

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT		1. CONTRACT ID CODE		PAGE OF PAGES	
				1 73	
2. AMENDMENT/MODIFICATION NO.		3. EFFECTIVE DATE		4. REQUISITION/PURCHASE REQ. NO.	
0001		07/14/2025		5. PROJECT NO. (If applicable)	
6. ISSUED BY		CODE		7. ADMINISTERED BY (If other than Item 6)	
ASPR-BARDA		ASPR-BARDA		CODE	
ASPR-BARDA					
200 Independence Ave., S.W.					
Room 640-G					
Washington DC 20201					
8. NAME AND ADDRESS OF CONTRACTOR (No., street, county, State and ZIP Code)		(x)		9A. AMENDMENT OF SOLICITATION NO.	
				75A50125R00007	
		x		9B. DATED (SEE ITEM 11)	
				07/13/2025	
				10A. MODIFICATION OF CONTRACT/ORDER NO.	
				10B. DATED (SEE ITEM 13)	
CODE		FACILITY CODE			

11. THIS ITEM ONLY APPLIES TO AMENDMENTS OF SOLICITATIONS

☒ The above numbered solicitation is amended as set forth in Item 14. The hour and date specified for receipt of Offers ☒ is extended. ☐ is not extended.

Offers must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation or as amended, by one of the following methods: (a) By completing Items 8 and 15, and returning 1 copies of the amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or electronic communication which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGEMENT TO BE RECEIVED AT THE PLACE DESIGNATED FOR THE RECEIPT OF OFFERS PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If by virtue of this amendment you desire to change an offer already submitted, such change may be made by letter or electronic communication, provided each letter or electronic communication makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

12. ACCOUNTING AND APPROPRIATION DATA (If required)

13. THIS ITEM ONLY APPLIES TO MODIFICATION OF CONTRACTS/ORDERS. IT MODIFIES THE CONTRACT/ORDER NO. AS DESCRIBED IN ITEM 14.

CHECK ONE	A. THIS CHANGE ORDER IS ISSUED PURSUANT TO: (Specify authority) THE CHANGES SET FORTH IN ITEM 14 ARE MADE IN THE CONTRACT ORDER NO. IN ITEM 10A.
	B. THE ABOVE NUMBERED CONTRACT/ORDER IS MODIFIED TO REFLECT THE ADMINISTRATIVE CHANGES (such as changes in paying office, appropriation data, etc.) SET FORTH IN ITEM 14, PURSUANT TO THE AUTHORITY OF FAR 43.103(b).
	C. THIS SUPPLEMENTAL AGREEMENT IS ENTERED INTO PURSUANT TO AUTHORITY OF:
	D. OTHER (Specify type of modification and authority)

E. IMPORTANT: Contractor ☐ is not ☐ is required to sign this document and return _____ copies to the issuing office.

14. DESCRIPTION OF AMENDMENT/MODIFICATION (Organized by UCF section headings, including solicitation/contract subject matter where feasible.)

The purpose of this amendment is to extend the proposal and to clarify the proposal question due date.

The cutoff date for all questions on this RFP is on July 31, 2025 at 2 p.m. ET. The due date for all proposal submissions is August 27, 2025 at 2 p.m.

Except as provided herein, all terms and conditions of the document referenced in Item 9 A or 10A, as heretofore changed, remains unchanged and in full force and effect.

15A. NAME AND TITLE OF SIGNER (Type or print)		16A. NAME AND TITLE OF CONTRACTING OFFICER (Type or print)	
		YIFAN YANG	
15B. CONTRACTOR/OFFEROR	15C. DATE SIGNED	16B. UNITED STATES OF AMERICA	16C. DATE SIGNED
_____		_____	
(Signature of person authorized to sign)		(Signature of Contracting Officer)	

Biomedical Advanced Research and Development Authority (BARDA)
Request for Proposals (RFP) for

“Enzymatic Debridement Products for Treatments of Deep and Full-
Thickness Severe Burn Injuries”

RFP #: 75A50125R00007

Amendment 0001



Issued: 07/14/2025

Questions Due: 7/31/2025

Proposal Responses Due: 08/27/2025

Contracting Officer: Jon Gonzalez Jonathan.Gonzalez@hhs.gov
Contract Specialist: Yifan Yang – Yifan.yang@hhs.gov

[MedicalCountermeasures.gov](https://www.mediccountermeasures.gov)

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) Alternate 1, the Health and Human Services Acquisition Regulation (HHSAR)

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

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.

The cutoff date for all questions on this RFP is on July 31, 2025 at 2 p.m. ET. All questions shall be submitted via e-mail to Jonathan.Gonzalez@hhs.gov and Yifan.Yang@hhs.gov. The due date for all proposal submissions is August 27, 2025 at 2 p.m. All proposals must be submitted via email to Jonathan.Gonzalez @hhs.gov and Yifan.Yang@hhs.gov. The submission email must include business and technical proposal documents as separate documents.

PART I – THE SCHEDULE

SECTION B – SUPPLIES OR SERVICE AND PRICE / COST

B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

Treatment and care for burn injuries is both resource and labor intensive. The national capacity is typically limited and presents a significant limitation to when a sudden surge capacity is required in a burn mass casualty incident (BMCI). A BMCI in a geographic area could overwhelm a regional existing capacity and present to substantial resource constraints. To mitigate this challenge, BARDA has collaboratively worked with the burn care community to identify areas of improvement in the delivery of this care. This collaboration has identified numerous area which BARDA has systematically addressed over the years. The two major areas where enhanced treatment options could provide a meaningful difference are in the initial care and triage of patients, and secondly, in the long-term treatment and recovery steps of burn care. The focus of this RFP is to address the long-term treatment and recovery steps of burn care.

Surgical debridement is the current standard of care for removing dead skin tissue (eschar) from severe burn injuries, the required first step in definitive care. This involves shaving the burn area with bladed instruments and/or use of high-pressure water jets, both of which remove healthy tissue as well as the targeted necrotic tissue. These current debridement methods are labor-intensive, require highly specialized surgical training and resources, and invokes additional risk to the patient due to unavoidable removal of healthy skin. Furthermore, surgical debridement is usually delayed for the first few days after injury to allow for observation and visual assessment of its healing trajectory. This presents additional risks to the patient and potentially prolongs hospital stays. Enzymatic debridement products more selectively remove necrotic burned skin and can be applied in non-surgical settings (e.g. patient bedside) to free up operating room resources, a critical capability for mass casualty response. This enables earlier patient care, can reduce resource burden, and potential improves patient outcomes. Such products should be compatible with current procedures to allow easy integration into routine care for ready availability and medical end user familiarity during BCMI's. This Statement of Objective (SOO) focuses on products which enzymatically debride severe burns to reduce the need for surgical resources for definitive burn care.

Based on this background, the objective of this RFP is to support procurement of an FDA-approved enzymatic debridement product and potentially support development of a next generation product for increased preparedness value. This product must be capable of removing necrotic skin from both partial and full thickness thermal burn wounds in pediatric and adult burn patients. The procurement strategy would involve creating a deployable cache of product (Preparedness Inventory) managed by the vendor and in coordination with their commercial (Planned) inventory. This establishes a vendor-managed inventory (VMI) as a **collaborative access-maintenance system** of product to maintain ready for emergency deployment (also see Section C- Objectives). To prevent product expiry and waste, the vendor will sell older units from the Preparedness Inventory through their commercial sales mechanism and rotate in newer product. BARDA will pay for this maintenance and the right to access/deploy this cache in the event of a national emergency. Funding will also provide BARDA the option to access an additional, pre-negotiated amount of the vendor's commercial (Planned) inventory to also deploy for larger emergencies and/or to increase the size of the Preparedness Inventory for increased preparedness. This system allows for national preparedness and response flexibility while limiting waste of unused product by not creating an inventory too large to be rotated into commercial sales when not needed for response. In addition, is critical the USG invest in next generation debridement products that are more cost effective, sustainable, and capable to addressing national health threat needs. Towards those goals, PBS funding would additionally support the development of a more effective, room temperature stable formulation and explore the potential for its use on blast trauma wounds for additional preparedness capability and return on investment.

B.1.1. Definitions

Collaborative Access-Maintenance Vendor Managed Inventory (CAM-VMI) - The Contractor and USG agree to build and manage two separate product inventories. One termed 'Preparedness Inventory' would maintain a negotiated number of product units procured by the USG directly from the manufacturer. The Preparedness inventory shall serve as a product cache to be used for national security purposes on demand and deployed by the vendor as directed by USG. A second Planned (commercial) inventory shall be maintained by the contractor as part of the routine commercial sales operations. The Contractor shall be responsible for the management and appropriate maintenance of the products in both inventories at a common location and management system. As mutual benefit, the inventory management shall enable reciprocal flow of product units between both inventories by the contractor to support the sales operation. Such reciprocal flow tasks would allow product rotation or allow access for additional units required to meet market demand but replenished within 2 months or as allowed by USG. The USG agrees to pay a fee for the contractor to manage the Preparedness inventory of commercially useable product covering rotation tasks; and the entire product inventory shall be available for emergency deployment when directed by USG.

The Contractor and USG agree to pre-negotiated terms (including price per unit). for priority access to the Planned commercial inventory should the Preparedness inventory not be sufficient to meet the national emergency need. The USG would trigger the option to purchase up to the available Planned (commercial) inventory and/or future supplies and direct them for emergency deployment.

The Contractor and USG agree to periodically revise and expand the size of the Preparedness and Planned (commercial) inventory requiring coordination of procurement for additional units from manufacturer, development of next generation of products etc. The Contractor shall also develop, periodically exercise, and maintain an active plan for deployment of the products from both the inventories to all the burn care centers on demand via their commercial processes and infrastructure (including subcontractors) or in collaboration with the Strategic National Stockpile (SNS).

Commercial Product - As defined in FAR 2.101.

Food and Drug Administration (FDA) Approval - The Food and Drug Administration (FDA) has determined that a product is safe and effective for its intended use. The Contractor shall provide FDA product validation as part of the technical proposal.

Government Furnished Property (GFP) - All property owned or leased by the Government. Government property includes both Government-furnished property and contractor-acquired property. Government property includes material, equipment, special tooling, special test equipment, and real property. Government property does not include intellectual property and software. The Government shall not own any property under this contract.

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 that the final contract will consist of a base period of performance of up to ten (10) years with 6 options.

The Base Period and Options consists of Firm Fixed Price and Cost Plus Fixed Fee CLINs to support procurement, maintenance, and emergency deployment of enzymatic debridement products as well as additional product development.

B.2.1. BASE PERIOD and OPTIONS

Anticipated Period of Performance	Structure	CLIN	Supplies/Services	Quantity	Unit Price (\$)	Total (\$)
09/30/2025-09/29/2026	FFP	CLIN 001 BASE	<u>Initial Procurement of Product to Establish PREPAREDNESS CACHE under VMI</u> Purchase commercially available units	2750.00		
09/30/2025-09/29/2035	FFP	CLIN 002 BASE	<u>VMI Maintenance</u> Prevent expiry, rotate through commercial sales, monthly reporting	120 mons.		
09/30/2025-09/29/2035	FFP	CLIN 003a BASE	<u>Emergency Deployment</u> Emergency deployment of Preparedness Cache under VMI to burn centers as directed.	1.00		
09/30/2025-09/29/2035	FFP	CLIN 003b BASE	<u>Emergency Exercises</u> 3 mock deployment exercises by vendor	3.00		
09/30/2026-09/29/2027	FFP	CLIN 004a OPTION 1	<u>Ramp Up Procurement</u> Purchase additional units (up to 5000 units) of available product as required from the commercial / PLANNED INVENTORY.	up to 5000.00		
09/30/2026-09/29/2035	FFP	CLIN 004b OPTION1	<u>Ramp Up VMI Maintenance</u> Additional maintenance support (assumes execution in Year 2 for the remaining POP)	108 mon.		
09/30/2026-09/29/2035	FFP	CLIN 005 OPTION 2	<u>Ramp Up Procurement Emergency Deployment</u> Emergency deployment to burn centers as directed	1.00		
09/30/2026-09/29/2027	CPFF	CLIN 006 OPTION 3	<u>Formulation and Development: Room temperature stability of product and changes in mfr process; testing; excipients</u>	1.00		
09/30/2026-09/29/2028	CPFF	CLIN 007 OPTION 4	<u>Clinical Development: Clinical studies to demonstrate superiority of the new formulation (or non-inferiority)</u>	1.00		
09/30/2027-09/29/2030	CPFF	CLIN 008 OPTION 5	<u>Manufacturing Development (including validation): Integration of changes & testing in mfr. Process; Potential for validation of new US-based facility; Additional mfr. capacity.</u>	1.00		

09/30/2027-09/29/2035	CPFF	CLIN 009 OPTION 6	<u>Regulatory Tasks for FDA Approval: Regulatory activities for new sBLA filing for FDA approval</u>	1.00		
09/30/2029-09/29/2035	FFP	CLIN 010 OPTION 7	<u>Procurement of New Formulated Product: Expanding procurement of new formulated product; preparedness inventory.</u>	Up to 5000.00		
09/30/2027-09/29/2030	CPFF	CLIN 011 OPTION 8	<u>Expanded Indications for Use in Trauma: Studies (clinical/non-clinical) for expanding indications for use in blast trauma (concomitant or standalone traumatic injuries along with burns)</u>	1.00		
Total Cost						

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 before incurrence of the cost will be included in this Section if the Contracting Officer has granted his/her approval prior to contract award.

The Contractor and U.S. Government (USG) agree the USG shall pay a fee for the contractor to hold, and maintain in reserve, a negotiated level of commercially useable product for its intended purpose in delivery of care; and the entire product inventory shall be available for purchase by USG. The Contractor and USG also agree to a pre-negotiated price for procurement on demand of the products in the inventory, to mutual terms for periodically expanding the size of the inventory, and for the contractor to deploy the procured product via their commercial processes and infrastructure or in collaboration with the Strategic National Stockpile (SNS)

Collaborative access and maintenance of two inventories: Contractor and U.S. Government (USG) Governs establishment of a collaborative model with two inventories- 'Preparedness Inventory' and 'Planned (commercial) Inventory' and their management by the vendor.

Priority Access: The Contractor and USG agree to pre-negotiated terms (including price per unit) for priority access to the Planned commercial inventory

Procurement for surge response capacity & emergency deployment: The Contractor and USG agree to periodically revise and expand the size of the Preparedness and Planned (commercial) inventory requiring coordination of procurement for additional units from manufacturer, development of next generation of products etc. The Contractor shall also develop, periodically exercise, and maintain an active plan for deployment of the products from both the inventories to all the burn care centers on demand via their commercial processes and infrastructure (including subcontractors) or in collaboration with the Strategic National Stockpile (SNS).

a. Person-in-Plant

With seven (7) days advance notice to the Contractor in writing from the Contracting Officer, the Government may place a man-in-plant in the Contractor's or Subcontractor's facility, who

shall be subject to the Contractor's or Subcontractor's policies and procedures regarding security and facility access at all times while in the Contractor's or Subcontractor's facility. The Government's representative shall be provided reasonable access, during normal business hours, of the production areas being utilized in performance on the Contract. As determined by federal law, no Government representative shall publish, divulge, disclose, or make known in any manner, or to any extent not authorized by law, any information coming to him in the course of employment or official duties, while stationed in a contractor or subcontractor plant.

An article substantially similar to this Person-in-Plant article shall be incorporated into any subcontract for experimental or manufacturing work.

b. Security

A security plan will be required as part of the contract. Please include an initial security plan with your proposal.

c. Subcontracts

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

- Is of the cost-reimbursement type; or
- Is of the fixed price type and exceeds \$250,000 or 5% of the contract, whichever is less.

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

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

d. Overtime Compensation

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

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

In an effort to build a robust medical countermeasure pipeline through increased collaboration, the Government may share technical deliverables with Government entities responsible for Medical Countermeasure Development. In accordance with recommendations from the Public Health Emergency Medical Countermeasure Enterprise Review, agreements established in the Integrated Portfolio Advisory Committee (PAC) Charter, and agreements between BARDA and the Department of Defense, the National Institutes of Health, the Centers for Disease Control, and the Food and Drug Administration, BARDA may share technical deliverables and test results created in the performance of this Contract with colleagues within the Integrated Portfolio.

This advance understanding does not authorize the Government to share financial information outside of the United States Government. The Contractor is advised to review the terms of FAR 52.227-14, Rights in Data – General, regarding the government's rights to deliverables submitted during performance as well as the government's rights to data contained within those

deliverables.

f. Rights in Data

The contract will incorporate the FAR Clause 52.227-14, Rights in Data—General. The Contractor is advised to review the terms of FAR 52.227-14, Rights in Data--General, regarding the government's rights to deliverables submitted during performance as well as the government's rights to data contained within those deliverables.

g. Invoice Submission during end of Fiscal Year

The government will not accept invoices for processing from Sep 6th through Oct 5th because of end of year fiscal requirements. Any invoices received from September 6th through October 5th will be canceled and returned to the Contractor for resubmission beginning on October 6th.

B.4 ORGANIZATIONAL CONFLICT OF INTEREST

- 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.

B.5. PROVISIONS TO APPLICABLE COSTS

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

- a) Acquisition, by purchase or lease, of any interest in real property.
- b) Rearrangement or alteration of facilities.
- c) Purchase or 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 including 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

While BARDA can support all activities in support of FDA regulatory filings, we cannot pay the fees requires for those filings. In other words, funds should no ever go from one USG agency (BARDA) to another (FDA).

SECTION C – DESCRIPTION / SPECIFICATIONS / WORK STATEMENT

C.1. STATEMENT OF OBJECTIVES

BACKGROUND and PURPOSE

Treatment and care for burn injuries is labor intensive and influenced by the unique properties of each case with complicating factors including patient age, pre-existing health conditions, burn wound size, depth, and location. The challenges of providing definitive burn care are heightened when delivering treatment after a mass casualty event in a resource strained environment. The anticipated high number of injured in a mass casualty incident especially in a geographical area would pose significant limitations on the ability to provide conventional standards of care for victims. To mitigate some of these challenges BARDA has collaboratively worked with the burn care community to identify areas to improve the delivery of care and treatment procedures. Two major areas where enhanced medical countermeasures (MCM) can provide a meaningful difference are in the triage of initial care and in a definitive burn care setting.

A large burn mass casualty incident could quickly overwhelm the US healthcare infrastructure. Severe burn injuries (especially, >10% TBSA) typically require highly specialized care for effective delivery of resource-intensive therapies including surgeries. Nationally, this capability is critically limited at multiple levels and would challenge timely access and treatment of those injured even in a relatively small incident. This makes it imperative to leverage technology that reduces the time and surgical burden to remove (debride) necrotic skin from partial and full thickness burns as the critical, first treatment step in definitive care. Reducing the time to eschar removal in a more selective way than the current standard of care by surgery has the potential to greatly improve the patient's quality of life while reducing hospital length of stay and the need for reconstructive surgery.

OBJECTIVE

For building national burn care preparedness under the conditions described above, BARDA intends to procure FDA approved products that enzymatically remove necrotic tissue (eschar) from partial and full thickness burns in both children and adults. Such enzymatic debridement products can significantly reduce the surgical time and resource burden required to treat severe burns to reduce patient morbidity and mortality.

To build national preparedness and address the unmet needs identified in burn care, products shall meet all these capabilities (**as also cited in Section M.3 Mandatory Criteria**):

1. Enzymatic debridement product is approved for use in the US by the FDA for removal of necrotic skin from both partial and full thickness thermal burns in both adults and pediatrics.
2. Product has the potential to function in non-surgical suites settings (e.g., patient bedside) to achieve complete debridement as per approved indication to enable the next step in burn care.
3. Offeror has the infrastructure to support management of product rotation across multiple caches via a vendor-managed inventory (VMI) and commercial sales to prevent expiry and waste. The Offeror also has the capability for product distribution to end users (such as burn centers) and in an emergency response distribution.
4. Provide an explicit statement of acknowledgement understanding the definition and concur to negotiate entering into the agreement as defined under the Collaborative Access-Maintenance Vendor Managed Inventory (CAM-VMI) in Section B.1.1 Definitions. The final negotiated agreement would be part of the Advanced Understanding statements of the potential contract.

As an FDA approved product, it is expected that the product will be used in all intended settings such as within US burn centers. Information on the integration of the products into these routine healthcare settings would be important towards the indicated goal to build national preparedness and availability for use by trained physicians.

Under this RFP, BARDA plans to establish a collaborative access-maintenance vendor-managed inventory (VMI) system. In this system, the Offeror is required to maintain a pre-specified, Preparedness Inventory of product units which are accessible on demand for emergency deployment. The Preparedness Inventory is maintained in conjunction with routine Planned Inventory established by the vendor as part of the normal (commercial) operations.

In the event of a need (such as a mass casualty) upon notification by the U.S. Government (USG), the Preparedness Inventory shall be deployed as directed within pre-specified time using the established distribution system by the vendor. Additional MCMs from the Planned inventory shall be available to USG for deployment under pre-negotiated terms.

SCOPE

This RFP focuses on procurement of an FDA-approved enzymatic debridement product for a collaborative access-maintenance VMI described above. Critical attributes of the product shall include the capability to selectively remove necrotic burned skin in non-surgical settings to reduce the time and need for surgical debridement. Additionally, advanced development such as room temperature formulation/dose-sparing / additional indications of the FDA approved product is also within the scope of work. The following areas of work are considered within the overall scope of this RFP:

- a) VMI management and product deployment (distribution).
- b) Operational regulatory and (QSR) quality management infrastructure.
- c) Reporting on the market penetration and integration in health care.
- d) Advanced development and FDA approval of next generation product

To meet the scope outlined above, Offeror shall address the objectives outlined in the following six sections following the guidelines provided in Section L (INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS). Proposals will be evaluated per criteria under Section M.4 on the Offeror's ability to meet objectives described below:

- [Base] Initial Procurement and VMI Establishment (CLIN 1)
- [Base] Vendor Managed Inventory (VMI) Maintenance (CLIN 2)
- [Base] Emergency Deployment/Exercises (CLIN 3a, CLIN 3b)
- [Option 1] Ramp Up Procurement/VMI Maintenance (CLIN 4a, CLIN 4b)
- [Option 2] Ramp Up Procurement Emergency Deployment (CLIN 5)
- [Option 3] Formulation and Development (CLIN 6)
- [Option 4] Clinical Development (CLIN 7)
- [Option 5] Manufacturing Development (CLIN 8)
- [Option 6] Regulatory Tasks (CLIN 9)
- [Option 7] Procurement of New Formulation (CLIN 10)
- [Option 8] Expanded Indications for Use in Trauma (CLIN 11)
- [Base & Options] Project Management & Quality Assurance Objectives (All CLINs)

1) Initial Procurement and VMI Establishment (CLIN 1)

Upon procurement by the BARDA, the vendor shall create a Preparedness Inventory. The intended goal is for the products to be ready for immediate deployment in an emergency to burn centers per USG request and direction. If a mass casualty or other emergency occurs per the determination of the USG, the vendor shall be notified of USG's instruction to deploy part or all

the Preparedness Inventory. The size of this product cache would be subject to negotiations but would be a minimum of 2750 units. As part of normal operations, products in the Preparedness Inventory will be rotated out into the vendor's Planned Inventory established for commercial sales and replaced with newer product received from manufacturer. This will establish a Collaborative Access-Maintenance Vendor-Managed Inventory (VMI). The routine commercial Planned Inventory shall be large enough to support rotation of Preparedness Inventory to prevent product expiry and at any time have a shelf-life of transfer for commercial use. The Offeror shall include commercial sales data to demonstrate the capability. as part of the VMI process.

2) Vendor Managed Inventory (VMI) Maintenance (CLIN 2)

As part of the VMI program, the Offeror shall establish and maintain the Preparedness Inventory cache primarily ready for emergency deployment purposes. The Preparedness Inventory is maintained in conjunction with routine Planned Inventory established by the vendor as part of the normal (commercial) operations. The size shall support the stock rotation from the preparedness cache to routine sales using the principle of "First Expiry, First Out". While the number of units in the inventory would be subject to finalization as part of the negotiation the Offeror shall address capability to maintain a minimum of 2750 units. Ideally, with increased sales and growth in the market share over time, USG anticipates the Offeror would be able to support rotation and increase the size of the cache by an additional 5000 product units (to a total of 7750 units maintained under VMI). The vendor shall be responsible for all the supply chain operations (communications with the product manufacturer for delivery of the product for the Planned Inventory and the initial Preparedness Inventory. The Preparedness Inventory shall be procured at-cost.

Information on the availability of resources for inventory maintenance / management activities, systems for monitoring will be required to demonstrate the capability. The Offeror shall include data demonstrating tracking and shuffling inventory, and the ability to ensure a minimum shelf-life for all products in the VMI. Systems for regular reporting (such as monthly or as deemed appropriate) have to be demonstrated. The Offeror shall specify how the process is organized and managed with Standard Operating Procedures (SOPs) and Quality systems. The Offeror shall provide all necessary documentation for quality assurance and acceptance of the product by the USG.

3) Emergency Deployment and Exercise (CLIN 3a, and CLIN 3b)

- i) **CLIN 3a:** At any point during the duration of the contract, the USG may notify the Offeror of to deploy product units under the Preparedness Inventory. The offeror will be required to prepare a specified number of units for emergency deployment within 24 hours of notification. The Offeror shall package and ship product units via standard shipping methods as set up for the commercial products but directly to burn centers as identified by the USG. An option for an alternative shipment method as directed by ASPR/SNS shall be part of the deployment plan.
- ii) **CLIN 3b:** At least three times during the duration of the contract, USG and Offeror shall synchronize a mock-deployment exercises to ensure the procedures and personnel are trained to react to an emergency deployment. Any deficiencies identified shall be documented and rectified.

4) Ramp Up Procurement (CLIN 4a and CLIN 4b)

- i) **CLIN 4a:** Towards the original goals for national preparedness, USG may consider the need to increase in the size of the Preparedness Inventory cache for a more robust direct response to a larger burn emergency. An anticipated increase in the size of the cache for

access and maintenance and available for procurement could be up to 5000 units (or as negotiated) to be delivered within an agreed upon timeframe. If the commercial plans are not sustainable for the larger cache, the Offeror shall provide the shortest ramp up plan to deliver the additional devices and timeframe required.

- ii) **CLIN4b:** Akin to the VMI maintenance (CLIN 2) the ramp up to an increased size of this increased Preparedness Inventory and the resultant additional costs (if any) shall be described by the Offeror. The offeror shall provide all necessary documentation for quality assurance and acceptance of the product by the USG. The Offeror shall specify how the process is organized for the maintenance and management (rotation) of the larger inventory with SOPs and Quality systems. The Offeror shall provide all necessary documentation for quality assurance and acceptance of the product by the USG.

5) Ramp Up Emergency Deployment (CLIN 5)

Akin to CLIN 3a, procurement of additional units in CLIN 4 may result in additional costs for deployment of the larger number of units in an emergency within 24 hours of notification. The offeror shall package and ship device units via standard commercial shipping methods directly to burn centers as identified by the USG. An option for an alternative shipment method as directed by ASPR/SNS shall be part of the deployment plan.

6) Formulation and Development (CLIN 6)

Funding will support development of a next generation enzymatic debridement product formulation with increased preparedness value. This potentially includes room temperature stability for more cost-effective shipping and storage as well as increased effectiveness for dose-sparing. Studies will enable successful application of the new formulation as an Investigational New Drug (IND) with the FDA to enable entry into clinical studies. These efforts could include stability and non-clinical comparability testing as well as necessary changes to the manufacturing process. Offeror shall provide strong proof-of-concept data on a candidate product to justify funding towards final formulation and IND acceptance. This data shall demonstrate superior qualities vs the currently licensed, commercial product. The Offeror shall include all study plans remaining to execute towards that goal as supported by formal FDA feedback.

7) Clinical Development (CLIN 7)

Funding will support clinical development of a next generation enzymatic debridement product formulation with increased preparedness value. This involves completion of a pivotal human study to demonstrate the equivalence (non-inferiority) or superiority of the next generation product compared to the current product on the commercial market. Data from this completed study will enable application for FDA approval to towards market entry and integration in U.S. routine burn care. Offeror shall provide a clinical design and strategy for achieving FDA approval.

8) Manufacturing Development (including validation) (CLIN 8)

Successful clinical development and anticipated FDA approval will require changes in manufacturing process to enable product production at commercial scale and to support future procurements. This would include process validation with priority in a US-based facility for increased national security/availability. Offeror shall provide a list of required manufacturing

studies and processes to achieve a domestic based manufacturing line and describe its target commercial and surge production capacity.

9) Regulatory Tasks for FDA Approval (CLIN 9)

Funding will support execution of the Offeror's described regulatory path towards FDA approval of the new formulation (next generation) enzymatic debridement product. Offeror shall provide formal FDA feedback to support this described regulatory pathway as well as a budget for anticipated data requests from the FDA during the product review period (RFIs, additional data analyses, data audits, etc.).

10) Procurement of New Formulated Product (CLIN 10)

Successful development, approval, and integration of a more effective/room temperature stable product would increase the product's preparedness value in the intended Collaborative Access-Maintenance Vendor-Managed Inventory (VMI). The USG would support procurement of up to 5000 product units for placement into the Offeror's VMI infrastructure. As with CLINs 1,2, and 4a above, the vendor shall be responsible for all the supply chain operations (communications with the product manufacturer for delivery of the product for the Planned Inventory and the initial Preparedness Inventory. The Preparedness Inventory shall be procured at-cost.

Information on the availability of resources for inventory maintenance / management activities, systems for monitoring will be required to demonstrate the capability. The Offeror shall include data demonstrating tracking and shuffling inventory, and the ability to ensure a minimum shelf-life for all products in the VMI. Systems for regular reporting (such as monthly or as deemed appropriate) have to be demonstrated. The Offeror shall specify how the process is organized and managed with Standard Operating Procedures (SOPs) and Quality systems. The Offeror shall provide all necessary documentation for quality assurance and acceptance of the product by the USG.

11) Expanded Indications for Use in Trauma (CLIN 11)

Medical treatment from blast injuries can require debridement of skin wounds from other insults besides and in combination with thermal burns (e.g shrapnel). Treatment still requires effective, selective, non-surgical removal of only necrotic tissue to enable continued care. To this end, this CLIN intends to support the exploration of a next generation debridement product for improved treatment of blast skin injuries from non-burn insults. The development of one product that addresses the medical need for enzymatic skin debridement regardless of blast injury type would maximize the preparedness value to the USG for future procurements. The support this goal, the Offeror shall propose proof-of-concept studies (non-clinical and/or clinic) to test the product's effectiveness for debriding blast-derived necrotic skin. This product shall be the same formulation developed/procured under CLINs 6-10 to this demonstrate its multi-use, multi-threat preparedness capability. Proposed study designs should be supported by FDA feedback that would support a long-term plan towards FDA approval for these expanded indications for blast trauma treatment.

12) Project Management Objectives (Applicable to all CLINs)

The Offeror is directed towards details provided in the section on Reporting Requirements. All work under this contract shall have a Project Management and Risk Mitigation section covering objectives in this CLIN.

- i) The Offeror shall provide a monthly inventory spreadsheet detailing the product available (under collaborative access-maintenance) to deploy within 24 hours notification from the Government.
- i) Monthly maintenance costs must be tracked and invoiced at the negotiated frequency accordingly.
- ii) The Offeror shall participate in regular meetings at the negotiated frequency to coordinate and oversee the contracting effort.
- iii) The Offeror shall provide a list of individuals to serve as primary and secondary points of contact who will be available 24 hours a day, seven days a week, for the purpose of a public health emergency notification.
- iv) The Offeror shall provide a security plan that includes physical and information technology (IT) security associated with all aspects of process, storage, and inventory of the assets when under the Offeror's direct control.

The offeror shall track and provide all key personnel, report changes which affect work under all active CLINs especially, collaborative access-maintenance under VMI, activities to be performed by all proposed subcontractors. Offeror shall monitor key personnel role and impending or proposed changes and roles within the project.

C.2. REPORTING REQUIREMENTS

See Section F for specific reporting requirements.

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

C.3. MEETINGS / SITE VISITS

The Contractor and BARDA/CMA 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 and/or teleconferences, site visits to the Contractor's and/or subcontractor's facilities, and meetings with individual Contractors and other HHS officials to discuss the technical, regulatory, and contractual aspects of the program. The Contractor shall provide data, reports, and presentations to USG personnel and USG-contracted subject matter experts as required by the CO/COR facilitating review of activities.

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

Periodic site visits shall occur on an ad hoc basis.

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

Other U.S. Government Audits

The USG reserves the right to conduct an audit of the Contractor with 48 hours advance notice. The USG reserves the right to accompany the Contractor on routine and for-cause site-visits/audits of

subcontractor(s). At the discretion of the USG and independent of testing conducted by the Contractor, BARDA reserves the right to conduct site visits/audits and collect samples of product held by the Contractor and subcontractor(s).

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

SECTION D – PACKAGING, MARKING AND SHIPPING

D.1. PACKAGING OF PRODUCT

Packaging shall be consistent with the FDA-approved labeling and packaging for this product at the time of manufacture.

D.2 MARKING

Marking of product and shipping packages shall be in accordance with FDA-approved labeling direction to be provided at the time of manufacture.

D.3 METHOD OF DELIVERY

Unless otherwise specified by the Contracting Officer, all deliverable items to be furnished to the Government under this contract (including invoices) shall be made as described in SECTION F.3.

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

SECTION E – INSPECTION AND ACCEPTANCE

E.1. INSPECTION AND ACCEPTANCE

Inspection and acceptance of the product, services, and documentation called for herein shall be accomplished by the Contracting Officer or the Contracting Officer's Representative. Acceptance of a commercial product will be consistent with customary commercial practice under FAR 12.301(a):

Center for the Biomedical Advanced Research and Development Authority
Administration for Strategic Preparedness & Response
400 7th Street SW
Washington, D.C. 20024

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

E.2. FEDERAL ACQUISITION REGULATION CLAUSES INCORPORATED BY REFERENCE

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

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

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

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

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

E.3. INSPECTION, ACCEPTANCE AND CONTRACT MONITORING

Inspection and acceptance of the product, services, and documentation called for herein shall be accomplished by the Contracting Officer or designated COR consistent with customary commercial practice under FAR 12.301(a)..

At the discretion of the Government and independent of activities conducted by the Contractor, with 48-hours' notice to the Contractor, the Government reserves the right to conduct site visits and inspections related to this Contract on an as needed basis during normal business hours, including collection of product samples and intermediates held at the location of the Contractor, or its subcontractor. The Contractor shall coordinate these visits and shall have the opportunity to accompany the Government on any such visits. Under time-sensitive or critical situations, the Government reserves the right to suspend the 48-hour notice to the Contractor. The areas included under the site visit could include, but are not limited to: security, regulatory and quality systems, manufacturing processes and cGMP/GLP/GCP compliance related to activities funded under this Contract.

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

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

E.4 – NONCONFORMING SUPPLIES OR SERVICES

FAR 46.407 Nonconforming Supplies or Services

(a)The contracting officer should reject supplies or services not conforming in all respects to contract requirements (see 46.102). In those instances where deviation from this policy is found to be in the Government's interest, such supplies or services may be accepted only as authorized in this section.

(b)The contracting officer ordinarily must give the contractor an opportunity to correct or replace nonconforming supplies or services when this can be accomplished within the required delivery schedule. Unless the contract specifies otherwise (as may be the case in some cost-reimbursement contracts), correction or replacement must be without additional cost to the Government. Paragraph (e)(2) of the clause at 52.246-2, Inspection of Supplies-Fixed-Price, reserves to the Government the right to charge the contractor the cost of Government reinspection and retests because of prior rejection.

(c)(1) In situations not covered by paragraph (b) of this section, the contracting officer ordinarily must reject supplies or services when the nonconformance is critical or major or the supplies or services are otherwise incomplete. However, there may be circumstances (e.g., reasons of economy or urgency) when the contracting officer determines acceptance or conditional acceptance of supplies or services is in the best interest of the Government. The contracting officer must make this determination based upon-

(i)Advice of the technical activity that the item is safe to use and will perform its intended purpose;

(ii)Information regarding the nature and extent of the nonconformance or otherwise incomplete supplies or services;

(iii)A request from the contractor for acceptance of the nonconforming or otherwise incomplete supplies or services (if feasible);

(iv)A recommendation for acceptance, conditional acceptance, or rejection, with supporting rationale; and

(v)The contract adjustment considered appropriate, including any adjustment offered by the contractor.

(2) The cognizant contract administration office, or other Government activity directly involved, must furnish this data to the contracting officer in writing, except that in urgent cases it may be furnished orally and later confirmed in writing. Before making a decision to accept, the contracting officer must obtain the concurrence of the activity responsible for the technical requirements of the contract and, where health factors are involved, of the responsible health official of the agency concerned.

(d)If the nonconformance is minor, the cognizant contract administration office may make the determination to accept or reject, except where this authority is withheld by the contracting office of the contracting activity. To assist in making this determination, the contract administration office may establish a joint contractor-contract administrative office review group. Acceptance of supplies and services with critical or major nonconformances is outside the scope of the review group.

(e)The contracting officer must discourage the repeated tender of nonconforming supplies or services, including those with only minor nonconformances, by appropriate action, such as rejection and documenting the contractor's performance record.

(f)When supplies or services are accepted with critical or major nonconformances as authorized in paragraph (c) of this section, the contracting officer must modify the contract to provide for an equitable price reduction or other consideration. In the case of conditional acceptance, amounts withheld from payments generally should be at least sufficient to cover the estimated cost and related profit to correct deficiencies and complete unfinished work. The contracting officer must document in the contract file the basis for the amounts withheld. For services, the contracting officer can consider identifying the value of the individual work requirements or tasks (subdivisions) that may be subject to price or fee reduction. This value may be used to determine an equitable adjustment for nonconforming services. However, when supplies or services involving minor nonconformances are accepted, the contract need not be modified unless it appears that the savings to the contractor in fabricating the nonconforming supplies or performing the nonconforming services will exceed the cost to the Government of processing the modification.

(g)Notices of rejection must include the reasons for rejection and be furnished promptly to the contractor. Promptness in giving this notice is essential because, if timely nature of rejection is not furnished, acceptance may in certain cases be implied as a matter of law. The notice must be in writing if-

(1) The supplies or services have been rejected at a place other than the contractor's plant;

(2) The contractor persists in offering nonconforming supplies or services for acceptance; or

(3) Delivery or performance was late without excusable cause.

(h)The contracting officer shall provide disposition instructions for counterfeit or suspect counterfeit items in accordance with agency policy. Agency policy may require the contracting officer to direct the contractor to retain such items for investigative or evidentiary purposes.

SECTION F – DELIVERIES OR PERFORMANCE

F.1. PERIOD OF PERFORMANCE

The base period of performance of this contract is anticipated for one hundred twenty (120) months from the date of award.

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, if required, 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 Contracting Officer (CO), Yifan Yang Yifan.yang@hhs.gov and the Contracting Officer Representative (COR), Julio.Barrera-Oro@hhs.gov. No hard copies will be accepted.

F.3.2. Reporting Requirements

In addition to those reports required by other terms of this RFP, the Contractor 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 Inventory Report

This report shall include a table of the available products within the Collaborative Access-Maintenance VMI during each reporting period. The first reporting period consists of the first full month of performance plus any fractional part of the initial month. Thereafter, the reporting period shall consist of each calendar month.

The Contractor shall submit a Monthly Inventory Report on or before the 15th calendar day following the last day of each reporting period and shall include the following:

Title Page: The title page for this report shall include the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission.

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

The inventory report shall contain the following information:

- a. Device/Unit SKU
- b. Device/unit description/identifier (e.g., device/unit name, component name, etc.)
- c. Quantity
- d. Addition date and Expiration date

Contracting Officer's 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 Inventory Report will not be required in the same month Annual Inventory Report is due.

B. Annual Inventory Report

This report shall include a summation of the product inventory rotations during the reporting period. The first reporting period consists of the first full year of performance plus any fractional part of the initial year. Thereafter, the reporting period shall consist of each calendar year.

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

Title Page: The title page for this report shall include the contract number and title; the type of report and period that it covers; the Contractor's name, address, telephone number, fax number, and e-mail address; and the date of submission.

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

The inventory report shall contain the following information:

- a. Device/Unit SKU
- b. Device/unit description/identifier (e.g., device/unit name, component name, etc.)
- c. Quantity
- d. Expiration date

Contracting Officer's 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.

C. 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 (5) 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/or specific analysis of data generated with USG funds upon request from the COR.

- g) The Offeror shall notify the Contracting Officer's Representative and Contracting Officer within 24 hours of all FDA arrivals to conduct site visits/audits by any regulatory agency. The 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 Contracting Officer's Representative and Contracting Officer copies of the plan for addressing areas of non-conformance to FDA regulations for GLP guidelines as identified in the audit report, status updates during the plans execution, and a copy of all final responses to the FDA. The Offeror shall also provide redacted copies of any FDA audits received from sub-Offerors that occur as a result of this contract or for this product. The redactions shall be limited to issues that are unrelated to the sub-offeror'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.

D. Other Requirements/Deliverables

a) Risk Mitigation Plan/Matrix

The Contractor shall develop and maintain a risk management plan that highlights potential problems and/or issues that may arise during the life of the contract, their impact on cost, schedule and performance, and appropriate remediation plans. This plan shall reference relevant WBS/SOW elements where appropriate. The USG has provided a Risk Mitigation Matrix template (See attachment 9 below) This report shall be due within 90 days of contract award. Updates shall be due as requested by the COR.

b) Press Releases

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

c) Security Report

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

d) Security Plan

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

e) Quality Management System Plan

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

f) Manufacturing Plan

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

F.4. DELIVERABLE SCHEDULE

Item No.	Description	Email	Deliverable Schedule
1	Kickoff Meeting	CO: (1) electronic copy COR: (1) electronic copy	Within 30 days after contract award. Contractor shall provide agenda to CO/COR at least 5 business days in advance of meeting, and minutes within 5 business days after the meeting.

2	Monthly 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 Inventory & Progress Report	CO: (1) electronic copy COR: (1) electronic copy	Reports are due on or before the 15 th of each month following the end of each reporting period.
4	Annual Inventory & Progress Report	CO: (1) electronic copy COR: (1) electronic copy	Reports are due on or before the 30 th calendar day following the end of each reporting period.
5	Publications	CO: (1) electronic copy COR: (1) electronic copy	Reports are due within 30 calendar days for manuscripts and 15 calendar days for abstracts.
6	Press Releases	CO: (1) electronic copy COR: (1) electronic copy	Reports/Notices are due for approval to the CO not less than five (5) business days prior to the issuance of any potential press release.
7	Security Report	CO: (1) electronic copy COR: (1) electronic copy	Reports are due within 24 hours after occurrence of an activity or incident.
8	Security Plan	CO: (1) electronic copy COR: (1) electronic copy	Final plan due within 30 days of contract award.
9	Manufacturing Plan	CO: (1) electronic copy COR: (1) electronic copy	Due within 60 days of contract award.
10	Quality Management System Plan	CO: (1) electronic copy COR: (1) electronic copy	Due within 30 days of contract award
11	SOP Receipt and Inspection to VMI SOP-BARDA-RQA-7565.00	CO: (1) electronic copy COR: (1) electronic copy	As needed per the contract - Quality Disposition Letter, RQA Product Receipt and Inspection Form, Risk Assessment and Risk Register, VMI Report, etc.
12	Risk Mitigation Plan/Matrix	CO: (1) electronic copy COR: (1) electronic copy	Report is due within 90 days of contract award. Updates are due as requested by the COR.
13	FDA/ Regulatory Agency Correspondence and Meeting Summaries	CO: (1) electronic copy COR: (1) electronic copy	Reports are due within 5 business days of each meeting for Contractor's minutes, upon receipt of minutes from FDA/ regulatory agency, and upon request from the COR or Co-COR.
14	Experimental Protocols	CO: (1) electronic copy COR: (1) electronic copy	Upon request from the COR or Co-COR.
15	Study Reports	CO: (1) electronic copy COR: (1) electronic copy	Study reports (clinical, non-clinical, manufacturing) are due within 30 days of completion of study data analyses

F.5. FEDERAL ACQUISITION REGULATION CLAUSES INCORPORATED BY REFERENCE, FAR 52.252-2 (FEBRUARY 1998)

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

FAR 52.242-15, Stop-Work Order (Apr 1989), Alternate 1 (April 1984)

SECTION G – CONTRACT ADMINISTRATION

AUTHORITIES OF GOVERNMENT PERSONNEL

Notwithstanding the Contractor's responsibility for total management during the period of performance, the administration of this contract will require maximum coordination between the Government and the Contractor.

The following individuals will be the Government's points of contact during the performance of this contract:

Contracting Officer

Name: Jon Gonzalez

Email: Jonathan.Gonzalez@hhs.gov

All communications pertaining to contractual and/or administrative matters under this contract shall be sent to:

Contracting Specialist

Name: Yifan Yang

Email: yifan.yang@hhs.gov

Contracting Officer's Representative

Name: Julio Barrera-Oro

Email: yifan.yang@hhs.gov

Note: The Contracting Officer is the only individual authorized to modify the contract.

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 Contracting Officer can make any changes to the terms, conditions, general provisions or other stipulations of this contract. Any other commitment, either explicit or implied, is invalid.

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

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

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

The Government's Contracting Officer's Representative (COR) is:

Julio Barrera-Oro

As delegated by the CO, the COR is responsible for: (1) monitoring the Contractor's technical progress, including the surveillance and assessment of performance and recommending to the Contracting Officer changes in requirements; (2) assisting the 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. CONTRACTOR'S POINTS OF CONTACT

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

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 Contractor voluntarily diverting any of the specified individuals to other programs or contracts the Contractor shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the Contractor is terminated for cause or separates from the Contractor voluntarily with less than thirty (30) days' notice, the Contractor shall provide the maximum notice practicable under the circumstances. The Contractor shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. The contract will be modified to add or delete key personnel as necessary to reflect the agreement of the parties.

The following individual(s) is/are considered to be essential to the work being performed hereunder:

Name	Title
TBD	Principle Investigator (PI)
TBD	Quality Assurance (QA) / Quality Control (QC)
TBD	Manufacturing / Vendor Management and Logistics Lead
TBD	Project Manager

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.

(End of Clause)

G.5.1 INVOICE ELEMENTS

- a. The Offeror agrees to include (as a minimum) the following information on each invoice:
 - i. Offeror's Name & Address

- ii. Offeror's Tax Identification Number (TIN)
- iii. Contract Number
- iv. Invoice Number
- v. Invoice Date
- vi. Contract Line Item Number (CLIN)
- vii. Requisition number associated with each CLIN
- viii. Quantity
- ix. Unit Price & Extended Amount for each line item
- x. Total Amount of Invoice
- xi. Name, title and telephone number of person to be notified in the event of a defective invoice
- xii. Payment Address

b. The invoice shall be signed by a person authorized to bind the Offeror.

c. The Offeror shall not submit an invoice prior to delivery of goods or services.

d. 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 submissions 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 FAR 52.212-4 Contract Terms and Conditions – Commercial Products and Commercial Services 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.ero.ctwai.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 log in 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 Strategic Preparedness & 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 Unique Entity Identifier (UEI) 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. CONTRACT COMMUNICATIONS/CORRESPONDENCE

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

G.7. POST AWARD EVALUATION OF OFFEROR PERFORMANCE

- (a) *Purpose:* In accordance with FAR Subpart 42.15, the Contractor's performance will be periodically evaluated by the government in order to provide current information for current and future source selection purposes. These evaluations will therefore be marked "Source Selection Information."
- (b) *Performance Evaluation Period:* The Contractor's performance will be evaluated at least annually.
- (c) *Evaluators:* The performance evaluation will be completed jointly by the Contracting Officer's Representative and the Contracting Officer.
- (d) *Performance Evaluation Factors:* The Contractor's performance will be evaluated in accordance with FAR Subpart 42.15 and Attachment #5, Contract Performance Evaluation Report.
- (e) *Contractor Review:* A copy of the evaluation will be provided to the Contractor as soon as practicable after completion of the evaluation. The Contractor shall submit comments, rebutting statements, or additional information to the Contracting Officer within 30 calendar days after receipt of the evaluation.
- (f) *Resolving Disagreements between the Government and the Contractor:* Disagreements between the parties regarding the evaluation will be reviewed at a level above the Contracting Officer. The ultimate conclusion on the performance evaluation is a decision of the contracting agency. Copies of the evaluation, Contractor's response, and review comments, if any, will be retained as part of the evaluation.

- (g) *Release of Offeror Performance Evaluation Information:* The completed evaluation will not be released to other than Government personnel and the Contractor whose performance is being evaluated. Disclosure of such information could cause harm both to the commercial interest of the Government and to the competitive position of the Contractor being evaluated, as well as impede the efficiency of Government operations.
- (h) *Source Selection Information:* Departments and agencies may share past performance information with other Government departments and agencies when requested to support future award decisions. The information may be provided through interview and/or by sending the evaluation and comment document to the requesting source selection official.
- (i) *Retention Period:* The agency will retain past performance information for a maximum period of 3 years after completion of contract performance for the purpose of providing source selection information for future contract awards.
- (j) *Electronic Access to Contractor Performance Evaluations:* Contractors may access evaluations through a secure website for review and comment at the following: <http://cpars.gov>

SECTION H – SPECIAL CONTRACT REQUIREMENTS

H.1 CLINICAL AND NON-CLINICAL TERMS OF AWARD

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

Approval by the COR is required before work under a protocol may begin. The COR comments will be forwarded to the Contractor within ten (10) business days. The Contractor must address, in writing, all concerns (e.g. study design, safety, regulatory, ethical, and conflict of interest) noted by the COR.

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

Execution of clinical and non-clinical studies requires written authorization from the Government. The Government will provide written authorization to the Contractor upon either 1) receiving documentation in which all COR comments have been satisfactorily addressed; or 2) receiving documentation that the FDA has reviewed and commented on the protocol.

The Government shall have unlimited rights to all protocols, data resulting from execution of these protocols, and final reports funded by BARDA under this contract, as set forth in the FAR clauses referenced in PART II of this contract. The Government reserves the right to request that the Contractor provide any contract deliverable in a non-proprietary form to ensure the Government has the ability to review and distribute the deliverables as the Government deems necessary. Important information regarding performing human subject research is available at <https://www.niaid.nih.gov/research/clinical-research>.

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

H.2. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4(b) (December 2015) (Not applicable at this time)

H.3. HUMAN MATERIALS (ASSURANCE OF OHRP COMPLIANCE) (Not applicable at this time)

H.4. RESEARCH INVOLVING HUMAN FETAL TISSUE (Not applicable at this time)

H.5. REPORTING MATTERS INVOLVING FRAUD, WASTE AND ABUSE

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

Office of Inspector General

Department of Health and Human Services TIPS HOTLINE

P.O. Box 23489 Washington, D.C. 20026

H.6. PROHIBITION ON CONTRACTOR INVOLVEMENT WITH TERRORIST ACTIVITIES

The Contractor acknowledges that U.S. Executive Orders and Laws, including but not limited to 13224 and P.L. 107-56, prohibit transactions with, and the provision of resources and support to, individuals and organizations associated with terrorism. It is the legal responsibility of the Contractor to ensure compliance

with these Executive Orders and Laws. This clause must be included in all subcontracts issued under this contract.

H.7. IDENTIFICATION AND DISPOSITION OF DATA

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

H.8. EXPORT CONTROL NOTIFICATION

Contractors are responsible for ensuring compliance with all export control laws and regulations that may be applicable to the export of and foreign access to their proposed technologies. Contractors may consult with the Department of State with any questions regarding the International Traffic in Arms Regulation (ITAR) (22 CFR Parts 120-130) and /or the Department of Commerce regarding the Export Administration Regulations (15 CFR Parts 730-774).

H.9. CONFLICT OF INTEREST

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

H.10. NEEDLE DISTRIBUTION

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

H.11. RESTRICTION ON ABORTIONS

The Contractor shall not use contract funds for any abortion.

H.12. CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH

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

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

H.13. DISSEMINATION OF FALSE OR DELIBERATELY MISLEADING INFORMATION

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

H.14. ACCESS TO DOCUMENTATION/DATA

The Government shall have physical and electronic access to all documentation and data generated under this contract, including: all data documenting Contractor performance; all data generated; all communications and correspondence with regulatory agencies and bodies to include all audit observations, inspection reports, milestone completion documents, and all Offeror commitments and responses. Contractor shall provide the Government with an electronic copy of all correspondence and submissions to the FDA within 5 business days of receipt. The Government shall acquire unlimited rights to all data funded or furnished without proprietary restrictions under this contract in accordance with FAR Subpart 27.4 and FAR Clause 52.227-14.

H.15. RESERVED

H.16. ACKNOWLEDGMENT OF FEDERAL FUNDING

Contractors funded with Federal dollars, in whole or in part, shall acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. This requirement is in addition to the continuing requirement to provide an acknowledgment of support and disclaimer on any publication reporting the results of a contract funded activity. The Offeror shall acknowledge the support of the Department of Health and Human Services, Administration for Strategic Preparedness and Response, Center for the Biomedical Advanced Research and Development Authority whenever publicizing the work under this contract in any media by including an acknowledgment substantially as follows: "This project has been funded in whole or in part with Federal funds from the Administration for Strategic Preparedness and Response, Center for the Biomedical Advanced Research and Development Authority, under Contract No. XXXX".

Publication and Publicity (Not Including Press Releases)

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

In addition to the requirements set forth in HHSAR Clause 352.227-70, Publications and Publicity incorporated by reference in Section I of this contract, Contractors are required to state:

- (1) The percentage and dollar amount of the total program or project costs financed with Federal money and;
- (2) The percentage and dollar amount of the total costs financed by non-governmental sources. For purposes of this contract "publication" is defined as an issue of printed material offered for distribution or any communication or oral presentation of information, including any manuscript or scientific meeting abstract. Any publication containing data generated under this contract must be submitted for BARDA review no less than thirty (30) calendar days for manuscripts and fifteen (15) calendar days for abstracts before submission for public presentation or publication. Contract support shall be acknowledged in all such publications substantially as follows: "This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Center for the Biomedical Advanced Research and Development Authority, under Contract No. (to be inserted upon award)."

Press Releases

Misrepresenting contract results or releasing information that is injurious to the integrity of BARDA may be construed as improper conduct. Press releases shall be considered to include the public release of information to any medium, excluding peer-reviewed scientific publications. With the exception of ad-hoc press releases required by applicable law or regulations, the Contractor shall ensure that the COR has received an advance copy of any press release related to the contract not less than five (5) business days prior to the issuance of the press release.

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

"This project has been funded in whole or in part with Federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response; Center for the Biomedical Advanced Research and Development Authority, under Contract No. (to be inserted upon award)"

H.17. PROHIBITION ON THE USE OF APPROPRIATED FUNDS FOR LOBBYING ACTIVITIES AND HHSAR 352.203-70 ANTI-LOBBYING (December 2015)

Pursuant to the HHS annual appropriations acts, except for normal and recognized executive- legislative relationships, the Contractor shall not use any HHS contract funds for:

- (a) Publicity or propaganda purposes;
- (b) The preparation, distribution, or use of any kit, pamphlet, booklet, publication, electronic communication, radio, television, or video presentation designed to support or defeat the enactment of legislation before the Congress or any State or local legislature or legislative body, except in presentation to the Congress or any state or local legislature itself; or designed to support or defeat any proposed or pending regulation, administrative action, or order issued by the executive branch of any state or local government, except in presentation to the executive branch of any state or local government itself; or
- (c) Payment of salary or expenses of the Contractor, or any agent acting for the Contractor, related to any activity designed to influence the enactment of legislation, appropriations, regulation, administrative action, or Executive order proposed or pending before the Congress or any state government, state legislature or local legislature or legislative body, other than for normal and recognized executive-legislative relationships or participation by an agency or officer of a state, local, or tribal government in policymaking and administrative processes within the executive branch of that government.
- (d) The prohibitions in subsections (a), (b), and (c) above shall include any activity to advocate or promote any proposed, pending, or future federal, state, or local tax increase, or any proposed, pending, or future requirement for, or restriction on, any legal consumer product, including its sale or marketing, including, but not limited to, the advocacy or promotion of gun control.

H.18. LABORATORY LICENSE REQUIREMENTS

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

H.19. 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.20. 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.21. RESTRICTION ON EMPLOYMENT OF UNAUTHORIZED ALIEN WORKERS

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

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

H.22. 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.23. DISSEMINATION OF INFORMATION (May 2004)

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

H.24. MANUFACTURING STANDARDS

The Good Manufacturing Practice Regulations (GMP)(21 CFR Parts 820) will be the standard to be applied for manufacturing, processing, packaging, storage and delivery of this product.

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

H.25. 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.26. HUMAN SUBJECTS

The Contractor shall submit all human clinical protocols and informed consent documents to BARDA for review and comment prior to submission to another entity.

Research involving human subjects shall not be conducted under this contract until the study protocol has been approved by the Department of Health and Human Services, written notice of such approval has been

provided by the CO, and the Contractor has provided to the CO a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the protocol. The human subject certification can be met by submission of the Contractor's self-designated form, provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

When research involving Human Subjects will take place at collaborating sites or other performance sites, the Contractor shall obtain, and keep on file, a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310) certifying IRB review and approval of the research.

For any resultant award involving human subjects engaged in biomedical, behavioral, clinical, or other research, in which identifiable, sensitive information is collected or used, the Contractor shall protect the privacy of individuals who are subjects of such research in accordance with subsection 301(d) of the Public Health Service (PHS) Act (42 U.S.C. 241).

H.27. 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/for-professionals/faq/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.28. CONTINUED BAN ON FUNDING ABORTION AND CONTINUED BAN ON FUNDING OF HUMAN EMBRYO RESEARCH, HHSAR 352.270-13 (December 2015)

- a. The Contractor shall not use any funds obligated under this contract for any abortion.
- b. The Contractor shall not use any funds obligated under this contract for the following:
 - i. The creation of a human embryo or embryos for research purposes; or
 - ii. 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 part 46 and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).
- c. The term "human embryo or embryos" includes any organism, not protected as a human subject under 45 CFR part 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes of human diploid cells.
- d. The Contractor shall not use any Federal funds for the cloning of human beings.

H.29. 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; Administration for Strategic 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: <https://pmc.ncbi.nlm.nih.gov/>

H.30. INSTITUTIONAL RESPONSIBILITY REGARDING CONFLICTING INTERESTS OF INVESTIGATORS

The Contractor shall comply with the requirements of 45 CFR Part 94, Responsible Prospective

Contractors, which promotes objectivity in research by establishing standards to ensure that investigators (defined as the principal investigator and any other person who is responsible for the design, conduct, or reporting of research funded under BARDA contracts) will not be biased by any conflicting financial interest. 45 CFR Part 94 is available at the following Web site:

<https://www.ecfr.gov/current/title-45/subtitle-A/subchapter-A/part-94> As required by 45 CFR Part 94, the Contractor shall, at a minimum:

a. Maintain a written, enforceable policy on conflict of interest that complies with 45 CFR Part 94 and inform each investigator of the policy, the investigator's reporting responsibilities, and the applicable regulations. The Contractor must take reasonable steps to ensure that investigators working as collaborators or subcontractors comply with the regulations.

b. Designate an official(s) to solicit and review financial disclosure statements from each investigator participating in BARDA-funded research. Based on established guidelines consistent with the regulations, the designated official(s) must determine whether a conflict of interest exists, and if so, determine what actions should be taken to manage, reduce, or eliminate such conflict. A conflict of interest exists when the designated official(s) reasonably determines that a Significant Financial Interest could directly and significantly affect the design, conduct, or reporting of the BARDA-funded research. The Contractor may require the management of other conflicting financial interests in addition to those described in this paragraph, as it deems appropriate. Examples of conditions or restrictions that might be imposed to manage actual or potential conflicts of interests are included in 45 CFR Part 94, under Management of Conflicting Interests.

c. Require all financial disclosures to be updated during the period of the award, either on an annual basis or as new reportable Significant Financial Interests are obtained.

d. Maintain records, identifiable to each award, of all financial disclosures and all actions taken by the Contractor with respect to each conflicting interest 3 years after final payment or, where applicable, for the other time periods specified in 48 CFR Part 4, subpart 4.7, Contract Records Retention.

e. Establish adequate enforcement mechanisms and provide for sanctions where appropriate.

If a conflict of interest is identified, the Contractor shall report to the Contracting Officer, the existence of the conflicting interest found. This report shall be made and the conflicting interest managed, reduced, or eliminated, at least on a temporary basis, within sixty (60) days of that identification.

If the failure of an investigator to comply with the conflict of interest policy has biased the design, conduct, or reporting of the BARDA-funded research, the Contractor must promptly notify the Contracting Officer of the corrective action taken or to be taken. The Contracting Officer will take appropriate action or refer the matter to the Contractor for further action, which may include directions to the Contractor on how to maintain appropriate objectivity in the funded research.

The Contracting Officer may at any time inquire into the Contractor's procedures and actions regarding conflicts of interests in BARDA-funded research, including a review of all records pertinent to compliance with 45 CFR Part 94. The Contracting Officer may require submission of the records or review them on site. On the basis of this review, the Contracting Officer may decide that a particular 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 Contractor has not managed, reduced, or eliminated the conflict of interest. The issuance of a Stop Work Order by the Contracting Officer may be necessary until the matter is resolved.

If the Contracting Officer determines that BARDA-funded clinical research, whose purpose is to evaluate the safety or effectiveness of a drug, medical device, or treatment, has been designed, conducted, or reported by an investigator with a conflict of interest that was not disclosed or managed, the Contractor must require disclosure of the conflict of interest in each public presentation of the results of the research.

H.31. FOREIGN TRANSFER OF ASSETS OR TECHNOLOGY

This clause shall remain in effect during the term of the Contract and for five (5) years thereafter.

a. Definitions

AFFILIATES: Associated business concerns, non-profit organizations, or individuals if, directly or indirectly, (1) either one controls or can control the other; or (2) a third party controls or can control both.

ASSET(S): Tangible or intangible manifestations of technologies having economic value and capable of being conveyed between economic or Governmental entities that is the focus/scope of development by the U.S. Government ("USG") and Contactor in this Contract.

ASSET(S): Tangible or intangible manifestations of technologies having economic value and capable of being conveyed between economic or Governmental entities that is the focus/scope of development by the U.S. Government (the "USG") and Contactor in this Contract.

FOREIGN FIRM OR INSTITUTION: A firm or institution organized or existing under the laws of a country other than the United States of America (U.S.), its territories, or possessions. The term includes, for purposes of this Contract, any agency or instrumentality of a foreign government; and firms, institutions or business organizations which are owned or substantially controlled by foreign governments, firms, institutions, or individuals.

TECHNOLOGY: Technical Data, Computer Software, manufactured materials and Subject Inventions funded by the USG under this Contract. Technology also includes contractor know how and personnel expertise, as well as other Assets necessary to assure successful completion of this Contract.

U.S. FIRM OR INSTITUTION: A firm or institution organized or existing under the laws of the United States, its territories, or possessions. The term includes, for purposes of this Contract, any agency or instrumentality of the USG; and firms, institutions or business organizations which are owned or substantially controlled by U.S. citizens, firms, institutions, governmental agencies or individuals.

b. General

The Parties agree that research findings and technological developments made under this Contract constitute an investment by the USG on behalf of its citizens in the interest of their economic and national health security. These investments are made for the primary benefit of the citizenry of the U.S. with those same benefits potentially accruing to the people of all nations. Therefore, the USG has a fiduciary responsibility to protect the full invested value of the Assets and Technology developed under this Contract. The USG is also cognizant of the duty the Contractor has to its shareholders and other stakeholders with a vested interest in the economic success of the Contractor. At times both parties are aware their respective interests may diverge. Therefore, in the course of conducting business through the Contract, access to technology developments under this Contract by Foreign Firms or Institutions must be carefully considered.

c. Export Controls

Contractor agrees to comply with all applicable laws regarding export controls and not to export any Asset or Technology to any U.S. embargoed countries.

d. Post-award Transfer of Ownership of Assets or Technology

The Contractor shall provide notice to the Contracting Officer and COR within three (3) business days of any discussions of a proposed transfer of ownership or establishment of a licensing agreement of any Asset or Technology funded under this Contract from the Contractor to a Foreign Firm or Institution. Notice will also be given within three (3) business days of any discussions of a proposed transfer of operational, corporate, or economic control of Assets and Technology funded under this Contract to Foreign Firms or Institutions. This Article shall not apply to transfers by the Contractor to Affiliated entities of the Contractor, as well as technology transfers for the purposes of manufacturing in accordance with the Statement of Work.

Prior to transferring any Asset funded by the USG under this Contract, the Contractor should carefully review the USG rights under FAR Subpart 42.12 pertaining to Novation, specifically FAR section 42.1204. That provision provides that the USG may recognize a third party assignment only if the transfer of Assets and Technology is determined to be in the USG's interests. The Contractor should be aware that the USG

is under no obligation to recognize a successor in interest. If the Contracting Officer determines that a transfer of Assets and Technology may have adverse consequences to the economic well-being or national health security interests of the U.S., the Contractor, and the Contracting Officer shall jointly endeavor to find alternatives to the proposed transfer which obviate or mitigate potential adverse consequences of the transfer but which may provide substantially equivalent benefits to the Contractor.

In addition to the USG licensing rights to subject inventions and technical data funded under this Contract, see FAR clause 52.227-11 (Patent Rights-Ownership by the Contractor) and FAR Clause 52.227-14 (Rights in Data - General), the USG shall have a first right of refusal for the purchase of the Asset and/or Technology funded under the Contract. The USG may waive this first right of refusal in writing submitted to the Contractor within ninety (90) calendar days of the initial notification to the USG of the Contractor's intent to conduct any form of Asset or corporate transfer.

Except for transfers to affiliates of the Contractor, including those entities necessary to complete the Statement of Work, the Contractor shall provide written notice to the Contracting Officer and COR of the scheduled transfer to a Foreign Firm or Institution at least ninety (90) calendar days prior to the scheduled date of transfer. Such notice shall cite this Article and shall specifically identify the Asset or Technology proposed for the transfer and the general terms of the transfer. No transfer shall take place without written concurrence from the Contracting Officer.

e. Transfer to a Prohibited Source

In the event of a transfer of an Asset and/or Technology by the Contractor to a Foreign Firm or Institution which is identified as a Prohibited Source pursuant to Federal Acquisition Regulation Subpart 25.7: (a) the Government may terminate this contract for cause and (b) the license rights to the technical data and subject invention under the relevant FAR IP Clauses (FAR Clause 52.227-11 and FAR Clause 52-227-14) shall survive the termination. Upon request of the USG, the Contractor shall provide written confirmation of such licenses.

f. Lower Tier Agreements

The Contractor shall include this Article, suitably modified, to identify the Parties, in all subcontracts or lower tier agreements, regardless of tier.

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/browse/index/far>

Reg	Clause	Date	Clause Title
FAR	52.202-1	Jun 2020	Definitions
FAR	52.203-3	Apr 1984	Gratuities
FAR	52.203-5	May 2014	Covenant Against Contingent Fees
FAR	52.203-6	Jun 2020	Restrictions on Subcontractor Sales to the Government
FAR	52.203-7	Jun 2020	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	Jun 2020	Limitation on Payments to Influence Certain Federal Transactions
FAR	52.203-13	Nov 2021	Contractor Code of Business Ethics and Conduct
FAR	52.203-14	Nov 2021	Display of Hotline Poster(s)
FAR	52.203-17	Nov 2023	Contractor Employee Whistleblower Rights
FAR	52.203-19	Jan 2017	Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements
FAR	52.204-10	Jun 2020	Reporting Executive Compensation and First-Tier Subcontract Awards
FAR	52.204-13	Oct 2018	System for Award Management Maintenance
FAR	52.204-14	Oct 2016	Service Contract Reporting Requirements
FAR	52.204-21	Nov 2021	Basic Safeguarding of Covered Contractor Information Systems
FAR	52.204-23	Dec 2023	Prohibition on Contracting for Hardware, Software, and Services Developed or Provided by Kaspersky Lab Covered Entities
FAR	52.204-25	Nov 2021	Prohibition on Contracting for Certain Telecommunications and Video Surveillance Services or Equipment
FAR	52.204-27	Jun 2023	Prohibition on a ByteDance Covered Application
FAR	52.204-30	Dec 2023	Federal Acquisition Supply Chain Security Act Orders- Prohibition (Dec 2023)
FAR	52.209-6	Jan 2025	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, Proposed for Debarment, or Voluntarily Excluded
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	Nov 2021	Market Research
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	52.215-11	Jun 2020	Price Reduction for Defective Certified Cost or Pricing Data—Modifications.
FAR	52.215-12	Jun 2020	Subcontractor Certified Cost or Pricing Data
FAR	52.215-13	Jun 2020	Subcontractor Certified Cost or Pricing Data—Modifications
FAR	52.215-14	Nov 2021	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	52.215-20	Nov 2021	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data
FAR	52.215-21	Nov 2021	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data -Modifications

FAR	52.215-22	Oct 2009	Limitations on Pass-Through Charges-Identification of Subcontract Effort
FAR	52.215-23	Jun 2020	Limitations on Pass-Through Charges
FAR	52.216-7	Aug 2018	Allowable Cost and Payment
FAR	52.216-8	Jun 2011	Fixed Fee
FAR	52.219-8	Jan 2025	Utilization of Small Business Concerns
FAR	52.219-9	Jan 2025	Small Business Subcontracting Plan
FAR	52.219-16	Sep 2021	Liquidated Damages - Subcontracting Plan
FAR	52.219-28	Jan 2025	Post-Award Small Business Program Rerepresentation
FAR	52.222-2	July 1990	Payment for Overtime Premiums
FAR	52.222-3	Jun 2003	Convict Labor
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	52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act
FAR	52.222-50	Nov 2021	Combating Trafficking in Persons
FAR	52.222-54	Jan 2025	Employment Eligibility Verification
FAR	52.224-1	Aor 1984	Privacy Act Notification
FAR	52.224-2	Apr 1984	Privacy Act
FAR	52.225-1	Oct 2022	Buy American Act - Supplies
FAR	52.225-13	Feb 2021	Restrictions on Certain Foreign Purchases
FAR	52.226-7	May 2024	Drug-Free Workplace
FAR	52.226-8	May 2024	Encouraging Contractor Policy to Ban Text Messaging While Driving
FAR	52.227-1	Jun 2020	Authorization and Consent, Alternate 1 (APR 1984)
FAR	52.227-2	Jun 2020	Notice and Assistance Regarding Patent and Copyright Infringement
FAR	52.227-3	Apr 1984	Patent Indemnity
FAR	52.227-11	May 2014	Patent Rights – Ownership by the Contractor
FAR	52.227-14	May 2014	Rights in Data – General
FAR	52.227-16	Jun 1987	Additional Data Requirements
FAR	52.228-7	Mar 1996	Insurance – Liability to Third Persons
FAR	52.229-3	Feb 2013	Federal, State and Local Taxes
FAR	52.230-2	Jun 2020	Cost Accounting Standards
FAR	52.230-6	Jun 2010	Administration of Cost Accounting Standards
FAR	52.230-7	Apr 2005	Proposal Disclosure-Cost Accounting Practice Changes
FAR	52.232-9	Apr 1984	Limitation on Withholding of Payments
FAR	52.232-17	May 2014	Interest
FAR	52.232-18	Apr 1984	Availability of Funds
FAR	52.232-20	Apr 1984	Limitation of Cost
FAR	52.232-23	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	Mar 2023	Providing Accelerated Payments to Small Business Subcontractors
FAR	52.233-1	May 2014	Disputes
FAR	52.233-3	Aug 1996	Protest After Award, Alternate I (Jun 1985)
FAR	52.233-4	Oct 2004	Applicable Law for Breach of Contract Claim
FAR	52.242-1	Apr 1984	Notice of Intent to Disallow Costs
FAR	52.242-3	Dec 2022	Penalties for Unallowable Costs
FAR	52.242-4	Jan 1997	Certification of Final Indirect Costs
FAR	52.242-5	Jan 2017	Payments to Small Business Subcontractors
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

FAR	52.243-6	Apr 1984	Change Order Accounting
FAR	52.244-2	Jun 2020	Subcontracts, Alternate 1 (Jun 2020)
FAR	52.244-5	Aug 2024	Competition in Subcontracting
FAR	52.244-6	Jan 2025	Subcontracts for Commercial Products and Commercial Services (Deviation Feb 2025)
FAR	52.246-23	Feb 1997	Limitation of Liability
FAR	52.246-25	Feb 1997	Limitation of Liability—Services
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	52.249-14	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>

HHSAR	352.203-70	Dec 2015	Anti-Lobbying
HHSAR	352.208-70	Dec 2015	Printing and Duplication
HHSAR	352.211-2	Dec 2015	Conference Sponsorship Requests and Conference Materials Disclaimer
HHSAR	352.211-3	Dec 2015	Paperwork Reduction Act
HHSAR	352.215-70	Dec 2015	Late Proposals and Revisions
HHSAR	352.216-70	Dec 2015	Additional Cost Principles for Hospitals (Profit and Non-Profit)
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	352.231-70	Dec 2015	Salary Rate Limitation
HHSAR	352.232-71	Feb 2022	Electronic Submission of Payment Requests
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
HHSAR	352.204-70	Dec 2015	Prevention and Public Health Fund -Reporting Requirement
HHSAR	353.204-75	Oct 2024	Supply Chain Risk Assessment During Contract Performance

I.3. ADDITIONAL CONTRACT CLAUSES

I.3.1. Additional Federal Acquisition Regulation (FAR) (48 CFR Chapter 1) Clauses – In Full Text

FAR 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.

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

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

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

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

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

(c) The total duration of this contract shall not exceed ten years.

PART III – ATTACHMENTS

SECTION J – LIST OF ATTACHMENTS

The following Attachments are provided with this Solicitation:

1. Offeror's Points of Contact
2. Electronic Invoicing and Payment Requirements – IPP
3. Sample Invoice Form
4. Proposal Intent Response Form
5. Summary of Related Activities
6. Reserved
7. SF-LLL, Disclosure of Lobbying Activities, with Instructions:
<https://www.gsa.gov/forms-library/disclosure-lobbying-activities>
8. Small Business Subcontracting Plan
9. Risk Mitigation Plan/Matrix Template
10. Past Performance Questionnaire
11. BARDA Security Requirements
12. Security Plan Template with Instructions

SECTION K – REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

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

1. Go to the System for Award Management (SAM) and complete the Representations and Certifications. 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.

The SAM website may be accessed at: <https://www.sam.gov/SAM/> and

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. INCORPORATION BY REFERENCE OF FAR 52.203-11 CERTIFICATION AND DISCLOSURE REGARDING PAYMENTS TO INFLUENCE CERTAIN FEDERAL TRANSACTIONS (SEPT 2024)

K.2. FAR 52.204-8 ANNUAL REPRESENTATIONS AND CERTIFICATIONS (Jan 2025) (Deviation Feb 2025)

(a)

(1) The North American Industry classification System (NAICS) code for this acquisition is 541714.

(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 541519 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 with its Alternate I applies to solicitations issued by DoD, NASA, or the Coast Guard.
- (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) 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](#), Public Disclosure of Greenhouse Gas Emissions and Reduction Goals-Representation. This provision applies to solicitations that include the provision at [52.204-7](#).~~

(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.

- K.3. FAR 52.204-17 OWNERSHIP OR CONTROL OF OFFEROR (Aug 2020)**
- K.4. FAR 52.204-19 INCORPORATION BY REFERENCE OF REPRESENTATIONS AND CERTIFICATIONS (Dec 2014)**
- K.5. FAR 52.204-24 REPRESENTATION REGARDING CERTAIN TELECOMMUNICATIONS AND VIDEO SURVEILLANCE SERVICES OR EQUIPMENT (Nov 2021)**
- K.6. FAR 52.204-26 COVERED TELECOMMUNICATIONS EQUIPMENT OR SERVICES-REPRESENTATION (Oct 2020)**
- K.7. FAR 52.209-5 CERTIFICATION REGARDING RESPONSIBILITY MATTERS (Aug 2020)**

(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 Federal agency;
- (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 \$10,000 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 or 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 nonresponsive.

(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.

(End of provision)

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
- (2) 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 (FAPIS) 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 FAPIS as required through maintaining an active registration in the System for Award Management which can be accessed via <https://www.sam.gov> (see 52.204-7).

(End of provision)

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, Name and Address of Owner and Operator of the Plant or State, County, ZIP Code)	Facility if Other than Offeror or Respondent
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(End of provision)

K.10. FAR 52.219-1 SMALL BUSINESS PROGRAM REPRESENTATIONS (Feb 2024)

(a) Definitions. As used in this provision-

Economically disadvantaged women-owned small business (EDWOSB) concern means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States and who are economically disadvantaged in accordance with 13 CFR part 127, and the concern is certified by SBA or an approved third-party certifier in accordance with 13 CFR 127.300. It automatically qualifies as a women-owned small business concern eligible under the WOSB Program.

Service-disabled veteran-owned small business (SDVOSB) concern means a small business concern-

(1) (i) Not less than 51 percent of which is owned and controlled by one or more service-disabled veterans or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more service-disabled veterans; and

(ii) The management and daily business operations of which are controlled by one or more service-disabled veterans or, in the case of a service-disabled veteran with permanent and severe disability, the spouse or permanent caregiver of such veteran or;

(2) A small business concern eligible under the SDVOSB Program in accordance with 13 CFR part 128 (see subpart 19.14).

(3) Service-disabled veteran, as used in this definition, means a veteran as defined in 38 U.S.C. 101(2), with a disability that is service-connected, as defined in 38 U.S.C. 101(16), with a disability that is service-connected, as defined in 38 U.S.C. 101(16), and who is registered in the Beneficiary Identification and Records Locator Subsystem, or successor system that is maintained by the Department of Veterans Affairs' Veterans Benefits Administration, as a service-disabled veteran.

Service-disabled veteran-owned small business (SDVOSB) concern eligible under the SDVOSB Program means an SDVOSB concern that—

(1) Effective January 1, 2024, is designated in the System for Award Management (SAM) as certified by the Small Business Administration (SBA) in accordance with 13 CFR 128.300; or

(2) Has represented that it is an SDVOSB concern in SAM and submitted a complete application for certification to SBA on or before December 31, 2023.

Service-disabled veteran-owned small business (SDVOSB) Program means a program that authorizes contracting officers to limit competition, including award on a sole-source basis, to SDVOSB concerns eligible under the SDVOSB Program.

Small business concern—

(1) Means a concern, including its affiliates, that is independently owned and operated, not dominant in its field of operation, and qualified as a small business under the criteria in 13 CFR part 121 and the size standard in paragraph (b) of this provision.

(2) Affiliates, as used in this definition, 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.

Small disadvantaged business concern, consistent with 13 CFR 124.1001, means a small business concern under the size standard applicable to the acquisition, that-

(1) Is at least 51 percent unconditionally and directly owned (as defined at 13 CFR 124.105) by-

(i) One or more socially disadvantaged (as defined at 13 CFR 124.103) and economically disadvantaged (as defined at 13 CFR 124.104) individuals who are citizens of the United States, and

(ii) Each individual claiming economic disadvantage has a net worth not exceeding the threshold at 13 CFR 124.104(c)(2) after taking into account the applicable exclusions set forth at 13 CFR 124.104(c)(2); and

(2) The management and daily business operations of which are controlled (as defined at 13 CFR 124.106) by individuals who meet the criteria in paragraphs (1)(i) and (ii) of this definition.

Veteran-owned small business concern means a small business concern-

(1) Not less than 51 percent of which is owned by one or more veterans (as defined at 38 U.S.C.101(2)) or, in the case of any publicly owned business, not less than 51 percent of the stock of which is owned by one or more veterans; and

(2) The management and daily business operations of which are controlled by one or more veterans.

Women-owned small business concern means a small business concern-

(1) That is at least 51 percent owned by one or more women; or, in the case of any publicly owned business, at least 51 percent of the stock of which is owned by one or more women; and

(2) Whose management and daily business operations are controlled by one or more women.

Women-owned small business (WOSB) concern eligible under the WOSB Program (in accordance with 13 CFR part 127) means a small business concern that is at least 51 percent directly and unconditionally owned by, and the management and daily business operations of which are controlled by, one or more women who are citizens of the United States, and the concern is certified by SBA or an approved third-party certifier in accordance with 13 CFR 127.300.

(b) (1) The North American Industry Classification System (NAICS) code for this acquisition is 541714

(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 (i.e., nonmanufacturer), is 500 employees, or 150 employees for information technology value-added resellers under NAICS code 541519, 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.

(c) Representations. (1) The offeror represents as part of its offer that—

(i) it ☐ is, ☐ is not a small business concern; or

(ii) It ☐ is, ☐ is not a small business joint venture that complies with the requirements of 13 CFR 121.103(h) and 13 CFR 125.8(a) and (b). [The offeror shall enter the name and unique entity identifier of each party to the joint venture: ____.]

(2) [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents that it ☐ is, ☐ is not, a small disadvantaged business concern as defined in 13 CFR 124.1001.

(3) [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents as part of its offer that it ☐ is, ☐ is not a women-owned small business concern.

(4) Women-owned small business (WOSB) joint venture eligible under the WOSB Program. The offeror represents as part of its offer that it ☐ is, ☐ is not a joint venture that complies with the requirements of 13 CFR 127.506(a) through (c). [The offeror shall enter the name and unique entity identifier of each party to the joint venture: ____.]

(5) Economically disadvantaged women-owned small business (EDWOSB) joint venture. The offeror represents as part of its offer that it ☐ is, ☐ is not a joint venture that complies with the requirements of 13 CFR 127.506(a) through (c). [The offeror shall enter the name and unique entity identifier of each party to the joint venture: ____.]

(6) Veteran-owned small business concern. [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents as part of its offer that it ☐ is, ☐ is not a veteran-owned small business concern.

(7) SDVOSB concern. [Complete only if the offeror represented itself as a veteran-owned small business concern in paragraph (c)(6) of this provision.] The offeror represents as part of its offer that it ☐ is, ☐ is not an SDVOSB concern.

(8) SDVOSB joint venture eligible under the SDVOSB Program. [Complete only if the offeror represented itself as a SDVOSB concern in paragraph (c)(7) of this provision]. The offeror represents as part of its offer that it ☐ is, ☐ is not a SDVOSB joint venture eligible under the SDVOSB Program that complies with the requirements of 13 CFR 128.402. [The offeror shall enter the name and unique entity identifier of each party to the joint venture:____.]

(9) HUBZone small business concern. [Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.] The offeror represents, as part of its offer, that—

(i) It ☐ is, ☐ is not a HUBZone small business concern listed, on the date of this representation, as having been certified by SBA as a HUBZone small business concern in the Dynamic Small Business Search and SAM, and will attempt to maintain an employment rate of HUBZone residents of 35 percent of its employees during performance of a HUBZone contract (see 13 CFR 126.200(e)(1)); and

(ii) It ☐ is, ☐ is not a HUBZone joint venture that complies with the requirements of 13 CFR 126.616(a) through (c). [The offeror shall enter the name and unique entity identifier of each party to the joint venture: ____.] Each HUBZone small business concern participating in the HUBZone joint venture shall provide representation of its HUBZone status.

(d) Notice. Under 15 U.S.C. 645(d), any person who misrepresents a firm's status as a business concern that is small, HUBZone small, small disadvantaged, service-disabled veteran-owned small, economically disadvantaged women-owned small, or women-owned small eligible under the WOSB Program in order to obtain a contract to be awarded under the preference programs established pursuant to section 8, 9, 15,

31, and 36 of the Small Business Act or any other provision of Federal law that specifically references section 8(d) for a definition of program eligibility, shall-

- (1) Be punished by imposition of fine, imprisonment, or both;
- (2) Be subject to administrative remedies, including suspension and debarment; and
- (3) Be ineligible for participation in programs conducted under the authority of the Act.

(End of provision)

SECTION L – INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

L.1. CONTRACT TYPE

This RFP is being solicited as a Full and Open Competition firm fixed-price and cost plus fixed fee hybrid contract. The Government reserves the right to make multiple awards from the RFP.

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 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 visits of areas such manufacturing plant, inventory management sites, distribution centers and regional offices and headquarters if deemed necessary by BARDA/CMA. 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. Proposals not submitted in electronic copy **will be** rejected. Electronic submissions shall be sent via e-mail and shall be received **no later than August 27th, 2025 – 2:00 PM ET**. No files shall be password protected. Facsimile submissions are not authorized.

Electronic Submission

Electronic submissions shall be in Adobe PDF, MS Word, Microsoft Excel, and Microsoft Project (as appropriate) via e-mail to yifan.yang@hhs.gov and veronica.stroud@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 Criteria, Technical Proposal and Business Proposal) must begin with a Cover Page.

B. MANDATORY QUALIFICATION CRITERIA

The Offeror shall provide a dedicated section that addresses the mandatory criteria for eligibility. The Offeror must clearly crosswalk the mandatory criteria elements as described in Section M.3. to the documentation provided to support criteria compliance. **There is a two (2) page limit for mandatory qualification 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 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 75 pages. The appendices shall not exceed an additional 75 pages. The total technical proposal submission including appendices shall not exceed 150 pages. Pages in excess of the page limit will not be reviewed.**

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 Statement of Work (SOW) associating cost with identified task and all labor categories and labor rates for work under a prospective contract. Offerors must use the attached excel spreadsheet when putting together the business proposal cost spreadsheet. **There is no page limit for the business proposal.**

L.3. MANDATORY QUALIFICATION CRITERIA

The mandatory criteria for eligibility must be met at the time of receipt of proposal as determined by the Contracting Officer in order for any proposals to be considered for award. Any Offeror(s) who submit proposals that do not meet the Mandatory Qualification Criteria for eligibility will not be evaluated further. All proposals that satisfy the mandatory criteria for eligibility will proceed to the second phase (technical evaluation) where they 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 factors listed in Section M.4. Technical Evaluation Criteria while responding to the requirements listed in SECTION C.

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 Statement of Work to respond to the Government's requirements as defined in the Statement of Objectives. 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.

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. 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) are 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 total limit of 150 pages)

- Proposal Title Page including RFP title, number, name of organization and UEI number
- Table of Contents
- 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 (Collaborative Access-Maintenance under VMI) activities to be performed by the Offeror and all proposed subcontractors, 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. The Offeror(s) shall consider the list of key personnel as proposed in Article G.4.; however, additional key personnel shall be included should they play a substantial role in the execution of the SOO.
- B. Offeror(s) shall describe any activities to be subcontracted, if applicable. 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).
- C. For the purpose of procurement, the Offeror's proposal and SOW shall address the following areas:
 - Describe processes to maintain and execute delivery / shipment of product units to burn centers.
 - Commercial sales data to demonstrate the capability to store a surplus inventory of a minimum of 2750 product units.
 - Information on the availability of resources for inventory maintenance / management activities. The Offeror shall include data demonstrating the approved shelf-life of the device, tracking and shuffling inventory and the ability to ensure a minimum shelf-life for all products in the collaborative access-maintenance VMI. The Offeror shall specify how the process is organized and managed with Standard Operating Procedures (SOPs).
 - Demonstrate ability to provide all necessary documentation for quality assurance and acceptance of the product by the USG.
 - Describe how the product will be packaged and shipped directly to burn centers.
 - Demonstrate the ability to conduct mock-deployment exercises to ensure the procedures and personnel are trained to react to an emergency deployment.
 - A production plan and timeline that describes the facilities, processes, resources and capabilities necessary to manufacture product under normal market conditions to meet commercial needs and have enough excess capacity to meet the Collaborative Access-Maintenance VMI quantity requirements for national preparedness.

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 should identify any of the activities below that are in progress or completed and adjust their SOW accordingly.

(3) Section 3:Statement of Objectives

The Statement of Objectives, included in SECTION C, 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. 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 statement of work (SOW) including the Work Breakdown Structure (WBS), in the context of work accomplished to date. This shall also include Project Gantt, 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 #16)**
- 2) **Curriculum vitae** of key personnel. There shall be enough detail to ensure the USG that key individuals will be able to perform the work described in the Technical Proposal. The resumes shall contain information on education, background, recent experience, and specific or technical accomplishments, as they pertain to their 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.
- 3) A **Risk Mitigation Plan (Attachment #13)** 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) Other supporting documents as necessary such as
 - a. Report on the market penetration of the product, number of burn and trauma centers it is used as reflected by active orders, number of trained care providers with knowledge to use the product, number of trainings being held to educate the care providers, number of publications especially sharing the role and value of the product in delivery of care or its benefits and challenges.
 - b. Data on impact of the integration of the product in routine use in delivery of health care. Health economic data on the value proposition of the product, savings or costs which drive decisions for adoption of the product into hospital formularies etc.

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 for all CLINs must contain sufficient information to allow the Government to perform a basic analysis of the proposed price of the work. This information shall include the amounts of the basic elements of the proposed cost or price.

CLINs	Structure	ITEM
001 Base	FFP	Initial Procurement of Product to Establish VMI
002 Base	FFP	VMI Maintenance
003a Base	FFP	Emergency Deployment
003b Base	FFP	Emergency Exercises
004a Option 1	FFP	Ramp Up Procurement
004b Option 1	FFP	Ramp Up VMI Maintenance
005 Option 2	FFP	Ramp Up Procurement Emergency Deployment
006 Option 3	CPFF	Formulation Development
007 Option 4	CPFF	Clinical Development
008 Option 5	CPFF	Manufacturing Development
009 Option 6	CPFF	Regulatory Tasks
010 Option 7	FFP	Procurement
011 Option 8	CPFF	Expansion to Trauma

CLIN 001 Initial Procurement and VMI Establishment (CLIN 1): Business proposal shall specify the cost breakdown of various activities covered as outlined in the Statement of objective (SOO) section C.1 and the associated Statement of Work. The products procured for the Preparedness Inventory are expected to be identical to the commercial Planned Inventory. The business proposal shall describe and outline the tasks and justification for the price associated with the purchase of these product units. The unit price of the products in the Preparedness Inventory is a firm-fixed with the product manufacturer. As per the Collaborative Access-Maintenance VMI, the Offeror is expected to establish the Planned Inventory (for commercial operations). The costs associated with Planned Inventory are the sole responsibility of the Offeror and not to be included under this CLIN.

CLIN 002 Vendor Managed Inventory (VMI) Maintenance: The business proposal shall describe and outline the costs and resources associated with maintaining the Preparedness inventory and rotating with the Planned Inventory, including any overall project management costs, via a Collaborative Access-Maintenance VMI model.

CLIN 003a, Emergency Deployment and CLIN 003b Emergency Exercises: Business proposal shall specify the cost breakdown of activities as outlined in the SOW necessary to prepare and deploy units via commercial carriers to multiple burn centers within 24 hours of notification by the U.S. Government. The same system for deployment as used by the Offeror for regular distribution of the commercial products is anticipated to be used in an emergency. The proposal shall also include a cost breakdown for conducting three mock-deployment exercises.

CLIN 004a, Ramp Up Procurement and CLIN 4b VMI Maintenance: Towards the original goals for national preparedness, USG may consider the need to increase in the size of the Preparedness Inventory cache by up to 5000 units with the final number determined during negotiations. The business proposal shall describe the justification for the costs associated with management of this increased cache. The business proposal shall demonstrate the capability and the cost for the above goals.

CLIN 005 Ramp Up Procurement Emergency Deployment: Business proposal shall specify and justify the cost breakdown of activities necessary to prepare and deploy additional devices (up to 5000 units) via the same commercial carriers to multiple burn centers.

CLIN 006 Formulation and Development: Business proposal shall specify and justify the cost breakdown of activities necessary to execute all studies towards final formulation development and manufacturing of a next generation enzymatic debridement product for thermal burns as well as costs for IND application to FDA

CLIN 007 Clinical Development: Business proposal shall specify and justify the cost breakdown of activities necessary to fully execute a pivotal clinical study demonstrating the next generation product's comparability to the commercially licensed equivalent product.

CLIN 008 Manufacturing Development: Business proposal shall specify and justify the cost breakdown of activities necessary to establish a domestic manufacturing line for the next generation debridement product a scale suitable to address the commercial demand for routine burn care with a surge capacity to enable additional procurements of up to 500 product units.

CLIN 009 Regulatory Tasks for FDA Approval: Business proposal shall specify and justify the cost breakdown of activities necessary to submit a regulatory filing to FDA for product approval and commercial sales in the U.S. burn market. Budget should include costs to address anticipated data requests from the FDA during the product review period (RFIs, additional data analyses, data audits, etc.).

CLIN 010 Procurement of New Formulated Product: Business proposal shall specify and justify the cost breakdown of activities necessary to procure up to 5000 units and integrate into the established VMI system.

CLIN 011 Expanded Indications for Use in Trauma: Business proposal shall specify and justify the cost breakdown of activities necessary to execute studies (non-clinical and/or clinical) to demonstrate use potential of the next generation product for debriding necrotic skin from blast injury derived skin injuries.

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 fully burdened cost and/or price per unit and the total price;
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.

Offeror shall certify and provide proof of freedom to operate such as proof of ownership of, or rights to, Intellectual Property or commercialization rights to but not own the IP per se.

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.

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 your 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 three (3) relevant (similar in nature to the solicitation work scope) contracts completed during the past three years. Contracts listed may include those entered into with 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 #14**) 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:

Yifan Yang
Contracting Officer
ASPR-BARDA-CMA
400 7th Street SW
Washington, DC 20024
Email: yifan.yang@hhs.gov

Veronica Stroud
Contracting Specialist
ASPR-BARDA-CMA
400 7th Street SW
Washington, DC 20024
Email: Veronica.Stroud@hhs.gov

All questionnaires shall be submitted via mail and 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 both responsibility determinations, and as an evaluation factor against which the Offeror's relative rankings will be compared to assure the best value tradeoff 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) Summary of Related Activities (**Attachment #9**)
- 3) Completed Disclosure of Lobbying Activities (**Attachment #11**)
- 4) Small Business Subcontracting Plan (**Attachment #12**)
- 5) Past Performance Questionnaires (**Attachment #14**)
- 6) A completed Representations and Certifications contained in Part IV, SECTION K, of this solicitation

(5) Small Business Subcontracting Plan (Attachment #12)

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

If the proposed contract exceeds a total estimated cost of \$750,000 for the entire period of performance, the Offeror shall be required to submit an acceptable subcontracting plan (Attachment #12) in accordance with the terms of the clause entitled "Small Business Subcontracting Plan," FAR Clause No. 52.219-9, incorporated herein by reference in this Request for Proposals:

(a) THIS PROVISION DOES NOT APPLY TO SMALL BUSINESS CONCERNS.

(b) The term "subcontract" means any agreement (other than one involving an employer-employee relationship) entered into by a Federal Government prime Contractor or subcontractor calling for supplies or services required for the performance of the original contract or subcontract. This includes, but is not limited to, agreements/purchase orders for supplies and services such as equipment purchase, copying services, and travel services.

(c) The Offeror understands that:

- (1) No contract will be awarded unless and until an acceptable plan is negotiated with the Contracting Officer which plan will be incorporated into the contract, as a material part thereof.
- (2) An acceptable plan must, in the determination of the Contracting Officer, provide the maximum practicable opportunity for Small Businesses, Small Disadvantaged Businesses, Women-Owned Small businesses, HUBZone Small Businesses, Veteran-Owned Small Businesses, and Service Disabled Veteran-Owned Small Businesses to participate in the performance of the contract.
- (3) If a subcontracting plan acceptable to the Contracting Officer is not negotiated within the time limits prescribed by the contracting activity and such failure arises out of causes within the control and with the fault or negligence of the Offeror, the Offeror shall be ineligible for an award. The Contracting Officer shall notify the Offeror in writing of the reasons for determining a subcontracting

plan unacceptable early enough in the negotiation process to allow the Offeror to modify the plan within the time limits prescribed.

(4) Prior compliance of the Offeror with other such subcontracting plans under previous contracts will be considered by the Contracting Officer in determining the responsibility of the Offeror for award of the contract.

(5) It is the Offeror's responsibility to develop a satisfactory subcontracting plan with respect to Small Business Concerns, Small Disadvantaged Business Concerns, Women-Owned Small Business Concerns, HUBZone Small Business Concerns, Veteran-Owned Small Business Concerns, and Service Disabled Veteran-Owned Small Business Concerns that each such aspect of the Offeror's plan will be judged independent of the other.

(6) The Offeror will submit, as required by the Contracting Officer, subcontracting reports in accordance with the instructions thereon and as further directed by the Contracting Officer. Subcontractors will also submit these reports to the Government's Contracting Officer or as otherwise directed, with a copy to the prime Offeror's designated small and disadvantaged business liaison.

(d) Each plan must contain the following:

(1) Goals, expressed in terms of percentages of total planned subcontracting dollars, for the use of Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Business Concerns as subcontractors.

(2) A statement of total dollars planned to be subcontracted. A statement of total dollars to be subcontracted to each of the following type of small business concerns: Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(3) A description of the principal types of supplies and services to be subcontracted with an identification of which supplies and services are expected to be subcontracted to Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned and/or Service Disabled Veteran-Owned Small Business Concerns.

(4) A description of the method used to develop the subcontracting goals.

(5) A description of the method used to identify potential sources for solicitation purposes.

(6) A statement as to whether or not indirect costs were included in establishing subcontracting goals. If they were, a description of the method used to determine the proportionate share of indirect costs to be incurred with Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses.

(7) The name of the individual employed by the Offeror who will administer the Offeror's subcontracting program and a description of his/her duties.

(8) A description of the efforts the Offeror will make to assure that Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses have an equitable chance to compete for subcontracts.

(9) Assurances that the Offeror will include in all subcontracts the contract clause "Utilization of Small Business Concerns." Assure that all subcontractors, other than small businesses, in excess of \$750,000 adopt a plan similar to the plan agreed upon by the Offeror.

(10) Assurances that the Offeror (and any required subcontractors) will cooperate in studies or surveys as required and submit the required reports in the Electronic Subcontracting Reporting System (eSRS); Individual Subcontracting Report (ISR, formerly the SF 294) and the Summary of Subcontracting Report (SSR, formerly the SF 295) to the Government.

(11) List the types of records the Offeror will maintain to demonstrate procedures that have been adopted to comply with the requirement and goals in the plan, including establishing source lists. Also, the Offeror shall describe its efforts to locate Small, Small Disadvantaged, Women-Owned, HUBZone, Veteran-Owned, and Service Disabled Veteran-Owned Small Businesses and award subcontracts to them.

The minimum subcontracting goals for this solicitation are as follows:

- 33.25% for Small Business (Includes SDB, WOSB, HUBZone, VOSB, and SDVOSB)
- 5% for Small Disadvantaged Business
- 5% for Women-Owned Small Business
- 3% for HUBZone Small Business
- 3% for Veteran-Owned Small Business
- 3% for Service-Disabled Veteran-owned Small Business

A Subcontracting Plan must be submitted with the original proposal and will be subject to negotiations if your proposal is determined to be in the Competitive Range. Small Business Subcontracting Plan Format (must be submitted with your original Business Proposal) is outlined in **Attachment #12**.

Assistance with Obtaining Small Business Sources: If assistance is needed to locate small business sources, contact the Small Business Specialist (SBS) supporting the OPDIV. SBS contact information is located on the OSDBU website (<http://www.hhs.gov/about/smallbusiness/osdbustaff.html>) or you may contact the OSDBU headquarters at (202) 690-7300.

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, you must include in your proposal a description and the estimated cost of each item, and state whether you propose to furnish the item with your 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 Offerors. 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 Offerors 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 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, and 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 CAS 405.

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.

The cutoff date for all questions on this RFP is July 29, 2025 at 2:00PM ET. All questions shall be submitted via e-mail to yifan.yang@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. THIS REQUIREMENT IS NOT SET-ASIDE FOR SMALL BUSINESS

This requirement is not set-aside for small business. However, the Federal Acquisition Regulation (FAR) requires in every solicitation, (except for foreign acquisitions) the inclusion of the North American Industry Classification System (NAICS) Code and corresponding size standard which best describes the nature of the requirement in the solicitation.

L.11. USE OF THE METRIC SYSTEM OF MEASUREMENT

Offerors shall use only the metric system of measurement.

L.12. POTENTIAL AWARD WITHOUT DISCUSSIONS

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

L.13. 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	52.203-18	Jan 2017	Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements-Rerepresentation.I
FAR	52.204-5	Oct 2014	Women-Owned Business (Other than Small Business)
FAR	52.204-7	Nov 2024	System for Award Management
FAR	52.204-16	Aug 2020	Commercial and Government Entity Code Reporting
FAR	52.204-18	Aug 2020	Commercial and Government Entity Code Maintenance
FAR	52.204-22	Jan 2017	Alternative Line Item Proposal
FAR	52.204-29	Dec 2023	Federal Acquisition Supply Chain Security Act Orders- Representations and Disclosures
FAR	52.207-1	May 2006	Notice of Standard Competition
FAR	52.209-13	Nov 2021	Violation of Arms Control Treaties or Agreements-Certification
FAR	52.215-1	Nov 2021	Instructions to Offerors- Competitive Acquisition, Alternate 1 (Oct 1997)
FAR	52.215-22	Oct 2009	Limitations on Pass- Through Charges – Identification of Subcontract Effort
FAR	52.225-2	Oct 2022	Buy American Certificate
FAR	52.225-25	Jun 2020	Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran – Representation and Certifications

L.14. ADDITIONAL FEDERAL ACQUISITION REGULATIONS (FAR) IN FULL TEXT

52.216-1 Type of Contract (Apr 1984)

The Government contemplates award 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:

Yifan Yang
Office of Contracts Management and Acquisition (CMA), BARDA
Administration for Strategic Preparedness & Response (ASPR)
United States Department of Health & Human Services (HHS)
200 C 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. IPP WAIVER REQUEST INSTRUCTION

Offerors may request a waiver from using the Department of Treasury Invoice Processing Platform (IPP) for payment requests, which may be approved by the Contracting Officer for a specific situation, as follows:

- As specified in OMB Memorandum M-15-19, electronic invoicing is not appropriate for the Federal procurement: of relocation services, utilities, or for vendors using PII for identification
- Contractor is in the process of transitioning to electronic submission of payment requests but needs time to complete such transition. Contractor must indicate timeline for transition.
- Contractor demonstrates that electronic submission is unduly burdensome. Contractor must provide full explanation to include substantiating documents when necessary.

IPP waiver requests and supporting documentation shall be included in the business proposal. In addition, any businesses based outside CONUS will not be required to use IPP unless directed by the Contracting Officer at the time of award

L.15. HHSAM Part 304, Appendix 304-A, Supply Chain Risk Assessment Solicitation Language

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

Proposals will be evaluated against the factors identified in this section. The evaluation of the proposals from a technical standpoint will be done in two (2) phases. First by determination of eligibility by meeting the mandatory qualification criteria (section M.3), and second, by evaluating technical criteria (section M.4). Only those proposals, that meet the mandatory criteria, will be further reviewed in the second phase for evaluation of the technical criteria and the cost/price evaluation (section M.2).

Selection of Contractor(s) for contract award will be based on an evaluation of proposals against three factors. The factors in order of importance are technical merit (including capability to deliver the solutions), cost, and past performance. Although technical factors are of paramount consideration in the award of the contract, past performance, and cost are also important to the overall contract award decision. Activities in the technical proposal must connect directly to the associated costs/price in the business proposal. The tradeoff process described in FAR 15.101-1 shall be employed.

The Government may make one or more award(s) to the Offeror(s) whose proposal provides the best overall value to the Government. In the case of multiple awards, the Government will make their determination of best overall value to the Government by considering, as a part of its award determination, different technological capabilities that best satisfies the Government's overarching technological capability needs.

A proposal must document the overall assurance of the offeror's capability for successful implementation of the objectives outlined in the Statement of Objectives in Section B of this solicitation. An Offeror's proposal should sufficiently address each of the evaluation criteria specified below as they relate to the Statement of Objectives. The merits of each proposal will be evaluated carefully. Each proposal must document the feasibility of successful implementation of the requirements within the RFP. In addition, the Contractor(s) shall provide context to demonstrate their understanding of the overall project requirements; and a description of their approach to provide integrated support across the entire breadth of the proposal to meet all the requirements.

The Contracting Officer reserves the right to make an award without discussions. The Government 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.

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.

The evaluation of cost/price will not occur if the vendor does not meet the mandatory qualification criteria or is evaluated and determined "Unacceptable" as part of its technical evaluation.

Price will be evaluated separately from past performance and other non-price factors and will be evaluated for fairness and reasonableness. The evaluation of cost/price will not occur if the vendor does not meet the mandatory qualification criteria or if any one of the three technical evaluation criteria is evaluated and determined "Unacceptable" as part of its technical evaluation. The evaluated price will be evaluated for fairness and reasonableness in terms of:

- a. Level of effort, in that the proposed labor mix and labor hours are based on reasonable assumptions.

- b. Consistency with the technical approach, in that the prices are consistent with and reflect the proposed staffing requirement for all years.
- c. Fairness and reasonableness of proposed price(s). Price(s) that are unreasonable, not fully supported/substantiated, or both, may cause the overall technical evaluation to be adjusted in one or more of the non-price evaluation factors.

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 QUALIFICATION CRITERIA

Listed below are the Mandatory Qualification Criteria. The Offeror(s) shall provide a dedicated section that addresses the mandatory criteria for eligibility. The mandatory criteria for eligibility must be met as determined by the evaluators and the Contracting Officer for any proposals to be considered for further technical review and award. Only proposals that satisfy the Mandatory Eligibility Criteria will be considered for additional evaluation.

A dedicated initial section in the technical proposal of not more than two (2) pages is required where the Offeror shall provide a response to satisfy the requirements listed under the Mandatory Qualification Criteria. The Offeror shall address and satisfy the following conditions:

1. Enzymatic debridement product is approved for use in the US by the FDA for removal of necrotic skin from both partial and full thickness thermal burns in both adults and pediatrics.
2. Product has the potential to function in non-surgical suites settings (e.g., patient bedside) to achieve complete debridement as per approved indication to enable the next step in burn care.
3. Offeror has the infrastructure to support management of product rotation across multiple caches via a vendor-managed inventory (VMI) and commercial sales to prevent expiry and waste. The Offeror also has the capability for product distribution to end users (such as burn centers) and in an emergency response distribution.
- 4- Provide an explicit statement of acknowledgement understanding the definition and concur to negotiate entering into the agreement as defined under the Collaborative Access-Maintenance Vendor Managed Inventory (CAM-VMI) in Section B.1.1 Definitions. The final negotiated agreement would be part of the Advanced Understanding statements of the potential contract.

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 cost/price in the business proposal.

The technical evaluation criteria are as follows: 1) Vendor Management Capability for Supporting Access-Maintenance and on-demand procurement, 2) Technical Merit for Late-Stage Product Development 3) Personnel and Experience in management of the tasks to meet the objectives, and 4) Manufacturing Capabilities and Facilities. These evaluation criteria are of equal importance.

Evaluation Criterion 1: Vendor Management Capability for Supporting Collaborative Access-Maintenance and On-Demand Procurement

The Offeror shall provide evidence of demonstrated ability and appropriateness to perform the following capabilities efficiently and effectively, as relevant to the Statement of Objectives (SOO).

- Adequacy of proposed plan (SOW) to address the VMI maintenance, as outlined in the SOO.
- A clear proposed plan to address the Procurement Objectives of the SOO, including the potential for additional ramp up procurement.
- Demonstration of capability and capacity limits to deliver product units from the VMI and establish distribution system for commercial use.
- Presence of a security plan to protect the entire facilities and operations.

Evaluation Criteria 2: Technical Merit for Late-Stage Product Development

The Offeror(s) shall provide evidence of demonstrated ability and appropriateness to efficiently and effectively perform the following capabilities, as relevant in the Statement of Objectives:

- Adequacy of proposed work plan to address the General Objectives
- Demonstrated knowledge and understanding of the Regulatory, Non-Clinical, and Clinical Objectives
- Demonstrated understanding of proposed plan to address the Chemistry, Manufacturing, and Control Objectives
- Demonstrated experience and understanding of the size and scope of the proposed late-stage product development work and the technical effort needed to complete it.
- The adequacy of the proposed timelines/milestone schedule for meeting late-stage product development objectives.
- Documented knowledge of the FDA and its components and requirements for licensure/approval status of proposed work.
- Documented Freedom to Operate such as proof of ownership of, or rights to, Intellectual Property
- Demonstrated understanding of the degree of development for product technology and its readiness for the marketplace

Evaluation Criterion 3: Personnel and Organizational Experience

The Offeror(s) shall provide details about organizational experience and key personnel responsible for executing the collaborative access-maintenance VMI.

The Offeror shall provide the following details concerning the key personnel and other personnel:

- Education, training, experience, expertise, and effort of the proposed key personnel and other personnel in terms of experience based on the requirements identified in the SOO.
 - Evidence of an organization chart indicating clear lines of authority and responsibility for the project's management. The Offeror(s) shall also identify the number of personnel available to support this contract (e.g. technicians, administrative support).

Evaluation Criterion 4: Organizational Manufacturing/ VMI and Deployment Capabilities

The Offeror shall provide evidence of demonstrated ability and appropriateness to perform the following capabilities efficiently and effectively, as relevant to the Statement of Objectives (SOO).

- Demonstrated capability to support both initial and additional procurements.
- Operational regulatory and (QSR) quality management infrastructure as relevant for VMI and distribution related activities.

- Reporting on the market penetration and integration in health care.
- Reporting on risk management.

M.5. MERIT RATINGS

The following rating method shall be used in the evaluation of the technical proposal: Excellent, Good, Fair and Poor..

Evaluators will work in consensus to assign a merit rating to each of the four evaluation criteria listed above. The individual criterion merit ratings will be considered by the Technical Evaluation Panel members who will assign one overall merit rating for the technical proposal.

Receiving a technical evaluation rating of unacceptable in any single factor will result in the overall proposal being determined unacceptable and, therefore, ineligible for award. Cost/Price and Past Performance will not be evaluated for any proposal with an overall 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 timeframe 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 following rating method shall be used in the evaluation of past performance information:

- **Acceptable** – Based on the Offeror's performance record little to no doubt exists that the Offeror will successfully perform the required effort. Sources of information indicate that the Offeror's performance is at least average or that unfavorable reports are offset by favorable reports.
- **Unacceptable** – Based on the Offeror's performance record some to serious doubt exists that the Offeror will successfully perform the required effort. Sources of information made unfavorable to unsatisfactory reports about the Offeror's performance and they express concern about doing business with the Offeror again or would not do business with the Offeror again.

- **Neutral** – The lack of a relevant performance record, or the unavailability of past performance information, which results in an undetermined past performance assessment. A “neutral” past performance rating 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. SMALL BUSINESS SUBCONTRACTING PLAN

The Offeror's proposed Small Business Subcontracting Plan will be evaluated to determine whether it meets or exceeds the departments goals stated in Section L.5.3 (5).

Failure to submit and negotiate an acceptable subcontracting plan (if a plan is applicable) prior to conclusion of negotiations shall make the Offeror ineligible for award of a contract.

M.8. 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.9. HHSAM Part 304, Appendix 304-A, Supply Chain Risk Assessment Solicitation Language

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.

Failure by the offeror to affirmatively demonstrate adequate compliance with the general standards of prospective contractor responsibility at FAR 9.104-1, and any special standards established for this acquisition under FAR 9.104-2, may result in a determination of non-responsibility. As with all aspects of prospective contractor responsibility, a finding of non-responsibility can be made at any time prior to contract award. Per FAR 9.103(b), if the prospective contractor is a small business concern, responsibility will be determined in accordance with Subpart 19.6, Certificates of Competency and Determinations of Responsibility. If the prospective contractor is a Section 8(a) participant, see Subpart 19.8.

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

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

- All Invoice submissions 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 Products and Commercial Services 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.
 - Registration emails are sent via email from ipp.noreply@mail.eroctwai.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.
 - 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 log in 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 Strategic Preparedness & Response (ASPR) (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 Unique Entity Identifier (UEI) 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.

ATTACHMENT #3**SAMPLE INVOICE/PAYMENT REQUEST AND CONTRACT FINANCIAL REPORT**

<p>(a) Designated Billing Office Name and Address:</p> <p style="margin-left: 40px;">DHHS/ASPR/BARDA/CMA Attn: Contracting Officer US DEPT OF HEALTH & HUMAN SERVICES ADMINISTRATION FOR STRATEGIC PREPAREDNESS & RESPONSE Division of Contract Management & Acquisitions Constitution Center 400 7th SW Washington, DC 20024</p> <p>(b) Contractor's Name, Address, Point of Contact, VIN, and UEI Number:</p> <p style="margin-left: 40px;">ABC CORPORATION 100 Main Street Anywhere, USA Zip Code</p> <p>Name, Title, Phone Number, and E-mail Address of person to notify in the event of an improper invoice or, in the case of payment by method other than Electronic Funds Transfer, to whom payment is to be sent.</p> <p>VIN: UEI:</p>	<p>(c) Invoice/Financing Request No.:</p> <p>(d) Date Invoice Prepared:</p> <p>(e) Contract No. and Order No. (if applicable): _____</p> <p>(f) Effective Date:</p> <p>(g) Total Estimated Cost of Contract/Order:</p> <p>(h) Total Fixed-Fee (if applicable):</p> <p>(i) <input type="checkbox"/> Two-Way Match: <input type="checkbox"/> Three-Way Match:</p> <p>(j) Office of Acquisitions:</p> <p>(k) Central Point of Distribution:</p>
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(l) This invoice/financing request represents reimbursable costs for the period from _____ to _____

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

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

(Name of Official)

(Title)

* Attach details as specified in the contract

ATTACHMENT #4

PROPOSAL INTENT RESPONSE FORM

RFP No:

RFP Title:

Please review the Request for Proposal (RFP). Furnish the information requested below and return this page to the Contracting Officer/Contract Specialist identified on **Section A-Solicitation/Contract Form** by TBD

Your expression of intent is not binding but will greatly assist us in planning for proposal evaluation. Choose one of the following Options:

☐ Do intend to submit a proposal

☐ Do Not intend to submit a proposal If you are not responding to this RFP, please provide your reason(s):

Please provide the following contact information:

Name (First, Middle Initial, Last):

Title:

Organization:

E-mail:

ATTACHMENT #5

SUMMARY OF RELATED ACTIVITIES

The following specific information must be provided by the Offeror pertaining to the Project Director, Principal Investigator, and each of any other proposed key professional individuals designated for performance under any resulting contract.

- a. Identify the total amount of all presently active federal contracts/cooperative agreements/grants and commercial agreements citing the committed levels of effort for those projects for each of the key individuals* in this proposal.

Professional's Name and Title/Position:

<u>Identifying Number</u>	<u>Agency</u>	<u>Total Effort Committed</u>
---------------------------	---------------	-------------------------------

- 1.
- 2.
- 3.
- 4.

*If an individual has no obligation(s), so state.

- b. Provide the total number of outstanding proposals, exclusive of the instant proposal, having been submitted by your organization, not presently accepted but in an anticipatory stage, which will commit levels of effort by the proposed professional individuals*.

Professional's Name and Title/Position:

<u>Identifying Number</u>	<u>Agency</u>	<u>Total Effort Committed</u>
---------------------------	---------------	-------------------------------

- 1.
- 2.
- 3.
- 4.

*If no commitment of effort is intended, so state.

- c. Provide a statement of the level of effort to be dedicated to any resultant contract awarded to your organization for those individuals designated and cited in this proposal.

<u>Name</u>	<u>Title/Position</u>	<u>Total Proposed Effort</u>
-------------	-----------------------	------------------------------

- 1.
- 2.
- 3.
- 4.

ATTACHMENT #6

RESERVED

ATTACHMENT #7

DISCLOSURE OF LOBBYING ACTIVITIES, WITH INSTRUCTIONS

Please complete form available here:

<https://www.gsa.gov/forms-library/disclosure-lobbying-activities>

Copy and paste the above link into your browser.

ATTACHMENT #8

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

RISK MITIGATION PLAN/MATRIX TEMPLATE

[illegible]

ATTACHMENT #10**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: Yifan Yang Contracting Officer
yifan.yang@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 subOfferor(s): %	
	6. Information on subOfferor(s) (where more than % of work was completed by the subOfferor).	
	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
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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	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
A-2. Accuracy of reports	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
A-3. Effectiveness of personnel	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
A-4. Technical excellence	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
B. Cost Control							
B-1. Record of forecasting and controlling target costs	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
B-2. Current accurate and complete billings	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
B-3. Best value (balance of performance vs. cost).	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
B-4. Relationship of negotiated costs to actuals	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
B-5. Cost efficiencies	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
C. Schedule							
C-1. Met interim milestones	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
C-2. Reliability	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
C-3. Responsive to technical direction	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
C-4. Completed on time including wrap-up and contract administration	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
C-5. Met delivery schedules	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
D. Business Relations							
D-1. Effective management, including subcontracts	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
D-2. Reasonable/cooperative behavior	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
D-3. Responsive contract requirements	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
D-4. Notification of problems	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
D-5. Flexibility	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
D-6. Pro-active vs. reactive	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
D-7. Effective small/small disadvantaged business subcontracting program	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
E. Security							
E-1. Understanding of physical security compliance.	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
E-2. Compliance with communication and information security.	<input type="checkbox"/> N/A	<input type="checkbox"/> 1	<input type="checkbox"/> 2	<input type="checkbox"/> 3	<input type="checkbox"/> 4	<input type="checkbox"/> 5	
F. Customer Satisfaction							
F-1. The Offeror is committed to customer satisfaction	<input type="checkbox"/> Yes	<input type="checkbox"/> No					
F-2. Would you recommend selection of this firm again?	<input type="checkbox"/> Yes	<input type="checkbox"/> 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, or letters).
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 impacted the 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 #11

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 (subcontractors, 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	<p>Layered (internal/external) CCTV coverage with time-lapse video recording for buildings and areas where critical assets are processed or stored.</p> <p>CCTV coverage should include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract.</p> <p>Video recordings must be maintained for a minimum of 30 days.</p> <p>CCTV surveillance system must be on emergency power backup.</p>
Facility Lighting	<p>Lighting must cover facility perimeter, parking areas, critical infrastructure, and entrances and exits to buildings.</p> <p>Lighting must have emergency power backup.</p> <p>Lighting must be sufficient for the effective operation of the CCTV surveillance system during hours of darkness.</p>
Shipping and Receiving	<p>Should have CCTV coverage and an electronic access control system.</p> <p>Should have procedures in place to control access and movement of drivers picking up or delivering shipments.</p> <p>Must identify drivers picking up BARDA products by government issued photo identification.</p>
Access Control	<p>Should have an electronic intrusion detection system with centralized monitoring.</p> <p>Responses to alarms must be immediate and documented in writing.</p> <p>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</p>

	<p>control should signal an alarm notification of unauthorized attempts to access restricted areas.</p> <p>Should have procedures to prevent employee piggybacking.</p> <p>Access to critical infrastructure (generators, air handlers, fuel storage, etc.) should be controlled and limited to those with a legitimate need for access.</p> <p>Should have a manual key accountability and inventory process.</p> <p>Physical access controls should present a layered approach to critical assets within the facility.</p>
Employee/Visitor Identification	<p>Should issue company photo identification to all employees.</p> <p>Photo identification should be displayed above the waist anytime the employee is on company property.</p> <p>Visitors should be sponsored by an employee and must present government issued photo identification to enter the property.</p> <p>Visitors should be logged in and out of the facility and should be escorted by an employee while on the premises.</p>
Security Fencing	<p>Requirements for security fencing will be determined by the criticality of the program and the potential threat environment.</p>
Protective Security Forces	<p>Requirements for a security force will be determined by the criticality of the program and the potential threat environment.</p>
6. Security Operations	
Information Sharing	<p>Establish formal liaison with law enforcement and implement procedures for receiving and disseminating threat information.</p>
Training	<p>Conduct new employee security awareness training.</p> <p>Conduct and maintain records of annual security awareness training.</p>
Security Management	<p>Designate a knowledgeable security professional to manage security of the facility.</p> <p>Ensure subOfferor compliance with BARDA security requirements.</p>
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	<p>Applicable documents shall be identified and marked as procurement sensitive, proprietary or with appropriate government markings.</p> <p>Sensitive, proprietary, and government documents should be maintained in a lockable filing cabinet / desk or other storage device and not be left unattended.</p> <p>Access to sensitive information should be restricted to those with a need to know.</p>
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	<p>Limit information systems access to authorized users.</p> <p>Identify information system users, processes acting on behalf of users, or devices and authenticate identities before allowing access.</p> <p>Limit physical access to information systems, equipment, and server rooms with electronic access controls.</p>
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	<p>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.</p> <p>Ensure the actions of individual information system users can be uniquely traced to those users.</p>
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	<p>Protect information system media, both paper and digital.</p> <p>Limit access to information on information systems media to authorized users</p> <p>Sanitize and destroy media no longer in use.</p> <p>Control the use of removable media through technology or policy.</p>
Physical and Environmental Protection	<p>Limit access to information systems, equipment, and the respective operating environments to authorized individuals.</p> <p>Protect the physical and support infrastructure for all information systems.</p> <p>Protect information systems against environmental hazards.</p>
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	<p>Drivers should be vetted in accordance with BARDA Personnel Security Requirements.</p> <p>Drivers should be trained on specific security and emergency procedures.</p> <p>Drivers should be equipped with backup communications.</p> <p>Driver identity should be 100 percent confirmed before pick-up of any BARDA product.</p> <p>Drivers should never leave BARDA product unattended and two drivers may be required for longer transport routes or critical products during times of emergency.</p>
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	<p>BARDA products should be secured with tamper resistant seals during transport and the transport trailer should be locked and sealed.</p> <p>Tamper resistant seals should be verified as “secure” after the product is placed in the transport vehicle.</p> <p>BARDA product should be continually monitored by GPS technology while in transport and any deviations from planned routes should be investigated and documented.</p> <p>Contingency plans should be in place to keep the product secure during emergencies such as accidents and transport vehicle breakdowns.</p>
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 #12

SECURITY PLAN TEMPLATE WITH INSTRUCTIONS

COMPANY SECURITY PLAN TEMPLATE

Prepared by:
Program Protection Office

Center for the 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 Center for the 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
 - a. Statement of Threats
 - i. Industrial Espionage
 - ii. Criminal
 - iii. Terrorism
 - iv. Natural Disasters
 - b. Vulnerability + Consequence of Loss=Risk
- III. Threat Levels
 - a. Low – Protective Measures
 - b. Medium – Protective Measures
 - c. High – Protective Measures
- IV. Physical Security
 - a. General Description
 - b. Access Control
 - i. Perimeter
 - ii. Internal
 - iii. Badge Policy
 - 1. Permanent employees
 - 2. Visitors
 - 3. Others
 - c. Parking Areas
 - d. Security Lighting
 - e. Other Building Features
 - f. Signage
 - g. Designation of Restricted Areas
 - i. Entry Points
 - ii. Electronic Access Control
 - iii. Electronic Intrusion Detection
 - iv. Closed Circuit Television
 - v. Other Control Measures
- V. Personnel Security Program
 - a. General Description
 - b. Recruitment of New Employees
 - i. Interview process
 - ii. Background Checks
 - iii. Suitability / Adjudication Guidelines
 - iv. Non-Disclosure Agreements
 - v. Rules of Behavior
 - vi. Access Determination/Badge System
 - c. Temporary Employees
 - i. Interview
 - ii. Background Checks
 - iii. Non-Disclosure Agreements
 - iv. Access Determination/Badge System
 - d. Offeror Support
 - e. Termination
 - i. Denial of Access
 - ii. Post Employee Interview
 - iii. Non-Disclosure Agreements
- VI. Information Security
 - a. General Description
 - b. Identification of Sensitive Information
 - c. Physical Document Control
 - i. Marking
 - ii. Secure Storage
 - iii. Destruction Policy

- d. Information Technology Security
 - i. General Description
 - ii. Media Control
 - 1. Media Protection
 - 2. Sanitization and Disposal of Information
 - 3. Input/Output Controls
 - iii. Equipment
 - 1. Workstations
 - 2. Laptops and Other Portable Computing Devices
 - iv. Personally Owned Equipment and Software
 - v. IT Disaster Recovery
 - 1. Backup Data.
 - 2. Store Backup Data
- VII. Security Awareness Training and Reporting Requirements
 - a. Training
 - i. New Employees
 - ii. Annual
 - b. Security Reporting
 - i. Reporting of Compromise
 - ii. 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) to alter 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.