SOLICITATION, OFFER AND AWARD

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

2. CONTRACT NUMBER	3. SOLICITATION NUMBER	4. TYPE OF SOLICITATION	5. DATE ISSUED	6. REQUISITION/PURCHASE NUMBER
	75A50126R00001	☐ SEALED BID (IFB) ☒ NEGOTIATED (RFP)	08/17/2026	

7. ISSUED BY	CODE	8. ADDRESS OFFER TO (If other than Item 7)
ASPR/DAAPO/BARDA/DCMA US DEPT OF HEALTH & HUMAN SERVICES CONSITUTION CENTER 400 7th St SW Washington DC 20024	ASPR/DAAPPO/BARDA/DC	

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

SOLICITATION

9. Sealed offers in original and _____ copies for furnishing the supplies or services in the Schedule will be received at the place specified in Item 8, or if hand carried, in the depository located in _____ until 1700 ET (Hour) local time 10/30/2026 (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)			C. E-MAIL ADDRESS
		AREA CODE	NUMBER	EXT.	
	LAURA E SADDISON				laura.saddison@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 price 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. ACKNOWLEDGEMENT 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 TITLE OF PERSON AUTHORIZED TO SIGN OFFER *(Type or print)*

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

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 AND OPEN COMPETITION:	23. SUBMIT INVOICES TO ADDRESS SHOWN IN *(4 copies unless otherwise specified)*	ITEM
☐ 10 U.S.C. 2304 (c) ( ) ☐ 41 U.S.C. 3304 (a) ( )		

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

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

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

Biomedical Advanced Research and Development Authority (BARDA)
Request for Proposals (RFP) for
Vaccine Medical Countermeasures for Pandemic Influenza Preparedness and Response

RFP #:75A50126R00001

Issued: August 17, 2026

Initial Questions Due: August 31, 2026 by 12:00 p.m. (EST)
Supplemental Questions Due: September 24, by 12:00 p.m. (EST)

Proposal Responses Due: October 30, 2026 by 5:00 p.m. (EST)

Contracting Officer: Laura Saddison (Laura.Saddison@hhs.gov)

MedicalCountermeasures.gov

NOTE TO OFFERORS

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

If your proposal is not received by the Contracting Officer (CO) or his/her designee at the time and place specified, it will be considered late and handled in accordance with the Federal Acquisition Regulation (FAR), FAR 52.215-1 (Instructions to Offerors – Competitive Acquisition), the Health and Human Services Acquisition Regulation (HHSAR), and HHSAR Clause 352.215-70, "Late Proposals and Revisions" located in Sections L 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 K, 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 Contractor's proposal may be included in the resultant contract. The contract schedule is intended to provide the Contractor with information to aid in understanding the likely terms and conditions of any resultant contract.

Questions related to this RFP should be directed via email to Laura Saddison (Laura.Saddison@hhs.gov) and Jill Johnson (Jill.Johnson@hhs.gov). The government will respond to questions at its discretion and as time and resources allow. Questions deemed outside the scope of this RFP will not receive a response.

PART 1 – THE SCHEDULE

SECTION B - SUPPLIES OR SERVICES AND PRICES/COSTS

B.1 BRIEF DESCRIPTION OF SERVICES AND SUPPLIES

The Center for the Biomedical Advanced Research and Development Authority (BARDA) within the Administration for Strategic Preparedness and Response (ASPR), U.S. Department of Health and Human Services (HHS), has a long-standing Vaccine Medical Countermeasures (MCMs) for Pandemic Influenza Preparedness and Response Program that ensures a constant state of pandemic readiness by enabling the rapid production of influenza vaccines and adjuvants by manufacturers of FDA-licensed vaccines in the event of a public health emergency. As part of this program, BARDA has established pandemic-ready manufacturing and critical enablers for a permanent readiness posture against high threat influenza virus strains through regulatory readiness, vaccine implementation strategies in the event of a public health emergency, and an inventory of vaccine countermeasures, including vaccine seed stocks, bulk antigen and adjuvant, and final container antigen and adjuvant.

Unlike with seasonal influenza vaccines, two doses of adjuvanted pandemic influenza vaccine will likely be required to protect an immunologically naïve population from severe disease (all age groups). This is expected to require at least 330 million regimens (or 660 million doses) to vaccinate the entire U.S. population. Therefore, a strong domestic vaccine manufacturing capability is critical for national security and response to seasonal and pandemic influenza. To support pandemic readiness, it is crucial to have commercially sustainable manufacturing processes that ensure continuous warm-base production capacity that is not solely U.S. Government (USG)-maintained.

BARDA seeks Contractor(s) to support the continuation of the Vaccine MCMs for Pandemic Influenza Preparedness and Response Program.[1] The Contractor(s) must furnish all the necessary services, qualified personnel, materials, supplies, equipment and facilities (U.S. facilities preferred) not otherwise provided by the USG as needed to provide MCMs, such as vaccines, antigens, and adjuvants, for pandemic preparedness and response or as required in response to a public health emergency; produce antigen and vaccines against influenza virus or other viruses with pandemic potential as required by BARDA; produce antigens, adjuvants, and/or vaccines to support USG efforts to further improve influenza vaccines (for which feasibility data is available); and support rapid regulatory decisions and manufacturing readiness by generating and submitting to FDA all relevant data (e.g., analytical, nonclinical, clinical, and/or chemistry, manufacturing, and controls (CMC)), including data generated during interpandemic periods.

[1] https://www.medicalcountermeasures.gov/barda/influenza-and-emerging-infectious-diseases/pandemic-vaccines-adjuvants

B.2. PRICES/ COSTS/ PERIOD OF PERFOMRANCE /CONTRACT LINE ITEM NUMBERS (CLINs) and ACTIVITIES

a. Statement of Work: The Statement of Work (SOW) contained in Section C of the solicitation package delineates the specifics of the supplies or services to be furnished.

b. Offeror should provide pricing for all CLINs and Activities, except those which have "TBD" or "N/A" in the "Maximum Potential Quantity for the PoP" column. Provide pricing based upon the CLIN, Activity Number, Activity Name, and description in the SOW for the five (5)-year (60-month) base period of performance (PoP), and provide pricing based upon Activity Name and description for the one (1) five-year option period. Note that the Activities in the SOW reflect Base Period numbering (i.e., Activities identified in SOW would be revised in conjunction with any resultant option award with description data unchanged).

c. Price/Cost, e.g., Firm-fixed-price or cost reimbursable, for "TBD" Activities, i.e., Activities 1010, 1011, 1012, 1013, 1014, 1015, 1016, 1017 will be determined as a result of the issuance of a Request for Task Order Response (RTOR) to resultant contract awardee(s).

d. Minimum/Maximum: The Contractor shall be reimbursed by the Government in an amount not less than a total of $50,0000.00 nor more than a total of $ (maximum). The minimum guarantee is $50,000.00 for the duration of any resultant contract (base + options).

e. Ordering Period: The prices set forth below will cover the ordering period of 120 months from date of award. DATE through DATE.

f. Any material manufactured or data generated under this contract is deliverable to the Government. Upon delivery, inspection, and acceptance of the Activity(-ies) described in SECTION C Statement of Work, and identified in the schedule of pricing below, the Government shall pay to the Contractor the unit price(s) set forth below.

g. ***At the Contracting Officer's discretion***, offerors may be asked to propose alternative Activity Contract Types when responding to task order, blanket purchase agreement (BPA), or call order solicitations.

h. Firm-Fixed-Unit-Price (FFUP): The FFUP unit price shall be firm and not subject to adjustment based on offeror's actual costs of performance. The unit price shall include all direct and indirect labor, materials and supplies, equipment and facilities, travel (if applicable), subcontractor costs, overhead, general and administrative expenses, and profit necessary to perform the work in accordance with the Statement of Work (SOW). The Government will pay offeror the fixed unit price for each unit actually ordered and accepted. The government does not guarantee that the "Maximum Potential Quantity for the PoP" will be ordered. Payment will be based solely on the number of units ordered and satisfactorily delivered or performed and accepted by the government. Offerors shall propose a single fixed unit price for each FFUP activity. Extended prices will be calculated for evaluation purposes only. Offeror assumes full responsibility for performance costs and resulting profit or loss.

i. Tariffs, Duties, and Trade Remedies: Offerors shall not include any anticipated or speculative tariff, duty, or trade remedy costs in the pricing of any Activity(-ies) other than ACTIVITIES 1018 and 2018.

j. CLIN 1000 BASE PERIOD: _____ (60 months from Base Award)

Activity	Activity Name	Contract Type	UNIT	UNIT PRICE	MAXIMUM POTENTIAL QUANTITY FOR THE PoP	TOTAL EXTENDED PRICE (60-month Base Period)
1001	Candidate Vaccine Virus (CVV)	FFP	EA			
1002	CGMP Influenza Vaccine Master and/or Working Seed Lot(s)	FFP	LOT			
1003	Influenza Vaccine Research Lot(s)	FFP	LOT			
1004	CGMP Influenza Vaccine: Investigational Lot(s)	FFP	LOT			
1005	CGMP Influenza Vaccine: Commercial Scale Bulk Lot(s)	FFP	LOT			
1006	CGMP Adjuvant: Clinical or Commercial Scale Bulk Lot(s)	FFP	LOT			
1007A	Formulation and Filling: Antigen	FFUP	EA			
1007B	Formulation and Filling: Adjuvant	FFUP	EA			
1007C	Formulation and Filling: Co-formulated Antigen and Adjuvant	FFUP	EA			

1007D	Access to Filling Capacity or Disruption Fee for Commercial Products	FFP	EA	TBD		
1008	Labeling and Packaging	FFUP	EA			
1009A	Storage and Stability: Commercial Scale Bulk Lots of Antigen	FFUP	LOT		Per Lot Per Month	
1009B	Storage and Stability: Antigen in Final Container	FFUP	Final Container		Per FC Per Month	
1009C	Storage and Stability: Clinical/ Commercial Scale Bulk lots of Adjuvant	FFUP	LOT		Per Lot Per Month	
1009D	Storage and Stability: Adjuvant in Final Container	FFUP	Final Container		Per FC Per Month	
1010	Shipping	FFP	EA	TBD		
1011	Analytical Laboratory Testing/Assay	FFP	EA	TBD		
1012	Nonclinical Studies	FFP	Study	TBD		
1013	Clinical Studies	FFP	Study	TBD		
1014	Disposal of Product	FFP	EA	TBD		
1015	Emerging Pathogen	Cost	EA	TBD		
1016	Validation Activities or Technology Transfer Activities	FFP	EA	TBD		

1017	Manufacturing Enhancements	FFP	EA	TBD		
1018	Tariffs, Duties, and Trade Remedies on any ACTIVITY(-IES)	Cost	EA	TBD		
1019	Standard Data Reporting	NSP	Monthly	N/A	Not Separately Priced (NSP)	
1020	Additional Reporting	NSP	Report	N/A	Not Separately Priced (NSP)	
Total Estimated Dollar Amount – Base Period (60 Months)						

k. CLIN 2000 OPTION PERIOD 1: _____ (60 months from the exercise of Option Period 1)

Activity	Activity Name	Contract Type	UNIT	UNIT PRICE	MAXIMUM POTENTIAL QUANTITY FOR THE PoP	TOTAL EXTENDED PRICE (60-month Option Period 1)
2001	Candidate Vaccine Virus (CVV)	FFP	EA			
2002	CGMP Influenza Vaccine Master and/or Working Seed Lot(s)	FFP	LOT			
2003	Influenza Vaccine Research Lot(s)	FFP	LOT			
2004	CGMP Influenza Vaccine: Investigational Lot(s)	FFP	LOT			
2005	CGMP Influenza Vaccine: Commercial Scale Bulk Lot(s)	FFP	LOT			

2006	CGMP Adjuvant: Clinical or Commercial Scale Bulk Lot(s)	FFP	LOT			
2007A	Formulation and Filling: Antigen	FFUP	EA			
2007B	Formulation and Filling: Adjuvant	FFUP	EA			
2007C	Formulation and Filling: Co-formulated Antigen and Adjuvant-	FFUP	EA			
2007D	Access to Filling Capacity or Disruption Fee for Commercial Products	FFP	EA	TBD		
2008	Labeling and Packaging	FFUP	EA			
2009A	Storage and Stability: Commercial Scale Bulk Lots of Antigen	FFUP	LOT		Per Lot Per Month	
2009B	Storage and Stability: Antigen in Final Container	FFUP	Final Container		Per FC Per Month	
2009C	Storage and Stability: Clinical/ Commercial Scale Bulk lots of Adjuvant	FFUP	LOT		Per Lot Per Month	
2009D	Storage and Stability: Adjuvant in Final Container	FFUP	Final Container		Per FC Per Month	
2010	Shipping	FFP	EA	TBD		
2011	Analytical Laboratory Testing/Assay	FFP	EA	TBD		

2012	Nonclinical Studies	FFP	Study	TBD		
2013	Clinical Studies	FFP	Study	TBD		
2014	Disposal of Product	FFP	EA	TBD		
2015	Emerging Pathogen	Cost	EA	TBD		
2016	Validation Activities or Technology Transfer Activities	FFP	EA	TBD		
2017	Manufacturing Enhancements	FFP	EA	TBD		
2018	Tariffs, Duties, and Trade Remedies on any ACTIVITY(-IES)	Cost	EA	TBD		
2019	Standard Data Reporting	NSP	Monthly	N/A	Not Separately Priced (NSP)	
2020	Additional Reporting	NSP	Report	N/A	Not Separately Priced (NSP)	
Total Estimated Dollar Amount – Option Period 1 (60 Months)						

Total Contract Value (Base + Option Period 1): _____

B.3. CONTRACT TYPE/TASK ORDER TYPES

This RFP seeks to award multiple Indefinite-Delivery, Indefinite-Quantity (IDIQ) contracts with services and supplies obtained through the issuance of firm-fixed price (FFP), firm-fixed-unit-price (FFUP), cost reimbursable (Cost), and/or hybrid task orders and delivery orders.

During the ordering period of the IDIQ, authorized officials assigned to the IDIQ may order, and the Offeror shall provide supplies and services at the negotiated unit price.

In accordance with FAR 16.504-5(h)(2) contracting officers may establish one or more Blanket Purchase Agreements (BPAs) to fill repetitive needs for supplies or services under this IDIQ contract.

B.4. PUBLIC READINESS AND EMERGENCY PREPAREDNESS ACT ("PREP ACT")

COVERAGE

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

Exceptions to this include activities related to the following:

- Analytical studies conducted in whole or in part outside the United States that do not involve using materials in humans.
- Clinical trials conducted in whole or in part outside the United States in which the sponsor maintains clinical trial insurance for injuries to study participants.
- Uses for which Recipient provides its written consent by signing a Material Transfer Agreement, Technology Transfer and Evaluation Agreement, Clinical Trial Agreement, or similar authorizing use of materials outside of the United States.

B.5. ADVANCE UNDERSTANDINGS

The final contract contains 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. Although BARDA provides descriptions of certain legal requirements, the contractor is responsible for confirming those requirements and complying with them.

B.5.1 Vendor Production Facilities

1. List the manufacturing sites and lines available for each of the manufacturing phases, including validation status of each site and line.
2. Indicate whether the site and line will be available to BARDA in the event of a public health emergency.
3. Include as an attachment a current blueprint of the facilities (or a reasonable facsimile). Clearly indicate the sites and lines for each manufacturing phase and include their capacities and capabilities as appropriate (Attachment 3).
4. The manufacturing facility locations must be reported within Activity 1019 and Activity 2019 as part of Standard Data Reporting.

Vendor Production Facilities: Bulk Production

	Bulk Manufacturing Process	Validated Bulk Manufacturing Site (Address)	Validated Bulk Manufacturing Line #	Final Bulk Container Type (Carboy, Bottle, Bag, etc.) and Size	Final Bulk Container Target Fill Volume	Maximum Dose Quantity Can Produce in 180 days
Antigen Only						
Adjuvant Only						
Co-formulated Antigen + Adjuvant						

Other (please indicate)						

Vendor Production Facilities: Formulation, Fill-Finish

	Validated Formulation Site (Address)	Validated Fill Finish Site (Address)	Validated Fill Finish Line #	Final Fill Presentation Type (MDV, SDV, PFS, sprayer, etc.) and Size	Final Fill Presentation Target Fill Volume	Maximum Dose Quantity Fill Finish Line Can Produce in 180 days	Line(s) used for other Commercial Products? (Yes/No)
Antigen Only							
Adjuvant Only							
Co-formulated Antigen + Adjuvant							
Other (please indicate)							

B.5.2 Potency Reagent Production and Calibration

List the roles and responsibilities in terms of potency reagent production and calibration activities within the interpandemic period, noting any differences for pandemic response, for each manufacturing platform.

Partner	Responsibilities
BARDA	1. Select virus strains for CVV preparation and/or bulk vaccine antigen manufacturing 2. Coordinate potency reagent production and calibration through working with CBER and manufacturer
CBER	1. Prepare antigens for sheep antiserum production as needed 2. Immunize sheep and collect/lyophilize antisera 3. Lyophilize reference antigens for manufacturer as needed 4. Calibrate primary liquid standard (PLS) provided by manufacturer 5. Calibrate lyophilized antisera generated by CBER and lyophilized reference antigen provided by manufacturer (or reference antigen provided by manufacturer and lyophilized by CBER).

	6. Ship calibrated lyophilized antisera and lyophilized reference antigen to manufacturer for release and stability testing
Manufacturer (specify manufacturing process)	1. Generate PLS and lyophilized reference antigen and ship to CBER for calibration (Reference antigen may also be lyophilized by CBER). 2. In-house release testing of bulk vaccine antigen and fill/finished antigen or vaccine using CBER calibrated antisera and reference antigens.

B.5.3 Analytical Laboratory Assays

Provide a table of pricing for common analytical assays used for potency, alternative potency, release, stability testing, etc. Examples include single radial immunodiffusion (SRID), high-performance liquid chromatography (HPLC), sodium dodecyl sulfate polyacrylamide gel electrophoresis (SDS-PAGE), immunoblot (Western blot), mass spectrometry, etc. Typical real time and accelerated stability testing time points at appropriate temperatures should be included. Indicate the location (e.g., in-house versus outsourced) where the most common testing is performed. Responses to TBD and unpriced Activities will rely on these tables to evaluate proposed costs.

B.5.4 Schedule of Labor Category Hourly Rates for TBD ACTIVITIES:

Provide a table of manufacturing, QA, QC, clinical, regulatory, process development, etc. position titles, description of the education levels attained, years of relevant experience, and hourly rates. Responses to TBD and unpriced Activities will rely on these tables to evaluate proposed costs. The table below is for example purposes only:

Position	Description	Hourly Rate
QA or Manufacturing -1	B, 3+ years entry level role	$
QA or Manufacturing -2	B, 3+ years	$
QA or Manufacturing-Manager	B, 6+ years;	$
QA or Manufacturing-Director	B, 10+ years, M 5+ years	$
QA or Manufacturing-Vice President	B, 20+ years, M 10+ years	$
Technician-1	H, 6+ years	$

H: High School; B: Bachelor; M: Master; D: Doctor

**Overtime Compensation is not unauthorized under the subject contract.*

B.5.5 Fair Product Pricing

a. If, at any time prior to, or during, the base term and any exercised options of this contract, Contractor enters into any agreement with a Covered Nation under which the Covered Nation commits to purchase (i) the same or a lesser volume of Product than the U.S. Government commits to purchase (ii) at a price lower than the price the U.S. Government is obligated to pay for Product under this contract, Contractor shall provide notice of such lower price to the U.S. Government within 30 days of the execution of the Contractor-Covered Nation agreement and the U.S. Government may elect, at its discretion, to receive the benefit of this provision and purchase the Product at that lower price.

b. Upon any such election by the U.S. Government, this contract shall be deemed to have been amended and modified such that, from the date on which the lower priced Product are first supplied or delivered to the applicable Covered Nation (the "Amended Pricing Effective Date"), the U.S. Government will receive that lower price for Product for which Contractor has not invoiced the U.S. Government following that Amended Pricing Effective Date.

c. Any price reductions provided hereunder are not intended as an inducement or reward for any procurement or purchasing decisions by the U.S. Government of any Contractor product.

d. For purposes of this section, "Covered Nation" shall mean a nation that is a high-income country as defined by the World Bank and "Product" shall mean one dose of Contractor's product that is the subject of this contract.

e. The USG shall not be entitled to the price of Product purchased by a Covered Nation for purposes of donation or resale by the Covered Nation to non-governmental organizations, intergovernmental organizations, or "lower-income" or "lower middle-income countries" as those terms are defined by the World Bank as of the date of the effective date of agreement between Contractor and the Covered Nation.

f. For clarity, if Contractor enters into an agreement with more than one nation, a multinational organization, or a multilateral organization, and a Covered Nation receives Product under such an agreement or benefits from the price under such an agreement, the Parties agree that the relevant volume for purposes of this contract shall be the total Product volume specified in such agreement and not the Product volume any one Covered Nation receives.

B.5.6 Donation of Excess Product

a. In the event the Government determines that doses of Product funded under the contract are no longer needed by the Government, the Government may donate, either directly or through a nongovernmental organization or intergovernmental organization, remaining doses to any "lower income" or "lower middle-income countries", as those terms are defined by the World Bank as of the date of donation ("Donee Nation"), that: (1) (a) has an active marketing approval in place for use of Product at the time of donation or, (b) if no marketing approval is in place, has an active regulatory authorization. Prior to any donation, the USG shall use reasonable efforts to promote Donee Nations' compliance with Product Handling Guidance (Attachment 1).

b. The Government shall notify Contractor prior to any planned donation to a Donee Nation. Contractor agrees to work with the Government in good faith to ensure all applicable regulatory submissions, import/export permits, and other requirements for donation are completed in advance of shipment to the extent that donation is authorized under Paragraph “a” above. Nothing in this Paragraph shall require the Contractor to seek regulatory approval in any particular country.

c. Contractor will be responsible for shipment of Product to the receiving Donee Nation; provided, however, Contractor shall have no obligation to repackage or relabel the product already purchased by the USG for delivery to the U.S. market and provided further that Contractor shall only be responsible for shipment of the product to one reasonable location within the receiving Donee Nation, or as otherwise agreed between the Parties. Contractor shall be responsible for the cost of shipping.

d. The parties acknowledge that Article B.4 regarding PREP Act coverage does not apply to the provision of any product under this paragraph to a Donee Nation. The USG makes no representations as to PREP Act coverage thereto.

B.5.7 Sharing of contract deliverables within United States Government (USG)

Subject to the data rights provisions of FAR 52.227-14 and 52.227-14 Alt. II, 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 War (DOW), the National Institutes of Health (NIH), the Centers for Disease Control and Prevention (CDC), and the Food and Drug Administration (FDA), BARDA may share technical deliverables and test results created in the performance of this Contract with the United States Government and entities within the Integrated Portfolio. This advance understanding does not authorize the Government to share financial or technical information, technical deliverables, or any other data 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.

B.5.8 Dissemination of Information

Performance under this contract may require the Contractor to access non-public data and information proprietary to a U.S. Government agency, another U.S. Government Contractor or of such nature that its dissemination or use other than as specified in the work statement would be harmful to the interests of the U.S. Government or others. Neither the Contractor, nor Contractor personnel, shall divulge nor release data nor information relating to product delivery timing or sites that is developed or obtained under performance of this contract, except upon written approval of the Contracting Officer (CO) which the Contracting Officer will provide in accordance with other Government policies and/or guidance. The Contractor

shall not use, disclose, or reproduce proprietary data that bears a restrictive legend, other than as specified in this contract, or any information at all regarding this agency. The Contractor shall comply with all applicable Government requirements for protection of non-public Government or third-party information. Unauthorized disclosure of nonpublic information is prohibited by the Government's rules. Unauthorized disclosure may result in termination of the contract, replacement of a Contractor employee, or other appropriate redress.

B.5.9 Sharing Research Data

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.

B.5.10 Dissemination of False or Deliberately Misleading Information

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

B.5.11 Rights of Refusal

The Government's rights to data first developed in the performance of this Contract, the Government's limited rights to preexisting data used during the development effort under this Contract and the Government's rights to use Subject Inventions developed under this Contract shall survive any transfer of such title to a Subject Invention any third party. The Government may either exercise or waive this first right of refusal in writing and submit to the Contractor within ninety (90) calendar days of the initial notification to the Government of the Contractor's intent to conduct any such transfer of title to a Subject Invention. This Article shall not apply to transfers of title to technology created with the use of funding obtained outside of this Contract.

B.5.12 Person in Plant

Upon request from BARDA, in writing from the Contracting Officer, the Government may place a person-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/her 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.5.13 Notification of Critical Programmatic Concerns, Risks, or Potential Risks

Contractor shall communicate to BARDA and document all critical programmatic concerns, issues, or probable risks that have or are likely to significantly impact project schedule or cost. Incidents that present liability to the project even without schedule impact, must also be reported.

- Contractor must notify BARDA within 48 hours of activity or incident or within 24 hours for a security related activity or incident.
- Email or telephone with written follow-up to CO and COR.
- Additional updates due to COR and CO within 48 hours of additional developments.
- Contractor shall submit within five (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 five (5) business days of receiving such concern(s).

B.5.14 Conflict of Interest

Prior to commencement of any work, the Contractor and subcontractors agree to notify the CO promptly that, to the best of their knowledge and belief, no actual or potential conflict of interest exists or to identify to the CO any actual or potential conflict of interest the Contractor or subcontractors may have. In emergency situations, however, work may begin but notification shall be made within five (5) business days. The Contractor and subcontractors agree that if an actual or potential organizational conflict of interest is identified during performance, the Contractor and subcontractors shall promptly make a full disclosure in writing to the CO; this disclosure shall include a description of actions which the Contractor and subcontractors have taken or proposes to take, after consultation with the CO, to avoid, mitigate, or neutralize the actual or potential conflict of interest. The Contractor and subcontractors shall continue performance until notified by the CO of any contrary action to be taken. Remedies include termination of this contract for convenience, in whole or in part, if the CO deems such termination necessary to avoid an organizational conflict of interest. If the Contractor or subcontractors were 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 CO, BARDA may terminate the contract for default, debar the Contractor or subcontractor from Government contracting, or pursue such other remedies as may be permitted by law or this contract.

B.5.15 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 must 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 must include the following information:
    i. The name, title, and contact information for the Consultant, including the name and contact information for his/her company/firm/etc.
    ii. The name, title, and contact information for a Contractor's point of contact, including the name and contact information for the prime contractor if the consulting services were received by a subcontractor.
    iii. The nature of the consulting services received. The contractor must perform a Conflict of Interest (COI) check prior to using any consultant.

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.5.16 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.

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.

B.5.17 The Offeror will be responsible for maintaining Government Property in accordance with FAR 52.245-1.

B.5.18 Invoices: Cost and Personnel Reporting, Variance from the Negotiated Budget

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

b. The Contractor agrees to provide a detailed breakdown on invoices of the following cost categories:
    i. Direct Labor - List individuals by name, title/position, hourly/annual rate, level

of effort, and amount claimed.

ii. Fringe Benefits - Cite rate and amount
iii. Overhead - Cite rate and amount
iv. Materials & Supplies - Include detailed breakdown when total amount is over $1,000.
v. Travel - Identify travelers, dates, destination, purpose of trip, and amount. Cite Course of Action (COA), if appropriate. List separately domestic travel, general scientific meeting travel, and foreign travel.
vi. Consultant Fees - Identify individuals and amounts.
vii. Subcontracts - Attach subcontractor invoice(s).
viii. Equipment - Cite authorization and amount.
ix. General and Administrative (G&A) - Cite rate and amount.
x. Total Cost
xi. Fixed Fee
xii. Total Cost-Plus-Fixed-Fee (CPFF)

B.5.19 Registration with the Select Agent Program for Work Involving the Possession, Use, and/or Transfer of Select Biological Agents or Toxins

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

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

For prime or subcontract awards to foreign institutions who possess, use, and/or transfer Select Agents under this contract, the institution must provide information satisfactory to the Government that a process equivalent to that described in 42 CFR 73 (https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=8a4be60456973b5ec6bef5dfeaffd49a&r=PART&n=42y1.0.1.6.61) for U.S. institutions is in place and will be administered on behalf of all Select Agent work sponsored by these funds before using these funds for any work directly involving the Select Agents. The Contractor must provide information addressing the following key elements appropriate for the foreign institution: safety, security, training, procedures for ensuring that only approved/appropriate individuals have access to the Select Agents, and any applicable laws, regulations, and policies equivalent to 42 CFR 73. The Government will assess the policies and procedures for comparability to the U.S. requirements described in 42 CFR Part 73. When requested by the contracting officer, the Contractor shall provide key information delineating any laws, regulations, policies, and procedures applicable to the foreign institution for the safe and secure possession, use, and transfer of Select Agents. This includes summaries of safety, security, and training plans, and applicable laws, regulations, and policies. For the purpose of security risk assessments, the Contractor must provide the names of all individuals at the foreign institution who will have access to the Select Agents and procedures for ensuring that only approved and appropriate individuals

have access to Select Agents under the contract.

No BARDA funds may be used for a restricted experiment with a Select Agent or Toxin at either a domestic or a foreign institution without written approval from the Contracting Officer.

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

B.5.20 Animal Welfare

All research involving live, vertebrate animals shall be conducted in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). The PHS policy can be accessed at: https://olaw.nih.gov/policies-laws/phs-policy.htm. Animal studies will not begin until the Contractor's or subcontractor's IACUC provide final approval of the study protocol.

B.5.21 Information on Compliance with Animal Care Requirements

Registration with the U.S. Department of Agriculture (USDA) is required to use regulated species of animals for biomedical purposes. USDA is responsible for the enforcement of the Animal Welfare Act (7 U.S.C. 2131 et. seq.), https://www.nal.usda.gov/animal-health-and-welfare/animal-welfare-act.

The PHS Policy is administered by the OLAW https://olaw.nih.gov/. An essential requirement of the PHS Policy (https://olaw.nih.gov/policies-laws/phs-policy.htm) is that every institution using live vertebrate animals must obtain an approved assurance from OLAW before they can receive funding from any component of the U.S. Public Health Service. If the Contractor does not have an assurance and will be utilizing a subcontractor to perform the animal work, then the Contractor and subcontractor must have an Inter-Institutional Assurance in place to allow the Contractor to utilize the assurance of the subcontractor to meet the Government's requirements for assurance. The request for this negotiation of this assurance must be submitted to OLAW by the Government on behalf of the Contractor.

The PHS Policy requires that Assured institutions base their programs of animal care and use on the Guide for the Care and Use of Laboratory Animals https://nap.nationalacademies.org/catalog/12910/guide-for-the-care-and-use-of-laboratory-animals-eighth and that they comply with the regulations (9 CFR, Subchapter A) https://www.nal.usda.gov/animal-health-and-welfare/animal-welfare-act issued by the USDA under the Animal Welfare Act. The Guide may differ from USDA regulations in some respects. Compliance with the USDA regulations is an absolute requirement of this Policy.

The Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC) http://www.aaalac.org is a professional organization that inspects and evaluates programs of animal care for institutions at their request. Those that meet the high standards are given the accredited status. As of the 2015 revision of the PHS Policy, the only accrediting body recognized by PHS is the AAALAC. While AAALAC accreditation is not required to conduct biomedical research, it is highly desirable. AAALAC uses the Guide as

their primary evaluation tool. They also use the Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching. It is published by the Federation of Animal Science Societies https://www.fass.org.

B.5.22 Approval of Required Assurance by Law

Under governing regulations, federal funds that are administered by the Department of Health and Human Services, BARDA shall not be expended by the Contractor for research involving live vertebrate animals, nor shall live vertebrate animals be involved in research activities by the Contractor under this award unless a satisfactory assurance of compliance with 7 U.S.C. 2136 and 9 CFR Sections 2.25-2.28 is submitted by Recipient 30 days prior to commencing research involving live vertebrate animals and approved by the Office of Laboratory Animal Welfare (OLAW). Each performance site (if any) must also assure compliance with 7 U.S.C. 2136 and 9 CFR Sections 2.25-2.28 with the following restriction: Only activities that do not directly involve live vertebrate animals (i.e., are clearly severable and independent from those activities that do involve live vertebrate animals) may be conducted by individual performance sites pending OLAW approval of their respective assurance of compliance with 7 U.S.C. 2136 and 9 CFR Sections 2.25-2.28. Additional information regarding OLAW may be obtained at https://olaw.nih.gov/policies-laws/phs-policy.htm.

B.5.23 Clinical Terms of Award

Efforts performed under this contract, whether performed domestically, OCONUS, or Tribal Nations or jurisdictions must be conducted ethically and in accordance with U.S Food and Drug Administration (FDA) guidance and all applicable laws, directives, and regulations which includes the following:

- Electronic Records; Electronic Signatures (21 CFR Part 11)
- Regulatory Hearing Before the Food and Drug Administration (21 CFR Part 16)
- Protection of Human Subjects (21 CFR Part 50)
- Financial Disclosure by Clinical Investigators (21 CFR Part 54)
- Institutional Review Boards (21 CFR Part 56)
- Good Laboratory Practice for Nonclinical Laboratory Studies (21 CFR Part 58)
- Investigational New Drug Application (21 CFR Part 312)
- Applications for FDA Approval to Market a New Drug (21 CFR Part 314)
- Bioavailability and Bioequivalence Requirements (21 CFR Part 320)
- New Animal Drugs for Investigational Use (21 CFR Part 511)
- New Animal Drug Applications (21 CFR Part 514)
- Licensing (21 CFR Part 601)
- Investigational Device Exemptions (21 CFR Part 812)

- Premarket Approval of Medical Devices (21 CFR Part 814)

BARDA has the responsibility to obtain documentation concerning mechanisms and procedures that are in place to protect the safety of participants in BARDA-funded clinical studies. Therefore, the Contractor must develop a protocol for the clinical study funded under the Contract and submit all such protocols, protocol amendments, and other essential clinical study documentation (for example and not limited to Statistical Analysis Plan, Investigators Brochure, and Informed Consent) to the Contracting Officer's Representative (COR) for evaluation and comment. The Contractor must address, in writing, all concerns (e.g., study design, safety, regulatory, ethical, conflict of interest) noted by the COR prior to submission to another entity, pursuant to the terms set forth by the Deliverables section of the Contract.

Research involving human subjects shall not be conducted under this contract until the Contractor has provided to the Contracting Officer (CO) a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 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.

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 certifying IRB review and approval of the research. Additionally, the Contractor must obtain and keep reliance documentation for cooperative/multi-site research where a single IRB is required.

The Contractor shall maintain the following information: (1) a list of the names and titles of the principal investigator and any other individuals working under the contract who are responsible for the design and/or conduct of the research; (2) the title of the education program(s) in the protection of human subjects that has been completed for each named personnel and; (3) a one sentence description of the educational program(s) listed in (2) above. This requirement extends to investigators and all individuals responsible for the design and/or conduct of the research who are working as subcontractors or consultants under the contract.

Prior to any substitution of the Principal Investigator or any other individuals responsible for the design and/or conduct of the research under the contract, the Contractor shall provide the following written information to the Contracting Officer: the title of the education program and a one sentence description of the program that has been completed by the replacement.

BARDA shall have unlimited rights to all protocols, data resulting from execution of these protocols, and final reports funded by BARDA under the Contract, as set forth in FAR Clause 52.227-14, Rights in Data—General. BARDA reserves the right to request that the Contractor provide any contract deliverable identified in the Deliverables Section in a non-proprietary form to ensure BARDA has the ability to review and distribute the deliverables as BARDA deems necessary.

All BARDA-funded investigators and staff who are involved in the conduct, oversight, or management of clinical studies must be trained in Good Clinical Practice (GCP), consistent with principles of the International Conference on Harmonisation (ICH) E6 (R3). GCP training may be achieved through a class or course, academic training program, or certification from a recognized clinical research professional organization. GCP training must be refreshed at least every three years to remain current with regulations, standards, and guidelines. The Contractor shall provide completion of training documentation to the COR.

For clarity, the Investigator is the individual responsible for the conduct of the clinical study at a study site. If a clinical study is conducted by a team of individuals at a study site, the investigator is the responsible leader of the team and may be called the principal investigator. Clinical staff are those individuals that have been identified by the investigator, who are responsible for study coordination, data collection, and data management. Clinical study staff may also be called the research coordinator, study coordinator, research nurse, study nurse, or sub-investigator.

Execution of clinical studies require written authorization from BARDA before enrollment activities may begin. The CO will provide written authorization to the Contractor upon: 1) receiving documentation in which all COR comments have been satisfactorily addressed; and 2) receiving documentation that the FDA has reviewed and commented on the protocol. For purposes of the Contract, “Execution” or “Start” of a clinical study shall mean the initiation of screening activities for enrollment (hereafter referred to as “enrollment”) of the first subject.

Following are the Clinical Terms of Award regarding safety and monitoring:

i. Institutional Review Board (IRB) or Independent Ethics Committee (IEC) Approval and Continuing Review

For the Contractor and other institutions involved in the research (e.g., a multicenter clinical study), the Contractor shall ensure that each participating institution’s IRB or IEC review and approve the protocol and conduct continuing review as required by applicable regulations. The Contractor must also obtain and provide initial and annual documentation of continuing review and approval to the COR in accordance with applicable regulations and the Deliverables section of the Contract (see sub-section 2 for pre-enrollment submission requirements).

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 IRB or IEC approval status of the ongoing protocol, including the following:

- All amendments, clarifications, 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;
- Notification of termination or temporary suspension of participant accrual;

- Notification of termination or temporary suspension of the protocol;
- Notification of any change in IRB approval; and
- Any other IRB/IEC communications, determinations, or reportable events that could affect participant safety, rights, or welfare.

The Contractor must notify the COR and CO electronically of any of the above changes within three (3) business days, 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 at any time during the performance of this contract the Contractor is not in compliance with any of the requirements and or standards stated 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 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.

ii. BARDA Pre-Enrollment Documentation Review and Authorization to Initiate Enrollment

Before participant accrual or enrollment at each participating institution, the Contractor must submit documentation to the COR sufficient to demonstrate that the required human-subject protection and regulatory elements are in place:

- IRB- or IEC-approved clinical study protocol identified by version number, date, or both, including details of study design, proposed interventions, participant eligibility, and exclusion criteria;
- Documentation of IRB or IEC approval, including OHRP Federal Wide Assurance (FWA) number, IRB or IEC registration number, and IRB and/or IEC name;
- IRB- or IEC- approved informed consent document, identified by version number, date, or both and dates it is valid;
- Plans for data and safety monitoring 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 that the study may legally begin enrollment, as applicable (e.g., IND in effect; IDE approved/deemed approved for significant risk devices; IRB approval for NSR device studies); and
- For IND studies, documentation of completed and signed Form FDA 1572 from each participating clinical investigator at each site.

Participant enrollment may not begin until the COR has completed review of the submission and the CO provided written authorization to initiate enrollment.

iii. Data and Safety Monitoring Requirements in Clinical Studies

BARDA requires a study data and safety monitoring plan for managing/implementing the appropriate and objective oversight of all BARDA-funded clinical studies that ensures the safety of participants and the validity and integrity of the data prior to initiating any enrollment. As a minimum standard, BARDA requires independent safety monitoring for clinical studies of investigational drugs, devices, or biologics; clinical studies of licensed products; and clinical studies of any type involving more than minimal risk to volunteers. Independent monitoring can take a variety of forms.

Decisions regarding the type of monitoring to be used must be made jointly by BARDA and the Contractor before enrollment starts. Discussions with the COR and Medical Safety Program (MSP) physician regarding appropriate data and safety monitoring as determined by the COR and approval of the final monitoring plan by the COR must occur before participant enrollment begins and must include discussions about the appointment of one of the following:

- Independent Safety Monitor – a physician or other expert with appropriate clinical expertise and qualifications 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, including one or more individuals with appropriate clinical expertise and qualifications, and biostatisticians who review study data and monitor participant safety.
- 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.
- 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 may start. 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 during the study. BARDA shall appoint an unblinded physician observer as a member of the IMC or SMC. The Contractor will share conflict of interest reports with the CO and COR.

iv. Investigational New Drug or Investigational Device Exemption Requirements

Consistent with federal regulations, clinical studies 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), unless the study meets criteria for exemption under applicable FDA regulations (e.g., IND exemptions under 21 CFR 312.2 and IDE exempt investigations under 21 CFR 812.2(c)), or qualifies for abbreviated IDE requirements (e.g., NSR device studies under 21 CFR 812.2(b)).

Exceptions must be granted in writing by FDA. If the proposed clinical study 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 as stated below before initiating a clinical study.

Under IND: The Contractor must not administer an investigational new drug to human subjects until the IND is in effect (generally 30 calendar days after FDA receives the IND, unless FDA notifies the sponsor of a clinical hold or authorizes earlier initiation) and IRB approval has been obtained.

Under IDE, Significant Risk: For significant risk device studies, subject enrollment may begin only after FDA approval (or deemed approval) of the IDE and IRB approval have been obtained. FDA must notify the sponsor of its decision within 30 days of receipt of the IDE application, or the IDE is deemed approved.

Under IDE, Nonsignificant Risk: For nonsignificant risk device studies, an IDE submission to FDA is generally not required; the study may begin after IRB approval under the abbreviated IDE requirements, consistent with FDA regulations and IRB determinations.

v. Required Time-Sensitive Notification

Under an IND or IDE, the sponsor must comply with all applicable FDA safety reporting requirements, including 21 CFR 312.32 (IND) and 21 CFR 812.150 (IDE), and applicable current FDA guidance on IND safety reporting and electronic submission of IND safety reports. Under these Clinical Terms of Award, the Contractor must also submit copies to the responsible COR as follows:

1. IND 7-day safety reports (fatal or life-threatening and unexpected suspected adverse reactions) and IND 15-day safety reports (serious and unexpected suspected adverse reactions that are neither fatal nor life-threatening):

   A copy of all safety reporting and follow-up submissions to FDA must be submitted to the COR within 24 hours of each submission.

2. IND – method of submission:

   IND safety reports must be submitted to FDA electronically in the format and manner required for the applicable IND and report type (e.g., submission via FDA's electronic submission systems, and/or submission in eCTD or alternate FDA-accepted electronic format, as applicable). Where FDA permits or requires other means of rapid communication for submission/notification, the Contractor will use such methods as appropriate.

3. IDE unanticipated adverse device effect (UADE) reporting:

For investigations conducted under an IDE, the Contractor must report the results of an evaluation of any unanticipated adverse device effect (UADE) to FDA and all reviewing IRBs and participating investigators within ten (10) working days after the sponsor first receives notice of the effect, consistent with 21 CFR 812.150. A copy of each UADE report must be submitted to the COR within 24 hours of FDA notification.

B.5.24 Single Institutional Review Board (sIRB)

For Institutional Review Board (IRB), the Contractor shall use a single Institutional Review Board (sIRB) of record for multi-site studies per 45 CFR 46.114. All domestic sites participating in multi-site studies involving a non-exempt human subjects research funded wholly or partially by the BARDA shall use a sIRB to conduct the ethical review required by the Department of Health and Human Services regulations for the Protection of Human Subjects at 45 CFR Part 46. Any IRB serving as the sIRB of record for BARDA funded research shall be registered with the Department of Health and Human Services (HHS) Office for Human Research Protections (OHRP) and shall have membership sufficient to adequately review the proposed study.

The Contractor shall provide to the CO a properly completed "Protection of Human Subjects Assurance Identification/IRB Certification/Declaration of Exemption", Form OMB No. 0990-0263 certifying IRB review and approval of the research that encompasses all sites of performance.

When the Government provided sIRB through a separate entity, the Contractor agrees to use of the sIRB. The Contractor shall provide to the CO sIRB information and data in a timely manner as necessary to meet the policy and/or regulatory requirements of the Protection of Human Subjects at 45 CFR Part 46.

<u>Exceptions to the Single IRB Policy:</u>

The Contractor may request an exception in the following instances:

a. Sites for which Federal, state, or tribal laws, regulations or policies require local IRB review (policy-based exceptions);

b. Other exceptions, to be determined by OHRP if there is a compelling justification; and

c. Time Limited Exception: ancillary studies to ongoing research without a sIRB - new multi-site non-exempt human subjects' ancillary studies, that would otherwise be expected to comply with the sIRB policy but are associated with the ongoing multi-site parent studies, will not be required to use a sIRB of record until the parent study is expected to comply with the sIRB policy.

Other exceptions are expected to be granted rarely.

Contractors must include the name of the site(s) for which an IRB other than the sIRB of

record is proposed to review the study for the site(s).

Contractors must substantiate their exception request with sufficient information that demonstrates a compelling justification for other exceptions to the sIRB policy. The rationale should include why the sIRB of record cannot serve as the reviewing IRB for the site(s), and why the local IRB is uniquely qualified to be the reviewing IRB for specific site(s). For instance, the justification may consider ethical or human subjects protections issues, population needs, or other compelling reasons that IRB review for the site(s) cannot be provided by the single IRB of record.

Contractors shall contact their CO for exception requests. For policy-based exceptions, the Contractor shall provide the appropriate citation to verify the requirement for local IRB review.

B.5.25 Certificates of Confidentiality

Section 2012 of the 21st Century Cures Act, enacted December 13, 2016, enacts new provisions governing the authority of the Secretary of Health and Human Services (Secretary) to protect the privacy of individuals who are the subjects of research, including significant amendments to the previous statutory authority for such protections, under subsection 301(d) of the Public Health Service Act.

The Government considers research in which identifiable, sensitive information is collected or used, to include:

Human subjects research as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46), including exempt research (except for human subjects' research that is determined to be exempt from all or some of the requirements of 45 CFR 46) if the information obtained is recorded in such a manner that human subjects cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

Research involving the collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual;

Research that involves the generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that human subjects can be identified or the identity of the human subjects can readily be ascertained as defined in the Federal Policy for the Protection of Human Subjects (45 CFR 46); or

Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual, as defined in subsection 301(d) of the Public Health Service Act.

The Contractor shall not:

a. Disclose or provide, in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or

b. Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

The Contractor is permitted to disclose only in below circumstances. The Contractor shall notify the CO minimum ten (10) calendar days prior to disclosure.

a. Required by Federal, State, or local laws (e.g., as required by the Federal Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to State and local health departments), excluding instances of disclosure in any Federal, State, or local civil, criminal, administrative, legislative, or other proceeding.

b. Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual.

c. Made with the consent of the individual to whom the information, document, or biospecimen pertains; or made for the purposes of other scientific research that is in compliance with applicable Federal regulations governing the protection of human subjects in research.

In accordance with 45 CFR Part 75.303(a), the contractor shall maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the award is managed in compliance with Federal Statutes and regulations.

Additional details about BARDA Certificates of Confidentiality (CoC) policy are available at: https://www.medicalcountermeasures.gov/barda/rqa#coc

B.5.26 Clinical Study Reporting Compliance

The Contractor and subcontractors are required to comply with all terms and conditions of award and all applicable regulations and laws. The Contractor must:

1. Register all BARDA-funded clinical studies in ClinicalTrials.gov and study results posted on ClinicalTrials.gov as detailed in 42 CFR Part 11 - Clinical Trials Registration and Results Information Submission and further described in the “Clinical Trial Reporting Requirements” (https://www.clinicaltrials.gov/policy/reporting-requirements) and Food and Drug Administration’s (FDA) Role: ClinicalTrials.gov Information

(https://www.fda.gov/science-research/clinical-trials-and-human-subject-protection/fdas-role-clinicaltrialsgov-information).

2. Post one IRB-approved version of an Informed Consent Form to ClinicalTrials.gov per the Revised Common Rule (https://www.hhs.gov/ohrp/regulations-and-policy/regulations/finalized-revisions-common-rule/index.html) as detailed in 45 CFR 46.102(b) and 45 CFR 46.116(h).
3. Submit the protocol and statistical analysis plan in a common electronic document format specified at ClinicalTrials.gov as detailed in 42 CFR 11.48(a)(5).
4. Include in the informed consent documents the following exact statement:
    - "A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time."
    - See FDA's guidance on Informed Consent Elements, 21 CFR 50.25(c) for more information.

Failure to comply with the terms and conditions of the award may provide a basis for enforcement actions. Identifying clinical study record as non-compliant in ClinicalTrials.gov may lead to termination, consistent with 2 CFR 200.339 and/or other authorities, as appropriate. If the BARDA-funded clinical study is also an applicable clinical trial, non-compliance with the requirements specified in 42 USC 282(j) and 42 CFR Part 11 may also lead to the actions described in 42 CFR 11.66. Clinical trials subject to the regulation are called "applicable clinical trials."

The Contracting Officer (CO) may take one or more of the following enforcement actions, if the Contractor fails to provide evidence of compliance within 30 calendar days.

a. Temporary withholding of payments until the Contractor or subcontractor takes corrective action.
b. Disallow costs for all or part of the activity associated with the noncompliance of the Contractor or subcontractor.
c. Suspend or terminate the Federal award in part or in its entirety.
d. Initiate suspension or debarment proceedings as authorized under 2 CFR part 180 and the Department of Health and Human Services (HHS) awarding regulations at 2 CFR part 376.
e. Withhold further Federal funds (new awards or continuation funding) for the project or program.
f. Pursue other legally available remedies.

B.5.27 Posting Clinical Trial Informed Consent Forms to Clinicaltrials.gov

The Revised Common Rule Sections 46.102(b) and 46.116(h) requires Contractors to post one IRB-approved version of an Informed Consent Form that has been used to enroll participants on a public federal website designated for posting such Consent

Forms. Contractors shall post the Informed Consent Form to the NIH clinical trials registry and results database ClinicalTrials.gov. Note: ClinicalTrials.gov only accepts Informed Consent Forms written in English; non-English language forms must be submitted to Regulations.gov. The Informed Consent Form must be posted after recruitment closes, and no later than 60 days after the final study visit. The Contracting Officer (CO) and/or Contracting Officer's Representative (COR) may permit or require redactions as appropriate.

B.5.28 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.

B.5.29 Inclusion of Women and Members of Racial and/or Ethnic Minority Groups in Research Involving Human Subjects

BARDA-conducted and supported clinical research must conform to the NIH Policy and Guidelines on the Inclusion of Women and Members of Racial and/or Ethnic Minority Groups as Subjects in Clinical Research (NIH Inclusion Policy) in accord with Public Health Service Act sec. 4928 U.S.C. sec 289a-2. The policy requires that women and members of racial and/or ethnic minority groups and their subpopulations must be included in clinical research projects involving human subjects, unless a clear and compelling rationale and justification establishes to the satisfaction of the BARDA Clinical Division that inclusion is inappropriate with respect to the health of the subjects or the purpose of the research. BARDA may determine that exclusion under other circumstances is acceptable, based on a compelling rationale and justification. Cost is not an acceptable reason for exclusion except when the study would duplicate data from other sources. Women of childbearing potential should not be routinely excluded from participation in clinical research.

All investigators proposing research involving human subjects should read the UPDATED " NIH Policy and Guidelines on the Inclusion of Women and Members of Racial and/or Ethnic Minority Groups in Clinical Research." as Subjects in Clinical Research, Amended July 17, 2025," published in the NIH Guide for Grants and Contracts on October 9, 2001 at the following web site: https://grants.nih.gov/policy-and-compliance/policy-topics/inclusion/women-and-minorities.

The Contractor must submit the results of valid analyses by sex and race/ethnicity to Clinicaltrials.gov for all Phase III clinical trials. This requirement does not apply to Phase III trials not considered to be applicable clinical trials under 42 CFR Part 11. The Contractor must report applicable NIH-defined Phase III clinical trials involving research subjects of all ages, including foreign awards and domestic awards with a foreign component. The Contractor must specify outcomes on sex and race/ethnicity, as required based on prior evidence, and as explained in the NIH Policy and Guidelines on the Inclusion of Women and Members of Racial and/or Ethnic Minority Groups as

Subjects in Clinical Research.

Note: Applicable clinical trials are required to be registered in ClinicalTrials.gov not later than 21 calendar days after the enrollment of the first participant. Results information, including the results of the valid analyses by sex and race/ethnicity, from those trials must be submitted not later than one year after the trial's primary completion date. Submission of results information can be delayed in certain circumstances for up to two additional years for trials of products regulated by the FDA that are unapproved, unlicensed, or uncleared or for trials of products for which approval, licensure, or clearance of new use is being sought.

B.5.30 Security Requirements

The Contractor will submit a security plan within 90 days afteraward, adjudicate any comments to ensure security plan approval, and adhere to the security requirements as outlined in Attachment 2.

The Contractor shall report to BARDA any activity or incident that is in violation of established security standards; or indicates the loss or theft of BARDA products as described in Attachment 2.

B.5.31 Acknowledgement of Federal Funding

Section 507 of Public Law 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

Unless authorized in writing by the CO, the Contractor shall not display any USG logo or seal including Operating Division or Staff Division logos on any publications.

The Contractor shall not reference the products(s) or services(s) awarded under this contract in commercial advertising, as defined in FAR 31.205-1, in any manner which states or implies USG approval or endorsement of the product(s) or service(s) provided.

Contract support shall be acknowledged in all such publications substantially as follows:

"*The [work/study/project] described in this presentation was funded [in part/in whole] with federal funds from the U.S. Department of Health and Human Services (HHS); Administration for Strategic Preparedness and Response (ASPR); Biomedical Advanced Research and Development Authority (BARDA), under contract number XXXX. The contract and federal funding are not an endorsement of the study results, product, or company.*"

Press Releases and Social Media Announcements

Misrepresenting contract results or releasing information that is injurious to the integrity of BARDA may be construed as improper conduct. Press releases and social media

announcements 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 acknowledge the support of the U.S. Department of Health and Human Services, Administration for Strategic 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 supported in whole or in part with federal funds from the U.S. Department of Health and Human Services; Administration for Strategic Preparedness and Response; Biomedical Advanced Research and Development Authority (BARDA), under contract number XXXX.*"

B.5.32 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 20 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.

B.5.33 Public Access to Archived Publications Resulting from ASPR Funded Research

ASPR Public Access Policy (https://www.aspr.gov/sites/default/files/2026-03/ASPR-Public-Access-Policy-508.pdf) requires all ASPR-funded investigators 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, whether resulting from research supported in whole or in part with Federal funds from the Department of Health and Human Services; Administration for Strategic Preparedness and Response (ASPR). Submission of the electronic version of the Author Accepted Manuscript to PMC shall be made publicly available without embargo upon the Official Date of Publication. 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, including all associated tables, graphics, and supplemental material. 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 by the manuscript author through the National Institutes of Health Manuscript Submission (NIHMS):

https://www.nihms.nih.gov/login/?next=/submission/.

B.5.34 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 control 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 and which are the direct and sole result of Contractor's and/or Subcontractor's performance of the services under this Contract.

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

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

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

b. General

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

must be carefully considered.

c. 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).

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

The Contractor shall provide notice to the CO 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 42.9 pertaining to Novation, specifically FAR section 42.903. 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 CO 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 CO 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 exclusively under the Contract. The USG may waive this first right of refusal in writing submitted to the Contractor within 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 CO and COR of the scheduled transfer to a Foreign Firm or Institution at least 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 CO.**

e. Lower Tier Agreements

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

B.5.35 No Personal Services / No Inherently Government Functions

Pursuant to FAR 37.2, no personal services shall be performed under this contract. All work requirements shall flow only from the COR to the Contractor's Project Manager. No Contractor employee will be directly supervised by the Government. All employee assignments, and daily work direction, shall be given by the applicable Contractor supervisor. If the Contractor believes any Government action or communication has been given that would create a personal services relationship between the Government and any Contractor employee, the Contractor shall promptly notify the Contracting Officer of this communication or action.

Pursuant to FAR 37.3, the Contractor shall not perform any inherently governmental actions under this contract. No Contractor employee shall hold him or herself out to be a Government employee, agent, or representative. No Contractor employee shall state orally or in writing at any time that he or she is acting on behalf of the Government. In all communications with third parties in connection with this contract, Contractor employees shall identify themselves as Contractor employees and specify the name of the company for which they work. In all communications with other Government Contractors in connection with this contract, the Contractor employee shall state that they have no authority to in any way change this contract and that if the other Contractor believes this communication to be a direction to change their contract, they shall notify the Contracting Officer for that contract and not carry out the direction until a clarification has been issued by the Contracting Officer.

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

B.6. MULTIPLE AWARD ORDERING

Under the Indefinite Quantity clause, orders may be issued to all or some contractors awarded a contract under this solicitation. Additional quantities may be ordered based upon the Government’s need and contractor’s ability to produce the requirement.

B.6.1. On Ramp Procedures

The Government will review IDIQ performance and requirements on a regular basis (at least yearly) and determine the necessity for on-ramping. The Government reserves the right, *at its discretion*, to announce and issue new solicitations. The criteria for on-ramping may include, *but are not limited to*, (i) adding additional Contractors which meet the requirements as new contractors, products, or services materialize; (ii) increase the small business pool; and (iii) increase competition. The Government may implement on-ramp procedures at any time by reopening the competition and utilizing the same basis of award as the initial

solicitation. Any resulting awards will have identical terms and conditions to existing awards. On-ramping may be used to increase the contractor pool, introduce new technologies and/or products not currently available and contingent upon FDA approval. Implementing this procedure will not affect the overall period of performance.

B.6.2 Off Ramp Procedures

The Government reserves the right to implement off-ramp procedures, which would result in the removal of IDIQ holders. The criteria for off-ramping may include, *but are not limited to*, IDIQ holders not proposing on order request(s), no longer meeting mandatory minimum eligibility criteria, and/or unsatisfactorily meeting SOW requirements. If implemented, off-ramp procedures will remove IDIQ holders by not exercising the option period or cancelling the holders' IDIQ.

B.7. PROVISIONS TO APPLICABLE COSTS

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

a. Acquisition, by purchase or lease, of any interest in real property;
b. Rearrangement or alteration of facilities;
c. Purchase of lease of any item of general purpose office furniture or office equipment regardless of dollar value;
d. Accountable Government Property;
e. Overtime
f. General scientific meetings/conferences (including fees and travel costs);
g. Travel costs including foreign travel;
    - Provide a breakout of costs for each year including the purpose and number of trips, origin and destination(s), duration and travelers per trip.
h. Costs incurred in the performance of any cost-reimbursement type subcontract (including consulting agreements);
i. Costs to be paid for the performance of a fixed-price subcontract that exceeds the Simplified Acquisition Threshold (SAT);
j. Refreshments and Meal Expenditures;
k. Promotional Items
l. Printing

SECTION C – DESCRIPTION/SPECIFICATIONS/WORK STATEMENT

C.0. STATEMENT OF OBJECTIVES

C.1. BACKGROUND

The Center for the Biomedical Advanced Research and Development Authority (BARDA) within the Administration for Strategic Preparedness and Response (ASPR), U.S. Department of Health and Human Services (HHS), has a long-standing Vaccine Medical Countermeasures (MCMs) for Pandemic Influenza Preparedness and Response Program that ensures a constant state of pandemic readiness by enabling the rapid production of influenza vaccines and adjuvants by manufacturers of FDA-licensed vaccines in the event of a public health emergency. As part of this program, BARDA has established pandemic-ready manufacturing and critical enablers for a permanent readiness posture against high threat influenza virus strains through regulatory readiness, vaccine implementation strategies in the event of a public health emergency, and an inventory of vaccine countermeasures, including vaccine seed stocks, bulk antigen and adjuvant, and final container antigen and adjuvant.

Unlike with seasonal influenza vaccines, two doses of adjuvanted pandemic influenza vaccine will likely be required to protect an immunologically naïve population from severe disease (all age groups). This is expected to require at least 330 million regimens (or 660 million doses) to vaccinate the entire U.S. population. Therefore, a strong domestic vaccine manufacturing capability is critical for national security and response to seasonal and pandemic influenza. To support pandemic readiness, it is crucial to have commercially sustainable manufacturing processes that ensure continuous warm-base production capacity that is not solely U.S. Government (USG)-maintained.

BARDA seeks Contractor(s) to support the continuation of the Vaccine MCMs for Pandemic Influenza Preparedness and Response Program. The Contractor(s) must furnish all the necessary services, qualified personnel, materials, supplies, equipment and facilities (U.S. facilities preferred) not otherwise provided by the USG as needed to provide MCMs, such as vaccines, antigens, and adjuvants, for pandemic preparedness and response or as required in response to a public health emergency; produce antigen and vaccines against influenza virus or other virus with pandemic potential as required by BARDA; produce antigen, adjuvants, and/or vaccines to support USG efforts to further improve influenza vaccines (for which feasibility data is available); and support rapid regulatory decisions and manufacturing readiness by generating and submitting to FDA all relevant data (e.g., analytical, nonclinical, clinical, and/or CMC), including data generated during interpandemic periods.

The solicitation is open to Offerors that have FDA-licensed influenza vaccine(s) and Offerors that have demonstrated successful experience in the manufacturing of influenza vaccines at commercial scale and have submitted a Biologics License Application (BLA) to the FDA for an influenza vaccine.

C.2. SCOPE OF WORK

Independently and not as an agent of the USG, the Contractor must furnish all the necessary services, qualified personnel, materials, supplies, equipment, and facilities (U.S. facilities preferred) not otherwise provided by the USG as needed to perform the work described below.

The Contractor must:

1. Provide MCMs, such as vaccines, antigens, and adjuvants, for pandemic preparedness and response or as required in response to a public health emergency;

2. Produce antigen and vaccines against influenza virus or other virus with pandemic potential as required by BARDA;

3. Produce antigens, vaccines, and/or adjuvants to support USG efforts to further improve influenza vaccines (for which feasibility data are available); and

4. Support rapid regulatory decisions and manufacturing readiness by generating and submitting to FDA all relevant data (e.g., analytical, nonclinical, clinical, and/or chemistry, manufacturing, and controls (CMC)), including data generated during interpandemic periods.

C.3. Detailed Description of Contract Activity Numbers:

Note: Numbers referenced for Activities below reflect numbers identified for base period of performance. CLINs will differ for option periods with item name and scope unchanged.

ACTIVITY 1001: Candidate Vaccine Virus (CVV)
The Contractor must:

- Prepare non-GLP and/or GLP influenza CVVs as directed by BARDA and specified in the Statement of Work of the Task Order.
- Perform CVV characterization to include, but not limited to: HA/NA sequencing, genetic stability, ferret pathogenicity, 2-way antigenicity, HA titer, sterility, exclusivity. Provide results of *in vitro* and *in vivo* testing as necessary and specified in the SOW.
- For CVVs with HPAI virus strains, perform additional characterization to include, but not limited to: chicken embryo lethality, plaque assay.
- Update and submit the regulatory documentation supporting the use of the material during interpandemic periods, pandemic periods, pre-pandemic preparation, pandemic response and, where appropriate, manufacture of licensed or authorized doses.
- Deliver a final report including, at minimum:
    - Manufacturing location (building, room, city, country)
    - Dates of major manufacturing steps
    - Major process inputs and parameters (e.g., number of eggs, bioreactor size, working volume, cell bank number, CVV ID, source and lot number, Master Virus Seed (MVS) and/or Working Virus Seed (WVS) lot number)
    - Volume produced, lot size, quantity/number
    - Yield (e.g., $TCID_{50}$/mL, FFU/mL, etc.)
    - Manufacturing and testing deviations
    - CVV USDA Select Agent Exclusion (for HPAI strains) or other evidence supporting regulatory compliance for CVV use in BSL-2 environment.
    - Certificate(s) of analysis (in English)
    - Certificate(s) of compliance (in English)
    - Storage location and inventory (e.g., building, room, refrigerator/freezer, shelf)

ACTIVITY 1002: CGMP Influenza Vaccine Master and/or Working Virus Seed Lot(s)
The Contractor must provide yield-optimized MVS and/or WVS lot(s), or equivalent(s) (e.g., bacterial cell banks), for influenza vaccine product. The Contractor must:

- Manufacture MVS and/or WVS lot(s), or equivalent(s), for influenza vaccine using the qualified influenza CVV reference strain and/or virus sequence as specified by BARDA. Manufacture must use the same facilities, systems, equipment, processes, and testing as those described and referenced in the FDA-licensed influenza vaccine or as described in the submitted BLA, according to Current Good Manufacturing Practices (CGMP) as applicable and store at appropriate conditions during lot release testing.
- Characterize MVS and/or WVS according to qualified methods in-place within the contractor facilities following relevant standard operating procedures (SOPs). The MVS and/or WVS lot(s), or equivalent(s), must be suitable to transition directly into commercial scale manufacturing.
- Provide seed lot testing results in accordance with specifications as requested by FDA as part of the FDA-licensed influenza vaccine.
- Provide seed lot samples to the FDA for identity verification, and perform other testing as specified by BARDA, and by mutual agreement with the Contractor.
- Update and submit the regulatory documentation supporting the use of the material during interpandemic periods, pandemic periods, pre-pandemic preparation, pandemic response and, where appropriate, manufacture of licensed or authorized doses.
- Store seed lots according to FDA CGMP guidelines.
- Conduct stability and other testing as appropriate or specified by BARDA.
- Add manufactured seed lots to ongoing inventory reports and controlled storage, with disposal only upon BARDA approval.
- Submit standard data report according to instructions in ‘Reporting Requirements.’
- Deliver a final report including, at minimum:
    - Manufacturing location (building, room, city, country)
    - Dates of major manufacturing steps
    - Major process inputs and parameters (e.g., number of eggs, bioreactor size, working volume, cell bank number, CVV ID and source and lot number, MVS/ WVS lot number)
    - Volume produced, lot size, quantity/number
    - Manufacturing and testing deviations
    - Certificate(s) of analysis (in English)
    - Certificate(s) of compliance (in English)
    - CBER Seed Certification Letter
    - Storage location and inventory (e.g., building, room, refrigerator/freezer, shelf)
    - Photographs of produced material clearly marked with an appropriate “U.S. Government Property” label
    - Stability or other testing results

ACTIVITY 1003: Influenza Vaccine Research Lot(s)
The Contractor must provide an influenza vaccine small scale research lot. The Contractor must:

- Prepare research lot(s) as directed by BARDA and specified in the SOW of the Task

Order
- Provide data derived from the manufacturing process.
- Deliver a final report including, at minimum:
    - Manufacturing location (building, room, city, country)
    - Dates of major manufacturing steps
    - Major process inputs and parameters (e.g., number of eggs, bioreactor size, working volume, cell bank number, CVV ID and source and lot number, MVS/WVS lot number)
    - Volume produced, lot size, quantity/number
    - Antigen potency and/or quantity per volume (e.g., µg/mL, FFU/mL)
    - Manufacturing and testing deviations
    - Certificate(s) of analysis (in English)
    - Certificate(s) of compliance (in English)
    - Storage location and inventory (e.g., building, room, refrigerator/freezer, shelf)
    - Photographs of produced material clearly marked with an appropriate "U.S. Government Property" label
    - Stability or other testing results

ACTIVITY 1004: CGMP Influenza Vaccine: Investigational Lot(s)
The Contractor must provide influenza vaccine investigational lot(s) and indicate minimum batch size requirements. The Contractor must:

- Manufacture the investigational vaccine lot(s) in manufacturing facilities according to CGMP under 21 CFR parts 210, 211, and 600. Use a validated production method for influenza vaccine manufacture that is described and referenced in the FDA license or submitted BLA.
- As directed by BARDA or per FDA license or submitted BLA, execute activities related to potency reagent standards manufacture and testing including PLS, reference antigen (lyophilized by the Contractor or provide to CBER for lyophilization), and purified HA for antisera production by CBER as necessary. Communicate and submit material to FDA/CBER as early as possible. In collaboration with FDA/CBER, develop appropriate reagents as appropriate for interpandemic periods or according to a pandemic response.
- Perform lot release testing using lot release specifications of the FDA-licensed influenza vaccine and calibrated reagents and provide results to BARDA.
- Formulate and fill material at the concentration or dosage determined by BARDA.
- Update and submit the regulatory documentation supporting the use of the material during interpandemic periods, pandemic periods, pre-pandemic preparation, pandemic response and, where appropriate, manufacture of licensed or authorized doses.
- Make batch records available for review by BARDA.
- Set aside samples for stability testing as negotiated with BARDA.
- Storage methods including containers, stoppers, and other relevant storage supplies need to be approved by BARDA if different from the FDA license or submitted BLA.
- Submit standard data report according to instructions in 'Deliverable Table.'
- Deliver a final report including, at minimum:
    - Manufacturing location(s) (building, room, city, country)
    - Dates of major manufacturing steps
    - Major process inputs and parameters (e.g., number of eggs, bioreactor size, working volume, cell bank number, CVV ID and source and lot number,

MVS/WVS lot number)
- Volume produced, lot size, quantity/number
- Antigen Potency and/or quantity per volume (e.g., µg/mL, FFU/mL)
- Manufacturing and testing deviations
- Certificate(s) of analysis (in English)
- Certificate(s) of compliance (in English)
- Storage location and inventory (e.g., building, room, refrigerator/freezer, shelf)
- Photographs of produced material clearly marked with an appropriate "U.S. Government Property" label
- Stability or other testing results

ACTIVITY 1005: CGMP Influenza Vaccine: Commercial Scale Bulk Lot(s)
The Contractor must provide influenza vaccine bulk product and indicate minimum batch size. The Contractor must:

- Manufacture the commercial scale bulk vaccine lot in manufacturing facilities according to CGMP under 21 CFR parts 210, 211, and 600. Use a validated production method for influenza vaccine manufacture that is described and referenced in the FDA license or submitted BLA.
- Based on the minimum HA content required for licensed drug product formulation, the contractor must ensure antigen yield is equal to or greater than the minimum HA concentration required to formulate influenza virus antigen in final containers at the appropriate target dose, inclusive of projected stability loss over at least one (1) year.
- As directed by BARDA or per FDA license or submitted BLA, execute activities related to reagent standards manufacture and testing including purified HA for antibody production, PLS antigen reference, secondary antigen reference and antibody production. Communicate and submit material to FDA/CBER as early as possible. In collaboration with FDA/CBER, develop appropriate reagents as appropriate for interpandemic periods or according to a pandemic response.
- Update and submit the regulatory documentation supporting the use of the material during interpandemic periods, pandemic periods, pre-pandemic preparation, pandemic response and, where appropriate, manufacture of licensed or authorized doses.
- Perform lot release testing using lot release specifications of the FDA-licensed influenza vaccine and calibrated reagents and provide results to BARDA.
- Make batch records available for review by BARDA.
- Set aside samples for stability study testing for at least 120 months or as negotiated with BARDA.
- Storage methods including containers, stoppers, and other relevant storage supplies need to be approved by BARDA, if different from the FDA license or submitted BLA.
- Submit standard data report according to instructions in 'Deliverable Table.'
- Deliver a final report including, at minimum:
    - Manufacturing location (building, room, city, country)
    - Dates of major manufacturing steps
    - Major process inputs and parameters (e.g., number of eggs, bioreactor size, working volume, cell bank number, CVV ID and source and lot number, MVS/WVS lot number)
    - Volume produced, lot size, quantity/number
    - Antigen Potency and/or quantity per volume (e.g., µg/mL, FFU/mL)
    - Manufacturing and testing deviations
    - Certificate(s) of analysis (in English)

- Certificate(s) of compliance (in English)
- Storage location and inventory (e.g., building, room, refrigerator/freezer, shelf)
- Photographs of produced material clearly marked with an appropriate “U.S. Government Property” label
- Stability or other testing results
- CBER lot release, as appropriate

ACTIVITY 1006: CGMP Adjuvant: Clinical or Commercial Scale Bulk Lot(s)
The Contractor must provide adjuvant bulk product suitable for formulation and fill-finishing for use in a clinical study or use during a public health emergency. Minimum batch size required for formulation and filling must be indicated. Proposed adjuvant must be in Phase 2 development in combination with an influenza or emerging pathogen antigen. Clinical evidence of antigen sparing, dose sparing, and/or adjuvant benefit for the influenza or emerging pathogen antigen is required. The Contractor must:

- Manufacture the bulk adjuvant product at clinical or commercial scale according to CGMP under 21 CFR parts 210, 211, and 600, as applicable, and store at appropriate conditions during lot release testing.
- Make batch records available for BARDA review.
- Set aside samples for stability study testing for at least 120 months or as negotiated with BARDA.
- Execute lot release testing of bulk adjuvant.
- Storage methods including containers, stoppers, and other relevant storage supplies need to be approved by BARDA if different from the FDA license or submitted BLA.
- Update and submit the regulatory documentation supporting the use of the material during interpandemic periods, pandemic periods, pre-pandemic preparation, pandemic response and, where appropriate, manufacture of licensed or authorized doses.
- Submit standard data report according to instructions in ‘Deliverable Table.’
- Deliver a final report including, at minimum:
    - Manufacturing location(s) (building, room, city, country)
    - Dates of major manufacturing steps
    - Major process inputs and parameters (e.g., bioreactor/skid type and size, working volume, lot number)
    - Volume produced, lot size, quantity/number
    - Manufacturing and testing deviations
    - Certificate(s) of analysis (in English)
    - Certificate(s) of compliance (in English)
    - Storage location and inventory (e.g., building, room, refrigerator/freezer, shelf)
    - Photographs of produced material clearly marked with an appropriate “U.S. Government Property” label
    - Stability or other testing results

ACTIVITY 1007: Formulation and Filling
The unit for this item is Each (e.g., vial, syringe, sprayer). Indicate minimum batch size required for formulation and filling. Sub-Activities may include:

1007A: Antigen
1007B: Adjuvant
1007C: Co-formulated antigen and adjuvant
1007D: Access to Filling Capacity or Disruption Fee for Commercial Products

- For 1007D: Include cost associated with disruption to schedule to accommodate

USG needs. This cost should only cover the fee intended to reimburse contracted vendor for penalty fees needed to disrupt the schedule.

The Contractor must:

- Formulate and fill antigen and/or adjuvant in final containers specified in Activities 1007 A-C.
- Complete all formulation, fill-finish activities of antigen and/or adjuvant out at facilities in compliance with FDA-CGMP guidelines and if applicable, in accordance with the formulation and filling requirements that apply to FDA-licensed influenza vaccine, unless otherwise requested, specified, and approved by BARDA.
- Formulate material at the concentration or dosage determined by BARDA.
- Fill each unit to a volume approved by BARDA.
- Assure compliance of formulation and filling activities with the license as required by BARDA.
- Execute lot release product testing of the final container using lot release specifications of the FDA-licensed influenza vaccine product.
- Update and submit the regulatory documentation supporting the use of the material during interpandemic periods, pandemic periods, pre-pandemic preparation, pandemic response and, where appropriate, manufacture of licensed or authorized doses.
- Make batch records available for BARDA review.
- Set aside final containers for stability study testing for at least 120 months or as negotiated.
- Submit standard data report according to instructions in 'Deliverable Table.'
- Provide interim report data at the conclusion of each manufacturing phase as specified in the Standard Data Reporting Requirements.
- Deliver a final report including, at minimum:
    - Manufacturing location(s) (building, room, city, country)
    - Dates of major manufacturing steps
    - Major process inputs and parameters (e.g., number of eggs, bioreactor size, working volume, cell bank number, CVV ID, source and lot number, lot number history from MVS/WVS lot number through fill lot number)
    - Summary of Final Container (FC) Inventory (Total Volume produced, FC fill volume, vial size, total FC quantity filled, FC retained for stability, FC retained for QC Testing, FC losses (i.e., rejected FC totals)
    - Antigen potency and/or quantity per volume (e.g., µg/mL, FFU/mL)
    - Manufacturing and testing deviations
    - Certificate(s) of analysis (in English)
    - Certificate(s) of compliance (in English)
    - Storage location (e.g., building, room, refrigerator/freezer, shelf)
    - Photographs of produced material clearly marked with an appropriate "U.S. Government Property" label
    - Stability or other testing results
    - CBER lot release, as appropriate

ACTIVITY 1008: Label and Packaging
Indicate minimum batch size. The Contractor must:

- Affix labels onto filled final containers with BARDA approved text. BARDA will require coding on primary containers and secondary packages for product identification,

serialization, lot number, and expiration dating in accordance with FDA and GS1 / ISO standards. In the event of a public health emergency, BARDA may require different container labeling criteria for distribution and administration to the U.S. population.

- Package filled and labeled final containers as required/specified by BARDA.
- Co-package antigen with adjuvant as required/specified by BARDA.
- Execute lot release product testing of the finished product using lot release specifications of the FDA-licensed influenza vaccine product.
- Update and submit the regulatory documentation supporting the use of the material during interpandemic periods, pandemic periods, pre-pandemic preparation, pandemic response and, where appropriate, manufacture of licensed or authorized doses.
- Submit standard data report according to instructions in 'Deliverable Table.'
- Provide interim report data at the conclusion of each manufacturing phase as specified in the Standard Data Reporting Requirements.
- Deliver a final report including, at minimum:
    - Label artwork for primary and secondary packaging
    - Manufacturing location (building, room, city, country)
    - Dates of major manufacturing steps
    - Major process inputs and parameters (e.g., number of eggs, bioreactor size, working volume, cell bank number, CVV ID and source and lot number, lot number history from MVS/WVS lot number through fill lot number)
    - Summary of Final Container (FC) Inventory (Total Volume produced, FC fill volume, vial size, total FC quantity filled, FC retained for stability, FC retained for QC Testing, FC losses (i.e., rejected FC totals)
    - Manufacturing and testing deviations
    - Certificate(s) of analysis (in English)
    - Certificate(s) of compliance (in English)
    - Storage location (e.g., building, room, refrigerator/freezer, shelf)
    - Photographs of produced material clearly marked with an appropriate "U.S. Government Property" label
    - Stability or other testing results

ACTIVITY 1009: Storage and Stability Testing of USG-Owned Inventory
Sub-Activities may include:

- 1009A: Storage and Stability of commercial scale bulk lots of antigen
    - The unit for this item is a lot, which equals storage and stability for one (1) lot/month.
- 1009B: Storage and Stability of antigen in final container
    - The unit for this item is a final container which equals storage and stability for a single (1) final container/month.
- 1009C: Storage and Stability of clinical/commercial scale bulk lots of adjuvant
    - The unit for this item is a lot which equals a single (1) month of storage and stability for a single (1) lot/month.
- 1009D: Storage and Stability of adjuvant in final container
    - The unit for this item is a final container which equals storage and stability for a single (1) final container/month.

The Contractor must:

- Maintain materials in a state of readiness for downstream CGMP-governed

manufacturing, clinical evaluation, and distribution of licensed or authorized doses as directed by BARDA. Conduct stability testing according to a stability testing plan approved by BARDA.

- Update and submit the regulatory documentation supporting the continued use of the stored material during interpandemic periods, pandemic periods, and, where appropriate, manufacture of licensed or authorized doses.
- Provide temperature-controlled storage of materials at the Contractor site approved by BARDA, according to CGMP and the Contractor's product specifications and internal quality control system(s).
- Label stored materials as USG Property and physically segregate from other products.
- Report interim data and results to BARDA on a monthly basis.
- Report testing and storage deviations.
- Ensure that sufficient representative samples are available at the time of award of the "Storage and Stability" task order to support all required stability testing for a minimum of 120 months from the date of manufacture, and for any additional period beyond 120 months as required to demonstrate continued product stability, or as otherwise directed or negotiated by BARDA.
- Resample product lots and perform all associated testing, analyses, and related services, as necessary to support continued and extended stability studies to demonstrate product stability, including stability testing beyond 120 months, at no additional cost to the Government.
- The Contractor is solely responsible for any transfer of bulk material to an alternate container, and for all associated testing, analyses, and related services, when such transfer is performed for the Contractor's convenience or as a result of the Contractor's decision to modify, update, or implement changes to its processes, and when such transfer is intended to support storage and subsequent stability testing not specified in the originally approved stability plan. All such activities shall be performed at no additional cost to the Government and shall not occur without the prior written approval of the Contracting Officer. Ensure that any material relocated for the Contractor's convenience or as a result of the Contractor's business or process decisions is adequately insured by the Contractor, at no additional cost to the Government. Such relocation shall not occur without the prior written approval of the Contracting Officer. If using a subcontracted storage site, provide the quality agreement, specify the location and terms of the storage contract, and receive approval by BARDA.
- Submit standard data report according to instructions in 'Deliverable Table,' including a comprehensive inventory (e.g., lot number, number of lots, number of vials) by Stock Keeping Unit (SKU), including inventory quantity changes, current quantity, storage facility/location, manufacturing date, latest stability result for potency, date of next expected stability result and the current expiration date (if applicable).

ACTIVITY 1010: Shipping
The unit for this item is each. The Contractor must:

- Package, handle, and ship material to the destination specified in the SOW of the Task Order. Material must be shipped in a condition fit for its intended use.
- Arrange for transit, delivery and insurance of material shipped using qualified processes.
- Complete and submit to BARDA an 'Agent Request Form' (see Attachment 4) or similar upon BARDA request.
- Send EDI 856 Advance Shipping Notices upon BARDA request.

- Send Safety Data Sheet(s) and HDA Standard Rx Product Information Form(s) upon BARDA request.
- Provide BARDA transportation documents (e.g., bill of lading and associated documents).
- Submit standard data report according to instructions in 'Deliverable Table.'
- Deliver a final report including, at minimum:
    - Manufacturing location (building, room, city, country)
    - Dates of major steps
    - Summary of Total Inventory Shipped (lot number, total quantity shipped, origin, destination)
    - Deviations (e.g., temperature excursions, etc.)

- ***Due to the highly speculative nature of shipping for this requirement, it is not possible to estimate, with any degree of certainty, the scope and amount required over the life of the IDIQ. As such, this Activity will not be priced at the IDIQ level, but instead at the task order (TO) or Blanket Purchase Agreement (BPA) level. TO/BPA Contracting Officers must determine price reasonableness prior to TO or BPA award.***

ACTIVITY 1011: Analytical Laboratory Testing/Assay
The Contractor must:

- Conduct laboratory testing and/or assay as required by BARDA and specified in the SOW of the Task Order.
- Provide costs for testing (include release, potency measurements, stability, others as applicable) as described in the Technical/Business Proposal Instruction for Activity 1011 and per Advance Understandings.
- Update and submit the regulatory documentation supporting the use of the material during interpandemic periods, pandemic periods, pre-pandemic preparation, pandemic response and, where appropriate, manufacture of licensed or authorized doses.
- Deliver a final report and a redacted version of the final report, including, at minimum, the information identified in the 'Deliverables Table' and specified in the RTOR.
- Maintain a quality agreement with subcontractor testing sites (if applicable).
- ***Due to the highly speculative nature of this requirement, it is not possible to estimate, with any degree of certainty, the scope and amount required over the life of the IDIQ. As such, this Activity will not be priced at the IDIQ level. Instead, this Activity must be priced at the task order (TO) or Blanket Purchase Agreement (BPA) level. TO/BPA Contracting Officers must determine price reasonableness prior to TO or BPA award.***

ACTIVITY 1012: Nonclinical Study(-ies)
The Contractor must:

- Conduct nonclinical study(-ies) as required by BARDA and specified in the SOW of the Task Order and in accordance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals (PHS Policy). The PHS policy can be accessed at: https://olaw.nih.gov/policies-laws/phs-policy.htm.
- Update and submit the regulatory documentation supporting the use of the material during interpandemic periods, pandemic periods, pre-pandemic preparation, pandemic

response and, where appropriate, manufacture of licensed or authorized doses.
- Transfer samples to a USG-supported storage facility upon request for potential analyses and future use by the USG.
- Provide samples for testing in laboratories designated by BARDA.
- Deliver a final report and a redacted version of the final report as applicable, including, at minimum, the information identified in the 'Deliverables Table' and specified in the RTOR.
- ***Due to the highly uncertain and speculative nature of nonclinical studies, it is not possible to estimate, with any degree of certainty, the scope and amount required over the life of the IDIQ. As such, this Activity will not be priced at the IDIQ level. Instead, this Activity must be priced at the task order (TO) or Blanket Purchase Agreement (BPA) level. TO/BPA Contracting Officers must determine price reasonableness prior to TO or BPA award.***

ACTIVITY 1013: Clinical Study(-ies)
The Contractor must:

- Conduct clinical study(-ies) as required by BARDA and specified in the SOW of the Task Order.
- Perform regulatory activities including opening and maintaining an IND for the clinical trial(s) required by BARDA.
- Update and submit the regulatory documentation supporting the use of the material during interpandemic periods, pandemic periods, pre-pandemic preparation, pandemic response and, where appropriate, manufacture of licensed or authorized doses.
- Primary and/or secondary and/or exploratory endpoint analyses may be performed at a BARDA-supported laboratory as specified in the SOW of the Task Order.
- Transfer samples to a BARDA-supported storage facility upon request for potential analyses and future use by BARDA.
- Share samples for testing in BARDA-designated laboratories.
- Provide notification of designated safety events to the CO and COR within 24 hours of being notified of the event.
- Collect safety data as required by the SOW of the Task Order and Clinical Study protocol.
- Upon request, submit standard data reports according to instructions in 'Reporting Requirements.'
- Deliver a final report including, at minimum, the information identified in the 'Deliverables Table' and specified in the RTOR.
- ***Due to the highly uncertain and speculative nature of clinical studies, it is not possible to estimate, with any degree of certainty, the scope and amount required over the life of the IDIQ. As such, this Activity will not be priced at the IDIQ level, but instead at the task order (TO) or Blanket Purchase Agreement (BPA) level. TO/BPA Contracting Officers must determine price reasonableness prior to TO or BPA award.***

ACTIVITY 1014: Disposal of Product
The Contractor is responsible for disposition of product related to this contract (e.g., expired, out of specification), as required by BARDA. The unit for this item is each (any unit of issue identified in SOW). The Contractor must:

- Notify BARDA prior to any disposal of material acquired in current and prior contracts, records, documentation, and/or reports for consultation and disposition.
- Dispose of material following all federal and state regulations for the appropriate waste category: hazardous waste (e.g., thimerosal-containing product), regulated medical waste (e.g. LAIV), solid waste (e.g., non thimerosal-containing product, non LAIV), etc.
- Provide documentation (e.g. Certificate of Destruction, COD) and reports on the performed and completed disposal activity, which must include lot/batch identifying details with total quantity disposed (total lots, volume/mass, final containers).
- Deliver a final report including, at minimum, the information identified in the 'Deliverables Table' and specified in the RTOR.
- ***Due to the highly speculative nature of product disposal for this requirement, it is not possible to estimate, with any degree of certainty, the scope and amount required over the life of the IDIQ. As such, this Activity will not be priced at the IDIQ level, but instead at the task order (TO) or Blanket Purchase Agreement (BPA) level. TO/BPA Contracting Officers must determine price reasonableness prior to TO or BPA award.***

ACTIVITY 1015: Emerging Pathogen(s)

- The Contractor must perform activities as required by BARDA and as specified in an RTOR.
- Develop, update, and submit the regulatory documentation supporting the use of the material during interpandemic periods, pandemic periods, pre-pandemic preparation, pandemic response and, where appropriate, manufacture of licensed or authorized doses.
- ***Due to the highly uncertain and speculative nature of this Activity, it is not possible to estimate, with any degree of certainty, the scope and amount required over the life of the IDIQ. As such, this Activity will not be priced at the IDIQ level, but instead at the task order (TO) or Blanket Purchase Agreement (BPA) level. TO/BPA Contracting Officers must ensure enforcement of applicable FAR cost principles and determine cost reasonableness prior to TO or BPA award.***

ACTIVITY 1016: Validation Activities or Technology Transfer Activities

For situations in which a manufacturing activity would require validation activities, a technology transfer, or other activities related to a new product (e.g., new presentation or formulation of antigen and/or adjuvant at an existing location, or an existing product at a new location, etc.), the Contractor must:

- Perform validation activities or technology transfer activities (e.g., within the facility, to a CMO) if needed to complete requirements in the SOW of the Task Order. Validation activities must be carried out at facilities in compliance with FDA-CGMP guidelines.
- Assure compliance of process validation following regulation for validating pharmaceutical (drug) manufacturing (section 501(a)(2)(B) of the Act (21 U.S.C. 351(a)(2)(B)) and FDA regulations describing CGMP for finished pharmaceuticals provided in 21 CFR parts 210 and 211.
- Update and submit the regulatory documentation supporting the use of the material

during interpandemic periods, pandemic periods, pre-pandemic preparation, pandemic response and, where appropriate, manufacture of licensed or authorized doses.

- Provide to BARDA all validation plans for technology transfer.
- Provide technology transfer report(s).
- Provide process validation report(s) to BARDA. The report should include, at minimum:
    - Manufacturing location (building, room, city, country)
    - Dates of major manufacturing steps
    - Major process inputs and parameters (e.g., number of eggs, bioreactor size, working volume, cell bank number, CVV ID and source and lot number, MVS and/or WVS, lot number history)
    - Volume produced, lot size, quantity/number
    - Potency and/or quantity per volume (e.g., µg/mL, FFU/mL)
    - Manufacturing and testing deviations
    - Certificate(s) of analysis (in English)
    - Certificate(s) of compliance (in English)
- ***Due to the highly speculative nature of validation and technology transfer activities for this requirement, it is not possible to estimate, with any degree of certainty, the scope and amount required over the life of the IDIQ. As such, this Activity will not be priced at the IDIQ level, but instead at the task order (TO) or Blanket Purchase Agreement (BPA) level. TO/BPA Contracting Officers must determine price reasonableness prior to TO or BPA award.***

ACTIVITY 1017: Manufacturing Enhancements
The Contractor must:

- Develop enhancements to the underlying manufacturing process(es) to improve production yield, breadth, accessibility, durability, reactogenicity, or other improvements as outlined in the SOW of the Task Order.
- Develop innovations in manufacturing or testing to allow more rapid vaccine upscaling and deployment.
- Update and submit the regulatory documentation supporting the use of the material during interpandemic periods, pandemic periods, pre-pandemic preparation, pandemic response and, where appropriate, manufacture of licensed or authorized doses.
- Provide final report including at minimum:
    - Manufacturing location (building, room, city, country)
    - Dates of major manufacturing steps
    - Major process inputs and parameters (e.g., number of eggs, bioreactor size, working volume, cell bank number, CVV ID and source and lot number, MVS/WVS lot number)
    - Volume produced, lot size, quantity/number
    - Potency and/or quantity per volume (e.g., µg/mL, FFU/mL)
    - Manufacturing or testing deviations
    - Certificate(s) of analysis (in English)
    - Certificate(s) of compliance (in English)
    - Testing parameters and feasibility data including comparison to a commonly acceptable standard or benchmark.

- ***Due to the highly speculative nature of manufacturing enhancements for this requirement, it is not possible to estimate, with any degree of certainty, the scope***

and amount required over the life of the IDIQ. As such, this Activity will not be priced at the IDIQ level, but instead at the task order (TO) or Blanket Purchase Agreement (BPA) level. TO/BPA Contracting Officers must determine price reasonableness prior to TO or BPA award.

ACTIVITY 1018: Tariffs, Duties, and Trade Remedies (Pass-Through)
This Activity is established to reimburse Contractor for actual, allowable tariffs, duties, or trade remedy costs imposed by the U.S. Government after contract award, including but not limited to Section 232 of the Trade Expansion Act and Section 301 of the Trade Act of 1974, anti-dumping, or countervailing duties, that directly impact the cost of supplies, materials, components, or equipment required on any ACTIVITY(-IES).

The Contractor must separate and individually invoice any government-imposed tax or duty on goods associated with ACTIVITY(-IES) performed under this contract, applied in accordance with applicable laws and regulations.

Reimbursement under this Activity is limited to:

- Tariff costs actually incurred and paid
- Costs that are allocable solely to this contract
- Costs that are not included in any other Activity

No profit, fee, overhead, general and administrative expenses, or markups shall be applied to costs reimbursed under this Activity.

Due to the highly speculative nature of tariffs for this requirement, it is not possible to estimate, with any degree of certainty, the scope and amount required over the life of the IDIQ. As such, this Activity will not be priced at the IDIQ level, but instead at the task order (TO) or Blanket Purchase Agreement (BPA) level. TO/BPA Contracting Officers must determine price reasonableness prior to TO or BPA award.

ACTIVITY 1019: Standard Data Reporting Requirements
The Contractor must submit detailed data regarding project materials, sources, and manufacturing sites. This is required to be complete prior to BARDA deliverable acceptance and subsequent invoicing.

These standard reporting requirements will be applicable, at a minimum, to every regular cadence report, interim product reporting, and final deliverables. In the event of a public health emergency, BARDA may require daily reporting of manufacturing campaigns during readiness and/or response operations.

The Contractor must conform to the file specification and layout as provided by BARDA to submit data and is expected to adopt minor modifications periodically provided by BARDA. Final data elements with associated definitions and standard units of measure (e.g., mass, volume per batch) will be agreed upon prior to data submissions.

Data categories will include but are not limited to the following:

- Manufacturing locations

- Seed development or other starting material manufacturing
- Critical materials
- Manufacturing production projections
- Bulk drug substance and/or adjuvant production to include per batch yield data
- Fill, finish, and release of product or adjuvant
- Storage/inventory of starting materials, bulk substance, or filled/final product or adjuvant
- Stability information of bulk substance and/or finished product
- Shipment of bulk substance or final finished product
- Disposal of bulk substance or final product
- Location and nature of nonclinical study and/or clinical study sites

ACTIVITY 1020: Additional Reporting
The Contractor must:

- Submit inventory reports, monthly progress reports, executive summaries, Government Property reports, interim product reports, ad hoc reports of urgent developments related to this program, and a final report as described in detail in the Reporting Requirements and Deliverables. Reports must be delivered as separate BARDA-specific and DOW/DHA-specific (or other U.S. Government agency) reports to enable direct sharing with BARDA partners.
- Annually, submit an updated table describing facility availability and capacity to complete all CLIN activities throughout the year per a BARDA defined template to be provided (Attachment 3).
- Annually review, assess, and update, as applicable, all Contract-required plans, plan deliverables, and associated supporting documentation to ensure they remain current, accurate, and consistent with contract requirements, operational capabilities, regulatory requirements, and BARDA direction. Updated versions must be submitted to the Government in accordance with the Reporting Requirements and Deliverables or as otherwise requested by the COR or CO.
- Respond to request(s) for additional information from BARDA pertaining to activities related to Contract, including provision of raw data or specific analyses of data generated with contract funding to the COR or CO, upon request.
- Make appropriate updates to the regulatory documentation supporting relevant regulatory file and continued use of the stored material for pre-pandemic preparation, pandemic response and, where appropriate, manufacture of licensed or authorized doses.
- Provide BARDA with clinical and regulatory support for specific studies and research and development.
- Respond to data calls as required by BARDA and in a standard format as defined by BARDA.

C.4. Interagency Collaboration and Use by the Department of War (DOW)

Given the national security implications of pandemic influenza and other emerging biological threats, BARDA may collaborate with other United States Government (USG) agencies to

advance preparedness and response capabilities under this program. In particular, the Department of War (DOW) and its components, including but not limited to the Defense Health Agency (DHA), may partner with BARDA to support the development, manufacturing, stockpiling, and evaluation of medical countermeasures (MCMs) under this contracting vehicle.

To facilitate a coordinated national biodefense posture, DOW components may utilize this contract through interagency agreements, Economy Act transactions, or other authorized funding mechanisms to support activities consistent with the scope of this program. Such activities may include, but are not limited to, pandemic influenza vaccine development, advanced manufacturing capabilities, antigen and adjuvant production, clinical evaluation, regulatory data generation, and surge manufacturing readiness.

Work conducted on behalf of DOW under this contract shall remain within the technical scope of the Vaccine Medical Countermeasures for Pandemic Influenza Preparedness and Response Program and shall be coordinated with BARDA to ensure alignment with national public health preparedness priorities. Funding for such efforts may be provided by DOW or other participating agencies in accordance with applicable federal laws, regulations, and interagency agreements.

C.5. Additional Requirements

Standard Operating Procedures (SOPs)

- Upon request from the COR or CO, the Contractor must make internal and, to the extent possible, Subcontractor SOPs available for review by the Government on-site at Contractor's facility. At the Contractor's election, SOPs may be provided electronically.

Data Management

- The Contractor must develop and implement data security, data management, and data quality control systems/procedures; including transmission, storage, confidentiality, and retrieval of all contract data; as applicable provide for the statistical design and analysis of data resulting from the research; provide raw data or specific analyses of data generated with contract funding to the COR or CO, upon request.

Manufacturing

- Contractors holding a U.S. license for an influenza vaccine or submitted a BLA to the U.S. FDA must perform all work described in the ACTIVITIES according to those of their FDA-licensed or BLA-submitted influenza vaccine product processes. This includes use of the same validated facilities, systems, equipment, and manufactured processes for CGMP manufacturing of licensed influenza vaccine, antigen, and adjuvant product. Contractors must use the same validated and approved assays and equipment for lot release of influenza vaccine, antigen, and adjuvant product and final container influenza vaccine, antigen, and adjuvant products and stability studies. Contractors must use the same validated facilities, systems, and equipment suitable for CGMP storage of influenza vaccine, antigen, and adjuvant products. Exceptions may be requested from BARDA.

- If a Contractor’s manufacturing facility is outside the continental U.S. (OCONUS), manufactured material must be shipped to the U.S. within 60 days of lot release and entered into storage per Storage and Stability ACTIVITY. An exception to this requirement may be requested from BARDA. Shipment of the material to the U.S. must

be coordinated with BARDA and other offices/agencies involved in importation of vaccines as appropriate. Importation of bulk antigen and adjuvant into the U.S. may require testing which must be performed according to applicable federal guidelines (e.g., FDA, USDA, CDC). The Contractor must bear all costs for shipping and testing required for import into the U.S. Under FAR 52.243-2 Alt V (changes clause – Cost reimbursement), This requirement can be unilaterally modified by BARDA during a public health emergency, as defined by BARDA, to allow for international formulation and filling prior to shipment to the U.S. Vendors should follow the process in FAR 52.243-2 Alt V to seek reimbursement of this expense. If the Contractor has domestic/international facilities for primary and secondary manufacturing or storage, products must be shipped from/to different facilities at no additional cost to the U.S. government.

- BARDA must be notified in advance of any planned facility shutdowns and as soon as feasible for any unplanned facility shutdowns (e.g., facility upgrades, maintenance, etc.).

- Alternative potency assays may be used when CBER reagents are not available and must be approved by BARDA. When reagents become available, potency determination must be bridged to SRID testing. Parallel testing with both assays must continue for at least 3 time points of the stability program to document comparability. Where appropriate and/or requested by BARDA, such comparability documentation is to be submitted to FDA to evaluate feasibility of alternate potency testing for lot release under 21 CFR 610.9 Equivalent Methods and Processes.

- Non-marketed product(s): the Contractor must develop and submit a Commercial Sustainability Plan that outlines a comprehensive strategy to ensure the long-term availability, affordability, and scalability of the non-marketed product(s) procured under this contract. This plan must address the transition from government-supported warm-base to a commercially viable model, including a risk-based approach to ensure a reliable supply chain, pathways for regulatory approval, manufacturing scale-up, market entry, and post-market support.

Quality Assurance

- Contractor must accommodate periodic or ad hoc site visits, auditing, inspection, and review of release documents, test results, equipment, and facilities when requested by BARDA.

  BARDA may assess Contractor's facility and quality systems and make a determination in regard to the site's acceptability and compliance in relation to its ability to manufacture, process, pack, properly and safely store and handle the USG-owned product.

- Incidents: BARDA must be informed of all major and critical issues involving any of the material or studies managed under this contract within 48 hours of the incident and within 24 hours of a security activity or incident. Initial impact assessment and remediation plan must be provided within five (5) business days of the incident. Investigation reports with applicable Corrective and Preventative Actions (CAPAs) must be submitted within forty-five (45) business days of incident onset.

Biosafety

- Manufacturing facilities must be in compliance with appropriate biosafety level bio-containment procedures.

- As applicable, contractors must use the approved facilities, equipment, and policies to receive, store, utilize, and dispose of bio-hazardous materials in appropriate conditions.

- As appropriate, Contractors must employ approved biosafety measures compliant with CDC biosafety guidelines (Biosafety in Microbiological and Biomedical Laboratories (BMBL), https://www.cdc.gov/labs/bmbl/) including protective garments, equipment, sufficient monitoring to assure safe handling of potentially hazardous materials for the safety and protection of workers.

- Contractors must conduct work under the contract in accordance with all applicable and current Federal, state, and local laws, codes, ordinances and regulations.

U.S. Government Property

- Materials manufactured and/or stored under this contract are 'U.S. Government Property.' These materials must be maintained in the Contractor's quality and inventory systems, ready for use in the continued manufacture of bulk material or final container doses intended for clinical assessment, use under the license, or use as part of a public health emergency.

- **Notification must be given to BARDA prior to any disposal** of material, records, documentation, and/or reports for consultation and disposition.

Assessments

- The Contractor must conduct or participate in assessments and tabletop exercises on an annual basis, or at such other times as may be requested by BARDA, for the purpose of evaluating preparedness and response postures.

SECTION D – PACKAGING, MARKING AND SHIPPING

D.1. SHIPPING

Method of Delivery
Unless otherwise specified by the Contracting Officer, all non-physical deliverable items (e.g., reports, plans, documents, invoices, etc.) to be furnished to the Government under this contract must be uploaded to BARDA's document sharing system as described in SECTION F.3.

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

D.2. PREPARATION OF PRODUCT FOR TRANSPORT

All vaccines shall be labeled, packaged, and marked in standard commercial manner (with labeling and packaging configuration directions to be provided at the time of the government places an order and subject to FDA approval). Products shall be packed to ensure maintenance of FDA recommended temperature during transit and safe arrival at destination. A mutually agreed upon temperature monitoring device shall be packed in each shipper containing influenza vaccine. The location of the sensing probe shall have been previously determined by the Contractor through the performance of shipping validation studies. The Contractor is required to maintain records that document the date of delivery receipt, and that the vaccine was properly maintained within the recommended cold chain temperatures during transit and receipt (Attachment 4). In the event of out of specification (OOS) results are obtained, such results shall be reported by the Contractor to BARDA within 24 hours of receipt of such results. The Contractor shall open a deviation according to its established deviation standard operating procedure and must work with BARDA to determine what investigations are needed and reach a conclusion as to whether the affected shipper contents are releasable. If the affected material cannot be released, the lost value of the affected material shall be borne by the Contractor.

D.3. Free On Board (FOB) DELIVERIES

Task orders will indicate FOB Destination or Origin. Unless otherwise stated in the task order, the default delivery term shall be FOB Destination.

The Contractor must describe the storage conditions for each product, specifically noting the acceptable temperature range required to maintain product quality. The Contractor is responsible for maintaining product temperature control until the product(s) arrives at the destination and has completed product inspection and acceptance by the USG. The Contractor must provide the Government with an ambient exposure letter that covers the time the product(s) leaves the Contractor's validated storage facility until arrival at the destination. Upon Government acceptance of the product(s) to the Government, the responsibility for temperature control shall transfer to the Government as well as the responsibility for logging ambient exposure time (temperatures between 8-25°C). The Contractor will provide and place temperature monitor(s) on each pallet of product 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).

For any product manufactured under this contract, title to such product will transfer upon delivery of drug product to Government-designated storage site(s) and the Government's corresponding written acceptance of the delivery of each such lot of product. These materials should be maintained in the Contractor's quality and inventory systems, ready for use in the continued manufacture of bulk material or final container doses intended for clinical use, use under Emergency Use Authorization, or use under a BLA.

SECTION E – INSPECTION AND ACCEPTANCE

E.1. INSPECTION AND ACCEPTANCE

- Upon receipt of final report, including the updated "Dose Tracking Template", BARDA COR will perform inspection (in person or virtually) and acceptance of product to be delivered under the contract.

  The COR will notify the Contractor of acceptance or rejection. If applicable, a task order for the storage of product may be issued. Any product produced or stored under this contract shall be subject to inspection by BARDA.

  Inspection and acceptance will take place at the contractor's facility(-ies) or virtually at:

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

E.2. FAR 52.252-2 CONTRACT CLAUSES INCORPORATED BY REFERENCE (Feb 1998)

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

FAR 52.246-2, Inspection of Supplies – Fixed Price (August 1996) FAR 52.246-4, Inspection of Services - Fixed Price (August 1996)
FAR 52.246-3, Inspection of Supplies – Cost Reimbursement (May 2001)
FAR 52.246-5, Inspection of Services - Cost-Reimbursement (April 1984)
FAR 52.246-7, Inspection of Research and Development – Fixed Price (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) (April 1984)
FAR 52.246-16, Responsibility for Supplies (April 1984)

SECTION F – DELIVERIES OR PERFORMANCE

F.1. ESTIMATED PERIOD OF PERFORMANCE

The base period of performance of this contract is anticipated for 60 months from date of award. The period of performance may be extended up to 60 months with the exercise of option(s), as set forth in SECTION B. If the Government exercises its option(s) pursuant to the OPTION PROVISION Article in Section H of this contract, the period of performance will be increased by an additional Sixty (60 months).

Period	Duration
Base Period	Sixty (60 Months)
Option Period 1	Sixty (60) Months

F.2. PLACE AND METHOD OF DELIVERY

1. The delivery of the items under this contract and related supplies shall be FOB Destination or FOB Origin as indicated in each task order award. If no FOB is indicated, the default will be FOB Destination. 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.

2. The place and time of delivery shall be negotiated within individual Task Orders and BPA Call Orders.

F.3. REPORTING REQUIREMENTS and DELIVERABLES

F.3.1. Submission of Contract Deliverables

Documents must be delivered electronically to the CO and to the COR via a specified shared location.

Monthly and annual progress reports should be delivered as separate BARDA-specific and DOW/DHA-specific (or other USG agency) reports to enable direct sharing with BARDA partners.

F.3.2. Deliverable Table

The Offeror may propose combining deliverables as appropriate and upon pre-approval of the COR.

	Deliverable	Deliverable Description	Reporting Procedures and Due Dates[2]
Security			
	Operational Security (OPSEC) Standard Operating Procedure (SOP)/Plan	This SOP/Plan will include identifying the critical information related to this award, why it needs to be protected, where it is located, who is responsible for it, and how to protect it.	•Contractor must submit an OPSEC SOP/Plan ▪ Within 90 calendar days after the initiation of the contract period of performance
	Security Plan	The contractor shall develop a comprehensive security program that provides overall protection of personnel, information, data, and facilities associated with fulfilling the Government requirement. This plan shall establish security practices and procedures that demonstrate how the contractor will meet and adhere to the security requirements outlined below prior to the commencement of product manufacturing. The contractor shall also ensure all subcontractors, consultants, researchers, etc. performing work on behalf of this effort, comply with all Government security requirements and prime contractor security plans.	•Contractor must submit a Security Plan • Draft within 30 calendar days after the initiation of the contract period of performance • The Government will perform an internal review in detail and submit comments within ten (10) business days to the CO and COR to be forwarded to the Contractor. The Contractor shall review the Draft Security Plan comments and submit a Final Security Plan to the U.S. Government within ten (10) calendar days after receipt of the comments. • The Security Plan shall include a timeline for compliance of all the required security measures outlined by the Government. • Upon completion of initiating all security measures, the Contractor shall supply to the CO and COR a letter certifying compliance to the elements outlined in the Final Security Plan.
Program Management			
	Project Management Plan (PMP)	The Project Management Plan should define the overall plan for how the project will be executed, monitored and controlled and must include a Study Responsibility Assignment Matrix for Contractor and subcontractor team(s).	•Contractor must submit a Project Management Plan (PMP) ▪ Within 30 calendar days after the initiation of the contract period of performance ▪ Updates should be provided to reflect any key changes, including new task order awards, and reviewed at least annually.

[1] A business day is defined as any day except any Saturday, any Sunday, any day which is a federal legal holiday in the United States, or any day declared to be a holiday by federal statute or executive order, or any day with respect to which the U.S. Office of Personnel Management has announced that Federal agencies in the Washington, DC, area are closed. For purposes of calculating any deadline imposed by this contract, any submissions received after 5 p.m. Eastern Time are deemed to be submitted on the next business day.

	Deliverable	Deliverable Description	Reporting Procedures and Due Dates[2]
		The PMP may be a single detailed document or composed of one or more subsidiary planning documents. These additional planning documents provide guidance and direction for specific management, planning, and control activities such as schedule, cost, risk, staffing, change control, communications, quality, procurement, deployment, etc. Each of the subsidiary planning documents should be detailed to the extent required by the specific project.	
	Communication Plan	The Contractor must develop and implement an effective Communication Plan that details the flow of information between BARDA, Contractor, collaborators, vendors, and other organizations. This should include communications with other USG agencies (e.g., CDC) as appropriate, regarding label contents, expiry dating, healthcare provider educational materials. The Communication Plan must also include processes for external communications and press release review.	•Contractor must submit a Communication Plan • Within 30 calendar days after the initiation of the contract period of performance • Updates should be provided to reflect any key changes and reviewed at least annually.
	Regulatory Plan	The Contractor must provide a Regulatory Plan that outlines the regulatory strategy for the product. The plan must include information leading to distribution readiness and information needed to support the Immunization Information Systems (IIS) data code set development.	•The Contractor must submit a Draft within 45 calendar days after the initiation of the contract period of performance; updates to the Regulatory Strategy/Plan must be submitted concurrently with Monthly Technical Progress Reports •BARDA will provide Contractor with a list of concerns in response to plan submitted •Contractor must address, in writing, all concerns raised by BARDA within 20 business days of Contractor's receipt of BARDA's concerns
	Commercial Sustainability Plan	The Contractor must provide a Commercial Sustainability Plan that outlines a comprehensive strategy to ensure the long-term availability, affordability, and scalability of the non-marketed product(s) procured under this contract. This plan must address the transition from government-supported warm-base to a commercially viable model, including a risk-based approach to	•The Contractor must submit a Draft within 45 calendar days after the initiation of the contract period of performance; updates to Commercial Sustainability Plan must be submitted concurrently with Monthly Technical Progress Reports •BARDA will provide Contractor with a list of concerns in response to plan submitted •Contractor must address, in writing, all concerns raised by BARDA within 20 business days of Contractor's receipt of BARDA's concerns

	Deliverable	Deliverable Description	Reporting Procedures and Due Dates[2]
		ensure a reliable supply chain, pathways for regulatory approval, manufacturing scale-up, market entry, and post-market support.	• Updates should be provided to reflect any key changes and reviewed at least annually.
	Manufacturing Plan	The Contractor must develop and submit a comprehensive Manufacturing Plan in accordance with the requirements listed in Attachment 17, Manufacturing Plan.	• Due within 120 calendar days after the initiation of the contract period of performance • The CO and COR will review the deliverable and provide feedback within 30 calendar days. • Contractor must provide a final version of the deliverable within 30 calendar days after receiving BARDA comments/edits. • Contractor must submit to CO and COR an updated deliverable ▪ Within 60 calendar days after each contract anniversary ▪ Prior to any events specified in Attachment 17 as communicated by the CO and COR ▪ If there are no updates at the times listed above, Contractor must submit to CO and COR a written confirmation that no substantive changes have occurred and that the current plan remains accurate. • Contractor must notify the COR within 15 calendar days after identifying a material change affecting the accuracy of this deliverable; Contractor to include this update in the next submission unless an earlier due date is established. • In the case of a public health emergency, the timeline for this deliverable will follow an accelerated timeline. Template available upon request.
	Business and Supply Continuity Plan	The Contractor must develop and submit a comprehensive Business and Supply Continuity Plan detailing the delivery of product continuity plan and support services to internal and external customers in the aftermath of a catastrophic event. This deliverable must be submitted in accordance with the requirements listed in Attachment 18, Business and Supply Continuity Plan.	• Contractor must submit to CO and COR within 120 calendar days after the effective date of the contract. • Contractor must submit to CO and COR an updated deliverable within 60 calendar days after each contract anniversary. Template available upon request.
	Surge Manufacturing and Supply Chain Readiness Assessment	The Contractor must develop and submit a Surge Manufacturing and Supply Chain Readiness Assessment for BARDA supported product. The assessment must identify, or the CO must provide, the applicable planning scenario, target quantity, product presentation, requested delivery timeline, planning assumptions, due date, and any relevant public health emergency context. This deliverable must be submitted in accordance with the requirements listed in Attachment 19, Surge	• Upon request of the COR, the Contractor must perform and submit to the CO and COR a Surge Manufacturing and Supply Chain Readiness Assessment. The Government anticipates requesting this assessment on an annual basis; however, each assessment shall address the specific scenario identified by BARDA. The due date for each assessment will be established by the COR at the time of the request.

	Deliverable	Deliverable Description	Reporting Procedures and Due Dates[2]
		Manufacturing and Supply Chain Readiness Assessment.	
	Risk Management Plan (RMP)	The Contractor must provide an overall RMP as well as a RMP for each awarded task order that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan must include assigned risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule, and performance.	• Due within 45 calendar days after the initiation of the base contract period of performance; updates to the RMP are due 1) with the response to a Request for Task Order Response (RTOR) and 2) concurrent with Monthly Technical Progress Reports and must include each task order, but may be communicated more frequently. • BARDA will provide Contractor with a list of concerns in response plan submitted • Contractor must address, in writing, all concerns raised by BARDA within 20 business days of Contractor's receipt of BARDA's concerns
	Vendor-Managed Inventory (VMI) Plan	Contractor must draft a VMI Plan in accordance with a template to be provided by BARDA as applicable	• The Contractor must submit the Draft VMI Plan and supporting SOPs Draft within 60 calendar days of award • Finalized and signed by all stakeholders within 90 calendar days of award • Updates should be provided to reflect any key changes and reviewed at least annually.
	Quality Management Plan (QMP)	Contractor must develop an overall project Quality Management Plan to include a description of all quality activities and personnel involved in ensuring all activities are conducted and data are maintained under CGXP, and all products are managed to ensure that GMP requirements are met. All quality management plans must include subcontractor quality management plans specifically addressing how subcontractor quality will be managed. All subcontractors must have a current quality agreement with the Contractor and a recent vendor qualification audit.	Contractor must submit a Quality Management Plan: ▪ Draft within 60 calendar days of award ▪ Finalized and signed by stakeholders within 90 calendar days of award Updates should be provided to reflect any key changes and reviewed at least annually.
	Quality Agreement	The Quality Agreement defines the duties of BARDA and Contractor for the supply, quality acceptance, and storage of the product types under the contract as such both parties (Contractor and BARDA) adhere to compliance requirements set forth in Current Good Manufacturing Practices (21 CFR Parts 210 and 211), and Biological Products (21 CFR Part 600). BARDA will issue a draft Quality Agreement to the Performer to review and sign. The terms of the	The Contractor must submit the Quality Agreement: ▪ Draft within 60 calendar days of award ▪ Finalized and signed by stakeholders within 90 calendar days of award Updates should be provided to reflect any key changes and reviewed at least annually.

	Deliverable	Deliverable Description	Reporting Procedures and Due Dates[2]
		Quality Agreement shall set forth the requirements under the contract.	
	BARDA Audit	Contractor must accommodate periodic or ad hoc site visits, auditing, inspection and review of release documents, test results, equipment and facilities when requested by BARDA. If BARDA, the contractor, or other parties identify any issues during an audit, the contractor must capture the issues, identify potential solutions and submit a report to BARDA detailing the finding and corrective action(s). The Contractor must allow for up to four (4) USG Quality representative(s) to conduct an audit.	• If issues are identified during the audit, Contractor shall submit a report to BARDA detailing the finding and corrective action(s) within 10 business days of the audit • COR and CO will review the report and provide a response to the Contractor within 10 business days • Once corrective action is completed, the Contractor will provide a final report to BARDA
Technical Reporting: General			
	Kickoff Meeting	The Contractor must complete a Kickoff meeting after the initiation of the contract period of performance	• Within 30 calendar days after the initiation of the contract period of performance, pending concurrence by the Contracting Officer • Contractor must submit agenda and itinerary, if applicable, at least 5 business days in advance of in-person meeting or teleconference • COR edits/approves and instructs Contractor to distribute agenda at least 3 business days prior to meeting • Contractor submits meeting minutes to COR within 3 business days after the meeting • COR reviews, comments, and approves minutes within 10 business days
	Monthly and Annual Technical Progress Reports and Meetings	The Contractor must participate in biweekly or monthly teleconferences to discuss the performance of the contract/task order. The Monthly and Annual Technical Progress reports must address each of the below items and be cross-referenced to the Work Breakdown Structure (WBS), Statement of Work (SOW), Integrated Master Schedule (IMS), and Contract Performance Report (CPR) – or as applicable. Monthly and annual progress reports should be delivered as separate BARDA-specific and DOW/DHA-specific (or other USG agency) reports to enable direct sharing with BARDA partners.	• The Contractor must submit monthly reports on the 15th day of the Month covering the preceding month; Annual Reports submitted on the 15th of the calendar month after each contract anniversary. ▪ Monthly progress reports are not required for the months when the Annual Report(s) are due, and Monthly/Annual Report(s) are not due during a month when the Final Report (final version, not draft) is due. The COR and CO will review the monthly reports with the Contractor and provide feedback • Contractor must provide FINAL versions of reports within 10 business days after receiving BARDA comments/edits • Meeting frequency can be adjusted as needed during the course of the contract.

	Deliverable	Deliverable Description	Reporting Procedures and Due Dates[2]
		1. An Executive Summary highlighting the progress, issues and relevant manufacturing, nonclinical, clinical, and regulatory activities. The Executive Summary should highlight all critical issues for that reporting period and resolution approach; limited to 2 pages 2. Management, contractual, and administrative updates including a description of all meetings, calls, etc. that have taken place during the reporting period. Include progress on administration, contractual, and management issues. For contractual issues include an updated table of contractual issues with columns for Issue Number, Task Order, Issue Description, Date of Initial Request, Impact and Status/Comment. 3. Progress in meeting contract or task order milestones organized by WBS, overall project assessment, problems encountered and recommended solutions. For each activity related to Task Order and Gantt chart, document the results of work completed during the period covered. The report must be in sufficient detail to explain comprehensively the results achieved. The description must include baseline and updated project timelines, milestones and summaries of product manufacturing and testing. The report must 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. 4. The Contractor must submit monthly detailed clinical reports during active clinical study enrollment to include data on relevant activities during the period covered, by study site, including: cumulative enrollment; new enrollments; screen failures; patients dropped from study; AE and	

	Deliverable	Deliverable Description	Reporting Procedures and Due Dates[2]
		SAEs; study initiation visits; activation or inactivation of study sites; investigator appointments or changes; and status of IRB/IEC review/approval/renewal 5. A three-month rolling forecast of the key planned activities, referencing the WBS/IMS 6. A tracking log of progress on regulatory submissions with the FDA number, description of submission, date of submission, status of submission, and next steps 7. Estimated and Actual Expenses • This report must also contain a narrative or table detailing whether there is a significant discrepancy (>10%) at this time between the % of work completed and the cumulative costs incurred to date. Monthly and actual expenses should be broken down to the appropriate WBS level. This section of the report should also contain estimates for the Subcontractors' expenses from the previous month if the Subcontractor did not submit a bill in the previous month. If the subcontractor was not working or did not incur any costs in the previous month, then a statement to this effect should be included in this report for those respective subcontractors. If the COR and CO are satisfied that the Contractor's reporting is sufficient to convey this information, this section may be waived. • Summary of any invoices submitted during the reporting period. Include an updated table with columns for Invoice number, Date Submitted, Amount, Activity/Comments and Date paid. The summary invoice table should include all invoices from contract award to reporting period.	

	Deliverable	Deliverable Description	Reporting Procedures and Due Dates[2]
		8. Publication activities and progress for any manuscript, scientific meeting abstract, poster, presentation, and other public-facing material or information containing data generated under this contract 9. ACTION ITEMS - Summary table of activities or tasks to be accomplished by a certain date and by whom. 10. APPENDIX: Standard Data Reporting (ACTIVITY 0019)	
	Gantt Chart/Timeline	The Gantt Chart/Timeline should be detailed to the extent required by the specific project.	• At first project meeting and as updated no later than once per month as part of the monthly report. Provided in pdf and Microsoft Excel. If there are urgent readiness or response activities, this may be required daily.
	Integrated Master Schedule (IMS)	The Contractor must provide an IMS that illustrates project tasks, dependencies, durations throughout the period of performance, and milestones (GO/NO-GO). The IMS must map to the WBS, and provide baseline, and actual or forecast dates for completion of tasks Contractor must notify BARDA of significant proposed changes to the IMS. Significant changes are defined as increases in cost above 5% or schedule slippage of more than 30 days, which would require a PoP extension. Contractor must provide a high-level management strategy for risk mitigation.	• The Contractor must submit the IMS in both PDF and an agreed-upon electronic format (e.g., Microsoft Excel) to the COR • The first Draft of the IMS is due within 30 calendar days after the initiation of the contract period of performance • Thereafter an updated IMS is due concurrent with Monthly Technical Progress Reports and must incorporate each task order • The Contractor must submit significant proposed changes to the IMS at least 10 business days prior to the Contractor anticipating the need to implement changes. • During a public health emergency, the Contractor must submit the IMS within 10 business days after the initiation of the task order period of performance, updates are due weekly, and any significant change (i.e., a change which would impact the schedule by greater than one week) must be reported immediately to the COR and/or designee.
	Draft and Final Contract and Task Order Technical Progress Report	A draft Final Contract and Task Order Technical Progress Report must contain a summation of the work performed and the results obtained over the entire contract. This report must be in sufficient detail to fully describe the progress achieved under all milestones for all task orders. Report must contain a timeline of originally planned and baselined activities and milestones overlaid with actual progress attained	• The Contractor must submit the Draft Final Technical Progress Report 45 calendar days before the end of the PoP and the Final Technical Progress Report on or before the completion date of the PoP • COR will provide feedback on draft report within 15 calendar days of receipt, which the Contractor must consider incorporating into the Final Report

	Deliverable	Deliverable Description	Reporting Procedures and Due Dates[2]
		during the contract. Descriptions and rationale for activities and milestones that were not completed as planned should be provided. The draft report must be duly marked as 'Draft.' The Final Technical Progress Report incorporating feedback received from BARDA and containing a summation of the work performed and the results obtained for the entire contract PoP. The final report must document the results of the entire contract. The final report must be duly marked as 'Final'. A cover letter with the report will contain a summary (not to exceed 200 words) of salient results achieved during the performance of the contract or task order.	
	Technical, Subgroup, or Ad hoc Teleconference(s)	The Contractor must participate in technical, subgroup, or ad hoc teleconferences as needed or upon BARDA request to discuss the technical performance on the contract. Meeting frequency may be defined as needed during the course of the project.	•Contractor must submit agenda to COR no later than 2 business days in advance of Technical or Subgroup meeting •COR edits/approves and instructs Contractor to distribute agenda prior to meeting •Contractor must distribute agenda and presentation materials at least 24 hours in advance of meeting •Contractor must submit meeting minutes to COR within 3 business days of the meeting •COR reviews, comments, and approves minutes within 6 business days
	Daily, Weekly, or As-Required Check-In with BARDA	Upon request of the Government, the Contractor must participate in a daily or as-required check-in update with the project staff (via teleconference or email) during pandemic readiness or response efforts or public health emergency. Meeting frequency may be increased or decreased as needed during the course of the project. The updates will address key cost, schedule, and technical updates. Daily updates may be shared with senior Government leaders and should be provided on a non-confidential basis, unless the update includes confidential information in which case Contractor must provide the update in both confidential and non-confidential formats. Daily check-ins may occur on weekdays, excluding federal holidays.	• A standing agenda must be used, to include key cost, schedule, technical updates, as well as updates on ad hoc communications between the USG and the Contractor. • No meeting minutes are required • Contractor must provide bulleted email updates following any call or in lieu of a call by 2:00PM ET for that day.

	Deliverable	Deliverable Description	Reporting Procedures and Due Dates[2]
		Upon request of the Government, check-ins may also occur on weekends and on federal holidays, provided at least 24 hours' notice.	
	Periodic Review Meetings	At the discretion of the Government, the Contractor must hold up to four per year recurring Project Review Meetings, held by teleconference or face-to face either in Washington, D.C. or at work sites of the Contractor or sub-contractors. Face-to-face meetings shall alternate between Washington, D.C. and Contractor, sub-contractor sites. The meetings will be used to discuss contract progress in relation to the Program Management deliverables described in this contract as well as nonclinical, clinical, technical, regulatory, and ethical aspects of the program.	• Contractor must submit an agenda and itinerary, if applicable, at least 5 business days, and Contractor must provide presentation materials at least 3 business days, in advance of the meeting • COR edits/approves and instructs Contractor to distribute agenda prior to meeting by at least 3 business days • Contractor provides meeting minutes to COR within 3 business days after the meeting • COR reviews, comments, and approves minutes within 10 business days
	Request(s) for Additional Information	Upon BARDA request, the Contractor must provide complete responses to ad hoc requests for additional information. These requests may address key cost, schedule, and technical updates. Responses may be shared with senior Government leaders and should be provided on a non-confidential basis unless the response includes confidential information in which case Contractor must provide the response in both confidential and non-confidential formats.	• Contractor must submit a response to BARDA by email within 24 hours after Contractor receipt of the request for additional information.
Technical Reporting: Manufacturing			
	Vendor Production Facilities Table	Using a BARDA-supplied template (see Attachment 3), the Contractor must periodically review and submit production facilities information for each phase of the manufacturing process as specified in Advance Understanding B.5.1. • List the manufacturing sites and lines available for each of the manufacturing phases, including validation status of each site and line. • Indicate whether the site and line will be available to BARDA in the event of a public health emergency.	• Contractor must submit Vendor Production Facilities Report within 30 calendar days after the initiation of the base contract period of performance. • Updates should be provided to reflect any key changes and reviewed at least annually.

	Deliverable	Deliverable Description	Reporting Procedures and Due Dates[2]
		• Include as an attachment a current blueprint of the facilities (or a reasonable facsimile). Clearly indicate the sites and lines for each manufacturing phase and include their capacities and capabilities as appropriate.	
	Potency Reagent Production and Calibration	The Contractor must periodically review and update (as needed) the Potency Reagent Production and Calibration Table provided in the base contract Advance Understanding B.5.2. List the roles and responsibilities in terms of potency reagent production and calibration activities within the interpandemic period, noting any differences for pandemic response, for each manufacturing platform.	•Updates should be provided to reflect any key changes and reviewed at least annually.
	Manufacturing Reports and Projections	The Contractor must submit detailed data regarding work locations, manufacturing process steps, and manufacturing dose tracking projections/actuals utilizing the "Dose Tracking Template" (Attachment 5) or similar, including product for clinical study use. This must be included in the monthly technical report as an appendix and is required for invoicing. BARDA may provide a table in tabular format for Contractor to be used to submit such data which would include but not be limited to the following: • Detailed data regarding locations where work will be performed including addresses, points of contact, and work performed per location (including sub-contractors and critical vendors of reagents and supplies for critical infrastructure protection) • Storage/inventory of ancillary materials (e.g., vials, needles, syringes, etc.) • Shipment of ancillary materials (e.g., vials, needles, syringes, etc.) • Disposal of ancillary materials (e.g., vials, needles, syringes, etc.) • Seed development or other starting material manufacturing • Manufacturing production projections • Bulk drug substance actuals and/or adjuvant production actuals	•Contractor must update the "Dose Tracking Template" at minimum weekly during manufacturing campaigns and daily during response operations (i.e., a public health emergency), with the first deliverable submission within 30 calendar days of award. Updates must be provided weekly in advance of commercial-scale manufacturing and daily once material for use in response operations begins manufacture. •Contractor must submit an updated "Dose Tracking Template", for work locations: ▪ Within 30 calendar days after a substantive location or capabilities change ▪ Within 2 business days of a substantive change if the work performed supports medical countermeasure development that addresses a public health emergency as determined by BARDA in its sole discretion. •Dose Tracking must be completed via spreadsheet or other format (e.g., XML or JSON) as agreed to by USG and Contractor.

	Deliverable	Deliverable Description	Reporting Procedures and Due Dates[2]
		• Fill, finish, and release of product or adjuvant • Storage/inventory of starting materials, bulk substance, or filled/final product or adjuvant • Stability information of bulk substance, filled product, finished product • Shipment of bulk substance or final finished product • Reallocation(s) of bulk substance, filled product, finished product • Disposal of bulk substance or final product In the event of a public health emergency, HHS may require daily reporting of manufacturing campaigns during response operations.	
	Manufacturing Campaign Reports	In the event of a public health emergency or a large scale manufacturing campaign, the Contractor must provide Manufacturing Campaign Reports to BARDA as described under "Manufacturing Reports and Projections." The Manufacturing Campaign Reports should include lot history, major deviations, PPQ reports, Certificates of Analysis (CoAs), batch reports, storage location, purity, potency, yield. If Manufacturing Campaign Reports are provided to FDA, the Contractor must provide Reports to BARDA for review and comment prior to submission to FDA. The COR and CO reserve the right to request within the Period of Performance (PoP) a non-proprietary Manufacturing Campaign Report for distribution within the USG.	• Contractor must submit Manufacturing Campaign Reports at least 15 business days prior to FDA submission in an agreed-upon electronic format. • The Government will provide written comments to the manufacturing report within 15 business days after the submission • If corrective action is recommended, Contractor must address, in writing, the concerns raised by BARDA. • Contractor must revise the reports to address BARDA's concerns and/or recommendations prior to FDA submission. • The Contractor must submit Final FDA submission to BARDA concurrently or no later than 1 business day after submission to the FDA.
	Supply Chain and Distribution Tracking	Distribution Concept of Operations. The USG and MCM Manufacturers play an important role in the distribution of vaccines to the American people under a nationwide response. BARDA will work with the manufacturer to monitor what is in the manufacturing pipeline using the "Dose Tracking Templates" (see above). BARDA will relay final drug product information as it is being released to the CDC for allocation and ordering by the jurisdiction public	Contractor must provide the following information in order to coordinate the movement and delivery of final drug product from manufacturing locations to USG distribution centers: • Shipment Plan to include detailed timelines between PO receipt and delivery of final drug product at the distribution center. Upon USG request, Contractor must support expedited shipments. Ultracold drug product should be planned to be direct-shipped to end users from the manufacturer.

	Deliverable	Deliverable Description	Reporting Procedures and Due Dates[2]

		health departments. This information will be returned to BARDA as CDC replenishment orders (CDC Purchase Order, PO) on a daily basis with shipping instructions on where to send final drug product.
		
		Order quantity will be determined by the USG based on need. Order quantity may not be limited to lot-sized shipments or pallet-sized shipments. Manufacturers will use the PO information to ship final drug product as bulk shipments to designated distribution centers for final distribution to end users and end user networks. BARDA will provide the Contractor with a list of distribution centers and contact information prior to the start of a distribution campaign.
			• Provide Points of Contact information (name, title, phone, email) for manufacturing / supply chain personnel for each manufacturing, CMO, storage, and distribution locations:
			  ○ Head of Manufacturing
			  ○ Production Planning
			  ○ Logistics
			  ○ Distribution
			  ○ Labeling
			
			• Provide vaccine labeling, packaging, and distribution information as soon as it becomes available. Plan to support CDC Immunization Information Systems (IIS) codeset development. At a minimum, provide the following:
			  ○ MSDS
			  ○ Health Distribution Alliance (HDA) Form
			  ○ Primary Container Information
			  ○ Number of doses per primary container
			  ○ Unit of Sale (carton, box, package, other)
			  ○ Quantity per Unit of Sale
			  ○ Quantity per Carton
			  ○ National Drug Code (NDC)
			  ○ Structured Product Labeling (SPL)
			  ○ Unit of Sale dimensions (H, W, L)
			  ○ Unit of Sale weight
			  ○ Intermediate Package
			  ○ Intermediate Package dimensions
			  ○ Intermediate Package weight
			  ○ Quantity Unit of Sale per pallet
			  ○ Quantity cartons per pallet
			  ○ Pallet dimensions, fully loaded with finished product (H, W, L)
			  ○ Storage Requirements
			  ○ Stability Information
			
			• The Contractor must deliver stability data for as part of the monthly report or sooner if results are Out of Tolerance (OOT) or Out of Specification (OOS).

	Deliverable	Deliverable Description	Reporting Procedures and Due Dates[2]
			• The Contractor must obtain concurrence on planned shipment protocols prior to transport • Vaccine products should be packaged in 100-dose units to facilitate pick/pack process. • Send electronic/scanned copies of all bulk shipment related documents to the COR for three-way matching on the day shipment occurs.
	Packing List	Contractor must include the following data elements according to the Drug Supply Chain Security Act (DSCSA), required for receiving, on the packing lists sent with all bulk shipments to BARDA-designated location(s): • Transaction Information (TI), Transaction History (TH), Transaction Statement (TS) • Purchase Order (PO) number (which BARDA will provide at the time the bulk order is submitted) • Contract number • Copy of the MSDS (with QR code) in the packing list envelope	
	Advance Shipment Notices (ASNs)	Contractor must transmit bulk shipment ASNs to BARDA-designated location via Electronic Data Interchange (EDI)	Send EDI 856 Advance Shipment Notice for all products shipped to a USG directed location. USG will provide EDI mapping specifications that include the generated PO number
Technical Reporting: Nonclinical Studies[3], Analytical Studies			
	Draft and Final Nonclinical Study or Analytical Study Report(s)	Contractor must provide Draft and Final Study Reports to BARDA for review and comment.	• Draft report due within 45 calendar days after completion of analysis and at least 15 business days prior to submission to FDA

[3] For nonclinical work: Animal Welfare Act (AWA)-compliant institutional Agreement with nonclinical subcontractors (who are not Office of Laboratory Welfare [OLAW]) must be submitted to BARDA contract file prior to contract award. Nonclinical studies require annual reporting of licensure/regulatory documents (OLAW, Association for Assessment and Accreditation of Laboratory Animal Care [AAALAC], Select Agent registration, etc.)

	Deliverable	Deliverable Description	Reporting Procedures and Due Dates[2]
			• The Contractor must submit Subcontractor-prepared reports received by the Contractor to the COR and CO for review and comment no later than 5 business days after receipt by Contractor • The Government will provide written comments to the Draft Report within 15 business days after the submission • Final report due 30 calendar days after receiving comments on the Draft Final Report; If corrective action is recommended, Contractor must address all concerns raised by BARDA in writing • Contractor must consider revising reports to address BARDA's recommendations prior to FDA submission
	Nonclinical or Analytical Study Protocols	The Contractor must submit draft and final study protocols to CO and COR	The Contractor must submit Draft study protocols to COR electronically prior to finalization. ▪ BARDA will provide comments within 10 business days of receipt of draft protocol ▪ Contractor must respond in writing to BARDA comments and recommendations within 10 business days of receipt and must be addressed prior to finalization of protocol. ▪ COR must approve the final protocol The Contractor must submit Final study protocols to COR electronically no later than 10 business days prior to FDA submission
	Nonclinical or Analytical Study Final Data Submission Package	BARDA must have access to methods and reagents. BARDA must have unlimited rights to all nonclinical- and analytical-related protocols, raw data generated from the execution of these protocols, and final reports, funded by BARDA under this contract, as defined in Rights in Data – General clause in FAR 52.227-14. At BARDA's request, the Contractor must provide any nonclinical- or analytical study related contract	Contractor must submit at least 15 business days prior to contract end date. Partial datasets may also be requested for delivery prior to submission of the Final Data Submission Package.

	Deliverable	Deliverable Description	Reporting Procedures and Due Dates[2]
		deliverable without any restrictive legends to ensure BARDA has the ability to review and distribute the nonclinical-related deliverables, as BARDA deems necessary.	
Technical Reporting: Clinical Studies			
	Clinical Study Protocols	The Contractor must submit draft and final clinical study protocols to CO and COR	The Contractor must submit Draft study protocols to COR electronically prior to finalization. ▪ BARDA will provide comments within 10 business days of receipt of draft protocol ▪ Contractor must respond in writing to BARDA comments and recommendations within 10 business days of receipt and must be addressed prior to finalization of protocol. ▪ COR must approve the final protocol. The Contractor must submit Final study protocols to COR electronically no later than 10 business days prior to FDA submission
	Clinical Study Documentation	The Contractor must provide the following documents for any portion of a study funded under this contract. Additional documentation may be requested as part of the Request for Task Order Response. •Pharmacy Manual •Overall Recruitment and Retention plan •Informed Consent Form (ICF) template •Statistical Analysis Plan •Plan to enroll based on US demographic based on most recent census •Investigator Brochure •eCRF •Monitoring Plan •Safety Monitoring Plan •DSMB/SMC Charter and reports	•The Contractor must submit Draft study documents to COR electronically prior to finalization. ▪ BARDA will provide comments within 10 business days of receipt of draft document ▪ Contractor must respond in writing to BARDA comments and recommendations prior to finalization of protocol. •The Contractor must submit Final study documents to COR electronically no later than 10 business days prior to FDA submission. •Contractor must submit draft Statistical Analysis Plan no later than 20 business days after protocol is finalized. The final Statistical Analysis Plan must be submitted 5 business days prior to study database unblinding.

	Deliverable	Deliverable Description	Reporting Procedures and Due Dates[2]
		• Lab manual • Draft and Final Tables, Listings, and Figures (TLFs), ad hoc TLFs • Plan for notifying participants of his/her treatment assignment (e.g., in the case of a public health emergency) The Contractor must make arrangements for up to four (4) BARDA representative(s) to be present during clinical site monitoring visits.	• Contractor must retain the capability to procure, ship, deliver, install, and train on the use of all required supplies, including, but not limited to, documents, files, and equipment. • Final TLFs must be submitted to the COR 3 weeks after database lock.
	Draft and Final Clinical Study Report(s)	Contractor must provide Draft and Final Clinical Study Reports to BARDA for review and comment.	• Draft report due within 45 calendar days after completion of analysis and at least 15 business days prior to submission to FDA • The Contractor must submit Subcontractor-prepared reports received by the Contractor to the COR and CO for review and comment no later than 5 business days after receipt by Contractor • The Government will provide written comments to the Draft Report for Clinical Study Reports within 15 business days after the submission • Final report due 30 calendar days after receiving comments on the Draft Final Report for Clinical Study; If corrective action is recommended, Contractor must address all concerns raised by BARDA in writing • Contractor must consider revising reports to address BARDA's recommendations prior to FDA submission
	ClinicalTrials.Gov Posting and Results Reporting	Contractor must comply with the registration and results reporting requirements of Section 402(j) of the Public Health Service Act (commonly referred to as FDAAA 801 or clinicaltrials.gov requirements).	• Contractor must register all Applicable Clinical Trials (ACTs), as defined by Section 402(j) of the Public Health Service Act: ▪ No later than 21 calendar days after enrollment of the first participant • Contractor must submit results for all ACTs: ▪ no later than one year after the primary completion date, unless the deadline is extended in accordance with Section 402(j) ▪ Contractor must update registration and results information as required by Section 402(j)

	Deliverable	Deliverable Description	Reporting Procedures and Due Dates[2]
	Clinical Report during Active Enrollment and Safety Follow-up Periods	The Contractor must submit weekly detailed clinical reports during active clinical trial enrollment and monthly during the course of the study as part of the monthly reporting cycle. The format will be agreed to by the COR. Reports must include at a minimum: •IRB approval status •Site information (FWA number, site type (e.g., commercial site, academic site), site activation status) •Number of subjects screened and enrolled by age, race, ethnicity, geographic distribution •Safety reporting (SAEs), Development Safety Update Reports (DSURs) •Protocol deviations •Database management •Specimen collection status •Pharmacy manuals •Summary of IEC or SMC meetings (blinded) The Contractor must 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.	•Contractor must submit Clinical Reports on a weekly basis starting when first participant is enrolled and ending when last participant is enrolled. •Contractor must submit Clinical Reports monthly as part of the monthly report until database lock. •Contractor must provide notification of designated safety events to the CO and COR within 24 hours of Contractor notification
	Specimen Collection for Future Use	The Contractor must collect, and store serum samples (or other samples collected) at key immune time points consented for future use as determined by BARDA. The volume of sera (or other sample) per timepoint must be defined in the study protocol. The samples and associated clinical data (metadata) must be transferred to a BARDA-managed repository upon request at a date to be mutually agreed with the US Government but no later than the task order period of performance end. The Contractor must remove any personal identifying information (PII) from the samples and assign each with a unique subject identification	Contractor must provide monthly specimen inventory reports during the course of the clinical study. Specimens and associated clinical data must be transferred to BARDA upon request from the CO or COR according to the task order.

	Deliverable	Deliverable Description	Reporting Procedures and Due Dates[2]
		number before transferring to BARDA. The Contractor must provide a specimen disposition report prior to transferring the material to the repository.	
	Clinical Trial Final Study Package	BARDA must have unlimited rights to all clinical-related protocols, data generated from the execution of these protocols, and final reports, funded by BARDA under this contract, as defined in Rights in Data-General clause in FAR 52.227-14. At BARDA's request, the Contractor must provide any clinical-related contract deliverable without any restrictive legends to ensure BARDA has the ability to review and distribute the clinical-related deliverables, as BARDA deems necessary. If clinical trial data is included, that data must be provided consistent with applicable privacy laws to protect personally identifiable information (PII).	Contractor must submit the Clinical Trial Final Study Package at least 15 business days prior to contract end date. Partial datasets may also be requested for delivery prior to submission of the Final Data Submission Package.
	Data Exchange Package(s) Submitted to Regulatory Agency(-ies)	As part of Final or Draft Submission Package(s), upon BARDA request, and also as part of deliverables, the Contractor must provide raw data, Tabulation Data (e.g., CDISC-compliant SDTM SAS XPT datasets), Analysis Datasets (e.g., CDISC-compliant ADaM SAS XPT datasets), and any additional documents including but not limited to Reviewer's Guide (PDF), SDTM annotated CRF(s) (PDF), data definition file(s) (XML) to BARDA. Other data exchange standards or file formats might be used if discussed with and agreed by BARDA. The Contractor must provide the software programs (e.g., SAS programs, R programs, etc.) used to create any ADaM datasets and generate tables and figures associated with all analyses, including primary and secondary efficacy analyses. *List of abbreviations: XPT = SAS Transport Format (XPORT) Version 5; PDF = Portable Document Format; XML = Extensible Mark-up Language;*	Contractor must provide the Technical Documents and/or datasets within 20 business days of request from the CO or COR

	Deliverable	Deliverable Description	Reporting Procedures and Due Dates[2]
		CDISC = Clinical Data Interchange Standards Consortium	
	Additional Data Package(s)	Upon request, the Contractor must provide raw data, tabulation Data and/or analysis data in a BARDA-agreed upon format and supporting documents that might be including but not limit to the list of files in package, technical specification documents, data analysis programs. Data exchange standards and file formats must be discussed and agreed upon with BARDA.	Contractor must provide the data package(s) within 20 business days of request from the CO or COR
	Clinical study datasets in a public health emergency	In the event of a public health emergency, the Contractor must make clinical study datasets publicly available if requested by BARDA.	Contractor must post clinical study datasets on a web-based platform easily accessible by the public: • 3 months from any interim analysis supporting any action (e.g., regulatory filing, protocol change), if applicable • 3 months from primary analysis • 3 months from final analysis
Quality Assurance			
	BARDA Facility Inspection	Contractor must accommodate periodic or ad hoc site visits, auditing, inspection and review of release documents, test results, equipment and facilities when requested by BARDA. BARDA may assess Contractor's facility and quality systems and make a determination in regard to the site's acceptability and compliance in relation to its ability to manufacture, process, pack, properly and safely store and handle the BARDA-owned product. The assessment agenda may include, but not be limited to, a review of the following areas covering the receiving, holding, and shipping preparation of Product: • Standard Operating Procedures • Software and equipment validations • Deviation system • Corrective action and preventive action system • Quality assurance	Upon completion of a BARDA Facility Inspection visit, Contractor shall receive a written formal assessment report from BARDA. Upon receipt of the written formal assessment report, Contractor must respond in writing to the required and/or suggested improvement recommendations with proposed corrective actions and target dates for completion within 30 calendar days.

	Deliverable	Deliverable Description	Reporting Procedures and Due Dates[2]
		• Change control • Training management system • Facility maintenance • Equipment maintenance and calibration • Environmental monitoring (Excludes Microbiological and Particulate Monitoring) • Facility sanitation program • Document control system • Vendor management program • Organization and personnel qualifications and responsibilities • Regulatory inspection history (482, 483, warning letter, etc.) BARDA may also conduct "for cause" audits to address Product quality or safety concerns within ten (10) business days of notification to Contractor. Contractor must accommodate one audit for no more than 3 auditors for 3 days per year.	
	Other Facility Inspection	In the event of any notice of inspection and unscheduled inspection or actions by all regulatory agencies, other enforcement agencies (e.g., FDA, DEA, OSHA), that occurs in relation to this contract and for the product, or for any other regulatory or enforcement inspection that has the reasonable potential to impact the performance of this contract, including, but not limited to clinical studies and manufacturing facilities, the Contractor must provide the USG with an exact copy (non-redacted) of the FDA Form 483 or summary and the Establishment Inspection Report (EIR) and any other inspection reports. The Contractor must provide the COR and CO with copies of the plan and FDA submissions for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the inspection report, status updates during the plan's execution, and a copy of all final responses to the FDA. The Contractor must also provide redacted copies of any FDA inspection	•Contractor must notify CO and COR immediately (no later than a 24-hour period) upon notice of inspection or upon arrival of the inspector(s) for unscheduled inspection(s). •Contractor must provide copies of any FDA inspection report received from subcontractors that occur as a result of this contract or for this product within 1 business day of receiving correspondence from the FDA, a subcontractor, or third party •Within 10 business days of inspection report, Contractor must provide CO with a plan for addressing areas of nonconformance, if any are identified

	Deliverable	Deliverable Description	Reporting Procedures and Due Dates[2]
		reports received from subcontractors that occur as a result of this contract or for this product. The Contractor must make arrangements for up to four (4) BARDA representative(s) to be present during the opening, any daily debriefs, and the final debrief by the regulatory inspector.	
	Quality Assurance Audits and Subcontractor Monitoring Visits	BARDA reserves the right to participate in QA audits and site visits performed by the Contractor. Upon completion of the audit/site visit the Contractor must 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 must provide responses from the subcontractors to address these concerns and plans for corrective action. The Contractor must allow for up to four (4) USG representative(s) to be present during the audit as necessary for appropriate oversight, including manufacturing person in plant, at nonclinical sites, at clinical sites, CROs, and any other clinical vendor involved in the conduct of the nonclinical study or clinical study under contract.	•Contractor must notify CO and COR a minimum of 10 business days in advance of upcoming audits/site visits of subcontractors •Contractor must notify the COR and CO within 5 business days of report completion and provide Draft Report. •COR and CO will review the report and provide a response to the Contractor with 10 business days before audit can be finalized. •Contractor must provide a final audit report and corrective and preventive actions (CAPAs) to address all findings in the report. •Contractor must provide a final closeout report that all CAPAs were addressed to COR and CO •Contractor must notify BARDA within 24 hours of any critical and/or major findings
	Incident Report	Contractor must communicate to BARDA and document all critical programmatic concerns, issues, or probable risks that have or are likely to significantly impact project schedule and/or cost and/or performance. "Significant" is defined as a 10% or greater cost or schedule variance within a task, but should be confirmed in consultation with BARDA. Incidents that present liability to the project even without cost/schedule impact, such as breach of GCP during a clinical study, must also be reported	•Due within 48 hours of activity or incident; or •Due within 24 hours for a security activity or incident that is in violation of established security standards or indicates the loss or theft of government products associated with this Contract ▪ Email or telephone with written follow-up to COR and CO ▪ Additional updates due to COR and CO within 48 hours of additional developments ▪ Contractor must submit within 5 business days an initial impact assessment and remediation plan (if deemed necessary by either party) to address any potential issues

	Deliverable	Deliverable Description	Reporting Procedures and Due Dates[2]
			▪ If corrective action is deemed necessary, Contractor must submit in writing, investigation reports with a Corrective Action and Preventive Actions Plan (CAPA) and its consideration of concerns raised by BARDA within 45 business days of the initial impact assessment.
Advanced R&D Products			
	Technical Documents	Upon request, Contractor must provide CO and COR with deliverables from the following contract funded activities: quality agreements between Contractors and sub-contractors, process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, Certificate of Analysis, Clinical Studies Data or Reports, clinical study documents. The CO and COR reserve the right to request within the PoP a non-proprietary technical document for distribution within the Government	•Contractor must provide technical document within 10 business days of CO or COR request. Contractor can request additional time on an as needed basis •If corrective action is recommended, the Contractor must address, in writing, concerns raised by BARDA in writing
	Animal Model or Other Technology Transfer Package	Contractor must provide Animal Model or Other Technology Transfer Package containing relevant methodology and data sufficient to enable other practitioners in the field to successfully replicate experimental conditions developed and tested with USG support	•Contractor must provide a draft package within 20 business days of COR or CO request •Contractor must revise the package to address BARDA's concerns, recommendations and/or requests for additional detail
Regulatory Deliverables			
	FDA Correspondence	The Contractor must memorialize all original and unredacted correspondence between Contractor and FDA and submit to BARDA, including formal and informal emails, correspondence, telephone calls, and official information requests (IRs)	•Contractor must provide copies of all original and unredacted FDA correspondence within 5 business days of correspondence
	FDA Submissions	The Contractor must provide BARDA the opportunity to review and comment upon all draft submissions before submission to the FDA.	•Contractor must submit draft FDA submissions to BARDA at least 15 business days prior to FDA submission •BARDA will provide feedback to Contractor within 10 business days of receipt •The Contractor must address, in writing, its consideration of all concerns raised by BARDA prior to FDA submission

	Deliverable	Deliverable Description	Reporting Procedures and Due Dates[2]
		Contractor must provide BARDA with an electronic copy of the final FDA submission. All documents must be duly marked as either "Draft" or "Final"	•The Contractor must submit Final FDA submissions to BARDA concurrently or no later than five (5) calendar days of submission
	FDA Meetings and Interactions	The Contractor must forward the dates and times of any meeting with the FDA to BARDA, including formal meetings, site visits, inspections, audits, ad hoc meetings, technical meetings, etc. The Contractor must arrange for up to four (4) BARDA staff to attend any FDA meeting. (BARDA staff typically include the COR and three (3) subject matter experts)	•Contractor must notify BARDA of any and all upcoming FDA meetings at minimum within 24 hours of meeting request. This includes formal (Type A, B, or C meetings or any and all other technical meetings). •Contractor must provide advance copies of any correspondence it plans to send to FDA. •Contractor must provide within 24 hours of its receipt, unredacted copies of all written communications it receives from the FDA. •Contractor must notify BARDA within 24 hours of any informal or ad hoc meeting occurrence. •The Contractor must forward initial Contractor- and FDA-issued draft minutes AND final minutes of **any** meeting with the FDA to BARDA within 2 business days of receipt.
Press Releases, Publications, Abstracts, Presentations			
	Press Releases and Social Media Announcements	Contractor agrees to accurately and factually represent the work conducted under this contract in all press releases and external communications.	• Contractor must submit to the CO and COR an advance copy of any press release to this contract no fewer than 5 business days prior to the issuance of the press release • Contractor must submit to the CO and COR an advance copy of any social media announcement related to this contract no fewer than 3 business days prior to the issuance of the social media announcement. • The Contractor must submit any final press release to BARDA no later than one (1) calendar day prior to its release
	Publications	The Contractor must submit any manuscript or scientific meeting abstract/presentation containing data generated under this contract to BARDA for review prior to submission. Acknowledgment of BARDA funding must be included as noted in contract article B.5.31	• Contractor must submit all manuscript or scientific meeting abstracts/presentations to COR, CO prior to submission/presentation by 30 business days for manuscripts and 15 business days for abstracts or posters • Contractor must address all concerns raised by BARDA in writing • Final submissions must be submitted to BARDA concurrently or no later than within one (1) calendar day of its submission • Contractor must list all publication material in the Monthly Technical Progress Report
	Contractor Clinical Publication Timeline and USG Right to Publish Data	The Contractor and Government are committed to transparent and timely publication of clinical study	• Contractor must notify CO and COR within 30 of primary analysis results and study end date [last subject last visit] if they plan not to publish data.

	Deliverable	Deliverable Description	Reporting Procedures and Due Dates[2]
		data to ensure rapid distribution of information during a public health emergency. Within 30 days of the primary analysis, results from clinical studies funded in whole or in part under this contract and consistent with Good Publications Practices. Sponsor must submit clinical study primary endpoint analysis for publication to a peer reviewed journal. Within 90 days of study end date [database lock] for studies funded in part or whole under this contract and consistent with Good Publication Practices, Sponsor must submit clinical study data for publication to a peer reviewed journal. If the Contractor does not elect to publish data, Contractor must provide CO and COR with clinical study data to support the government publication of data as deemed appropriate by the government, without the Contractor involvement. The government reserves the right to publish a counter-analysis of the data.	• Within 10 calendar days of a request for clinical data from the CO, the Contractor must provide CO with requested data, information and materials in the form(s) requested by the government, to support the government publication of the clinical study data funded in part or whole under this contract
	Contractor Nonclinical Publication Timeline and USG Right to Publish Data	The Contractor and Government are committed to transparent and timely publication of nonclinical data to ensure rapid distribution of information, particularly during a public health emergency. Within 90 days of study end date [audited or quality-controlled draft final report prepared and reviewed by the Government] for studies funded in part or whole under this contract and consistent with Good Publication Practices, Sponsor must submit nonclinical study data for publication to a peer reviewed journal. If the Contractor does not elect to publish data, Contractor must provide CO and COR with nonclinical data to support the government publication of data as deemed appropriate by the government, without the Contractor involvement. The	• Contractor must notify CO within 30 calendar days of study end date [audited or quality-controlled draft final report prepared and submitted for Government review] if they plan not to publish data. • Within 10 calendar days of a request for nonclinical data from the CO, the Contractor must provide CO with requested data, information and materials in the form(s) requested by the government, to support the government publication of the nonclinical study data funded in part or whole under this contract

	Deliverable	Deliverable Description	Reporting Procedures and Due Dates[2]
		government reserves the right to publish a counter-analysis of the data.	

SECTION G – CONTRACT ADMINISTRATION

AUTHORITIES OF GOVERNMENT PERSONNEL

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

G.1. CONTRACTING OFFICER (CO)

Laura Saddison
Biomedical Advanced Research and Development Authority
Administration for Strategic Preparedness and Response
400 7th St SW
Washington, D.C. 20024
Laura.Saddison@hhs.gov

The CO is the only individual who can legally commit the Government to the expenditure of public funds. No person other than the CO can make any changes to the terms, conditions, general provisions or other stipulations of this contract. Any other commitment, either explicit or implied, is invalid.

The CO is the only person with authority to act as agent of the Government under this contract. Only the CO has authority to: (1) direct or negotiate any changes in the statement of work; (2) modify or extend the period of performance; (3) change the delivery schedule; (4) authorize reimbursement to the Contractor any costs incurred during the performance of this contract; (5) obligate the U.S. Government; (6) obligate contract funding; or (7) otherwise change any terms and conditions of this contract.

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

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

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

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

G.3. CONTRACTOR'S POINTS OF CONTACT

The Offeror must 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. INVOICE SUBMISSION – HHSAR 352.232-71 Electronic Submission of Payment

Requests (Feb 2022)

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

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

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

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

G.4.1 ELECRONIC INVOICING AND PAYMENT REQUREMENTS – INVOICE PROCESSING PLATFORM

1. All Invoice submissions for goods and or services delivered to facilitate payments must be made electronically through the U.S. Department of Treasury’s Invoice Processing Platform System (IPP).
2. Invoice Submission for Payment means any request for contract financing payment or invoice payment by the Contractor. To constitute a proper invoice, the payment request must comply with the requirements identified in the applicable Prompt Payment clause included in the contract, or the clause 52.212-4 Contract Terms and Conditions – Commercial Items included in commercial items contracts. The IPP website address is: https://www.ipp.gov.
3. The Agency will enroll the Contractors new to IPP. The Contractor must follow the IPP registration email instructions for enrollment to register the Collector Account for submitting invoice requests for payment. The Contractor Government Business Point of Contact (as listed in SAM) will receive Registration email from the Federal Reserve Bank of St. Louis (FRBSTL) within 3 – 5 business days of the contract award for new contracts or date of modification for existing contracts.
    a. Registration emails are sent via email from ipp.noreply@mail.eroc.twai.gov. Contractor assistance with enrollment can be obtained by contacting the IPP Production Helpdesk via email to IPPCustomerSupport@fiscal.treasury.gov or phone (866) 973-3131.
    b. The Contractor POC will receive two emails from **IPP Customer Support**, the first email contains the initial administrative IPP User ID. The second email, sent within 24 hours of receipt of the first email, contains a temporary password. You must log in with the temporary password within 30 days.
4. If your company is already registered to use IPP, you will not be required to reregister.
5. If the Contractor is unable to comply with the requirement to use IPP for submitting invoices for payment as authorized by HHSAR 332.7002, a written request must be submitted to the Contracting Officer to explain the circumstances that require the

authorization of alternate payment procedures.

G.4.2. Additional Administration for Preparedness and Response (ASPR) requirements:

(i) The contractor shall submit invoices under this contract once per quarter. For indefinite delivery vehicles, separate invoices must be submitted for each order.

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

(iii) Invoices must include the Unique Entity ID Number (UEI) of the Contractor.

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

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

- Direct Labor - include all persons, listing the person's name, title, number of hours worked, hourly rate, the total cost per person and a total amount for this category;
- Indirect Costs (i.e., Fringe Benefits, Overhead, General and Administrative, Other Indirects)- show rate, base and total amount;
- Consultants (if applicable) - include the name, number of days or hours worked, daily or hourly rate, and a total amount per consultant;
- Travel - include for each airplane or train trip taken the name of the traveler, date of travel, destination, the transportation costs including ground transportation shown separately and the per diem costs. Other travel costs shall also be listed;
- Subcontractors (if applicable) - include, for each subcontractor, the same data as required for the prime Contractor;
- Other Direct Costs - include a listing of all other direct charges to the contract, i.e., office supplies, telephone, duplication, postage; and
- Fee – amount as allowable in accordance with the Schedule and FAR 52.216-8 if applicable.

G.5. PAYMENT CONDITIONS

1. The contractor may not invoice for any ACTIVITY prior to delivery and acceptance of services and/or product.

2. Accepted product which falls into any of the following categories shall be replaced by the contractor at no cost to the USG.
    a. If product does not meet any criterion outlined in this contract.
    b. If an incident occurs resulting in any amount of product loss, including but not limited to leaking or broken container(s), broken vial(s), temperature excursions, etc.
    c. If product is deemed to be recalled for any reason, as outlined in the Recalls, Market Withdrawals, & Safety Alerts published by U.S. Food and Drug

Administration (https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts); or based upon Chapter 7 of the Regulatory Procedures Manual (https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-manuals/regulatory-procedures-manual).

G.5.1. REIMBURSEMENT OF COST

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

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

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

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

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

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

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

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

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

G.6. PROVIDING ACCELERATED PAYMENT TO SMALL BUSINESS SUBCONTRACTORS, FAR 52.232-40 (MARCH 2023)

(a) (1) In accordance with 31 U.S.C. 3903 and 10 U.S.C. 3801, within 15 days after receipt of accelerated payments from the Government, the Contractor shall make accelerated payments to its small business subcontractors under this contract, to the maximum extent practicable and prior to when such payment is otherwise required

under the applicable contract or subcontract, after receipt of a proper invoice and all other required documentation from the small business subcontractor.

(2) The Contractor agrees to make such payments to its small business subcontractors without any further consideration from or fees charged to the subcontractor.

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

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

G.7. GOVERNMENT PROPERTY

Contractor is responsible for maintaining Government Property (GP) in accordance with FAR 52.245-1. The products purchased, shipped and stored under this contract are considered GP and should be appropriately stored, labeled and inventoried.

As defined in FAR 45.101 and 52.245-1, “Contractor-acquired property” means property acquired, fabricated, or otherwise provided by the contractor for performing a contract and to which the Government has title. “Government property” means all property owned or leased by the Government. Government property includes both Government-furnished property and contractor-acquired property. Government property includes material, equipment, special tooling, special test equipment, and real property. Government property does not include intellectual property and software.

Contractor agrees to abide by the applicable provisions of HHS Publication (OS) 686, entitled, Contractor's Guide for Control of Government Property, (1990), available at https://oamp.od.nih.gov/sites/default/files/DGS/HHS%20Contracting%20Guide%20for%20Contract%20of%20Government%20Property-Appendix%20Q.pdf

G.8. POST AWARD EVALUATION OF CONTRACTOR PERFORMANCE

G.8.1. Post-Award Evaluation of Contractor Performance

a. Purpose: In accordance with FAR 42.1102(a), past performance evaluations shall be prepared at least annually and at the time the work under a contract or order is completed, via CPARS, the Government-wide evaluation tool (www.cpars.gov).

b. Evaluators: The performance evaluation will be completed jointly by the Contracting Officer's Representative and the Contracting Officer.

c. Performance Evaluation Factors: Per FAR 42.1103(b)(2), evaluation factors for each assessment must include, at a minimum: technical (quality of product or service); cost control (not applicable for firm-fixed-price); schedule/timeliness; management or business relations; small business subcontracting; other (as

applicable).

d. Offeror Review: A copy of the evaluation will be electronically sent to the Contractor as soon as practicable after completion of the evaluation. The Contractor shall submit comments, rebutting statements, or additional information to the Contracting Officer within 14 calendar days after receipt of the evaluation.

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

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

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

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

i. 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.9. CONTRACT COMMUNICATIONS/CORRESPONDENCE

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

G.10. NEGOTIATED INDIRECT COST RATES

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

Rate Type	Provisional Rates	Allocation Base

In accordance with FAR 52.216-7(d), the contractor shall submit an adequate final indirect cost rate proposal to the contracting officer and the cognizant auditor within the six-month period following the end of each of its fiscal years during the period of contract performance. The contracting office may grant, in writing, reasonable extensions, for exceptions circumstances only, when requested in writing by the contractor.

G.11 KEY PERSONNEL, HHSAR 352.237-75 (December 2015)

The key personnel specified in this section are considered to be essential to work performance. If proposed Key Personnel change between the time of the Offeror's proposal and contract award, the Offeror needs to provide immediate written notification to the Contracting Officer.

Offeror shall provide a list of FTEs in the table below that are considered to be key personnel to the work being performed hereunder:

Title	Name
Program Director (PD) or Principal Investigator (PI)	
Project Manager	
Chief Scientific/Medical Officer	
Clinical Lead	
Regulatory Affairs Lead	
Manufacturing Lead	
Quality Assurance Lead	

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

SECTION H – SPECIAL CONTRACT REQUIREMENTS

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

H.1. CARE OF LIVE VERTEBRATE ANIMALS, HHSAR 352.270-5(b) (DEC 2015)

(a) Before undertaking performance of any contract involving animal-related activities where the species is regulated by the United Sates Department of Agriculture (USDA), the Contractor shall register with the Secretary of Agriculture of the United States in accordance with 7 U.S.C. 2136 and 9 CFR 2.25 through 2.28. The Contractor shall furnish evidence of the registration to the Contracting Officer.

(b) The Contractor shall acquire vertebrate animals used in research from a dealer licensed by the Secretary of Agriculture under 7 U.S.C. 2133 and 9 CFR 2.1-2.11, or from a source that is exempt from licensing under those sections.

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

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

Note: The Contractor may request registration of its facility and a current listing of licensed dealers from the Regional Office of the Animal and Plant Health Inspection Service (APHIS), USDA, for the region in which its research facility is located. The location of the appropriate APHIS Regional Office, as well as information concerning this program may be obtained by contacting the Animal Care Staff, USDA/APHIS, 4700 River Road, Riverdale, Maryland 20737 (Email: animalcare@usda.gov; Web site: https://www.aphis.usda.gov/animal-care. Office of Laboratory Animal Welfare Phone number 301-851-3751.

H.2. RESTRICTION ON USE OF HUMAN SUBJECTS, HHSAR 352.270-6 (DEC 2015)

Pursuant to 45 CFR part 46, Protection of Human Research Subjects, the Contractor shall not expend funds under this award for research involving human subjects or engage in any human

subjects research activity prior to the Contracting Officer's receipt of a certification that the research has been reviewed and approved by the Institutional Review Board (IRB) registered with OHRP. This restriction applies to all collaborating sites, whether domestic or foreign, and subcontractors. The Contractor must ensure compliance by collaborators and subcontractors.

H.3. PROTECTION OF HUMAN SUBJECTS, HHSAR 352.270-4b (DEC 2015)-RESEARCH INVOLVING HUMAN SUBJECTS COMMITTEE (RIHSC) APPROVAL OF RESEARCH PROTOCOLS REQUIRED (DEC 2015)

(a) The Contractor agrees to protect the rights and welfare of human subjects involved in research under this contract by complying with 45 CFR part 46 and the clause at HHSAR 352.270-4b.

(b) Initial proof of compliance with 45 CFR part 46 shall consist of:

1. A copy of a current Federal-wide Assurance on file with OHRP. The copy of a current Federal-wide Assurance shall be included with the Contractor's proposal;
2. A letter from the Contractor's local IRB (the Institutional Review Board (IRB) specified in the Offeror's Assurance of Compliance) stating that it has reviewed and approved the proposed research protocol. The letter from the local IRB shall be submitted to the Contracting Office; and
3. A copy of a letter from the RIHSC stating that it or its designee has reviewed and approved the proposed research protocol. This shall be submitted to the Contracting Officer within three business days of its issuance.

The Contractor shall not advertise for, recruit, or enroll human subjects, or otherwise commence any research involving human subjects under this contract, until RIHSC has reviewed and approved its research. The Contractor may commence other limited aspects of contract performance prior to receiving RIHSC or its designee approval of its proposed research protocol. Research involving human subjects may commence immediately upon the Contractor's receipt of RIHSC or its designee approval; however, the Contractor shall submit a copy of RIHSC's or its designee's letter of approval to the Contracting Officer within three business days of its receipt.

Failure to obtain RIHSC or its designee approval of proposed research protocols may result in the termination of this contract.

(c) The Contractor further agrees that:

(1) The Contractor will provide a letter from RIHSC, at least annually, stating that RIHSC or its designee has reviewed and approved the research protocols for research performed under this contract. This shall be submitted to the Contracting Officer for inclusion in the contract file.

(2) The Contractor will submit all proposed modifications and amendments to research protocols for research performed under this contract to RIHSC for review and approval. Modifications and amendments include, but are not limited, to changes to consent forms and advertising materials, and the addition or deletion of investigators. Changes may be instituted immediately after the Contractor has received both the local IRB and RIHSC or its designee approval (except when necessary to eliminate apparent immediate hazards to the subject);

however, the Contractor shall submit a copy of the letter evidencing RIHSC's or its designee's approval of the proposed changes to the Contracting Officer within three business days of its receipt.

H.4. 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, 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.

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

Anyone who becomes aware of suspected cases of fraud, waste, or abuse in Federal HHS programs should report to the online OIG Hotline form. You may also call, mail, or fax using the information below.

Online: https://oig.hhs.gov/fraud/report-fraud/
Phone: 1-800-HHS-TIPS (1-800-447-8477)

Fax: (800) 223-8164
TTY: 1-800-377-4950

U.S. Department of Health and Human Services
Office of Inspector General
ATTN: OIG HOTLINE OPERATIONS
P.O. Box 23489
Washington, DC 20026

H.6. Rights in Data

The contract incorporates FAR Clause 52.227-14, Rights in Data—General and 52.227-14 Alt II.

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.

Unlimited rights mean the rights of the Government to use, disclose, reproduce, prepare derivative works, distribute copies to the public, and perform publicly and display publicly, in any manner and for any purpose, and to have or permit others to do so. the Government shall have unlimited rights in-

i. Data first produced in the performance of this contract;
ii. Form, fit, and function data delivered under this contract;
iii. Data delivered under this contract (except for restricted computer software) that constitute manuals or instructional and training material for installation, operation, or routine maintenance and repair of items, components, or processes delivered or furnished for use under this contract; and
iv. All other data delivered under this contract unless provided otherwise for limited rights data or restricted computer software

H.7 Tariff Notification and Reimbursement Requirements

The Contractor shall notify the Contracting Officer in writing within 30 calendar days of becoming aware of any newly imposed or modified tariff that may result in costs reimbursable under Activities 1018 and 2018.

Requests for reimbursement under Activities 1018 and 2018 shall include, at a minimum:

i. Customs entry summaries (e.g. CBP Form 7501)
ii. Proof of payment of tariffs or duties
iii. Country-of-origin documentation
iv. Certification that no applicable tariff exclusion, waiver or refund is available

The Government reserves the right to audit tariff-related costs in accordance with FAR 52.215-2, Audit and Records – Negotiation.

H.8 Patent and Invention Reporting Requirements in iEdison

Use of iEdison System

Pursuant to the Bayh-Dole Act (35 U.S.C. §§ 200–212), its implementing regulations at 37 CFR Part 401, and FAR 52.227-11, the Contractor **shall report all subject inventions, election of title, patent applications, and related Bayh-Dole documentation exclusively through the National Institute of Standards and Technology (NIST) "iEdison" reporting system**.

Submission Requirements

The Contractor shall, in accordance with the timelines specified in FAR 52.227-11:

(1) Disclose each subject invention in iEdison within two (2) months of the inventor's disclosure to the Contractor;
(2) Elect title to subject inventions in iEdison within the period required by FAR 52.227-11

(3) Submit confirmatory licenses, government support statements, and utilization reports through iEdison; and
(4) Identify the Contract number in all iEdison submissions.

Account Setup
The Contractor shall establish and maintain an active iEdison account capable of submitting invention reports later than thirty (30) days after award. Information about registration and account requirements is available on the NIST iEdison website through the BARDA iEdison Agency Administrator.

Failure to Report
Failure to comply with these reporting requirements may result in remedies under FAR 52.227-11, including the Government's right to take title to subject invention or pursue other contractual remedies.

Flow-Down
The Contractor shall include the substance of this clause in all subcontracts at any tier where the subcontractor will perform research and/or development activities.

H.9 Multiple Award Ordering Instructions

A. Authority and Applicability: Orders issued under this IDIQ contract must comply with FAR Sections 16.504, 16.505, 16.506, 16.507, 16.508, HHSAR 316.5 and applicable HHS acquisition policy memoranda.

B. Ordering Period: Base Ordering Period: 60 months after date of award (DATE to DATE). Option 1 Ordering Period: 61 months to 120 months after date of award (DATE TO DATE). The Government may extend the ordering period by exercising options pursuant to FAR 52.217-9 and 52.217-8. Contractor will not be required to perform beyond the date specified in FAR 52.216-22(d) Indefinite Quantity.

C. Minimum and Max Quantities: Minimum Guarantee: $50,000 and Maximum Contract Ceiling: $_____ inclusive of all options. The minimum guarantee will be satisfied at the task order level.

D. Scope of Orders: Orders must be within scope of Section C (Statement of Work), issued within the ordering period and not exceed the contract maximum value.

E. Authorized Ordering Activities: Orders may be issued by warranted BARDA CMA Contracting Officers only. Interagency acquisitions are authorized.

F. Uniform Ordering Procedures; Ordering procedures are at the discretion of the ordering contracting officer.

G. Blanket Purchase Agreements (BPAs): In accordance with FAR 16.504-5(h)(2) contracting officers may establish one or more BPAs to fill repetitive needs for

supplies or services under this IDIQ contract.

H. Fair Opportunity Procedures: For orders or BPA valued above the Micro-Purchase Threshold (MPT), the Contracting Officer shall provide each awardee a fair opportunity to be considered unless an exception at FAR 16.507-6 applies. The Contracting Officer shall:

    a. Not use allocation methods or preferred awardee designations that would not result in fair consideration being given to all awardees
    b. Tailor procedures to the risk and complexity of each order
    c. Include the procedures in the solicitation and contract
    d. Consider price or cost as one of the factors in every selection decision
    e. Keep submission requirements to a minimum
    f. May use oral presentations, multiphase approaches or advisory down-selects
    g. When Past Performance under this IDIQ is sufficient, it may be relied upon without considering outside efforts.

I. The approved Acquisition Plan at the IDIQ level satisfies all Acquisition Plan requirements for task orders and BPAs awarded under this IDIQ.

PART II – CONTRACT CLAUSES

SECTION I – CONTRACT CLAUSES

THE FOLLOWING GENERAL CLAUSE LISTING(S) WILL BE APPLICABLE TO THE CONTRACT RESULTING FROM THIS RFP. OFFERORS ARE ENCOURAGED TO REVIEW THESE CLAUSES AND TO DISCUSS ANY QUESTIONS THEY MAY HAVE ABOUT THEM PRIOR TO THE CLOSING DATE OF THE RFP.

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

This contract incorporates the following clauses by reference, with the same force and effect as if they were given in full text. Upon request, the Contracting Officer will make the full text available. The full text of a clause may be accessed electronically at: https://www.acquisition.gov/far-overhaul/far-part-deviation-guide. HHSAR clauses at https://www.hhs.gov/grants-contracts/contracts/contract-policies-regulations/hhsar/index.html

a. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

FAR Clause	Clause Title	Effective Date
Federal Acquisition Regulation (FAR)		
52.202-1	Definitions	Jun 2020
52.203-3	Gratuities	Apr 1984
52.203-5	Covenant Against Contingent Fees	May 2014
52.203-6	Restrictions on Subcontractor Sales to the Government	Jun 2020
52.203-7	Anti-Kickback Procedures	Jun 2020
52.203-8	Cancellation, Rescission, and Recovery of Funds for Illegal or Improper Activity	May 2014
52.203-10	Price or Fee Adjustment for Illegal or Improper Activity	May 2014
52.203-12	Limitation on Payments to Influence Certain Federal Transactions	Jun 2020
52.203-13	Contractor Code of Business Ethics and Conduct	Nov 2021
52.203-14	Display of Hotline Poster(s)	Nov 2021
52.203-16	Preventing Personal Conflicts of Interest	Jun 2020
52.203-17	Contractor Employee Whistleblower Rights	Nov 2023
52.203-18	Prohibition on Contracting with Entities that Require Certain Internal Confidentiality Agreements or Statements – Representation	Jan 2017
52.203-19	Prohibition on Requiring Certain Internal Confidentiality Agreements or Statements	Jan 2017
52.204-5	Women-Owned Business (Other Than Small Business)	Oct 2014
52.204-7	System for Award Management-Registration.	Nov 2025
52.204-10	Reporting Executive Compensation and First-Tier Subcontract Awards	Nov 2025
52.204-13	System for Award Management Maintenance	Nov 2025
52.204-15	Service Contract Reporting Requirement for Indefinite Delivery Contracts	Nov 2025
52.204-19	Incorporation by Reference of Representations and Certifications	Dec 2014
52.208-90		Nov 2025

	Government Supply Sources	
52.209-6	Protecting the Government's Interest When Subcontracting with Contractors Debarred, Suspended, or Proposed for Debarment, or Voluntarily Excluded	Nov 2025
52.209-7	Information Regarding Responsibility Matters	Nov 2025
52.209-9	Updates of Publicly Available Information Regarding Responsibility Matters	Nov 2025
52.209-10	Prohibition on Contracting with Inverted Domestic Corporations	Nov 2025
52.210-1	Market Research	Jul 2025
52.211-5	Material Requirements	Jul 2025
52.213-4	Terms and Conditions – Simplified Acquisitions (Noncommercial)	Nov 2025
52.215-2	Audit and Records-Negotiation	Nov 2025
52.215-8	Order of Precedence-Uniform Contract Format	Nov 2025
52.215-10	Price Reduction for Defective Certified Cost or Pricing Data	Aug 2011
52.215-11	Price Reduction for Defective Certified Cost or Pricing Data—Modifications	Nov 2025
52.215-12	Subcontractor Certified Cost or Pricing Data	Nov 2025
52.215-13	Subcontractor Certified Cost or Pricing Data - Modifications	Nov 2025
52.215-14	Integrity of Unit Prices	Nov 2021
52.215-15	Pension Adjustments and Asset Reversions	Nov 2025
52.215-17	Waiver of Facilities Capital Cost of Money	Oct 1997
52.215-18	Reversion or Adjustment of Plans for Postretirement Benefits (PRB) Other Than Pensions	Nov 2025
52.215-19	Notification of Ownership Changes	Nov 2025
52.215-20	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data	Nov 2025
52.215-21	Requirements for Certified Cost or Pricing Data and Data Other Than Certified Cost or Pricing Data-Modifications	Nov 2025
52.215-22	Limitations on Pass-Through Charges-Identification of Subcontract Effort	Nov 2025
52.215-23	Limitations on Pass-Through Charges	Nov 2025
52.216-4	Economic Price Adjustment – Labor and Material	Jan 2017
52.216-7	Allowable Cost and Payment	Nov 2025
52.216-8	Fixed Fee	Jun 2011
52.216-11	Cost Contract – No Fee	Apr 1984
52.216-12	Cost-Sharing Contract – No Fee	Apr 1984
52.216-27	Single or Multiple Awards	Oct 1995
52.217-7	Option for Increased Quantity-Separately Priced Line Item	Mar 1989
52.217-8	Option to Extend Services	Nov 1999
52.219-8	Utilization of Small Business Concerns	Nov 2025
52.219-9	Small Business Subcontracting Plan	Nov 2025
52.219-16	Liquidated Damages – Subcontracting Plan	Nov 2025
52.219-28	Post-Award Small Business Program Representation	Nov 2025

52.222-2	Payment for Overtime Premiums	Jul 1990
52.222-3	Convict Labor	Jun 2003
52.222-35	Equal Opportunity for Veterans	Nov 2025
52.222-36	Equal Opportunity for Workers with Disabilities	Nov 2025
52.222-37	Employment Reports on Veterans	Nov 2025
52.222-40	Notification of Employee Rights Under the National Labor Relations Act	Dec 2010
52.222-50	Combating Trafficking in Persons	Nov 2025
52.222-54	Employment Eligibility Verification	Nov 2025
52.222-90	Addressing DEI Discrimination by Federal Contractors	Apr 2026
52.223-3	Hazardous Material Identification and Material Safety Data- Alt I	Nov 2025
52.223-23	Sustainable Products and Services	Nov 2025
52.224-1	Privacy Act Notification	Apr 1984
52.224-2	Privacy Act	Apr 1984
52.224-3	Privacy Training	Jan 2017
52.225-1	Buy American Act-Supplies	Nov 2025
52.225-8	Duty-Free Entry	Oct 2025
52.225-14	Inconsistency between English Version and Translation of Contract.	Feb 2000
52.226-7	Drug Free Workplace	May 2024
52.226-8	Encouraging Contractor Policies to Ban Text Messaging While Driving	May 2024
52.227-1	Authorization and Consent, Alternate 1 (APR 1984)	Jun 2020
52.227-2	Notice and Assistance Regarding Patent and Copyright Infringement	Jun 2020
52.227-3	Patent Indemnity	Apr 1984
52.227-11	Patent Rights – Ownership by the Contractor	May 2014
52.227-14	Rights in Data-General	May 2014
52.227-14	Rights in Data-General Alt II	Dec 2007
52.227-16	Additional Data Requirements	Jun 1987
52.228-7	Insurance – Liability to Third Persons	Mar 1996
52.229-3	Federal, State and Local Taxes	Feb 2013
52.230-2	Cost Accounting Standards	Nov 2025
52.230-3	Disclosure and Consistency of Cost Accounting Practices	Nov 2025
52.230-6	Administration of Cost Accounting Standards	Nov 2025
52.230-7	Proposal Disclosure – Cost Accounting Practice Changes	Apr 2005
52.232-1	Payments	Apr 1984
52.232-2	Payments under Fixed-Price Research and Development Contracts	Apr 1984
52.232-8	Discounts for Prompt Payment	Feb 2002
52.232-9	Limitation on Withholding of Payments	Apr 1984
52.232-11	Extras	Apr 1984

52.232-17	Interest	May 2014
52.232-18	Availability of Funds	Apr 1984
52.232-20	Limitation of Cost	Nov 2025
52.232-22	Limitation of Funds	Nov 2025
52.232-23	Assignment of Claims	May 2014
52.232-25	Prompt Payment	Jan 2017
52.232-33	Payment by Electronic Funds Transfer-System for Award Management	Oct 2018
52.232-39	Unenforceability of Unauthorized Obligations	Jun 2013
52.232-40	Providing Accelerated Payments to Small Business Subcontractors	Mar 2023
52.233-1	Disputes	Nov 2025
52.233-2	Service of Protest	Nov 2025
52.233-3	Protest after Award	Nov 2025
52.233-4	Applicable Law for Breach of Contract Claim	Nov 2025
52.240-91	Security Prohibitions and Exclusions	Nov 2025
52.240-93	Basic Safeguarding of Covered Contractor Information	Nov 2025
52.242-1	Notice of Intent to Disallow Costs	Apr 1984
52.242-2	Production Progress Reports	Apr 1991
52.242-3	Penalties for Unallowable Costs	Nov 2025
52.242-4	Certification of Final Indirect Costs	Jan 1997
52.242-5	Payments to Small Business Subcontractors	Jan 2017
52.242-13	Bankruptcy	Jul 1995
52.242-14	Suspension of Work	Apr 1984
52.242-15	Stop-Work Order, Alternate I	Apr 1984
52.242-15	Stop-Work Order	Aug 1989
52.243-1	Changes-Fixed-Price Alternate V	Apr 1984
52.243-2	Changes-Cost-Reimbursement Alternate V	Apr 1984
52.243-6	Change Order Accounting	Jul 2025
52.243-7	Notification of Changes	Jul 2025
52.244-2	Subcontracts, Alternate I	Jun 2020
52.244-5	Competition in Subcontracting	Aug 2024
52.244-6	Subcontracts for Commercial Products and Commercial Services (JAN 2025) (DEVIATION FEB 2025)	Nov 2025
52.245-1	Government Property	Sep 2021
52.245-9	Use and Charges	Apr 2012
52.246-2	Inspection of Supplies – Fixed Price	Aug 1996
52.246-3	Inspection of Supplies – Cost Reimbursement	May 2001
52.246-4	Inspection of Services – Fixed Price	Aug 1996
52.246-5	Inspection of Services – Cost Reimbursement	Apr 1984

52.246-7	Inspection of Research and Development – Fixed Price	Aug 1996
52.246-8	Inspection of Research and Development – Cost Reimbursement	May 2001
52.246-9	Inspection of Research and Development (ShortForm)	Apr 1984
52.246-15	Certificate of Conformance	Apr 1984
52.246-16	Responsibility for Supplies	Apr 1984
52.246-23	Limitation of Liability	Feb 1997
52.246-25	Limitation of Liability-Services	Feb 1997
52.247-29	F.o.b. Origin	Feb 2006
52.247-34	F.o.b. Destination	Jan 1991
52.247-63	Preference for U.S.-Flag Air Carriers	Jan 2025
52.249-2	Termination for Convenience of the Government (Fixed-Price)	Apr 2012
52.249-6	Termination (Cost-Reimbursement)	May 2004
52.249-8	Default (Fixed-Price Supply and Service)	Apr 1984
52.249-9	Default (Fixed-Price Research and Development)	Apr 1984
52.249-14	Excusable Delays	Apr 1984
52.252-6	Authorized Deviations in Clauses.	Nov 2020
52.253-1	Computer Generated Forms	Nov 2025

b. DEPARTMENT OF HEALTH AND HUMAN SERVICES ACQUISITION REGULATION (HHSAR) (48 CFR CHAPTER 3) CLAUSES:

Clause	Clause Title	Effective Date
HHS Acquisition Regulations (HHSAR)		
352.203-70	Anti-Lobbying	Dec 2015
352.208-70	Printing and Duplication	Feb 2026
352.211-1	Public Accommodations and Commercial Facilities	Nov 2025
352.211-2	Conference Sponsorship Requests and Conference Materials Disclaimer	Nov 2025
352.211-3	Paperwork Reduction Act	Nov 2025
352.215-70	Late Proposals and Revisions	Dec 2015
352.216-70	Allowable Cost and Payment for Hospitals	Mar 2026
352.223-70	Safety and Health	Dec 2015
352.224-70	Privacy Act	Dec 2015
352.224-71	Confidential Information	Dec 2015
352.227-70	Publications and Publicity	Dec 2015
352.231-70	Salary Rate Limitation	Feb 2026
352.232-71	Electronic Submission of Payment Requests	Apr 2026
352.233-71	Litigation and Claims	Dec 2015

352.235-71	Protection of Human Subjects	Mar 2026
352.235-72	Needle Exchange	Mar 2026
352.235-73	Continued Ban on Funding Abortion and Continued Ban on Funding of Human Embryo Research	Mar 2026
352.235-75	Care of Live Vertebrate Animals	Mar 2026
352.237-75	Key Personnel	Dec 2015
352.239-74	Electronic and Information Technology Accessibility	Dec 2015
352.204-70	Prevention and Public Health Fund-Reporting Requirement	Dec 2015
352.270-70	Non Discrimination for Conscience	Mar 2026

I.2 ADDITIONAL FAR CONTRACT CLAUSES INCLUDED IN FULL TEXT

This contract incorporates the following clauses in full text. FEDERAL ACQUISITION REGULATION (FAR) (48 CFR CHAPTER 1) CLAUSES:

FAR 52.216-18 Ordering (Aug 2020)

(a) Any supplies and services to be furnished under this contract shall be ordered by issuance of delivery orders or task orders by the individuals or activities designated in the Schedule. Such orders may be issued from _____ through _____ *[insert dates]*.

(b) All delivery orders or task orders are subject to the terms and conditions of this contract. In the event of conflict between a delivery order or task order and this contract, the contract shall control.

(c) A delivery order or task order is considered "issued" when—

(1) If sent by mail (includes transmittal by U.S. mail or private delivery service), the Government deposits the order in the mail;

(2) If sent by fax, the Government transmits the order to the Contractor's fax number; or

(3) If sent electronically, the Government either—

(i) Posts a copy of the delivery order or task order to a Government document access system, and notice is sent to the Contractor; or

(ii) Distributes the delivery order or task order via email to the Contractor's email address.

(d) Orders may be issued by methods other than those enumerated in this clause only if authorized in the contract.

FAR 52.216-19 Order Limitations (Oct 1995)

(a) *Minimum order*. When the Government requires supplies or services covered by this

contract in an amount of less than _____ *[insert dollar figure or quantity]*, the Government is not obligated to purchase, nor is the Contractor obligated to furnish, those supplies or services under the contract.

(b) *Maximum order*. The Contractor is not obligated to honor-

(1) Any order for a single item in excess of _____ *[insert dollar figure or quantity]*;

(2) Any order for a combination of items in excess of _____ *[insert dollar figure or quantity]*; or

(3) A series of orders from the same ordering office within _____ days that together call for quantities exceeding the limitation in paragraph (b)(1) or (2) of this section.

(c) If this is a requirements contract (*i.e.,* includes the Requirements clause at subsection 52.216-21 of the Federal Acquisition Regulation (FAR)), the Government is not required to order a part of any one requirement from the Contractor if that requirement exceeds the maximum-order limitations in paragraph (b) of this section.

(d) Notwithstanding paragraphs (b) and (c) of this section, the Contractor shall honor any order exceeding the maximum order limitations in paragraph (b), unless that order (or orders) is returned to the ordering office within _____ days after issuance, with written notice stating the Contractor's intent not to ship the item (or items) called for and the reasons. Upon receiving this notice, the Government may acquire the supplies or services from another source.

FAR 52.216-22 Indefinite Quantity Alternate II (Nov 2025)

(a) This is an indefinite-quantity contract for the supplies or services specified, and effective for the period stated, in the Schedule. The quantities of supplies and services specified in the Schedule are estimates only and are not purchased by this contract.

(b) Delivery or performance shall be made only as authorized by orders issued in accordance with the Ordering clause. The Contractor shall furnish to the Government, when and if ordered, the supplies or services specified in the Schedule up to and including the quantity designated in the Schedule as the "maximum." The Government shall order at least the quantity of supplies or services designated in the Schedule as the "minimum."

(c) Except for any limitations on quantities in the Order Limitations clause or in the Schedule, there is no limit on the number of orders that may be issued. The Government may issue orders requiring delivery to multiple destinations or performance at multiple locations.

(d) Any order issued during the effective period of this contract and not completed within that period shall be completed by the Contractor within the time specified in the order. The contract shall govern the Contractor's and Government's rights and obligations with respect to that order to the same extent as if the order were completed during the contract's effective period; provided, that the Contractor shall not be required to make any deliveries under this contract after _____ [insert date after award].

(e) The Government may cancel this contract in whole or in part by providing written notice. The cancellation will take effect 30 calendar days after the contractor receives the notice of cancellation. No further orders may be issued against the contract, but orders already awarded will be completed unless a termination action is taken against the contractor.

(f) The Contractor may request to cancel this contract by submitting a written cancellation request to the contracting officer. The cancellation will take effect 90 calendar days after the Government receives the cancellation request, unless the contracting officer informs the contractor, before cancellation is effective, that cancellation is not approved. A contractor who requests cancellation is not eligible for the minimum guarantee. If cancelled, no further orders may be issued against the contract, but orders already awarded will be completed unless a termination action is taken against the order.

FAR 52.216-27 Single or Multiple Awards (Oct 1995)

The Government may elect to award a single delivery order contract or task order contract or to award multiple delivery order contracts or task order contracts for the same or similar supplies or services to two or more sources under this solicitation.

FAR 52.216-32 Task-Order and Delivery-Order Ombudsman (Sept 2019)

(a) In accordance with 41 U.S.C. 4106(g), the Agency has designated the following task-order and delivery-order Ombudsman for this contract. The Ombudsman must review complaints from the Contractor concerning all task-order and delivery-order actions for this contract and ensure the Contractor is afforded a fair opportunity for consideration in the award of orders, consistent with the procedures in the contract. [https://www.hhs.gov/grants-contracts/grants-business-contacts/competition-advocates/index.html]

(b) Consulting an ombudsman does not alter or postpone the timeline for any other process (e.g., protests).

(c) Before consulting with the Ombudsman, the Contractor is encouraged to first address complaints with the Contracting Officer for resolution. When requested by the Contractor, the Ombudsman may keep the identity of the concerned party or entity confidential, unless prohibited by law or agency procedure.

FAR 52.217-8 Option to Extend Services (Nov 1999)

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

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

(a)The Government may extend the term of this contract by written notice to the Contractor

within 30 days; provided that the Government gives the Contractor a preliminary written notice of its intent to extend at least 60 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 126 months.

FAR 52.237-3 Continuity of Services (Jan 1991)

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

(1) Furnish phase-in training; and

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

(b)The Contractor shall, upon the Contracting Officer's written notice,

(1) furnish phase-in, phase-out services for up to 90 days after this contract expires and

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

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

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

PART III – LIST OF DOCUMENTS, EXHIBITS AND OTHER ATTACHMENTS

SECTION J – LIST OF ATTACHMENTS

All attachments are located at the end of Section M and are incorporated into this RFP:

J.1. SOLICITATION ATTACHMENTS:

The following Attachments are provided with this Solicitation:

1. Product Handling Guidance Donee Nations
2. ASPR Security Requirements
3. Vendor Production Facilities.xlsx
4. Agent Request Form
5. BARDA Dose Tracker Template.xlsx
6. HHS Protection of Human Subjects (https://www.hhs.gov/ohrp/register-irbs-and-obtain-fwas/forms/index.html)
7. Breakdown of Proposed Costs.xlsx
8. Summary of Related Activities
9. ACH Vendor/ Miscellaneous Payment Enrollment Form
10. SF-LLL, Disclosure of Lobbying Activities
11. SF-LLL, Disclosure of Lobbying Activities Instructions
12. HHS Subcontracting Plan Template
13. Risk Mitigation Plan/Matrix Template
14. Past Performance Questionnaire
15. RFP Contractor Q&A
16. Bill of Materials (BOM) Template
17. Manufacturing Plan
18. Business and Supply Continuity Plans (BCP SCP)
19. Surge Manufacturing and Supply Chain Readiness Assessment

PART IV – REPRESENTATIONS AND INSTRUCTIONS

SECTION K – REPRESENTATIONS, CERTIFICATIONS AND OTHER STATEMENTS OF OFFERORS

IF YOU INTEND TO SUBMIT A PROPOSAL, YOU MUST:

1. Go to the System for Award Management (SAM) and complete the online Representations and Certifications. System updates may lag policy updates. The System for Award Management (SAM) may continue to require entities to complete representations based on provisions that are not included in agency solicitations. Contracting officers will not consider these representations when making award decisions or enforcing requirements. Entities are not required to, nor are they able to, update their entity registration to remove these representations in SAM.

The SAM website can be accessed at: https://www.sam.gov.

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

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

K.1. PRODUCT LICENSURE

1. The influenza antigens, vaccines, and adjuvants purchased, stored, and shipped under this contract must be manufactured under a current establishment and product licensure issued by the FDA. Offeror must indicate number below:
   i. Name of Vaccine (as applicable):
   ii. License Number(s) (as applicable):

2. The Contractor agrees to comply with CGMP guidelines (21 CFR Parts 210-211, 600) for manufacturing, processing, and packing of drugs, chemicals, biologicals, and reagents.

K.2. FAR 52.203-2 CERTIFICATE OF INDEPENDENT PRICE DETERMINATION (APR 1985)

K.3. INCORPORATION BY REFERENCE OF FAR 52.203-11 CERTIFICATION AND DISCLOSURE REGARDING PAYMENTS TO INFLUENCE CERTAIN FEDERAL TRANSACTIONS (SEPT 2024)

K.4. FAR 52.209-5 CERTIFICATION REGARDING RESPONSIBILITY MATTERS (Nov 2025)

(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; and

(D) Have □, have not □, within a three-year period preceding this offer, been notified of any delinquent Federal taxes in an amount that exceeds the threshold at 9.104-5(a)(2) for which the liability remains unsatisfied. Federal taxes are considered delinquent if both of the following criteria apply:

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

(*2*) *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.

(ii) The Offeror has □ has not □, within a 3-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).

(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 Government will consider the certification in connection with a determination of the Offeror's responsibility. Failure of the Offeror to furnish a certification or provide such additional information as requested by the Contracting Officer may render the Offeror non-responsible.

(d) This provision does not require establishment of a system of records in order to render, in good faith, the certification required by paragraph (a). 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 the Government later determines that the Offeror knowingly rendered an erroneous certification, in addition to other remedies available to the Government, the Contracting Officer may terminate the contract resulting from this solicitation for default.

K.5. FAR 52.209-7 INFORMATION REGARDING RESPONSIBILITY MATTERS (Nov 2025)

(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 proceedings 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).

K.6. FAR 52.209-11 Representation by Corporations Regarding Delinquent Tax Liability or a Felony Conviction under any Federal Law (Nov 2025)

(a) The Government will not enter into a contract with any corporation that—

(1) Has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability, where the awarding agency is aware of the unpaid tax liability, unless an agency has considered suspension or debarment of the corporation and made a determination that suspension or debarment is not necessary to protect the interests of the Government; or

(2) Was convicted of a felony criminal violation under any Federal law within the preceding 24 months, where the awarding agency is aware of the conviction, unless an agency has considered suspension or debarment of the corporation and made a determination that this action is not necessary to protect the interests of the Government.

(b) The Offeror represents that–

(1) It is □ is not □ a corporation that has any unpaid Federal tax liability that has been assessed, for which all judicial and administrative remedies have been exhausted or have lapsed, and that is not being paid in a timely manner pursuant to an agreement with the authority responsible for collecting the tax liability; and

(2) It is □ is not □ a corporation that was convicted of a felony criminal violation under a Federal law within the preceding 24 months.
(End of provision)

K.7. FAR 52.209-13 Violation of Arms Control Treaties or Agreements-Certification (Nov 2025)

(a) This provision does not apply to acquisitions at or below the simplified acquisition threshold or to acquisitions of commercial products and commercial services as defined in Federal Acquisition Regulation 2.101.

(b) *Certification*. [*Offeror shall check either (1) or (2).*]

__ (1) The Offeror certifies that–

(i) It does not engage and has not engaged in any activity that contributed to or was a significant factor in the President's or Secretary of State's determination that a foreign country is in violation of its obligations undertaken in any arms control, nonproliferation, or disarmament agreement to which the United States is a party, or is not adhering to its arms control, nonproliferation, or disarmament commitments in which the United States is a participating state. The determinations are described in the most recent unclassified annual report provided to Congress pursuant to section 403 of the Arms Control and Disarmament Act (22 U.S.C. 2593a). The report is available at https://www.state.gov/bureaus-offices/under-secretary-for-arms-control-and-international-security-affairs/bureau-of-arms-control-verification-and-compliance/; and

(ii) No entity owned or controlled by the Offeror has engaged in any activity that

contributed to or was a significant factor in the President's or Secretary of State's determination that a foreign country is in violation of its obligations undertaken in any arms control, nonproliferation, or disarmament agreement to which the United States is a party, or is not adhering to its arms control, nonproliferation, or disarmament commitments in which the United States is a participating state. The determinations are described in the most recent unclassified annual report provided to Congress pursuant to section 403 of the Arms Control and Disarmament Act (22 U.S.C. 2593a). The report is available at https://www.state.gov/bureaus-offices/under-secretary-for-arms-control-and-international-security-affairs/bureau-of-arms-control-verification-and-compliance/; or

__ (2) The Offeror is providing separate information with its offer in accordance with paragraph (d)(2) of this provision.

(c) Procedures for reviewing the annual unclassified report (see paragraph (b)(1) of this provision). For clarity, references to the report in this section refer to the entirety of the annual unclassified report, including any separate reports that are incorporated by reference into the annual unclassified report.

(1) Check the table of contents of the annual unclassified report and the country section headings of the reports incorporated by reference to identify the foreign countries listed there. Determine whether the Offeror or any person owned or controlled by the Offeror may have engaged in any activity related to one or more of such foreign countries.

(2) If such activity might have occurred, review all findings in the report associated with those foreign countries to determine whether or not each such foreign country was determined to be in violation of its obligations undertaken in an arms control, nonproliferation, or disarmament agreement to which the United States is a party, or to be not adhering to its arms control, nonproliferation, or disarmament commitments in which the United States is a participating state. For clarity, in the annual report an explicit certification of non-compliance is equivalent to a determination of violation. However, the following statements in the annual report are not equivalent to a determination of violation:

(i) An inability to certify compliance.
(ii) An inability to conclude compliance.
(iii) A statement about compliance concerns.

(3) If so, determine whether the Offeror or any person owned or controlled by the Offeror has engaged in any activity that contributed to or is a significant factor in the determination in the report that one or more of these foreign countries is in violation of its obligations undertaken in an arms control, nonproliferation, or disarmament agreement to which the United States is a party, or is not adhering to its arms control, nonproliferation, or disarmament commitments in which the United States is a participating state. Review the narrative for any such findings reflecting a determination of violation or non-adherence related to those foreign countries in the report, including the finding itself, and to the extent necessary, the conduct giving rise to the compliance or adherence concerns, the analysis of compliance or adherence concerns, and efforts to resolve compliance or adherence concerns.

(4) The Offeror may submit any questions with regard to this report by email to NDAA1290Cert@state.gov. To the extent feasible, the Department of State will respond to such email inquiries within 3 business days.

(d) Do not submit an offer unless—

(1) A certification is provided in paragraph (b)(1) of this provision and submitted with the offer; or

(2) In accordance with paragraph (b)(2) of this provision, the Offeror provides with its offer information that the President of the United States has

(i) Waived application under 22 U.S.C. 2593e(d) or (e); or

(ii) Determined under 22 U.S.C. 2593e(g)(2) that the entity has ceased all activities for which measures were imposed under 22 U.S.C. 2593e(b).

(e) *Remedies*. The certification in paragraph (b)(1) of this provision is a material representation of fact

upon which reliance was placed when making award. If the Government later determines that the Offeror knowingly submitted a false certification, in addition to other remedies available to the Government, such as suspension or debarment, the Contracting Officer may terminate any contract resulting from the false certification.

K.8. FAR 52.215-6 PLACE OF PERFORMANCE (Nov 2025)

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

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

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

K.9. FAR 52.219-1 SMALL BUSINESS PROGRAM REPRESENTATIONS (Nov 2025)

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

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

HUBZone small business concern means a small business concern that meets the requirements described in 13 CFR 126.200, is certified by the Small Business Administration (SBA) and designated by SBA as a HUBZone small business concern in the Small Business Search (SBS) (13 CFR 126.103).

Service-disabled veteran-owned small business (SDVOSB) concern eligible under the SDVOSB Program means an SDVOSB concern that is designated in the System for Award Management (SAM) as certified by the Small Business Administration (SBA) in accordance with 13 CFR 128.300.

Small business concern—

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

121 and the size standard in paragraph (b) of this provision.

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

Small disadvantaged business concern means a small business concern that-

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

(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 paragraph (1) of this definition.

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

(b) (1) The North American Industry Classification System (NAICS) code for this acquisition is 541714 Research and Development in Biotechnology (except Nanobiotechnology).

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

(3) The small business size standard for a concern that submits an offer, other than on a construction or service acquisition, but proposes to furnish an end item that it did not itself manufacture, process, or produce (*i.e.*, nonmanufacturer), is 500 employees, or 150 employees for information technology value-added resellers under NAICS code 541519, if the acquisition—

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

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

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

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

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

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

(2) [*Complete only if the offeror represented itself as a small business concern in paragraph (c)(1) of this provision.]* The offeror represents that it □ is, □ is not a women-owned small disadvantage business concern.

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

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

(5) *SDVOSB joint venture eligible under the SDVOSB Program*. [*Complete only if the offeror is certified as a SDVOSB concern*]. The offeror represents as part of its offer that it □ is, □ is not a SDVOSB joint venture eligible under the SDVOSB Program that complies with the requirements of 13 CFR 128.402. [*The offeror shall enter the name and unique entity identifier of each party to the joint venture:*__.]

(6) *HUBZone joint venture eligible under the HUBZone Program.* [*Complete only if the offeror is a HUBZone small business concern.*] The offeror represents, as part of its offer, that it □ is, □ is not a HUBZone joint venture that complies with the requirements of 13 CFR 126.616(a) through (c). [*The offeror shall enter the name and unique entity identifier of each party to the joint venture:* __.] Each HUBZone small business concern participating in the HUBZone joint venture must be certified as a HUBZone concern.

(d) *Notice.* Under 15 U.S.C. 645(d), any person who misrepresents a firm's status as a business concern that is small, HUBZone small, small disadvantaged, service-disabled veteran-owned small, economically disadvantaged women-owned small, or women-owned small eligible under the WOSB Program in order to obtain a contract to be awarded under the preference programs established pursuant to section 8, 9, 15, 31, and 36 of the Small Business Act or any other provision of Federal law that specifically references section 8(d) for a definition of program eligibility, will be—

(1) Punished by imposition of fine, imprisonment, or both;

(2) Subject to administrative remedies, including suspension and debarment; and

(3) Ineligible for participation in programs conducted under the authority of the Act.

SECTION L – INSTRUCTIONS, CONDITIONS AND NOTICES TO OFFERORS OR RESPONDENTS

SOLICITATION CLAUSES INCORPORATED BY REFERENCE

The full text of a clause may be accessed electronically at: https://www.acquisition.gov/far-overhaul/far-part-deviation-guide. HHSAR clauses at https://www.hhs.gov/grants-contracts/contracts/contract-policies-regulations/hhsar/index.html

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

FAR 52.204-91, Contractor Identification (Nov 2025)
FAR 52.215-16, Facilities Capital Cost of Money (Jun 2003)
FAR 52.215-22, Limitations on Pass-Through Charges – Identification of Subcontract Effort (Nov 2025)
FAR 52.232-15, Progress Payments Not Included (Apr 1984)
HHSAR 352.235-70 Notice to Offerors (Mar 2026)
HHSAR 352.235-74 Requirement for Compliance with the Public Health Service Policy on Humane Care and Use of Laboratory Animals

SOLICITATION CLAUSES INCORPORATED BY FULL TEXT

FAR 52.215-1 Instructions to offerors – Competitive Acquisition (NOV 2025) Alternates I and II (NOV 2025)

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

In writing, *writing*, or *written* means any worded or numbered expression that can be read, reproduced, and later communicated, and includes electronically transmitted and stored information.

Proposal modification is a change made to a proposal before the request for proposal closing date and time, or made in response to an amendment, or made to correct a mistake at any time before award.

Proposal revision is a change to material elements of a proposal made after the request for proposal closing date, at the request of or as allowed by a Contracting Officer, as the result of negotiations.

Time, if stated as a number of days, is calculated using calendar days, unless otherwise specified, and will include Saturdays, Sundays, and legal holidays. However, if the last day falls on a Saturday, Sunday, or legal holiday, then the period shall include the next working day.

(b) *Amendments to requests for proposals*. If this request for proposal (RFP) is amended, all terms and conditions that are not amended remain unchanged. Offerors shall acknowledge receipt of any amendment to this RFP by the date and time specified in the amendment(s).

(c) Submission, modification, revision, and withdrawal of proposals (1) (i) Proposals and modifications to proposals shall be—(A) Submitted using the method and the format specified in the RFP;

(B) Addressed to the office specified in the RFP; and

(C) Showing the time and date specified for receipt, the RFP number, and the

name and address of the offeror.

(ii) Offerors using commercial carriers should ensure that the proposal is marked on the outermost wrapper with the information in paragraphs (c)(1)(i)(B) and (C) of this provision.

(2) The first page of the proposal must show—

(i) The RFP number;

(ii) The name, address, and telephone number of the offeror (and electronic address if available);

(iii) A statement specifying the extent of agreement with all terms, conditions, and provisions included in the RFP and agreement to furnish any or all items upon which prices are offered at the price set opposite each item;

(iv) Names, titles, and telephone number (and electronic addresses if available) of persons authorized to negotiate on the offeror's behalf with the Government in connection with this RFP; and

(v) Name, title, and signature of person authorized to sign the proposal. Proposals signed by an agent shall be accompanied by evidence of that agent's authority, unless that evidence has been previously furnished to the issuing office.

(3) (i) Offerors are responsible for submitting proposals, and any modifications or revisions, so as to reach the Government office designated in the RFP by the time specified in the RFP. If no time is specified in the RFP, the time for receipt is 4:30 p.m., local time, for the designated Government office on the date that proposal or revision is due.

(ii) (A) Any proposal, modification, or revision received at the Government office designated in the RFP after the exact time specified for receipt of offers is "late" and will not be considered unless it is received before award is made, the Contracting Officer determines that accepting the late offer would not unduly delay the acquisition; and-

(1) If it was transmitted through an electronic commerce method authorized by the RFP, it was received at the initial point of entry to the Government infrastructure not later than 5:00 p.m. one working day prior to the date specified for receipt of proposals; or

(2) There is acceptable evidence to establish that it was received at the Government installation designated for receipt of offers and was under the Government's control prior to the time set for receipt of offers; or

(3) It is the only proposal received.

(B) However, a late modification of an otherwise successful proposal that makes its terms more favorable to the Government, will be considered at any time it is received and may be accepted.

(iii) Acceptable evidence to establish the time of receipt at the Government installation includes the time/date stamp of that installation on the proposal wrapper, other documentary evidence of receipt maintained by the installation, or oral testimony or statements of Government personnel.

(iv) If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the RFP, and urgent Government requirements preclude amendment of the RFP, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the RFP on the first work day on which normal Government processes resume.

(v) Proposals may be withdrawn by written notice received at any time before award. Oral proposals in response to oral RFPs may be withdrawn orally. Proposals may be withdrawn in person by an offeror or an authorized representative, if the identity of the person requesting withdrawal is established and the person signs a receipt for the proposal before award.

(4) Unless otherwise specified in the RFP, the offeror may propose to provide any item or combination of items.

(5) Offerors shall submit proposals in response to this RFP in English, unless otherwise permitted by the RFP, and in U.S. dollars, unless the provision at FAR 52.225-17, Evaluation of Foreign Currency Offers, is included in the RFP.

(6) Offerors may submit modifications to their proposals at any time before the RFP closing date and time, and may submit modifications in response to an amendment, or to correct a mistake at any time before award.

(7) Offerors may submit revised proposals only if requested or allowed by the Contracting Officer.

(8) Proposals may be withdrawn at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

(9) Offerors may submit proposals that depart from stated requirements. Such proposals shall clearly identify why the acceptance of the proposal would be advantageous to the Government. Any deviations from the terms and conditions of the RFP, as well as the comparative advantage to the Government, shall be clearly identified and explicitly defined. The Government reserves the right to amend the RFP to allow all offerors an opportunity to submit revised proposals based on the revised requirements.

(d) *Offer expiration date*. Proposals in response to this RFP will be valid for the number of days specified on the RFP cover sheet (unless a different period is proposed by the offeror).

(e) *Restriction on disclosure and use of data*. Offerors that include in their proposals data that they do not want disclosed to the public for any purpose, or used by the Government except for evaluation purposes, shall-

(1) Mark the title page with the following legend:

Mark the title page with the following legend: This proposal includes data that shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed—in whole or in part—for any purpose other than to evaluate this proposal. If, however, a contract is awarded to this offeror as a result of, or in connection with, the submission of this data, the Government shall have the right to duplicate, use, or disclose the data to the extent provided in the resulting contract. This restriction does not limit the Government's right to use information contained in this data if it is obtained from another source without restriction. The data subject to this restriction are contained in sheets [*insert numbers or other identification of sheets*]; and

(2) Mark each sheet of data it wishes to restrict with the following legend:

Use or disclosure of data contained on this sheet is subject to the restriction on the title page of this proposal.

(f) Contract award. (1) The Government intends to award a contract or contracts resulting from this RFP to the responsible offeror(s) whose proposal(s) represents the best value after evaluation in accordance with the factors and subfactors in the RFP.

(2) The Government may reject any or all proposals if such action is in the Government’s interest.

(3) The Government may waive informalities and minor irregularities in proposals received.

(4) The Government intends to evaluate proposals and award a contract after conducting negotiations with offerors whose proposals have been determined to be within the competitive range. If the Contracting Officer determines that the number of proposals that would otherwise be in the competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range to the greatest number that will permit an efficient competition among the most highly rated proposals. Therefore, the offeror's initial proposal should contain the offeror's best terms from a price and technical standpoint.

(5) The Government reserves the right to make an award on any item for a quantity less than the quantity offered, at the unit cost or prices offered, unless the offeror specifies otherwise in the proposal.

(6) The Government reserves the right to make multiple awards if, after considering the additional administrative costs, it is in the Government’s best interest to do so.

(7) The Government may determine that a proposal is unacceptable if the prices proposed are materially unbalanced between line items or subline items. Unbalanced pricing exists when, despite an acceptable total evaluated price, the price of one or more line items is significantly overstated or understated as indicated by the application of cost or price analysis techniques. A proposal may be rejected if the Contracting Officer determines that the lack of balance poses an unacceptable risk to the Government.

(8) If a cost realism analysis is performed, cost realism may be considered by the source selection authority in evaluating performance or schedule risk.

(9) A written award or acceptance of proposal mailed or otherwise furnished to the successful offeror within the time specified in the proposal shall result in a binding contract without further action by either party.

(10) If a post-award debriefing is given to requesting offerors, the Government shall disclose the following information, if applicable:

(i) The agency's evaluation of the significant weaknesses or deficiencies in the debriefed offeror's offer.

(ii) The overall evaluated cost or price and technical rating of the successful and the debriefed offeror and past performance information on the debriefed offeror.

(iii) The overall ranking of all offerors, when any ranking was developed by the agency during source selection.

(iv) A summary of the rationale for award.

(v) For acquisitions of commercial products, the make and model of the product to be delivered by the successful offeror.

(vi) Reasonable responses to relevant questions posed by the debriefed offeror as to whether source-selection procedures set forth in the RFP, applicable regulations, and other applicable authorities were followed by the agency.

(vii) For DOW contracts in excess of $10 million but not in excess of $100 million with a small business or nontraditional defense contractor (10 U.S.C. 3014), an option for the

contractor to request disclosure of the agency's written source selection decision document, redacted to protect the confidential and proprietary information of other offerors for the contract award.

(viii) For award of a DOW contract in excess of $100 million, disclosure of the agency's written source selection decision document, redacted to protect the confidential and proprietary information of other offerors for the contract award.

FAR 352.215-70 Late Proposals and Revisions (DEC 2015) Deviation

Notwithstanding the procedures contained in FAR 52.215-1(c)(3) of the provision of this solicitation entitled Instructions to Offerors-Competitive Acquisition, the Government may consider a proposal received after the date specified for receipt if it appears to offer significant cost or technical advantage to the Government and it was received before proposals were distributed for evaluation, or within 5 calendar days after the exact time specified for receipt, whichever is earlier.

INSTRUCTION TO OFFERORS

L.1. Instructions for Submission

Read all instructions in this RFP before submitting proposals. All proposals shall be submitted electronically to the BDR Portal no later than 5:00 p.m. EST on 30 October 2026,

L.1.1 Electronic Portal Submission Instructions

All submissions must be submitted to the BDR Portal via the process described below.

Respondents will be required to register for a BDR Portal account before a proposal can be submitted. A BDR account can be created by visiting the BDR Portal (https://bdr.hhs.gov/) and following the applicable prompts.

The account creation process is simple but may take several days for authentication and access. Account creation will require the Respondent to enter a set of basic information (i.e., first and last name, email address, and phone number). Upon confirmation of a BDR Portal account, the Respondent will login using the prescribed two-factor authentication method. Once login is complete, the Respondent will be prompted to enter information about Respondent's organization and to input the submission with other project-specific information.

If you experience any issues, please reach out to BDR_Admin_Inbox@hhs.gov. Failure to propose your submission on time for any reason (e.g., due to late registration in BDR Portal) will result in the submission not being considered. Respondents will be provided an automated confirmation of successful submission.

Modifications, amendments, or withdrawals of proposals and other communications should also be made in the BDR Portal. Proposals will NOT be accepted via hard copy or email. Any proposal received after the exact time specified for receipt shall be treated as a late submission in accordance with Federal Acquisition Regulation (FAR) 52.215-1, "Instructions to Offerors – Alternates I and II (Nov 2025)."

No hard copy of this solicitation will be issued. Offerors will be sent any amendments to this solicitation electronically.

Proposals shall be prepared and submitted in the format and content in accordance with the instructions herein. Offerors must respond to all requirements of this solicitation with no additions or deletions. Non-conformance with the solicitation requirements shall render the offer non-responsive and the Offeror may be ineligible for award.

Proposals must be submitted in English and prices/costs proposed must be in United States currency.

The proposal cover letter must be signed by an official authorized to bind the organization and must stipulate that it is predicated upon all the terms and conditions of this RFP. The proposal shall be submitted in the number of copies, to the addressees, and marked as indicated under L.2

The proposal must be prepared based upon the Sections provided below. Each section shall be separate and complete in itself so that evaluation of one may be accomplished independently of, and concurrently with, evaluation of the other. Note, the technical proposal should not include pricing data.

The Offeror shall indicate if it has the necessary financial capacity, working capital, and other resources to perform the contract without assistance from any outside source. If not, indicate the amount required and the anticipated source.

L.2. PROPOSAL FORMAT

In order to maximize efficiency and minimize the time for proposal evaluation, it is required that all Offerors submit their proposals in accordance with the format and content specified. Offerors must respond to all requirements of the solicitation.

The electronic proposal shall be prepared so that if an evaluator prints the proposal it meets the following format requirements:

- Offerors must submit files in Microsoft Word, Microsoft Excel, or Adobe Acrobat (PDF – portable and searchable document format) formats as indicated below. ZIP files and other application formats are not acceptable. All files must be print-capable and without a password required. Filenames shall contain the appropriate filename extension (.docx, .doc, .xlsx, or .pdf). Filenames should not contain special characters. iOS users must ensure the entire filename and path are free of spaces and special characters. The file should not exceed 15 Megabytes of storage space. Movie and sound file attachments, URL Links, or other additional files, will not be accepted.

- 8.5 X 11 inch paper
- Single-spaced typed lines, including figures, glossaries
- 1 inch margins
- 12-point (ADA-compliant font) in the text
- 10-point (ADA-compliant font) for all tables
- No hyperlinks
- No .pdf format for the cost proposal

- Handwritten proposals will not be accepted.
- Offeror must routinely check sam.gov for any amendments to RFP. Offerors expressing an interest in this requirement will not be notified of changes and/or amendments to the solicitation.
- If you have any questions, ask the Contracting Officer or Contract Specialist specified in the RFP.

- Offerors are advised to read and carefully follow the instructions listed in this RFP. Failure to adhere to these instructions and to the specified limitations for size of paper and electronic proposals may result in the rejection of your proposal. Proposals will not be returned to the offeror.

- Proposal Organization and Page Limitations. The Offeror shall prepare the proposal as set forth below. The titles and contents of the sections, as well as the page limitations and number of required copies shall be as specified below. Each Section shall be submitted as a separate document. Under no circumstances shall any of the sections be merged together. Page limitations shall be treated as maximums. If exceeded, the excess pages will be removed and will not be read or considered in the evaluation of the proposal.

SECTION	SECTION TITLE	COPIES	PAGE LIMIT
N/A	Cover Letter	1 – electronic	Up to 5 pages
	Cover Letter Attachment: FAR and HHSAR Provisions contained in Section K	1 – electronic	Unlimited
I	Factor A: Capability	[redacted]	[redacted]
	Subfactor 1: Technical Methodology and Approach	1 – electronic	Up to 75 pages per manufacturing process
	Subfactor 2: Business/Organizational Experience	1 – electronic	Up to 15 pages per manufacturing process
	Subfactor 3: Facilities	1 – electronic	Up to 15 pages per manufacturing process
	Subfactor 4: Personnel	1 – electronic	Up to 15 pages per manufacturing process
II	Factor B: Past Performance	1 – electronic	3 pages per reference
III	Factor C: Cost/Price	1 – electronic	Unlimited

- Pages Counted - Each page shall be counted except for the following:
  - Table(s) of Contents
  - Glossaries
  - List of figures
  - Blank pages
  - FAR and HHSAR Provisions
  - Key Personnel Resumes or Curricula Vitae (not to exceed two pages in length)
  - Letters of Intent
  - Statement regarding Potential Organizational Conflicts of Interest
  - Acronym List / Definitions
  - Cost Documentation

L.3. PROPOSAL CONTENT

General Instructions: Offerors shall submit a complete proposal that is clear, concise, and provides a straightforward delineation of capabilities to perform the work specified in the Statement of Work (SOW). **The proposal shall not merely restate the SOW requirements but must describe the Offeror's specific approach to meeting them.** The Government will not assume an Offeror possesses any capability not explicitly described in its proposal. Failure to address any requirement may result in the proposal being evaluated less favorably or determined unacceptable. The level of detail shall be sufficient to permit a comprehensive evaluation in accordance with Section M.

Proposals shall be organized into the following distinct sections: Cover Letter, Factor A, Factor B, and Factor C and include the following:

L.3.1 Cover Letter

- The proposal shall include a cover letter signed by an individual authorized to bind the Offeror. The cover letter shall identify all enclosures being transmitted as part of the proposal. The letter shall reference the solicitation number 75A50126R00001.

- The following information shall be included in the cover letter:
  - Title of the solicitation;
  - Name and address of Offeror;
  - Address(es) of the location(s) at which the Offeror intends to perform the proposed effort,
  - Names and telephone numbers of persons authorized to conduct negotiations as well as the name of the official authorized to bind the Offeror’s organization shall be clearly identified;
  - Name, address, and telephone number of Contract Administration Office (the cognizant Government Audit Agency), (if available);
  - Offeror’s TIN and Unique Identity ID (UEI)
  - Confirmation that Offeror holds a U.S. influenza vaccine license or has developed an influenza vaccine, as evidenced by submission of a Biologics License Application (BLA) for FDA approval for seasonal or pandemic influenza.
  - Total Estimated dollar amount for Base period and Option Period 1;
  - Date of submission;
  - Proposal validity statement confirming that proposal shall be valid for 180 days from the date of submission; and
  - Authorized individual’s signature.

- Cover Letter Attachment: Completed Section K (Representations and Certifications). The Offeror shall attach the completed FAR and HHSAR Provisions identified in Section K to the cover letter. ALL provisions shall be signed and dated by an official authorized to contractually obligate the Offeror.

L.3.2 FACTOR A: Capability

The Offeror shall provide a complete and detailed proposal that demonstrates its capability to perform the requirements of the Statement of Work (SOW). The proposal shall be organized in accordance with the subfactors below and shall clearly address each element identified.

L.3.2.1 Subfactor 1: Technical Methodology and Approach

The proposal shall demonstrate the Offeror's capability to perform the ACTIVITIES identified in the Statement of Work (SOW) for which pricing is proposed, consistent with evaluation under Section M.5.

(a) As part of the Technical Approach, offerors must provide:

- Response to Mandatory Criteria (ensure that the Mandatory criteria are addressed in a clearly marked separate section of the technical proposal).
- A copy of the Offeror's license approval letter from the U.S. FDA, including all post-licensure commitments and due dates.
- If a BLA has been submitted to the U.S. FDA, a copy of the letter from the U.S. FDA stating that the BLA has been filed, including the date of receipt and Action Due date(s).
- A Contractor's Work Plan (CWP) including:
  - For each ACTIVITY, a detailed narrative for each major task and a corresponding Gantt chart. The Gantt chart must be time-phased, show logical dependencies between tasks, and identify critical path activities.
  - Timeline from task order execution through completion
  - Description of capability to support commercial-scale antigen and adjuvant manufacturing

(b) For each ACTIVITY:

- Detailed technical approach that includes descriptions of all work required to complete the task
- A Risk Management plan that addresses risk identification, the likelihood and impact of occurrence, and proposed mitigation strategies and contingency plans.

- Supporting data demonstrating capability (e.g., number of lots produced at commercial scale, master or working seed bank optimization results, lot release data, production yield, historical timelines for completion)

(c) For Tariff and supply chain considerations:
- Countries of origin
- Tariff exposure
- Cost tracking process and controls
- Risk mitigation strategies
- Supply chain narrative addressing the following: countries of origin for major components, raw materials, and critical inputs; identification of any known current tariff exposure based on existing trade actions; the Offeror's process and internal controls for tracking and segregating tariff-related costs and monitoring for tariff exclusions or changes; and the Offeror's risk mitigation strategy to minimize tariff impacts on schedule, cost, and supply chain resilience.

(d) Small Business Plan (if applicable)
- As part of this evaluation factor, Offerors classified as 'Other Than Small' for NAICS 541714 shall address the items below:
    - Specifically list and identify proposed small business (SB) concerns. Provide name of concern, address, point of contact, and phone number. Offeror must document that the concern proposed is identified as a SB at www.sam.gov or demonstrate that the concern meets the size standard related to the NAICS Code related to the work being performed by the subcontractor.

    - The extent of an Offeror's commitment to use SB concerns. Commitment should be as specific as possible, i.e., indicate if subcontract arrangements are already in place, letters of commitment, etc. The Offeror must show the extent of firm commitments to use SB concerns, how the concern will be actively involved in tasks awarded under the resulting IDIQ contract over its entire life

    - Offerors shall document a plan to maximize subcontracting opportunities to small businesses as it relates to meeting subcontracting small business goals. Offerors shall demonstrate steps taken to ensure small businesses are utilized whenever possible.

    - The complexity and variety of the work SBs are to perform. Provide detail on the type of work the SB will be performing.

    - The extent of participation of SB concerns in terms of the value of the total acquisition. Targets expressed as dollars or percentage of total contract value for each SB participating will be incorporated into and become part of any resulting contract. Therefore, the extent of participation of all SB concerns in terms of the value of the total acquisition must be identified.

- Ability to effectively manage and monitor subcontractors to include consideration for cost efficiency and cost effectiveness having numerous subcontractors.

- Offeror shall provide past experience in meeting proposed subcontracting goals along with processes that have been implemented to correct inabilities to meet subcontracting goals will also be evaluated. Past performance in meeting or succeeding SB subcontracting goals shall be demonstrated utilizing copies of Sam.gov (formerly eSRS) reports. Offerors shall include most recent Sam.gov (formerly eSRS) reports covering the last three (3) years. The Sam.gov (formerly eSRS) reports shall include contracts of similar size and scope to this requirement.

L.3.2.2 Subfactor 2: Business/Organizational Experience

(a) The proposal shall demonstrate:
- Product Licensure status (FDA approval or BLA submission) - Assume that the government has no prior knowledge of the Offeror's capabilities or experience and will base its evaluation only on the information presented in the Offeror's proposal.
- Program management approach, including:
  - Oversight of internal and subcontracted efforts,
  - Internal reporting structures.
- Experience in coordinating activities across:
  - Multiple sites
  - International locations
  - Subcontractors
- Organizational conflict of interest (OCI) disclosure and mitigation plan.
  - OCI as defined in FAR 2.101 means that because of other activities or relationships with other persons, a person is unable or potentially unable to render impartial assistance or advice to the Government, or the person's objectivity in performing the contract work is or might be otherwise impaired, or a person has an unfair competitive advantage.
    - Applying the principles of FAR subpart 9.5, the Offeror shall assess whether there is a potential OCI associated with the offer it plans to submit, including any potential subcontracts. The Offeror shall disclose all relevant information concerning any past, present, or planned interest (financial, contractual, organizational, or other) relating to the work to be performed under the proposed ACTIVITY and bearing on whether the Offeror has a potential OCI.
  - The Offeror shall provide a written statement with its offer that, to the best of its knowledge and belief, it has disclosed all relevant information regarding any organizational conflicts of interest as required in paragraph (b) of this provision.
  - The Contractor shall explain the actions it proposes to use to

address the potential OCIs disclosed pursuant to paragraph (b) above.
- The Contracting Officer is the final authority in determining whether an organizational conflict of interest exists and whether the organizational conflict of interest has been adequately addressed. Potential OCIs must be avoided, mitigated or otherwise resolved through appropriate means in order for the Offeror to be eligible for award.

L.3.2.3 Subfactor 3: Facilities

- The proposal shall provide information sufficient for the Government to evaluate:
  - Facility ownership and availability
  - Regulatory compliance history (last 3 years inspection reports) or if no inspections have taken place, a statement to that effect
  - For each ACTIVITY as appropriate, CGMP compliance of:
    - Systems
    - Equipment
    - Manufacturing processes
    - Records: Description of the system for retaining records/samples per GLP and CGMP guidelines
    - Validation status of assays and equipment as appropriate for each ACTIVITY
  - Biohazardous materials:
    - Describe facilities, equipment, and policies for handling biohazardous materials (e.g., Biosafety Level 2+), including receipt, storage, use, and disposal.
    - Current facility usage and demand impacting schedule
  - Security plans:
    - Physical
    - Personnel
    - Information and IT
    - Suitability of facilities for:
    - Storage
    - Formulation
    - Fill-finish
    - Packaging
    - Disposal
  - Information on current pandemic pre-purchasing agreements as they pertain to execution of all ACTIVITIES.

L.3.2.4 Subfactor 4: Personnel

- The proposal shall include:
  - Resumes or curricula vitae detailing education, recent experience, specific accomplishments, and relevant publications for Key Personnel identified in Section G.11. Key personnel qualifications shall be aligned to proposed ACTIVITIES.
  - Provide a clear description and schematic of the Offeror’s project

organization including subcontractors.

- Demonstrated:
  - Individual accomplishments
  - Team leadership on similar efforts
  - Education and technical/scientific qualifications
- Organizational structure and staffing approach
- Availability and commitment documentation for non-employees
- An organizational chart showing the team structure (including subcontractors), roles, responsibilities, and reporting lines.
- 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.

L.3.3 FACTOR B: Past Performance

The Offeror shall submit past performance information sufficient for the Government to evaluate relevance and performance confidence in accordance with Section M.5, Factor B.

The Offeror shall submit the following information as part of its 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.**

1. Provide past performance information of up to five (5) relevant (similar in nature to the solicitation work scope) contracts for the Offeror and up to three (3) for each major subcontractor completed during the past five years preceding due date of final proposals. Contracts listed may include those entered into with the Federal Government, agencies of state and local governments, and commercial customers. Additionally, any previous activities with BARDA may be included in the submitted past performance list even if the work was completed over five (5) years ago

   For each contract or subcontract provide the following in tabular format:

   (a) Name of Contracting Organization
   (b) Contract Number
   (c) Total Obligated Contract Value and Type (e.g., FFP, Cost-Plus)
   (d) Contract Ceiling
   (e) Description of Requirement
   (f) Contracting Officer's name, email and telephone number
   (g) Program Manager's name, email and telephone number
   (h) Statement from Offeror as to why this contract is relevant to this project.

2. In addition to the above requested information, 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.

L.3.4 FACTOR C: Cost/Price

- The Offeror shall propose cost/price in accordance with the ACTIVITY type in Schedule B. The ACTIVITY structure has FFP, FFUP, and Cost contract types. The Offeror shall not propose cost/price for ACTIVITIES identified as Not Separately Priced (NSP) or Unpriced. These ACTIVITIES will be negotiated and awarded as needed (also refer to Sections B.5.3 and B.5.4). For all priced ACTIVITIES (FFP, FFUP, and Cost), the Offeror shall prepare and submit information other than cost or pricing data in accordance with these instructions and FAR 15.403-1. The Government needs this information to properly assess the reasonableness, completeness, and accuracy of the Offeror's proposed Cost/Price. Compliance with these instructions is mandatory and failure to do so could possibly result in the rejection of your proposal. Cost Realism will be performed for all Cost type Activities. Price Realism may be performed at the discretion of the contracting officer for FFP and/or FFUP Activities. Note that unrealistically low or unreasonably high proposed costs or prices, initially or subsequently, may be grounds for eliminating a proposal from competition either on the basis that the Offeror does not understand the requirement or has made an unrealistically low or unreasonably high priced proposal. Offers should be sufficiently detailed to demonstrate their reasonableness and realism. The burden of proof for credibility of proposed costs/prices rests with the Offeror.

- The Offeror must provide data in a Microsoft Excel format. The cost data shall contain a complete and detailed cost breakdown, including all elements of costs and other cost data as considered appropriate to support the proposal. All data and formulas shall be visible/viewable and no fields or data should be hidden.

L.3.5 PROSPECTIVE CONTRACTOR RESPONSIBILITY AND ELIGIBILITY STANDARDS: SUPPLY CHAIN RISK ASSESSMENT

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

Federal Acquisition Regulation (FAR) Subpart 9.1 sets the standards and procedures for determining prospective contractor and subcontractor responsibility.

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

The Government may request additional information or a mitigation plan from the offeror that addresses risks identified in the supply chain risk assessment. Any requests for additional information resulting from the supply chain risk assessment do not constitute negotiations as described in FAR 15.204.

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

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

L.4 COMMUNICATIONS PRIOR TO CONTRACT AWARD

L.4.1 Questions, Responses

Questions concerning this RFP must be submitted via email to the Contracting Officer, Laura Saddison (Laura.Saddison@hhs.gov) and Jill Johnson (Jill.Johnson@hhs.gov). Initial questions are due no later than **August 31, 2026 by 12:00 p.m. EST** using Attachment 15. Supplemental Questions are due no later than **September 24, 2026 by 12:00 p.m. EST** using Attachment 15. Questions that are vague, illegible, or irrelevant to the requirement, or submitted after the specified date and time may not receive a response. The government will respond to questions at its discretion and as time and resources allow. Responses to questions will be in the form of an amendment and issued.

Responses to any questions received will be provided to all potential Offerors. All Program Office personnel have been strictly prohibited from discussing this requirement with any contractor personnel. The Offeror shall not direct any comments, questions or inquiries to any Government personnel except for the points of contact listed above.

Questions and Responses will be provided to all Offerors electronically.

Solicitation Amendments: In accordance with FAR 52.215-1(b), if amendments to the final solicitation are issued, all offerors must acknowledge the amendments by signing the accompanying Standard Form (SF) 30 and returning the signed SF 30 for all amendments issued with the Offeror's proposal submission. Failure to acknowledge all amendments issued by the Government may result in the offeror's proposal being found nonresponsive by the Government and eliminated from competition.

**Offerors are required to complete other forms – please reference Section J of this RFP.

L.4.2 Release of Information

Contract selection and award information will be disclosed to Offerors in accordance with

regulations applicable to negotiated acquisition. Prompt written notice will be given to unsuccessful Offerors as they are eliminated from the competition.

L.4.3 Preparation Costs

This RFP does not commit to the Government to pay for the preparation and submission of a proposal. The Government will not pay pre-contract costs for any work performed prior to contract award.

L.4.4 Potential to Award Without Negotiations

The Government reserves the right to award a contract without negotiations if the CO determines that the initial prices are fair and reasonable and negotiations are not necessary.

L.4.5 Privacy Act – Treatment of Proposal Information

The Privacy Act of 1974 (P.L. 93-579) requires that a Federal agency advise each individual whom it asks to supply information, the authority which authorizes the solicitation, whether disclosure is voluntary or mandatory, the principal purpose or purposes for which the information is intended to be used, the uses outside the agency which may be made of the information, and the effects on the individual, if any, of not providing all or any part of the requested information.

The HHS is requesting the information called for in this RFP pursuant to the authority provided by Sec. 301(a)(7) of the Public Health Service Act, as amended, and P.L. 92-218, as amended.

Providing the information requested is entirely voluntary. The collection of this information is for the purpose of conducting an accurate, fair, and adequate review prior to a discussion as to whether to award a contract. Failure to provide any or all the requested information may result in a less than adequate review.

L.5. Selection of Offerors

L.5.1 Evaluation of Proposals

The acceptability of the technical portion of each contract proposal will be evaluated based on the written technical proposal. The entire technical proposal shall be reviewed by a technical review committee. The committee will evaluate each proposal in strict conformity with the evaluation criteria of this RFP, utilizing confidence ratings and written critiques. The technical evaluation panel may request clarifying information from an Offeror via the Contracting Officer.

All sections of the proposal will be evaluated in accordance with the requirements of Section M.

The evaluation process may involve the use of contractors as Subject Matter Expert (SME) consultants or reviewers. Where appropriate the United States Government (USG) will employ non-disclosure agreements to protect information contained in offeror proposals. An Offeror’s submission of a Proposal under this Request for Proposals (RFP) indicates

concurrence with the aforementioned use of contractors as SMEs.

L.5.2 Clarifications

Offerors may be given the opportunity to clarify certain aspects of their proposal. Clarifications must comply with FAR 15.202(a)(2) and may be conducted at any time after receipt of proposals through contract award irrespective of whether a competitive range has been established.

Clarifications:

- can be used to enhance understanding of a proposal, allow reasonable interpretation of a proposal, or facilitate the Government's evaluation process.
- include, but are not limited to, addressing: ambiguities of the proposal; other concerns such as perceived deficiencies, weaknesses, errors, omissions, or mistakes; the relevance of an offeror's past performance information; and adverse past performance information to which the offeror has not previously had an opportunity to respond.
- do not permit offerors to revise their proposal. However, contracting officers may request additional information or documentation provided the cost/price or other material elements of the proposal are unchanged.

L.5.3 Competitive Negotiations

If the Government intends to conduct negotiations prior to making award, negotiations will comply with FAR 15.204-2 Competitive Negotiations and include the following:

a. Establishment of the competitive range

The competitive range will be comprised of the group of evaluated proposals that the CO determines are best suited for further negotiation. The CO may elect to limit the number of proposals included in the competitive range to the greatest number that will permit efficient competition. The CO will negotiate with each responsible offeror within the competitive range and may further negotiate with the offerors as needed. Written notice will be provided to unsuccessful offerors excluded from the competitive range in accordance with FAR 15.206-1(a).

b. Negotiations

Oral or written negotiations may be conducted with Offerors in the competitive range. All aspects of the proposals are subject to negotiations, including cost, technical approach, past performance, and contractual terms and conditions. The CO may also negotiate other aspects of the offeror's proposal that could, in the opinion of the CO, be altered or explained to enhance materially the proposal's potential for award. The CO is not required to negotiate in every area where the proposal could be improved. The CO may determine to eliminate a proposal from consideration for award upon concluding that the offeror is unlikely to receive an award. When a proposal is eliminated, written notice will be provided to the offeror in accordance with FAR 52.206-1(a).

When negotiations with an Offeror have finished and that Offeror is still in the competitive range, the Offeror will be provided with –

a. An opportunity to submit a written Final Proposal Revision (FPR);
b. A notice requiring the proposal revision in writing and stating that the Government intends to make award without obtaining further revisions;
c. A time certain to submit the FPR.

L.5.4 Number of Awards

HHS reserves the right to make a single award, multiple awards, or no award at all resulting from this RFP.

L.5.5 RFP Amendments

This RFP may be amended or canceled as necessary to meet HHS requirements.

L.5.6 Pre-Award Site Visits

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

L.5.7 Subcontractors

If subcontractors are proposed, please include a commitment letter from the subcontractor detailing:

- Willingness to perform as a subcontractor for specific duties (list duties).
- What priority will the work be given and how it will relate to other work.
- The amount of time and facilities available to this project.
- Information on their cognizant field audit offices.
- How rights to publications and patents are to be handled.
- A complete cost proposal in the same format as the Offeror's cost proposal.

SECTION M – EVALUATION FACTORS FOR AWARD

BARDA will evaluate proposals in accordance with the factors and subfactors detailed in Sections L and M.

M.1. FAR 52.217-5 Evaluation of Options (Nov 2025)

Except when it is determined in accordance with FAR 17.202(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 oblige the Government to exercise the option(s).

M.2. BASIS FOR AWARD

The Government intends to award multiple Indefinite Delivery, Indefinite Quantity (IDIQ) hybrid contracts with firm-fixed-price, firm-fixed-unit-price, cost reimbursable and/or hybrid task orders resulting from this solicitation. The source selection process will *not* be based on a Lowest Price Technically Acceptable (LPTA) or Tradeoff basis. For this effort, the Highest Technically Rated Offerors with a Fair and Reasonable Price (HTRO-FRP) will determine the best value basis for the award of contracts under this solicitation. Award(s) will be made to the Offerors whose proposals conform to the solicitation requirements and are judged to represent the HTRO-FRP best value to the Government.

The Factors are listed in descending order of importance. As there will be no tradeoff between any of the Non-Price Factors and Price, there is no relative weighting between the Non-Price Factors and the Price Factor. This is because the methodology will evaluate pricing of only those Offerors which achieve the highest technical ratings. Factor A is significantly more important than Factor B.

The Government intends to award a contract resulting from this solicitation to four (4) Offerors; however, the Government retains the right to award fewer or more than four (4) awards should it be determined in its best interest. In the event the Government does decide to award more than four (4) contracts resulting from this solicitation, it will award the contracts to a highest technically rated Offeror(s) with a fair and reasonable price. If one (or more) of the Offerors receiving a verified highest technical ratings is found to not have a fair and reasonable price, it will be eliminated from the competition.

Award will be made based on the best overall (i.e., best value) proposals that are determined to be the most beneficial to the Government, with appropriate consideration given to the following evaluation factors: Factor A – Capabilities: Subfactor 1—Technical Methodology and Approach, Subfactor 2—Business/Organizational Experience, Subfactor 3—Facilities, Subfactor 4 – Personnel, Factor B - Past Performance and Factor C - Price. Factor A is significantly more important than Factor B.

To receive consideration for award, an overall rating of no less than "High Confidence" must be achieved for Factor A and the Offeror's Price must be determined Fair and Reasonable. This methodology considers the non-price factors, when combined, to be significantly more important than price. All Offerors are advised that the Government may set

multiple competitive ranges, however, the competitive range(s) would be drawn only for the Factor A - Capabilities and/or the Price Volume and will not be conducted during or directly after Factor B – Past Performance. Offerors are hereby notified that if the Contracting Officer determines that the number of proposals that would otherwise be included in any competitive range exceeds the number at which an efficient competition can be conducted, the Contracting Officer may limit the number of proposals in the competitive range(s) to the greatest number that will permit an efficient competition among the most highly rated proposals.

M.3. Mandatory Eligibility Criteria

To be eligible for award, the Offeror must produce vaccines against influenza and influenza strains with pandemic potential. The Offeror must demonstrate successful experience in the manufacturing of influenza vaccine by:

1. Holding a U.S. influenza vaccine license; or
2. Have developed an influenza vaccine as evidenced by:
    a. Submission of a BLA for seasonal or pandemic influenza vaccine

Note: Failure to adequately document compliance of the above mandatory eligibility criteria will result in the proposal being deemed technically unacceptable and ineligible for award. The proposal will be considered to be non-responsive and the Offeror's proposal will not be further evaluated. No further discussions will be held.

M.4. Evaluation Ratings

Proposals that receive an acceptable rating for the mandatory eligibility criteria will be evaluated according to the confidence ratings as follows:

> Evaluation of proposals will be based on an independent, comprehensive review and assessment of the work proposed against stated source selection criteria and evaluation factors. The Government will evaluate each proposal against the evaluation factors detailed below and assign confidence ratings to the non-cost/price factor(s). The Offeror must clearly state how it intends to meet and, if possible, exceed the ACTIVITY requirements. Mere acknowledgement or restatement of an ACTIVITY requirement is not acceptable, unless specifically stated otherwise. *Evaluation credit may be given for technical solutions exceeding mandatory minimums.*

For each evaluated proposal, the technical factors will each be assigned one of the following confidence ratings:

- High Confidence – The U.S. Government has high confidence that the Offeror understands the requirement, proposes a sound approach, and will be successful in performing the contract.

- Some Confidence - The U.S. Government has some confidence that the Offeror understands the requirement, proposes a sound approach, and will be successful in performing the contract.

- Low Confidence - The U.S. Government has low confidence that the Offeror understands the requirement, proposes a sound approach, or will be successful in performing the contract.

M.5. Evaluation Criteria

BARDA will evaluate proposals in accordance with the factors and subfactors detailed in Sections L and M.

The evaluation factors are:

- TECHNICAL FACTOR A: CAPABILITIES
- NON-TECHNICAL FACTOR B: PAST PERFORMANCE
- NON-TECHNICAL FACTOR C: COST/PRICE

FACTOR A – CAPABILITIES

Within the capability description of your organization, proposal evaluation will depend on how clearly actual approaches are described to delineate capabilities to satisfactorily perform contract being sought, and how effectively strengths or unique approaches are highlighted. Repeating the requirements without sufficient elaboration will not be acceptable. The Government shall not assume an Offeror possesses any capability unless specified in the proposal. Proposal lacking elaboration, relying on general assertions of compliance, may be assessed less favorably.

Subfactor 1 - Technical Methodology and Approach

The Technical Methodology and Approach of the proposal will be evaluated based on:

- A proposal that delineates/describes the capability to perform the activities identified in the statement of work for the ACTIVITIES for which vendor will be proposing pricing.
- A Contractor's Work Plan (CWP) that includes detailed and realistic Gantt charts to complete all activities identified in the statement of work, at the varying scales with a time-phased and task-linked budget specifying activities to be supported by the government. Gantt charts describing the timeline from final agreement to execute a task order through completion.
- Realism of each ACTIVITY risk management plan with anticipated difficulties and potential approaches for identification, mitigation, and contingency planning.
- The capability of the Offeror to respond to ACTIVITIES related to the development and manufacture of commercial scale lots of vaccine and adjuvant as specified in the proposal.
- Small business plan submitted.
- Evaluation credit may be given for technical solutions exceeding mandatory minimums

Subfactor 2 – Business /Organizational Experience

The Business/Organizational Experience will be evaluated based upon:

- Inclusion of Product Licensure
- Demonstrated ability to complete all proposed ACTIVITIES.

- Program management approach and tools Offeror will employ to accomplish the effort (including oversight of internal and subcontracted efforts, and internal reporting structures).
- Plan and experience to coordinate activities across multiple sites, including international locations and subcontracted companies considered recent.

Subfactor 3 – Facilities

The Facilities of the Offeror will be evaluated based upon:

- Facility ownership.
- Facility regulatory compliance history from inspection reports over last three years demonstrating acceptability for intended purpose.
- Facility capabilities (including validation state of assays, systems, equipment and manufactured processes).
- Documentation of facilities, systems, equipment, and manufactured compliance with CGMP manufacturing as appropriate for each ACTIVITY.
- Current facility usage (demand) within the Offeror's biopharmaceutical manufacturing franchise as it pertains to the timeliness of ACTIVITY response execution.
- Facility physical, personnel, and information security elements (policies and procedures).
- The storage facility will be evaluated for suitability for that purpose.
- Formulation, Fill, Finish and Final packaging facility will be evaluated for suitability for that purpose.
- A concept plan that describes feasibility for production of pandemic vaccines for HHS purchases during interpandemic and pandemic periods shall be evaluated.
- Integration into the Offeror's biological product franchise.

Subfactor 4 – Personnel

The Key Personnel will be evaluated based upon:

- Individual contributor participation and accomplishments in previous programs relevant to the completion of ALL proposed ACTIVITIES.
- Team leadership of successful efforts of similar magnitude and scope of ALL proposed ACTIVITIES.
- Educational background and technical/scientific qualifications

FACTOR B – PAST PERFORMANCE:

This factor will evaluate the Offeror on its performance under contracts for similar support, both inside and outside the Government, in order to assess a rating of the Offeror's ability to successfully perform the required effort. Only performance within the past five (5) years is considered recent.

The Past Performance evaluation is accomplished by reviewing aspects of the Offeror's performance on relevant contracts. In determining relevance, consideration will be given to

efforts that are of same or similar scope and dollar value to that which is described in the solicitation. This information may include data on efforts performed by other divisions, critical subcontractors or teaming contractors, if such resources will be brought to bear or significantly influence the performance on the proposed effort. For subcontractors, the relevancy determination will focus on the present and past performance work history as it relates to the specific scope of work the subcontractor is proposed to do for this effort. The Government reserves the right to use both data provided by the Offeror and data obtained from other sources. Offerors without a record of relevant performance or for whom information on present and past performance is not available will receive a neutral rating. A strong record of relevant performance may be considered more advantageous to the Government than a neutral rating.

Once past performance relevancy is determined, then a performance confidence assessment will be made after review of at least three (3) questionnaire submissions as follows:

Past Performance Confidence Assessments	
Rating	Description
Substantial Confidence	Based upon offeror's recent/relevant performance record, the Government has a high expectation that the offeror will successfully perform the required effort.
Satisfactory Confidence	Based upon offeror's recent/relevant performance record, the Government has a reasonable expectation that the offeror will successfully perform the required effort.
Limited Confidence	Based upon offeror's recent/relevant performance record, the Government has a low expectation that the offeror will successfully perform the required effort.
No Confidence	Based upon offeror's recent/relevant performance record, the Government has no expectation that the offeror will successfully perform the required effort.
Unknown Confidence (Neutral)	No recent/relevant performance record is available or the offeror's performance record is so sparse that no meaningful confidence assessment rating can be reasonable assigned.

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

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

Each Offeror will be evaluated on its performance under 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 rating 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.

FACTOR C – COST/PRICE:

Only Offerors determined to be the highest technically rated will have their price proposals evaluated.

The highest technically rated Offeror(s) cost/price proposal(s) will be evaluated for reasonableness. For a price to be reasonable, it must represent a price to the government that a

prudent person would pay when consideration is given to prices in the market. Normally, price reasonableness is established through adequate price competition but may also be determined through cost and price analysis techniques as described in FAR 15.404.

The basis of evaluation may include the use of various price analysis techniques to ensure a fair and reasonable price such as:

- Comparison of proposed prices received in response to the solicitation.
- Comparison of proposed prices with resources proposed.
- Obtaining information/reports from cognizant Government Audit Agency (if available) or other outside agencies, and the BARDA Independent Government Cost Estimate.
- Review and analysis of other than cost and pricing data.

Cost/price analytical techniques will be used to not only determine whether the estimate is reasonable but also to provide valuable insight into the Offeror's understanding of the project, perception of risks, and ability to organize and perform the work.

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

The result of these cost/price analytical techniques will be considered in making the best value trade-off decision.