptcy	Jul 1995
52.243-2	Changes—Cost-Reimbursement, Alternate I (Apr 1984)	Apr 1984
52.243-2	Changes—Cost-Reimbursement, Alternate V (Apr 1984)	Aug 1987
52.243-6	Change Order Accounting	Apr 1984
52.243-7	Notification of Changes	Jan 2017
52.244-2	Subcontracts, Alternate I (Jun 2007)	Oct 2010
52.244-5	Competition in Subcontracting	Dec 1996
52.244-6	Subcontracts for Commercial Items	Jan 2019
52.245-1	Government Property	Jan 2017
52.245-9	Use and Charges	Apr 2012
52.246-25	Limitation of Liability—Services	Feb 1997
52.249-6	Termination (Cost-Reimbursement)	May 2004
52.249-14	Excusable Delays	Apr 1984
52.253-1	Computer Generated Forms	Jan 1991

1.2 Department of Health and Human Services Acquisition Regulation (HHSAR) Clauses

Full text of HHSAR clauses may be accessed electronically at this address: <http://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar>

HHSAR Clause	Title	Date
352.203-70	Anti-Lobbying	Dec 2015
352.208-70	Printing and Duplication	Dec 2015
352.222-70	Contractor Cooperation in Equal Employment Opportunity Investigations	Dec 2015
352.223-70	Safety and Health	Dec 2015
352.224-71	Confidential Information	Dec 2016
352.227-70	Publications and Publicity	Dec 2015
352.231-70	Salary Rate Limitation	Dec 2015
352.233-71	Litigation and Claims	Dec 2015
352.237-75	Key Personnel	Dec 2015
352.239-74	Electronic and Information Technology Accessibility	Dec 2015
352.270-9	Non-discrimination for Conscience	Dec 2015

I.3 Additional Contract Clauses

I.3.1 Additional Federal Acquisition Regulation (FAR) Clauses in Full Text

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 thirty (30) calendar days; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least thirty (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 five (5) years and six (6) months.

(End of Clause)

52.203-18 Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements--Representation (Jan 2017)

a) Definition. As used in this provision—

“Internal confidentiality agreement or statement”, “subcontract”, and “subcontractor”, are defined in the clause at 52.203-19, Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements.

b) In accordance with section 743 of Division E, Title VII, of the Consolidated and Further Continuing Appropriations Act, 2015 (Pub. L. 113-235) and its successor provisions in subsequent appropriations acts (and as extended in continuing resolutions), Government agencies are not permitted to use funds appropriated (or otherwise made available) for contracts with an entity that requires employees or subcontractors of such entity seeking to report waste, fraud, or abuse to sign internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting such waste, fraud, or abuse to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information.

c) The prohibition in paragraph (b) of this provision does not contravene requirements applicable to Standard Form 312, (Classified Information Nondisclosure Agreement), Form 4414 (Sensitive Compartmented Information Nondisclosure Agreement), or any other form issued by a Federal department or agency governing the nondisclosure of classified information.

d) Representation. By submission of its offer, the Offeror represents that it will not require its employees or subcontractors to sign or comply with internal confidentiality agreements or statements prohibiting or otherwise restricting such employees or subcontractors from lawfully reporting waste, fraud, or abuse related to the performance of a Government contract to a designated investigative or law enforcement representative of a Federal department or agency authorized to receive such information (e.g., agency Office of the Inspector General).

(End of provision)

52.222-35 Equal Opportunity Veterans (Oct 2015)

a) Definitions. As used in this clause—

“Active duty wartime or campaign badge veteran,” “Armed Forces service medal veteran,” “disabled veteran,” “protected veteran,” “qualified disabled veteran,” and “recently separated veteran” have the meanings given at FAR 22.1301.

b) Equal opportunity clause. The Contractor shall abide by the requirements of the equal opportunity clause at 41 CFR 60-300.5(a), as of March 24, 2014. This clause prohibits discrimination against qualified protected veterans, and requires affirmative action by the Contractor to employ and advance in employment qualified protected veterans.

c) Subcontracts. The Contractor shall insert the terms of this clause in subcontracts of \$150,000 or more unless exempted by rules, regulations, or orders of the Secretary of Labor. The Contractor shall act as specified by the Director, Office of Federal Contract Compliance Programs, to enforce the terms, including action for noncompliance. Such necessary changes in language may be made as shall be appropriate of identify properly the parties and their undertakings.

(End of Clause)

52.222-36 Equal Opportunity for Workers with Disabilities (Jul 2014)

- a) Equal opportunity clause. The Contractor shall abide by the requirements of the equal opportunity clause at 41 CFR 60.741.5(a), as of March 24, 2014. This clause prohibits discrimination against qualified individuals on the basis of disability, and requires affirmative action by the Contractor to employ and advance in employment qualified individuals with disabilities.
- b) Subcontracts. The Contractor shall include the terms of this clause in every subcontract or purchase order in excess of \$15,000 unless exempted by rules, regulations, or orders of the Secretary, so that such provisions will be binding upon each subcontractor or vendor. The Contractor shall act as specified by the Director, Office of Federal Contract Compliance Programs of the U.S. Department of Labor, to enforce the terms, including action for noncompliance. Such necessary changes in language may be made as shall be appropriate to identify properly the parties and their undertakings.

(End of Clause)

PART III – LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

J. LIST OF ATTACHMENTS

- Attachment 2: INVOICING INSTRUCTIONS FOR COST REIMBURSEMENT CONTRACTS
- Attachment 3: SAMPLE INVOICE/PAYMENT REQUEST AND CONTRACT FINANCIAL REPORT
- Attachment 4: FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT
- Attachment 5: INSTRUCTION FOR COMPLETING FINANCIAL REPORT OF INDIVIDUAL PROJECT/CONTRACT
- Attachment 6: INCLUSION ENROLLMENT REPORT
- Attachment 7: RESEARCH PATIENT CARE COSTS
- Attachment 8: CONTRACTING SITE – CONTRACT NUMBER – INVENTORY SHEET
- Attachment 9: DISCLOSURE OF LOBBYING ACTIVITIES
- Attachment 10: DATA ITEM DESCRIPTION
- Attachment 11: SEVEN PRINCIPLES OF EARNED VALUE MANAGEMENT LITE

ATTACHMENT #2

INVOICE/FINANCING REQUEST 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 G of the Contract Schedule.

Frequency: Payment requests shall not be submitted more frequently than once every two weeks in accordance with the Allowable Cost and Payment Clause incorporated into this contract. 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 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 site 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 government 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, including those 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 G 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. Include numbering in format of year_month #.
- (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. For incrementally funded contracts/orders, enter the amount currently obligated and available for payment.

(h) **Total Fixed-Fee:** Insert the total fixed-fee (where applicable) or the portion of the fixed-fee applicable to a particular invoice as defined in the contract.

(i) **Two-Way/Three-Way Match:** Identify whether payment is to be made using a two-way or three-way match. To determine required payment method, refer to the Invoice Submission Instructions in SECTION G of the Contract Schedule.

(j) **Office of Acquisitions:** Insert the name of the Office of Acquisitions, as identified in the Invoice Submission Instructions 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) **Direct Labor:** Include salaries and wages paid (or accrued) for direct performance of the contract. List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or % of effort), breakdown by task performed by personnel, and amount claimed.

(2) **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.

(3) **Accountable Personal Property:** Include any property having a unit acquisition cost of \$5,000 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* (<https://archive.org/details/contractorsguide00unit>) (e.g. personal computers). Note this is not permitted for reimbursement without pre-authorization from the CO.

On a separate sheet of paper attached to the payment request, list each item for which reimbursement is requested. 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.

(4) **Materials and Supplies:** Include all consumable material and supplies regardless of amount. Detailed line-item breakdown (e.g. receipts, quotes, etc.) is required.

(5) **Premium Pay:** List remuneration in excess of the basic hourly rate.

(6) **Consultant Fee:** List fees paid to consultants. Identify consultant by name or category as set forth in the contract or COA, as well as the effort (i.e., number of hours, days, etc.) and rate billed.

(7) **Travel:** Include domestic and foreign travel. Foreign travel is travel outside of Canada, the United States and its territories and possessions. However, for an organization located outside Canada, the United States and its territories and possessions, foreign travel means travel outside that country. Foreign travel must be billed separately from domestic travel.

(8) **Subcontract Costs:** List subcontractor(s) by name and amount billed. Provide subcontract invoices/receipts as backup documentation. If subcontract is of the cost-reimbursement variety, detailed breakdown will be required. Regardless, include backup documentation (e.g. subcontractor invoices, quotes, etc.).

- (9) **Other:** Include all other direct costs not fitting into an aforementioned category. 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, if applicable.
- (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 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 HHS Salary Rate Limitation Provisions in Section H of the contract."

**Note the Contracting Officer may require the Contractor to submit detailed support for costs claimed on payment requests. Every cost must be determined to be allocable, reasonable, and allowable per FAR Part 31.

Attachment 3 - SAMPLE INVOICE/PAYMENT REQUEST AND CONTRACT FINANCIAL REPORT

<p>(a) Designated Billing Office Name and Address:</p> <p style="margin-left: 20px;">ATTN: Contracting Officer U.S. Department of Health & Human Services Office of the Assistant Secretary for Preparedness and Response Biomedical Research and Development Authority Contract Management and Acquisition (CMA) O'Neill House Office Building Room Number: 21C06 Washington, DC 20515</p> <p>(b) Contractor's Name, Address, Point of Contact, VIN, and DUNS or DUNS+4 Number:</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>(i) <input type="checkbox"/> Two-Way Match: _____ <input type="checkbox"/> Three-Way Match: _____</p> <p>(j) Office of Acquisitions: _____</p> <p>(k) Central Point of Distribution: _____</p>
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(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 4

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)
	Negotiate	Actual							
A	B	C	D	E	F	G	H	I	J

Attachment 5
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 the Government in monitoring the application of financial and personnel resources to the BARDA funded 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 electronic copy of the report(s) shall be sent to the contracting officer at the address shown in the contract, no later than 30 working days after the end of the period reported. However, the contract may provide for a copy to be sent directly to the Contracting Officer's 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.

Attachment 6
INCLUSION ENROLLMENT REPORT

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

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

Attachment 7 - Research Patient Care Costs

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.

Attachment 8 - Report of Government Owned, Contractor Held Property

REPORT OF GOVERNMENT OWNED, CONTRACTOR HELD PROPERTY							
CONTRACTOR:				CONTRACT NUMBER:			
ADDRESS:				REPORT DATE:			
ADDRESS1:							
ADDRESS2:				FISCAL YEAR:			
CITY:							
STATE:							
ZIP:							
CLASSIFICATION	BEGINNING OF PERIOD		ADJUSTMENTS			END OF PERIOD	
	#ITEMS	VALUE	GFP ADDED	CAP ADDED	DELETIONS	#ITEMS	VALUE
LAND >=\$25K							
LAND <\$25K							
OTHER REAL >=\$25K							
OTHER REAL <\$25K							
PROPERTY UNDER CONST >=\$25K							
PROPERTY UNDER CONST <\$25K							
PLANT EQUIP >=\$25K							
PLANT EQUIP <\$25K							
SPECIAL TOOLING >=\$25K							
SPECIAL TOOLING <\$25K							
SPECIAL TEST EQUIP >=\$25K							
SPECIAL TEST EQUIP <\$25K							
AGENCY PECULIAR >=\$25K							
AGENCY PECULIAR <\$25K							
MATERIAL >=\$25K (CUMULATIVE)							
PROPERTY UNDER MFR >=\$25K							
PROPERTY UNDER MFR <\$25K							
SIGNED BY:							
SIGNATURE				DATE SIGNED:			
NAME PRINTED				Email			
TITLE				TELEPHONE			

Report of Government Owned, Contractor Held Property (Rev 10/2014)

DISCLOSURE OF LOBBYING ACTIVITIES

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

(See reverse for public burden disclosure.)

<p>1. Type of Federal Action:</p> <p><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</p>	<p>2. Status of Federal Action:</p> <p><input type="checkbox"/> a. bid/offer/application <input type="checkbox"/> b. initial award <input type="checkbox"/> c. post-award</p>	<p>3. Report Type:</p> <p><input type="checkbox"/> a. initial filing <input type="checkbox"/> b. material change</p> <p>For Material Change Only: year _____ quarter _____ date of last report _____</p>
<p>4. Name and Address of Reporting Entity:</p> <p><input type="checkbox"/> Prime <input type="checkbox"/> Subawardee Tier _____, if known:</p> <p>Congressional District, if known: 4c</p>	<p>5. If Reporting Entity in No. 4 is a Subawardee, Enter Name and Address of Prime:</p> <p>Congressional District, if known:</p>	
<p>6. Federal Department/Agency:</p>	<p>7. Federal Program Name/Description:</p> <p>CFDA Number, if applicable: _____</p>	
<p>8. Federal Action Number, if known:</p>	<p>9. Award Amount, if known:</p> <p>\$ _____</p>	
<p>10. a. Name and Address of Lobbying Registrant (if individual, last name, first name, MI):</p>	<p>b. Individuals Performing Services (including address if different from No. 10a) (last name, first name, MI):</p>	
<p>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.</p>	<p>Signature: _____ Print Name: _____ Title: _____ Telephone No.: _____ Date: _____</p>	
<p>Federal Use Only:</p>		<p>Authorized for Local Reproduction Standard Form LLL (Rev. 7-97)</p>

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.

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.)

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.

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.

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.

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.

DI-MGMT-81466A

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



TABLE OF CONTENTS

OVERVIEW	1
EVM IMPLEMENTATION TIERS	3
SEVEN PRINCIPLES OF EVM	4
Principle 1: Plan all Work Scope	4
Principle 2: Break Work into Finite Pieces and Define Person/Organization Responsible for Work	4
Principle 3a: Integrate Scope, Schedule and Budget into a Performance Measurement Baseline	5
Principle 3b: Control Changes to the Baseline	6
Principle 4: Use Actual Costs Incurred and Recorded in Accomplishing the Work Performed	7
Principle 5: Objectively Assess Accomplishments at the Work Performance Level	7
Principle 6a: Analyze Significant Variances From the Plan	8
Principle 6b: Prepare an Estimate at Completion Based on Performance to Date and Work to be Performed	9
Principle 7: Use EVMS Information in the Company's Management Processes	9
APPENDICES	11
APPENDIX 1: Glossary of Terms	11
Appendix 2 Supplemental EVM Implementation Guideline	21
Appendix 3 Sample EVM Documents	24

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.

7 Principles of EVM Tier 2 System Implementation Intent Guide

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.

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 earn 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

7 Principles of EVM Tier 2 System Implementation Intent Guide

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.

7 Principles of EVM Tier 2 System Implementation Intent Guide

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>

(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.

7 Principles of EVM Tier 2 System Implementation Intent Guide

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

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

7 Principles of EVM Tier 2 System Implementation Intent Guide

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

7 Principles of EVM Tier 2 System Implementation Intent Guide

	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

7 Principles of EVM Tier 2 System Implementation Intent Guide

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.

7 Principles of EVM Tier 2 System Implementation Intent Guide

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

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

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

7 Principles of EVM Tier 2 System Implementation Intent Guide

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

7 Principles of EVM Tier 2 System Implementation Intent Guide

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

Sample Control Account Plan