UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15 (d) OF
THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): September 10, 2018

SIGA TECHNOLOGIES, INC.

(Exact name of registrant as specified in its charter)

Delaware	**0-23047**	**13-3864870**
(State or other jurisdiction of incorporation or organization)	(Commission file number)	(I.R.S. employer identification no.)
31 East 62nd Street **New York, New York** (Address of principal executive offices)		**10065** (Zip code)

Registrant's telephone number, including area code: (212) 672-9100

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01. Entry into a Material Definitive Agreement.

On September 10, 2018, SIGA Technologies, Inc., a Delaware corporation (the "Company"), issued a press release announcing that it has signed a multi-year contract (the "New BARDA Contract") with the Biomedical Advanced Research and Development Authority ("BARDA"), a division of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response, for the delivery of oral and intravenous (IV) formulations of TPOXX® ("TPOXX"), the Company's antiviral treatment for smallpox, to the Strategic National Stockpile. The New BARDA Contract also covers advanced development of the IV formulation of TPOXX and post-marketing activities for the oral formulation of TPOXX. The New BARDA Contract is valued at up to $629 million, and consists of a five-year base period of performance and a total contract period of performance (base period plus option exercises) of up to ten years (if necessary). The contract contains base period activities and a series of options, and is designed to maintain a stockpile of 1.7 million courses of antiviral treatment for smallpox.

Under the New BARDA Contract, base period activities are valued at approximately $52 million and include:

- Development activities for the IV formulation of TPOXX (IV TPOXX).
- Delivery to the Strategic National Stockpile of a limited number of courses (approximately 35,700 courses) of the oral formulation of TPOXX (oral TPOXX) for an approximate value of $11 million; such courses being readily available for delivery or to be manufactured using currently-held active pharmaceutical ingredient.
- Delivery of bulk drug substance to be used for the manufacture of IV TPOXX and the use of such bulk drug substance to manufacture 20,000 courses of final drug product of IV TPOXX, with such activities having a total value of $8 million for 7-day (14-vial) courses; additionally, the Company will be paid for the storage, if applicable, and delivery of final drug product of IV TPOXX.

With options valued at approximately $577 million in total (if all options are fully exercised), the New BARDA Contract is primarily comprised of options that are exercisable at the sole discretion of BARDA.

Options within the contract include:

- Series of options to procure up to approximately 1,452,300 courses in total of oral TPOXX (exclusive of the courses to be purchased for base period activities), with such options having a total value of up to approximately $450 million.
- Series of options to procure up to 192,000 courses in total (exclusive of the courses to be purchased for base period activities) of final drug product of IV TPOXX, with such options having a cumulative total value of up to approximately $77 million for the combination of bulk drug substance and final drug product manufacturing; or alternatively, to procure up to 192,000 equivalent courses in total (exclusive of the equivalent courses to be purchased for base period activities) of bulk drug substance that could be used in the future for the manufacture of final drug product of IV TPOXX, with such alternative having a value of up to approximately $31 million.
- Series of options for vendor-managed storage of either bulk drug substance that would be used in the manufacture of the IV TPOXX or final drug product of IV TPOXX (total option value of approximately $6 million).
- Separate options to cumulatively provide up to approximately $44 million of funding for post-marketing activities for oral TPOXX and IV TPOXX.

The New BARDA Contract becomes the third active contract between the Company and BARDA. Under its May 2011 procurement contract with BARDA, BARDA funded late-stage development of oral TPOXX for the treatment of smallpox, which culminated in the U.S. Food and Drug Administration (FDA) approval on July 13, 2018, and the acquisition of 2 million courses of oral TPOXX, which the Company has delivered. Under a development contract with BARDA, the Company receives funding from BARDA for the development of the IV formulation of TPOXX to provide a treatment option for patients who are too sick or unable to swallow oral capsules. It is anticipated that patients taking the IV formulation would eventually transition to the oral formulation, once they are able to swallow capsules. To accommodate this dosing regimen, the New BARDA Contract includes an initial order and options for the purchase of up to 212,000 treatment courses (in total) of IV therapy, and each treatment course is expected to cover seven (7) days (14 vials) of treatment. Oral TPOXX approval and procurement is based upon 14 total days of therapy.

The foregoing description is qualified in its entirety by reference to the New BARDA Contract, a copy of which is attached as Exhibit 10.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(d) The following exhibits are included in this report:

Exhibit No.	Description
10.1	Contract, dated as of September 10, 2018, between SIGA Technologies, Inc. and the Biomedical Advanced Research and Development Authority of the United States Department of Health and Human Services (portions of this exhibit have been omitted and separately filed with the Securities and Exchange Commission with a request for confidential treatment).
99.1	Press Release, dated September 10, 2018.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

SIGA TECHNOLOGIES, INC.

By: /s/ Daniel J. Luckshire
Name: Daniel J. Luckshire
Title: Chief Financial Officer

Date: September 10, 2018

Exhibit 10.1

AWARD/CONTRACT	1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700) ▶	RATING	PAGE OF PAGES 1	48
2. CONTRACT *(Proc. Inst. Indent.)* NO. HHS0100201800019C	3. EFFECTIVE DATE See Block 20C	4. REQUISITION/PURCHASE/PROJECT NO. OS227460		

5. ISSUED BY CODE HHS/OS/ASPR/BARDA	6. ADMINISTERED BY *(If other than Item 5)* CODE ASPR-BARDA01
US DEPT OF HEALTH & HUMAN SERVICES ASST SEC OF PREPAREDNESS & RESPONSE ACQ MANAGEMENT, CONTRACTS, & GRANTS O'NEILL HOUSE OFFICE BUILDING Washington DC 20515	ASPR-BARDA 330 Independence Ave, SW, Rm G644 Washington DC 20201

7. NAME AND ADDRESS OF CONTRACTOR *(No., street, county, State and ZIP Code)*	8. DELIVERY ☐ FOB ORIGIN ☒ OTHER *(See below)*
SIGA TECHNOLOGIES, INC. 1385150 SIGA TECHNOLOGIES, INC. 31 East 62nd street NEW YORK NY 100658446	9. DISCOUNT FOR PROMPT PAYMENT
	10. SUBMIT INVOICES (4 copies unless otherwise specified) TO THE ADDRESS SHOWN IN ▶ ITEM
CODE 1385150 FACILITY CODE	
11. SHIP TO/MARK FOR CODE HHS	12. PAYMENT WILL BE MADE UP BY CODE PSC
HHS 200 Independence Avenue, SW Washingyon DC 20201	PSC
13. AUTHORITY FOR USING OTHER THAN FULL AND OPEN COMPETITION ☐ 10 U.S.C. 2304 (C) ( ) ☐ 41U.S.C. 253 (C) ( )	14. ACCOUNTING AND APPROPRIATION DATA 2018.199TWNP.26402

15A. ITEM NO	15B. SUPPLIES/SERVICES	15C. QUANTITY	15D. UNIT	15E. UNIT PRICE	15F. AMOUNT
	Continued				
			15G. TOTAL AMOUNT OF CONTRACT ▶		$51,641,805.00

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

17. ☒ CONTRACTOR'S NEGOTIATED AGREEMENT *(Contractor is required to sign this document and return 1 copies to issuing office.)* Contractor agrees to furnish and deliver all items or perform all the services set forth or otherwise identified above and on any continuation sheets for the consideration stated herein. The rights and obligations of the parties to this contract shall be subject to and governed by the following documents: (a) this award/contract, (b) the solicitation, if any, and (c) such provisions, representations, certifications, and specifications, as are attached or incorporated by reference herein. *(Attachments are listed herein.)*

18. ☒ SEALED-BID AWARD *(Contractor is not required to sign this document.)* Your bid on Solicitation Number 18-100-SOL-00011, including the additions or changes made by you which additions or changes are set forth in full above, is hereby accepted as to the items listed above and on any continuation sheets. This award consummates the contract which consists of the following documents: (a) the Government's solicitation and your bid, and (b) this award/contract. No further contractual document is necessary. (Block 18 should be checked only when awarding a sealed-bid contract.)

19A. NAME AND TITLE OF SIGNER *(Type or print.)*	20A. NAME OF CONTRACTING OFFICER
Phillip L. Gomez, III, CEO	BROOKE T. BERNOLD
19B. NAME OF CONTRACTOR	19C. DATE SIGNED
BY /s/ Phillip L. Gomez, III *(Signature of person authorized to sign.)*	10 SEPT 2018
20B. UNITED STATES OF AMERICA	20C. DATE SIGNED
BY /s/ Brooke T. Bernold *(Signature of the Contracting Officer.)*	10 SEPT 2018

PART I – THE SCHEDULE

SECTION B – SUPPLIES OR SERVICES AND PRICES/COSTS

ARTICLE B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

This contract covers the purchase and delivery of at least one antiviral against smallpox disease as caused by the smallpox virus. SIGA will provide up to 1.7 million treatment courses of the antiviral(s) against smallpox.

Medical countermeasures (MCM) against smallpox are urgently needed should a future outbreak of this disease occur; while smallpox was declared eradicated by the WHO in 1980, advances in genetic engineering, the possibility of clandestine stocks in addition to the WHO-sanctioned smallpox repositories in the Russian Federation and in the United States make the possibility of an outbreak or an intentional release of smallpox a present threat. The 2016 Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Strategy and Implementation Plan identifies smallpox virus as a high-priority threat as determined by the Secretary of Homeland Security. Strategies to mitigate the threat of smallpox include the development and stockpiling of vaccines for the general population as well as the development of therapeutic antivirals to treat symptomatic cases of smallpox. BARDA is seeking an antiviral therapeutic(s) that can be safely and effectively used for the U.S. civilian population in individuals with symptomatic orthopoxvirus (e.g. smallpox) infections.

The United States Government (USG) desires an antiviral product which can be available both in a parenteral and nonparenteral (e.g. IV and oral dosing formulations) to be stored in the Centers for Disease Control and Prevention (CDC) Strategic National Stockpile (SNS), or stored as vendor-managed inventory (VMI), that can meet the PHEMCE product requirements for therapeutic MCMs for smallpox. This notice seeks candidate antivirals which are available both in a parenteral and nonparenteral formulation, which have efficacy data in at least two animal models accepted by the FDA for evaluation of smallpox countermeasures as a result of the Antiviral Drugs Advisory Committee meeting (Dec 14-15, 2011 – e.g. rabbitpox and monkeypox), and data demonstrating the candidate antiviral is safe and well tolerated in human subjects. Under this RFP, BARDA plans to support the procurement of smallpox antiviral(s), which will either be delivered to the SNS or maintained as VMI, using Project BioShield (PBS) funds. PBS fund will also support the necessary late-stage development to complete the regulatory pathway for approval of the product(s) being procured (if applicable) and/or efforts related to post-marketing commitments.

The contract will also support the necessary late-stage development to achieve approval of the alternative formulation of the product(s) being procured.

Under the base period-of-performance, SIGA will complete remaining development activities necessary to achieve licensure of the antiviral and manufacture and deliver antiviral product. The contract options may be exercised to perform additional studies necessary for licensure, support post-licensure commitments as required by the FDA, and procure additional antiviral regimens.

The Research and Development (R&D) effort will progress in specific stages that cover the base performance segment and options, if necessary, as specified in this contract. The period of performance for the base period is 60 months. The period of performance for the base period and all options shall not exceed 10 years.

*** Certain material has been omitted pursuant to a request for confidential treatment. Such omitted material has been filed separately with the Securities and Exchange Commission.**

ARTICLE B.2. BASE PERIOD

Base Period Cost Reimbursement CLIN					
CLIN	**Period of Performance**	**Supplies/Services**	**Estimated Cost**	**Fixed Fee**	**Cost + Fixed Fee (CPFF)**
0001 (Base)	[redacted]*	Late stage development activities towards FDA approval for a **parenteral (IV)** antiviral	[redacted]*	[redacted]*	32,009,375

Base Period Fixed Price CLINs					
CLIN	**Period of Performance**	**Supplies/Services**	**Treatment Courses (# of Product)**	**Unit Price ($)**	**Total ($)**
0002 (Base)	[redacted]*	Initial purchase and delivery of a **nonparenteral (oral)** formulated antiviral as final drug product (FDP) to SNS.	35,718	[redacted]*	$11,072,580
0003 (Base)	[redacted]*	Initial procurement of **parenteral (IV)** formulated antiviral as bulk drug substance (BDS) *course = 14 vials	20,000	[redacted]*	$3,200,000
0004 (Base)	[redacted]*	Fill/finish of final drug product (from bulk drug substance procured under CLIN0003).	20,000	[redacted]*	4,800,000
0005 (Base)	[redacted]*	Storage of final drug product in VMI for 5 years (from bulk drug substance procured under CLIN0003). *Monthly rate/TC = [redacted]*	20,000	[redacted]*	[redacted]*
0006 (Base)	[redacted]*	Delivery of FDP to the SNS (from bulk drug substance procured under CLIN0003)	20,000	[redacted]*	[redacted]*

ARTICLE B.3. OPTION PRICES

Optional Cost Reimbursement CLINs					
CLIN	**Period of Performance**	**Supplies/ Services**	**Total Est. Cost**	**Fixed Fee**	**Total Cost Plus Fixed Fee ($)**
0007 (Option)	[redacted]*	Phase IV post marketing commitments (**nonparenteral (oral)** formulation) including [redacted]*	[redacted]*	[redacted]*	$40,812,609
0008 (Option)	[redacted]*	Phase IV post marketing commitments (**parenteral (IV)** formulation) including [redacted]*	[redacted]*	[redacted]*	$3,586,806

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Optional Fixed Price CLINs					
CLIN	**Period of Performance**	**Supplies/Services**	**Treatment Courses (# of Product)**	**Unit Price ($)**	**Total ($)**
0009 (Option)	[redacted]*	Additional procurement of **nonparenteral (oral)** formulated antiviral as FDP and delivery to the SNS	363,070	[redacted]*	$112,551,700
0010 (Option)	[redacted]*	Additional procurement of **nonparenteral (oral)** formulated antiviral as FDP and delivery to the SNS	363,070	[redacted]*	$112,551,700
0011 (Option)	[redacted]*	Additional procurement of a **nonparenteral (oral)** formulated antiviral as FDP and delivery to the SNS	363,070	[redacted]*	$112,551,700
0012 (Option)	[redacted]*	Additional procurement of **nonparenteral (oral)** formulated antiviral as FDP and delivery to the SNS	363,072	[redacted]*	$112,552,320
0013 (Option)	[redacted]*	Surge Capacity – Additional procurement of **parenteral (IV)** formulated antiviral as bulk drug substance (BDS) *course = 14 vials	64,000	[redacted]*	$10,240,000
0014 (Option)	[redacted]*	Surge Capacity – Storage of **parenteral (IV)** formulated antiviral as bulk drug substance (BDS) in VMI for 5 years (from bulk drug substance procured under CLIN0013). *Monthly rate per TC = [redacted]*	64,000	[redacted]*	[redacted]*
0015 (Option)	[redacted]*	Surge Capacity –Fill/finish of final drug product (from bulk drug substance procured under CLIN0013)	64,000	[redacted]*	$15,360,000
0016 (Option)	[redacted]*	Surge Capacity – Storage of final drug product in VMI for 5 years (from bulk drug substance procured under CLIN0013). *Monthly rate per TC = [redacted]*	64,000	[redacted]*	[redacted]*

*** Certain material has been omitted pursuant to a request for confidential treatment. Such omitted material has been filed separately with the Securities and Exchange Commission.**

0017 (Option)	[redacted]*	Surge Capacity – Delivery of FDP to the SNS (from bulk drug substance procured under CLIN0013) *[redacted]*	64,000	[redacted]*	[redacted]*
0018 (Option)	[redacted]*	Surge Capacity – Additional procurement of **parenteral (IV)** formulated antiviral as bulk drug substance (BDS) *course = 14 vials	64,000	[redacted]*	$10,240,000
0019 (Option)	[redacted]*	Surge Capacity – Storage of **parenteral (IV)** formulated antiviral as bulk drug substance (BDS) in VMI for 5 years (from bulk drug substance procured under CLIN0018). *Monthly rate per TC = [redacted]*	64,000	[redacted]*	[redacted]*
0020 (Option)	[redacted]*	Surge Capacity –Fill/finish of final drug product from bulk drug substance procured under CLIN0018).	64,000	[redacted]*	$15,360,000
0021 (Option)	[redacted]*	Surge Capacity – Storage of final drug product in VMI for 5 years (from bulk drug substance procured under CLIN0018). *Monthly rate per TC: [redacted]*	64,000	[redacted]*	[redacted]*
0022 (Option)	[redacted]*	Surge Capacity – Delivery of FDP to the SNS (from bulk drug substance procured under CLIN0018). [redacted]*	64,000	[redacted]*	[redacted]*
0023 (Option)	[redacted]*	Surge Capacity – Additional procurement of **parenteral (IV)** formulated antiviral as bulk drug substance (BDS) *course = 14 vials	64,000	[redacted]*	$10,240,000
0024 (Option)	[redacted]*	Surge Capacity – Storage of **parenteral (IV)** formulated antiviral as bulk drug substance (BDS) in VMI for 5 years (from bulk drug substance procured under CLIN0023). *Monthly rate per TC = [redacted]*	64,000	[redacted]*	[redacted]*
0025 (Option)	[redacted]*	Surge Capacity –Fill/finish of final drug product (from bulk drug substance procured under CLIN0023).	64,000	[redacted]*	$15,360,000
0026 (Option)	[redacted]*	Surge Capacity – Storage of final drug product in VMI for 5 years (from bulk drug substance procured under CLIN0023). *Monthly rate per TC: [redacted]*	64,000	[redacted]*	[redacted]*
0027 (Option)	[redacted]*	Surge Capacity – Delivery of FDP to the SNS (from bulk drug substance procured under CLIN0023). *[redacted]*	64,000	[redacted]*	[redacted]*

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ARTICLE B.4. 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) Rearrangement or alteration of facilities;
c) Purchase of lease of any item of general purpose office furniture or office equipment regardless of dollar value (General purpose equipment is defined as any items of personal property which are usable for purposes other than research, such as office equipment and furnishings, pocket calculators, etc.);
d) Accountable Government Property (defined as both real and personal property with an acquisition cost of $1,000 or more and a life expectancy of more than two years) and "sensitive items" (defined as items of personal property, supplies and equipment that are highly desirable and easily converted to personal use), regardless of acquisition value;
e) Overtime
f) General scientific meetings/conferences;
g) Travel costs including domestic/foreign travel;
h) Costs incurred in the performance of any cost-reimbursement type subcontract (including consulting agreements);
i) Costs to be paid for the performance of a fixed-price subcontract that exceeds $150,000.00;
j) Patient care costs
k) Refreshments and Meal Expenditures - Requests to use contract funds to provide light refreshments and/or meals to either federal or nonfederal employees must be submitted to the Contracting Officer's Representative (COR), with a copy to the Contracting Officer, at least six (6) weeks in advance of the event and are subject to "HHS Policy on Promoting Efficient Spending: Use of Appropriate Funding for Conferences and Meeting, Food and Promotional Items and Printing and Publications." The request shall contain the following information: (a) name, date, and location of the event at which the light refreshments and/or meals will be provided; (b) a brief description of the purpose of the event; (c) a cost breakdown of the estimated light refreshments and/or meals costs; (d) the number of nonfederal and federal attendees receiving light refreshments and/or meals; and (e) if the event will be held at a government facility;
l) Promotional Items
m) Printing (as defined in the Government Printing and Binding Regulations).

This article does not apply to the contract's Fixed Price CLINs.

ARTICLE B.5. ADVANCE UNDERSTANDINGS

a. Subcontracts and Consultants

Award of any FFP subcontract or FFP consulting agreement in excess of $150,000 or any cost reimbursement subcontract or consulting agreement shall not proceed without the prior written consent of the Contracting Officer via a Contracting Officer Authorization (COA) Letter. COA letters will only be issued upon review of the supporting documentation required by FAR Clause 52.244-2, Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, a copy of the signed, executed subcontract and consulting agreement shall be provided to the Contracting Officer within thirty (30) calendar days of full execution. This section does not apply to the contract's Fixed Price CLINs.

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b. Site Visits, Inspections and General Audits

At the discretion of the USG and independent of activities conducted by the Contractor, with five (5) business days' notice to the Contractor, the USG reserves the right to conduct site visits and inspections on an as needed basis, including collection of product samples and intermediates held by the Contractor, or subcontractor. In case of subcontractor visits and inspections that are independent of activities conducted by the Contractor, the USG shall demonstrate cause for such visit and/or inspection. All costs reasonably incurred by the Contractor and subcontractor for such visit and/or inspection shall be allowable costs. The Contractor shall coordinate these visits and shall have the opportunity to accompany the USG on any such visits. Under time-sensitive or critical situations, the USG reserves the right to suspend the five (5) business days' notice to the Contractor.

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

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

c. QA Audits

BARDA reserves the right to participate in QA audits of the Contractor's Subcontractor(s) in direct performance of this contract. BARDA reserves the right to conduct audits of the Prime Contractor's facilities. Upon completion of the QA audit the Contractor shall provide a report capturing the findings, results, and next steps in proceeding with any potential subcontractors. If action is requested for a subcontractor, detailed corrective and preventative plans for addressing areas of non-conformance to ICH and FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to the COR for review and acceptance. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.

- Contractor shall notify CO and COR of upcoming, ongoing, or recent audits/site visits of subcontractors as part of bi-weekly communications.
- Contractor shall notify the COR and CO within 5 business days of report completion. The Contractor shall complete the report within 60 days of the audit/site visit, or as negotiated with the COR in writing dependent upon the audit findings.

d. Man-in-Plant

At the discretion of the Government and seven calendar (7) days advance notice to the Contractor in writing from the Contracting Officer, the Government may place a man-in-plant in the Contractor's facility for the sole purpose of monitoring activities directly related to the performance of this contract during normal business hours, who shall be subject to the Contractor's policies and procedures regarding security, facility access, and training at all times while in the Contractor's facility. As determined by federal law, no Government representative shall publish, divulge, disclose, or make known in any manner, or to any extent not authorized by law, any information coming to him in the course of employment or official duties, while stationed in a contractor plant.

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e. Sharing of contract deliverables within United States Government (USG)

In an effort to build a robust medical countermeasure pipeline through increased collaboration, BARDA may share technical deliverables with USG entities responsible for Medical Countermeasure Development. In accordance with recommendations from the Public Health Emergency Medical Countermeasure Enterprise Review, agreements established in the Integrated Portfolio's Portfolio Advisory Committee (PAC) Charter, and agreements between BARDA and the Department of Defense and the National Institutes of Health, BARDA may share technical deliverables and data created in the performance of this contract with colleagues within the Integrated Portfolio. This advance understanding does not authorize BARDA to share financial information outside HHS. The Contractor is advised to review the terms of FAR 52.227-14, Rights in Data – General, regarding the Government's rights to deliverables submitted during performance as well as the Government's rights to data contained within those deliverables.

f. Overtime Compensation

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

g. Contract Number Designation

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

HHSO100201800019C

h. Quality Agreement

The Quality Agreement shall define, establish, and document the responsibilities of both the Contractor and the USG (i.e. – CDC/SNS-Quality Control and BARDA) for event-driven and product shipping, receiving, acceptance into the inventory and/or custody by the USG. Quality Agreement documents shall be drafted, approved, and signed by all parties prior to the commencement of product procurement, shipment, and acceptance (whether it is shipped to the CDC/SNS or maintained as VMI). The Contractor shall provide documentation and resolution for all concerns raised by USG and commits to cooperation in execution of this agreement. The parties expressly agree that the Government will not request Contractor to, nor will it distribute or relocate any Drug Product or final packaged Drug Product from the Contractor or Subcontractor's facility(ies) which has not been fully released by Contractor. A COA will be required prior to invoicing against procurement CLINs.

i. CAS Compliance

Pursuant to 48 CFR 9903.202-1 and FAR Part 30, SIGA shall submit a CAS Disclosure Statement to the Contracting Officer no later than 90 days after contract award. SIGA shall submit monthly progress reports detailing their progress in becoming CAS compliant. If SIGA is unable to comply with the requirement to be CAS complaint within 90 days after award, the contract may be terminated for default.

j. Risk of Loss

Subject to the provisions in FAR 52.249-8, Default (Fixed-Price Supply and Service), SIGA will retain the physical risk of loss until product is accepted at the SNS. Prior to delivery to the SNS, Contractor in its capacity as a storage provider will have physical risk of loss for such product during the period of storage.

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SECTION C - DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

ARTICLE C.1. STATEMENT OF OBJECTIVES

Independently and not as an agent of the Government, the Contractor shall furnish all the necessary services, qualified personnel, material, equipment, and facilities not otherwise provided by the Government as needed to perform the Statement of Objectives dated [redacted]* set forth in SECTION J - List of Attachments, attached hereto and made a part of the contract.

ARTICLE C.2. REPORTING REQUIREMENTS

See Section F for specific reporting requirements.

Performance of the contract will be monitored by the CO/COR on a regular basis. The Contracting Officer will be responsible for inspection and acceptance of deliverables and services. Monitoring of the contract will be based on periodic reporting by the Contractor.

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

ARTICLE C.3. MEETINGS/SITE VISITS

The Contractor and BARDA/AMCG shall participate in regular meetings to coordinate and oversee the contracting effort as requested by the Contracting Officer (CO)/Contracting Officer's Representative (COR). Such meetings may include, but are not limited to, a kickoff meeting to be held at a location determined by the COR, status update meetings and/or teleconferences, site visits to the Contractor's and/or subcontractor's facilities, and meetings with individual Contractors and other HHS officials to discuss the technical, regulatory, and ethical aspects of the program. The Contractor shall provide data, reports, and presentations to groups of outside experts and USG personnel and USG-contracted subject matter experts as required by the CO/COR facilitating review of activities.

The purpose of the kickoff meeting will be to orient the Contractor to HHS/BARDA and review contract requirements. This meeting usually occurs within a month after contract award.

Bi-weekly or monthly status update meetings/teleconferences shall be scheduled and established by the between the Contracting Officer's Representative (COR), the Contractor's Project Leaders/delegates and Contracting Officer (CO). During this meeting the Contractor's Project Leaders/delegates and designees will discuss the activities since the last call, any problems that have arisen and the activities planned until the next call takes place. The Contractor's Project Leaders/delegates may choose to include other key personnel on the conference call to give detailed updates on specific projects or this may be requested by the Contracting Officer's Representative.

The Contractor shall participate in Project Meetings to coordinate the performance of the contract, as requested by the Contracting Officer's Representative. These meetings may include face-to-face meetings with AMCG and BARDA in Washington, D.C. and at work sites of the Contractor. Such meetings may include, but are not limited to, meetings of the Contractor to discuss study designs, site visits to the Contractor's facilities, and meetings with the Contractor and HHS officials to discuss the technical, regulatory, and ethical aspects of the program. Subject to the data rights provisions in this contract, the Contractor will provide data, reports, and presentations to groups of outside experts and USG personnel as required by the Contracting Officer and Contracting Officer's Representative in order to facilitate review of contract activities.

Periodic site visits shall occur on an ad hoc basis (At least twice a year).

*** Certain material has been omitted pursuant to a request for confidential treatment. Such omitted material has been filed separately with the Securities and Exchange Commission.**

Within thirty (30) calendar days of an FDA audit of Contractor or subcontractor facilities, the Contractor shall provide copies of the audit findings, final report, and a plan for addressing areas of nonconformance to FDA regulations and guidance for GLP, GMP or GCP guidelines as identified in the final audit report.

Other U.S. Government Audits

The USG reserves the right to conduct an audit of the Contractor with 48 hours advance notice. The USG reserves the right to accompany the Contractor on routine and for-cause site-visits/audits of subcontractor(s). At the discretion of the USG and independent of testing conducted by the Contractor, BARDA reserves the right to conduct site visits/audits and collect samples of product held by the Contractor and subcontractors.

Pre-award site visits may be made with short notice. Contractors are expected to guarantee the availability of key staff or other staff determined by the Government as essential for purposes of this site visit.

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SECTION D – PACKAGING, MARKING AND SHIPPING

ARTICLE D.1. METHOD OF DELIVERY

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.3.

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

ARTICLE D.2. FOB DESTINATION DELIVERIES

The Contractor shall describe the storage conditions for each product, specifically noting the acceptable temperature range required to maintain product quality. The Contractor shall be responsible for maintaining product temperature control until the product(s) arrives at the SNS and has completed product acceptance by the USG. The Contractor shall provide the Government with an ambient exposure letter that covers the time the product(s) leaves the Contractor's validated storage facility until arrival at DSNS. Upon Government acceptance of the product(s) to the Government, the responsibility for temperature control shall transfer to the Government as well as the responsibility for logging ambient exposure time (temperatures between 8-25°C). The Contractor will provide and place TempTale(s) on each pallet of product while the product is inside the Contractor's validated storage facility prior to placing the product(s) onto the truck(s) of the designated carrier. The Government's acceptance of the aforementioned responsibility applies only to temperature control and does not indicate its acceptance of the lot(s).

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SECTION E – INSPECTION AND ACCEPTANCE

ARTICLE E.1. INSPECTION AND ACCEPTANCE

The Contracting Officer or the duly authorized representative will perform inspection and acceptance of materials and services to be provided under this contract.

For the purpose of this SECTION E, the designated Contracting Officer's Representative (COR) is the authorized representative of the Contracting Officer. The COR will assist in resolving technical issues that arise during performance. The COR however is not authorized to change any contract terms or authorize any changes in the Statement of Work or modify or extend the period of performance, or authorize reimbursement of any costs incurred during performance. The Contractor is advised to review FAR 52.243-1 Changes – Fixed Price Contracts Alternate V and FAR 52.243-2 Changes-Cost reimbursement contracts Alternative V, which is incorporated by reference into this contract in ARTICLE I.1.

Inspection and acceptance of reports will be performed at:

[redacted]*

Technical inspection and acceptance will be take place at:

[redacted]*

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duty authorized representative within 30 days of receipt.

Inspection and acceptance of batch records and analytical reports in accordance with the Quality Agreement noted in B.5.h may make physical inspection at the Contractor's or subcontractor's facilities unnecessary. Inspection and acceptance of other physical items will be performed at the Contractor's or a subcontractor's facilities as required by the Government.

Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duly authorized representative within 30 days of receipt.

ARTICLE E.2. FEDERAL ACQUISITION REGULATION CLAUSES INCORPORATED BY REFERENCE

The contract incorporates the following clause by reference with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

FAR 52.246-2, Inspection of Supplies – Fixed Price (August 1996)

FAR 52.246-4, Inspection of Services - Fixed Price (August 1996)

FAR 52.246-5, Inspection of Services - Cost-Reimbursement (April 1984)

FAR 52.246-8, Inspection of Research and Development – Cost-reimbursement (May 2001)

*** Certain material has been omitted pursuant to a request for confidential treatment. Such omitted material has been filed separately with the Securities and Exchange Commission.**

FAR 52.246-9, Inspection of Research and Development (Short Form) (April 1984)

FAR 52.246-16, Responsibility for Supplies (April 1984)

SECTION F – DELIVERIES OR PERFORMANCE

ARTICLE F.1. PERIOD OF PERFORMANCE

The base period of performance of this contract shall be for sixty (60) months from the date of award. The period of performance may be extended up to an additional 5 years (10 years in total for the base plus option periods) with the exercise of option(s), structured as CLINs, as set forth in SECTION B. The period of performance for the base period of this contract shall be consistent with the dates set forth in SECTION B. If the Government exercises option(s), the period of performance will be extended as described under in SECTION B of this contract.

ARTICLE F.2. DELIVERIES

Successful performance of the final contract shall be deemed to occur upon performance of the work described in SECTION C of this RFP and upon delivery and acceptance of the items described in SECTION F.3 by the Contracting Officer or their duly authorized representative.

ARTICLE F.3. CONTRACT DELIVERABLES AND REPORTING REQUIREMENTS

ARTICLE F.3.1. Submission of Contract Deliverables

Documents shall be delivered electronically via email to the Contracting Officer (CO) and the Contracting Officer's Representative (COR). When electronic deliverables are not preferable by the Contracting Officer, all deliverables and reports furnished to the Government under any potential resultant contract (including invoices) shall be addressed as follows:

UPS/FedEx/Courier	USPS Mail Packages
[redacted]*	[redacted]*

UPS/FedEx/Courier	USPS Mail Packages
[redacted]*	[redacted]*

ARTICLE F.3.2. REPORTING REQUIREMENTS

In all cases the reports are intended to provide sufficient detail to understand the Contractor's approach and progress to addressing the technical requirements. The reports supplement, and do NOT replace, routine (i.e. daily) communication between the COR and project manager and/or their designee(s) regarding project plans and progress. These reports shall be subject to the technical inspection and requests for clarification by the COR, and approval by the CO/COR. These reports shall be brief, factual, and prepared in accordance with the following format:

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 on or before the 15th calendar day following the last day of each reporting period and shall include the following:

Title Page: The title page for this report shall include 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.

Distribution List: A list of individuals receiving the Technical Progress report.

*** Certain material has been omitted pursuant to a request for confidential treatment. Such omitted material has been filed separately with the Securities and Exchange Commission.**

Progress:

SECTION I - An introduction covering the purpose and scope of the contract effort.

SECTION II Part A: SUMMARY - A description or table summarizing ongoing activities.

SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE – This section shall include 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). Please include all Quality Management System, Quality Control, and Quality Assurance Plans as part of this report or as requested by the COR.

SECTION II Part C: TECHNICAL PROGRESS – This section shall document the results of work completed and costs incurred during the period covered in relation to the proposed progress, effort, and budget. The report shall be in sufficient detail to explain comprehensively the results achieved.

SECTION II Part D: ISSUES – This section 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; and if a project activity is delinquent, then what corrective action steps are planned. Revised timelines shall be provided.

SECTION II Part E: PROPOSED WORK – This section shall include a summary of work proposed as a rolling three (3) month forecast for the next reporting period, by a certain date, and by whom.

SECTION II Part F: MANUFACTURING AND SUPPLY CHAIN MANAGEMENT – This section shall include a summary of the manufacturing and supply-chain related activities. Also include in this section updates to the production plan, capacity projections, stability results, inventory and shipment/distribution information.

SECTION II Part G: CONTRACTING OFFICER APPROVALS – This section shall include a table indicating each Contracting Officer Approval (COA) request, its current status (e.g. date submitted, date approved, date returned), amount requested, and the vendor for which the COA authorizes subcontracted work to be performed.

Invoices: Summary of any invoices submitted during the reporting period.

A Monthly Progress Report will not be required in the same month Annual Progress Reports or a Final Report are due.

A. Annual Progress Report

This report shall include a summation 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 year of performance plus any fractional part of the initial year. Thereafter, the reporting period shall consist of each calendar year.

The Contractor shall submit an Annual Progress Report on or before the 30th calendar day following the last day of each reporting period and shall include the following:

Title Page: The title page for this report shall include 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.

Distribution List: A list of individuals receiving the Technical Progress report.

*** Certain material has been omitted pursuant to a request for confidential treatment. Such omitted material has been filed separately with the Securities and Exchange Commission.**

Progress:

SECTION I - An introduction covering the purpose and scope of the contract effort.

SECTION II Part A: SUMMARY - A description or table summarizing ongoing activities.

SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE – This section shall include 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). Please include all Quality Management System, Quality Control, and Quality Assurance Plans as part of this report or as requested by the COR.

SECTION II Part C: TECHNICAL PROGRESS – This section shall document the results of work completed and costs 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.

SECTION II Part D: ISSUES – This section 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; and if a project activity is delinquent, then what corrective action steps are planned. Revised timelines shall be provided.

SECTION II Part E: PROPOSED WORK – This section shall include a summary of work proposed as a rolling three (3) month forecast for the next reporting period, by a certain date, and by whom.

SECTION II Part F: MANUFACTURING AND SUPPLY CHAIN MANAGEMENT – This section shall include a summary of the manufacturing and supply-chain related activities. Also include in this section updates to the production plan, capacity projections, stability results, inventory and shipment/distribution information.

SECTION II Part G: CONTRACTING OFFICER APPROVALS – This section shall include a table indicating each Contracting Officer Approval (COA) request, its current status (e.g. date submitted, date approved, date returned), amount requested, and the vendor for which the COA authorizes subcontracted work to be performed.

Invoices: Summary of any invoices submitted during the reporting period.

An Annual Progress Report will not be required for the period when the Final Technical Progress Report is due.

B. Draft Final Report and Final Report

These reports are to include a summation of the work performed and results obtained for execution of various studies or technical work packages during the entire contract period of performance. This report shall be in sufficient detail to describe comprehensively the results achieved. The Draft Final Progress Report shall be due forty-five (45) calendar days prior to the expiration date of the contract and the Final Progress Report is due no later than 30 days following the expiration date of the contract. The report shall conform to the following format:

Title Page: The title for these reports shall include 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.

Distribution List: A list of individuals receiving the Technical Progress report.

Progress:

*** Certain material has been omitted pursuant to a request for confidential treatment. Such omitted material has been filed separately with the Securities and Exchange Commission.**

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.

SECTION II: RESULTS - A detailed description of the work performed and the results obtained including all expenses for the entire contract period of performance.

D. FDA Regulatory Agency Correspondence, Meeting Summaries, and Submissions.

a) Within five business days of any formal meeting with the FDA or other regulatory agency, the Contractor shall forward the initial draft minutes to the COR. The Contractor shall forward the final minutes when available.

b) Within five business days of any informal meeting with the FDA or other regulatory agency, the Contractor shall forward the initial draft minutes to the COR. The Contractor shall forward the final minutes when available and if applicable.

c) The Contractor shall forward the dates and times of any meeting with the FDA and other regulatory agencies to the COR as soon as the meeting times are known and make arrangements for appropriate BARDA staff to attend the meetings.

d) The Contractor shall provide the COR the opportunity to review and comment upon any documents to be submitted to the FDA or other regulatory agency. The Contractor shall provide the COR with five (5) business days in which to review and provide comments back to the Contractor prior to the Contractor's submission to the FDA.

e) The Contractor shall forward Standard Operating Procedures (SOPs) upon request from the COR.

f) The Contractor shall provide raw data and/or specific analysis of data generated with USG funds upon request from the COR.

g) The Contractor shall notify the Contracting Officer's Representative and Contracting Officer within 24 hours of all FDA arrivals to conduct site visits/audits by any regulatory agency. 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 Contracting Officer's Representative and Contracting Officer copies of the plan for addressing areas of non-conformance to FDA regulations for GLP 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 redactions shall be limited to issues that are unrelated to the subcontractor's performance on any award made under this RFP. The Contractor shall make arrangements with the COR for the appropriate BARDA representative(s) to be present during the final debrief by the regulatory inspector.

E. Other Requirements/Deliverables

a) Integrated Master Project Plan

[redacted]*

*** Certain material has been omitted pursuant to a request for confidential treatment. Such omitted material has been filed separately with the Securities and Exchange Commission.**

1. Technology Packages

Technology packages developed under the contract that includes complete protocols must be submitted at the request of the Contracting Officer's Representative. See FAR clauses 52.227-11, Patent Rights-Ownership by the Contractor, and 52.227-14, Rights in Data. This report shall be due upon request from the COR.

2. Experimental Protocols

The Contractor shall submit to the COR all study/experiment/test plans, designs, and protocols prior to execution for approval or upon request by the COR when required.

3. Annual/Final Invention Report

All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Contractor, including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification. An Annual Invention Report shall be due on or before the 30th calendar day after the completion of each reporting period. A Final Invention Report (see FAR 27.303 (b)(2)(ii)) shall be due on or before the expiration date of the contract. If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer.

4. Publications

Any manuscript or scientific meeting abstract containing data generated under this contract must be submitted to COR for review prior to submission. Reports shall be due within 30 calendar days for manuscripts and 15 calendar days for abstracts.

5. Press Releases

The Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases. The Contractor shall ensure the Contracting Officer has received and approved an advanced copy of any press release not less than five (5) business days prior to the issuance of any potential press release.

6. Security Report

The Contractor shall report to the government any activity; or incident that is in violation of established security standards; or indicates the loss or theft of government products. Reports shall be due within 24 hours after occurrence of an activity or incident.

7. Security Plan

Please see attachments 15 and 16 for security requirements and a template for the Security Plan.

8. Quality Management System Plan

The Contractor shall submit to the COR a Quality Management System Plan for approval no later than 60 days from the date of award.

9. Manufacturing Plan

The Contractor shall submit to the COR a comprehensive manufacturing plan for review and approval no later than 60 days from the date of award.

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ARTICLE F.3.3. DELIVERABLE SCHEDULE

Successful performance of the final contract shall be deemed to occur upon performance of the work set forth in the Statement of Work dated [redacted]*, set forth in SECTION J - List of Attachments of this contract and upon delivery and acceptance by the Contracting Officer, or the duly authorized representative, of the following items in accordance with the stated delivery schedule below:

Item No.	Description	Addresses	Deliverable Schedule
1	Bi-Weekly Meetings and Meeting Minutes	CO: (1) electronic copy COR: (1) electronic copy	Meeting minutes are due no later than five business days following each meeting.
2	Monthly Progress Report	CO: (1) electronic copy COR: (1) electronic copy	Reports are due on or before the 15th of each month following the end of each reporting period.
3	Annual Progress Report	CO: (1) electronic copy COR: (1) electronic copy	Reports are due on or before the 30th calendar day following the end of each reporting period.
4	Draft Final Progress Report	CO: (1) electronic copy COR: (1) electronic copy	Report is due 45 Calendar days prior to the expiration date of the contract.
5	Final Progress Report	CO: (1) electronic copy COR: (1) electronic copy	Report is due no later than 30 calendar days after the expiration date of the contract.
6	FDA/ Regulatory Agency Correspondence and Meeting Summaries	CO: (1) electronic copy COR: (1) electronic copy	Reports are due within 5 business days of each meeting for Contractor's minutes, upon receipt of minutes from FDA/ regulatory agency, and upon request from the COR.
7	Integrated Master Project Plan -Critical Path Milestones - Work Breakdown Structure - Risk Mitigation Plan/Matrix	CO: (1) electronic copy COR: (1) electronic copy	Report is due within 90 days of contract award. Updates are due as requested by the COR.
8	Technology Packages	CO: (1) electronic copy COR: (1) electronic copy	Upon request from the COR.

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9	Experimental Protocols	CO: (1) electronic copy COR: (1) electronic copy	Upon request from the COR.
10	Annual/Final Invention Report	CO: (1) electronic copy COR: (1) electronic copy	An Annual Invention Report is due on or before the 30th calendar day after the completion of each reporting period. A Final Invention Report is due on or before the expiration date of the contract.
11	Publications	CO: (1) electronic copy COR: (1) electronic copy	Reports are due within 30 calendar days for manuscripts and 15 calendar days for abstracts.
12	Press Releases	CO: (1) electronic copy COR: (1) electronic copy	Reports/Notices are due for approval to the CO not less than five (5) business days prior to the issuance of any potential press release.
13	Security Report	CO: (1) electronic copy COR: (1) electronic copy	Reports are due within 24 hours after occurrence of an activity or incident.
14	Security Plan	CO: (1) electronic copy COR: (1) electronic copy	Final plan due within 30 days of contract award.
15	Manufacturing Plan	CO: (1) electronic copy COR: (1) electronic copy	Due within 60 days of contract award.
16	Delivery Schedule	CO: (1) electronic copy COR: (1) electronic copy	Due within 30 days of contract award

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

This contract incorporates the following clause(s) by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available. The full text of each clause may be accessed electronically at this address: http://www.acquisition.gov/far.

FAR 52.242-15, Stop-Work Order (August 1989)

FAR 52.242-15, Stop-Work Order, Alternate 1 (April 1984)

FAR 52.246-7, Inspection of Research and Development – Fixed Price (August 1996)

*** Certain material has been omitted pursuant to a request for confidential treatment. Such omitted material has been filed separately with the Securities and Exchange Commission.**

SECTION G – CONTRACT ADMINISTRATION

ARTICLE G.1. CONTRACTING OFFICER

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

[redacted]*

The Contracting Officer is the only individual who can legally commit and bind 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. Any other commitment, either explicit or implied, is invalid.

The CO is the only person with authority to act as agent of the Government under this contract. Only the Contracting Officer has authority to: (1) direct or negotiate any changes in the statement of objectives; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor for any costs incurred during the performance of this contract; (5) obligate or de-obligate funds into the contract; (6) sign written licensing agreements; or (7) 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.

The Government may unilaterally change its CO designation.

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

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

[redacted]*

The COR is responsible for:

a. Monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements;

b. Assisting the Contracting Officer in interpreting the statement of work and any other technical performance requirements;

c. Performing technical evaluation as required;

d. Performing technical inspections and assisting the Contracting Officer in acceptances of deliverables required by this contract;

e. Assisting in the resolution of technical problems encountered during performance;

f. The Government may unilaterally change its COR designation(s).

*** Certain material has been omitted pursuant to a request for confidential treatment. Such omitted material has been filed separately with the Securities and Exchange Commission.**

ARTICLE G.3. KEY CONTRACTOR'S POINTS OF CONTACT

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

ARTICLE G.4. KEY PERSONNEL

The key personnel specified in this contract are considered to be essential to work performance. At least 30 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) days' 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 individual(s) is/are considered to be essential to the work being performed hereunder:

Name	Title
[redacted]*	[redacted]*
[redacted]*	[redacted]*
[redacted]*	[redacted]*
[redacted]*	[redacted]*
[redacted]*	[redacted]*
[redacted]*	[redacted]*
[redacted]*	[redacted]*
[redacted]*	[redacted]*
[redacted]*	[redacted]*

ARTICLE G.5. INVOICE SUBMISSION

(a) The Contractor shall submit an electronic copy of contract monthly invoices/financial reports to the Contracting Officer as defined above, in ARTICLE G of this contract.

(b) Contractor invoices/financial reports shall conform to the form, format, and content requirements of the instructions for Invoice/Financing requests made a part of the contract at Section J, Attachments 2 & 3.

(c) Monthly invoices must include the cumulative total expenses to date, adjusted (as applicable) to show any amounts suspended by the Government.

(d) The Contractor agrees to immediately notify the Contracting Officer in writing if there is an anticipated overrun (any amount) or unexpended balance (greater than 10 percent) of the estimated costs for the base period or any options (See estimated costs under Articles B.2 and B.3) and the reasons for the variance. Also refer to the requirements of FAR Clause 52.232-20, Limitation of Cost.

(e) 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 below 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.

*** Certain material has been omitted pursuant to a request for confidential treatment. Such omitted material has been filed separately with the Securities and Exchange Commission.**

(f) All invoice submissions shall be in accordance with FAR Clause 52.232-25, Prompt Payment.

(g) The Contractor may not invoice for any CLIN prior to delivery and acceptance of services.

(h) Invoices shall submit invoices electronically to the Contracting Officer (CO), the Contracting Specialist (CS), the Contracting Officer's Representative (COR), PSC (PSC_Invoices@psc.hhs.gov, and e-Room electronically. Unless otherwise specified by the Contracting Officer, all deliverables, invoices, and reports furnished to the Government under the resultant contract shall be addressed as follows:

[redacted]*	[redacted]*
[redacted]*	[redacted]*

ARTICLE G.6. INDIRECT COST RATES

The following [redacted]* rates will be utilized for billing purposes during the period of performance:

G&A: [redacted]*%

Overhead: [redacted]*%

Fringe: [redacted]*%

[redacted]*

ARTICLE G.7. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (DECEMBER 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.

*** Certain material has been omitted pursuant to a request for confidential treatment. Such omitted material has been filed separately with the Securities and Exchange Commission.**

ARTICLE G.8. REIMBURSEMENT OF COST

The Government shall reimburse the Contractor those costs 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 and FAR Subpart 31.2.

ARTICLE G.9. CONTRACT COMMUNICATIONS/CORRESPONDENCE

The Contractor shall identify all correspondence, reports, and other data pertinent to this contract by imprinting thereon the contract number HHSO100201800019C from Page 1 of the contract.

ARTICLE G.10. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

(a) *Purpose:* In accordance with FAR Subpart 42.15, the Contractor's performance will be periodically evaluated by the government in order to provide current information for current and future source selection purposes. These evaluations will therefore be marked "Source Selection Information."

(b) *Performance Evaluation Period*: The Contractor's performance will be evaluated at least annually.

(c) *Evaluators*: The performance evaluation will be completed jointly by the Contracting Officer's Representative and the Contracting Officer.

(d) *Performance Evaluation Factors*: The Contractor's performance will be evaluated in accordance with FAR Subpart 42.15 and Attachment #5, Contract Performance Evaluation Report. The final performance evaluation will be prepared at the time of completion of work. In addition to the final evaluation, interim evaluation(s) will be prepared Annually as to coincide with the Anniversary date of the contract.

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

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

(g) *Release of* Contractor *Performance Evaluation Information*: The completed evaluation will not be released to other than Government personnel and the Contractor whose performance is being evaluated. Disclosure of such information could cause harm both to the commercial interest of the Government and to the competitive position of the Contractor being evaluated, as well as impede the efficiency of Government operations.

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

(i) *Retention Period*: The agency will retain past performance information for a maximum period of 3 years after completion of contract performance for the purpose of providing source selection information for future contract awards.

(j) Electronic Access to Contractor Performance Evaluations: Contractors may access evaluations through a secure website for review and comment at the following: http://cpars.gov

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ARTICLE G.11. GOVERNMENT PROPERTY

(a) In addition to the requirements of the clause, GOVERNMENT PROPERTY, incorporated in SECTION I of this contract, the Contractor shall comply with the provisions of HHS Publication, "Contractor's Guide for Control of Government Property," which is incorporated into this contract by reference. This document can be accessed at:

http://www.hhs.gov/hhsmanuals/ (HHS Logistics Management Manual)

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

(b) Notwithstanding the provisions outlined in the HHS Publication, "Contractor's Guide for Control of Government Property," which is incorporated in this contract in paragraph 1 above, the Contractor shall use the form entitled, "Report of Government Owned, Contractor Held Property" for submitting summary reports required under this contract, as directed by the Contracting Officer or his/her designee. This form is included as an attachment in SECTION J of this contract.

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SECTION H – SPECIAL CONTRACT REQUIREMENTS

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

ARTICLE H.1. PROTECTION OF HUMAN SUBJECTS

(a) Contractor agrees that the rights and welfare of human subjects involved in research under this contract shall be protected in accordance with 45 CFR Part 46 and with the Contractor's current Assurance of Compliance on file with the Office for Human Research Protections (OHRP), Department of Health and Human Services. The Contractor further agrees to provide certification at least annually that the Institutional Review Board has reviewed and approved the procedures, which involve human subjects in accordance with 45 CFR Part 46 and the Assurance of Compliance.

(b) The Contractor shall bear full responsibility for the performance of all work and services involving the use of human subjects under this contract and shall ensure that work is conducted in accordance with the protocol(s) approved by either the IRB or IEC. The parties hereto agree that the Contractor retains the right to control and direct the performance of all work under this contract. The Contractor shall not deem anything in this contract to constitute the Contractor or any subcontractor, agent or employee of the Contractor, or any other person, organization, institution, or group of any kind whatsoever, as the agent or employee of the Government. The Contractor agrees that it has entered into this contract and will discharge its obligations, duties, and undertakings and the work pursuant thereto, whether requiring professional judgment or otherwise, as an independent Contractor without imputing liability on the part of the Government for the acts of the Contractor or its employees.

(c) 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 Contracting Officer determines, in consultation with OHRP that the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part, and the Contractor's name may be removed from the list of those Contractors with approved Human Subject Assurances.

ARTICLE H.2. CLINICAL RESEARCH

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

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

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ARTICLE H.2.1. Safety and Monitoring Issues

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

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

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

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

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

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

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

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

ARTICLE H.2.2. Data and Safety Monitoring Requirements

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

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

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1. **Independent Safety Monitor** – a physician or other appropriate expert who is independent of the study and available in real time to review and recommend appropriate action regarding adverse events and other safety issues.

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

3. **Data and Safety Monitoring Board** – an independent committee charged with reviewing safety and trial progress and providing advice with respect to study continuation, modification, and termination. The Contractor may be required to use an established BARDA DSMB or to organize an independent DSMB. All phase III clinical trials must be reviewed by a DSMB; other trials may require DSMB oversight as well. Please refer to: NIAID Principles for Use of a Data and Safety Monitoring Board (DSMB) for Oversight of Clinical Trials Policy. The Government retains the right to place a nonvoting member on the DSMB.

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

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

H.2.3. BARDA Protocol Review Process Before Patient Enrollment Begins

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

1. IRB or IEC approved clinical research protocol identified by version number, date, or both, including details of study design, proposed interventions, patient eligibility, and exclusion criteria;

2. Documentation of IRB or IEC approval, including OHRP FWA number, IRB or IEC registration number, and IRB or IEC name;

3. IRB or IEC approved informed consent document, identified by version number, date, or both and date it is valid;

4. Plans for the management of side effects;

5. Procedures for assessing and reporting adverse events;

6. Plans for data and safety monitoring (see B above) and monitoring of the clinical study site, pharmacy, and laboratory;

7. Documentation that the Contractor and all study staff responsible for the design or conduct of the research have received Good Clinical Practice (GCP) training in the protection of human subjects.

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

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ARTICLE H.2.4. Required Time-Sensitive Notification

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

1. *Expedited safety report of unexpected or life-threatening experience or death* – A copy of any report of unexpected or life-threatening experience or death associated with the use of an IND drug, which must be reported to FDA by telephone or fax as soon as possible but no later than seven days after the IND sponsor's receipt of the information, must be submitted to the Contracting Officer's Representative within 24 hours of FDA notification.

2. *Expedited safety reports of serious and unexpected adverse experiences* – A copy of any report of unexpected and serious adverse experience associated with use of an IND drug or any finding from tests in laboratory animals that suggests a significant risk for human subjects, which must be reported in writing to FDA as soon as possible but no later than 15 calendar days after the IND sponsor's receipt of the information, must be submitted to the Contracting Officer's Representative within 24 hours of FDA notification.

3. *IDE reports of unanticipated adverse device effect* – A copy of any reports of unanticipated adverse device effect submitted to FDA must be submitted to the Contracting Officer's Representative within 24 hours of FDA notification.

4. *Expedited safety reports* – shall be sent to the COR concurrently with the report to FDA.

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

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

Safety reporting for research not performed under an IND or IDE

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

ARTICLE H.3. HUMAN MATERIALS

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

ARTICLE H.4. NEEDLE EXCHANGE

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

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ARTICLE H.5. ACKNOWLEDGEMENT OF FEDERAL FUNDING

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.

ARTICLE H.6. RESTRICTIONS ON ABORTIONS

The Contractor shall not use funds for any abortion.

ARTICLE H.7. GUN CONTROL

The Contractor shall not use contract funds in whole or in part, to advocate or promote gun control.

ARTICLE H.8. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

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

Additionally, in accordance with the March 4, 1997 Presidential Memorandum entitled “Prohibition on Federal Funding for Cloning of Human Beings”, federal funds may not be used for cloning of human beings.

ARTICLE H.9. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

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

ARTICLE H.10. CARE OF LIVE VERTEBRATE ANIMALS

(a) Before undertaking performance of any contract involving animal-related activities where the species is regulated by the United Sates 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.

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(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).

ARTICLE 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.

ARTICLE H.12. PAPERWORK REDUCTION ACT

(a) This contract involves a requirement to collect or record information calling either for answers to identical questions from 10 or more persons other than Federal employees, or information from Federal employees which is outside the scope of their employment, for use by the Federal government or disclosure to third parties; therefore, the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq*.) shall apply to this contract. No plan, questionnaire, interview guide or other similar device for collecting information (whether repetitive or single time) may be used without the Office of Management and Budget (OMB) first providing clearance. Contractors and the Contracting Officer's Representative shall be guided by the provisions of 5 CFR part 1320, Controlling Paperwork Burdens on the Public, and seek the advice of the HHS operating division or Office of the Secretary Reports Clearance Officer to determine the procedures for acquiring OMB clearance.

(b) The Contractor shall not expend any funds or begin any data collection until the Contracting Officer provides the Contractor with written notification authorizing the expenditure of funds and the collection of data. The Contractor shall allow at least 120 days for OMB clearance. The Contracting Officer will consider excessive delays caused by the Government which arise out of causes beyond the control and without the fault or negligence of the Contractor in accordance with the Excusable Delays or Default clause of this contract.

ARTICLE H.13. RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS

The Contractor shall not use contract funds to maintain or establish a computer network unless such network blocks the viewing, downloading, and exchanging of pornography.

ARTICLE H.14. CERTIFICATION OF FILING AND PAYMENT OF TAXES

The Contractor must be in compliance with Section 518 of the Consolidated Appropriations Act of FY 2014.

ARTICLE H.15. SUBCONTRACTING PROVISIONS

(a) Small Business Subcontracting Plan

1. The Small Business Subcontracting Plan, dated [redacted]* is attached hereto and made a part of this contract.

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

(b) Subcontracting Reports

The Contractor shall submit the following Subcontracting reports electronically via the "electronic Subcontracting Reporting System (eSRS) at http://www.esrs.gov.

1. Individual Subcontract Reports (ISR)
   Regardless of the effective date of this contract, the Report shall be due on the following dates for the entire life of this contract:
   - [redacted]*
   - [redacted]*
   - [redacted]*

2. Summary Subcontract Report (SSR)
   Regardless of the effective date of this contract, the Summary Subcontract Report shall be submitted annually on the following date for the entire life of this contract:
   - [redacted]*

For both the Individual and Summary Subcontract Reports, the Contracting Officer shall be included as a contact for notification purposes at the following e-mail address defined in SECTION F.3.

ARTICLE H.16. 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 Contractor 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, Contractors 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 Contractors 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.

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In order to facilitate the Government's determination whether proposed EIT services meet applicable Section 508 accessibility standards, Contractors 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 Contractor 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)

ARTICLE H.17. 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.

ARTICLE H.18. INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR CONFLICTS OF INTERESTS

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-in/textidx?c=ecfr&SID=0af84ca649a74846f102aaf664da1623&rgn=div5&view=text&node=45:1.0.1.1.51&idno=45

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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:

    4. Income from seminars, lectures, or teaching, and service on advisory or review panels for government agencies, Institutions of higher education, academic teaching hospitals, medical centers, or research institutes with an Institution of higher learning; and

    5. 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.

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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, thorough 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.

ARTICLE H.19. 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:

*** Certain material has been omitted pursuant to a request for confidential treatment. Such omitted material has been filed separately with the Securities and Exchange Commission.**

"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. HHSO100201800019C"

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 that: (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 non-Governmental sources.

ARTICLE H.20. 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

ARTICLE H.21. 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.

ARTICLE H.22. ACCESS TO DOCUMENTATION/DATA

The Government shall have physical and electronic access to all documentation and data generated under this contract, including: all data documenting Contractor performance, all data generated, all communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, milestone completion documents, and all Contractor commitments and responses. The Contractor shall provide the Government with an electronic copy of all correspondence with the FDA within 24 hours of receipt. The Government shall acquire unlimited rights to all data funded under any contract awarded in response to this RFP in accordance with FAR Subpart 27.4 and FAR Clause 52.227-14.

ARTICLE H.23. IDENTIFICATION AND DISPOSITION OF DATA

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

ARTICLE H.24. DISSEMINATION OF INFORMATION

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

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ARTICLE H.25. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

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

ARTICLE H.26. PUBLIC ACCESS TO ARCHIVED PUBLICATIONS RESULTING FROM ASPR FUNDED RESEARCH

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

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

ARTICLE H.27. Public Health Service Act

Effective December 3, 2016, the Secretary of the Department of Health and Human Services has issued an amended declaration pursuant to section 319F-3 of the Public Health Service Act (42 U.S.C. § 247d-6d) to provide liability protection for activities related to Ebola virus disease vaccines consistent with the terms of the declaration. The rVSV-ZEBOV-GP vaccine being developed under this contract, which is also known as V920 or BPSC1001, is identified in the declaration as a covered countermeasure, and, as such, the government shall provide liability protection for activities related to V920, consistent with terms of the declaration. The Government agrees that the medical countermeasure delivered by the Contractor under this contract will not be administered for use in humans , unless the Secretary executes a Declaration under the Public Readiness and Emergency Preparedness Act (PREP Act), Section 319F-3 of the Public Health Service Act, 42 U.S.C. 247d-6d, to provide that such medical countermeasures delivered under this contract and used anywhere in the world are covered countermeasures to which section 319F-3(a) applies.

ARTICLE H.28. CONFLICT OF INTEREST

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

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ARTICLE H.29. IN-PROCESS REVIEW

In Process Reviews (IPR) will be conducted at the discretion of the Government to discuss the progression of the milestones. The Government reserves the right to revise the milestones and budget pending the development of the project. Deliverables may be required when the IPRs are conducted. The Contractor's success in completing the required tasks under each work segment must be demonstrated through the Deliverables and Milestones specified under SECTION F. Those deliverables will constitute the basis for the Government's decision, at its sole discretion, to proceed with the work segment, or unilaterally institute changes to the work segment, or terminate the work segment.

IPRs may be scheduled at the discretion of the Government to discuss progression of the contract. The Contractor shall provide a presentation following a prescribed template which will be provided by the Government at least 30 days prior to the IPR. The Contractor shall provide a draft presentation to the Contracting Officer at least 10 days prior to the IPR.

ARTICLE H.30. PRIVACY ACT APPLICABILITY

1) Notification is hereby given that the Contractor and its employees are subject to criminal penalties for violation of the Privacy Act to the same extent as employees of the Government. The Contractor shall assure that each of its employees knows the prescribed rules of conduct and that each is aware that he or she can be subjected to criminal penalty for violation of the Act. A copy of 45 CFR Part 5b, Privacy Act Regulations, may be obtained at http://www.gpoaccess.gov/cfr/index.html

2) The Project Officer/COR is hereby designated as the official who is responsible for monitoring Contractor compliance with the Privacy Act.

3) The Contractor shall follow the Privacy Act guidance as contained in the Privacy Act System of Records number 09-25-0200. This document may be obtained at the following link: http://oma.od.nih.gov/ms/privacy/pa-files/0200.htm

ARTICLE H.31. BARDA AUDITS

Contractor shall accommodate periodic or ad hoc site visits by the Government. If the Government, the Contractor, or other parties identifies any issues during an audit, the Contractor shall capture the issues, identify potential solutions, and provide a report to the Government.

- If issues are identified during the audit, Contractor shall submit a report to the CO and COR 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 within 10 business days.
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

ARTICLE H.32. SECURITY REPORTING REQUIREMENT

Violations of established security standards per the Security Plan noted in Section F.2.E.g shall be reported to the CO and COR within 24 hours upon discovery of any compromise, intrusion, loss or interference of its security processes and procedures. The Contractor shall ensure that all software components that are not required for the operation and maintenance of the database/control system has been removed and/or disabled. The Contractor shall provide to the CO and the COR information appropriate to Information and Information Technology software and service updates and/or workarounds to mitigate all vulnerabilities associated with the data and shall maintain the required level of system security.

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The Contractor will investigate violations to determine the cause, extent, loss or compromise of sensitive program information, and corrective actions taken to prevent future violations. The CO in coordination with BARDA will determine the severity of the violation. Any contractual actions resulting from the violation will be determined by the CO.

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PART II - CONTRACT CLAUSES

SECTION I - CONTRACT CLAUSES

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

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

General Clauses for Cost-Reimbursement/Fixed Price Research and Development Contract

Reg	Clause	Date	Clause Title
FAR	52.202-1	Nov 2013	Definitions
FAR	52.203-3	Apr 1984	Gratuities
FAR	52.203-5	May 2014	Covenant Against Contingent Fees
FAR	52.203-6	Sep 2006	Restrictions on Subcontractor Sales to the Government
FAR	52.203-7	May 2014	Anti-Kickback Procedures
FAR	52.203-8	May 2014	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity
FAR	52.203-10	May 2014	Price or Fee Adjustment for Illegal or Improper Activity
FAR	52.203-12	Oct 2010	Limitation on Payments to Influence Certain Federal Transactions
FAR	52.203-13	Oct 2015	Contractor Code of Business Ethics and Conduct
FAR	52.203-14	Oct 2015	Display of Hotline Poster(s)
FAR	52.203-17	Apr 2014	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights
FAR	52.203-18	Jan 2017	Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements-Representation.
FAR	52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper
FAR	52.204-7	Oct 2016	System for Award Management
FAR	52.204-10	Oct 2016	Reporting Executive Compensation and First-Tier Subcontract Awards
FAR	52.204-13	Oct 2016	System for Award Management Maintenance
FAR	52.209-6	Oct 2015	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment
FAR	52.209-9	Jul 2013	Updates of Publicly Available Information Regarding Responsibility Matters
FAR	52.209-10	Nov 2015	Prohibition on Contracting with Inverted Domestic Corporations
FAR	52.210-1	Apr 2011	Market Research
FAR	52.211-11	Sept 2000	Liquidated Damages—Supplies, Services, or Research and Development (Sept 2000)
FAR	52.215-2	Oct 2010	Audit and Records – Negotiation
FAR	52.215-8	Oct 1997	Order of Precedence - Uniform Contract Format
FAR	52.215-10	Aug 2011	Price Reduction for Defective Cost or Pricing Data
FAR	52.215-11	Aug 2011	Price Reduction for Defective Certified Cost or Pricing Data—Modifications.
FAR	52.215-12	Oct 2010	Subcontractor Certified Cost or Pricing Data
FAR	52.215-13	Oct 2010	Subcontractor Certified Cost or Pricing Data—Modifications
FAR	52.215-15	Oct 2010	Pension Adjustments and Asset Reversions
FAR	52.215-18	Jul 2005	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) other than Pensions
FAR	52.215-19	Oct 1997	Notification of Ownership Changes

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Reg	Clause	Date	Clause Title
FAR	52.215-21	Oct 2010	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data -Modifications
FAR	52.215-23	Oct 2009	Limitations on Pass-Through Charges
FAR	52.216-7	Jun 2013	Allowable Cost and Payment
FAR	52.216-8	Jun 2011	Fixed Fee
FAR	52.219-8	Nov 2016	Utilization of Small Business Concerns
FAR	52.219-9	Jan 2017	Small Business Subcontracting Plan
FAR	52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan
FAR	52.219-28	July 2013	Post-Award Small Business Program Representation
FAR	52.222-1	Feb 1997	Notice to the Government of Labor Disputes
FAR	52.222-2	July 1990	Payment for Overtime Premiums
FAR	52.222-3	Jun2003	Convict Labor
FAR	52.222-21	Apr 2015	Prohibition of Segregated Facilities
FAR	52.222-26	Sept 2016	Equal Opportunity
FAR	52.222-29	Apr 2015	Notification of Visa Denial.
FAR	52.222-35	Oct 2015	Equal Opportunity for Veterans
FAR	52.222-36	Jul 2014	Equal Opportunity for Workers with Disabilities
FAR	52.222-37	Feb 2016	Employment Reports on Veterans
FAR	52.222-38	Feb 2016	Compliance with Veterans' Employment Reporting Requirements
FAR	52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act
FAR	52.222-43	May 2014	Fair Labor Standards Act and Service Contract Labor Standards—Price Adjustment (Multiple Year and Option Contracts)
FAR	52.222-50	Mar 2015	Combating Trafficking in Persons
FAR	52.222-54	Oct 2015	Employment Eligibility Verification
FAR	52.223-6	May 2001	Drug-Free Workplace
FAR	52.223-18	Aug 2011	Encouraging Contractor Policy to Ban Text Messaging While Driving
FAR	52.224-1	April 1984	Privacy Act Notification
FAR	52.224-2	April 1984	Privacy Act
FAR	52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
FAR	52.225-25	Oct 2015	Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran—Representation and Certifications
FAR	52.226-1	Jun 2000	Utilization of Indian Organizations and Indian-Owned Economic Enterprises.
FAR	52.227-1	Dec 2007	Authorization and Consent, Alternate 1 (APR 1984)
FAR	52.227-2	Dec 2007	Notice and Assistance Regarding Patent and Copyright Infringement
FAR	52.227-3	Apr 1984	Patent Indemnity
FAR	52.227-11	May 2014	Patent Rights – Ownership by the Contractor
FAR	52.227-14	May 2014	Rights in Data - General
FAR	52.227-14	Dec 2007	Rights in Data - General, Alternate 2
FAR	52.227-16	June 1987	Additional Data Requirements
FAR	52.228-7	Mar 1996	Insurance – Liability to Third Persons
FAR	52.229-3	Feb 2013	Federal, State and Local Taxes
FAR	52.230-2	Oct 2015	Cost Accounting Standards
FAR	52.230-6	June 2010	Administration of Cost Accounting Standards
FAR	52.232-1	Apr 1984	Payments
FAR	52.232-2	Apr 1984	Payments under Fixed-Price Research and Development Contracts
FAR	52.232-8	Feb 2002	Discounts for Prompt Payment

*** Certain material has been omitted pursuant to a request for confidential treatment. Such omitted material has been filed separately with the Securities and Exchange Commission.**

Reg	Clause	Date	Clause Title
FAR	52.232-9	Apr 1984	Limitation on Withholding of Payments
FAR	52.232-11	Apr 1984	Extras
FAR	52.232-17	May 2014	Interest
FAR	52.232-18	Apr 1984	Availability of Funds
FAR	52.232-20	Apr 1984	Limitation of Cost
FAR	52.232-22	Apr 1984	Limitation of Funds
FAR	52.232-23	May 2014	Assignment of Claims
FAR	52.232-25	Jan 2017	Prompt Payment
FAR	52.232-33	Jul 2013	Payment by Electronic Funds Transfer--System for Award Management
FAR	52.232-40	Dec 2013	Providing Accelerated Payments to Small Business Subcontractors
FAR	52.233-1	May 2014	Disputes
FAR	52.233-3	Aug 1996	Protest After Award
FAR	52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
FAR	52.242-1	Apr 1984	Notice of Intent to Disallow Costs
FAR	52.242-3	May 2014	Penalties for Unallowable Costs
FAR	52.242-4	Jan 1997	Certification of Final Indirect Costs
FAR	52.242-13	Jul 1995	Bankruptcy
FAR	52.243-1	Aug 1987	Changes - Fixed-Price Alternate V (Apr 1984).
FAR	52.243-2	Aug 1987	Changes—Cost-Reimbursement Alternate V (Apr 1984).
FAR	52.243-6	Apr 1984	Change Order Accounting.
FAR	52.243-7	Jan 2017	Notification of Changes
FAR	52.244-2	Oct 2010	Subcontracts, Alternate 1 (Jun 2007)
FAR	52.244-5	Dec 1996	Competition in Subcontracting
FAR	52.244-6	Nov 2017	Subcontracts for Commercial Items
FAR	52.245-1	Jan 2017	Government Property
FAR	52.245-9	Apr 2012	Use and Charges
FAR	52.246-23	Feb 1997	Limitation of Liability.
FAR	52.246-25	Feb 1997	Limitation of Liability—Services
FAR	52.248-1	Oct 2010	Value Engineering
FAR	52.249-2	Apr 2012	Termination for the Convenience of the Government (Fixed-Price)
FAR	52.249-6	May 2004	Termination (Cost-Reimbursement)
FAR	52.249-8	Apr 1984	Default (Fixed-Price Supply and Service)
FAR	52.249-9	Apr 1984	Default (Fixed-Price Research and Development)
FAR	52.249-14	Apr 1984	Excusable Delays
FAR	52.253-1	Jan 1991	Computer Generated Forms

ARTICLE I.2. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR Chapter 3) CLAUSES

Full text of the HHSAR clauses can be found at https://www.hhs.gov/grants/contracts/contract-policies-regulations/hhsar/index.html

HHSAR	352.203-70	Dec 2015	Anti-Lobbying
HHSAR	352.211.2	Dec 2015	Conference Sponsorship Requests and Conference Materials Disclaimer
HHSAR	352.215-70	Dec 2015	Late Proposals and Revisions
HHSAR	352.216-70	Dec 2015	Additional Cost Principles
HHSAR	352.222-70	Dec 2015	Contractor Cooperation in Equal Employment Opportunity Investigations

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HHSAR	352.223-70	Dec 2015	Safety and Health
HHSAR	352.224-70	Dec 2015	Privacy Act
HHSAR	352.224-71	Dec 2015	Confidential Information
HHSAR	352.227-70	Dec 2015	Publications and Publicity
HHSAR	352.233-71	Dec 2015	Litigation and Claims
HHSAR	352.270-5a	Dec 2015	Notice of Contractors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals
HHSAR	352.270-6	Dec 2015	Restriction on use of Human Subjects

ARTICLE I.3. ADDITIONAL CONTRACT CLAUSES

ARTICLE I.3.1. Additional HHS Acquisition Regulation (HHSAR) Clauses – In Full Text

352.231-70 Salary rate limitation (Dec 2015)

(a) The Contractor shall not use contract funds to pay the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II in effect on the date the funding was obligated

(b) For purposes of the salary rate limitation, the terms “direct salary,” “salary,” and “institutional base salary” have the same meaning and are collectively referred to as “direct salary” in this clause. An individual’s direct salary is the annual compensation that the Contractor pays for an individual’s direct effort (costs) under the contract. Direct salary excludes any income that an individual may be permitted to earn outside of duties to the Contractor. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative costs).

The salary rate limitation does not restrict the salary that an organization may pay an individual working under a Department of Health and Human Services contract or order; it merely limits the portion of that salary that may be paid with federal funds.

(c) The salary rate limitation also applies to individuals under subcontracts.

(d) If this is a multiple-year contract or order, it may be subject to unilateral modification by the Contracting Officer to ensure that an individual is not paid at a rate that exceeds the salary rate limitation provision established in the HHS appropriations act used to fund this contract.

(e) See the salaries and wages pay tables on the U.S. Office of Personnel Management website for federal Executive Schedule salary levels.

(End of clause)

ARTICLE I.3.2. Additional Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clauses – In Full Text

52.217-7 Option for Increased Quantity -- Separately Priced Line Item (Mar 1989)

The Government may require the delivery of the numbered line item, identified in the Schedule as an option item, in the quantity and at the price stated in the Schedule. The Contracting Officer may exercise the option by written notice to the Contractor within 30 days. Delivery of added items shall continue at the same rate that like items are called for under the contract, unless the parties otherwise agree.

52.217-8 Option to Extend Services (Nov 1999)

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

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

(a) The Government may extend the term of this contract by written notice to the Contractor within 30 days; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension.

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

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

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PART III - LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J - LIST OF ATTACHMENTS

The following documents are attached and incorporated in this contract:

1. Statement of Objectives, dated [redacted]*, 5 pages
2. Statement of Work, dated [redacted]*, 2 pages
3. Invoice Instructions for Cost-Reimbursement Type Contracts
4. Invoice Instructions for Fixed-Priced Type Contracts
5. Sample Invoice Form
6. Form SF-LLL, Disclosure of Lobbying Activities, 2 pages
7. Protection of Human Subjects, 2 pages
8. Small Business Subcontracting Plan, dated [redacted]*

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PART IV – REPRESENTATIONS AND INSTRUCTIONS

SECTION K – REPRESENTATIONS AND CERTIFICATIONS

The following documents are incorporated by reference in this contract:

1. The Contractor's representations and certifications, including those completed electronically via the System for Award Management (SAM), are incorporated by reference into the contract.

2. Animal Welfare Assurance Numbers (Prime and Subcontractors).

3. Human Subjects Assurance Identification Numbers (Prime and Subcontractors).

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SECTION C – DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

C.1. STATEMENT OF OBJECTIVES

[redacted]*

C.2. REPORTING REQUIREMENTS

See Section F for specific reporting requirements.

Performance of the contract will be monitored by the CO/COR on a regular basis. The Contracting Officer will be responsible for inspection and acceptance of deliverables and services. Monitoring of the contract will be based on periodic reporting by the Contractor.

C.3. MEETINGS/SITE VISITS

The Contractor and BARDA/AMCG shall participate in regular meetings to coordinate and oversee the contracting effort as requested by the Contracting Officer (CO)/Contracting Officer's Representative (COR). Such meetings may include, but are not limited to, a kickoff meeting to be held at a location determined by the COR, status update meetings and/or teleconferences, site visits to the Contractor's and/or subcontractor's facilities, and meetings with individual Contractors and other HHS officials to discuss the technical, regulatory, and ethical aspects of the program. The Contractor shall provide data, reports, and presentations to groups of outside experts and USG personnel and USG-contracted subject matter experts as required by the CO/COR facilitating review of activities.

The purpose of the kickoff meeting will be to orient the Contractor to HHS/BARDA and review contract requirements. This meeting usually occurs within a month after contract award. Expect Bi-weekly or monthly status update meetings/teleconferences. The schedule for these meetings will be established by the CO and COR.

Periodic site visits shall occur on an ad hoc basis (At least twice a year).

Within thirty (30) calendar days of an FDA audit of Contractor or subcontractor facilities, the Contractor shall provide copies of the audit findings, final report, and a plan for addressing areas of nonconformance to FDA regulations and guidance for GLP, GMP or GCP guidelines as identified in the final audit report.

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Statement of Work

[redacted]*

*** Certain material has been omitted pursuant to a request for confidential treatment. Such omitted material has been filed separately with the Securities and Exchange Commission.**

ATTACHMENT #3

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 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.

(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*)(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 Section G of the Contract Schedule), the Contractor shall include the following certification at the bottom of the payment request:

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

**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 #4

INVOICE/FINANCING REQUEST INSTRUCTIONS FOR FIXED PRICE TYPE CONTRACTS

General The Contractor shall submit vouchers or invoices as prescribed herein.

Format Standard Form l034, Public Voucher for Purchases and Services Other Than Personal, and Standard Form l035, Public Voucher for Purchases and Services Other than Personal--Continuation Sheet, and the payee's letterhead or self-designed form should be used to submit claims for reimbursement.

Number of Copies: As indicated in the contract.

Frequency Invoices submitted in accordance with the Payment Clause shall be submitted monthly upon delivery of goods or services unless otherwise authorized by the Contracting Officer.

Preparation and Itemization of the Invoice The invoice shall be prepared as follows:

(a) Designated Billing Office and address:

HHS/ASPR/BARDA

200 C Street SW

Washington DC 20024

ATTN: Contracting Officer

(b) Invoice Number

(c) Date of Invoice

(d) Contract number and date

(e) Payee's name and address. Show the Contractor's name (as it appears in the contract), correct address, and the title and phone number of the responsible official to whom payment is to be sent. When an approved assignment has been made by the Contractor, or a different payee has been designated, then insert the name and address of the payee instead of the Contractor.

(f) Description of goods or services, quantity, unit price, (where appropriate), and total amount.

(g) Charges for freight or express shipments other than F.O.B. destination. (If shipped by freight or express and charges are more than $25, attach prepaid bill.)

(h) Equipment - If there is a contract clause authorizing the purchase of any item of equipment, the final invoice must contain a statement indicating that no item of equipment was purchased or include a completed form HHS-565, Report of Capitalized Nonexpendable Equipment.

Currency: Where payments are made in a currency other than United States dollars, billings on the contract shall be expressed, and payment by the United States 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.

ATTACHMENT #5

SAMPLE INVOICE FORM

Company Name

Designated Billing Office Name and Address: DHHS/OS/ASPR/AMCG Attn: Contracting Officer 200 C St., S.W. Washington, D.C. 20201 **Contractor's Address and Contact Information:** POC: Name of accountant or COO or signatory authority for invoice Title: Phone: E-Mail: **TIN:** **DUNS #:**	**Invoice/Finance Number:** **Date Invoice Prepared:** **Contract No.** **Effective Date:** **Total Estimated Cost of Order:** **Office of Acquisitions:** Contracting Officer (insert name here) Office of Acquisitions Management, Contracts, and Grants (AMCG) **Central Point of Distribution:**

This invoice represents reimbursable costs for the period from

	Amount Billed		
Expenditure Category	**Current**	**Cumulative**	**Contract Value**
Direct Costs:			
Direct Labor			
Fringe Benefits **0.00%**			
Total Labor Costs:			
Overhead 0.00%			
Travel			
Subcontracts			
Consultant Fees			
Materials and Supplies			
Other			
Total Direct Costs			
G&A Rate **0.00%**			
Subtotal:			
Fixed Fee **0.0%**			
Total Amount Claimed			
Adjustments			
Grand Total	**$ -**		

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

Name/signature of signatory authority for invoicing

DISCLOSURE OF LOBBYING ACTIVITIES

Approved by OMB
4040-0013

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

[redacted]*

*** Certain material has been omitted pursuant to a request for confidential treatment. Such omitted material has been filed separately with the Securities and Exchange Commission**

ATTACHMENT #6

PROTECTION OF HUMAN SUBJECTS

[redacted]*

*** Certain material has been omitted pursuant to a request for confidential treatment. Such omitted material has been filed separately with the Securities and Exchange Commission.**

ATTACHMENT #12

SMALL BUSINESS SUBCONTRACTING PLAN

OFFICE OF SMALL AND DISADVANTAGED BUSINESS UTILIZATION
SMALL BUSINESS SUBCONTRACTING PLAN

[redacted]*

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Exhibit 99.1

SIGA Technologies Awarded BARDA Contract for TPOXX®

- Contract Valued at Up to $629 Million –

- Contract Includes Delivery of Oral and Intravenous (IV) Formulations of TPOXX; Development of IV TPOXX; Post-marketing Activities –

September 10, 2018

NEW YORK -- SIGA Technologies, Inc. (SIGA) (NASDAQ:SIGA), a commercial-stage pharmaceutical company focused on the health security market, today announced that it has signed a multi-year contract with the Biomedical Advanced Research and Development Authority (BARDA), a division of the U.S. Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response, for the delivery of oral and intravenous (IV) formulations of TPOXX® to the Strategic National Stockpile. The contract also covers advanced development of the IV formulation and post-marketing activities for the oral formulation of TPOXX. The contract (HHSO100201800019C) is valued at up to $629 million, and consists of a five-year base period of performance and a total contract period of performance (base period plus option exercises) of up to ten years (if necessary). The contract contains base period activities and a series of options, and is designed to maintain a stockpile of 1.7 million courses of antiviral treatment for smallpox.

On July 13, 2018, the U.S. Food and Drug Administration (FDA) approved oral TPOXX® (tecovirimat) for the treatment of smallpox to mitigate the impact of a potential outbreak. TPOXX, a small-molecule antiviral treatment for smallpox, is the first therapy specifically approved for this indication.

"This contract builds on the strong foundation of the SIGA and BARDA partnership and we look forward to working closely with BARDA to ensure the current U.S. stockpile is adequately maintained" said Phil Gomez, CEO of SIGA Technologies. "The contract provides excellent value to the U.S. Government for the mitigation of the risks of a smallpox outbreak, outlines a roadmap for sustaining the current stockpile, and adds the IV formulation of TPOXX as an available alternative treatment option."

Under contract HHSO100201800019C, base period activities are valued at approximately $52 million and include:

- Development activities for the IV formulation of TPOXX (IV TPOXX).
- Delivery to the Strategic National Stockpile (SNS) of a limited number of courses (approximately 35,700 courses) of the oral formulation of TPOXX (oral TPOXX) for an approximate value of $11 million; such courses being readily-available for delivery or will be manufactured using currently-held active pharmaceutical ingredient.
- Delivery of bulk drug substance to be used for the manufacture of IV TPOXX and the use of such bulk drug substance to manufacture 20,000 courses of final drug product of IV TPOXX, with such activities having a total value of $8 million for 7-day (14-vial) courses; additionally, SIGA will be paid for the storage, if applicable, and delivery of final drug product of IV TPOXX.

With options valued at approximately $577 million in total (if all options are fully exercised), contract HHSO100201800019C is primarily comprised of options that are exercisable at the sole discretion of BARDA.

Options within the contract include:

- Series of options to procure up to approximately 1,452,300 courses in total of oral TPOXX (exclusive of the courses to be purchased for base period activities), with such options having a total value of up to approximately $450 million.
- Series of options to procure up to 192,000 courses in total (exclusive of the courses to be purchased for base period activities) of final drug product of IV TPOXX, with such options having a cumulative total value of up to approximately $77 million for the combination of bulk drug substance and final drug product manufacturing; or alternatively, to procure up to 192,000 equivalent courses in total (exclusive of the equivalent courses to be purchased for base period activities) of bulk drug substance that could be used in the future for the manufacture of final drug product of IV TPOXX, with such alternative having a value of up to approximately $31 million.
- Series of options for vendor-managed storage of either bulk drug substance that would be used in the manufacture of the IV TPOXX or final drug product of IV TPOXX (total option value of approximately $6 million).
- Separate options to cumulatively provide up to approximately $44 million of funding for post-marketing activities for oral TPOXX and IV TPOXX.

This BARDA contract (HHSO100201800019C) becomes the third active contract between the Company and BARDA. Under contract HHSO100201100001C, BARDA funded late-stage development of oral TPOXX for the treatment of smallpox, which culminated in the U.S. Food and Drug Administration (FDA) approval on July 13, 2018, and the acquisition of 2 million courses of oral TPOXX which the Company has delivered. Under contract HHSO100201100023C, the Company receives funding from BARDA for the development of the IV formulation of TPOXX to provide a treatment option for patients who are too sick or unable to swallow oral capsules. It is anticipated that patients taking the IV formulation would eventually "step-down" to the oral formulation, once they are able to swallow capsules. To accommodate this dosing regimen, contract HHSO100201800019C includes an initial order and options for the purchase of up to 212,000 treatment courses (in total) of IV therapy, and each treatment course is expected to cover seven (7) days (14 vials) of treatment. Oral TPOXX approval and procurement is based upon 14 total days of therapy.

This contract will be 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 HHS0100201800019C.

ABOUT SIGA TECHNOLOGIES, INC. and TPOXX®

SIGA Technologies, Inc. is a commercial-stage pharmaceutical company focused on the health security market. Health security comprises countermeasures for biological, chemical, radiological and nuclear attacks (biodefense market), vaccines and therapies for emerging infectious diseases, and health preparedness. Our lead product is TPOXX®, also known as tecovirimat and ST-246®, an orally administered and IV formulation antiviral drug for the treatment of human smallpox disease caused by variola virus. TPOXX is a novel small-molecule drug of which 2 million oral courses have been delivered to the Strategic National Stockpile under Project BioShield. The oral formulation of TPOXX was approved by the Food and Drug Administration (FDA) for the treatment of smallpox on July 13, 2018. For more information about SIGA, please visit www.siga.com.

About Smallpox[1]

Smallpox is a contagious, disfiguring and often deadly disease that has affected humans for thousands of years. Naturally-occurring smallpox was eradicated worldwide by 1980, the result of an unprecedented global immunization campaign. Samples of smallpox virus have been kept for research purposes. This has led to concerns that smallpox could someday be used as a biological warfare agent. No cure or treatment for smallpox exists. A vaccine can prevent smallpox, but the risk of the vaccine's side effects is too high to justify routine vaccination for people at low risk of exposure to the smallpox virus.

1 http://www.mayoclinic.org/diseases-conditions/smallpox/basics/definition/con-20022769

FORWARD-LOOKING STATEMENTS

This press release contains certain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, including statements relating to the future exercise of options by BARDA for procurement of TPOXX®. Such forward-looking statements are subject to various known and unknown risks and uncertainties, and SIGA cautions you that any forward-looking information provided by or on behalf of SIGA is not a guarantee of future performance. More detailed information about SIGA and risk factors that may affect the realization of forward-looking statements, including the forward-looking statements in this press release, is set forth in SIGA's filings with the Securities and Exchange Commission, including SIGA's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, and in other documents that SIGA has filed with the SEC. SIGA urges investors and security holders to read those documents free of charge at the SEC's web site at http://www.sec.gov. Interested parties may also obtain those documents free of charge from SIGA. Forward-looking statements are current only as of the date on which such statements were made, and except for our ongoing obligations under the United States of America federal securities laws, we undertake no obligation to update publicly any forward-looking statements whether as a result of new information, future events, or otherwise.

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