SOLICITATION, OFFER AND AWARD

1. THIS CONTRACT IS A RATED ORDER UNDER DPAS (15 CFR 700)	RATING	PAGE	OF PAGES
		1	111

2. CONTRACT NUMBER	3. SOLICITATION NUMBER	4. TYPE OF SOLICITATION	5. DATE ISSUED	6. REQUISITION/PURCHASE NUMBER
	75A50121R00003	☐ SEALED BID (IFB) ☒ NEGOTIATED (RFP)	6/17/2021	

7. ISSUED BY CODE

HHS/OS/ASPR/BARDA/CMA
200 C Street SW, Washington, DC 20024

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

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

SOLICITATION

9. Sealed offers in original and 0 copies for furnishings the supplies or services in the Schedule will be received at the place specified in item 8, or if hand carried, in the depository located in See Section L for Instructions until 4:00PM *(Hour)* local time 7/19/2021 *(Date)*

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

10. FOR INFORMATION CALL:	A. NAME	B. TELEPHONE *(NO COLLECT CALLS)* AREA CODE	NUMBER	EXTENSION	C. E-MAIL ADDRESS
	Jill Johnson	202	816	1148	Jill.Johnson@hhs.gov

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OFFER *(Must be fully completed by offeror)*

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

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

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

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

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

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

AWARD *(To be completed by Government)*

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

22. AUTHORITY FOR USING OTHER THAN FULL OPEN COMPETITION: ☐ 10 U.S.C. 2304 (c) ☐ 41 U.S.C. 3304(a) ( )	23. SUBMIT INVOICES TO ADDRESS SHOWN IN *(4 copies unless otherwise specified)*	ITEM

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

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

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

NOTE TO OFFERORS

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

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

Potential Offerors must be registered in the System for Award Management (SAM) prior to 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 June 28, 2021 at 12PM ET. All questions shall be submitted via e-mail to Jill.Johnson@hhs.gov.

PART I – THE SCHEDULE

SECTION B – SUPPLIES OR SERVICE AND PRICE / COST

B.1. BRIEF DESCRIPTION OF SUPPLIES OR SERVICES

In 2007, the Public Health Emergency Medical Countermeasure Enterprise (PHEMCE) recommended that an improved anticonvulsant to treat seizures caused by nerve agent exposure be developed and procured. Attributes of this product would include a non-IV route of administration (e.g. IM) that is fast acting, has greater efficacy than existing products, and that is approved by the Food and Drug Administration (FDA) for adult and pediatric indications. The 2007 PHEMCE Implementation Plan for Chemical, Biological, Radiological, and Nuclear (CBRN) Threats called for updating the CHEMPACK formulary with improved medical countermeasures, such as anticonvulsants, as they became available. Requirements for the desired anticonvulsant were listed in the Improved Anticonvulsant Product Specific Requirements (2011), and the PHEMCE recommended that the CHEMPACK formulary be updated with the improved anticonvulsant midazolam. Midazolam is now approved to treat status epilepticus seizures in adult populations, inclusive of seizures subsequent to nerve agent intoxication. Acquisition of pediatric and adult midazolam autoinjectors and their approval for the treatment of status epilepticus would fulfill this requirement. The goal of this acquisition is to replace all expired diazepam autoinjectors (Convulsant Antidote Nerve Agent, CANA) in the Strategic National Stockpile's (SNS) CHEMPACK Program with autoinjectors containing the improved anticonvulsant midazolam in an autoinjector for rapid intramuscular administration. Midazolam autoinjectors would be used in the prehospital setting (EMS CHEMPACKs) and in the hospital setting in a mass casualty situation to increase the ease and speed of administration.

Prepositioning antidotes throughout the country addresses the time constraints on effective medical treatment, and thus reduces the time of delivery of life saving nerve agent medical countermeasures. CHEMPACKs supplement the supply of these antidotes available in local hospitals, Emergency Medical Service (EMS) systems, and other local response organizations. CHEMPACKs account for all the diazepam acquired and maintained by the SNS, specifically for the treatment of nerve agent-induced seizures. Project BioShield (PBS) funds will fund Human Factors evaluations for the new autoinjectors, late-stage clinical development, regulatory approval for midazolam autoinjectors (as a drug/device combination product) to treat status epilepticus in adult and pediatric populations, and procurement of pediatric and adult midazolam autoinjectors for the SNS CHEMPACK Program. The urgent need for an improved anticonvulsant (midazolam) autoinjectors within the Strategic National Stockpile to treat seizures caused by nerve agents requires BARDA to enter into a late stage development and procurement contract. This effort is particularly pressing given that the diazepam autoinjectors in CHEMPACKs are currently expired and nearing the end of viability via the Shelf Life Extension Program (SLEP).

B.2. PRICES / COSTS

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 up to five (5) years and a total contract period of performance (base plus option periods) up to 10 years with the exercise of options. The Base Period includes a Cost-Plus Fixed Fee (CPFF) Contract Line Item Number (CLIN) to support Advanced Research and Development (ARD) necessary for the completion of remaining regulatory activities to obtain FDA approval for midazolam autoinjectors (as a drug/device combination product) to treat status epilepticus in adult and pediatric populations. Eight optional CLINs include both Firm-Fixed Price (FFP) CLINs to support procurement of midazolam autoinjectors for the

SNS/CHEMPACK Program as well as Supplementary CPFF CLINs dedicated to additional late stage development; post-marketing commitments as established by the FDA; BARDA Security requirements as necessary. Purchase of midazolam autoinjectors may occur once the autoinjectors are FDA approved for status epilepticus indication, or acceptable for use under an EUA. The options may be exercised within the previous period of performance of the contract, if needed. Below are the anticipated CLINs.

B.2.1. BASE PERIOD

Base Period Cost Reimbursement CLIN		
Anticipated Period of Performance	**CLIN**	**Supplies/Services**
2021-2026	0001 (Base)	Program Management: Identification and Selection of Pediatric Dose; Device design changes to support Pediatric autoinjector; Development, qualification and validation of pediatric device manufacturing; Human factors studies for adult and pediatric devices; Regulatory activities to support FDA approval of drug/device combination for midazolam autoinjectors to treat SE in pediatric and adult populations.

B.2.2. OPTIONS

Optional Cost Reimbursement CLINs		
Anticipated Period of Performance	**CLIN**	**Supplies/Services**
2023-2028	0004 (Option 3)	Post Marketing Commitments (PMC) and manufacturing optimizations required for maintaining the approval including any studies to monitor safety and efficacy for status epilepticus or during a nerve agent emergency.
2025-2030	0007 (Option 6)	Post Marketing Commitments (PMC) and manufacturing optimizations required for maintaining the approval including any studies to monitor safety and efficacy for status epilepticus or during a nerve agent emergency.

Anticipated Period of Performance	**CLIN**	**Supplies/Services**	**Quantity**
2021-2026	0002 (Option 1)	Procurement of Adult Autoinjector Devices	306,000

2021-2026	0003 (Option 2)	Procurement of Pediatric Dose Autoinjector Devices	54,000
2023-2028	0005 (Option 4)	Procurement of Adult Dose Autoinjector Devices	173,000
2023-2028	0006 (Option 5)	Procurement of Pediatric Dose Autoinjector Devices	35,000
2025-2030	0008 (Option 7)	Procurement of Adult Dose Autoinjector Devices	173,000
2025-2030	0009 (Option 8)	Procurement of Pediatric Dose Autoinjector Devices	35,000

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.

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

No security plan is required at this point for this effort. It is anticipated that a security waiver will be approved.

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 and exceeds $250,000; 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. Approval of Human and Animal Protocols

The Contractor shall submit all human and animal protocols and human informed consent documents as referenced under this Contract to the COR for review and approval **prior** to seeking other approvals (Institutional Review Board, Human Use Committee, Institutional Animal Care and Use Committee) unless the contractor already had such approvals prior to contract award. The Government requires no fewer than eight (8) business days to perform a review. The Contractor shall take this review time into account and submit protocols as early as possible to avoid delays. The Government's comments and feedback shall be addressed prior to approval. The COR will review and provide approval of protocols. Human informed consents shall also be submitted and reviewed with any human protocol.

g. 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, regarding the government's rights to deliverables submitted during performance as well as the government's rights to data contained within those deliverables.

h. 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 <u>any</u> 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

SECTION C – DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

C.1. STATEMENT OF OBJECTIVES

BACKGROUND AND PURPOSE

This Request for Proposal (RFP) covers the advanced research and development, procurement, and delivery of adult and pediatric midazolam autoinjectors that have received FDA approval for the treatment of status epilepticus seizures (including seizures caused by nerve agents) in adult and pediatric populations (2+ years of age). Acceptance of the autoinjectors into the SNS/CHEMPACKs requires that the finished product meet all specifications and reliability requirements as determined by the FDA. The goal of this acquisition is to replace all of expired diazepam autoinjectors (Convulsant Antidote Nerve Agent, CANA) in the Strategic National Stockpile's (SNS) CHEMPACK Program with autoinjectors containing the improved anticonvulsant midazolam in an autoinjector for rapid intramuscular administration. Midazolam autoinjectors would be used in the prehospital setting (EMS CHEMPACKs) and in the hospital setting in a mass casualty situation involving nerve agents to increase the ease and speed of administration. Midazolam autoinjectors will be FDA approved for pediatric and adult populations and will be available separately for both populations (i.e., pediatric and adult autoinjectors). A needle-free autoinjector is preferred for numerous reasons, including the avoidance of cross contamination, prevention of needle-stick injuries, simplification of disposal (no sharps), and improved dispensing of medication (no void volume).

The US government (USG) has a requirement to acquire, hold, and distribute medical countermeasures that will mitigate injuries caused by chemical, biological, physical radiologic and nuclear exposures. The department of Health and Human Services (HHS) has the responsibility of maintaining a definitive supply of medical Countermeasures for use in public health emergencies. In 2003, The Strategic National Stockpile (SNS) created the CHEMPACK Program to acquire nerve agent antidotes and provide them to the 50 states, four cities, and several territories for pre-positioning in locations that are convenient for responders. CHEMPACKs supplement the supply of these antidotes available in local hospitals, EMS systems, and other local response organizations. CHEMPACKs account for all of the diazepam acquired and maintained by the SNS specifically for the treatment of nerve agent-induced seizures. The 2007 HHS Public Health Emergency Medical Countermeasures Enterprise (PHEMCE) Implementation Plan for CBRN Threats called for updating the CHEMPACK formulary with improved medical countermeasures, such as anticonvulsants, as they become available. In 2011, the PHEMCE recommended that the CHEMPACK formulary be updated with the improved anticonvulsant midazolam, which is now approved to treat status epilepticus seizures in adult populations, inclusive of seizures subsequent to nerve agent intoxication. Acquisition of pediatric and adult midazolam autoinjectors and their approval for the treatment of status epilepticus (as a drug/device combination product) would fulfill this requirement. Fulfilling this requirement is of particular importance since diazepam autoinjectors (CANA) in CHEMPACKs are currently expired and maintained under Shelf Life Extension (SLEP).

This acquisition will allow BARDA to invest Project Bioshield funds for late-stage clinical development, regulatory approval for midazolam autoinjectors (as a drug/device combination product) to treat status epilepticus in adult and pediatric populations, and procurement of pediatric and adult midazolam autoinjectors for the SNS/CHEMPACK Program.

SCOPE

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

The USG is seeking to procure and maintain approximately 652,000 adult midazolam autoinjectors and 124,000 pediatric midazolam autoinjectors for the treatment of status epilepticus seizures (including seizures caused by nerve agents) in adults and pediatric populations (2+ years). Midazolam autoinjectors shall be delivered to the SNS/CHEMPACK Program. CHEMPACKs account for all stock of diazepam autoinjectors for treatment of nerve agent-induced seizures, acquired and maintained by the SNS under the Shelf Life Extension Program (SLEP). Diazepam autoinjectors will be replaced by midazolam autoinjectors under this planned procurement. The USG will utilize this procurement of midazolam autoinjectors to prepare for a mass casualty event involving nerve agents. Adult and pediatric midazolam autoinjectors shall be delivered to the SNS/CHEMPACK Program and shall be FDA approved as a drug/device combination product for the treatment of status epilepticus in both populations, or acceptable for use under an EUA.

The scope of the base period will include late-stage development activities necessary to support FDA approval of midazolam autoinjectors for the SE indication. Optional CLINs will include procurement of autoinjectors as well as additional late-stage development activities, fulfillment of additional USG security requirements as necessary, Post-Marketing Commitments Procurement options represent a series of incremental purchases of midazolam autoinjectors until the entire requirement for the manufacturing and procurement of approximately 652,000 adult midazolam autoinjectors and 124,000 pediatric midazolam autoinjectors is met.

The statement of objectives is outlined in the following sections that the Offeror(s) shall address in their proposed statement of work:

Section 1: Program Management and Risk Mitigation Objectives

Section 2 Late Stage Product Development Objectives

Section 3: Supply and Delivery of Product Objectives

Section 4: Post-Marketing Commitments and/or Requirements (Option)

Section 5: Additional Procurements (Option)

1. PROGRAM MANAGEMENT AND RISK MITIGATION OBJECTIVES

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

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

1.2. The Offeror shall develop and maintain a risk mitigation plan that is acceptable to the CO and COR. This shall include a risk matrix per Attachment 13. The Offeror shall provide a security plan which is associated with all aspects of manufacture of product, process, storage, and inventory of the midazolam autoinjectors. The Security Plan shall include all sites within the supply chain, including proposed shipping carriers. For those sites/carriers that are not defined at the time of award or are added during the period of performance, individualized Security Plans shall be provided to the USG prior to inclusion of sites/carriers into the supply chain. BARDA's Program Protection Office will be

authorized to review and approve Security Plans and will conduct annual audits / site visits to ensure a reliable product is delivered to the USG. Security requirements and a template for a Security Plan are included in Attachments 15 and 16, respectively.

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

2. LATE STAGE PRODUCT DEVELOPMENT OBJECTIVES: BASE (CLIN 0001) and OPTIONS (CLINs 0004 and 0007)

2.1 GENERAL PRODUCT DEVELOPMENT OBJECTIVES

2.1.2. The Offeror shall demonstrate that they can manufacture midazolam autoinjectors that are considered approvable according to FDA guidance and regulation for the treatment of status epilepticus in adult and pediatric populations.

2.1.3. If no midazolam autoinjector is FDA approved, the Offeror must conduct development activities and seek pre-EUA authorization from the FDA for the treatment of status epileptics in adult and pediatric populations. Examples of such development activities could include human factor and bioequivalence studies.

2.1.4. Midazolam autoinjectors must demonstrate compliance with FDA reliability standards outlined in the Draft Guidance for Technical Considerations for Demonstrating Reliability of Emergency-Use Injectors Submitted under a BLA, NDA or ANDA. For more information, visit https://www.fda.gov/regulatory-information/search-fda-guidance-documents/technical-considerations-demonstrating-reliability-emergency-use-injectors-submitted-under-bla-nda.

2.1.5. The product shall have a status epilepticus indication for use in adults and pediatric populations (2+ years).

2.1.6. The product shall be FDA approved or have an authorized EUA with a minimum of three years stability at the intended storage temperature.

2.1.7. The product shall be manufactured at a scale capable of meeting the USG requirements for stockpiling.

2.2. REGULATORY OBJECTIVES

2.2.1. The Offeror shall maintain and update, as required by the FDA, all regulatory documentation (Design History File (DHF), clinical documentation, regulatory binder, etc.) that will be used to support use under EUA and/or FDA approval.

2.2.2. The Offeror shall obtain FDA concurrence on the appropriate path for regulatory evaluation and FDA approval of midazolam autoinjectors, as a drug/device combination product, for the treatment of status epilepticus in adult and pediatric populations.

2.2.3. The Offeror shall prepare all documentation for and conduct all necessary meetings with the FDA to support submission of a New Drug Application (NDA).

2.2.4. If investigational product is distributed under EUA authorization, upon FDA approval, the Offeror shall re-label such product to be consistent with the approved product, in accordance with regulatory requirements from the FDA.

2.2.5. The Offeror shall satisfy any Post Marketing Commitments (PMC) required for maintaining the approval including any studies to monitor safety and efficacy during a nerve agent emergency.

2.3. CLINICAL OBJECTIVES

2.3.1. The Offeror shall conduct all necessary clinical studies to support regulatory approval of midazolam autoinjectors for the treatment of status epilepticus in adult and pediatric populations.

2.3.2. The Offeror shall prepare and submit to BARDA a Final Study Report containing 100% quality controlled data and the completion of the clinical study. This report should be prepared in accordance with FDA and ICH Guidelines.

2.4. CHEMISTRY, MANUFACTURING, CONTROL (CMC) OBJECTIVES

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

2.4.2. The Offeror shall provide a Manufacturing Plan that includes a facility regulatory compliance plan addressing cGMP standards; description of the manufacturing facility quality assurance and regulatory acceptance including quality systems, validation master plan and regulatory milestones.

2.4.3. The Offeror shall complete any remaining manufacturing and quality control activities needed to support FDA approval. And/or, the Offeror shall establish a regulatory strategy and filing processes for successful FDA approval of the product.

2.4.4. The Offeror shall conduct long-term stability studies on midazolam autoinjectors to establish an expiry period of at least three years.

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

a) Final product manufacturing according to cGMP standards, process & equipment validation of analytical methods and assays appropriate for product characterization and product release, including tests for the identity, purity, potency, and for demonstrating stability of midazolam autoinjectors to support FDA approval. Assure selected materials and vendors are cGMP compliant.

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

c) Develop and maintain documentations such as those describing quality control (QC) and quality assurance (QA) monitoring plan, manufacturing process, facility

information, product storage and monitoring inventory systems, process flow for personnel, material and waste disposal.

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

3. SUPPLY AND DELIVERY OF PRODUCT OBJECTIVES (OPTION CLINs 0002 and 0003)

3.1. Delivered Midazolam autoinjectors must be FDA approved or acceptable for use under EUA, in accordance with all federal, state and local regulations, as well as international regulations, if applicable. During the initial option period, the USG estimates procuring 306,000 adult dose autoinjector devices and 54,000 pediatric dose autoinjector devices, and if all options are exercised, the USG estimates procurement of 346,000 autoinjectors for the adult population and 70,000 autoinjectors for the pediatric population. Offerors must propose price per autoinjector, including required labeling/packaging and delivery to SNS/CHEMPACKs. The source of transportation used by the Offeror for the delivery of product must meet USG security requirements. Product will be delivered to the SNS/CHEMPACK Program in a manner consistent with FDA guidance for EUA or FDA Approved Medical Products, under section 564 of the Federal Food, Drug, and Cosmetic Act, which was amended by the Project BioShield Act of 2004 and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013. Further guidance can be found at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/emergency-use-authorization-medical-products-and-related-authorities .

3.2. The Offeror shall store midazolam autoinjectors at their own facility, in compliance with cGMP, until release testing has been completed. The final packaged midazolam autoinjectors will be shipped to and stored at the SNS/CHEMPACKs.

3.3. The Offeror shall maintain cGMP compliance and quality control of stored midazolam autoinjectors and stability assays to ensure expiry dating for the duration of the contract.

4. POST-MARKETING COMMITMENTS AND/OR REQUIREMENTS (OPTION CLINs 0004 and 0007)

4.1. The Offeror shall commit to comply with Post-Marketing Commitments and/or Requirements (PMCR) as specified by the FDA. Cost estimates may be based on tentative plans in place prior to direction from the FDA. Based on guidance from the FDA, select items from section 4 of the Statement of Objectives may be moved to the PMCR section.

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5. ADDITIONAL PROCUREMENT (OPTION CLINS: 0005, 0006, 0008, and 0009)

5.1. During subsequent Option Periods, the USG estimates procuring a total of 346,000 adult dose autoinjector devices and 70,000 pediatric dose autoinjector devices. These efforts include manufacturing, stability testing, and storage. Offerors must propose price per autoinjector, including required labeling/packaging and delivery to SNS/CHEMPACKs.

5.2. To maintain preparedness, the USG shall at its discretion execute optional procurements (See Section 5 for applicable requirements). These option CLINs (**0005, 0006, 0008, and 0009**) shall support procurements of midazolam autoinjectors. The procurement will

consist of fully packaged midazolam autoinjectors in adult and pediatric configurations shipped to the SNS/CHEMPACK Program.

C.2. REPORTING REQUIREMENTS

See Section F for specific reporting requirements.

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

C.3. MEETINGS/SITE VISITS

The Offeror and BARDA/CMA shall participate in regular meetings to coordinate and oversee the contracting effort as requested by the Contracting Officer (CO)/Contracting Officer's Representative (COR). Such meetings may include, but are not limited to, a kickoff meeting to be held at a location determined by the COR, status update meetings and/or teleconferences, site visits to the Offeror's and/or Offeror's subcontractor facilities, and meetings with individual Offerors and other HHS officials to discuss the technical, regulatory, and contractual aspects of the program. The Offeror 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 Offeror to HHS/BARDA and review contract requirements. This meeting usually occurs within a month after contract award. Bi-weekly or monthly status update meetings/teleconferences 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 (anticipate at least twice a year).

Within thirty (30) calendar days of an FDA audit of Offeror or Offeror's subcontractor facilities, the Offeror shall provide copies of the audit findings, final report, and a plan for addressing areas of nonconformance to FDA regulations and guidance for 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 Offeror with 48 hours advance notice. The USG reserves the right to accompany the Offeror on routine and for-cause site-visits/audits of Offeror subcontractor(s). At the discretion of the USG and independent of testing conducted by the Offeror, BARDA reserves the right to conduct site visits/audits and collect samples of product held by the Offeror and Offeror's subcontractor(s).

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

SECTION D – PACKAGING, MARKING AND SHIPPING

D.1. METHOD OF DELIVERY

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

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

D.2. FOB DESTINATION DELIVERIES

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

SECTION E – INSPECTION AND ACCEPTANCE

E.1. INSPECTION AND ACCEPTANCE

Inspection and acceptance of the product, services, and documentation called for herein shall be accomplished by the Contracting Officer or a duly authorized representative. Technical inspection and acceptance will take place at:

Biomedical Advanced Research and Development Authority
Office of the Assistant Secretary for Preparedness and Response
200 C Street, S.W.
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 clause by reference, with the same force and effect as if it were given in full text. Upon request, the Contracting Officer will make its full text available.

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

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

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

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

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

SECTION F – DELIVERIES OR PERFORMANCE

F.1. PERIOD OF PERFORMANCE

The base period of performance of this contract is anticipated for sixty (60) months from the date of award. The period of performance may be extended up to 60 months with the exercise of option(s), structured as CLINs, as set forth in SECTION B.

F.2. DELIVERIES

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

F.3. CONTRACT DELIVERABLES AND REPORTING REQUIREMENTS

F.3.1. Submission of Contract Deliverables

Documents shall be delivered electronically via email to the Contracting Officer (CO), Jill.Johnson@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 Offeror shall submit to the CO and the COR technical progress reports as identified in any potential resultant contract. These reports shall be subject to the technical inspection and requests for clarification by the COR, and approval by the CO/COR. These reports shall be brief, factual, and prepared in accordance with the following format:

A. Monthly Progress Report

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

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

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

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

Progress:

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

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

SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE – This section shall include a description of all meetings, conference calls, etc. that have taken place during the

reporting period. Include progress on administration and management issues (e.g. evaluating and managing subOfferor performance and personnel changes). Offerors must include all Quality Management System, Quality Control, and Quality Assurance Plans as part of this report or as requested by the COR.

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

SECTION II Part D: ISSUES – This section shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress; why the differences have occurred and what corrective actions are planned; and if a project activity is delinquent, then what corrective action steps are planned. Revised timelines shall be provided.

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

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

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

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

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

B. Annual Progress Report

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

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

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

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

Progress:

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

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

SECTION II Part B: MANAGEMENT AND ADMINISTRATIVE UPDATE – This section shall include a description of all meetings, conference calls, etc. that have taken place during the reporting period. Include progress on administration and management issues (e.g. evaluating and managing subOfferor performance and personnel changes). Offerors must include all Quality Management System, Quality Control, and Quality Assurance Plans as part of this report or as requested by the COR.

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

SECTION II Part D: ISSUES – This section shall include a description of problems encountered and proposed corrective action; differences between planned and actual progress; why the differences have occurred and what corrective actions are planned; and if a project activity is delinquent, then what corrective action steps are planned. Revised timelines shall be provided.

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

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

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

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

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

C. Draft Final Report and Final Report

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

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

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

Progress:

SECTION I: EXECUTIVE SUMMARY - Summarize the purpose and scope of the contract effort including a summary of the major accomplishments relative to the specific activities set forth in the Statement of Work.

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

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

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

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

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

d) The Offeror shall provide the COR the opportunity to review and comment upon any documents to be submitted to the FDA or other regulatory agency. The Offeror shall provide the COR with five (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 subOfferor's performance on any award made under this RFP. The Offeror shall make arrangements with the COR for the appropriate BARDA representative(s) to be present during the final debrief by the regulatory inspector.

E. Other Requirements/Deliverables

a) Integrated Master Project Plan

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

I. Critical Path Milestones

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

II. Work Breakdown Structure

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

III. Risk Mitigation Plan/Matrix

The Offeror shall develop and maintain a risk management plan that highlights potential problems 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 **http://www.phe.gov/about/amcg/contracts/Pages/toolkit.aspx**) to be completed by any prospective Offeror. This report shall be due within 90 days of contract award. Updates shall be due as requested by the COR.

1. Technology Packages

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

2. Experimental Protocols

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

3. Annual/Final Invention Report

All reports and documentation required by FAR Clause 52.227-11, Patent Rights-Ownership by the Offeror, including, but not limited to, the invention disclosure report, the confirmatory license, and the Government support certification. An Annual Invention Report shall be due on or before the 30th calendar day after the completion of each

reporting period. A Final Invention Report (see FAR 27.303 (b)(2)(ii)) shall be due on or before the expiration date of the contract. If no invention is disclosed or no activity has occurred on a previously disclosed invention during the applicable reporting period, a negative report shall be submitted to the Contracting Officer.

4. **Publications**

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

5. **Press Releases**

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

6. **Security Report**

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

7. **Security Plan**

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

8. **Quality Management System Plan**

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

9. **Manufacturing Plan**

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

F.4. DELIVERABLE SCHEDULE

Item No.	Description	Addresses	Deliverable Schedule
1	Kickoff Meeting	CO: (1) electronic copy COR: (1) electronic copy	Within 30 days of 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	Bi-Weekly Meetings and Meeting Minutes	CO: (1) electronic copy COR: (1) electronic copy	Meeting minutes are due no later than five business days following each meeting.

3	Monthly Progress Report	CO: (1) electronic copy COR: (1) electronic copy	Reports are due on or before the 15th of each month following the end of each reporting period.
4	Annual Progress Report	CO: (1) electronic copy COR: (1) electronic copy	Reports are due on or before the 30th calendar day following the end of each reporting period.
5	Draft Final Progress Report	CO: (1) electronic copy COR: (1) electronic copy	Report is due 45 Calendar days prior to the expiration date of the contract.
6	Final Progress Report	CO: (1) electronic copy COR: (1) electronic copy	Report is due no later than 30 calendar days after the expiration date of the contract.
7	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 Offeror's minutes, upon receipt of minutes from FDA/ regulatory agency, and upon request from the COR.
8	Integrated Master Project Plan -Critical Path Milestones - Work Breakdown Structure - Risk Mitigation Plan/Matrix	CO: (1) electronic copy COR: (1) electronic copy	Report is due within 90 days of contract award. Updates are due as requested by the COR.
9	Technology Packages	CO: (1) electronic copy COR: (1) electronic copy	Upon request from the COR.
10	Experimental Protocols	CO: (1) electronic copy COR: (1) electronic copy	Upon request from the COR.
11	Annual/Final Invention Report	CO: (1) electronic copy COR: (1) electronic copy	An Annual Invention Report is due on or before the 30th calendar day after the completion of each reporting period. A Final Invention Report is due on or before the expiration date of the contract.
12	Publications	CO: (1) electronic copy COR: (1) electronic copy	Reports are due within 30 calendar days for manuscripts and 15 calendar days for abstracts.
13	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.
14	Incident Report	CO: (1) electronic copy	Reports are due within 24 hours after occurrence

		COR: (1) electronic copy	of an activity or incident.
15	Security Plan	CO: (1) electronic copy COR: (1) electronic copy	Final plan due within 30 days of contract award.
16	Manufacturing Plan	CO: (1) electronic copy COR: (1) electronic copy	Due within 60 days of contract award.
17	Quality Management System Plan	CO: (1) electronic copy COR: (1) electronic copy	Due within 30 days of contract award
18	Go/No-Go In-Process Review (IPR)	CO: (1) electronic copy COR: (1) electronic copy	Contractor shall provide presentation materials to CO and COR 10 business days prior to the IPR. Submit written justification of progress towards satisfying Go/No-Go criteria. CO/COR will provide a written response within 10 days.
19	Standard Operating Procedures	CO: (1) electronic copy	Upon request from the CO.
20	FDA Audits	CO: (1) electronic copy COR: (1) electronic copy	Notify the CO and COR within 10 business days of a scheduled FDA audit or within 24 hours of an ad hoc site visit/audit if FDA does not provide advance notice. Provide copies of any FDA audit report received from subcontractors that occur as a result of this contract or for this product within 5 business days of receiving correspondence from the FDA or third party. Within 10 business days of audit report, provide CO with a plan for addressing areas of nonconformance, if any are identified.
21	QA Audit Reports	CO: (1) electronic copy COR: (1) electronic copy	Notify CO and COR 10 days in advance of upcoming, ongoing, or recent audits/site visits of subcontractors as part of weekly communications. Notify CO and COR within 5 business days of report completion.
22	BARDA Audit	CO: (1) electronic copy COR: (1) electronic copy	If issues are identified during the audit, Contractor shall submit a report to the CO and COR detailing the finding(s) and corrective action(s) within 10 business days of the audit. The CO and COR will review the report and provide a response to the Contractor within 10 business days. Once corrective action is completed, the Contractor will provide a final report to the CO and COR.
23	Raw Data/Data Analysis		Contractor shall provide data or data analysis to the CO and COR within 20 business days of request, amend reports if required, and adjudicate all comments.

24	Clinical Study Status Update	CO: (1) electronic copy COR: (1) electronic copy	Contractor shall submit updates to COR by the end of the 25th business day of each new month and during biweekly meetings.
25	Delivery Schedule to the ASPR/SNS as described in Section C: Procurement and Delivery of Product Objectives, and Additional Procurement	CO: (1) electronic copy COR: (1) electronic copy	Due within 30 days of contract award

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 (August 1989)

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

SECTION G – CONTRACT ADMINISTRATION

G.1. CONTRACTING OFFICER (CO)

The Contracting Officer is the only individual who can legally commit and bind the Government to the expenditure of public funds. No person other than the 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 Offeror for any costs incurred during the performance of this contract; (5) obligate or de-obligate funds into the contract; (6) sign written licensing agreements; or (7) otherwise change any terms and conditions of this contract.

No information, other than that which may be contained in an authorized modification to this contract duly issued by the 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:

To be identified at the time of contract award.

As delegated by the CO, the COR is responsible for: (1) monitoring the Offeror's technical progress, including the surveillance and assessment of performance and recommending to the 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. OFFEROR'S POINTS OF CONTACT

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

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

The key personnel specified in this contract are considered to be essential to work performance. At least 30 days prior to the Offeror voluntarily diverting any of the specified individuals to other programs or contracts the Offeror shall notify the Contracting Officer and shall submit a justification for the diversion or replacement and a request to replace the individual. The request must identify the proposed replacement and provide an explanation of how the replacement's skills, experience, and credentials meet or exceed the requirements of the contract (including, when applicable, Human Subjects Testing requirements). If the employee of the Offeror is terminated for cause or separates from the Offeror voluntarily with less than thirty (30) days' notice, the Offeror shall provide the maximum notice practicable under the circumstances. The Offeror shall not divert, replace, or announce any such change to key personnel without the written consent of the Contracting Officer. 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	Program Director (PD)/Principal Investigator (PI)
TBD	Chief Scientific/Medical Officer
TBD	Clinical Development/Clinical Study Director
TBD	Nonclinical Development Lead
TBD	Quality Assurance (QA)
TBD	Quality Control (QC)
TBD	Manufacturing Lead
TBD	Regulatory Affairs (Lead)
TBD	Pharmacovigilance (Lead)
TBD	Project Manager

G.5. INVOICE SUBMISSION

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

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

1. Offeror's Name & Address

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

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

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

(e) The Offeror shall include the following certification at the bottom of the payment request: "I hereby certify that the salaries billed in this payment request are in compliance with the current HHS Salary Rate Limitation Provisions in Section I of the contract."

G.6. CONTRACT COMMUNICATIONS/CORRESPONDENCE

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

G.7. POST AWARD EVALUATION OF OFFEROR PERFORMANCE

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

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

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

(d) *Performance Evaluation Factors*: The Offeror's performance will be evaluated in accordance with FAR Subpart 42.15 and Attachment #5, Contract Performance Evaluation Report.

(e) Offeror *Review*: A copy of the evaluation will be provided to the Offeror as soon as practicable after completion of the evaluation. The Offeror 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* Offeror: 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, Offeror's response, and review comments, if any, will be retained as part of the evaluation.

(g) *Release of* Offeror *Performance Evaluation Information*: The completed evaluation will not be released to other than Government personnel and the Offeror whose performance is being evaluated. Disclosure of such information could cause harm both to the commercial interest of

the Government and to the competitive position of the Offeror being evaluated, as well as impede the efficiency of Government operations.

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

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

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

G.8 NEGOTIATED INDIRECT COST RATES (Applied to CPFF CLINs)

(a) Notwithstanding the provisions of the clause entitled "Allowable Cost and Payment" in Section I, Contract Clauses, allowable indirect costs under this contract shall be obtained by applying negotiated indirect cost rates to bases agreed upon by the parties, as specified below.

(b) Pending establishment of final rates for any period, the Contractor shall be reimbursed for allowable indirect costs at the following rate(s):

CLASS	PERIOD	TYPE	RATE	BASE

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.

1. Non-Clinical Terms of Award

This contract does not involve the use of animals.

2. Clinical Terms of Award

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

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

a. Safety and Monitoring Issues

i. Institutional Review Board or Independent Ethics Committee Approval

Within 30 days of award and then with the annual progress report, the Contractor must submit to the COR a copy of the current IRB-or IEC-approved informed consent document, documentation of continuing review and approval and the OHRP federal wide assurance number for the institution or site.

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

The Contractor must ensure that the application as well as all protocols is reviewed by their IRB or IEC.

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

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

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

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

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

ii. Data and Safety Monitoring Requirements

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

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

Final decisions regarding the type of monitoring to be used must be made jointly by BARDA and the Contractor before enrollment starts. Discussions with the responsible BARDA Project Officer regarding appropriate safety monitoring and approval of the final monitoring plan by BARDA must occur before patient enrollment begins and may include discussions about the appointment of one of the following.

- **Independent Safety Monitor** – a physician or other appropriate expert who is independent of the study and available in real time to review and recommend appropriate action regarding adverse events and other safety issues.
- **Independent Monitoring Committee (IMC) or Safety Monitoring Committee (SMC)** – a small group of independent investigators and biostatisticians who review data from a particular study.

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

When a monitor or monitoring board is organized, a description of it, its charter or operating procedures (including a proposed meeting schedule and plan for review of adverse events), and roster and *curriculum vitae* from all members must be submitted to and approved by the COR before enrollment starts. The Contractor will also ensure that the monitors and board members report any conflicts of interest and the Contractor will maintain a record of this. The Contractor will share conflict of interest reports with the CO and COR.

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

iii. BARDA Protocol Review Process Before Patient Enrollment Begins

The COR has a responsibility to ensure that mechanisms and procedures are in place to protect the safety of participants in BARDA-supported clinical trials. Therefore, before patient accrual or participant enrollment, the Contractor must ensure the following (as applicable) are in place at each participating institution, prior to patient accrual or enrollment:

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

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

iv. Investigational New drug or Investigational Device Exemption Requirements

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

Administration (FDA) investigational new drug (IND) or investigational device exemption (IDE).

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

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

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

v. Required Time-Sensitive Notification

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

i. Expedited safety report of unexpected or life-threatening experience or death: A copy of any report of unexpected or life-threatening experience or death associated with the use of an IND drug, which must be reported to FDA by telephone or fax as soon as possible but no later than seven (7) days after the IND sponsor's receipt of the information, must be submitted to the COR within 24 hours of FDA notification.

ii. Expedited safety reports of serious and unexpected adverse experiences: A copy of any report of unexpected and serious adverse experience associated with use of an IND drug or any finding from tests in laboratory animals that suggests a significant risk for human subjects, which must be reported in writing to FDA as soon as possible but no later than 15 days after the IND sponsor's receipt of the information, must be submitted to the COR within 24 hours of FDA notification. For medical devices, adverse events should be reported under the MedWatch (MDR) program with reporting timelines of 5 days for serious adverse events or 30 days for reportable events.

iii. IDE reports of unanticipated adverse device effect:

A copy of any reports of unanticipated adverse device effect submitted to FDA must be submitted to the COR within 24 hours of FDA notification.

iv. Expedited safety reports: Sent to the COR concurrently with the report to FDA.

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

In case of problems or issues, the Contracting Officer's Representative will contact the Contractor within ten (10) business days by email or fax, followed within thirty (30) calendar days by an official letter to the Contractor's Project Manager, with a copy to the institutions' office of sponsored programs, listing issues and appropriate actions to be discussed.

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

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

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

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

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

c. Contractors involving other agencies or institutions in activities considered to be engaged in research involving human subjects must ensure that such other agencies or institutions obtain their own FWA if they are routinely engaged in research involving human subjects or ensure that such agencies or institutions are covered by the Contractors' FW' via designation as agents of the institution of via individual investigator agreements (see OHRP website at: http://www.hhs.gov/ohrp/policy/guidanceonalternativetofwa.pdf - PDF).

d. If at any time during the performance of this contract, the Contractor is not in compliance with any of the requirements and/or standards stated in paragraphs (a) and (b) above, the Contracting Officer may immediately suspend, in whole or in part, work and further payments under this contract until the Contractor corrects the noncompliance. The Contracting Officer may communicate the notice of suspension by telephone with confirmation in writing. If the Contractor fails to complete corrective action within the period of time designated in the Contracting Officer's written notice of suspension, the Contracting Officer may, after consultation with OHRP, terminate this contract in whole or in part.

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

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

The Contractor shall provide written documentation that all human materials obtained as a result of research involving human subjects conducted under this contract, by collaborating sites, or by subcontractors identified under this contract, were obtained with prior approval by the Office for Human Research Protections (OHRP) of an Assurance to comply with the requirements of 45 CFR 46 to protect human research subjects. This restriction applies to all collaborating sites without OHRP- approved Assurances, whether domestic or foreign, and compliance must be ensured by the Contractor.

Provision by the Contractor to the Contracting Officer of a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263(formerly Optional Form 310), certifying IRB review and approval of the protocol from which the human materials were obtained constitutes the written documentation required. The human subject certification can be met by submission of a self-designated form provided that it contains the information required by the "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 (formerly Optional Form 310).

H.4. RESEARCH INVOLVING HUMAN FETAL TISSUE

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

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

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 CRF Parts 120-130) and /or the Department of Commerce regarding the Export Administration Regulations (15 CRF 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. EPA ENERGY STAR REQUIREMENTS

In compliance with Executive Order 12845 (requiring Agencies to purchase energy efficient computer equipment), all microcomputers, including personal computers, monitors, and printers that are purchased using Government funds in performance of a contract shall be equipped with or meet the energy efficient low-power standby feature as defined by the EPA Energy Star program unless the equipment always meets EPA Energy Star efficiency levels. The microcomputer, as configured with all components, must be Energy Star compliant.

This low-power feature must already be activated when the computer equipment is delivered to the agency and be of equivalent functionality of similar power managed models. If the equipment will be used on a local area network, the vendor must provide equipment that is fully compatible with the network environment. In addition, the equipment will run commercial off-the-shelf software both before and after recovery from its energy conservation mode.

H.16. ACKNOWLEDGMENT OF FEDERAL FUNDING

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

Publication and Publicity

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, Section 507 of P.L. 104-208 mandates that Contractors funded with Federal dollars, in whole or in part, acknowledge Federal funding when issuing statements, press releases, requests for proposals, bid solicitations and other documents. Contractors are required to state:

(1) The percentage and dollar amounts of the total program or project costs financed with Federal money and;

(2) The percentage and dollar amount of the total costs financed by 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; Office of the Assistant Secretary for Preparedness and Response; 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 two (2) business days prior to the issuance of the press release.

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

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

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 I 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.

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 http://www.hhs.gov/ocr/privacy/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 of death greater than that allowed for research on fetuses in utero under 45 CFR part 46 and Section 498(b) of the Public Health Service Act (42 U.S.C. 289g(b)).
c. The term ``human embryo or embryos'' includes any organism, not protected as a human subject under 45 CFR part 46 as of the date of the enactment of this Act, that is derived by fertilization, parthenogenesis, cloning, or any other means from one or more human gametes of human diploid cells.
d. The Contractor shall not use any Federal funds for the cloning of human beings.

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; Office of the Assistant Secretary for Preparedness and Response. ASPR defines the author's final manuscript as the final version accepted for journal publication, and includes all modifications from the publishing peer review process. The PMC archive will preserve permanently these manuscripts for use by the public, health care providers, educators, scientists, and ASPR. The Policy directs electronic submissions to the NIH/NLM/PMC: http://www.pubmedcentral.nih.gov.

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/cgi-bin/text-idx?tpl=/ecfrbrowse/Title45/45cfr94_main_02.tpl

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 interested 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 though 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/far/index.html

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	52.203-7	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	5.203-11	Sep 2007	Certification and Disclosure Regarding Payments to Influence Certain Federal Transactions
FAR	52.203-12	Jun 2020	Limitation on Payments to Influence Certain Federal Transactions
FAR	52.203-13	Jun 2020	Contractor Code of Business Ethics and Conduct
FAR	52.203-14	Jun 2020	Display of Hotline Poster(s)
FAR	52.203-17	Jun 2020	Contractor Employee Whistleblower Rights and Requirement To Inform Employees of Whistleblower Rights
FAR	52.203-18	Jan 2017	Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements-Representation.
FAR	52.203-19	Jan 2017	Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements
FAR	52.204-4	May 2011	Printed or Copied Double-Sided on Postconsumer Fiber Content Paper
FAR	52.204-5	Oct 2014	Women-Owned Business (Other than Small Business)
FAR	52.204-7	Oct 2018	System for Award Management
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	52.207-1	May 2006	Notice of Standard Competition
FAR	52.209-5	Aug 2020	Certification Regarding Responsibility Matters
FAR	52.209-6	Jun 2020	Protecting the Government's Interests When Subcontracting With Contractors Debarred, Suspended, or Proposed for Debarment
FAR	52.209-9	Oct 2018	Updates of Publicly Available Information Regarding Responsibility Matters
FAR	52.209-10	Nov 2015	Prohibition on Contracting with Inverted Domestic Corporations
FAR	52.210-1	Jun 2020	Market Research
FAR	52.215-2	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	Jun 2020	Integrity of Unit Prices
FAR	52.215-15	Oct 2010	Pension Adjustments and Asset Reversions

FAR	52.215-18	Jul 2005	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) other than Pensions
FAR	52.215-19	Oct 1997	Notification of Ownership Changes
FAR	52.215-21	Jun 2020	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	Oct 2018	Utilization of Small Business Concerns
FAR	52.219-9	Jun 2020	Small Business Subcontracting Plan
FAR	52.219-16	Jan 1999	Liquidated Damages - Subcontracting Plan
FAR	52.219-28	May 2020	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	52.222-21	Apr 2015	Prohibition of Segregated Facilities
FAR	52.222-24	Feb 1999	Preaward On-site Equal Opportunity Compliance Evaluation
FAR	52.222-25	Apr 1984	Affirmative Action Compliance
FAR	52.222-26	Sept 2016	Equal Opportunity
FAR	52.222-35	Jun 2020	Equal Opportunity for Veterans
FAR	52.222-36	Jun 2020	Equal Opportunity for Workers with Disabilities
FAR	52.222-37	Jun 2020	Employment Reports on Veterans
FAR	52.222-38	Feb 2016	Compliance with Veterans' Employment Reporting Requirements
FAR	52.222-40	Dec 2010	Notification of Employee Rights Under the National Labor Relations Act
FAR	52.222-50	Oct 2020	Combating Trafficking in Persons
FAR	52.222-54	Oct 2015	Employment Eligibility Verification
FAR	52.223-6	May 2001	Drug-Free Workplace
FAR	52.223-18	Jun 2020	Encouraging Contractor Policy to Ban Text Messaging While Driving
FAR	52.225-13	Jun 2008	Restrictions on Certain Foreign Purchases
FAR	52.225-25	Jun 2020	Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran—Representation and Certifications
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	52.227-15	Dec 2007	Representation of Limited Rights Data and Restricted Computer Software
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 2020	Administration of Cost Accounting Standards
FAR	52.230-7	Apr 2005	Proposal Disclosure-Cost Accounting Practice Changes
FAR	52.232-2	Apr 1984	Payments under Fixed-Price Research and Development Contracts
FAR	52.232-9	Apr 1984	Limitation on Withholding of Payments
FAR	52.232-17	May 2014	Interest
FAR	52.232-20	Apr 1984	Limitation of Cost
FAR	52.232-22	Apr 1984	Limitation of Funds
FAR	52.232-23	May 2014	Assignment of Claims
FAR	52.232-25	Jan 2017	Prompt Payment

FAR	52.232-33	Oct 2018	Payment by Electronic Funds Transfer--System for Award Management
FAR	52.232-39	Jun 2013	Unenforceability of Unauthorized Obligations
FAR	52.232-40	Dec 2013	Providing Accelerated Payments to Small Business 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	May 2014	Penalties for Unallowable Costs
FAR	52.242-4	Jan 1997	Certification of Final Indirect Costs
FAR	52.242-13	Jul 1995	Bankruptcy
FAR	52.243-1	Aug 1987	Changes - Fixed-Price Alternate V (Apr 1984).
FAR	52.243-2	Aug 1987	Changes—Cost-Reimbursement Alternate V (Apr 1984).
FAR	52.243-6	Apr 1984	Change Order Accounting
FAR	52.243-7	Jan 2017	Notification of Changes
FAR	52.244-2	Jun 2020	Subcontracts, Alternate 1 (Jun 2020)
FAR	52.244-5	Dec 1996	Competition in Subcontracting
FAR	52.244-6	Oct 2020	Subcontracts for Commercial Items
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	52.249-9	Apr 1984	Default (Fixed-Price Research and Development)
FAR	52.249-14	Apr 1984	Excusable Delays
FAR	52.253-1	Jan 1991	Computer Generated Forms

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

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

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	352.222-70	Dec 2015	Contractor Cooperation in Equal Employment Opportunity Investigations
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	352.233-71	Dec 2015	Litigation and Claims
HHSAR	352.237-75	Dec 2015	Key Personnel
HHSAR	352.239-74	Dec 2015	Electronic and Information Technology Accessibility
HHSAR	352.270-5a	Dec 2015	Notice of Offerors of Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals
HHSAR	352.270-6	Dec 2015	Restriction on use of Human Subjects
HHSAR	352.270-9	Dec 2015	Non-Discrimination for Conscience

I.3. ADDITIONAL CONTRACT CLAUSES

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

52.217-6 Option for Increased Quantity (Mar 1989)

The Government may increase the quantity of supplies called for in the Schedule at the unit price specified. The Contracting Officer may exercise the option by written notice to the Contractor within 10 days of exercise of the option. Delivery of the added items shall continue at the same rate as the like items called for under the contract, unless the parties otherwise agree.

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, including the exercise of any options under this clause, 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. Invoice Instructions for Cost Reimbursement Contracts
3. Invoice Instructions for Fixed Price Contracts
4. Sample Invoice Form
5. Proposal Intent Response Form
6. Protection of Human Subjects
   https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/index.html
7. HHS Section 508 Product Assessment Template
   http://www.hhs.gov/web/508/contracting/technology/vendors.html
8. Breakdown of Proposed Costs with Excel Spreadsheet (Click on "Electronic Contract Business Proposal")
   https://oamp.od.nih.gov/content/breakdown-proposed-estimated-cost-plus-fee-and-labor-hours
9. Summary of Related Activities
10. ACH Vendor/ Miscellaneous Payment Enrollment Form
11. SF-LLL, Disclosure of Lobbying Activities, with Instructions:

    https://www.gsa.gov/forms-library/disclosure-lobbying-activities
12. Small Business Subcontracting Plan
13. Risk Mitigation Plan/Matrix Template
14. Past Performance Questionnaire
15. BARDA Security Requirements
16. 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. 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. FAR 52.203-11 INCORPORATION BY REFERENCE OF CERTIFICATION AND DISCLOSURE REGARDING PAYMENTS TO INFLUENCE CERTAIN FEDERAL TRANSACTIONS (SEPT 2007)

K.2. FAR 52.204-8 ANNUAL REPRESENTATIONS AND CERTIFICATIONS (Mar 2020)

(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 which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

(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) 52.209-2, Prohibition on Contracting with Inverted Domestic Corporations—Representation.
(vii) 52.209-5; Certification Regarding Responsibility Matters. This provision applies to solicitations where the contract value is expected to exceed the simplified acquisition threshold.
(viii) 52.209-11, Representation by Corporations Regarding Delinquent Tax Liability or a Felony Conviction under any Federal Law. This provision applies to all solicitations.
(ix) 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.
(x) 52.215-6, Place of Performance. This provision applies to solicitations unless the place of performance is specified by the Government.
(xi) 52.219-1, Small Business Program Representations (Basic & Alternate I). This provision applies to solicitations when the contract will be performed in the United States or its outlying areas.

(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.

(xii) 52.219-2, Equal Low Bids. This provision applies to solicitations when contracting by sealed bidding and the contract will be performed in the United States or its outlying areas.
(xiii) 52.222-22, Previous Contracts and Compliance Reports. This provision applies to solicitations that include the clause at 52.222-26, Equal Opportunity.
(xiv) 52.222-25, Affirmative Action Compliance. This provision applies to solicitations, other than those for construction, when the solicitation includes the clause at 52.222-26, Equal Opportunity.
(xv) 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 items.
(xvi) 52.223-1, Biobased Product Certification. This provision applies to solicitations that require the delivery or specify the use of USDA-designated items; or include the clause at 52.223-2, Affirmative Procurement of Biobased Products Under Service and Construction Contracts.
(xvii) 52.223-4, Recovered Material Certification. This provision applies to solicitations that are for, or specify the use of, EPA- designated items.
(xviii) 52.223-22, Public Disclosure of Greenhouse Gas Emissions and Reduction Goals—Representation. This provision applies to solicitations that include the clause at 52.204-7.

(xix) 52.225-2, Buy American Certificate. This provision applies to solicitations containing the clause at 52.225-1.
(xx) 52.225-4, Buy American--Free Trade Agreements--Israeli Trade Act Certificate. (Basic, Alternates I, II, and III.) This provision applies to solicitations containing the clause at 52.225- 3.

(A) If the acquisition value is less than $25,000, the basic provision applies.
(B) If the acquisition value is $25,000 or more but is less than $50,000, the provision with its Alternate I applies.
(C) If the acquisition value is $50,000 or more but is less than $80,317, the provision with its Alternate II applies.
(D) If the acquisition value is $80,317 or more but is less than $100,000, the provision with its Alternate III applies.

(xxi) 52.225-6, Trade Agreements Certificate. This provision applies to solicitations containing the clause at 52.225-5.
(xxii) 52.225-20, Prohibition on Conducting Restricted Business Operations in Sudan--Certification. This provision applies to all solicitations.
(xxiii) 52.225-25, Prohibition on Contracting with Entities Engaging in Certain Activities or Transactions Relating to Iran—Representation and Certification. This provision applies to all solicitations.
(xxiv) 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) 52.223-9, with its Alternate I, Estimate of Percentage of Recovered Material Content for EPA-Designated Products (Alternate I only).
___ (vii) 52.227-6, Royalty Information.
___ (A) Basic.
___ (B) Alternate I.
___ (viii) 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 accessed through https://www.sam.gov. After reviewing the SAM information, the Offeror verifies by submission of the offer that the representations and certifications currently posted electronically that apply to this solicitation as indicated in paragraph (c) of this provision have been entered or updated within the last 12 months, are current, accurate, complete, and applicable to this solicitation (including the business size standard applicable to the NAICS code referenced for this solicitation), as of the date of this offer and are incorporated in this offer by reference (see FAR 4.1201); except for the changes identified below [Offeror to insert changes, identifying change by clause number, title, date]. These amended representation(s) and/or certification(s) are also incorporated in this offer and are current, accurate, and complete as of the date of this offer.

FAR Clause	Title	Date	Change

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

(End of provision)

K.3. FAR 52.204-17 INCORPORATION BY REFERENCE OF 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 (Oct 2020)

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

K.7. FAR 52.209-5 CERTIFICATION REGARDING RESPONSIBILITY MATTERS (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 □ 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 nonresponsible.

(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 (FAPIIS) is current, accurate, and complete as of the date of submission of this offer with regard to the following information:

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

(i) In a criminal proceeding, a conviction.

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

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

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

(B) The payment of a reimbursement, restitution, or damages in excess of $100,000.

(iv) In a criminal, civil, or administrative proceeding, a disposition of the matter by consent or compromise with an acknowledgment of fault by the Contractor if the proceeding could

have led to any of the outcomes specified in paragraphs (c)(1)(i), (c)(1)(ii), or (c)(1)(iii) of this provision.

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

(d) The offeror shall post the information in paragraphs (c)(1)(i) through (c)(1)(iv) of this provision in FAPIIS as required through maintaining an active registration in the System for Award Management which can be accessed via https://www.sam.gov (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, State, County, ZIP Code)	Name and Address of Owner and Operator of the Plant or Facility if Other than Offeror or Respondent
_____	_____
_____	_____

(End of provision)

K.10. FAR 52.219-1 SMALL BUSINESS PROGRAM REPRESENTATIONS (Mar 2020)

(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. It automatically qualifies as a women-owned small business concern eligible under the WOSB Program.

"Service-disabled veteran-owned small business concern"—

(1) Means a small business concern—

(i) Not less than 51 percent of which is owned 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.

(2) "Service-disabled veteran" 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). 38 U.S.C. 101(16).

"Small business concern" means a concern, including its affiliates that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and

qualified as a small business under the criteria in 13 CFR Part 121 and the size standard in paragraph (b) of this provision.

"Small disadvantaged business concern," consistent with 13 CFR 124.1002, 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 $750,000 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.

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

(2) The small business size standard is 1,000 employees.

(3) The small business size standard for a concern which submits an offer in its own name, other than on a construction or service contract, but which proposes to furnish a product which it did not itself manufacture, is 500 employees.

(c) Representations.

(1) The Offeror represents as part of its offer that it □ is, □ is not a small business concern.

(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 o is, o is not, a small disadvantaged business concern as defined in 13 CFR 124.1002.

(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 o is, o is not a women-owned small business concern.

(4) Women-owned small business (WOSB) concern eligible under the WOSB Program. [Complete only if the Offeror represented itself as a women-owned small business concern in paragraph (c)(3) of this provision.] The Offeror represents as part of its offer that—

(i) It is, is not a WOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It is, is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (c)(4)(i) of this provision is accurate for each WOSB concern eligible under the WOSB Program participating in the joint venture. [The Offeror shall enter the name or names of the WOSB concern eligible under the WOSB Program and other small businesses that are participating in the joint venture: _____.] Each WOSB concern eligible under the WOSB Program participating in the joint venture shall submit a separate signed copy of the WOSB representation.

(5) Economically disadvantaged women-owned small business (EDWOSB) concern. [Complete only if the Offeror represented itself as a women-owned small business concern eligible under the WOSB Program in (c)(4) of this provision.] The Offeror represents as part of its offer that—

(i) It □ is, □ is not an EDWOSB concern eligible under the WOSB Program, has provided all the required documents to the WOSB Repository, and no change in circumstances or adverse decisions have been issued that affects its eligibility; and

(ii) It □ is, □ is not a joint venture that complies with the requirements of 13 CFR part 127, and the representation in paragraph (c)(5)(i) of this provision is accurate for each EDWOSB concern participating in the joint venture. [The Offeror shall enter the name or names of the EDWOSB concern and other small businesses that are participating in the joint venture: _____.] Each EDWOSB concern participating in the joint venture shall submit a separate signed copy of the EDWOSB representation.

(6) [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 o is, o is not a veteran-owned small business concern.

(7) [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 o is, o is not a service-disabled veteran-owned small business concern.

(8) [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, on the List of Qualified HUBZone Small Business Concerns maintained by the Small Business Administration, and no material changes in ownership and control, principal office, or HUBZone employee percentage have occurred since it was certified in accordance with 13 CFR Part 126; and

(ii) It □ is, □ is not a HUBZone joint venture that complies with the requirements of 13 CFR Part 126, and the representation in paragraph (c)(8)(i) of this provision is accurate for each HUBZone small business concern participating in the HUBZone joint venture. [The Offeror shall enter the names of each of the HUBZone small business concerns participating in the HUBZone joint venture: _____.] Each HUBZone small business concern participating in the HUBZone joint venture shall submit a separate signed copy of the HUBZone representation.

(d) Notice.

(1) If this solicitation is for supplies and has been set aside, in whole or in part, for small business concerns, then the clause in this solicitation providing notice of the set-aside contains restrictions on the source of the end items to be furnished.

(2) 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—

(i) Be punished by imposition of fine, imprisonment, or both;

(ii) Be subject to administrative remedies, including suspension and debarment; and

(iii) Be ineligible for participation in programs conducted under the authority of the Act.

K.11 FAR 52.232-40 PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS (Dec 2013)

(a) Upon receipt of accelerated payments from the Government, the Offeror shall make accelerated payments to its small business subcontractors under this contract, to the maximum

extent practicable and prior to when such payment is otherwise required under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subOfferor.

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

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

SECTION L – INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS

L.1. CONTRACT TYPE

This RFP is being solicited as Full and Open Competition, cost reimbursement/firm fixed-price hybrid type contract. The Government reserves the right to make multiple awards off of 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 visit of the manufacturing plant 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 July 19, 2021 at 4:00 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 Jill.Johnson@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, DUNS 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 EVALUATION 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 no page limit for mandatory evaluation criteria.**

C. TECHNICAL PROPOSAL

The technical proposal shall consist of a cover page, table of contents, responses to the technical evaluation criteria and the information requested in the SOO in the form of a Statement of Work (SOW). Appendices may be provided with the technical proposal, with the appropriate tabs. **The total technical proposal submission, including appendices, shall not exceed 200 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 EVALUATION 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 Evaluation 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.5. 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. The proposed technical approach shall be in line with the proposed regulatory pathway to achieve marketing authorization of the midazolam autoinjector devices.

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 200-page total limit)**
- Proposal Title Page including RFP title, number, name of organization and DUNs 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 activities to be performed by the Offeror and all proposed subcontractors to expand capabilities (example: non-clinical efficacy studies, clinical studies, etc.), including identification of all proposed subcontractors and a list of key personnel for the Offeror and the proposed subcontractors with degrees, titles and roles within the project.

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

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

a. Product and facility availability for production and procurement under optional CLINs 0002 and 0003 is estimated at 306,000 adult dose autoinjector devices and 54,000 pediatric dose autoinjector devices. If all options are exercised, an additional amount of 346,000 autoinjector devices for the adult population and 70,000 for the pediatric population may also be procured. The USG has the discretion to determine the timing and the amount of product to be procured based upon the Offeror's proposal, cost per autoinjector device, and availability of funds.

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

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

(3) Section 3: Technical Criteria
The Statement of Objectives, included as 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. This plan shall be in as much detail as considered necessary to fully explain the proposed technical approach or method. In

the event that the Offeror has already performed activities that achieve objectives set forth in the SOO, the proposal shall note the activities that have already been accomplished against a given objective, instead of proposing work to meet said objective. The proposal shall reflect a clear understanding of the nature of the work being undertaken. The proposal must include information on how the project is to be organized, staffed, and managed. This information shall demonstrate the Offeror's understanding of important events or tasks and their management. The Offeror shall explain how the management and coordination of consultant and/or subOfferor 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 negotiations 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) **Protection of Human Subjects (Attachment #6):** Offeror(s) shall represent how they will adequately address the requirements for protection of human subjects, when applicable, as required under http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

5) HHS Section 508 Product Assessment Template **(Attachment #7)**

6) Vendor Payment Enrollment Form **(Attachment #10)**

7) Other supporting documents as necessary.

L.5. BUSINESS PROPOSAL

L.5.1 Business Proposal Instructions

The proposal must be signed by an official authorized to bind the Offeror's organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. The business proposal for all CLINs must contain sufficient information to allow the Government to perform a basic analysis of the proposed cost (Cost-Reimbursement CLINs) or price (Fixed Price CLINs) of the work. This information shall include the amounts of the basic elements of the proposed cost or price. These elements must include, as applicable, direct labor, fringe benefits, travel, materials, subcontracts, purchased parts, shipping, indirect costs and rate, fee, and profit. **Offerors must propose costs for each CLIN in Section B separately (different tabs or separate spreadsheets). Offerors must submit proposals for these procurement CLINs appropriately as outlined in Section C. However, for the purpose of developing the business proposal, use the following breakdown:**

FFP CLINs	Number of Dose Autoinjector Devices
CLIN 0002	**306,000 Adult Dose Autoinjectors**
CLIN 0003	**54,000 Pediatric Dose Autoinjectors**
CLIN 0005	**173,000 Adult Dose Autoinjectors**
CLIN 0006	**35,000 Pediatric Dose Autoinjectors**
CLIN 0008	**173,000 Adult Dose Autoinjectors**
CLIN 0009	**35,000 Pediatric Dose Autoinjectors**

CLIN-0001 (Late Stage Development & Approval/Licensure): Costs shall be broken out for each sub-CLIN consistent with the organization of the Technical Proposal (see Section L.4.1).

CLIN-0002 (Initial Procurement of Adult Autoinjector Devices): Although procurement of ***approximately*** 306,000 autoinjectors may be supported by this CLIN, the Business Proposal for initial procurement shall be aligned with the Offeror's ***realistic capacity*** to deliver product in addition to the corresponding price per autoinjector device. Offerors are encouraged to provide volume discounts for CLINs 0002, 0003, 0005, 0006, 0008, and 0009.

CLIN-0003 (Initial Procurement of Pediatric Autoinjector Devices): Although procurement of ***approximately*** 54,000 autoinjectors may be supported by this CLIN, the Business Proposal for initial procurement shall be aligned with the Offeror's ***realistic capacity*** to deliver product in addition to the corresponding price per autoinjector device. Offerors are encouraged to provide volume discounts for CLINs 0002, 0003, 0005, 0006, 0008, and 0009.

CLIN-0004 (Post marketing commitments and manufacturing optimizations): This CLIN may be utilized to support additional post-marketing requirements for the status epilepticus indication and additional manufacturing optimizations. The costs outlined within the Business Proposal shall be consistent with the development plan detailed in the Technical Proposal.

CLIN-0005 (Additional Procurement of Adult Autoinjector Devices): This CLIN may be utilized to support additional procurement phases for approximately 173,000 autoinjectors. The Offeror shall provide pricing per CLIN that address the specifics of these procurement phases with respect to adult autoinjectors for delivery to SNS/CHEMPACK. Within the Business Proposal, costs for these CLINs shall rely upon "not to exceed" autoinjector values. Offerors are encouraged to provide volume discounts for CLINs 0002, 0003, 0005, 0006, 0008, and 0009.

CLIN-0006 (Additional Procurement of Pediatric Autoinjector Devices): This CLIN may be utilized to support additional procurement phases for approximately 35,000 autoinjectors. The Offeror shall provide pricing per CLIN that address the specifics of these procurement phases with respect to pediatric

autoinjectors for delivery to SNS/CHEMPACK. Within the Business Proposal, costs for these CLINs shall rely upon “not to exceed” autoinjector values. Offerors are encouraged to provide volume discounts for CLINs 0002, 0003, 0005, 0006, 0008, and 0009.

CLIN-0007 (Post-marketing Commitments and manufacturing optimizations): This CLIN may be utilized to support additional post-marketing requirements for the status epilepticus indication, and additional manufacturing optimizations. The costs outlined within the Business Proposal shall be consistent with the development plan detailed in the Technical Proposal

CLIN-0008 (Additional Procurement of Adult Autoinjector Devices): This CLIN may be utilized to support additional procurement phases for approximately 173,000 autoinjectors. The Offeror shall provide pricing per CLIN that address the specifics of these procurement phases with respect to adult autoinjectors for delivery to SNS/CHEMPACK. Within the Business Proposal, costs for these CLINs shall rely upon “not to exceed” autoinjector values. Offerors are encouraged to provide volume discounts for CLINs 0002, 0003, 0005, 0006, 0008, and 0009.

CLIN-0009 (Additional Procurement of Pediatric Autoinjector Devices): This CLIN may be utilized to support additional procurement phases for approximately 35,000 autoinjectors. The Offeror shall provide pricing per CLIN that address the specifics of these procurement phases with respect to pediatric autoinjectors for delivery to SNS/CHEMPACK. Within the Business Proposal, costs for these CLINs shall rely upon “not to exceed” autoinjector values. Offerors are encouraged to provide volume discounts for CLINs 0002, 0003, 0005, 0006, 0008, and 0009.

Offerors must submit proposals for these procurement CLINs appropriately as outlined in Section C. For Fixed-Priced procurement CLINs, offerors must ensure that all costs associated with procurement and delivery of product objectives (reference section 5 of the SOO) are factored into the cost per autoinjector (i.e. shipment, storage, stability testing, quality control, etc.)

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 DUNS number of Offeror;

3. Name and telephone number of point of contact;

4. Name, address, and telephone number of Contract Administration Office, (if available);

5. Name, address, and telephone number of Audit Office (if available);

6. Proposed cost and/or price; profit or fee (as applicable); and total;

7. The following statement: By submitting this proposal, the Offeror, if selected for discussions, grants the Contracting Officer or an authorized representative the right to examine, at any time before award, any of those books, records, documents, or other records directly pertinent to the information requested or submitted.

8. Date of submission; and

9. Name, title and signature of authorized representative.

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

The data submitted for Cost-Reimbursement CLINs shall be at the level of detail described below:

Direct Labor

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

Materials

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

Subcontracted Items

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

Purchased Parts

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

Fringe Benefits

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

Indirect Costs

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

Travel

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

Other Costs

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

L.5.3. Business Proposal – Other Information

(1) Commitment of Public Funds

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

(2) Communications Prior to Contract Award

Offeror(s) shall direct all communications to the attention of the Contract Specialist or Contracting Officer cited on the face page of this RFP. Communications with any other Government official regarding this RFP is strictly prohibited and may disqualify 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 five (5) 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 Jill.Johnson@hhs.gov.

All questionnaires shall be submitted via email as part of the proposal submission no later than the closing date and time 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 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) Protection of Human Subjects **(Attachment #6)**
3) Breakdown of Proposed Costs with Excel Spreadsheet **(Attachment #8)**
4) Summary of Related Activities **(Attachment #9)**
5) Completed Disclosure of Lobbying Activities **(Attachment #11)**
6) Small Business Subcontracting Plan **(Attachment #12)**
7) Past Performance Questionnaires **(Attachment #14)**
8) 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 Offeror or subOfferor 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% 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 June 28, 2021 at 12:00PM ET. All questions shall be submitted via e-mail to Jill.Johnson@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 52.252-2 Clauses Incorporated by Reference (Feb 1998):

FAR Clause 52.204-16, Commercial and Government Entity Code Reporting (Aug 2020)
FAR Clause 52.204-18, Commercial and Government Entity Code Maintenance (Aug 2020)
FAR Clause 52.215-1, Instructions to Offerors – Competitive Acquisition (Jan 2017)
FAR Clause 52.215-1, Instructions to Offerors, Alternate I (Oct 1997)
FAR Clause 52.215-16, Facilities Capital Cost of Money (Jun 2003)

FAR Clause 52.215-22, Limitations on Pass-Through Charges – Identification of Subcontract Effort (Oct 2009)

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:

Jill Johnson
Contracting Officer
Office of Contracts Management and Acquisition (CMA), BARDA
Assistant Secretary for 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.

Section M – EVALUATION FACTORS FOR AWARD

M.1. BASIS OF AWARD

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

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

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

M.2. COST/PRICE EVALUATION

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

Cost Realism ***(for Cost-Reimbursement CLINs only)***: The specific elements of each Offeror's proposed costs are realistic when the proposed cost elements are evaluated and found to: 1) be realistic for the work to be performed; 2) reflect a clear understanding of the requirements; and 3) be consistent with the unique methods of performance and materials described in each Offeror's technical proposal.

Cost Realism will be evaluated only on each Offeror's proposal which the Government will use to determine the most probable cost to perform the contract in a manner consistent with the Offeror's proposal. Cost realism analysis will be conducted in accordance with FAR 15.404-1(d). The result of the cost realism analysis will be considered in the making the best value trade-off decision.

M.3. MANDATORY EVALUATION CRITERIA

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

- The Offeror must demonstrate that they have adequate facilities, infrastructure, and equipment to manufacture the requested quantities for midazolam autoinjectors as stated in Section B – Cost Schedule. Such autoinjectors must be at Phase 3 clinical level of development or higher.
- The Offeror must demonstrate that their autoinjectors comply with FDA reliability standards outlined in the Draft Guidance for Technical Considerations for Demonstrating Reliability of Emergency-Use Injectors Submitted under a BLA, NDA or AND. For more information, please visit:
  https://www.fda.gov/regulatory-information/search-fda-guidance-documents/technical-considerations-demonstrating-reliability-emergency-use-injectors-submitted-under-bla-nda)
- The Offeror must demonstrate that it has obtained FDA feedback regarding their regulatory approach. (The offeror shall provide relevant FDA communication)
- The Offeror must demonstrate their autoinjectors can be used in emergency situations by first responders and untrained personnel (Human Factors Studies are acceptable).

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) Technical Manufacturing Capabilities, 2) Regulatory Strategy and Processes, and 3) Project Management Capabilities. Each technical evaluation criterion is of equal importance.

Evaluation Criterion 1: Technical Manufacturing Capabilities

The Offeror will be evaluated on their ability to deliver final finished sterile form of midazolam hydrochloride in prefilled intramuscular autoinjectors (AI) for adult and pediatric populations meeting current good manufacturing practice (cGMP).

In addition, the Offeror will be evaluated on their demonstrated ability and appropriateness to efficiently and effectively perform the following capabilities, as relevant in the Statement of Objectives (SOO):

- Ability to deliver detailed technical plans to execute necessary all necessary studies and protocol development for midazolam autoinjectors (AIs) as a drug/device combination product. Technical plans to conduct of any necessary studies, including efficacy/bioequivalence studies, shall also be delivered.
- Ability to deliver final finished sterile formulation of midazolam (under cGMP) in prefilled intramuscular AIs according to specifications, meeting quality management system for manufacturing and design. Manufacturing process and device design of prefilled AIs shall include the Active Pharmaceutical Ingredient (API), receipt of raw materials, production, packaging, repackaging, labeling, relabeling, quality control, release, storage and distribution, and related controls for manufacturing with validation of all critical processes.
- A needle-free midazolam autoinjector is ***preferred*** for various reasons including the avoidance of cross contamination, prevention of needle-stick injuries, simplification of disposal (no sharps), and improved dispensing of medication (no void volume).
- In addition to final finished form delivery, demonstrated ability to release labeled and packaged adult and pediatric midazolam prefilled AIs for all necessary clinical studies.
- Ability to deliver rapid scale-up of commercial volumes according to specifications with Process Qualification (PPQ) and consistency lots.
- Current production capabilities for autoinjectors, such as surge capability, start-up time, ramp-up time.
- In addition to meeting above manufacturing and processing capabilities, ability to manufacture or acquire autoinjectors from subcontractors under manufacturing quality agreements with:

- Adequate dose volumes, needle lengths (if applicable), drug administration speed, and force necessary to activate delivery mechanism and compress subcutaneous tissue for safe and effective intramuscular delivery of midazolam to pediatric and adult populations.
- Human factors validation for safe and effective use under high stress and austere environments for administration by trained emergency and medical personnel (e.g., validation of clear, easy, concise user instructions, clear indication of proper delivery, portability, rugged design, and training material).
- Safety considerations (e.g., unintended injection prevention features and needle shield, when applicable).
- Ease of maintenance and storage considerations (e.g., demonstration of prolonged shelf-life or with established protocol).

Evaluation Criterion 2: Regulatory Strategy and Processes

The Offeror will be evaluated on their ability to support regulatory activities required for the approval of midazolam pre-filled autoinjectors with appropriate labeling (as described in 21 CFR 201.57, and applicable guidance's on regulatory requirements for medical devices) for the treatment of status epilepticus in adult and pediatric populations.

The regulatory strategy and processes will be evaluated based on the following factors:

- Documentation of a feasible regulatory approach to address regulatory requirements within the Office of Combination Products, FDA and in accordance with 21 CFR 314, 21 CFR 820, 21 CFR 210, 21 CFR 211 and ISO 14971 at the appropriate stages of product development for FDA approval of midazolam autoinjectors as a drug/device combination product for adult and pediatric populations. This includes documentation that demonstrates compliance with FDA reliability standards outlined in the Draft Guidance for Technical Considerations for Demonstrating Reliability of Emergency-Use Injectors Submitted under a BLA, NDA or ANDA. For more information, visit: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/technical-considerations-demonstrating-reliability-emergency-use-injectors-submitted-under-bla-nda

- Evidence of satisfactory regulatory-compliance throughout the product development cycle: Capacity to manage processes associated with all stages of product development, including but not limited to sponsor responsibilities for Investigational New Drug Applications (INDs) and New Drug Applications (NDAs); GMP- compliant manufacturing; GLP and GCP-compliant-investigations; adverse event reporting, reference listed drug product labeling amendment approval; incorporation of appropriate device-related information; and post-approval modifications and reporting requirements.

- Evidence of a regulatory and quality program, including team(s), and/or consultants with appropriate education, training, and experience with GxPs, the drug approval process with the FDA's, and implementation of a quality management system.

- Appropriate identification of potential regulatory risks associated with the proposed product(s) and a practical mitigation strategy for possible complications.

- Suitable plan to address regulations and provide supporting information required to demonstrate the safe and effective use of midazolam pre-filled autoinjectors in adult and pediatric population as in 21 CFR 201.57(iv) and all relevant regulations.

- Ability to provide specific information and/or appropriate regulatory documentation on autoinjectors such as design, materials, performance testing, operation and manufacturing (as per Quality System Regulation (21 CFR Part 820) requirements) to support NDA submission, or provide authorization to reference specific auto-injector information in FDA documentations for approved drug/device combination product or cleared device or device master file submissions as applicable.

Evaluation Criterion 3: Project Management Capabilities

The Offeror will be evaluated on key personnel who will be responsible for executing late stage development activities for the autoinjectors, and to oversee and execute delivery activities to the SNS/CHEMPACK Program. The Offeror shall consider the list of key personnel as proposed below, however, additional key personnel shall be included should they play a substantial role in the execution of the SOO.

Project management capabilities will be evaluated based on the following factors:

1. The experience of proposed technical personnel
2. The Offeror's experience in relevant efforts with similar resources
3. The ability to manage the proposed effort

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

- Education, training, experience, expertise, and effort of the proposed key and other personnel in terms of experience based on the requirements identified in the Statement of Objectives (SOO).
- Full and complete 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 (technicians, QA, QC, administrative support). At a minimum, the Offeror(s) shall identify the following key personnel (or equivalent) and their demonstrated experience relevant to this requirement:

    - Program Director (PD)/Principle Investigator (PI)
    - Chief Scientific/Medical Officer
    - Clinical Development/Clinical Study Director
    - Nonclinical Development Lead
    - Quality Assurance (QA)
    - Quality Control (QC)
    - Manufacturing Lead
    - Regulatory Affairs (Lead)
    - Pharmacovigilance (Lead)
    - Project Manager

    The Offeror shall provide the following details regarding their project management capabilities:

    - Adequacy and documented availability, training, experience, and capabilities of proposed professional staff, sub-contractors, and other professional and technical staff in the management of technical proposal.
    - Project Management controls to keep multidisciplinary and multiple project tasks on time and on budget, quality control measures, monitoring and tracking, methods and resources to be used and identification of problems likely to occur with plans addressing them. Suitability of systems proposed for tracking project activities and monitoring progress, timelines and budgets.
    - Adequacy of the Project Management Plan to ensure efficient planning, initiation, implementation, conduct, and completion of activities to fulfill the requirements of the Statement of Objectives.

- Suitability of the plan for how the Offerors will communicate with the P/PM and the Contracting Officer, as well as establish lines of communication between all performance sites and activities.
- Suitability of the plan for soliciting, evaluating, negotiating, awarding and managing any proposed subcontracts in accordance with Federal regulations.
- Adequacy of the plan to identify and remediate problems in subcontractor performance.
- Adequacy of project management documentation including at a minimum, risk mitigation plans, Gantt charts, integrated master schedules, earned value management plan, security plan.
- Evidence that the Offeror has previously executed nonclinical and clinical studies for achieving licensure of a drug candidate(s) according to the performance specifications of the Statement of Objectives (SOO), project goals, objectives, criteria, timelines, risks, and risk mitigation strategies/plans.
- Inventory management: inventory control practices, regular rotation or repurposing. After the U.S. Government receives midazolam-filled autoinjectors, ability of the Offeror to prepare annual updates, conduct surveillance, and maintain the dossier.

M.5. MERIT RATINGS

Evaluators will assign one merit rating to each of the three evaluation criterion listed above. The individual merit ratings per Technical Evaluation Panel member will be consolidated into one overall merit rating for each evaluation criterion. An Offeror who receives a merit rating of Unacceptable for any criterion will not be eligible for award.

M.6. PAST PERFORMANCE

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

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

The government will assess the relative risks associated with each Offeror. Performance risks are those associated with an Offeror's likelihood of success in performing the acquisition requirements as indicated by that Offeror's record of past performance.
When assessing performance risks, the Government, to the fullest extent practicable, will focus on the past performance of the Offeror as it relates to all acquisition requirements.

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

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

The 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).

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

INVOICE/FINANCING REQUEST INSTRUCTIONS - FOR COST-REIMBURSEMENT TYPE CONTRACTS

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

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

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

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

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

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

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

Costs Requiring Prior Approval: Costs requiring the Contracting Officer's approval, including those set forth in an Advance Understanding in the contract, shall be identified and reference the Contracting Officer's Authorization (COA) Number. In addition, the Offeror shall show any cost set forth in an Advance Understanding as a separate line item on the payment request.

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

(a) **Interim Invoice/Contract Financing Request:** These are interim payment requests submitted during the contract performance period.

(b) **Completion Invoice:** The completion invoice shall be submitted promptly upon completion of the work, but no later than one year from the contract completion date, or within 120 days after

settlement of the final indirect cost rates covering the year in which the contract is physically complete (whichever date is later). The Offeror shall submit the completion invoice when all costs have been assigned to the contract and it completes all performance provisions.

(c) **Final Invoice:** A final invoice may be required after the amounts owed have been settled between the Government and the Offeror (e.g., resolution of all suspensions and audit exceptions).

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

(a) **Designated Billing Office Name and Address:** Enter the designated billing office name and address, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

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

(c) **Invoice/Financing Request Number:** Insert the appropriate serial number of the payment request.

(d) **Date Invoice/Financing Request Prepared:** Insert the date the payment request is prepared.

(e) **Contract Number and Order Number (if applicable):** Insert the contract number and order number (if applicable).

(f) **Effective Date:** Insert the effective date of the contract or if billing under an order, the effective date of the order.

(g) **Total Estimated Cost of Contract/Order:** Insert the total estimated cost of the contract, exclusive of fixed-fee. If billing under an order, insert the total estimated cost of the order, exclusive of fixed-fee. For incrementally funded contracts/orders, enter the amount currently obligated and available for payment.

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

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

(j) **Office of Acquisitions:** Insert the name of the Office of Acquisitions, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(k) **Central Point of Distribution:** Insert the Central Point of Distribution, as identified in the Invoice Submission Instructions in Section G of the Contract Schedule.

(l) **Billing Period:** Insert the beginning and ending dates (month, day, and year) of the period in which costs were incurred and for which reimbursement is claimed.

(m) **Amount Billed - Current Period:** Insert the amount claimed for the current billing period by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(n) **Amount Billed - Cumulative:** Insert the cumulative amounts claimed by major cost element, including any adjustments and fixed-fee. If the Contract Schedule contains separately priced line items, identify the contract line item(s) on the payment request and include a separate breakdown (by major cost element) for each line item.

(o) **Direct Costs:** Insert the major cost elements. For each element, consider the application of the paragraph entitled "Costs Requiring Prior Approval" on page 1 of these instructions.

(1) **Direct Labor:** Include salaries and wages paid (or accrued) for direct performance of the contract. List individuals by name, title/position, hourly/annual rate, level of effort (actual hours or % of effort), breakdown by task performed by personnel, and amount claimed.

(2) **Fringe Benefits:** List any fringe benefits applicable to direct labor and billed as a direct cost. Do not include in this category fringe benefits that are included in indirect costs.

(3) **Accountable Personal Property:** Include any property having a unit acquisition cost of $5,000 or more, with a life expectancy of more than two years, and sensitive property regardless of cost (see the HHS *Offeror's Guide for Control of Government Property*)(e.g. personal computers). Note this is not permitted for reimbursement without pre-authorization from the CO.

On a separate page attached to the payment request, list each item for which reimbursement is requested. Include reference to the following (as applicable):

- Item number for the specific piece of equipment listed in the Property Schedule, and

- COA number, if the equipment is not covered by the Property Schedule.

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

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

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

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

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

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

(9) **Other:** Include all other direct costs not fitting into an aforementioned category. If over $1,000, list cost elements and dollar amounts separately. If the contract contains restrictions on any cost element, that cost element must be listed separately.

(p) **Cost of Money (COM):** Cite the COM factor and base in effect during the time the cost was incurred and for which reimbursement is claimed, if applicable.

(q) **Indirect Costs:** Identify the indirect cost base (IDC), indirect cost rate, and amount billed for each indirect cost category.

(r) **Fixed-Fee:** Cite the formula or method of computation for fixed-fee, if applicable. The fixed-fee must be claimed as provided for by the contract.

(s) **Total Amounts Claimed:** Insert the total amounts claimed for the current and cumulative periods.

(t) **Adjustments:** Include amounts conceded by the Offeror, outstanding suspensions, and/or disapprovals subject to appeal.

(u) **Grand Totals**

(v) **Certification of Salary Rate Limitation:** If required by the contract (see Invoice Submission Instructions in Section G of the Contract Schedule), the 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 Salary Rate Limitation Provisions in Section H of the contract."

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

ATTACHMENT #3

INVOICE/FINANCING REQUEST INSTRUCTIONS FOR FIXED PRICE TYPE CONTRACTS

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

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

Number of Copies: As indicated in the contract.

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

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

(a) Designated Billing Office and address:

HHS/ASPR/BARDA
200 C Street SW
Washington DC 20024
ATTN: Contracting Officer

(b) Invoice Number

(c) Date of Invoice

(d) Contract number and date

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

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

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

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

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

ATTACHMENT #4
SAMPLE INVOICE/PAYMENT REQUEST

(a) Designated Billing Office Name and Address:

DHHS/OS/ASPR/BARDA/CMA
Attn: Jill Johnson, Contracting Officer
US DEPT OF HEALTH & HUMAN SERVICES
ASST SEC OF PREPAREDNESS & RESPONSE
Division of Contract Management & Acquisitions
O'NEILL HOUSE OFFICE BUILDING
Washington DC 20515

(b) Contractor's Name, Address, Point of Contact, VIN, and DUNS or DUNS+4 Number:

ABC CORPORATION
100 Main Street
Anywhere, USA Zip Code

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.

VIN:
DUNS or DUNS+4:

(c) Invoice/Financing Request No.:

(d) Date Invoice Prepared:

(e) Contract No. and Order No. (if applicable): _____

(f) Effective Date:

(g) Total Estimated Cost of Contract/Order:

(h) Total Fixed-Fee (if applicable):
(i) ☐Two-Way Match:
☐Three-Way Match:

(j) Office of Acquisitions:

(k) Central Point of Distribution:

(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 #5

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 May XX , 2021

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 #6

PROTECTION OF HUMAN SUBJECTS

DEPARTMENT OF HEALTH AND HUMAN SERVICES PUBLIC HEALTH SERVICE NATIONAL INSTITUTES OF HEALTH **PROPOSAL SUMMARY AND DATA RECORD**	RFP/CONTRACT NUMBER

PROJECT TITLE (Title or RFP or Contract Proposal)

LEGAL NAME AND ADDRESS OF OFFEROR	PLACE OF PERFORMANCE (Full address including ZIP)

TYPE OF CONTRACT PROPOSED

□ COST-REIMBURSEMENT □ FIXED PRICE □ COST-PLUS-FIXED-FEE □ OTHER

ESTIMATED TIME REQUIRED TO COMPLETE PROJECT

ESTIMATED DIRECT COSTS IN PROPOSED YEAR (From Budget	PROPOSED STARTING DATE

DOES THIS PROPOSAL INCLUDE A SUBCONTRACT □ YES □ NO (If yes, please furnish name and location of organization, description of services, basis for selection, responsible person employed by subOfferor and cost information.)

NAME AND TITLE OF PRINCIPAL INVESTIGATOR	SOCIAL SECURITY NO.	EST. HOURS WEEKLY	AREA CODE/TEL.NO.
NAME AND TITLE OF CO-INVESTIGATOR (Use attachment if necessary.)			

NAME AND TITLE OF INDIVIDUAL(S) AUTHORIZED TO NEGOTIATE CONTRACTS	AREA CODE/TELEPHONE NUMBER
NAME AND TITLE OF INDIVIDUAL(S) AUTHORIZED TO EXECUTE CONTRACTS	AREA CODE/TELEPHONE NUMBER

DOES THIS PROPOSAL INVOLVE EXPERIMENTS WITH HUMAN SUBJECTS □ YES □ NO

Institution's General Assurance re: Human Subjects DATE APPROVED _____ □ PENDING

Institution's Review Board's Approval of this Proposal DATE APPROVED _____ □ PENDING

An example of the informed consent for this study is enclosed □ YES □ NO
A Clinical Protocol is enclosed □ YES □ NO

OFFEROR'S ACKNOWLEDGMENT OF AMENDMENTS TO THE RFP (Use attachment if necessary)			
ERRATA NUMBER	DATE	ERRATA NUMBER	DATE

NAME, ADDRESS, AND PHONE NUMBER OF COGNIZANT GOVERNMENT AUDIT AGENCY	NUMBER OF EMPLOYEES CURRENTLY EMPLOYED
	DOLLAR VOLUME OF BUSINESS PER ANNUM
	THIS OFFER EXPIRES _____ DAYS FROM THE DATE OF THIS OFFER (120 days if not specified)

FOR THE INSTITUTION

SIGNATURE OF PRINCIPAL INVESTIGATOR	SIGNATURE OF BUSINESS REPRESENTATIVE
TYPED NAME AND TITLE	TYPED NAME AND TITLE
EMPLOYER IDENTIFICATION NUMBER	DATE OF OFFER

Provision of the Social Security Number is voluntary. Social Security Numbers are requested for the purpose of accurate and efficient identification, review, and management of NIH Extramural Programs. Authority for requesting this information is provided by Title III, Section 301, and Title IV of the Public Health Service Act, as amended.

ATTACHMENT #7

HHS Section 508 Product Assessment Template

Please complete form available here:
http://www.hhs.gov/web/508/contracting/technology/vendors.html

ATTACHMENT #8

Breakdown of Proposed Costs with Excel Spreadsheet

https://oamp.od.nih.gov/content/breakdown-proposed-estimated-cost-plus-fee-and-labor-hours

ATTACHMENT #9

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:

Identifying Number	Agency	Total Effort Committed
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:

Identifying Number	Agency	Total Effort Committed
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.

Name	Title/Position	Total Proposed Effort
1.		
2.		
3.		
4.		

ATTACHMENT #10

ACH VENDOR / MISCELLANEOUS PAYMENT ENROLLMENT FORM

Payment Information Form
The information requested on this form concerns your financial institution, your account at that institution, and personal information which needs to verified and completed.

Privacy Act Statement
The following information is provided to comply with the Privacy Act of 1974 (P.L. 93-579). All information collected on this form is required under the provisions of 31 USC 3322 and 31 CFR 210. This information will be used by the Treasury Department to transmit payment data, by electronic means to your financial institution. Failure to provide the requested information may delay or prevent the receipt of payments through the Automated Clearing House Payment System.

Check one of the following:

☐ Federal Employee: ☐ Offeror: ☐ Vendor:

Name: _____

Business Address: _____

_____

Remit To
(If same as above, leave blank. Must match address on invoice for internal control purposes.)
Address: _____

_____

Taxpayer Identification # (TIN): ___ ___ ___ ___ ___ ___ ___ ___ ___
(If you are an individual, this may be your Social Security number)

1. Payee's Telephone Number: (_____) _____

The following information must be completed by your financial institution representative:

2. Name of Financial Institution: _____

3. Address of Financial Institution:

_____

_____

_____

4. Financial Institution's 9-digit ABA Routing Number for

Transfer of Funds: ___ ___ ___ ___ ___ ___ ___ ___ ___

5. Depositor Account Title: _____

6. Depositor Account Number:														

7. Type of Account: ☐ Checking ☐ Savings

8. Signature and Title of Authorized Official of Financial Institution:

_____

Telephone Number: (_____) _____ Date: _____

********** The following must be signed by the payee**********

I have verified the information on this form.

_____ _____

Signature Date

ATTACHMENT #11

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 #12

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

ATTACHMENT #13

RISK MITIGATION PLAN/MATRIX TEMPLATE

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

ATTACHMENT #14

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: Jill Johnson, Contracting Officer
Jill.Johnson@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

b. MONTHS OFFEROR PERFORMANCE MONITORED BY EVALUATOR:

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

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

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

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

RATING GUIDELINES

RATING GUIDELINES QUALITY OF PRODUCT OR	Definition	Note
1 – Unsatisfactory	Performance does not meet most contractual requirements and recovery is not likely in a timely manner. The contractual performance of the element or sub-element contains a serious problem(s) for which the Offeror's corrective actions appear or were ineffective.	To justify an Unsatisfactory rating, identify multiple significant events in each category that the Offeror had trouble overcoming and state how it impacted the Government. A singular problem, however, could be of such serious magnitude that it alone constitutes an unsatisfactory rating. An Unsatisfactory rating should be supported by referencing the management tools used to notify the Offeror of the contractual deficiencies (e.g., management, quality, safety, or environmental deficiency reports, 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 #15

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

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

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

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

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

ATTACHMENT #16

SECURITY PLAN TEMPLATE WITH INSTRUCTIONS

COMPANY SECURITY PLAN TEMPLATE

Prepared by:
Program Protection Office

Office of Biomedical Advanced Research and Development Authority

Preface

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

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

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

General Outline of Security Plan Topics

I. Organization and Responsibilities
II. Site- Specific Risk Assessment
    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 workplace 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.