SOLICITATION, OFFER AND AWARD

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 7900)	RATING	PAGE	OF PAGES
		1	94

2. CONTRACT NUMBER	3. SOLICITATION NUMBER	4. TYPE OF SOLICITATION	5. DATE ISSUED	6. REQUISITION/PURCHASE NUMBER
	75A50125R00005	☐ SEALED BID (IFB) ☒ NEGOTIATED (RFP)		

7. ISSUED BY CODE 75A501

HHS / ASPR / DAAPPO / BARDA DCMA
CONSTITUTION CENTER OFFICE BLDG, WASHINGTON, DC 20024

8. ADDRESS OFFER TO *(If other than item 7)*

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

SOLICITATION

9. Sealed offers in original and _____ copies for furnishings the supplies or services in the Schedule will be received at the place specified in item 8, or if hand carried, in the depository located in _____ until _____ (Hour) local time _____ (Date)

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

10. FOR INFORMATION CALL:	A. NAME	B. TELEPHONE *(NO COLLECT CALLS)* AREA CODE	NUMBER	EXT.	C. E-MAIL ADDRESS
	Erin Greninger	771	210-7767		erin.greninger@hhs.gov

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OFFER *(Must be fully completed by offeror)*

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

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

13. DISCOUNT FOR PROMPT PAYMENT *(See Section I, Clause No. 52.232-8)*	10 CALENDAR DAYS (%)	20 CALENDAR DAYS (%)	30 CALENDAR DAYS (%)	CALENDAR DAYS(%)

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

15A. NAME AND ADDRESS OF OFFER-OR	CODE	FACILITY	16. NAME AND THE TITLE OF PERSON AUTHORIZED TO SIGN OFFER *(Type or print)*

15B. TELEPHONE NUMBER AREA CODE	NUMBER	EXT.	☐ 15C. CHECK IF REMITTANCE ADDRESS IS DIFFERENT FROM ABOVE - ENTER SUCH ADDRESS IN SCHEDULE.	17. SIGNATURE	18. OFFER DATE

AWARD *(To be completed by Government)*

19. ACCEPTED AS TO ITEMS	20. AMOUNT	21. ACCOUNTING AND APPROPRIATION

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

24. ADMINISTERED BY *(If other than Item 7)*	25. PAYMENT WILL BE MADE BY	CODE

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

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

Biomedical Advanced Research and Development Authority (BARDA)

Request for Proposals (RFP) for

Antibiotic for Treatment of Bacterial Pneumonia or Bloodstream Infections

RFP #: 75A50125R00005

Issued: July 12, 2025

Initial Questions Due: **July 29, 2025**

Supplemental Questions Due: **August 08, 2025**

Proposal Responses Due: **August 25, 2025**

Contracting Officer: Erin Greninger – Erin.Greninger@hhs.gov
Contract Specialist: Audrey Glover – Audrey.Glover@hhs.gov

Antibiotic for Treatment of Hospital-Acquired and Ventilator-Associated Bacterial Pneumonia or Bloodstream Infections Caused by Drug-Resistant Bacteria or Biothreat Pathogens

NOTE TO OFFERORS

The information in SECTION A - Solicitation/Contract Form, contains important information for any Offeror interested in responding to this solicitation. Any contract resulting from this solicitation will include in its SECTION A - Solicitation/Contract Form, accounting, appropriation, and general information applicable to the contract award.

If your proposal is not received by the Contracting Officer (CO) or his/her designee at the time and place specified, it will be considered late and handled in accordance with the Federal Acquisition Regulation (FAR), FAR 52.215-1 (Instructions to Offerors – Competitive Acquisition), the Health and Human Services Acquisition Regulation (HHSAR), and HHSAR Clause 352.215-70, "Late Proposals and Revisions" located in Section I of this solicitation.

Potential Offerors must be registered in the System for Award Management (SAM) prior to the submittal of a proposal.

The contract schedule, set forth in SECTIONS B through H, contains contractual information pertinent to this solicitation. It is not an exact representation of the contract document that may be awarded as a result of this solicitation. The contract cost or price and other contractual provisions unique to the Offeror's proposal may be included in the resultant contract.

The contract schedule is intended to provide the Offeror with information to aid in understanding the likely terms and conditions of any resultant contract.

Initial questions on this RFP are July 29, 2025, at Noon, EST and supplemental questions due August 8, 2025, at Noon, EST. All questions shall be submitted via e-mail to Erin.Greninger@hhs.gov and Audrey.Glover@hhs.gov.

PART I – THE SCHEDULE

SECTION B – SUPPLIES OR SERVICE AND PRICE / COST

B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

The United States Government (USG) seeks an antibiotic that treats bloodstream infections (BSI) or hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) caused by drug-resistant bacteria. The antibiotic could also be for the treatment and, if feasible, post-exposure prophylaxis (PEP) for one or more biothreat indications (*Y. pestis*, *F. tularensis*, or *B. pseudomallei*). Products that expand the USG's existing preparedness posture for treating antimicrobial-resistant infections will be the highest priority. The product must be either U.S. Food and Drug Administration (FDA)-approved within the last 15 years, or the program completed an end-of-Phase 2 meeting with the FDA and have a Phase 3 development plan that has been favorably reviewed by the FDA for HABP/VABP and/or BSI. The product must be broad-spectrum, targeting two or more drug-resistant pathogen(s) identified as Urgent or Serious Threats in the CDC's 2019 report: *Antibiotic Resistance Threats in the United States*. Generic antibiotics will not be considered under this solicitation.

Under this Request for Proposal (RFP), BARDA intends to use Project BioShield (PBS) funds to support the late-stage development, approval, and potential procurement of an antibiotic. It is anticipated that at least one award may be made from this RFP solicitation. The anticipated contract award(s) includes completion of the regulatory pathway for a BSI or HABP/VABP indication and/or biothreat indication(s) as well as any efforts related to post-marketing commitments/requirements (PMCR). If Offerors propose a biodefense indication, the biodefense development plan for treatment and, if feasible PEP, must have already been discussed with the FDA. This development plan must include the conduct of a Phase 3 clinical trial for a pneumonic indication if the product is not already approved for such an indication and such a study is recommended by the FDA to support the biothreat indication(s). An alternative development/regulatory path may be proposed if a pneumonic indication is not required by the FDA. FDA concurrence with this alternative approach must be provided with the proposal. During the course of the biothreat development program, the Offeror will provide necessary data to support an investigational or emergency use of the USG procured product in the event of a localized outbreak or emergency under an appropriate FDA regulatory mechanism. The timing of such submission by USG will depend on the available data. If milestones are met during development, BARDA may procure the antibiotic using PBS funds for delivery to the ASPR Strategic National Stockpile (SNS) or maintain the antibiotic as vendor-managed inventory (VMI).

B.2. PRICES / COSTS/ PERIOD OF PERFORMANCE

The final contract will contain the price/cost provisions agreed upon by the Government and the Offeror. It is anticipated the total contract period of performance (base plus option periods) will be up to 10 years. The base period includes a cost-plus-fixed-fee (CPFF) contract line-item number (CLIN) to support late-stage development for a BSI or HABP/VABP indication or a biothreat indication. Supplementary CPFF options will be dedicated to additional late-stage development; post-marketing commitments as established by the FDA; BARDA security requirements; on-shoring commercial manufacturing activities, as feasible; and shelf-life extension program activities, as necessary. Firm-fixed-price (FPP) options will include CLINs to support the procurement of treatment, or, if relevant, PEP courses of the antibiotic as final drug product (FDP) for delivery to the ASPR SNS, or as FDP that can be held in VMI until delivery to the ASPR SNS or another site as designated by the USG.

Option periods may be exercised within the base period of the contract if needed. Below is an example of the anticipated CLINs.

B.2.1. BASE PERIOD

Base Period CLIN					
CLIN	**Supplies/Services**	**Period of Performance**	**Estimated Cost**	**Fixed Fee**	**Cost + Fixed Fee**
0001 (Base)	Late-stage development to support FDA marketing authorization for BSI or HABP/VABP indication (nonclinical, clinical, regulatory) or plans for post-marketing requirements for products already approved for BSI or HABP/VABP. AND/OR, late-stage development to support Pre-EUA through FDA marketing authorization for biothreat indication(s) (non-clinical, clinical, regulatory).	9/30/25-9/30/30			

B.2.2. OPTION PERIODS

1. The Government may exercise an Option Period in accordance with FAR 52.217-8 Option to Extend Services (Nov 99) as set forth in ARTICLE I.3 of the contract.

2. Unless the government exercises its Option pursuant to the Option clause contained in ARTICLE I.3, the contract consists only of the Base Work segment specified in the Statement of Work, for the price set forth in ARTICLE B.2.1 of the contract.

3. The Government may require the contractor to provide supplies and services for Option Periods listed below, in accordance with ARTICLE I.3.

4. If the Government decides to exercise an Option(s), the Government will provide the Contractor a preliminary written notice of its intent as referenced in the applicable clause. Specific information regarding the timeframe for this notice is set forth in Article I.3 of this contract. The estimated cost of the contract will be increased as set forth below:

CLIN	**Supplies/Services**	**Period of Performance**	**Estimated Cost**	**Fixed Fee**	**Cost + Fixed Fee**
0002 (Option)	BARDA security requirements, onshoring commercial manufacturing activities, and shelf-life extension program activities for HABP/VABP or BSI indications.	10/01/25-9/30/30			
0003 (Option)	Continued BARDA security requirements, onshoring commercial manufacturing activities, and shelf-life extension program activities for HABP/VABP or BSI indications.	10/01/26-9/30/30			
0004 (Option)	Post-marketing study commitments/requirements for BSI or HABP/VABP, including relabeling of approved drug in the ASPR SNS or VMI (this is an option that may or may not be exercised as required by the FDA)	10/01/27-9/30/31			
0005 (Option)	Continued post-marketing study commitments/requirements for BSI or HABP/VABP, including relabeling of approved drug in the ASPR SNS or VMI (this is an option that may or may not be exercised as required	10/01/28-9/30/32			

	by the FDA)				
0006 (Option)	Ongoing late-stage development to support Pre-EUA through FDA marketing authorization for biothreat indication(s) (non-clinical, clinical, regulatory)	10/01/28-9/30/32			
0007 (Option)	Supplemental late-stage development as requested by FDA to support Pre-EUA through FDA marketing authorization for biothreat indication(s) (non-clinical, clinical, regulatory)	10/01/31-9/30/34			
Total			$	$	$

		Optional Fixed Price CLINs			
CLIN	**Supplies/Services**	**Period of Performance**	**Treatment Courses (# of Product)**	**Unit Price ($)**	**Total $**
0008A (Option)	Initial purchase, storage, and delivery of antibiotic as FDP ASPR SNS sites	10/01/32-9/30/34	2,500*		
0008B (Option)	Initial purchase, storage, and delivery of antibiotic as FDP to VMI	10/01/32-9/30/34	2,500*		
0009A (Option)	Additional procurement of antibiotics as FDP to ASPR SNS sites	10/01/32-9/30/34	2,500*		
0009B (Option)	Additional purchase, storage, and delivery of antibiotic as FDP to VMI	10/01/32-9/30/34	2,500*		
0010A (Option)	Additional procurement of antibiotics as FDP to ASPR SNS sites	10/01/32-9/30/34	2,500*		
0010B (Option)	Additional purchase, storage, and delivery of antibiotic as FDP to VMI	10/01/32-9/30/34	2,500*		
0011A (Option)	Additional procurement of antibiotics as FDP to ASPR SNS sites	10/01/32-9/30/34	2,500*		
0011B (Option)	Additional purchase, storage, and delivery of antibiotic as FDP to VMI	10/01/32-9/30/34	2,500*		
0012 (Option)	Distribution of product from VMI to sites as directed by the USG†	10/01/32-9/30/34	10,000		

* *Per Section L.5.1., Offerors must propose **2,500** treatment courses with a **realistic capacity** to deliver product in addition to the corresponding price per treatment course. However, the USG has discretion to determine the amount of product to be procured based on availability of funds and priorities/requirements.*

† *When budgeting these costs assume the longest route for delivery within the continental United States.*

B.3. ADVANCE UNDERSTANDINGS

The final contract may contain advance understandings between the Government and the Offeror. Specific elements of cost, which normally require prior written approval of the Contracting Officer (CO) before the incurrence of the cost, will be included in this Section if the Contracting Officer has granted his/her approval prior to contract award.

1. **Subcontracts**

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

- Is of the cost-reimbursement, time and materials, or labor hour type or;
- Is of the fixed price type and exceeds $250,000.00 or 5% of the contract value

The Contracting Officer shall request appropriate supporting documentation in order to review and determine authorization, pursuant with FAR Clause 52.244-2 Subcontracts. After receiving written consent of the subcontract by the Contracting Officer, Contractor shall provide a copy of the signed executed subcontract and consulting agreement to the Contracting Officer within ten (10) calendar days following execution of such agreement.

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

2. **Overtime Compensation**

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

3. **Rights in Data**

The contract will incorporate the FAR Clause 52.227-14, Rights in Data-General, Alternate II (DEC 2007).

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;
d) Accountable Government Property;
e) Overtime;
f) General scientific meetings/conferences;
g) Travel costs that include 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 $250,000.00;
j) Refreshments and Meal Expenditures;
k) Promotional Items;
l) Printing.

The Government will not reimburse FDA regulatory filing fees.

B.5 ORGANIZATIONAL CONFLICT OF INTEREST(S)

a. General: For the purpose of this provision/clause, "consultant" is defined as a company, firm, LLC, sole proprietor, joint venture member, independent contractor, subcontractor, affiliate, or similar entity that is not an employee of the Contractor.

b. Disclosure: The Contractor shall report contacts with consultants who are paid to furnish advice, information, direction, or assistance to the Contractor or any subcontractor in support of the preparation or submission of the Contractor's business or technical proposal.
The report shall include the following information:

a. The name, title, and contact information for the consultant, including the name and contact information for his/her company/firm/etc.

b. The name, title, and contact information for a Contractor point of contact, including the name and contact information for the prime contractor if the consulting services were received by a subcontractor.

c. The nature of the consulting services received.

c. **Resolution:** The responsible Contracting Officer will review the Contractor's disclosure to determine whether an actual or appearance of a conflict of interest exists based on the information disclosed by the Contractor and/or from other sources. The framework for the Contracting Officer's review will be FAR Subpart 9.5, Organizational and Consultant Conflicts of Interest. If an actual or appearance of a conflict of interest exists, the Contracting officer will take action which may include, but is not limited to, requesting a mitigation plan from the Contractor.

SECTION C – DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

1.1. STATEMENT OF OBJECTIVES

C.1.1 BACKGROUND AND PURPOSE

The prevalence of infections caused by antibiotic-resistant pathogens is a threat to the health security of the United States. Community- and hospital-acquired antibiotic-resistant infections can complicate the Department of Health and Human Services (HHS) response to emergencies, natural disasters, and chemical, biological, radiological, and nuclear (CBRN) events. The illness and injuries caused by CBRN threats can lead to secondary bacterial infections, many of which can be antibiotic-resistant. Antibiotic resistance also has the potential to render the current stockpile of antibiotic MCMs for biothreat pathogens ineffective. Development and procurement of antibiotics that overcome known forms of resistance and treat biothreat pathogens will enhance the USG's emergency preparedness.

BARDA and the PHEMCE recognize the critical need to prepare for an outbreak of antibiotic-resistant secondary bacterial infections. This acquisition will address this gap by supporting the late-stage development, FDA marketing authorization, procurement, and stockpile of antibiotics for the treatment of drug-resistant secondary bacterial infections. The acquired products will directly address PHEMCE requirements established in the Materiel Requirements for Medical Countermeasures to Antimicrobial Resistant Infections Resulting from CBRNE Exposures, and the 2014 National Strategy and Action Plan to Combat Antibiotic Resistant Bacteria. Supporting the development and stockpiling of MCMs that have the potential to treat antibiotic-resistant bacterial infections is necessary for a USG response to health security threats.

C.1.2 SCOPE

Independently and not as an agent of the USG, the Offeror shall furnish all the necessary services, qualified personnel, materials, supplies, equipment, and facilities not otherwise provided by the USG as needed to perform the work described below.

The USG is seeking to procure and maintain an antibiotic for the treatment of BSI or HABP/VABP and, if feasible, the treatment and/or PEP of a biothreat indication (*Y. pestis, F. tularensis, or B. pseudomallei)*. The USG has the discretion to determine the amount of product to be procured based on availability of funds and priorities/requirements. The USG may procure quantities of the antibiotic product when contract milestones are met. The antibiotic shall be delivered to the ASPR SNS, and/or maintained as VMI as determined by BARDA and the Contracting Officer. The treatment and/ PEP courses shall be provided as FDP.

The scope of the Base Period may include late-stage development activities necessary to support an FDA approval for BSI or HABP/VABP or FDA marketing authorization (nonclinical, clinical, and regulatory) for a biothreat indication. Option Period(s) will include additional late-stage development activities; BARDA security requirements, onshoring commercial manufacturing activities, and shelf-life extension program activities; post-marketing commitments/requirements; and purchases of antibiotic treatment and/or PEP courses.

The statement of objectives outlined in the following sections shall be addressed by the Offeror in their proposed statement of work:

Section 1: Program Management and Risk Mitigation Objectives
Section 2: Late-stage Product Development Objectives
Section 3: Post-Marketing Commitments/Requirements
Section 4: Procurement Objectives
Section 5: Storage and Delivery of Product Objectives

1. PROGRAM MANAGEMENT AND RISK MITIGATION OBJECTIVES

The Offeror is directed toward details provided in Section F for the items below.

1.1 The Offeror shall submit program/risk management documents as described in SECTION F – Deliveries or Performance.

1.2 The Offeror shall develop and maintain a risk mitigation plan that is acceptable to the CO and Contracting Officer's Representative (COR). This shall include a risk matrix per Attachment 14.

1.3 The Offeror shall provide a Security Plan that is associated with all aspects of FDP supply chain, including the manufacture of product, storage, inventory, and shipping of the FDP. The Security Plan shall include all sites within the supply chain, including proposed shipping carriers. For those sites/carriers that are not defined at the time of award or are added during the period of performance, individualized Security Plans shall be provided to the USG prior to inclusion of sites/carriers into the supply chain. BARDA's Program Protection Office will be authorized to review and approve Security Plans and will conduct annual audits/site visits to ensure a reliable product is delivered to the USG. Security requirements and a template for a Security Plan are included in Attachments 16 and 17, respectively.

1.4 The Offeror submitting a proposal will be required to provide a copy of their facility's security plan with their proposal in response to this solicitation. The Offeror is responsible for ensuring all proposed subcontractors provide a facility security plan to be included in the submission.

1.5 The Offeror must provide a Target Product Profile, a commercial development strategy for the product, and a corporate sustainability strategy.

2. LATE-STAGE PRODUCT DEVELOPMENT OBJECTIVES (BASE CLIN and OPTION CLINs)

2.1. GENERAL PRODUCT DEVELOPMENT OBJECTIVES

2.1.1. Unless already FDA approved, the Offeror must propose a development plan to support a primary indication of BSI or HABP/VABP including nonclinical, clinical, and chemistry, manufacturing, and control (CMC) activities as necessary. The product must have demonstrated data that will support NDA/sNDA approval for a BSI or HABP/VABP indication, including the relevant microbiological profile, target attainment and therapeutic efficacy through PK/PD studies. The proposed development plan must have been discussed with the FDA.

2.1.2. If proposing a development plan for a biodefense indication**,** the product minimally must have demonstrated *in vitro* efficacy against one or more of the following biothreat pathogens: *Y. pestis*, *F. tularensis*, or *B. pseudomallei*. All data supporting activity and efficacy against the biothreat pathogen(s), as well as a development plan that has been discussed with the FDA must be presented in the proposal.

2.1.3. The Offeror must propose plans to achieve five years of stability for the FDP, process validation, registration batches, and annual commercial manufacturing programs.

2.2. REGULATORY OBJECTIVES

2.2.1. The Offeror shall maintain and update, as required by the FDA, all required regulatory documentation (investigator brochure, regulatory binder, etc.), that will be used to support an investigational or emergency use in the event of a localized outbreak or public health event and marketing authorization packages for review by the FDA.

2.2.2. The Offeror shall obtain FDA concurrence on the appropriate path for regulatory evaluation and marketing authorization (i.e., traditional, accelerated, or Animal Rule).

2.2.3. The Offeror shall conduct all necessary meetings with the FDA to support the submission of an NDA or evaluation through an amendment to an existing marketed product to the FDA.

2.2.4. During the course of a potential biothreat development program, the Offeror will provide necessary data to support an investigational or emergency use of the USG procured product in the event of a localized outbreak or public health emergency under an appropriate FDA regulatory mechanism. Offeror shall share the data package with the USG for submission of a pre-EUA package to the

FDA. The timing of submitting this data package to regulators will depend on the available data and whether it will support the submission of a Pre-EUA (thus supporting an EUA request should an emergency be declared).

Note: The Offeror is strongly encouraged to review the FDA's guidance to industry on EUAs and hold a Type B meeting with the FDA prior to proposal submission to discuss the proposed biothreat development and regulatory path.

2.2.5. As a potential EUA requestor, the Offeror and the USG shall seek FDA concurrence that the IND/sNDA labeling is acceptable for an EUA and could be used under EUA without the need to re-label the product. If the FDA does not find the existing IND/sNDA labeling adequate for safe and effective use of the product under the EUA, the Offeror shall re-label the product in accordance with regulatory requirements from the FDA.

2.2.6. The Offeror shall re-label the investigational product (upon marketing authorization) to be consistent with the licensed product, in accordance with regulatory requirements from the FDA.

2.3. NONCLINICAL OBJECTIVES

2.3.1. The Offeror shall perform the appropriate late-stage nonclinical safety studies needed to establish product safety, as needed.

2.3.2. The Offeror shall conduct any FDA required efficacy studies to support FDA marketing authorization.

2.3.3. The Offeror shall conduct any FDA required PK studies to support FDA marketing authorization of a BSI or HABP/VABP and/or biothreat indication, if required.

2.3.4. The Offeror shall conduct any PK/PD modeling to establish an appropriate clinical dose and regimen for a BSI or HABP/VABP and/or biothreat indication.

2.4. CLINICAL OBJECTIVES

2.4.1. The Offeror shall conduct any FDA required efficacy studies to support FDA marketing authorization of a BSI or HABP/VABP indication.

2.4.2. The Offeror shall complete any remaining clinical studies to support clinical safety under the Animal Rule as necessary for a potential biothreat indication as directed by BARDA and the FDA. The Animal Rule neither replaces the need nor establishes special requirements, for an adequate human safety database for drug development. The expectation is that drugs will be evaluated for safety under preexisting requirements for establishing the safety of new drugs and biological products. FDA anticipates that the nonclinical and clinical safety development programs will proceed in a manner similar to that of drugs developed under traditional regulatory pathways.

2.5. CHEMISTRY, MANUFACTURING, CONTROL OBJECTIVES

2.5.1. The Offeror shall provide plans for full process validation for registration/primary batches.

2.5.2. The Offeror shall develop and establish the manufacturing process for active pharmaceutical ingredients (API) and FDP.

2.5.3. The Offeror shall provide the status of the contract manufacturing organization (CMO), including location, and whether any US domestic capacity currently exists for both API/DS and fill/finish of DP. If U.S. domestic capacity does not yet exist, provide a timeline and summary of the approach to onshore both API/DS manufacturing and fill finish of DP. If U.S.-based manufacturing is not feasible, the Offeror must explain why and include an analysis of the cost to establish U.S.-based manufacturing of the starting materials, API/DS, and fill/finish of DP.

2.5.4. The Offeror shall deliver the product with established acceptable product quality attributes meeting the proposed product safety and efficacy during product shelf life.

2.5.5. The Offeror shall provide a Manufacturing Plan that includes a facility regulatory compliance plan addressing current good manufacturing practice (cGMP) standard, a description of the manufacturing facility quality assurance (QA) and regulatory acceptance including quality systems, validation master plan, and regulatory milestones.

2.5.6. The Offeror shall complete any remaining manufacturing and quality control (QC) activities needed to support FDA marketing authorization, and the Offeror shall establish a regulatory strategy and filing processes for successful marketing authorization of the product.

2.5.7. The Offeror must propose plans to achieve five years of stability for the FDP, process validation, registration batches, and annual commercial manufacturing programs.

2.5.8. The Offeror shall demonstrate capability and compliance for all required CMC activities. These include but are not limited to those listed below:

a) Final product manufacturing, process and equipment validation, analytical methods, and assays appropriate for product characterization and product release, including tests for the identity, purity, potency, and for demonstrating stability of the intermediate and FDP to support FDA marketing authorization.

b) Identify a stable source and availability of reagents and reference standards for these assays required; execute product stability testing plans as evidenced by available data towards the intended product stability.

c) Develop and maintain documentation such as those describing QC and QA monitoring plan and manufacturing process, facility information, product storage and monitoring inventory systems, and process flow for material and waste disposal.

d) Packaging of FDP to provide for the most cost-effective product life-cycle value and performance and to allow for ease of distribution and use during a declared emergency.

e) Assures selected vendors are GMP compliant.

3. POST-MARKETING COMMITMENTS/REQUIREMENTS (PMCR)

3.1. The Offeror shall satisfy any PMCR required for maintaining FDA marketing authorization. Cost estimates for these studies may be based on tentative plans in place prior to direction from the FDA, if appropriate. The Offeror shall satisfy any PMCR required for maintaining the license, including any studies to monitor safety and efficacy during a biothreat emergency.

4. PROCUREMENT OBJECTIVES

4.1. It is anticipated that the USG may procure up to 10,000 patient courses per product. Procurements are anticipated to be made in increments based on the achievement of development milestones, USG requirements, and availability of funds. Specific milestones will be determined during contract negotiations. Examples are included in 4.2 and 4.3.

4.2. The USG may make an initial procurement when FDA approval (NDA or sNDA) is achieved for a BSI or HABP/VABP indication, based on the proposed development plan, and when the regulatory and quality requirements are met, as determined by BARDA.

4.3. For a biothreat indication, the USG may make an initial procurement prior to FDA approval when the following development and regulatory milestones (a-i) have been achieved for a biothreat indication:

a) *In vitro* microbiology data (MIC data for a panel of 50 biodefense isolates/strains)

b) Data on the activity or efficacy in animals that contribute to understanding the potential treatment and PEP effect in humans (e.g., proof-of-concept *in vivo* studies in one or more animal species)

c) Completed nonclinical toxicology and safety pharmacology studies that support the conduct of human clinical trials and marketing authorization for pharmaceuticals consistent with ICH M3(R2) taking into consideration the expected drug exposures and treatment duration related to the proposed use as a biothreat MCM.

d) Completed PK study in at least one sufficiently well-characterized animal model to be used for predicting the efficacy/response in humans for the biothreat indication.

e) Completed study demonstrating the exposure/response relationship as well as the fully effective dose in a well-characterized animal model expected to react with a response predictive for humans.

f) Selection of a human dose that is expected to be effective in humans based on the relationship between drug exposure and effectiveness established in animals and available human PK data.

g) Human safety information from clinical trials and individual patient experience at the expected drug exposures related to the proposed use as a biothreat MCM. The expectation is that the drug will be evaluated for safety under preexisting requirements for establishing safety of new drugs and the size and composition of the human safety database should be consistent with the proposed use of the drug.

h) Security, regulatory, and quality requirements (as determined by BARDA) must be met.

i) A Pre-EUA package for the product that includes the data from the development milestones has been filed for the biothreat indication(s) and all identified concerns have been adequately addressed.

4.4. The USG may procure additional quantities of antibiotics based on milestones achieved as relevant to the product's proposed development plan. The milestones listed below are examples of when additional procurements may be initiated. Specific milestones to trigger procurement(s) will be determined during contract negotiations.

4.2.1. Completion of a predetermined set of post-marketing commitments. Offeror should propose appropriate PMCRs based on the product's FDA requirements. Example PMCRs include 5-year post-marketing surveillance, an sNDA for pediatrics, or other sNDAs.

4.2.2. Transfer of manufacturing to domestic (USA based) manufacturing facilities for Active Pharmaceutical Ingredients (APIs)/Drug Substances (DS), Drug Products (DP), and fill/finish, if applicable. If an NDA includes approved offshore facilities (not USA based), completion of technology transfer to onshore manufacturing facilities, manufacturing of Process Performance Qualification (PPQ) batches, and applicable regulatory approval.

4.2.3. Successful achievement of five-year stability of drug product.

4.2.4. If a biothreat indication is being pursued, FDA approval of an sNDA for the biothreat indication.

5. STORAGE AND DELIVERY OF PRODUCT OBJECTIVES

5.1 The Offeror shall store FDP, in compliance with cGMP, until release testing has been completed. The FDP will be shipped to and stored at the ASPR SNS or maintained as VMI in a manner consistent with applicable FDA guidance and requirements. The source of transportation used by the Offeror for the delivery of the product will be subject to review as part of the overall Security Plan. Offeror must propose a price per treatment course for both VMI and ASPR SNS.

5.2 The Offeror shall maintain cGMP compliance and QC of stored FDP and stability assays to ensure expiry dating for the duration of the contract. As related to VMI, the contractor shall provide a general rotation plan and a rotation plan for the storage and delivery of the product, as applicable. In the plan, logistics for disposing of expired products should be provided. The plan shall also establish the timeframe for when BARDA is notified of expired products, to include batch numbers, and additional details as relevant, such as location of the batch, shipping destination, replacement of expired product in the inventory, etc. Proposed price rates should include the logistics noted.

5.3 The estimate for the total antibiotic procurement is 10,000 patient courses, composed of a combination of treatment and/or PEP, as applicable. However, the USG has the sole discretion to determine the amount of product to be procured based on the availability of funds and priorities/requirements. These efforts include manufacturing, stability testing, and storage. Offerors must propose a price per treatment course for both VMI and ASPR SNS.

5.4 The Offeror must implement a Vendor Managed Inventory (VMI) system and approach to store, manage, and deliver antibiotics manufactured under this project. The USG desires a VMI approach that utilizes a First-In-First-Out (FIFO) approach to inventory management while keeping the quantity of antibiotic (product manufactured under this Agreement to date minus product delivered to date) available for delivery to the USG as required (i.e. the USG will always have the most recently manufactured product available).

C.1.3. REPORTING REQUIREMENTS

See Section F for specific reporting requirements.

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

C.1.4. MEETINGS/SITE VISITS

The Offeror and BARDA shall participate in regular meetings to coordinate and oversee the contracting effort as requested by the CO/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 or teleconferences, site visits to the Offeror's and Offeror's subcontractor facilities, and meetings with individual Offerors and other HHS officials to discuss the technical, regulatory, and ethical aspects of the program. The Offeror 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 Offeror to HHS/BARDA and review contract requirements. This meeting usually occurs within a month after the contract award. Expect biweekly 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 30 calendar days of an FDA audit of the Offeror or Offeror's subcontractor facilities, the Offeror shall provide copies of the audit findings, final report, and a plan for addressing areas of nonconformance to FDA regulations and guidance for good laboratory practice (GLP), good manufacturing practice (GMP), or good clinical practice (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 Offeror with 48 hours advance notice. The USG reserves the right to accompany the Offeror on routine and for-cause site visits/audits of Offeror subcontractor(s). At the discretion of the USG and independent of testing conducted by the Offeror, BARDA reserves the right to conduct site visits/audits and collect samples of product held by the Offeror and Offeror's subcontractor(s).

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

SECTION D – PACKAGING, MARKING AND SHIPPING

D.1. METHOD OF DELIVERY

Unless otherwise specified by the Contracting Officer, all document 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 document deliverables shall be marked with the contract number and Offeror's name. The Offeror shall guarantee that all required materials shall be delivered in immediate usable and acceptable condition.

D.2. FOB DESTINATION DELIVERIES

For delivery of product to the ASPR SNS, the Offeror shall describe the storage conditions for each product, specifically noting the acceptable temperature range required to maintain product quality. The Offeror shall be responsible for maintaining product temperature control until the product(s) arrives at the ASPR SNS and has completed product acceptance by the USG. The Offeror will provide and place TempTale(s) on each pallet of product while the product is inside the Offeror's validated storage facility prior to placing the product(s) onto the

truck(s) of the designated carrier. The Offeror shall provide the Government with an ambient exposure letter that covers the time the product(s) leaves the Offeror's validated storage facility until arrival at the ASPR SNS. Upon delivery of the product(s) to the ASPR SNS, 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 Government's acceptance of the aforementioned responsibility applies only to temperature control and does not indicate its acceptance of the lot(s).

SECTION E – INSPECTION AND ACCEPTANCE

E.1. INSPECTION AND ACCEPTANCE

At the discretion of the USG, BARDA reserves the right to conduct site visits/audits held by the Offeror and Offeror's subcontractor(s). Inspection and acceptance of services and documentation called for herein shall be accomplished by the Contracting Officer or a duly authorized representative. Technical inspection and acceptance of documents will occur via email.

Product inspection and acceptance will take place at an Offeror-identified site for VMI or at a SNS site to be determined. The acceptance may be conducted in-person or virtually. Acceptance may be presumed unless otherwise indicated in writing by the Contracting Officer or the duty authorized representative within 30 days of receipt of the product.

E.2. FEDERAL ACQUISITION REGULATION CLAUSES INCORPORATED BY REFERENCE

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

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

FAR 52.246-3, Inspection of Supplies – Cost Reimbursement (May 2001)

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

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

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

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

F.1. ESTIMATED PERIOD OF PERFORMANCE

The estimated period of performance of this contract (base plus option periods) is anticipated to be up to 10 years from the date of award. Potential CLINs within the period of performance are set forth in SECTION B.

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.

F.3. CONTRACT DELIVERABLES AND REPORTING REQUIREMENTS

F.3.1. Submission of Contract Deliverables

Documents shall be delivered electronically via email to the CO and the COR. Additionally, the Contractor shall upload documents to the appropriate Government designated file sharing system. The Government shall provide two contractor representatives with authorized log-in access to the file share program. Each representative must complete mandatory training provided by the Government prior to gaining user access. A notification email shall be sent to the CO and COR upon electronic delivery of any documents.

F.3.2. Reporting Requirements

In addition to those reports required by other terms of this RFP, the Offeror shall submit to the CO and the COR technical progress reports as identified in any potential resultant contract. 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:

A. Monthly Progress Report

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

The Offeror 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 Offeror'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:

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). 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-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 included in this section are 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 an Annual Progress Report, or a Final Report are due.

B. 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 Offeror 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 Offeror's name, address, telephone number, fax number, and email address; and the date of submission.

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

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). 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-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 included in this section are 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 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.

C. Draft Final Report and Final Report

These reports are to include a summation of the work performed and results obtained for the 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 45 calendar days prior to the expiration date of the contract and the Final Progress Report is due before 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 Offeror'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:

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 Offeror shall forward the initial draft minutes to the COR. The Offeror shall forward the final minutes when available.

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

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

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

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

g) The Offeror shall notify the COR and CO within 24 hours of all FDA arrivals to conduct site visits/audits by any regulatory agency. The Offeror shall provide the USG with an exact copy (non-redacted) of the FDA Form 483 and the Establishment Inspection Report (EIR). The Offeror shall provide the COR and CO 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 plan's execution, and a copy of all final responses to the FDA. The Offeror shall also provide redacted copies of any FDA audits received from sub-contractor 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 Offeror 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

1. Integrated Master Project Plan

The Offeror shall provide an Integrated Master Project Plan (including tabular and Gantt forms) to the COR that indicates the critical path to annual deliverables and Work Breakdown Structure (WBS) elements. Attention shall be placed on providing sufficient turnaround time for the USG (BARDA, FDA, and ASPR) for the review of critical documentation. The Offeror shall integrate to demonstrate interdependencies among all CLINs. The Integrated Master Project Plan shall be incorporated into any potential contract and will be used to monitor the performance of the contract. This report shall be due 90 days after contract award. Updates shall be due as requested by the COR.

I. Critical Path Milestones

The Integrated Master Project Plan shall outline key, critical path milestones, with "Go/No Go" decision criteria (entrance and exit criteria for each phase of the project). This report shall be due 90 days after contract award. Updates shall be due as requested by the COR.

II. Work Breakdown Structure

The WBS shall be discernable and consistent. The COR may require the Offeror to furnish WBS data at the work package level or at a lower level if there is significant complexity and risk associated with the task. This report shall be due 90 days after contract award. Updates shall be due as requested by the COR.

III. Risk Mitigation Plan/Matrix

The Offeror shall develop and maintain a risk management plan that highlights potential problems or issues that may arise during the life of the contract, their impact on cost, schedule, and performance, and appropriate remediation plans. This plan shall reference relevant WBS/SOW elements where appropriate. The USG has provided a Risk Mitigation Matrix template (See **http://www.phe.gov/about/amcg/contracts/Pages/toolkit.aspx**) to be completed by any prospective Offeror. This report shall be due 90 days after contract award. Updates shall be due as requested by the COR.

2. Technology Packages

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

3. Experimental Protocols

The Offeror shall submit to the COR all study/experiment/test plans, designs, and protocols upon request by the COR.

4. Annual/Final Invention Report

All reports and documentation required by FAR Clause 52.227-11, Patent Rights- Ownership by the Offeror, 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 CO.

5. 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 30 calendar days prior for manuscripts and 15 calendar days for abstracts.

6. Press Releases

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

7. Security Report

The Offeror 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 the occurrence of an activity or incident.

8. Security Plan

The Offeror shall submit a Final Security plan 90 days after contract award. See Attachments 15 and 16 for security requirements and a template for the Security Plan.

9. Quality Management System Plan

The Offeror shall submit to the COR a Quality Management System Plan for approval no later than 90 days after the date of award.

10. Manufacturing Plan

The Offeror shall submit to the COR a comprehensive manufacturing plan for review and approval no later than 90 days after the date of award.

F.4. DELIVERABLE SCHEDULE

Item No.	Description	Addresses	Deliverable Schedule
1.	Kick-off Meeting	CO: (1) electronic copy COR: (1) electronic copy	Due within 60 days of contract award. Meeting minutes are due no later than five business days following the meeting.
2.	Biweekly 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.
3.	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.

4.	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.
5.	Draft and Final Study Protocols	CO: (1) electronic copy COR: (1) electronic copy	The contractor shall provide all Draft and Final Study Protocols to the COR for evaluation. (The CO and COR reserve the right to request within the period of performance a non-proprietary Study Protocol for distribution within the Group.)
6.	Draft Final Progress Report	CO: (1) electronic copy COR: (1) electronic copy	The report is due no later than 45 calendar days prior to the expiration date of the contract.
7.	Final Progress Report	CO: (1) electronic copy COR: (1) electronic copy	The report is due before the expiration date of the contract.
8.	Quarterly Financial 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.
9.	Annual Final Indirect Cost Proposal	CO: (1) electronic copy COR: (1) electronic copy	Proposals are due within the 6-month period following the expiration of each of its fiscal years.
10.	FDA Submissions	CO: (1) electronic copy COR: (1) electronic copy	The Contractor shall provide the CO and COR the opportunity to review and comment upon all draft submissions before submission to the FDA. The contractor shall provide the CO and COR with an electronic copy of the final FDA submission. All documents shall be duly marked as either “Draft” or “Final”.
11.	FDA/Regulatory Agency Correspondence and Meeting Summaries	CO: (1) electronic copy COR: (1) electronic copy	Reports are due within three business days of each meeting for the Offeror’s minutes, upon receipt of minutes from the FDA/regulatory agency, and upon request from the COR.
12.	Integrated Master Project Plan -Critical Path Milestones - Work Breakdown Structure - Risk Mitigation Plan/Matrix	CO: (1) electronic copy COR: (1) electronic copy	The report is due within 90 days of contract award. Updates are due as requested by the COR.
13.	Technology Packages	CO: (1) electronic copy COR: (1) electronic copy	Upon request from the COR.
14.	Experimental Protocols	CO: (1) electronic copy COR: (1) electronic copy	Upon request from the COR.

15.	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 The final Invention Report is due on or before the expiration date of the contract.
16.	Publications	CO: (1) electronic copy COR: (1) electronic copy	Reports are due within 30 calendar days for manuscripts and 15 calendar days for abstracts.
17.	Press Releases	CO: (1) electronic copy COR: (1) electronic copy	Reports/Notices are due for approval to the CO not less than five business days prior to the issuance of any potential press release.
18.	Security Report	CO: (1) electronic copy COR: (1) electronic copy	Reports are due within 24 hours after the occurrence of an activity or incident.
19.	Security Plan	CO: (1) electronic copy COR: (1) electronic copy	Final plan due within 90 days of contract award.
20.	Manufacturing Plan	CO: (1) electronic copy COR: (1) electronic copy	Due within 90 days of contract award.
21.	Target Product Profile	CO: (1) electronic copy COR: (1) electronic copy	Due within 90 days of contract award.
22.	Commercial Development Strategy	CO: (1) electronic copy COR: (1) electronic copy	Due within 90 days of contract award.
23.	Corporate Sustainability Strategy	CO: (1) electronic copy COR: (1) electronic copy	Due within 90 days of contract award.
24.	Quality Management System Plan	CO: (1) electronic copy COR: (1) electronic copy	Due within 90 days of contract award

25.	Delivery Schedule to the ASPR/SNS or maintained as VMI as described in SECTION C.4: Procurement and Delivery of Product Objectives	CO: (1) electronic copy COR: (1) electronic copy	Due within 30 days of agreement on delivery location
26.	Deviation and Notification Strategy	CO: (1) electronic copy COR: (1) electronic copy	Upon request from the COR
27.	Go/No-Go In-Process Review (IPR)	CO: (1) electronic copy COR: (1) electronic copy	The contractor shall provide presentation materials to CO and COR 10 business days prior to the IPR. Submit written justification of progress towards satisfying Go/No-Go criteria. CO/COR will provide a written response within 10 days.
28.	Study Reports	CO: (1) electronic copy COR: (1) electronic copy	Draft report due within 45 calendar days after completion of analysis and at least 15 business days prior to submission to FDA. Final report due 30 calendar days after receiving comments on the Draft Final Report for Clinical and Non-Clinical Studies. Final FDA submissions shall be provided to BARDA concurrently or no later than 1 business day after submission to the FDA.
29.	BARDA Audit	CO: (1) electronic copy COR: (1) electronic copy	If issues are identified during the audit, the Contractor shall submit a report to the CO and COR detailing the finding(s) and corrective action(s) within 10 business days of the audit.
30.	Raw Data/Data Analysis	CO: (1) electronic copy COR: (1) electronic copy	The contractor shall provide data or data analysis to the CO and COR within 20 business days of request, amend reports if required, and adjudicate all comments.
31.	Antibiotic procurement	Up to 10,000 treatment courses	The contractor will provide up to 10,000 treatment courses of antibiotic upon meeting procurement milestones

F.5. FEDERAL ACQUISITION REGULATION CLAUSES INCORPORATED BYREFERENCE, 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/comp/far/index.html.

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

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

SECTION G – CONTRACT ADMINISTRATION

G.1. CONTRACTING OFFICER (CO)

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 CO 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.

Erin Greninger
Biomedical Advanced Research and Development Authority
Administration for Strategic Preparedness and Response
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Washington, D.C. 20024
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The CO is the only person with authority to act as an agent of the Government under this contract. Only the CO has the 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 Offeror 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 CO, which may be received from any person employed by the United States Government, or otherwise, shall be considered grounds for deviation from any stipulation of this contract.

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

The Government's Contracting Officer's Representative is: *To be identified at the time of contract award.*

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

G.3. OFFEROR'S POINTS OF CONTACT

The Offeror 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.

G.4. KEY PERSONNEL, HHSAR 352.237-75 (December 2015)

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to the Offeror voluntarily diverting any of the specified individuals to other programs or contracts the Offeror 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 Offeror is terminated for cause or separates from the Offeror voluntarily with less than thirty (30) days' notice, the Offeror shall provide the maximum notice practicable under the circumstances. The Offeror shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. If the proposed Key Personnel change between the time of the Offeror's proposal and contract award, the Offeror needs to provide immediate written notification to the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

The contractor shall provide a list of FTEs in the table below that are considered to be essential to the work being performed hereunder:

Title	Name
Program Director/Principal Investigator	
Project Manager	
Chief Scientific/Medical Officer	
Clinical Development/Clinical Study Director	

G.5. INVOICE SUBMISSION - HHSAR 352.232-71 Electronic submission of payment requests Electronic Submission of Payment Requests (Feb 2022)

(a) Definitions. As used in this clause – (1) "Payment request" means a bill, voucher, invoice, or request for contract financing payment with associated supporting documentation. The payment request must comply with the requirements identified in FAR 32.905(b), "Content of Invoices" and the applicable Payment clause included in this contract.

(b) Except as provided in paragraph (c) of this clause, the Contractor shall submit payment requests electronically using the Department of Treasury Invoice Processing Platform (IPP) or successor system. Information regarding IPP, including IPP Customer Support contact information, is available at www.ipp.gov or any successor site.

(c) The Contractor may submit payment requests using other than IPP only when the Contracting Officer authorizes alternate procedures in writing in accordance with HHS procedures.

(d) If alternate payment procedures are authorized, the Contractor shall include a copy of the Contracting Officer's written authorization with each payment request

G.5.1 INVOICE ELEMENTS

(a) The Offeror shall submit invoices electronically to the CO, the COR, and the Program Support Center (PSC) (PSC_Invoices@psc.hhs.gov). The payment request shall be transmitted as an attachment via email. Invoice composition instructions are provided in Attachment #2 (Cost- Reimbursement Type Contracts) and Attachment #3 (Fixed Price Type Contracts). A sample invoice form is provided as Attachment#4.

(b) The Offeror agrees to include (as a minimum) the following information on each invoice:

1. Offeror's Name & Address
2. Offeror's Tax Identification Number (TIN)
3. Contract Number
4. Invoice Number
5. Invoice Date
6. Contract Line Item Number
7. Quantity
8. Unit Price & Extended Amount for each line item
9. Total Amount of Invoice
10. Name, title and telephone number of person to be notified in the event of a defective invoice
11. Payment Address, if different from the information in (b)1.

(c) The invoice shall be signed by a person authorized to bind the Offeror.

(d) The Offeror shall not submit an invoice prior to delivery of goods or services.

(e) The Offeror 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 current HHS Salary Rate Limitation Provisions in Section I of the contract."

G.5.2 ELECTRONIC INVOICING AND PAYMENT REQUIREMENTS – INVOICE PROCESSING PLATFORM (IPP)

All Invoice submission for goods and or services delivered to facilitate payments must be made electronically through the U.S. Department of Treasury's Invoice Processing Platform System (IPP).

• Invoice Submission for Payment means any request for contract financing payment or invoice payment by the Contractor. To constitute a proper invoice, the payment request must comply with the requirements identified in the applicable Prompt Payment clause included in the contract, or the clause 52.212-4 Contract Terms and Conditions – Commercial Items included in commercial items contracts. The IPP website address is: https://www.ipp.gov.

• The Agency will enroll the Contractors new to IPP. The Contractor must follow the IPP registration email instructions for enrollment to register the Collector Account for submitting invoice requests for payment. The Contractor Government Business.

• Point of Contact (as listed in SAM) will receive Registration email from the Federal Reserve Bank of St. Louis (FRBSTL) within 3 – 5 business days of the contract award for new contracts or date of modification for existing contracts.

o Registration emails are sent via email from ipp.noreply@mail.eroc.twai.gov. Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to IPPCustomerSupport@fiscal.treasury.gov or phone (866) 973-3131.

o The Contractor POC will receive two emails from IPP Customer Support, the first email contains the initial administrative IPP User ID. The second email, sent within 24 hours of receipt of the first email, contains a temporary password. You must login with the temporary password within 30 days.

• If your company is already registered to use IPP, you will not be required to re-register.

• If the Contractor is unable to comply with the requirement to use IPP for submitting invoices for payment as authorized by HHSAR 332.7002, a written request must be submitted to the Contracting Officer to explain the circumstances that require the authorization of alternate payment procedures.

Additional Administration for Preparedness and Response (ASPR) requirements:

(i) The contractor shall submit monthly invoices under this contract unless otherwise agreed upon by all parties. For indefinite delivery and blanket purchase agreement vehicles, separate invoices must be submitted for each order.

(ii) Invoices must break-out price/cost by contract line item number (CLIN) as specified in the pricing section of the contract.

(iii) Invoices must include the UEI number of the Contractor.

(iv) Invoices that include time and materials or labor hours CLINS must include supporting documentation to (1) substantiate the number of labor hours invoiced for each labor category, and (2) substantiate material costs incurred (when applicable).

(v) Invoices that include cost-reimbursement CLINs must be submitted in a format showing expenditures for that month, as well as contract cumulative amounts. At a minimum the following cost information shall be included, in addition to supporting documentation to substantiate costs incurred.

• Direct Labor - include all persons, listing the person's name, title, number of hours worked, hourly rate, the total cost per person and a total amount for this category;

• Indirect Costs (i.e., Fringe Benefits, Overhead, General and Administrative, Other Indirects)- show rate, base and total amount;

• Consultants (if applicable) - include the name, number of days or hours worked, daily or hourly rate, and a total amount per consultant;

• Travel - include for each airplane or train trip taken the name of the traveler, date of travel, destination, the transportation costs including ground transportation shown separately and the per diem costs. Other travel costs shall also be listed;

• Subcontractors (if applicable) - include, for each subcontractor, the same data as required for the prime Contractor;

• Other Direct Costs - include a listing of all other direct charges to the contract, i.e., office supplies, telephone, duplication, postage; and

• Fee – amount as allowable in accordance with the Schedule and FAR 52.216-8 if applicable.

G.6. REIMBURSEMENT OF COST

The Government shall reimburse the Contractor the cost determined by the Contracting Officer to be allowable (hereinafter referred to as allowable cost) in accordance with FAR Clause 52.216-7, Allowable Cost and Payment incorporated by reference in Section I, Contract Clauses, of this contract, and FAR Subpart 31.2. Examples of allowable costs include, but are not limited to, the following:

a) All direct materials and supplies that are used in performing the work provided for under the contract, including those purchased for subcontracts and purchase orders.

b) All direct labor, including supervisory, that is properly chargeable directly to the contract, plus fringe benefits.

c) All other items of cost budgeted for and accepted in the negotiation of this basic contract or modifications thereto.

d) Travel costs including per diem or actual subsistence for personnel while in an actual travel status in direct performance of the work and services required under this contract subject to the following:

(i) Air travel shall be by the most direct route using “air coach” or “air tourist” (less than first class) unless it is clearly unreasonable or impractical (e.g., not available for reasons other than avoidable delay in making reservations, would require circuitous routing or entail additional expense offsetting the savings on fare, or would not make necessary connections).

(ii) Rail travel shall be by the most direct route, first class with lower berth or nearest equivalent.

(iii) Costs incurred for lodging, meals, and incidental expenses shall be considered reasonable and allowable to the extent that they do not exceed on a daily basis the per diem rates set forth in the Federal Travel Regulation (FTR).

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

G.7. CONTRACT FINANCIAL REPORT

(a) Financial reports on the attached Financial Report of Individual Project/Contract shall be submitted by the Contractor to the CO with a copy to the COR in accordance with the instructions for completing this form, which accompany the form, in an original and one electronic copy, not later than the 30th business day after the close of the reporting period. The line entries for subdivisions of work and elements of cost (expenditure categories), which shall be reported within the total contract, are discussed in paragraph e., below. Subsequent changes and/or additions in the line entries shall be made in writing.

(b) Unless otherwise stated in the instructions for completing this form, all columns A through J, shall be completed for each report submitted.

(c) The first financial report shall cover the period consisting of the first full three calendar months following the date of the contract, in addition to any fractional part of the initial month. Thereafter, reports will be on a quarterly basis.

(d) The Contracting Officer may require the Contractor to submit detailed support for costs contained in one

or more interim financial reports. This clause does not supersede the record retention requirements in FAR Part 4.7.

(e) The listing of expenditure categories to be reported is incorporated as a part of the contract and can be found under SECTION J entitled, "Financial Report of Individual Project/Contract."

G.8. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBOFFERORS, FAR 52.232- 40 (DECEMBER 2013)

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

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

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

G.9. GOVERNMENT PROPERTY

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

https://archive.org/details/contractorsguide00unit

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

Notwithstanding the provisions outlined in the HHS Publication, "HHS Contracting 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 attached to this contract (see SECTION J – List of Attachments). Title will vest in the Government for equipment purchased as a direct cost.

G.10. CONTRACT COMMUNICATIONS/CORRESPONDENCE

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

G.11. POST AWARD EVALUATION OF OFFEROR PERFORMANCE

(a) *Purpose:* In accordance with FAR Subpart 42.15, the Offeror'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 Offeror's performance will be evaluated at least annually.

(c) *Evaluators*: The performance evaluation will be completed jointly by the COR and the CO.

(d) *Performance Evaluation Factors*: The Offeror's performance will be evaluated in accordance with FAR Subpart 42.15.

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

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

(g) *Release of Offeror Performance Evaluation Information*: The completed evaluation will not be released to other than Government personnel and the Offeror 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 Offeror 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 Offeror Performance Evaluations*: Offerors may access evaluations through a secure website for review and comment at the following: http://cpars.gov.

INDIRECT COST RATES

a. The following provisional rates are established and incorporated into the contract for interim reimbursement of indirect costs pending the establishment of final indirect cost rates in accordance with FAR 52.216-7. The provisional rates may be revised retroactively or prospectively during contract performance by mutual agreement of the contracting officer, or cognizant auditor and the contractor at either party's request, to prevent substantial overpayment or underpayment.

Rate Type	Provisional Rates	Allocation Base

b. In accordance with FAR Part 5.216-7(d), the contractor shall submit an adequate final indirect cost rates proposal to the contracting officer and the cognizant auditor within the six-month period following the end of each of its fiscal years during the period of contract performance. The contracting officer may grant, in writing, reasonable extensions, for exceptional circumstances only, when requested in writing by the contractor.

SECTION H – SPECIAL CONTRACT REQUIREMENTS

H.1. PROTECTION OF HUMAN SUBJECTS

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

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

c) Offerors 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 Federal wide Assurance (FWA) if they are routinely engaged in research involving human subjects or ensure that such agencies or institutions are covered by the Offeror's 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 CO determines, in consultation with OHRP that the Offeror is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the CO may immediately suspend, in whole or in part, work and further payments under this contract until the Offeror corrects the noncompliance. The CO may communicate the notice of suspension by telephone with confirmation in writing. If the Offeror fails to complete corrective action within the period designated in the CO's written notice of suspension, the CO may, after consultation with OHRP, terminate this contract in whole or in part, and the Offeror's name may be removed from the list of those Offerors with approved Human Subject Assurances.

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 Offeror 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.

H.2.1. Safety and Monitoring Issues

IRB or IEC Approval: Through Annual Progress Reports, the Offeror 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 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 Offeror 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.

Offerors must notify BARDA through the COR and 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 Offeror must provide information about the initial and ongoing review and approval, if any. See the NIH Guidelines for Research Involving Recombinant DNA Molecules.

H.2.2. Data and Safety Monitoring Requirements

The Offeror 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 3 clinical trials must have an assigned independent data and safety monitoring board (DSMB); other trials may require DSMB oversight as well. The Offeror shall inform the Government of any upcoming site visits or audits of Offeror facilities funded under this effort. BARDA reserves the right to accompany the Offeror on site visits or audits of Offerors and subcontractors as the Government deems necessary.

The type of monitoring to be used shall be mutually agreed upon between the Offeror 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:

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 Offeror may be required to use an established BARDA DSMB or to organize an independent DSMB. All Phase 3 clinical trials must be reviewed by a DSMB; other trials may require DSMB oversight as well. 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 non-voting member on the DSMB.

   When a monitor or monitoring board is organized, a description of the board, 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 Offeror 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 Offeror

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 Offeror and all study staff responsible for the design or conduct of the research have received GCP training in the protection of human subjects.

BARDA comments will be forwarded to the Offeror within two weeks (10 business days) of receipt of the above information. The Offeror 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 COA letter may be provided to the Offeror. This COA provides authorization to the Offeror to execute the specific clinical study funded in part or in whole by the Government.

H.2.4. Required Time-Sensitive Notification

Under an Investigational New Drug (IND) application, the sponsor must provide FDA safety reports of serious adverse events. Under these Clinical Terms of Award, the Offeror must submit copies to the responsible 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 COR 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 COR 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 COR 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 Offeror within 10 working days by email, followed within 7 calendar days by an official letter to the Offeror. The Offeror 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 Offeror.

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 Offeror 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.

H.4. NEEDLE EXCHANGE

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

H.5. ACKNOWLEDGEMENT OF FEDERAL FUNDING

The Offeror 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 non-governmental sources.

H.6. RESTRICTIONS ON ABORTIONS

The Offeror shall not use funds for any abortion.

H.7. GUN CONTROL

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

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

The Offeror 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 the cloning of human beings.

H.9. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

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

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 Offeror 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 Offeror shall furnish evidence of the registration to the CO.

(b) The Offeror 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 Offeror agrees that the care, use, and intended use of any live vertebrate animals in the performance of this contract shall conform with the Public Health Service (PHS) Policy on Humane Care of Use of Laboratory Animals (PHS Policy), the current Animal Welfare Assurance (Assurance), the Guide for the Care and Use of Laboratory Animals (National Academy Press, Washington, DC), and the pertinent laws and regulations of the United States Department of Agriculture (see 7 U.S.C. 2131 et seq. and 9 CFR subchapter A, Parts 1-4). In case of conflict between standards, the more stringent standard shall govern.

(d) If at any time during performance of this contract, the CO determines, in consultation with the Office of Laboratory Animal Welfare (OLAW), National Institutes of Health (NIH), that the Offeror is not in compliance with any of the requirements and standards stated in paragraphs (a) through (c) above, the CO may immediately suspend, in whole or in part, work and further payments under this contract until the Offeror corrects the noncompliance. Notice of the suspension may be communicated by telephone and confirmed in writing. If the Offeror fails to complete corrective action within the period of time designated in the CO's written notice of suspension, the CO may, in consultation with OLAW, NIH, terminate this contract in whole or in part, and the Offeror's name may be removed from the list of those Offerors with Animal Welfare Assurances.

Note: The Offeror 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).

H.11. ANIMAL WELFARE

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

H.12. PAPERWORK REDUCTION ACT

(a) This contract involves a requirement to collect or record information calling either for answersto 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. Offerors and the COR 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 Offeror shall not expend any funds or begin any data collection until the CO provides the Offeror with written notification authorizing the expenditure of funds and the collection of data. The Offeror shall allow at least 120 days for OMB clearance. The CO will consider excessive delays caused by the Government which arise out of causes beyond the control and without the fault or negligence of the Offeror in accordance with the Excusable Delays or Default clause of this contract.

H.13. RESTRICTION ON PORNOGRAPHY ON COMPUTER NETWORKS

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

H.14. 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 thatwhen Federal agencies develop, procure, maintain, or use electronic and information technology, Federal employees with disabilities have access to and use of information and data that is comparable to the access and use by Federal employees who are not individuals with disabilities, unless an undue burden would be imposed on the agency. Section 508 also requires that individuals with disabilities, who are members of the public seeking information or services from a Federal agency, have access to and use of information and data that is comparable to that provided to the public who are not individuals with disabilities, unless an undue burden would be imposed on the agency.

b. Accordingly, any Offeror responding to this solicitation must comply with established HHS EIT accessibility standards. Information about Section 508 is available at http://www.hhs.gov/web/508. The complete text of the Section 508 Final Provisions can be accessed at http://www.access-board.gov/guidelines-and-standards/communications-and-it/about-the-section-508-standards.

c. The Section 508 accessibility standards applicable to this solicitation are stated in the clause at 352.239-74, Electronic and Information Technology Accessibility.

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

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

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

H.15. 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 CO and the Offeror may, by mutual consent, identify elsewhere in this contract specific information and/or categories of information which the Government will furnish to the Offeror or that the Offeror is expected to generate which is confidential. Similarly, the CO and the Offeror 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 Offeror 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 Offeror 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 Offeror shall obtain a written determination from the Contracting Officer prior to any release, disclosure, dissemination, or publication.

f. Contracting Officer Determinations will reflect the result of internal coordination with appropriate program and legal officials.

g. The provisions of paragraph (d) of this article shall not apply to conflicting or overlapping provisions in other Federal, state, or local laws.

H.16. INSTITUTIONAL RESPONSIBILITY REGARDING INVESTIGATOR CONFLICTS OF INTERESTS

The Institution (includes any Offeror, public or private, excluding a Federal agency) shall comply with the requirements of 45 CFR Part 94, Responsible Prospective Offerors, 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: https://www.ecfr.gov/cgi-bin/text-idx?rgn=div5&node=45:1.0.1.1.51

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

1. 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:

2. With regard to any publicly traded entity, a significant financial interest exists if the value of any remuneration received from the entity in the 12 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;

3. 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 12 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

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

   Significant financial interests do not include the following:

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

   2. Income from investment vehicles, such as mutual funds and retirement accounts, as long as the Investigator does not directly control the investment decisions made in these vehicles.

   3. 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.

   4. 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.

   5. 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.

   6. 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.

7. 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).

8. Provide initial and ongoing Financial Conflict of Interest (FCOI) reports to the CO pursuant to Part 94.5(b).

9. 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 three 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.

10. Establish adequate enforcement mechanisms and provide for employee sanctions or other administrative actions to ensure Investigator compliance as appropriate.

11. Complete the certification in Section K - Representations, Certifications, and Other Statements of Offerors 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 CO of the corrective action taken or to be taken. The CO 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 CO 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 CO 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 CO 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 CO may be necessary until the matter is resolved.

If the CO determines that BARDA-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an Investigator with a financial conflict of interest that was not managed or reported by the Institution, the Institution shall require the Investigator involved to disclose the financial conflict of interest in each public presentation of the results of the research and to request an addendum to previously published presentations.

H.17. PUBLICATION AND PUBLICITY

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

"This project has been funded in whole or in part with Federal funds from the Administration for Strategic Preparedness and Response, Biomedical Advanced Research and Development Authority, under Contract No. _____"

Press Releases:

The Offeror 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.

H.18. 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 online form is at https://oig.hhs.gov/fraud/report-fraud and the mailing address is:

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

H.19. PROHIBITION ON OFFEROR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Offeror 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 Offeror to ensure compliance with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

H.20. 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 Offeror performance, all data generated, all communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, milestone completion documents, and all Offeror commitments and responses. The Offeror 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.

H.21. IDENTIFICATION AND DISPOSITION OF DATA

The Offeror will be required to provide certain data generated under this contract to HHS. HHS reserves the right to review any other data determined by HHS to be relevant to this contract. The Offeror shall keep copies of all data required by the FDA relevant to this contract for the time specified by the FDA.

H.22. 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 Offeror'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.

H.23. 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.

H.24. QUALITY ASSURANCE (QA) AUDIT REPORTS

BARDA reserves the right to participate in QA audits as related to activities funded under this contract. Upon completion of the audit/site visit the Contractor shall provide a report capturing the findings, results and next steps in proceeding with the subcontractor. If action is requested of the subcontractor, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Contractor shall provide responses from the subcontractors to address these concerns and plans for corrective action execution.

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

H.25. BARDA AUDITS

Contractor shall accommodate periodic or reasonable ad hoc site visits during normal business hours by the Government with forty-eight (48) hours advance notice. 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 with ten (10) business days.
- Once corrective action is completed, the Contractor will provide a final report to the CO and COR.

H.26. NOTIFICATION OF CRITICAL PROGRAMMATIC CONCERNS, RISKS, OR POTENTIAL RISKS

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

- Within 48 hours of activity or incident or within 24 hours for a security related activity or incident, Contractor must notify BARDA.
- Additional updates due to COR and CO within 48 hours of additional developments.
- Contractor shall submit within 5 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues.

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

H.27. REGISTRATION WITH THE SELECT AGENT PROGRAM FOR WORK INVOLVING THE POSSESSION, USE, AND/OR TRANSFER OF SELECT BIOLOGICAL AGENTS OR TOXINS

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

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

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

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

H.28. 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 such as an overall project summary report and/or slides will be required when the IPRs are conducted. The Contractor's success in completing the required tasks under each work segment must be demonstrated through the Deliverables and Milestones specified under SECTION F. Those deliverables will constitute the basis for the Government's decision, at its sole discretion, to proceed with the work segment, or 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 business days prior to the IPR. Subsequently, the contractor will be requested to provide a revised/final presentation to the Contracting Officer at least 10 business days prior to the IPR.

H.29. SHARING RESEARCH DATA

The Contractor's data sharing plan, due date to be determined at contract award, is hereby incorporated by reference. The Contractor agrees to adhere to its plan and shall request prior approval of the Contracting Officer for any changes in its plan.

BARDA endorses the sharing of final research data to serve health. This contract is expected to generate research data that must be shared with the public and other researchers.

BARDA recognizes that data sharing may be complicated or limited, in some cases, by institutional policies, local IRB rules, as well as local, state and Federal laws and regulations, including the Privacy Rule (see HHS-published documentation on the Health Information Privacy at https://www.hhs.gov/hipaa/index.html). The rights and privacy of people who participate in BARDA- funded research must be protected at all times; thus, data intended for broader use should be free of identifiers that would permit linkages to individual research participants and variables that could lead to deductive disclosure of the identity of individual subjects.

H.30. DISCLOSURE OF FINANCIAL PERFORMANCE AND TRANSFER OF TECHNOLOGY

This clause shall remain in effect during the term of the Contract.

a. Contractor Financial Performance

The Contractor shall provide quarterly a summary or collection of financial statements, such as balance sheets, income statements, and cash flow statements. These may include SEC filings or other documents that highlight Contractor revenues and expenditures to be agreed upon with consultation from the Contracting Officer and COR. Additionally, the company must notify the Contracting Officer of financial issues leading to potential liquidation of assets as soon as feasible after notifying the SEC.

b. Post-award Transfer of Ownership of Technology

The Contractor shall provide notice to the Contracting Officer and COR upon drafting of any new term sheet, between the Contractor and an external party, that outlines the transfer of ownership, or operational, corporate, or economic control of technology or establishment of a licensing agreement of any technology funded under this Contract from the Contractor to another institution. This clause excludes subcontracts.

PART II – CONTRACT CLAUSES

SECTION I – CONTRACT CLAUSES

FAR 52.252-2 Clauses Incorporated by Reference (Feb 1998)

This contract incorporates one or more clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make their full text available.

I.1. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR Chapter 1) CLAUSES

Full text of the FAR clauses may be accessed electronically at: https://www.acquisition.gov/far/index.html

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 SubOfferor 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	Offeror Code of Business Ethics and Conduct
FAR	52.203-14	Oct 2015	Display of Hotline Poster(s)
FAR	52.203-17	Apr 2014	Offeror Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights
FAR	52.203-19	Jan 2017	Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements
FAR	52.204-7	Oct 2018	System for Award Management
FAR	52.204-8	Jan 2025	Annual Representations and Certifications (JAN 2025) (DEVIATION FEB 2025)
FAR	52.204-10	Oct 2018	Reporting Executive Compensation and First-Tier Subcontract Awards
FAR	52.204-13	Oct 2018	System for Award Management Maintenance
FAR	52.204-18	Aug 2020	Commercial and Government Entity Code Maintenance
FAR	52.204-19	Dec 2014	Incorporation by Reference of Representations and Certifications
FAR	52.204-21	Jun 2016	Basic Safeguarding of Covered Contractor Information Systems

FAR	52.204-23	Jul 2018	Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab and Other Covered Entities
FAR	52.205-25	Aug 2020	Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment
FAR	52.204-27	June 2023	Prohibition on a ByteDance Covered Application
FAR	52.204-30	Dec 2023	Federal Acquisition Supply Chaing Security Act Orders - Prohibition
FAR	52.207-1	May 2006	Notice of Standard Competition
FAR	52.209-6	Oct 2015	Protecting the Government's Interests When Subcontracting With Offerors Debarred, Suspended, or Proposed for Debarment
FAR	52.209-9	Oct 2018	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	Jun 2020	Market Research
FAR	52.211-5	Aug 2000	Material Requirements
FAR	52.213-4	Jan 2025	Terms and Conditions – Simplified Acquisitions (Other Than Commercial Products and Commercial Services (Deviation Feb 2025)
FAR	52.215-2	Jun 2020	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	52.215-12	Jun 2020	SubOfferor Certified Cost or Pricing Data
FAR	52.215-13	Jun 2020	SubOfferor Certified Cost or Pricing Data—Modifications
FAR	52.215-14	Jun 2020	Integrity of Unit Prices
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
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	Aug 2018	Allowable Cost and Payment
FAR	52.217-2	Oct 1997	Cancellation Under Multi-year Contracts
FAR	52.216-8	Jun 2011	Fixed Fee
FAR	52.219-8	Oct 2018	Utilization of Small Business Concerns

FAR	52.219-16	Sept 2021	Liquidated Damages – Subcontracting Plan
FAR	52.219-19	Sept 2023	Small Business Subcontracting Plan
FAR	52.219-28	Nov 2020	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	Jun 2003	Convict Labor
FAR	52.222-11	May 2014	Subcontracts (Labor Standards) (Deviation Feb 2025)
FAR	52.222-12	May 2014	Contract Termination – Debarment (Deviation Feb 2025)
FAR	52.222-35	Jun 2020	Equal Opportunity for Veterans
FAR	52.222-36	Jun 2020	Equal Opportunity for Workers with Disabilities
FAR	52.222-37	Jun 2020	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	Aug 2018	Fair Labor Standards Act and Service Contract Labor Standards—Price Adjustment (Multiple Year and Option Contracts)
FAR	52.222-50	Oct 2020	Combating Trafficking in Persons
FAR	52.222-54	Oct 2015	Employment Eligibility Verification
FAR	52.223-6	May 2001	Drug-Free Workplace
FAR	52.223-10	May 2024)	Waste Reduction Program (Deviation Feb 2025)
FAR	52.223-18	Jun 2020	Encouraging Offeror Policy to Ban Text Messaging While Driving
FAR	52.223-23	May 2024	Sustainable Products and Services (Deviation Feb 2025)
FAR	52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
FAR	52.225-25	Aug 2018	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	Dec 2007	Rights in Data - General, Alternate II
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	52.232-1	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
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	52.232-20	Apr 1984	Limitation of Cost
FAR	52.232-23	May 2014	Assignment of Claims
FAR	52.232-25	Jan 2017	Prompt Payment
FAR	52.232-33	Oct 2018	Payment by Electronic Funds Transfer--System for Award Management
FAR	52.232-39	Jun 2013	Unenforceability of Unauthorized Obligations
FAR	52.232-40	Dec 2013	Providing Accelerated Payments to Small Business SubOfferors
FAR	52.233-1	May 2014	Disputes
FAR	52.233-2	Sep 2006	Service of Protest
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	52.242-2	Apr 1991	Production Progress Reports
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	52.243-7	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	Jan 2025	Subcontracts for Commercial Items (DEVIATION FEB 2025)
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	52.247-67	Feb 2006	Submission of Transportation Documents for Audit
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

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.

Reg	Clause	Date	Clause Title
HHSAR	352.203-70	Dec 2015	Anti-Lobbying
HHSAR	352.204-74	Oct 2024	Supply Chain Risk Assessment
HHSAR	352.204-75	Oct 2024	Supply Chain Risk Assessment During Contract Performance
HHSAR	352.208-70	Dec 2015	Printing and Duplication
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	352.223-70	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	352.237-75	Dec 2015	Key Personnel
HHSAR	352.239-74	Dec 2015	Electronic and Information Technology Accessibility
HHSAR	352.270-5a	Dec 2015	Notice of Offerors 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
HHSAR	352.270-9	Dec 2015	Non-Discrimination for Conscience

I.3. ADDITIONAL CONTRACT CLAUSES

I.3.1. Additional HHS Acquisition Regulation (HHSAR) Clauses – In FullText

352.231-70 Salary Rate Limitation (Dec 2015)

(a) The Offeror 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 Offeror 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 Offeror. 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 an HHS 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 CO 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.

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 CO may exercise the option by written notice to the Offeror 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 six months. The CO may exercise the option by written notice to the Offeror within 30 days.

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 Offeror within 30 days; provided that the Government gives the Offeror a preliminary written notice of its intent to extend at least 30 days before the contract expires. The preliminary notice does not commit the Government to an extension.

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

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

52.219-6 Notice of Total Small Business Set-Aside (Nov 2020)

(a) *Definition*. *Small business concern*, as used in this clause—

(1) Means a concern, including its affiliates that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the size standards in this solicitation.

(2) *Affiliates*, as used in paragraph (a)(1) of this clause, means business concerns, one of whom directly or indirectly controls or has the power to control the others, or a third party or parties control or have the power to control the others. In determining whether affiliation exists, consideration is given to all appropriate factors including common ownership, common management, and contractual relationships. SBA determines affiliation based on the factors set forth at 13 CFR 121.103.

(b) *Applicability*. This clause applies only to-

(1) Contracts that have been totally set aside for small business concerns; and

(2) Orders set aside for small business concerns under multiple-award contracts asdescribed in 8.405-5 and 16.505(b)(2)(i)(F).

(c) General.

(1) Offers are solicited only from small business concerns. Offers received from concerns that are not small business concerns shall be considered nonresponsive and will be rejected.

(2) Any award resulting from this solicitation will be made to a small business concern.

52.237-3 Continuity of Services (Jan 1991)

(a)The Contractor recognizes that the services under this contract are vital to the Government and must be continued without interruption and that, upon contract expiration, a successor, either the Government or another contractor, may continue them. The Contractor agrees to-

(1) Furnish phase-in training; and

(2) Exercise its best efforts and cooperation to effect an orderly and efficient transition to a successor.

(b) The Contractor shall, upon the Contracting Officer's written notice, (1) furnish phase-in, phase-out services for up to 90 days after this contract expires and (2) negotiate in good faith a plan with a successor to determine the nature and extent of phase-in, phase-out services required. The plan shall specify a training program and a date for transferring responsibilities for each division of work described in the plan, and shall be subject to the Contracting Officer's approval. The Contractor shall provide sufficient experienced personnel during the phase-in, phase-out period to ensure that the services called for by this contract are maintained at the required level of proficiency.

(c) The Contractor shall allow as many personnel as practicable to remain on the job to help the successor maintain the continuity and consistency of the services required by this contract. The Contractor also shall disclose necessary personnel records and allow the successor to conduct on-site interviews with these employees. If selected employees are agreeable to the change, the Contractor shall release them at a mutually agreeable date and negotiate transfer of their earned fringe benefits to the successor.

(d)The Contractor shall be reimbursed for all reasonable phase-in, phase-out costs (*i.e.,* costs incurred within the agreed period after contract expiration that result from phase-in, phase-out operations) and a fee (profit) not to exceed a pro rata portion of the fee (profit) under this contract.

PART III – ATTACHMENTS

SECTION J – LIST OF ATTACHMENTS

The following Attachments are provided with this Solicitation:

1. Offeror's Points of Contact

2. Sample Invoice Form

3. Breakdown of Proposed Costs with Excel Spreadsheet (Click on "Electronic Contract Business Proposal") https://oamp.od.nih.gov/content/breakdown-proposed-estimated-cost-plus-fee- and-labor-hours

4. SF-LLL, Disclosure of Lobbying Activities, with Instructions: https://www.gsa.gov/forms-library/disclosure-lobbying-activities

5. Risk Mitigation Plan/Matrix Template

6. Past Performance Questionnaire

7. BARDA Security Requirements

8. Security Plan Template with Instructions

9. Small business Subcontracting Plan

SECTION K – REPRESENTATIONS, CERTIFICATIONS, AND OTHER STATEMENTS OF OFFERORS

NOTE: IF YOU INTEND TO SUBMIT A PROPOSAL, YOU SHALL:

1. Complete the Online Representations and Certifications Application (ORCA) at website https://www.sam.gov

2. Complete and **INCLUDE as part of your BUSINESS PROPOSAL: SECTION K – REPRESENTATIONS AND CERTIFICATIONS**

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

K.1. FAR 52.203-11 INCORPORATION BY REFERENCE OF CERTIFICATION AND DISCLOSURE REGARDING PAYMENTS TO INFLUENCE CERTAIN FEDERAL TRANSACTIONS (SEPT 2007)

K.2. ANNUAL REPRESENTATIONS AND CERTIFICATIONS (Jan 2025) (DEVIATION FEB 2025)

(a)

(1) The North American Industry Classification System (NAICS) code for this acquisition is541714 .

(2) The small business size standard is 1000 employees.

(3) The small business size standard for a concern that submits an offer, other than on a construction or service acquisition, but proposes to furnish an end item that it did not itself manufacture, process, or produce is 500 employees, or 150 employees for information technology value-added resellers under NAICS code 541714 if the acquisition—

(i) Is set aside for small business and has a value above the simplified acquisition threshold;

(ii) Uses the HUBZone price evaluation preference regardless of dollar value, unless the offeror waives the price evaluation preference; or

(iii) Is an 8(a), HUBZone, service-disabled veteran-owned, economically disadvantaged women-owned, or women-owned small business set-aside or sole-source award regardless of dollar value.

(b)
(1) If the provision at 52.204-7, System for Award Management, is included in this solicitation, paragraph (d) of this provision applies.
(2) If the provision at 52.204-7, System for Award Management, is not included in this solicitation, and the Offeror has an active registration in the System for Award Management (SAM), the Offeror may choose to use paragraph (d) of this provision instead of completing the corresponding individual representations and certifications in the solicitation. The Offeror shall indicate which option applies by checking one of the following boxes:

(i) Paragraph (d) applies.

(ii) □ Paragraph (d) does not apply and the offeror has completed the individual representations and certifications in the solicitation.

(c)

(1) The following representations or certifications in SAM are applicable to this solicitation as indicated:
(i) 52.203-2, Certificate of Independent Price Determination. This provision applies to solicitations when a firm-fixed-price contract or fixed-price contract with economic price adjustment is contemplated, unless–
(A) The acquisition is to be made under the simplified acquisition procedures in part 13;

(B) The solicitation is a request for technical proposals under two-step sealed bidding procedures; or

(C) The solicitation is for utility services for which rates are set by law or regulation.
(ii) 52.203-11, Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions. This provision applies to solicitations expected to exceed $150,000.
(iii) 52.203-18, Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements-Representation. This provision applies to all solicitations.
(iv) 52.204-3, Taxpayer Identification. This provision applies to solicitations that do not include the provision at 52.204-7, System for Award Management.
(v) 52.204-5, Women-Owned Business (Other Than Small Business). This provision applies to solicitations that-

(A) Are not set aside for small business concerns;

(B) Exceed the simplified acquisition threshold; and

(C) Are for contracts that will be performed in the United States or its outlying areas.
(vi) 52.204-26, Covered Telecommunications Equipment or Services-Representation. This provision applies to all solicitations.
(vii) 52.209-2, Prohibition on Contracting with Inverted Domestic Corporations-Representation.
(viii) 52.209-5, Certification Regarding Responsibility Matters. This provision applies to solicitations where the contract value is expected to exceed the simplified acquisition threshold.
(ix) 52.209-11, Representation by Corporations Regarding Delinquent Tax Liability or a Felony Conviction under any Federal Law. This provision applies to all solicitations.
(x) 52.214-14, Place of Performance-Sealed Bidding. This provision applies to invitations for bids except those in which the place of performance is specified by the Government.
(xi) 52.215-6, Place of Performance. This provision applies to solicitations unless the place of performance is specified by the Government.
(xii) 52.219-1, Small Business Program Representations (Basic, Alternates I, and II). This provision applies to solicitations when the contract is for supplies to be delivered or services to be performed in the United States or its outlying areas, or when the contracting officer has applied part 19 in accordance with 19.000(b)(1)(ii).

(A) The basic provision applies when the solicitations are issued by other than DoD, NASA, and the Coast Guard.

(B) The provision

(C) The provision with its Alternate II applies to solicitations that will result in a multiple-award contract with more than one NAICS code assigned.
(xiii) 52.219-2, Equal Low Bids. This provision applies to solicitations when contracting by sealed bidding and the contract is for supplies to be delivered or services to be performed in the United States or its outlying areas, or when the contracting officer has applied part 19 in accordance with 19.000(b)(1)(ii).
(xiv) 52.222-22, RESERVED
(xv) RESERVED
(xvi) 52.222-38, Compliance with Veterans' Employment Reporting Requirements. This provision applies to solicitations when it is anticipated the contract award will exceed the simplified acquisition threshold and the contract is not for acquisition of commercial products or commercial services.
(xvii) 52.223-1, Biobased Product Certification. This provision applies to solicitations that require the delivery or specify the use of biobased products in USDA-designated product categories; or include the clause at 52.223-2, Reporting of Biobased Products Under Service and Construction Contracts.
(xviii) 52.223-4, Recovered Material Certification. This provision applies to solicitations that are for, or specify the use of, EPA–designated items.
(xix) 52.223-22, RESERVED
(xx) 52.225-2, Buy American Certificate. This provision applies to solicitations containing the clause at 52.225-1.
(xxi) 52.225-4, Buy American-Free Trade Agreements-Israeli Trade Act Certificate. (Basic, Alternates II and III.) This provision applies to solicitations containing the clause at 52.225-3.

(A) If the acquisition value is less than $50,000, the basic provision applies.

(B) If the acquisition value is $50,000 or more but is less than $100,000, the provision with its Alternate II applies.

(C) If the acquisition value is $100,000 or more but is less than $102,280, the provision with its Alternate III applies.
(xxii) 52.225-6, Trade Agreements Certificate. This provision applies to solicitations containing the clause at 52.225-5.
(xxiii) 52.225-20, Prohibition on Conducting Restricted Business Operations in Sudan-Certification. This provision applies to all solicitations.
(xxiv) 52.225-25, Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran-Representation and Certifications. This provision applies to all solicitations.
(xxv) 52.226-2, Historically Black College or University and Minority Institution Representation. This provision applies to solicitations for research, studies, supplies, or services of the type normally acquired from higher educational institutions.

(2) The following representations or certifications are applicable as indicated by the Contracting Officer:

[Contracting Officer check as appropriate.]
__ (i) 52.204-17, Ownership or Control of Offeror.
__ (ii) 52.204-20, Predecessor of Offeror.
__ (iii) 52.222-18, Certification Regarding Knowledge of Child Labor for Listed End Products.
__ (iv) 52.222-48, Exemption from Application of the Service Contract Labor Standards to Contracts for Maintenance, Calibration, or Repair of Certain Equipment- Certification.
__ (v) 52.222-52, Exemption from Application of the Service Contract Labor Standards to Contracts for Certain Services-Certification.
__ (vi) 52.227-6, Royalty Information.

__ (A) Basic.

__ (B) Alternate I.
__ (vii) 52.227-15, Representation of Limited Rights Data and Restricted Computer Software.

(d) The offeror has completed the annual representations and certifications electronically in SAM website accessed through https://www.sam.gov. After reviewing the SAM information, the offeror verifies by submission of the offer that the representations and certifications currently posted electronically that apply to this solicitation as indicated in paragraph (c) of this provision have been entered or updated within the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer and are incorporated in this offer by reference (see FAR 4.1201); except for the changes identified below [offeror to insert changes, identifying change by clause number, title, date]. These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer

FAR Clause # Title Date Change

_____

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

(End of provision)

System updates may lag policy updates. The System for Award Management (SAM) may continue to require entities to complete representations based on provisions that are not included in agency solicitations. Examples include 52.222-25, Affirmative Action Compliance, and paragraph (d) of 52.212-3, Offeror Representations and Certifications—Commercial Products and Commercial Services. Contracting officers will not consider these representations when making award decisions or enforce requirements. Entities are not required to, nor are they able to, update their entity registration to remove these representations in SAM.

K.3. FAR 52.204-17 INCORPORATION BY REFERENCE OF OWNERSHIP OR CONTROL OF OFFEROR (July 2016)

K.4. FAR 52.204-19 INCORPORATION BY REFERENCE OF REPRESENTATIONSAND CERTIFICATIONS (Dec 2014)

K.5. FAR 52.204-24 REPRESENTATION REGARDING CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (Oct 2020)

K.6. FAR 52.204-26 COVERED TELECOMMUNICATIONS EQUIPMENT OR SERVICES-REPRESENTATION (Oct 2020)

K.7. FAR 52.209-5 CERTIFICATION REGARDING RESPONSIBILITY MATTERS (Oct2015)

(a)(1) The Offeror certifies, to the best of its knowledge and belief, that—
(i) The Offeror and/or any of its Principals—
(A) Are [_] are not [_] presently debarred, suspended, proposed for debarment, or declared ineligible for the award of contracts by any Federalagency;

(B) Have [_] have not [_], within a three-year period preceding this offer, been convicted of or had a civil judgment rendered against them for: commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State, or local) contract or subcontract; violation of Federal or State antitrust statutes relating to the submission of offers; or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, tax evasion, violating Federal criminal tax laws, or receiving stolen property (if Offeror checks "have", the Offeror shall also see 52.209- 7, if included in this solicitation);

(C) Are [_] are not [_] presently indicted for, or otherwise criminally or civilly charged by a governmental entity with, commission of any of the offenses enumerated in paragraph (a)(1)(i)(B) of this provision;

(D) Have [_] have not [_], within a three-year period preceding this offer, been notified of any delinquent Federal taxes in an amount that exceeds $3,500 for which the liability remains unsatisfied.

(1) Federal taxes are considered delinquent if both of the following criteria apply:

(i) The tax liability is finally determined. The liability is finally determined if it has been assessed. A liability is not finally determined if there is a pending administrative or judicial challenge. In the case of a judicial challenge to the liability, the liability is not finally determined until all judicial appeal rights have been exhausted.

(ii) The taxpayer is delinquent in making payment. A taxpayer is delinquent if the taxpayer has failed to pay the tax liability when full payment was due and required. A taxpayer is not delinquent in cases where enforced collection action is precluded.

(2) Examples.

(i) The taxpayer has received a statutory notice of deficiency, under I.R.C. § 6212, which entitles the taxpayer to seek Tax Court review of a proposed tax deficiency. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek Tax Court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(ii) The IRS has filed a notice of Federal tax lien with respect to an assessed tax liability, and the taxpayer has been issued a notice under I.R.C. § 6320 entitling the taxpayer to request a hearing with the IRS Office of Appeals contesting the lien filing, and to further appeal to the Tax Court if the IRS determines to sustain the lien filing. In the course of the hearing, the taxpayer is entitled to contest the underlying tax liability because the taxpayer has had no prior opportunity to contest the liability. This is not a delinquent tax because it is not a final tax liability. Should the taxpayer seek tax court review, this will not be a final tax liability until the taxpayer has exercised all judicial appeal rights.

(iii) The taxpayer has entered into an installment agreement pursuant to I.R.C. § 6159. The taxpayer is making timely payments and is in full compliance with the agreement terms. The taxpayer is not delinquent because the taxpayer is not currently required to make full payment.

(iv) The taxpayer has filed for bankruptcy protection. The taxpayer is not delinquent because enforced collection action is stayed under 11 U.S.C. 362 (the Bankruptcy Code).

(ii) The Offeror has [_] has not [_], within a three-year period preceding this offer, had one or more contracts terminated for default by any Federal agency.

(2) "Principal," for the purposes of this certification, means an officer, director, owner, partner, or a person having primary management or supervisory responsibilities within a business entity (e.g., general manager; plant manager; head of a division or business segment; and similar positions).

This Certification Concerns a Matter Within the Jurisdiction of an Agency of the United

States and the Making of a False, Fictitious, or Fraudulent Certification May Render the Maker Subject to Prosecution Under Section 1001, Title 18, United States Code.

(b) The Offeror shall provide immediate written notice to the Contracting Officer if, at any time prior to contract award, the Offeror learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

(c) A certification that any of the items in paragraph (a) of this provision exists will not necessarily result in withholding of an award under this solicitation. However, the certification will be considered in connection with a determination of the Offeror's responsibility. Failure of the Offeror to furnish a certification or provide such additional information as requested by the Contracting Officer may render the Offeror non-responsible.

(d) Nothing contained in the foregoing shall be construed to require establishment of a system of records in order to render, in good faith, the certification required by paragraph (a) of this provision. The knowledge and information of an Offeror is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

(e) The certification in paragraph (a) of this provision is a material representation of fact upon which reliance was placed when making award. If it is later determined that the Offeror knowingly rendered an erroneous certification, in addition to other remedies available to the Government, the Contracting Officer may terminate the contract resulting from this solicitation for default.

K.8. FAR 52.209-7 INFORMATION REGARDING RESPONSIBILITY MATTERS (Oct 2018)

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

"Administrative proceeding" means a non-judicial process that is adjudicatory in nature in order to make a determination of fault or liability (*e.g.*, Securities and Exchange Commission Administrative Proceedings, Civilian Board of Contract Appeals Proceedings, and Armed Services Board of Contract Appeals Proceedings). This includes administrative proceeding at the Federal and State level but only in connection with performance of a Federal contract or grant. It does not include agency actions such as contract audits, site visits, corrective plans, or inspection of deliverables.

"Federal contracts and grants with total value greater than $10,000,000" means—

(1) The total value of all current, active contracts and grants, including all priced options; and the total value of all current, active orders including all priced options under indefinite- delivery, indefinite- quantity, 8(a), or requirements contracts (including task and delivery and multiple-award Schedules).

"Principal" means an officer, director, owner, partner, or a person having primary management or supervisory responsibilities within a business entity (*e.g.*, general manager; plant manager; head of a division or business segment; and similar positions).

(b) The Offeror [_] has [_] does not have current active Federal contracts and grants with total value greater than $10,000,000.

(c) If the Offeror checked "has" in paragraph (b) of this provision, the Offeror represents, by submission of this offer, that the information it has entered in the Federal Awardee Performance and Integrity Information System (FAPIIS) is current, accurate, and complete as of the date of submission of this offer with regard to the following information:

(1) Whether the Offeror, and/or any of its principals, has or has not, within the last five years, in connection with the award to or performance by the Offeror of a Federal contract or grant, been the subject of a proceeding, at the Federal or State level that resulted in any of the following dispositions:

(i) In a criminal proceeding, a conviction.

(ii) In a civil proceeding, a finding of fault and liability that results in the payment of a monetary fine, penalty, reimbursement, restitution, or damages of $5,000 or more.

(iii) In an administrative proceeding, a finding of fault and liability that results in—

(A) The payment of a monetary fine or penalty of $5,000 or more; or

(B) The payment of a reimbursement, restitution, or damages in excess of

$100,000.

(iv) In a criminal, civil, or administrative proceeding, a disposition of the matter by consent or compromise with an acknowledgment of fault by the Contractor if the proceeding could have led to any of the outcomes specified in paragraphs (c)(1)(i), (c)(1)(ii), or (c)(1)(iii) of this provision.

(2) If the Offeror has been involved in the last five years in any of the occurrences listed in (c)(1) of this provision, whether the Offeror has provided the requested information with regard to each occurrence.

(d) The Offeror shall post the information in paragraphs (c)(1)(i) through (c)(1)(iv) of this provision in FAPIIS as required through maintaining an active registration in the System for Award Management which can be accessed via https://www.sam.gov (see52.204-7).

K.9. FAR 52.215-6 PLACE OF PERFORMANCE (Oct 1997)

(a) The Offeror or respondent, in the performance of any contract resulting from this solicitation, □intends, □does not intend [check applicable block] to use one or more plants or facilities located at a different address from the address of the Offeror or respondent as indicated in this proposal or response to request for information.

(b) If the Offeror or respondent checks "intends" in paragraph (a) of this provision, it shall insert in the following spaces the required information:

Place of Performance (Street Address, City, State, County, ZIP Code)	Name and Address of Owner and Operator of the Plant or Facility if Other than Offeror or Respondent

K.10. FAR 52.222-56 Certification Regarding Trafficking in Persons Compliance Plan (Oct 2020)

(a) The term "commercially available off-the-shelf (COTS) item," is defined in the clause of this solicitation entitled "Combating Trafficking in Persons" (FAR clause 52.222-50).

(b) The apparent successful Offeror shall submit, prior to award, a certification, as specifiedin paragraph (c) of this provision, for the portion (if any) of the contract that-

(1) Is for supplies, other than commercially available off-the-shelf items, to be acquired outside the United States, or services to be performed outside the United States; and

(2) Has an estimated value that exceeds $550,000.

(c) The certification shall state that-

(1) It has implemented a compliance plan to prevent any prohibited activities identified in paragraph (b) of the clause at 52.222-50, Combating Trafficking in Persons, and to monitor, detect, and terminate the contract with a subcontractor engaging in prohibited activities identified at paragraph (b) of the clause at 52.222-50, Combating Trafficking in Persons; and

(2) After having conducted due diligence, either-

(i) To the best of the Offeror's knowledge and belief, neither it nor any of its proposed agents, subcontractors, or their agents is engaged in any such activities; or

(ii) If abuses relating to any of the prohibited activities identified in 52.222-50(b) have been found, the Offeror or proposed subcontractor has taken the appropriate remedial and referralactions.

SECTION L – INSTRUCTIONS, CONDITIONS, AND NOTICES TO OFFERORS

L.1. CONTRACT TYPE

This RFP is being solicited as a full and open, cost-plus-fixed-fee/firm-fixed-price hybrid type contract. It is anticipated that at least one award may be made from this solicitation, though more than one award is possible.

L.2. DELIVERY AND PACKAGING OF PROPOSAL

L.2.1. GENERAL

Offeror(s) are invited to submit a proposal in response to this solicitation. All proposals received will become part of the official file.

The following instructions establish the acceptable minimum requirements for the format and content of proposals.

The proposal must be signed by an official authorized to bind the Offeror's organization and must stipulate it is predicated upon all the terms and conditions of this RFP.

The proposal must be prepared in three parts, "Mandatory Evaluation Criteria," a "Technical Proposal" and a "Business Proposal." Each part shall be separate and complete in itself so that evaluation of one may be accomplished independently of the other. Submissions shall be single-spaced, paginated (consecutively starting with page 1), and readable in all required copies.

L.2.2. PRE-AWARD SITE VISIT

The Government reserves the right to conduct a pre-award site visit of the manufacturing plant and headquarters if deemed necessary by BARDA. Pre-Award site visits to Offerors within the Competitive Range may be made with short notice. Offerors are expected to guarantee the availability of key staff or other staff determined by the Government as essential for purposes of this site visit.

L.2.3. DELIVERY OF PROPOSAL

Proposals must be submitted in electronic format in order to be accepted. Electronic proposals shall be sent via email and shall be received **no later than August 25, 2025, by 12:00 PM, EST.** No files shall be password protected.

Facsimile submissions are not authorized.

Electronic submissions shall be in Adobe PDF, Microsoft Word, Microsoft Excel, and Microsoft Project (as appropriate) via e-mail to erin.greninger@hhs.gov and Audrey.glover@hhs.gov.

L.2.4. PACKAGING OF PROPOSAL

To expedite the proposal evaluation, all documents required for responding to the RFP shall be placed in the following order:

A. COVER PAGE
Include RFP title, number, name of organization, UEI No., identification of the proposal part, and indicate whether the proposal is an original or a copy. All proposal parts (Mandatory Evaluation Criteria, Technical Proposal, and Business Proposal) must begin with a Cover Page.

B. MANDATORY EVALUATION CRITERIA
The Offeror shall provide a dedicated section that addresses the mandatory criteria for eligibility. Clearly crosswalk the mandatory criteria elements as described in SECTION M.3 of this RFP (Evaluation Factors for Award) to the documentation provided to support criteria compliance. **There is no page limit for Mandatory Evaluation Criteria.**

C. TECHNICAL PROPOSAL
The Technical Proposal shall consist of a cover page, table of contents, responses to the technical evaluation criteria, and the information requested in the Statement of Objectives (SOO) in the form of a Statement of Work (SOW). Appendices may be provided with the Technical Proposal, with the

appropriate tabs. **The total page limit for the Technical Proposal (not including appendices) is 100 pages (Font: Times New Roman, Size: 12). The appendices shall not exceed an additional 100 pages. The total Technical Proposal submission including appendices shall not exceed 200 pages.**

D. BUSINESS PROPOSAL
The Business Proposal shall consist of a cover page, table of contents, and the information requested in the SOO in the form of a SOW associating cost with identified task and all labor categories and labor rates for work under a prospective contract**.** Use the excel spreadsheet in Attachment #10 when putting together your business proposal cost spreadsheet. **There is no page limit for the Business Proposal.**

L.3. MANDATORY EVALUATION CRITERIA

The mandatory criteria for eligibility must be met at the time of receipt of proposal as determined by the CO for any proposals to be considered for award. Any Offeror(s) who submit proposals that do not meet the Mandatory Evaluation Criteria for eligibility at the time of proposal submission will not be considered for further evaluation. All proposals that satisfy the mandatory criteria for eligibility will be considered for a second phase (technical evaluation) where it will be evaluated based on the technical criteria under SECTION M.4.

L.4. TECHNICAL PROPOSAL

L.4.1. Technical Proposal Instructions

Offeror(s) shall prepare their technical proposal submissions to address evaluation criteria listed in SECTION M.4 Technical Evaluation Criteria while responding to the requirements listed in SECTION C of this RFP (Description/Specifications/Work Statement).

The Technical Proposal shall reflect a clear understanding of the nature of the work being undertaken. The Technical Proposal must include information on capabilities of the Offeror and a SOW to respond to the Government's requirements as defined in the SOO. At a minimum, Offeror(s) shall address how the project is to be organized, staffed, and managed. Information shall be provided with sufficient detail to demonstrate the Offeror's ability to understand and manage important events and tasks. The Offeror(s) must submit a detailed explanation of the proposed technical approach in conjunction with the tasks to be performed in achieving the project objectives. The proposed technical approach shall be in line with the proposed regulatory pathway to achieve marketing authorization of the antibiotic.

Proposals will be evaluated (as prescribed in FAR 15) by a Technical Evaluation Panel in accordance with the evaluation criteria and merit ratings as described in SECTION M of this RFP (Evaluation Factors for Award). This evaluation produces adjectival ratings, which are based upon the information contained in the Offeror's proposal.

As part of the Technical Proposal, Offeror(s) will be required to submit a cross reference between the RFP and Technical Proposal to assist the government in their review.

It is strongly recommended Offeror(s) use the following template as the Table of Contents for the Technical Proposal. All information presented in the technical proposal shall be presented in the order specified below.

L.4.1.1. Technical Proposal – Components

(1) Section 1: Cover Page (does not count towards the 100 page total limit)

A. Proposal Title Page including RFP title, number, name of organization, and UEI number.

B. Table of Contents

C. Government notice for handling of proposals

(2) Section 2: Technical Proposal Overview
Provide a brief overview of the Technical Proposal, including the following:

A. A brief description of activities to be performed by the Offeror and all proposed subcontractors to expand capabilities (example: non-clinical efficacy studies, clinical studies, etc.), including

identification of all proposed subcontractors and a list of key personnel for the Offeror and the proposed subcontractors with degrees, titles, and roles within the project.

B. Offeror(s) shall describe the activities to be subcontracted, the method and level of integration between the prime and any proposed subcontractor(s), and the expected advantages of such an approach. A summary of staff expertise including the total number/trained number available to be assigned to this contract for the Offeror and all proposed subcontractor(s), and the total number of additional staff to be hired and trained.

C. For the purpose of procurement, the Offeror's proposal and SOW shall address the following areas:

a. Product and facility availability for production and procurement of up to 10,000 treatment courses of antibiotic final drug product. The USG has the discretion to determine the timing and the amount of product to be procured based upon the Offeror's proposal, cost per antibiotic treatment course, and availability of funds.

b. A production plan and timeline that describes the facilities, processes, resources, and capabilities necessary to manufacture product under normal market conditions.

Independently, and not as an agent of the USG, the Offeror shall furnish all the necessary services, qualified personnel, materials, supplies, equipment, facilities, transportation, and travel not otherwise provided by the USG as required to fulfill the programmatic objectives. The Offeror shall identify any of the activities below that are in progress or completed and adjust their SOW accordingly.

(3) Section 3: Statement of Work (SOW)

The SOO, included as SECTION C in this RFP, provides the Government's overall objectives, and the Offeror's required support to achieve those objectives. The proposed SOW shall provide a detailed plan indicating how each aspect of the SOO shall be accomplished. This plan shall be in as much detail as considered necessary to fully explain the proposed technical approach or method. If portions of the SOO have already been addressed by the Offeror, the proposal must note the activities that have already been accomplished against a given objective, instead of proposing work to meet said objective. The proposal shall reflect a clear understanding of the nature of the work being undertaken. The proposal must include information on how the project is to be organized, staffed, and managed. This information shall demonstrate the Offeror's understanding of important events or tasks and their management. The Offeror shall explain how the management and coordination of consultant and/or subcontractor efforts will be accomplished. The Offeror shall use the SOO, together with other applicable portions of the RFP, as a basis for preparing a proposed SOW including the WBS, in the context of work they have accomplished to date. This shall also include Project Gantt charts, Contract Milestones, and Deliverables table with appropriate success and go/no-go decision points as necessary.

The SOW shall be submitted as a separate part of the technical proposal and will be incorporated into the contract at award. **Proposals will be technically evaluated in accordance with Section M of this solicitation.**

L.4.2. Appendices to Technical Proposal

Items below can be revised during finalization of details with the successful Offeror(s) and will be incorporated into the contract.

1) The Offeror shall describe their **Security Plan**, which covers physical, personnel, transport mechanisms and staffing, and Information Technology (IT) infrastructure security. **(Attachment #17)**

2) **Organization Chart** and **Curriculum Vitae** of key personnel. Evidence of an organization chart indicating clear lines of authority and responsibility for the project's management must be included. There must be enough detail to ensure the USG that key individuals will be able to perform the work described in the Technical Proposal. The curriculum vitae shall contain information on education, background, recent experience, expertise, and specific or technical accomplishments, as they pertain

to individuals' ability to support the objectives of this project. The approximate percentage of time each individual will be available for this project must be stated. The proposed staff hours of each individual shall be allocated against each project task or subtask. At a minimum, Offeror(s) must identify the Key Personnel listed below (or equivalent) and their demonstrated experience relevant to this requirement. Offeror(s) shall also identify the number of Other Personnel listed below (or equivalent) available to support this contract and may include their demonstrated experience relevant to this requirement, if available.

Key Personnel:
- Program Director/Principal Investigator
- Project Manager
- Chief Scientific/Medical Officer
- Clinical Development/Clinical Study Director

Other Personnel:
- Chief Executive Officer
- Chief Development Officer
- Non-clinical Development Lead
- Quality Assurance Lead
- Quality Control Lead
- Manufacturing Lead
- Regulatory Affairs Lead
- Pharmacovigilance Lead

3) A **Risk Mitigation Plan (Attachment #14)** to address potential problems that may arise and remediation plans to circumvent major time disruption to the project. Each of these documents can be revised during negotiations with the successful Offeror(s) and will be incorporated into the contract. The risk mitigation will be finalized 90 days after contract award.

4) **Protection of Human Subjects (Attachment #8):** Offeror(s) shall represent how they will adequately address the requirements for protection of human subjects as required under http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

5) Vendor Payment Enrollment Form **(Attachment #12)**

6) Documentation to support Offeror's ownership of intellectual property of product or freedom to operate.

7) Other supporting documents as necessary.

L.5. BUSINESS PROPOSAL

L.5.1 Business Proposal Instructions

The proposal must be signed by an official authorized to bind the Offeror's organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. The Business Proposal must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost or price of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements will include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit. **Propose costs for each CLIN in SECTION B of this RFP (Supplies or Service and Price/Cost) separately (different tabs or separate spreadsheets).**

Submit proposals for these procurement CLINs appropriately as outlined in SECTION C. The USG retains the right to determine the amount of treatment courses procured per CLIN based on needs and availability of funds. However, for the purpose of developing the business proposal, use the following breakdown:

CLINs	Number of Antibiotic Treatment/PEP Courses
CLIN 0008	2,500
CLIN 0009	2,500

CLIN 0010	2,500
CLIN 0011	2,500

CLIN-0001 (Late-stage development to support FDA marketing authorization [nonclinical, clinical, regulatory] or plans for post-marketing requirements for products already FDA approved OR late-stage development to support Pre-EUA through FDA marketing authorization for biothreat indication(s) [nonclinical, clinical, regulatory]).

CLIN-0002 (BARDA security requirements, onshoring commercial manufacturing, & shelf-life extension program activities for HABP/VABP or BSI indications): This CLIN may be utilized to support security and information technology requirements as described in SECTION J, as well as onshoring commercial manufacturing activities and shelf-life extension program activities. The costs outlined within the Business Proposal must be consistent with the security plan detailed in the Technical Proposal.

CLIN-0003 (Continued BARDA security requirements, onshoring commercial manufacturing, & shelf-life extension program activities for HABP/VABP or BSI indications): This CLIN may be utilized to support security and information technology requirements as described in SECTION J, as well as onshoring commercial manufacturing activities and shelf-life extension program activities. The costs outlined within the Business Proposal must be consistent with the security plan detailed in the Technical Proposal.

CLIN-0004 (Post-marketing commitments/requirements, commercial): This CLIN may be utilized to support additional post-marketing requirements for BSI or HABP/VABP. Although a degree of uncertainty as to the Post-marketing Commitments/Requirements for a commercial indication is expected, the costs outlined within the Business Proposal must be consistent with the development plan detailed in the Technical Proposal.

CLIN-0005 (Continued Post-marketing commitments/requirements, commercial): This CLIN may be utilized to support additional post-marketing requirements for BSI or HABP/VABP. Although a degree of uncertainty as to the Post-marketing Commitments/Requirements for a commercial indication is expected, the costs outlined within the Business Proposal must be consistent with the development plan detailed in the Technical Proposal.

CLIN-0006 (Ongoing late-stage development for biothreat indication(s)): This CLIN may be utilized to support ongoing late-stage development to support Pre-EUA through FDA marketing authorization for biothreat indication(s).

CLIN-0007 (Supplemental late-stage development for biothreat indication(s)): This CLIN may be utilized to support supplemental late-stage development as requested by FDA to support Pre-EUA through FDA marketing authorization for biothreat indications(s).

CLIN-0008 (Initial Procurement): Although procurement of up to 2,500 antibiotic courses may be supported by this CLIN, the Business Proposal for initial procurement must be aligned with the Offeror's realistic capacity to deliver product in addition to the corresponding price per treatment course.

CLIN-0009 (*Additional Procurement*): This CLIN may be utilized to support additional procurement phases, up to 2,500 antibiotic treatment courses.

CLIN-0010 (*Additional Procurement*): This CLIN may be utilized to support additional procurement phases, up to 2,500 antibiotic treatment courses.

CLIN-0011 (*Additional Procurement*): This CLIN may be utilized to support additional procurement phases, up to 2,500 antibiotic treatment courses.

CLIN-0012 (Distribution): This CLIN may be utilized to support distribution of product from VMI to sites as directed by the USG.

Propose pricing per CLIN that address the specifics of these procurement phases with respect to volume and type of product (FDP), destination (VMI or ASPR SNS). Within the Business Proposal, costs for these CLINs must rely upon "not to exceed" treatment course values. In addition, provide volume discounts for CLINs 0008, 0009, 0010, and 0011. When budgeting distribution costs from VMI assume the longest route

for delivery within the continental United States.

Submit proposals for these procurement CLINs appropriately as outlined in SECTION C. For FFP procurement CLINs, ensure all costs associated with procurement and delivery of product objectives (reference section 5 of the SOO) are factored into the cost per treatment course (i.e. shipment, storage, stability testing, quality control, etc.). Offerors must propose a price per treatment course for both VMI and ASPR SNS.

L.5.2. Business Proposal – Components

The following information shall be provided on the first page of your pricing proposal:

1. Solicitation number;
2. Name, address, and UEI number of Offeror;
3. Name and telephone number of point of contact;
4. Name, address, and telephone number of Contract Administration Office, (if available);
5. Name, address, and telephone number of Audit Office (if available);
6. Proposed cost and/or price; profit or fee (as applicable); and total;
7. The following statement: By submitting this proposal, the Offeror, if selected for discussions, grants the Contracting Officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.
8. Date of submission; and
9. Name, title and signature of authorized representative.

This cover sheet information is for use by Offeror(s) to submit information to the Government when certified cost or pricing data are not required but information to help establish price reasonableness or cost realism if necessary. Such information is not required to be certified in accordance with FAR 15.406-2.

The data submitted shall be at the level of detail described below:

Direct Labor

Provide a time-phased (e.g., Annual, etc.) breakdown of labor hours and salary labor rates for all positions for work under the prospective contract. The hourly rates proposed for each labor category shall be unburdened. Submit appropriate payroll documentation to support actual individual unburdened labor rates. Identify all Key Personnel.

Materials

Provide a consolidated price summary of individual material quantities included in the various tasks, orders, or contract line items being proposed and the basis for pricing (vendor quotes, invoice prices, etc.).

Subcontracted Items

Include parts, components, assemblies, and services that are to be produced or performed by others in accordance with Offeror's design, specifications, or direction that are applicable only to the prime contract. Provide the type of subcontract, degree of competition, and basis for establishing source, and reasonableness of price, as well as the results of review and evaluation of subcontract proposals when required by FAR 15.404-3.

Purchased Parts

Includes material items not covered above. Provide priced quantities of items required for the proposal.

Fringe Benefits

Show fringe benefits as a separate line item per the excel spreadsheet template. Include the rate(s) and/or method of calculating fringe benefits. Provide a copy of your fringe benefit rate or institutional guidelines.

Indirect Costs

Indicate how the Offeror has computed and applied the Offeror's indirect costs, including cost breakdowns. Provide a basis for evaluating the reasonableness of proposed rates.
Indicate the rates used and provide an appropriate explanation. Where a rate agreement exists, provide a copy.

Travel

Provide the cost of travel including destination, duration, purpose, per diem, transportation, and the basis for pricing. For each trip, propose the number of travelers, number of days, and any other additional documentation as necessary.

Other Costs

List all other costs not otherwise included in the categories described above (e.g., computer services, consultant services) and provide basis for pricing. Provide letters of intent and/or consulting agreements for all consultants to verify typical hourly rates.

L.5.3. Business Proposal – Other Information

(1) Commitment of Public Funds

The Contracting Officer is the only individual who can legally commit the Government to the expenditure of public funds in connection with the proposed procurement. Any other commitment, either explicit or implied, is invalid.

(2) Communications Prior to Contract Award

Offeror(s) shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with any other Government official regarding this RFP is strictly prohibited and may disqualify an Offeror's proposal for further consideration.

(3) Past performance information

Offeror(s) shall submit the following information as part of their business proposal for both the Offeror and proposed major subcontractors. **For the purposes of this solicitation, a "major subcontract" is defined as a subcontract in excess of $500,000.**

The Offeror(s) shall provide a list of the last five contracts completed during the past three years and all contracts currently being performed that are similar in nature to the solicitation work scope. Contracts listed may include those entered into by the Federal Government, agencies of state and local governments, and commercial customers. Any previous activities with BARDA must be included in the submitted past performance list. Offeror(s) that are newly formed entities without prior contracts shall list contracts and subcontracts as required above for all key personnel. Include the following information for each contract or subcontract listed:

(a) Name of Contracting Organization
(b) Contract Number
(c) Total Contract Value
(d) Description of Requirement
(e) Contracting Officer's name, email, and telephone number
(f) Program Manager's name, email, and telephone number

(g) Statement from Offeror as to why this contract is relevant to this project.

In addition to the above requested information, the Offeror(s) shall submit a completed questionnaire **(Attachment #15)** for each of the contracts listed. The Government reserves the right to consider past performance information from any source. It is the responsibility of the Offeror(s) to ensure submission of these questionnaires to be delivered directly from their references to the Government. All questionnaires shall be submitted to erin.greninger@hhs.gov.

All questionnaires shall be submitted via email as part of the proposal submission no later than the closing date and time that is referenced in this solicitation. The Government reserves the right not to consider any past performance questionnaires that are received after the due date.

Each Offeror will be evaluated on their performance under existing and prior contracts for similar products or services. Performance information will be used for responsibility determinations and as an evaluation factor against which the Offeror's relative rankings will be compared to assure the best value to the Government. The Government will focus on information that demonstrates quality of performance relative to the size and complexity of the acquisition under consideration.

(4) Required Forms

All forms must be executed as necessary in the indicated places by an official authorized to bind the Offeror. The following forms shall be duly completed and submitted as a part of the Business Proposal:

1) Offeror's Points of Contact **(Attachment #1)**

2) Breakdown of Proposed Costs with Excel Spreadsheet **(Attachment#3)**

3) Completed Disclosure of Lobbying Activities **(Attachment#4)**

4) Past Performance Questionnaires **(Attachment #6)**

5) A completed Representations and Certifications contained in Part IV, SECTION K, of this solicitation

(5) HHSAR 352.205-74 Supply Chain Risk Assessment Instructions

As a part of its proposal, the offeror must submit the completed provision HHSAR 352.204-74, Supply Chain Risk Assessment (Deviation), including all potential subcontractor information and representations as required by paragraph (g) of the provision.

L.6. Other Administrative Data

(1) The proposal must stipulate that it is predicated upon all the terms and conditions of this RFP. In addition, it must contain a statement to the effect that it is firm for a period of at least 120 days from the date of receipt by the Government.

(2) The proposal must list any current commitments with the Government relating to the work or services and indicate whether these commitments will or will not interfere with the completion of work and services as contemplated under this proposal.

(3) The Offeror must demonstrate that it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source.

(4) It is HHS policy that the Offeror(s) provide all equipment and facilities necessary for performance of contracts; however, in some instances, an exception may be granted to provide Government furnished property or to authorize purchase with contract funds. If additional equipment must be acquired, Offeror's must include in the proposal a description and the estimated cost of each item, and state whether the Offeror proposes to furnish the item with its own funds. The Offeror must identify all Government-owned

property in its possession that it proposes to use in performing the prospective contract.

(5) An adequate accounting system is a preliminary requirement for all Offeror(s). Demonstration of an established system to provide cost accounting and financial data that are adequate for Government contract costing purposes will be required during pre-award. To be considered adequate, an accounting system consistent with Generally Accepted Accounting Principles (GAAP) and any other contractual requirements must be established. In addition to establishing a system that meets GAAP requirements for financial reporting, Offeror(s) must establish a system that records the incurrence of contract costs in accordance with government laws and regulations, particularly the Cost Accounting Standards (CAS) and the Federal Acquisition Regulations (FAR) cost principles. While the use and design of specific accounting records may vary, the record keeping systems for all government Offeror(s) must include a general ledger, a job cost ledger, labor distribution records, time records, subsidiary journals, a chart of accounts, and financial statements.

The accounting system must accomplish the following:

1. Identifies and segregates direct and indirect costs by cost element;
2. Identifies varying levels of indirect costs (e.g. fringe benefits, labor related overhead, and general and administration (G&A) costs);
3. Provides actual cost data at interim periods to allow for contract re-pricing or negotiating revised contract targets;
4. Accumulates costs on both a current and cumulative basis (e.g. year to date, project to date);
5. A timekeeping system that identifies employees' labor costs to appropriate cost objectives to facilitate accurate recording of employee labor costs;
6. Establishes the accounting period and perform reconciliations of time sheets to labor costs included in job cost ledgers and of basic cost records to the general books of account;
7. Excludes from costs charged to government contracts, amounts which are not allowable per terms of FAR Part 31, contract Cost Principles and Procedures, and augmented by CAS405.

L.7. INQUIRIES

Inquiries concerning the solicitation document shall be submitted in writing. Any additions, deletions, or changes to the solicitation will be made by an amendment.

OFFERORS ARE INSTRUCTED SPECIFICALLY TO CONTACT ONLY THE SOLICITATION CONTRACTING OFFICER (LISTED BELOW) IN CONNECTION WITH ANY ASPECT OF THIS REQUIREMENT PRIOR TO CONTRACT AWARD. PROPOSALS AND ALL CORRESPONDENCE RELATING TO THE SOLICITATION DOCUMENT SHALL BE SUBMITTED TO THE CONTRACTING OFFICER.

Initial questions on this RFP are July 29, 2025, at Noon, EST and supplemental questions due August 8, 2025, at Noon, EST. All questions shall be submitted via e-mail to Erin.Greninger@hhs.gov and Audrey.Glover@hhs.gov.

L.8. INCURRING COSTS

The costs of preparing responses to this solicitation are not considered an allowable direct charge on any resultant award. Proposal preparation costs will not be considered.

L.9. NAICS CODE AND SIZE STANDARD

The following information is to be used by the Offeror in preparing its Representations and Certifications (See SECTION K of this RFP), specifically in completing the FAR provision 52.219-1, Small Business Program Representation.

(1) The NAICS Code is 541714.
(2) The small business size standard is 1000 employees.

L.10. USE OF THE METRIC SYSTEM OF MEASUREMENT

Use only the metric system of measurement.

L.11. POTENTIAL AWARD WITHOUT DISCUSSIONS

The Government reserves the right to award a contract under this solicitation without discussions.

L.12. SOLICITATION PROVISIONS INCORPORATED BY REFERENCE

The following provisions are incorporated by reference in this solicitation, FAR 52.252-1 Solicitation Provisions Incorporated by Reference (Feb 1998):

FAR 52.204-16, Commercial and Government Entity Code Reporting (Jul 2016)
FAR 52.207-1, Notice of Standard Competition (May 2006)
FAR 52.215-1, Instructions to Offerors – Competitive Acquisition (Jan 2017)
FAR 52.215-1, Instructions to Offerors, Alternate I (Oct 1997)
FAR 52.215-16, Facilities Capital Cost of Money (Jun 2003)
FAR 52.215-22, Limitations on Pass-Through Charges – Identification of Subcontract Effort (Oct 2009)
FAR 52.232-15, Progress Payments Not Included (Apr 1984)

L.13. ADDITIONAL FEDERAL ACQUISITION REGULATIONS (FAR) IN FULL TEXT

52.216-1 Type of Contract (Apr 1984)

The Government contemplates up to two awards of a cost-plus-fixed-fee and firm-fixed-price hybrid contract resulting from this solicitation.

52.233.2 Service of Protest (Sept 2006)

(a) Protests, as defined in section 33.101 of the Federal Acquisition Regulation, that are filed directly with an agency, and copies of any protests that are filed with the Government Accountability Office (GAO), shall be served on the Contracting Officer (addressed as follows) by obtaining written and dated acknowledgment of receipt from:

Erin Greninger Contracting Officer
Office of Contracts Management and Acquisition (CMA) Administration for
Strategic Preparedness & Response (ASPR) United States Department of
Health & Human Services (HHS)
400 7th St SW, Washington, DC 20024

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

L.14. Supply Chain Risk Assessment

Instructions to Offerors: As a part of its proposal, the offeror must submit the completed provision HHSAR 352.204-74, Supply Chain Risk Assessment (Deviation), including all potential subcontractor information and representations as required by paragraph (g) of the provision.

Section M – EVALUATION FACTORS FOR AWARD

M.1. BASIS OF AWARD

Selection of an Offeror for contract award will be based on an evaluation of proposals against the factors identified in this section. The non-cost factors in order of importance are mandatory evaluation criteria, technical evaluation criteria, and past performance. Technical factors are of paramount consideration in the award of the contract. All evaluation factors other than cost or price, when combined, are significantly more important than cost/price. Technical activities in the Technical Proposal must connect directly to the associated costs in the Business Proposal. The tradeoff process described in FAR 15.101-1 may be employed. The Government intends to make an award to the Offeror whose proposal provides the best overall value to the Government.

The evaluation will be based on the demonstrated capabilities of the prospective Offerors in relation to the needs of the project as set forth in the solicitation. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements within the solicitation. Each Offeror must submit a proposal that separately and sufficiently addresses each of the evaluation criteria specified below as they relate to the Statement of Objectives.

The Contracting Officer reserves the right to make an award without discussion. However, the Government also reserves the right to conduct discussions if it is determined to be in the best interest of the Government. Therefore, Offerors are encouraged to ensure that initial proposals contain the Offeror's most favorable terms and reflect its best possible performance potential. BARDA may elect to make more than one contract award from this RFP solicitation.

M.2. COST/PRICE EVALUATION

The Offeror(s) cost/price proposal will be evaluated for reasonableness. For a price to be reasonable, it must represent a price to the government that a prudent person would pay when consideration is given to prices in the market. Normally, price reasonableness is established through adequate price competition but may also be determined through cost and price analysis techniques as described in FAR 15.404.

Cost Realism: Cost realism analysis will be conducted on the cost-reimbursement CLINs in accordance with FAR 15.404-1(d). The specific elements of each Offeror's proposed costs are realistic when the proposed cost elements are evaluated and found to: 1) be realistic for the work to be performed; 2) reflect a clear understanding of the requirements; and 3) are consistent with the unique methods of performance and materials described in each Offeror's Technical Proposal.

Analytical techniques will be used to not only determine whether the estimate is reasonable but also to provide valuable insight into the Offeror's understanding of the project, perception of risks, and ability to organize and perform the work. The result of this analysis will be considered in making the best value trade-off decision.

M.3. MANDATORY EVALUATION CRITERIA

Listed below are the Mandatory Evaluation Criteria. The Offeror shall provide a dedicated section that addresses the mandatory criteria for eligibility. The mandatory criteria for eligibility must be met at the time of receipt of the proposal as determined by the Contracting Officer (in consultation with a technical team) in order for any proposals to be considered for award. Any Offeror who submits a proposal that does not meet the Mandatory Evaluation Criteria for eligibility will be determined to be unacceptable and will not be considered for further evaluation. All proposals that satisfy the mandatory criteria for eligibility will be considered for a second phase (technical evaluation).

a. The Offeror must have freedom to operate, e.g., ownership of the relevant intellectual property, to develop the product/candidate for the proposed BSI or HABP/VABP or biothreat indication.

b. The product/candidate must be FDA-approved within the last 15 years, or the program completed an end-of-Phase 2 meeting with the FDA and have a Phase 3 development plan that has been favorably reviewed by the FDA for an HABP/VABP and/or BSI indication. The product must be broad-spectrum, with a demonstrated efficacy against two or more drug-resistant pathogens identified as Urgent or Serious Threats in the CDC's 2019 report: *Antibiotic Resistance Threatsin the United States*.

    1) If proposing a biothreat indication, Offerors must propose a biodefense development plan including nonclinical, clinical, and CMC activities that have been discussed with the FDA that if successful will achieve marketing authorization for the treatment and, if feasible, PEP of a biothreat indication(s).

This development plan must include the conduct of a Phase 3 clinical trial for a pneumonic indication if the product is not already approved for such an indication and such a study is recommended by the FDA to support the biothreat indication. An alternative development/regulatory path may be proposed if a pneumonic indication is not required by the FDA. FDA concurrence with this alternative approach must be provided with the proposal.

c. The product must have demonstrated a relevant microbiological profile, lung infection data for HABP/VABP or bloodstream data for BSI from a relevant model simulating human exposure, target attainment (though a completed BAL/ELF study for HABP/VABP), and therapeutic efficacy (through PK/PD studies).
   1) Data on the activity or efficacy in animals that contributes to understanding the potential treatment effect in humans (e.g., proof-of-concept *in vivo* studies in one or more animal species);

   2) Completed nonclinical toxicology and safety pharmacology studies that support the conduct of human clinical trials and marketing authorization for pharmaceuticals consistent with ICH M3(R2) taking into consideration the expected drug exposures and treatment duration related to the proposed use for a BSI or HABP/VABP indication;

   3) Selection of a human dose that is expected to be effective in humans based on the relationship between drug exposure and effectiveness established in animals and available human PK data;

d. If proposing a biothreat development plan, the product minimally must have demonstrated *in vitro* efficacy or *in vivo* animal model efficacy data against one or more of the following biothreat pathogens: *Y. pestis*, *F. tularensis*, or *B. pseudomallei.* All data supporting activity and efficacy against the biothreat pathogen(s) must be presented in the proposal.

e. Registration/Primary batches must be complete or ongoing with plans for full process validation established or validation complete.

f. The manufacturing process for the API and FDP must be developed and established.

g. U.S.-based manufacturing of the FDP, API/DS, and/or starting materials may be required under the August 6, 2020, Executive Order on “Ensuring Essential Medicines, Medical Countermeasures, and Critical Inputs Are Made in the United States,” unless an exception stated in that Executive Order applies. If U.S. domestic capacity does not yet exist, provide a timeline and summary of the approach to onshore the manufacturing of FDP, API/DS, and starting materials. If U.S.-based manufacturing is not feasible, the Offeror must explain why and include an analysis of the cost to establish U.S.-based manufacturing of the FDP, API/DP, and starting materials.

h. If the product has a Black Box Warning, the Offeror must provide a risk-benefit assessment to justify the product’s use during a public health emergency.

M.4. TECHNICAL EVALUATION CRITERIA

The evaluation factors are used by the Technical Evaluation Panel when reviewing the Technical Proposals. Technical activities must correspond directly to the cost/price in the Business Proposal.

The technical evaluation criteria are as follows: 1) Technical Merit for Late-Stage Product Development, 2) Personnel and Experience, and 3) Manufacturing Capabilities and Facilities. These evaluation criteria are of equal importance.

Evaluation Criteria 1: Technical Merit for Late-Stage Product Development

Proposals will be evaluated for:

1. Demonstration of a feasible regulatory approach that supports the acquisition of an antibiotic formulated for either oral or intravenous administration, or both oral and intravenous administration (e.g., Phase 1 trials, efficacy data, PK/PD data, and FDA feedback).
2. If proposing a biothreat indication, a demonstration of *in vitro* efficacy against biothreat pathogen(s) is required. *In vivo* animal model efficacy data are preferred for a candidate in Phase 3 development but are required if the product is not FDA approved for a pneumonic indication.

3. Adequacy of product characteristics and proposed plan to address the General Product Objectives as outlined in Section 2.1 of the SOO.
4. If proposing a biothreat indication, adequacy of the Offeror's proposed biothreat development plan, as outlined in Section 2.1 of the SOO.
5. Demonstration of an adequate development plan to address the Regulatory Objectives as outlined in Section 2.2 of the SOO to include a pathway to marketing authorization supported by FDA discussions, including documentation, if available.
6. Demonstration of a proposed plan to address the Nonclinical Objectives as outlined in Section 2.3 of the SOO to include evidence of safety and efficacy.
7. Demonstration of a proposed plan to address the Clinical Objectives as outlined in Section 2.4 of the SOO to include evidence of clinical safety and efficacy.
8. Demonstration of a proposed plan to address the Chemistry, Manufacturing, and Control Objectives as outlined in Section 2.5 of the SOO.
9. Demonstrated knowledge of potential post-marketing commitments/requirements in Section 3 of the SOO.
10. Adequacy of the proposed timelines/milestone schedule(s) for meeting late-stage product development objectives (marketing authorization in no more than five years).
11. Demonstration of a plan to address the stability and storage logistics of the API/DS and FDP.
12. Demonstration of the Offeror's ability to ensure controlled stability and storage (VMI) conditions.
13. Demonstration of the Offeror's ability to deliver FDP as VMI and/or to the ASPR SNS using validated shipping methods, as described in Section 4 of the SOO.
14. Demonstration of a proposed plan to address the distribution of products from VMI.

Evaluation Criteria 2: Personnel and Experience

Proposals will be evaluated for:

1. Demonstration of experience and capabilities of proposed key personnel, professional staff, subcontractors, and other professional and technical staff proposed in the management of product development and execution of delivery activities to the ASPR SNS or as VMI. The Program Manager identified in the proposal must be an employee of the Offeror and this individual should not be a subcontractor.
2. The Offeror(s) shall consider the list of key personnel as proposed in SECTION L.4.2; however, additional key or other personnel shall be included should they play a substantial role in the execution of the SOO.
3. Adequacy of the Project Management Plan to ensure efficient planning, initiation, implementation, conduct, and completion of activities to fulfill the requirements as outlined in Section 1 of the SOO.
4. Adequacy of project management documentation including at a minimum, risk mitigation plans, Gantt charts, integrated master schedules, and security plan.
5. Evidence that the Offeror has previously executed nonclinical and clinical studies for achieving licensure of a drug candidate(s) according to the performance specifications of the SOO, project goals, objectives, criteria, timelines, risks, and risk mitigation strategies/plans.

Evaluation Criteria 3: Manufacturing Capabilities and Facilities for Production of Antibiotics

The Offeror(s) shall provide details concerning the manufacturing processes and controls. Proposals will be evaluated for:

1. Demonstration of the capability to meet USG requirements to deliver either an oral and/or intravenous antibiotic as VMI or to the ASPR SNS upon award.
2. Demonstration of manufacturing capabilities to supply 10,000 treatment courses to meet the product acquisition goals of the requirement outlined in SECTION 4 of the SOO.
3. Offerors that manufacture their FDP, API/DS, and/or starting materials within the U.S will be evaluated more favorably. If manufacturing is not currently conducted in the U.S., onshoring plans for U.S. manufacturing of the FDP, API/DS, and/or starting materials shall be provided where feasible. If onshoring is not feasible, the Offeror must explain why and provide in the business proposal a cost analysis to establish U.S.-based manufacturing for the FDP, API/DS, and starting materials.
4. Adequacy of the plan to address each task and sub-task for Procurement and Delivery of Product Objectives as stated in Section 4 of the SOO.

5. Demonstration of access to appropriate facilities, equipment, services, and infrastructure including subcontractors, to execute manufacturing objectives as stated in Section 2.5 of the SOO.
    a. Documented capabilities for storage and release of the product for either storage as VMI OR subsequent delivery to the ASPR SNS.
    b. Adequacy of facilities and infrastructure to carry out the proposed manufacturing effort. (The Offeror may identify specific subcontractors and other partners).

M.5. MERIT RATINGS

Evaluators will assign one merit rating to each of the three-evaluation criteria listed above. The individual merit ratings will be considered by the Technical Evaluation Panel members in consensus who will assign one overall merit rating for each evaluation criterion. An Offeror who receives a merit rating of Unacceptable for any criterion will not be eligible for award. Cost/Price and Past Performance will not be evaluated for any proposal with a rating of Unacceptable in the technical evaluation.

M.6. PAST PERFORMANCE

Offeror's past performance information will be evaluated subsequent to the technical evaluation. However, this evaluation will not be conducted on any Offeror whose Technical Proposal does not meet the mandatory criteria or is determined to be technically unacceptable.

The evaluation will be based on information obtained from references provided by the Offeror, other relevant past performance information obtained from other sources known to the Government, and any information supplied by the Offeror concerning problems encountered on the identified contracts and corrective action taken.

The Government will assess the relative risks associated with each Offeror. Performance risks are those associated with an Offeror's likelihood of success in performing the acquisition requirements as indicated by that Offeror's record of past performance.

When assessing performance risks, the Government, to the fullest extent practicable, will focus on the past performance of the Offeror as it relates to all acquisition requirements.

The Government will consider the currency and relevance of the information, source of the information, context of the data, and general trends in the Offeror's performance.

The lack of a relevant performance record may result in an unknown performance risk assessment, which will neither be used to the advantage nor disadvantage of the Offeror.

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

M.7. EVALUATION OF OPTIONS

It is anticipated that any resultant contract from this solicitation will contain Option provision(s).

FAR 52.217-5, Evaluation of Options (July 1990)

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

M.8. PROSPECTIVE CONTRACTOR RESPONSIBILITY AND ELIGIBILITY STANDARDS: SUPPLY CHAIN RISK ASSESSMENT

Federal Acquisition Regulation (FAR) Subpart 9.1 sets the standards and procedures for determining prospective contractor and subcontractor responsibility. FAR 9.104-2 allows for special standards of responsibility.

Special standards in the responsibility determination: The government will assess the offeror's submitted information in provision HHSAR 352.204-74, Supply Chain Risk Assessment (Deviation), any required supporting data, and information from other sources for the purpose of evaluating foreign ownership, control or influence and other areas of supply chain risk, when necessary, and this information will be treated by HHS, to the extent permitted by law, as business or financial information submitted in confidence.

The Government may request additional information or a mitigation plan from the offeror that addresses risks identified in the supply chain risk assessment. Any requests for additional information resulting from the supply chain risk assessment do not constitute exchanges or discussions as described in FAR 15.306.

Any mitigation plans and amendments determined necessary and required to be implemented and sustained during contract performance will be incorporated into the contract.

In order to manage supply chain risk, the Government may consider information, public and non-public, relating to an offeror's supply chain in determining responsibility. The Government may remove the offeror from further consideration due to a Supply Chain Risk determination, which renders the offeror non-responsible. The Government reserves the right to limit the disclosure of information to the Offeror regarding the risk in accordance with all applicable laws or regulations.

ATTACHMENT #1

OFFEROR'S POINTS OF CONTACT

Complete the following and return with the BUSINESS PROPOSAL.

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

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

Name, Institutional Title and Address of Proposed Principal

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

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

*Use actual street address, not P.O. Box.

ATTACHMENT #2
SAMPLE INVOICE

Company Name

Designated Billing Office Name and Address: DHHS/OS/ASPR/CMA Attn: Contracting Officer 400 7th 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:** **UEI #:**	**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 Contracts Management and Acquisitions (CMA) **Central Point of Distribution:**

This invoice represents reimbursable costs for the period from

Expenditure Category	**Amount Billed**		
	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

ATTACHMENT #3

Breakdown of Proposed Costs with Excel Spreadsheet

ATTACHMENT #4

DISCLOSURE OF LOBBYING ACTIVITIES, WITH INSTRUCTIONS

Complete form available here: https://www.gsa.gov/forms-library/disclosure-lobbying-activities

Copy and paste the above link into your browser.

ATTACHMENT #5

RISK MITIGATION PLAN/MATRIX TEMPLATE

Offeror's Name Risk Mitigation Matrix Risks Identified from XXXX (Contract # or Specific Document) Date											
Prior to Risk Mitigations Strategy						Post Risk Mitigations					
Risks	Probability of Occurrence	Risk to project (Severity)	Risk to Cost	Risk to Schedule	Risk to Tech Performance	Risk Mitigation effort	Probability of Occurrence	Risk to project (Severity)	Risk to Cost	Risk to Schedule	Risk to Tech Performance

ATTACHMENT #6

PAST PERFORMANCE QUESTIONNAIRE

PAST PERFORMANCE QUESTIONNAIRE – APPLY TO PRIME OFFEROR:			
Your assistance is requested in support of a source selection. Request a representative of the contracting organization and a technical representative, the Program Manager (PM), and the Contracting Officer's Representative (COR), complete this questionnaire and e-mail to: **HHS/OS/ASPR/CMA** Attn: Erin Greninger, Contracting Officer erin.greninger@hhs.gov When complete, the information on this form is **SOURCE SELECTION SENSITIVE INFORMATION (41 U.S.C. 423)** and shall be protected accordingly.			
BLOCKS 1 THROUGH 8 TO BE COMPLETED BY THE OFFEROR			
1. OFFEROR NAME & ADDRESS:	2. CONTRACT NO.:		
	3. CONTRACT AWARD DATE:		
	4. PERIOD OF PERFORMANCE/COMPLETION DATE:		
	5. Approximate percentage of work being performed (or completed) by subcontractor(s): %		
	6. Information on subcontractor(s) (*where more than % of work was completed by the subcontractor*).		
	7. CONTRACT VALUE (WITH OPTIONS):	$	
	8. TYPE OF CONTRACT:		
9. TITLE OF CONTRACT AND DESCRIPTION OF CONTRACT REQUIREMENTS:			
BLOCKS 9 THROUGH 10F TO BE COMPLETED BY EVALUATION ORGANIZATION REPRESENTATIVE			
10. EVALUATION:			
a. EVALUATOR'S NAME	POSITION (PCO/PM/COR/OTHER)	ORGANIZATION	PHONE NUMBER/E-MAIL
b. MONTHS OFFEROR PERFORMANCE MONITORED BY EVALUATOR:			

c. RATINGS - Please check the block beside the response code that best reflects your evaluation of the Offeror's performance.

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

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

A. Quality of Product or Service							
A-1. Compliance with contract requirements	☐ N/A	1☐	2☐	3☐	4☐	5☐	
A-2. Accuracy of reports	☐ N/A	1☐	2☐	3☐	4☐	5☐	
A-3. Effectiveness of personnel	☐ N/A	1☐	2☐	3☐	4☐	5☐	
A-4. Technical excellence	☐ N/A	1☐	2☐	3☐	4☐	5☐	
B. Cost Control							
B-1. Record of forecasting and controlling target costs	☐ N/A	1☐	2☐	3☐	4☐	5☐	
B-2. Current accurate and complete billings	☐ N/A	1☐	2☐	3☐	4☐	5☐	
B-3. Best value (balance of performance vs. cost).	☐ N/A	1☐	2☐	3☐	4☐	5☐	
B-4. Relationship of negotiated costs to actuals	☐ N/A	1☐	2☐	3☐	4☐	5☐	
B-5. Cost efficiencies	☐ N/A	1☐	2☐	3☐	4☐	5☐	
C. Schedule							
C-1. Met interim milestones	☐ N/A	1☐	2☐	3☐	4☐	5☐	
C-2. Reliability	☐ N/A	1☐	2☐	3☐	4☐	5☐	
C-3. Responsive to technical direction	☐ N/A	1☐	2☐	3☐	4☐	5☐	
C-4. Completed on time including wrap-up and contract administration	☐ N/A	1☐	2☐	3☐	4☐	5☐	
C-5. Met delivery schedules	☐ N/A	1☐	2☐	3☐	4☐	5☐	
D. Business Relations							
D-1. Effective management, including subcontracts	☐ N/A	1☐	2☐	3☐	4☐	5☐	
D-2. Reasonable/cooperative behavior	☐ N/A	1☐	2☐	3☐	4☐	5☐	
D-3. Responsive contract requirements	☐ N/A	1☐	2☐	3☐	4☐	5☐	
D-4. Notification of problems	☐ N/A	1☐	2☐	3☐	4☐	5☐	
D-5. Flexibility	☐ N/A	1☐	2☐	3☐	4☐	5☐	
D-6. Pro-active vs. reactive	☐ N/A	1☐	2☐	3☐	4☐	5☐	
D-7. Effective small/small disadvantaged business subcontracting program	☐ N/A	1☐	2☐	3☐	4☐	5☐	
E. Security							
E-1. Understanding of physical security compliance.	☐ N/A	1☐	2☐	3☐	4☐	5☐	
E-2. Compliance with communication and information security.	☐ N/A	1☐	2☐	3☐	4☐	5☐	
F. Customer Satisfaction							
F-1. The Offeror is committed to customer satisfaction		☐ Yes	☐ No				
F-2. Would you recommend selection of this firm again?		☐ Yes	☐ No				

RATING GUIDELINES

RATING GUIDELINES QUALITY OF PRODUCT OR	Definition	Note
1 – Unsatisfactory	Performance does not meet most contractual requirements and recovery is not likely in a timely manner. The contractual performance of the element or sub-element contains a serious problem(s) for which the Offeror's corrective actions appear or were ineffective.	To justify an Unsatisfactory rating, identify multiple significant events in each category that the Offeror had trouble overcoming and state how it impacted the Government. A singular problem, however,could be of such serious magnitude that it alone constitutes an unsatisfactory rating. An Unsatisfactory rating should be supported by referencing the management tools used to notify the Offeror of the contractual deficiencies (e.g., management, quality, safety, or environmental deficiency reports, orletters).
2 – Marginal	Performance does not meet some contractual requirements. The contractual performance of the element or sub-element being evaluated reflects a serious problem for which the Offeror has not yet identified corrective actions. The Offeror's proposed actions appear only marginally effective or were not fully implemented.	To justify Marginal performance, identify a significant event in each category that the Offeror had trouble overcoming and state how it impactedthe Government. A Marginal rating should be supported by referencing the management tool that notified the Offeror of the contractual deficiency (e.g., management, quality, safety, or environmental deficiency report or letter).
3 – Satisfactory	Performance meets contractual requirements. The contractual performance of the element or sub- element contains some minor problems for which corrective actions taken by the Offeror appear or were satisfactory.	To justify a Satisfactory rating, there should have been only minor problems, or major problems the Offeror recovered from without impact to the contract/order. There should have been NO significant weaknesses identified. A fundamental principle of assigning ratings is that Offerors will not be evaluated with a rating lower than Satisfactory solely for not performing beyond the requirements of the contract/order.
4 – Very Good	Performance meets contractual requirements and exceeds some to the Government's benefit. The contractual performance of the element or sub- element being evaluated was accomplished with some minor problems for which corrective actions taken by the Offeror were effective.	To justify a Very Good rating, identify a significant event and state how it was a benefit to the Government. There should have been no significant weaknesses identified.
5 – Exceptional	Performance meets contractual requirements and exceeds many to the Government's benefit. The contractual performance of the element or sub-element being evaluated was accomplished with few minor problems for which corrective actions taken by the Offeror were highly effective.	To justify an Exceptional rating, identify multiple significant events and state how they were of benefit to the Government. A singular benefit, however, could be of such magnitude that it alone constitutes an Exceptional rating. Also, there should have been NO significant weaknesses identified.

ATTACHMENT #7

BARDA SECURITY

REQUIREMENTS

The following table outlines the minimum security requirements for any partner facility receiving a BARDA contract under which the USG purchases products or technologies.

1. Security Administration	
Security Program	The partner facility shall have a comprehensive security program that provides a security plan for the overall protection of personnel, information, data, and facilities associated with fulfilling the BARDA requirement. The proposal submitted shall include a security plan which establishes security practices and procedures that demonstrate how the Offeror will meet and adhere to the security requirements outlined below by time of contract award. The Offeror shall also ensure that other entities (subOfferors, consultants, etc.) performing work on behalf of the Offeror establishes and manages a security program that complies with BARDA security requirements.
2. Facility Security Plan	
As part of the partner facility's overall security program, they shall submit a written security plan with their proposal to BARDA for review and approval by the BARDA PPO. Performance of work under the BARDA contract will be in accordance with the approved security plan. The security plan will include the following processes and procedures at a minimum:	
Security Administration	Organization and responsibilities; security risk assessment for site; threat levels identification matrix; security procedures during elevated threats; liaison with law enforcement; security education and training
Personnel Security Policies and Procedures	Candidate recruitment process; background investigations; employment suitability policy; access determination; rules of behavior/ conduct; termination procedures; non-disclosure agreements.
Physical Security Policies and Procedures	Internal/external access control; protective services; identification/badging; visitor access controls; parking areas and access control; perimeter fencing/barriers; shipping, receiving and transport; security lighting; restricted areas; signage; intrusion detection systems; alarm monitoring/response; closed circuit television; product storage security; other control measures.
Information Security	Identification of sensitive information; access control; storage of information; document control; retention/ destruction requirements.
Information Technology/Cyber Security Policies and Procedures	Intrusion detection and prevention systems; threat identification; employee training; encryption systems; identification of sensitive information/media; password policy; removable media policy; laptop policy; access control and determination; system document control; system backup; system disaster recovery; incident response;

	system audit procedures; property accountability.
3. Site Security Master Plan	
The partner facility shall provide a site schematic for security systems which includes: main access points; security cameras; electronic access points; bio-containment laboratories	
4. Site Threat / Vulnerability / Risk Assessment	
The partner facility shall provide a written risk assessment for the facility addressing: criminal threat; terrorist threat; industrial espionage; natural disasters; and potential loss of critical infrastructure (power/water/natural gas, etc.) This assessment shall include recent data obtained from local law enforcement agencies.	
5. Physical Security	
Closed Circuit Television (CCTV) Monitoring	Layered (internal/external) CCTV coverage with time-lapse video recording for buildings and areas where critical assets are processed or stored. CCTV coverage should include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. Video recordings must be maintained for a minimum of 30 days. CCTV surveillance system must be on emergency power backup.
Facility Lighting	Lighting must cover facility perimeter, parking areas, critical infrastructure, and entrances and exits to buildings. Lighting must have emergency power backup. Lighting must be sufficient for the effective operation of the CCTV surveillance system during hours of darkness.
Shipping and Receiving	Should have CCTV coverage and an electronic access control system. Should have procedures in place to control access and movement of drivers picking up or delivering shipments. Must identify drivers picking up BARDA products by government issued photo identification.
Access Control	Should have an electronic intrusion detection system with centralized monitoring. Responses to alarms must be immediate and documented in writing. Employ an electronic system (i.e. card key) to control access to areas where assets critical to the contract are located (facilities, laboratories, clean rooms, production

	facilities, warehouses, server rooms, records storage, etc.) The electronic access control should signal an alarm notification of unauthorized attempts to access restricted areas. Should have procedures to prevent employee piggybacking. Access to critical infrastructure (generators, air handlers, fuel storage, etc.) should be controlled and limited to those with a legitimate need for access. Should have a manual key accountability and inventory process. Physical access controls should present a layered approach to critical assets within the facility.
Employee/Visitor Identification	Should issue company photo identification to all employees. Photo identification should be displayed above the waist anytime the employee is on company property. Visitors should be sponsored by an employee and must present government issued photo identification to enter the property. Visitors should be logged in and out of the facility and should be escorted by an employee while on the premises.
Security Fencing	Requirements for security fencing will be determined by the criticality of the program and the potential threat environment.
Protective Security Forces	Requirements for a security force will be determined by the criticality of the program and the potential threat environment.
6. Security Operations	
Information Sharing	Establish formal liaison with law enforcement and implement procedures for receiving and disseminating threat information.
Training	Conduct new employee security awareness training. Conduct and maintain records of annual security awareness training.
Security Management	Designate a knowledgeable security professional to manage security of the facility. Ensure subcontractor compliance with BARDA security requirements.
7. Personnel Security	
Records Checks	Verification of date of birth, citizenship, education credentials, five-year previous employment history, five-year previous residence history, FDA disbarment, and local

	/ national criminal history search.
Hiring and Retention Standards	Policies and procedures concerning hiring, and retention of employees to include employee conduct expectations.
8. Information Security	
Physical Document Control	Applicable documents shall be identified and marked as procurement sensitive, proprietary or with appropriate government markings. Sensitive, proprietary, and government documents should be maintained in a lockable filing cabinet / desk or other storage device and not be left unattended. Access to sensitive information should be restricted to those with a need to know.
Document Destruction	Documents shall be destroyed using approved destruction measures (i.e. shredders / approved third party vendors / pulverizing / incinerating).
9. Information Technology & Cybersecurity	
Access Control	Limit information systems access to authorized users. Identify information system users, processes acting on behalf of users, or devices and authenticate identities before allowing access. Limit physical access to information systems, equipment, and server rooms with electronic access controls.
Training	Ensure that personnel are trained and are made aware of the security risks associated with their activities and of the applicable laws, policies, standards, regulations, or procedures related to information technology systems.
Audit and Accountability	Create, protect, and retain information system audit records to the extent to the extent needed to enable the monitoring, analysis, investigation, and reporting of unlawful, unauthorized, or inappropriate system activity. Ensure the actions of individual information system users can be uniquely traced to those users.
Configuration Management	Establish and enforce security configuration settings.
Contingency Planning	Establish, implement, and maintain plans for emergency response, backup operations, and post-disaster recovery for information systems to ensure the availability of critical information resources at all times.

Incident Response	Establish an operational incident handling capability for information systems that includes adequate preparation, detection, analysis, containment, and recovery of cybersecurity incidents.
Media and Information Protection	Protect information system media, both paper and digital. Limit access to information on information systems media to authorized users Sanitize and destroy media no longer in use. Control the use of removable media through technology or policy.
Physical and Environmental Protection	Limit access to information systems, equipment, and the respective operating environments to authorized individuals. Protect the physical and support infrastructure for all information systems. Protect information systems against environmental hazards.
Network Protection	Employ intrusion prevention and detection technology.
10. Transportation Security	
Adequate security controls must be implemented to protect materials while in transit from theft, destruction, manipulation, or damage.	
Drivers	Drivers should be vetted in accordance with BARDA Personnel Security Requirements. Drivers should be trained on specific security and emergency procedures. Drivers should be equipped with backup communications. Driver identity should be 100 percent confirmed before pick-up of any BARDA product. Drivers should never leave BARDA product unattended and two drivers may be required for longer transport routes or critical products during times of emergency.
Transport Routes	Transport routes should be pre-planned and never deviated from except when approved or in the event of an emergency. Transport routes should be continuously evaluated based upon new threats, large planned events, weather, and other situations that may delay or disrupt transport.
Product Security	BARDA products should be secured with tamper resistant seals during transport and

	the transport trailer should be locked and sealed. Tamper resistant seals should be verified as "secure" after the product is placed in the transport vehicle. BARDA product should be continually monitored by GPS technology while in transport and any deviations from planned routes should be investigated and documented. Contingency plans should be in place to keep the product secure during emergencies such as accidents and transport vehicle breakdowns.
11. Security Reporting Requirements	
The partner facility shall immediately 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. The facts and circumstances associated with these incidents will be documented in writing for government review.	
12. Security Audits	
The partner facility agrees to formal security audits conducted at the discretion of the government. Security audits may include both prime and sub locations.	

ATTACHMENT #8

SECURITY PLAN TEMPLATE WITH INSTRUCTIONS

COMPANY SECURITY PLAN TEMPLATE

Prepared by: Program Protection Office

Office of Biomedical Advanced Research and Development Authority Preface

The intent of this document is to provide possible practices and procedures that entities may use to assist them in developing and implementing the written security plan required by the Office of Biomedical Advanced Research and Development Authority (BARDA). The ideas and suggestions provided in this document do not constitute or establish minimum standards but are provided as general guidance. Each security program will be assessed in its totality. This document was prepared as a reference guide and template to assist entities in the development of a site-specific security plan. Additionally, a BARDA Audit Checklist is provided at Appendix B.

A good security plan model could be to organize into the following sections: Physical Security, Personnel Security, Information Security, Security Awareness Training, Information Technology Security, and Transportation Security (shipping). For each section, we recommend that you provide a complete description of the relevant specific security measures you will use to reduce your vulnerabilities. You shall also discuss personnel roles and responsibilities for implementing each measure. There is set formula for what an acceptable security plan looks like. Sometimes very simple changes in procedures can achieve the same result as a much more costly equipment-based solution.

A layered approach to security is recommended when designing an overall security strategy. Security protective measures developed in unison are more cost effective and successful. Each layer alone may be capable of stopping an incident but in combination, their security value is multiplied, creating a much stronger, formidable system. A potential terrorist, criminal, or unauthorized person who has to overcome multiple security layers in order to carry out an attack is more likely to be pre-empted, deterred, or to fail during the attempt. The below illustration depicts the concept of layered security.

General Outline of Security Plan
Topics

i) Organization and Responsibilities
ii) Site- Specific Risk Assessment
    (1) Statement of Threats
        (a) Industrial Espionage
        (b) Criminal
        (c) Terrorism
        (d) Natural Disasters
    (2) Vulnerability + Consequence of Loss=Risk
iii) Threat Levels
    (1) Low – Protective Measures
    (2) Medium – Protective Measures
    (3) High – Protective Measures
iv) Physical Security
    (1) General Description
    (2) Access Control
        (a) Perimeter
        (b) Internal
        (c) Badge Policy
            (i) Permanent employees
            (ii) Visitors
            (iii) Others
    (3) Parking Areas
    (4) Security Lighting
    (5) Other Building Features
    (6) Signage
    (7) Designation of Restricted Areas
        (a) Entry Points
        (b) Electronic Access Control
        (c) Electronic Intrusion Detection
        (d) Closed Circuit Television
        (e) Other Control Measures
v) Personnel Security Program
    (1) General Description
    (2) Recruitment of New Employees
        (a) Interview process
        (b) Background Checks
        (c) Suitability / Adjudication Guidelines
        (d) Non-Disclosure Agreements
        (e) Rules of Behavior
        (f) Access Determination/Badge System
    (3) Temporary Employees
        (a) Interview
        (b) Background Checks
        (c) Non-Disclosure Agreements
        (d) Access Determination/Badge System
    (4) Offeror Support
    (5) Termination
        (a) Denial of Access
        (b) Post Employee Interview
        (c) Non-Disclosure Agreements
vi) Information Security
    (1) General Description
    (2) Identification of Sensitive Information

(3) Physical Document Control
  (a) Marking
  (b) Secure Storage
  (c) Destruction Policy
(4) Information Technology Security
  (a) General Description
  (b) Media Control
    (i) Media Protection
    (ii) Sanitization and Disposal of Information
    (iii) Input/Output Controls
  (c) Equipment
    (i) Workstations
    (ii) Laptops and Other Portable Computing Devices
  (d) Personally Owned Equipment and Software
  (e) IT Disaster Recovery
    (i) Backup Data.
    (ii) Store Backup Data

vii) Security Awareness Training and Reporting Requirements
(1) Training
  (a) New Employees
  (b) Annual
(2) Security Reporting
  (a) Reporting of Compromise
  (b) Reporting of Incidents

viii) Transportation Security

I. Organization and Responsibilities – Provide an overview of key company personnel with security responsibilities. Include an organization chart, key personnel, contact numbers, and areas of expertise.

II. Site Specific Risk Assessment - Provide an assessment of the threat environment and discuss potential hazards that could undermine or hinder completion of the contract. Threats, such as terrorism, industrial espionage/sabotage, may appear to pose a minimal risk to company operations but the possibility of their occurrence and its impact on operations cannot be ignored. Additionally, an all-hazards approach shall be considered when developing a security strategy. Loss of power, severe weather, and other natural or manmade disasters can be mitigated by thoughtful security and contingency planning. With limited security dollars, each company will design the countermeasures to vulnerabilities to meet its primary security objectives while addressing identified risks.

III. Threat Levels – Institute a graduated Threat Advisory System to advise employees of potential increased threats and to implement a set of corresponding protective measures which would further reduce vulnerability and increase response capability during periods of heightened alert. Threat levels can be as simple as: Low; Medium; High; or something that corresponds with local, state, or federal government procedures. During periods of heightened alert, entities shall consider the following no cost / low cost measures:

- Increase the visible security personnel presence wherever possible.
- Rearrange exterior vehicle barriers (if available) toaster traffic patterns near facilities.
- Institute a vehicle inspection program.
- Institute/increase vehicle, foot, and roving security patrols.
- Implement random security guard shift changes.
- Arrange for law enforcement vehicles to be parked randomly near entrances and exits.
- Approach all illegally parked vehicles in and around facilities, question drivers and direct them to move immediately, if owner cannot be identified, have vehicle towed by law enforcement.
- Report any suspicious activity immediately to law enforcement.
- Limit the number of access points and strictly enforce access control procedures.
- Implement stringent identification procedures to include conducting 100% "hands on" checks of security badges for all personnel, if badges are required.
- Remind personnel to properly display badges, if applicable, and enforce visibility.

- Require two forms of photo identification for all visitors.
- X-ray packages and inspect handbags and briefcases at entry if possible.
- Validate vendor lists for all routine deliveries and repair services.

IV. Personnel Security – Provide a detailed description of your Personnel Security Program that includes hiring practices, determination of suitability for employment, termination for cause processes, and individual training goals. Personnel Security focuses on verifying the identity and credentials of a candidate and assessing their trustworthiness based on past behavior. Examples of Personnel Security measures include:

- Conduct national and local criminal history check;
- Confirm past employment (five years);
- Verify education;
- Perform reference checks;
- Perform credit check;
- Confirm Citizenship and Social Security number;
- Conduct drug and alcohol testing;
- Sign non-disclosures agreements.

Entities shall also provide a description of methods and practices used to determine suitability for employment. Suitability refers to identifiable character traits and conduct sufficient to decide whether an individual is likely or not likely to be able to carry out the duties of a job with appropriate integrity, efficiency, and effectiveness. When adjudicating suitability, the process shall carefully weigh reliable information about the person, past and present, favorable and unfavorable, before reaching a final determination. Consideration shall also be given to the following when evaluating a potential employee's suitability:

- Nature, extent and seriousness of the conduct
- Circumstances surrounding the conduct, to include knowledgeable participation
- Frequency of the conduct
- Individual's age and maturity at the time of the conduct
- Extent to which participation was voluntary
- Presence or absence of rehabilitation and other permanent behavioral changes
- Motivation for the conduct
- Potential for pressure, coercion, exploitation, or duress
- Likelihood of continuation or recurrence.

V. Physical Security – Provide a detailed description of your Physical Security Program designed to prevent or deter attackers from accessing a facility, resource, or information. Physical Security program uses a coordinated approach using obstacles, barriers, equipment, and policies to limit access to company property to only those with a need.

a. Obstacles and barriers provide the ability to prevent, discourage, or delay entry into the protected space at its outer boundaries. Some examples of physical security techniques (in escalating order) include:

    - Install a fence around the site;
    - Fenced sites shall have a "clear zone" inside and outside the fence for unobstructed observation;
    - Fenced-in sites shall have the capability to have locked, secure gates;
    - Installation of a security alarm system;
    - Sufficient lighting in and around the site;
    - Random checks of lighting and fencing in and around the site;
    - Increase testing the security alarm systems;
    - Increase testing the site alarm system with local law enforcement; and
    - Locking hardware for gates shall be case-hardened chain and high-security padlocks;
    - Employ additional portable lighting in and around the site for critical assets, and
    - Employ obstacles or barriers in addition to standard fencing. Examples would be using concertina or razor wire to provide a double fence, or placing Jersey barriers to restrict vehicular traffic. While the concertina wire or Jersey barriers would have to already be on site, they can be put in place very quickly.

b. Badge System - An access badge system is an effective method to control entry to the company facilities, offices, and restricted areas other places that have access controlled entry points. Entry points may be doors, turnstiles, parking gates or other controlled entry points. Access badges use various technologies to identify the holder of the badge to the access control system. The most common technologies are magnetic stripe, proximity, barcode, smart cards and various biometric devices. The access badge contains information in digital form that is decoded by a card reader. The information is transmitted to the access control system. The access control system is a computer running access control software that makes access control decisions based on information about the holder of the access badge. If the credential has the proper privilege the access control system unlocks the controlled access point. Simultaneously, information about the transaction is stored in the access control system for later retrieval. Reports can be generated that will reveal who entered what portal at what time. Considerations for a badge system include:

- Establish a control and custody process for the identification badge program;
- Enforce display of badge for employees while at work and for visitors;
- Require photo identification badges for permanent employees and long term visitors;
- Limit site access to one entrance and exit for visitors;

c. Intrusion Detection - Use of alarms, lightning, and locks provide enhanced security for protected space and improve the reliability of traditional physical security tactics, such as employee training, guards, and fencing. Each improvement is designed to restrict access to authorized personnel. Additional security measures that directly enhance the physical protection of property include:

- Training for employees to recognize unauthorized people inside the facility;
- Institute periodic roving patrols of the facility perimeter by guard force;
- Install a property alarm system;
- Integrate alarm systems with security force and regularly exercise and check for reliability;
- Tie site alarm system into local law-enforcement department;
- Have a video camera monitor areas not under direct observation;
- Employ explosive detection devices; and
- Use metal detectors/x-ray machines to screen personnel, visitors, and bags.

d. Personnel Protection – Unfortunately, the threat of violence in the workplace is a variable which you may choose to address as part of your security plan. The first step in protecting the work force from physical threats is educating the individual to recognize threatening situations. This must also be supported by systems and infrastructure that provide the capability for a proper response. Robust communications, particularly the ability to communicate as well as function under duress, are an essential consideration. The response capability shall be described in terms of timing, capability, and quantity. Any response that can disrupt or otherwise degrade a potential attack scenario, without placing additional people at risk or otherwise raising the potential target value, may be considered as a security measure. For example:

- Determine if the organization has personnel deemed as critical and more likely to be targeted, if so, establish procedures for the protection of personnel deemed critical;
- Identify and assess potential safe havens within buildings to use in emergencies (safe havens are areas that are more survivable than other areas in buildings-basements, hallways, inner rooms, or stairwells- and that generally offer a significant barrier to an intruder);
- Inform employees about buildings that contain safe havens;
- Have an emergency evacuation plan;
- Ensure the emergency evacuation plan has escape routes, emergency lighting, and exits; and
- Establish emergency lockdown/shelter-in-place procedures, then;
    - Conduct drills moving employees to designated safe havens; and
    - Periodically run drills to test the emergency evacuation plan;
    - Establish procedures for retaining essential employees on site.

VI. Information Security – Provide a detailed description of your Information Security Program designed to protect information systems against unauthorized access to or modification of information, whether in storage, processing or transit, and against the denial of service to authorized users or the provision of service to unauthorized users, including those measures necessary to detect, document, and counter such threats. This program shall address

physical and electronic media.

a. Identifying physically marking and then protecting sensitive program information are the lynchpins of an effective information security program. BARDA contracts are unclassified but information within the program can be designated as proprietary, company confidential, Critical Infrastructure Program information, sensitive but unclassified, and other handling designations. By identifying sensitive information and using appropriate markings warns and informs the recipient of the degree of protection required. Examples of information security for the protection of physical media include:

   - Identify information that shall be considered sensitive (proposed listing at Appendix A)
   - Institute security training program on the marking, handling, dissemination, and destruction of physical and electronic media containing sensitive information.
   - Develop a destruction policy using approved methods (burning or shredding)
   - Establish destruction or turn-in policies for computer equipment.

b. The use of systems can enhance security and allows for the rapid dissemination of information. However, these systems must be secure or protected to prevent intrusion. Once again, some security measures are listed below. Develop one or more primary objectives and then use the measures below, or others you think of, to satisfy each primary objective. Examples of IT Systems security techniques include:

   - Install a computer-intrusion-detection system;
   - Monitor Internet activity in your organization;
   - Periodically test back-up power for communication systems;
   - Hire consultants to attempt to penetrate your system and/or assess your vulnerability to outside hackers;
   - Do not disseminate sensitive program information over the unsecured internet connection;
   - Develop policies limiting downloading capabilities from company computer systems; and
   - Identify specific sanitized laptops for use by company personnel on travel.

VII. Security Awareness Program – Describe in detail your Security Awareness Program which educates your personnel of company security policies and the need to protect the physical and, especially, information assets of your company. An effective Security Awareness Program gains the trust of its personnel and continually re-enforces practical security responsibilities throughout the service of each employee. Examples of security awareness programs include:

   - Security education training as part of new employee indoctrination;
   - Post reminders in the work place that includes Security points of contact for questions and to report violations;
   - Annual security education training, highlighting the need for continued vigilance and improvements made in the company security strategies and policies;
   - Host outside guest speakers to discuss the importance of security, threats, and personal protection;
   - Conduct after hour inspections to ensure compliance with company policies;
   - Provide incentives for recognized excellence in security awareness.

VIII. Transportation Security - Describe in detail your Transportation Security Program which protects materials while in transit from theft, destruction, manipulation, or damage.

a. A vehicle or shipment in transit represents not just a moving target, but a critical space in constant exposure to an uncontrolled environment harboring a diversity of threats. When defining primary objectives, it is important to remember that the cargo is the prime source of consequential damage. Security measures that do not, in some way, link directly to the covered materials, but just the vehicle, may be of limited value. Examples of transportation security considerations include:

   - Plan for primary (phone/cell phone), secondary (radio), and tertiary (satellite tracking) means of communications;
   - Install by-pass and shutdown mechanisms;
   - Install panic-button option in vehicles;
   - Install theft-protection devices to disable fuel, hydraulics, and/or electrical systems;

- Seal trailers/containers;
- Driver shall always have a communication device readily available
- Institute a two-person rule
- Inspect cargo manifest and match with cargo;
- See that all tractor/trailer access panels/doors are locked and seals remain intact/undamaged;
- Implement a search plan for tractors and trailers on the site;
- Routinely check truck transits to ensure routing plan is on file prior to departure
- Coordinate routes with law enforcement authorities
- Devise an Incident Management Plan
- Arrange with consignee to notify shipper and carrier if the cargo does not reach its destination, and
- Purchase all other necessary technology devices to be installed.

b. Tracking Systems - satellite systems and other technologies are excellent examples of graduated security capabilities. The frequency of location and status checks can be varied with alert levels and tailored to specific materials, reflecting the threat environment and potential consequences.

c. Cargo Status and Seals - Cargo seals, tamper-proof locks, and other technology may be utilized. Some cargo seals are designed to show signs of physical tampering, while others are electronic and can provide wireless notification if breached by an unauthorized individual. However, a basic locking system may be all that is necessary to deter theft. Of course, seals are not appropriate in all circumstances. For example, it would be counterproductive to use seals for bulk shipments which require multiple pickups or drops (unloading). Check paperwork to ensure it is complete and accurate.

ATTACHMENT #9
SMALL BUSINESS SUBCONTRACTING PLAN

A Subcontracting Plan is required if the estimated cost of the contract may exceed $750,000 ($1,500,000 for construction) Small businesses are excluded. The following outline meets the minimum requirements of section 8(d) of the Small Business Act, as amended, and implemented by the Federal Acquisition Regulations (FAR) Subpart 19.7. The U.S. Department of Health and Human Services (HHS), Office of Small and disadvantaged Business Utilization (OSDBU) recommends that offerors use the following format to submit proposed Individual Subcontracting Plans. It is not intended to replace any existing Corporate/Commercial Plan that is more extensive.

Questions should be forwarded to the Contracting Officer and/or Small Business Subcontracting Program Manager.

Please see the link below:

https://oamp.od.nih.gov/sites/default/files/DAPEDocs/hhs_subk_plan_template.docx