Biomedical Advanced Research and Development Authority (BARDA)

Rapid Response Partnership Vehicle (RRPV)

Request for Project Proposals (RPP)

Solicitation Number: RRPV 24-07-CentralIEIDLab

"Central Influenza and Emerging Infectious Diseases Vaccine Immunoassay Laboratory Services"

Request Issue date: June 14, 2024

Amendment No. 03 Issue Date: May 7, 2025
Questions Due Date: April 24, 2025, by 12pm Eastern

Proposal Due Date: May 30, 2025, by 1pm Eastern

Center for Biomedical Advanced Research and Development Authority (BARDA)
Contracts Management & Acquisition (CMA)
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MedicalCountermeasures.gov

Amendment No. 03 reflects the following:

Clarifies the Technical Proposal submission requirements in Section 3.5 and Attachment A – Technical Proposal Template and spells out acronyms in Section 4.2 page 19

1 Executive Summary

1.1 Rapid Response Partnership Vehicle Consortium

The Rapid Response Partnership Vehicle (RRPV) Consortium is an enterprise partnership in collaboration with industry and academia to facilitate research and development activities, in cooperation with the Center for the Biomedical Advanced Research and Development Authority (BARDA), Administration for Strategic Preparedness and Response (ASPR), U.S. Department of Health and Human Services (HHS).

The RRPV will help fortify national health security by developing medical countermeasures prior to and during a pandemic or public health emergency. The RRPV will focus on the acceleration of products and technology development, regulatory approval, commercialization, and sustainment to address pandemic influenza, emerging infectious diseases, and other biological threats.

Advanced Technology International (ATI) has been awarded an Other Transaction Agreement (OTA) by BARDA to serve as the Consortium Management Firm (CMF) for the RRPV. Under this OTA, the CMF executes and manages all Project Awards awarded to its consortium member organizations, in coordination with the Government sponsor.

RRPV is openly recruiting members to join a broad and diverse biomedical consortium that includes representatives from all organizations who work within stated technical focus areas; for more information on the RRPV mission, refer to the RRPV website at RRPV.org. For entities interested in joining the RRPV Consortium and responding to this solicitation, please visit http://www.rrpv.org/how-to-join.

1.2 Purpose

The potential for a human pandemic resulting from an emerging infectious disease continues to be a public health concern.

The threat of an influenza virus pandemic has greatly increased with the emergence of high pathogenicity avian influenza (HPAI) A(H5N1) and A(H7N9) viruses. Influenza pandemics have erupted at irregular intervals with five influenza pandemics occurring over the past century: the 1918 Pandemic (H1N1 virus), the 1957-1958 Pandemic (H2N2 virus), the 1968 Pandemic (H3N2 virus), the 1977 H1N1 virus re-emergence, and the 2009 Pandemic (H1N1pdm09 virus). HPAI viruses are a serious threat to wild and domesticated birds worldwide. Since HPAI A(H5N1) clade 2.3.4.4b virus was first detected in wild birds in the U.S. (South Carolina) in January 2022, this virus has spread widely across the country, approaching a near record-breaking number of birds affected when compared to previous avian influenza virus outbreaks. The first-ever detection in livestock was reported in the U.S. in 2024 – in dairy cattle in February, in alpacas in May, and in swine in October. There have also been an unprecedented number of cases of confirmed A(H5N1) infection detected in humans in the U.S. since the first reported case in the US in 2022. This is of special concern as HPAI viruses, namely subtypes A(H5) and A(H7), have been known to spread from domestic poultry and other birds to other species, including marine mammals (e.g., sea lions, seals) and farmed mink, in which mammal-to-mammal transmission may have occurred. While the risk to humans remains low, a nimble readiness and response posture requires optimized, fit-for-purpose immune assay development and testing capabilities to support the development of medical countermeasures to prevent the emergence and control the spread of novel influenza viruses with pandemic potential.

Therefore, we are seeking to partner with laboratories with existing capabilities to function as a central immunoassay laboratory and perform quality-assured immunoassays to support advanced research and development of influenza and emerging infectious disease vaccines using samples collected from nonclinical studies and clinical trials. Additionally, the central immunoassay laboratory will provide rapid

response capability to qualify/validate immune assays for newly emerged viral strains or variants and test clinical and/or nonclinical samples in an accelerated fashion in the event of an influenza virus outbreak. Data from these assays may be used in primary, secondary, and exploratory endpoint analyses for vaccine clinical trials, cross-reactivity testing for pandemic readiness and response purposes or perform correlates of protection analyses. Data may be used to support a U.S. FDA Biologics License Application (BLA), Emergency Use Authorization (EUA), or other regulatory agency submissions.

2 Administrative Overview

2.1 Request for Project Proposals (RPP)

RRPV is utilizing the Full Technical Proposal and Full Cost Proposal approach to award for this RPP. The U.S. Government will evaluate responses submitted and will recommend selections of the Proposal(s) that best meets their current priorities using the criteria in Section 5.

2.2 RPP Approach

It is expected that there will be a total of one or more qualified respondents to accomplish the statement of objectives. The U.S. Government intends to periodically review the required capabilities and determine whether it would be in the U.S. Government's best interest to initiate on-ramping to add new Performers to fulfill unmet qualifications, increased demand, increase competition, or for other reasons. The U.S. Government reserves the right to make no awards from this solicitation.

a) On-Ramping

As the infectious diseases landscape continues to evolve with the emergence of highly virulent strains, this program will utilize the flexibility of the OTA to modify the team of performers to rapidly respond to the emergence and spread of new strains of influenza virus or emerging infectious diseases with pandemic potential. In this light, the US Government intends to periodically review the required capabilities and determine whether it would be in the US Government's best interest to initiate on-ramping to add new Performers to fulfill unmet qualifications, increased demand, increase competition, or for other reasons. This is a discretionary unilateral authority of the U.S. Government. The U.S. Government may implement on-ramp procedures at any time by reopening the competition. The basis of the competition during on-ramping may rely upon substantially the same methodology as in the original solicitation. However, the U.S. Government may update the evaluation criteria with consideration to market conditions, the utility of the criteria, and the specific needs being sought through the on-ramping event. No set schedule will be established as to when a reopening of the solicitation will be considered or implemented, and there is no guarantee that a reopening will be executed during the term of the Other Transaction Task Order.

b) Refreshing Scope

The U.S. Government may implement technical refreshment of the scope to improve performance or react to changes in assay requirements.

Each proposal selected for award under this RPP will be executed as a Project Award under the RRPV by the RRPV CMF and be funded under the OTA Number 75A50123D00005. The same provisions will govern this Base Agreement as the OTA between the USG and ATI, unless otherwise noted in the Project Award.

At the time of the submission, Offerors must certify on the cover page of their Proposal that, if selected for award, they will abide by the terms and conditions of the latest version of the RRPV Base Agreement. Base Agreements are typically not executed until Offeror is selected for award. A copy of the RRPV Base Agreement is available upon request to rrpv-contracts@ati.org.

2.3 Period of Performance and Type of Funding Instrument Issued

The anticipated Period of Performance for this effort is estimated to be up to ten (10) years from date of award. It is anticipated that the primary place of performance will be the Performers' facilities, however this aspect can be negotiated as part of each Performer's submission.

Funding of proposals received in response to this RPP is contingent upon the availability of federal funds for this program.

2.4 Expected Award Date

Offeror should plan on the period of performance beginning in the fourth quarter of government fiscal year 2025. The U.S. Government reserves the right to change the proposed period of performance start date through negotiations via the RRPV CMF and prior to issuing a Project Award.

2.5 Anticipated Proposal Selection Notification

As the basis of selection is completed, the Government will forward their recommended selections to the RRPV CMF to notify Offerors. Offerors will be notified of the decision via email from the RRPV CMF of the results of the evaluation. All Offerors will receive feedback on eligible submissions.

2.6 Proprietary Information

The RRPV CMF will oversee submission of proposals submitted in response to this RPP. The RRPV CMF shall take the necessary steps to protect all proprietary information and shall not use such proprietary information for purposes other than proposal evaluation and agreement administration. Please mark all Confidential or Proprietary Information as such. An Offeror's submission of a proposal under this RPP indicates concurrence with the aforementioned CMF responsibilities.

2.7 Mandatory Eligibility Criteria

Offerors must satisfy the following requirements to submit a proposal in response to this Request for Project Proposals:

1. Offerors submitting proposals must be RRPV members when the proposal is submitted. As mentioned above, prospective Offerors may join the consortium at www.rrpv.org/how-to-join.

2. Offerors must provide redacted final qualification and validation reports that demonstrate their immunoassay laboratory previously qualified and/or validated hemagglutination inhibition (HAI) assay and microneutralization (MN) assay for seasonal or zoonotic (specifically non-H1, non-H3, non-B) influenza virus strains.

3. Offeror must provide evidence of relevant experience that supports organizational capacity and technical expertise to serve as the central influenza and emerging infectious diseases immunoassay laboratory.
    a. Provide a listing of clinical studies and their phase (with sample numbers and types) that the Offeror has supported previously by performing HAI and MN clinical sample testing. Offeror can redact confidential information.

4. The Offeror must provide a list of existing or proposed partnerships to address capability areas three (3) through six (6) if the Offeror does not have the in-house expertise. The Offeror must provide a letter of commitment from the proposed partner indicating a willingness to perform the specific duties under the capability area under which they will perform to fulfill the Government's needs. The central influenza and emerging infectious diseases immunoassay laboratory must manage teaming partners and submit deliverables to BARDA. BARDA will have a direct line of communication with the central laboratory, and in conjunction with the central laboratory, will communicate with teaming partners as needed.

5. The central influenza and emerging infectious diseases immunoassay laboratory must be based in the continental U.S.

Offerors must complete the table in the Technical Proposal to document whether they meet each of the above mandatory eligibility criterion. Supporting documents must be provided as attachments to the proposals, and other evidence must reference the section and page number within the proposal. Proposals found to not meet mandatory eligibility criteria as detailed above may be removed from consideration, no further evaluation will be performed, and feedback will not be provided to these Offerors.

2.8 Special Considerations

The following are special considerations in the selection and/or negotiation process; however, these are not required to be eligible to receive an award under this RPP.

Small Business Utilization. Small Businesses utilization is encouraged to the maximum extent practicable as a means to build an agile and resilient industrial and manufacturing base, which ultimately supports economic growth and development.

2.9 Cost Sharing

Cost sharing is defined as the resources expended by the Project Awardee on the tasks specified in the proposed Statement of Work (SOW). Cost sharing is encouraged, if possible, as it leads to stronger leveraging of U.S. Government-Performer collaboration. Cost sharing is expected if the performer is to use the assays developed with USG funding for commercial testing. For more information regarding cost share, please see Attachment B.

2.10 Intellectual Property and Data Rights

Intellectual Property (IP) rights for RRPV Project Awards will be defined in the terms of a Project Awardee's Base Agreement. The RRPV CMF reserves the right to assist in the negotiation of IP, royalties, licensing, future development, etc., between the U.S. Government and the Project Awardees during the entire award period.

The Offeror shall comply with the terms and conditions defined in the RRPV Base Agreement regarding Data Rights**. It is anticipated that anything delivered under this proposed effort would be delivered to the U.S. Government with unlimited data rights as defined in the RRPV Base Agreement unless otherwise specified in the proposal and agreed to by the Government.** All proposed data rights are subject to U.S. Government review and approval. Rights in technical data agreed to by the U.S. Government will be incorporated into the Project Award.

The Offeror shall complete the table provided in Attachment C (Statement of Work), Section 6.0 for any items to be furnished to the U.S. Government with restrictions. An example is provided below. If the Offeror does not assert data rights on any items, a negative response in Attachment C, Section 6.0, is required.

Technical Data or Computer Software to be Furnished with Restrictions or Computer Software	Basis for Assertion	Asserted Rights	Name of Organization Asserting Restrictions	Deliverables Affected
Technical Data Description	Previously developed exclusively at private expense	Limited	Organization XYZ	X.X

3 Proposals

3.1 Question and Answer Period

Table 1. Key dates related to this RPP

Date	Event
6/14/2024	RPP Released
4/11/2025	Amendment 02 released
4/24/2025 by 12 PM EDT	Questions due from potential Offerors
5/6/2025	Questions & Answers released (approximate)
5/30/2025 by 1 PM EDT	Proposals due

Please submit questions to Ms. Rebecca Harmon (rrpv-contracts@ati.org).

3.2 Proposal General Instructions

Offerors who submit Proposals in response to this RPP must submit by the date on the cover page of this RPP. Proposals received after the time and date specified will not be evaluated.

All proposals will be considered final versions. It is the responsibility of the Offerors to quality-check the thoroughness and completeness of their proposal to achieve the most favorable ratings.

Offerors are advised to read all sections in whole, as they may have changed from previous versions.

The Proposal format provided in this RRPV RPP is mandatory and shall reference this RPP number (RRPV 24-07-CentralIEIDLab). Offerors are encouraged to contact the Point of Contact (POC) identified herein up until the Proposal submission date/time to clarify requirements.

The U.S. Government will evaluate Proposals submitted and will recommend selection of the Proposal(s) that meet all the mandatory eligibility criteria and that best meets their current technology priorities using the criteria in Section 5.

All eligible Offerors shall submit Proposals for evaluation according to the criteria set forth in this RPP. Offerors are advised that only ATI, as the RRPV's CMF, with the approval of the Other Transaction Agreements Officer, is legally authorized to contractually bind or otherwise commit funding for selected Project Awards as result of this RPP.

3.3 Proposal Submission

Proposals shall be submitted by the date and time specified on the cover page to the following website: rrpv.hhs.gov

Offerors will be required to register for a BDR Portal account before a response can be submitted. A BDR account can be requested by contacting ATI at RRPV@ati.org. The account request process is simple but may take several days for approval and access. Upon confirmation of a BDR Portal account, the Offeror will login using the prescribed two-factor authentication method.

Failure to submit your proposals on time for any reason (e.g., due to late registration in BDR Portal) will result in the submission not being considered for award. Offerors will be provided an automated confirmation of successful submission.

Do not submit any classified information in the Proposal submission.

Offerors shall 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 must not require a password. File names 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 10 Megabytes of storage space. Movie and sound file attachments, URL Links, or other additional files, will not be accepted.

Once an Offeror has submitted a Proposal, the U.S. Government and the RRPV CMF will not discuss evaluation/status until the evaluation results have been provided to the Offerors.

3.4 Proposal Preparation Cost

The cost of preparing Proposals in response to this RPP is not considered a direct charge to any resulting award or any other contract.

3.5 Submission Format

Proposals shall reference this RPP number (RRPV 24-07-CentralIEIDLab). Each document below (i.e., Technical Proposal, Supporting documentation for Mandatory Eligibility, Cost Proposal Narrative, Cost Proposal Format, Statement of Work, and Program Management Plan) is mandatory and must each be submitted as separate files. Technical and Cost Proposals shall remain valid for 180 days unless otherwise specified by the Offeror in the proposal. Offerors are encouraged to contact the RRPV CMF with any questions so that all aspects are clearly understood by both parties. The proposal should include the following:

- **Mandatory Eligibility Criteria supporting documents (no page limit in supporting documents as attachments to technical proposal) – See Attachment A, Section 3.**
- **Technical Proposal submission (35-page limit, unless noted*)** – **See Attachment A:** One Technical Proposal (.pdf, .doc or .docx). The mandatory template is provided as Attachment A, and includes mandatory sections for a cover page*, information sheet*, Mandatory Eligibility Criteria Table*, executive summary, technical approach, cost realism, current and pending support, data rights*, and personnel resumes/CV.* While no template is required for the resume/CV, each resume/CV is limited to 3 pages.
- **Cost Proposal Narrative (no page limit) – See Attachment B:** One Word (.docx or .doc) or PDF file for Section I: Cost Proposal Narrative is required using the mandatory template. Separately, Section II: Cost Proposal Format is required in Excel (.xlsx) format, with working formulas to the maximum extent practicable. See Section 3.6 for additional information.
  Note: Offerors should propose costs on Capability Areas 1-3 only. Costing for Capability Areas 4--6 will be negotiated after award and at the time of request when the need arises.
- **Cost Proposal Formats (no page limit) – See Attachment B:** One Excel (.xlsx) document is required, with working formulas to the maximum extent practicable. See Section 3.6 for additional information.
- **Statement of Work/Milestone Payment Schedule (no page limit) – See Attachment C**: One Word (.docx or .doc). The Offeror is required to provide a detailed SOW/Milestone Payment Schedule using the mandatory template provided as Attachment C.
- **Program Management Plan submission (5-page limit) – See Attachment D:** One Word (.docx or .doc) or searchable PDF file. The Offeror is required to provide details on their proposed approach for Program Management and sub performer management. Submission should include a listing of personnel (including proposed consultants) who possess the necessary education, training, and experience to successfully perform the work identified in the technical proposal (Note: Personnel resumes must be included in the technical proposal). A summary of related activities must also be provided for personnel.

  The Offeror is required to provide an organizational chart for the project with affiliations (who will report to whom). Details on Offeror-provided facilities, infrastructure, and other resources, should include, but not limited to the following:

  - Overview of the management of Quality Systems at the facility;
  - List of capabilities conducted in-house and at the sub performer site;
  - List of key vendors or service providers, locations, and brief description of their expertise/experience.

The following formatting requirements apply:

- 12-point font (or larger), single-spaced, single-sided, 8.5 by 11 inches
- Smaller type may be used in figures and tables, but must be 8-point font (or larger)
- Margins on all sides (top, bottom, left, and right) should be at least 1-inch
- 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.

3.6 Cost Proposal

The Cost Proposal must include two sections, a Cost Proposal Narrative and a Cost Proposal Format. Offerors are encouraged to use their own cost formats such that the necessary detail is provided. The RRPV CMF will make optional cost proposal formats available on the Members-Only RRPV website. The provided Cost Proposal format template is **NOT** mandatory if the Offeror's formats provide the same level of detail.

Each cost should include direct costs and other necessary components as applicable, for example, fringe, General & Administrative Expense (G&A), Facilities & Administrative (F&A), Other Direct Costs (ODC), etc. Offerors shall provide a breakdown of material and ODC costs as applicable.

3.7 Special Requirements

Offerors must be prepared to comply with restrictions and reporting requirements for the use of animals and human subjects, as addressed in further detail in the RRPV Base Agreement and as detailed in Section 4 Technical Approach. In addition, BARDA has a strong preference for U.S.-based laboratories with high throughput capacity, using automation and laboratory electronic data systems (i.e., LIMS), laboratories that are part of global networks that aim to minimize variability in inter-laboratory results, including through the use of universal protocols and reagent sources, and laboratories that are registered with the CDC/USDA to work with zoonotic influenza viruses.

Additional information on the applicable regulatory terms is provided in the RRPV Base Agreement.

These restrictions include mandatory government review and reporting processes that will impact the Offeror's schedule.

4 Technical Requirements

4.1 Introduction

The Offeror shall clearly state how it intends to meet and, if possible, exceed the technical requirements. Mere acknowledgement or restatement of the requirements is not acceptable, unless specifically stated otherwise.

4.2 Scope

Overall Objective:

The overall objective of this Request for Project Proposals is to engage in a partnership with an organization(s) that can serve as the central immunoassay laboratory for influenza and emerging infectious diseases; qualify, validate, and perform influenza virus HAI and MN assays to support clinical trial endpoints and conduct concordance studies (if needed); and potentially expand to establish and perform other influenza immunoassays.

The Offeror must furnish all the necessary services, qualified personnel, materials, supplies, equipment, and facilities not otherwise provided by the U.S. Government as needed to perform the work described below. High throughput capacity is preferred with validated assay automation and laboratory electronic data systems (i.e., LIMS).

Required Project Activities

The Offeror will:

- Function as a U.S. Government centralized immunoassay laboratory with testing capability to support advanced research and development of influenza vaccines and emerging infectious diseases vaccines by, at minimum, perform influenza virus HAI and MN testing.
- Data from these tests may be used in primary, secondary, and exploratory endpoint analyses for vaccine clinical trials, inter-laboratory concordance studies, and/or to support a U.S. FDA BLA or EUA.
- Make available to BARDA all relevant standard operating procedure(s) (SOPs), sample receipt/handling and assay-related process documents/reports for review and approval (generally expected early in the award period, before critical assay sample receipt/handling and/or assay development occurs).
- Ensure that all assay-related SOP(s) and processes align with the procedure(s) used for assay qualification and/or validation.

Proposal Submission Requirements

The Offeror will:

- As the central laboratory, the Offeror must have a standardization plan to ensure that teaming partners follow the same structure and aim to minimize variability in inter-laboratory results including the use of standardized protocols and reagent sources. Analogous efforts should be made with all assay-associated data.
- Provide evidence of central laboratory capacity for sample receipt, end-to-end sample processing including assays, storage, QC/QA, results reporting with turnaround times as applicable (routine and emergency mode), and data storage and security.
- Submit to BARDA appropriate biosafety regulatory compliance permissions in place to work with zoonotic influenza viruses, although utilization of a BSL-3 laboratory may not be required.
- Provide evidence of capability to generate, propagate, and fully characterize reassortant influenza viruses and/or submit to BARDA relevant letters of support, or similar, from virus provider sources.
- The proposal should include alternative timelines and cost for accelerated assay development and sample testing to support an eventual response by the USG to a public health emergency.
- Submit to BARDA appropriate qualified scientific, technical, managerial personnel information (e.g., curricula vitae (CVs), current training certificates or records). In addition, submit organizational chart of all personnel involved in the study for both the performer and subperformer.
- Perform study(-ies) under a Quality Assurance Project Plan that delineates Offeror quality assurance audit plans as well as host BARDA- and/or prime performer-led GLP qualification audits, monitoring visits, and data audits.
- Perform clinical sample testing in accordance with Division of AIDS (DAIDS) in the National Institute of Allergy and Infectious Diseases (NIAID) GCLP guidelines (https://www.niaid.nih.gov/research/daids-clinical-research-laboratory-specimens-management).

- Deliver consistent performance over time of qualified or validated assay(s) through the use of routine quality control samples (i.e., internal- and/or external-sourced quality control samples testing) and periodic trending/performance panel samples testing as requested (USG- or other internal-/external-sourced panel samples).
- Support on-site Offeror laboratory visits, including pre-award visits, by BARDA. Share sample receipt/handling processes, assay processes (including sample preparation and tracking, assay throughput step recording, equipment and data systems (e.g., electronic data systems / LIMS), and data recording/reporting processes), and routine assay quality measures that are in place. Prior assay quality performance assessment results and assay critical reagents qualification processes and data should be available.

In addition, Offerors are required to include the following as part of their proposal submission:

- Provide evidence of the Offeror's ability to expand capabilities in support of this program using teaming partners. Offeror shall provide a list of either existing or proposed partnerships to ensure that all six capabilities described below are addressed.
- Describe the Offeror's history of utilizing standardization plans to ensure that teaming partners follow the same standard.

Summary of Requested Capabilities:

As summarized below, Offerors are required to submit technical proposals that respond to the Capability Areas 1-6. Note: Offerors should propose costs on Capability Areas 1-3 only. Costing for Capability Areas 4-6 will be negotiated after award and at the time of request when the need arises.

- **Capability 1:** Develop, qualify, or validate immunoassays to support clinical trial endpoints and/or nonclinical studies to evaluate immune responses to influenza and emerging diseases vaccines.
- **Capability 2:** Test samples from clinical trials and/or nonclinical studies using qualified or validated immunoassays.
- **Capability 3:** Prepare and develop vaccine potency reagents as required.
- **Capability 4:** Develop, optimize, and perform exploratory assays to support clinical and/or nonclinical sample testing as required.
- **Capability 5:** Conduct assay concordance as required.
- **Capability 6:** Conduct technology transfer to (or from) other laboratories as required to support the USG programs.

Detailed Description of Capabilities:

- **Capability 1:** Develop, qualify, or validate immunoassays to support clinical trial endpoints and/or nonclinical studies (including use of human and animal samples) to evaluate immune responses to influenza vaccines and emerging infectious diseases vaccines. Core immunoassays to support regulatory submissions include influenza HAI and MN assays. These core assays shall be qualified or validated to support regulatory submissions such as BLA or IND. Whether to qualify or validate the HAI and MN assays, or other assays indicated below, will be determined by BARDA based on regulatory requirements. Other assays that may be qualified for sample testing include flow cytometry assay (e.g., surface marker and intracellular cytokine staining (ICS)), enzyme-linked

immunosorbent spot (ELISpot) assay, enzyme-linked immunosorbent assay (ELISA), enzyme-linked lectin assay (ELLA), and reporter virus neutralization assay.

- **Workstream 1**

The Offeror will **qualify** influenza HAI and MN assays for testing clinical and/or nonclinical serum and mucosal samples from influenza vaccine candidate trials. Assay qualification will include at minimum assessment of the following parameters: precision [intra- and inter-assay precision], accuracy [relative accuracy], dilutional linearity, robustness, and specificity, and determination of lower and upper limits of quantification (LLOQ, ULOQ). **For planning and costing purposes**, assume up to two (2) HAI and MN assays annually (i.e., up to 4 assays total). BARDA will advise the Offeror upon award and by second quarter of each subsequent calendar year on which two (2) influenza virus strain-specific assays to qualify in HAI and MN assays. Influenza virus subtypes may include, but are not limited to, H5Nx (e.g., H5N1, H5N6, H5N8), H7Nx (e.g., H7N3, H7N9), H9N2, H10Nx (e.g., H10N3, H10N8), H3N2(v), H1N1(v), H2Nx (e.g., H2N2, H2N3), subtype B, or other emerging subtypes.

- Technical Requirements:
  - The Offeror must generate and manage overall assay qualification plans and projected timelines, assay qualification and assay reagent qualification protocol(s) and reports, which must be reviewed and approved by BARDA. Assay plan(s) and protocol(s) must be reviewed and approved by BARDA prior to their execution. Other assay-related plan/process documents must also be reviewed and approved by BARDA as requested, including, but not limited to, sample receipt/handling/tracking process documents, assay result reporting process documents, and laboratory equipment and data system validation documents.
  - The Offeror is required to source/provide all critical reagents, such as appropriate sera and antibodies for use as positive and negative quality control samples and internal and external trending panels as well as reference sera and other reagents, as needed.
  - Use of human samples (e.g., sera, nasal lining fluid, and saliva) are preferred for the entirety of assay development. If appropriate human immune sera are not available, immune sera from animal species may be used (e.g., ferret or rabbit) initially, but the assay must be re-qualified once appropriate human immune sera become available. Selection of immune sera to be used throughout assay development must be approved by BARDA prior to the start of assay qualification.
  - The Offeror may use reassortant influenza viruses for HAI and MN assays contingent on BARDA approval. The Offeror will propagate virus (e.g., A/Puerto Rico/8/1934 (PR8)-based reassortant influenza viruses) in embryonated chicken eggs or Madin-Darby canine kidney (MDCK) cells. The viruses may be sourced by the Offeror in collaboration with BARDA or influenza virus laboratories (e.g., international regulatory laboratories, academia, etc.) as appropriate.
  - The genomes of viruses used in the assays, or viruses used to generate critical components of an assay, must be sequenced to ensure alignment to parental or prototype virus strains as appropriate. The Offeror must submit a nucleic acid and protein sequence alignment between the virus stocks used for qualification and the parental or prototype virus strain to BARDA prior to execution of assay development.
  - If requested, the Offeror must provide working virus lot aliquot samples to BARDA for identity verification, as requested.

- Documentation Requirements:
    - Offeror must provide a plan(s) or SOPs for assay maintenance, including assay performance monitoring (i.e., review of routine quality control sample data, as well as participation in external trending panel testing) and qualification of critical assay reagents (e.g., virus lots, red blood cell sources, immunological reagents, cell lots, passage history, etc.).
    - The Offeror shall provide (i) virus certificate(s) of analysis, which includes virus propagation and characterization reports (HA titer, infectious titer, sterility, absence of mycoplasma, endotoxin level, and HA sequence alignments, etc.) and (ii) a final assay qualification report (including raw qualification data) that includes assessment of assay precision, accuracy, dilutional linearity, robustness, and specificity, and determination of lower and upper limits of quantification (LLOQ, ULOQ). **Note that for regulatory approval criteria purposes, the BARDA expectation is that the HAI LLOQ will be a titer ≤1:10.** The assay qualification report must also include source and lot information for all assay reagents and components, including biologicals. The report must be in eCTD submission ready format, as per CSN Clinical Related Documents for eCTD Formatting BARDA Held INDs (v. 2.0 14Jan22) and BARDA's Document QC Guide for BARDA to complete FDA submission level publishing.
    - The Offeror must provide a Project Management Plan (PMP) that defines the overall plan for how the project will be executed, monitored, and controlled and must include a Study Responsibility Assignment Matrix for Performer and sub-performer teams. The Performer must submit the PMP within 30 calendar days after the initiation of the agreement period of performance.
    - The Offeror must provide a Gantt Chart/timeline at first project meeting and as updated no later than every 30 calendar days. The Gantt Chart/timeline should be detailed to the extent required by the specific project.
- Regulatory Compliance:
    - The Offeror must provide documents (e.g., assay SOP, qualification protocol, and final report) that are Document-Level Published to BARDA to be incorporated into BARDA's eCTD Publishing Tool.
- Technology Transfer Requirements:
    - If necessary, the Offeror may seek technology transfer to or from other laboratories as necessary to perform the task(s) with comparable assay performance results to other similar qualified assays, or to the assay performed in the originating laboratory (if deemed appropriate by BARDA).

- **Workstream 2**

The Offeror will **validate** influenza virus HAI and MN assays, as needed, to test clinical and/or non-clinical samples including animal samples from influenza vaccine candidate clinical trials.

- Specific items included in this Workstream 2 are identical to those indicated above for Workstream 1 (assay qualification), except (i) that all items refer to assay validations or validated assays, not assay qualifications or qualified assays, and (ii) as noted in the several bulleted items immediately below.
- Partial validations of HAI or MN assays may be required to support clinical trial endpoints for platform-specific vaccine candidates, using samples obtained from human subjects after vaccination with those candidates. For example, partial validations for a given influenza subtype may be required for each egg-, cell-, mRNA-, or other platform-based

vaccine candidate, even though the target influenza subtype may be the same. At minimum, partial validations will include precision, dilutional linearity/relative accuracy and LOQ assessments. Additional assessments for partial validation may be required based on regulatory agency guidance.
    - Specification limits for quality control samples (used for assay system suitability assessment) must be determined prior to assay validation runs.
    - **For planning and costing purposes,** assume up to two (2) HAIs and MNs annually (i.e., up to 4 assays total) with full validation.

- **Workstream 3**
    - Develop and qualify ICS and ELISpot assays for testing immune cells (e.g., PBMC, MNC).
    - Bulleted items from Workstreams 1 and 2 apply to this Workstream, as appropriate, except using immune cells for ICS and stimulated immune cells for ELISpot.
    - **For planning and costing purposes,** assume 8 colors including surface and intracellular cytokine markers for ICS. For ELISpot assume measuring cytokines such as IFN-γ, IL-2, IL-4, and IL-6 from PBMCs activated by peptide pools from two virus strains annually.

- **Workstream 4**
    - Develop and qualify ELISA and ELLA for testing serum or mucosal samples.
    - Bulleted items from Workstreams 1 and 2 apply to this Workstream, as appropriate.
    - **For planning and costing purposes,** assume two virus strains annually for each of these assays using serum samples.

- **Workstream 5**
    - Develop and qualify reporter virus neutralization assay for serum or mucosal samples.
    - Bulleted items from Workstreams 1 and 2 apply to this Workstream, as appropriate.
    - **For planning and costing purposes,** assume two virus strains annually for each of these assays using serum samples.

- **Capability 2:** Test samples from clinical trials and/or nonclinical studies using qualified or validated immunoassays.

    - **Workstream 1**
        - The Offeror must test clinical trial samples in phase appropriate (qualified/validated) HAI and MN assays, as developed in the Workstreams 1 or 2 for Capability 1. A sample testing plan (which includes sample handling, batch format, repeat testing strategy, data reporting formats, testing schedule, etc.) should be written for each clinical trial for which samples are to be tested, for review and approval by BARDA prior to commencement of testing. Assay data will be transferred to BARDA (or its assignee) to support its programmatic goals.
        - Expected number of samples/throughput: Influenza virus strain-specific HAI and/or MN assay(s), approximate sample number to be tested, and required stage of development of the assay will be communicated to the Offeror at the time of request. **For planning and costing purposes**, assume one (1) clinical trial HAI and MN endpoint testing annually for 720 subjects x 5 timepoints x 2 influenza virus strains.
        - A BARDA designee will prepare and coordinate sample shipments to the Offeror for testing. Samples will be provided to the Offeror in a blinded manner (i.e., barcoded). The Offeror will transmit quality controlled (QC'd) /quality assured (QA'd) assay result data to

the clinical trial Sponsor or designee such as BARDA's Clinical Study Network (CSN) Standard Data Coordinating Center (SDCC) in a mutually agreed-upon format (e.g., csv file). A Data Transfer Agreement (DTA) must be in place prior to data transfer. Clinical trial analyses will be performed by the clinical trial Sponsor.

- The Offeror is required to source/provide all critical reagents, including appropriate positive and negative quality control samples, as well as reference samples and trending panel samples or other reagents, as appropriate.
- Turnaround time requirements:
  - The Offeror must test BARDA samples and provide quality assurance reviewed HAI and MN assay results to clinical trial Sponsor or designee within 60 calendar days of final sample set receipt, or as negotiated with BARDA. The Offeror shall staff/equip laboratories such that capacity is sufficient for 1,000 samples tested per week for HAI assay and 500 samples for MN assay (if multiple subtypes are being tested concurrently, the 1,000 samples/week is the total for all HAIs, and 500 samples/week for all MNs).
- Quality Control specifications:
  - The Offeror must have a Quality Assurance program that includes routine monitoring of assay performance and trending during the testing of samples. For example, assay results of routine quality control samples should be tracked and periodic internal and/or external trending panel testing should be performed. Sample panels from external sources for testing may be requested and supplied/arranged by BARDA.
  - At completion of testing for a given study or clinical trial, the Offeror must ship all remaining clinical trial samples, at appropriate temperature, to a BARDA-determined location.
- Data management, reporting requirements:
  - The Offeror must provide a final report to BARDA that includes sample test results, and performance parameters of assay quality control samples and any trending panel sample testing performed. The report must be in eCTD submission ready format, as per CSN Clinical Related Documents for eCTD Formatting BARDA held INDs (v. 2.0 14Jan22) and BARDA's Document QC Guide for BARDA to complete FDA submission level publishing.
  - The Offeror must provide a Project Management Plan (PMP) that defines the overall plan for how the project will be executed, monitored, and controlled and must include a Study Responsibility Assignment Matrix for Performer and sub-performer teams. The Performer must submit the PMP within 30 calendar days after the initiation of the agreement period of performance.
  - The Offeror must provide a Gantt Chart/timeline at first project meeting and as updated no later than every 30 calendar days. The Gantt Chart/timeline should be detailed to the extent required by the specific project.
- Regulatory compliance:
  - The Offeror must provide documents that are Document-Level Published to BARDA to be incorporated into BARDA's eCTD Publishing Tool.

- **Workstream 2**
  - The Offeror will perform flow cytometric (e.g., surface marker and ICS) and ELISpot assays to support nonclinical and/or clinical trial endpoints or other supportive data. Assay data will be transferred to BARDA (or its assignee) to support its programmatic goals. **For planning and costing purposes,** assume 500 samples for ICS and 500 samples ELISpot per year.

- PBMCs or other MNCs will be used for these assays. A BARDA designee will prepare and coordinate sample shipments to the Offeror for testing. Samples will be provided to the Offeror in a blinded manner (i.e., barcoded). The Offeror will transmit quality controlled (QC'd) /quality assured (QA'd) assay result data to the clinical trial Sponsor or designee such as BARDA's Clinical Study Network (CSN) Standard Data Coordinating Center (SDCC) in a mutually agreed-upon format (e.g., csv file). A Data Transfer Agreement (DTA) must be in place prior to data transfer. Clinical trial analyses will be performed by the clinical trial Sponsor.
- ELISpot assays will measure cytokines such as IFN-γ, IL-2, IL-4, and IL-6, or as negotiated, from activated immune cells.
- Flow cytometry assays will assess eight (8) surface and intracellular cytokine markers, or as negotiated.
- The Offeror is required to source/provide all critical reagents, including positive and negative quality control samples, as well as reference samples and trending panel samples or other reagents, as appropriate.
- Samples may be provided to the Offeror in a blinded manner (e.g., barcoded), and QC'd/QA'd assay result data will be transmitted to the clinical trial Sponsor or designee such as BARDA's Clinical Study Network (CSN) Standard Data Coordinating Center (SDCC) in a mutually agreed-upon format (e.g., csv file). A Data Transfer Agreement (DTA) must be in place prior to data transfer. Clinical trial analyses will be performed by the clinical trial Sponsor.
- At completion of testing, the Offeror must ship all remaining study or clinical trial samples, at appropriate temperature, to a BARDA-determined location.
- Provide a final report to BARDA that includes sample test results and performance parameters of assay quality control samples and trending panel sample testing.

- The Offeror must provide a Project Management Plan (PMP) that defines the overall plan for how the project will be executed, monitored, and controlled and must include a Study Responsibility Assignment Matrix for Performer and sub-performer teams. The Performer must submit the PMP within 30 calendar days after the initiation of the agreement period of performance.
- The Offeror must provide a Gantt Chart/timeline at first project meeting and as updated no later than every 30 calendar days. The Gantt Chart/timeline should be detailed to the extent required by the specific project.

- **Workstream 3**
  - The Offeror will perform ELISA and ELLA to test clinical or nonclinical samples including animal samples from influenza vaccine candidate studies or trials. **For planning and costing purposes,** assume 3,000 samples per year for each assay.
  - The Offeror must test clinical or nonclinical samples in a qualified or validated assay (as developed in Workstreams 1 and 2 for Capability 1. Assay data will be transferred to BARDA (or its assignee) to support its programmatic goals.
  - Samples for testing may include serum, plasma, mucosal secretions (e.g., nasal/salivary mucosal matrices).
  - The Offeror is required to source/provide all critical reagents, including positive and negative quality control samples, as well as reference samples and trending sample panels, as appropriate.
  - Samples may be provided to the Offeror in a blinded manner (e.g., barcoded), and QC'd/QA'd assay result data will be transmitted to the clinical trial Sponsor or designee

such as BARDA's Clinical Study Network (CSN) Standard Data Coordinating Center (SDCC) in a mutually agreed-upon format (e.g., csv file). A Data Transfer Agreement (DTA) must be in place prior to data transfer. Clinical trial analyses will be performed by the clinical trial Sponsor.

- At completion of testing, the Offeror must ship all remaining study or clinical trial samples, at appropriate temperature, to a BARDA-determined location.
- The Offeror must provide a final report to BARDA that includes sample test results and performance parameters of assay quality control samples and trending panel sample testing.
- The Offeror must provide a Project Management Plan (PMP) that defines the overall plan for how the project will be executed, monitored, and controlled and must include a Study Responsibility Assignment Matrix for Performer and sub-performer teams. The Performer must submit the PMP within 30 calendar days after the initiation of the agreement period of performance.
- The Offeror must provide a Gantt Chart/timeline at first project meeting and as updated no later than every 30 calendar days. The Gantt Chart/timeline should be detailed to the extent required by the specific project.

- **Workstream 4**
  - The Offeror will perform reporter virus neutralization assays for samples from clinical trials and/or nonclinical studies, as needed. **For planning and costing purposes,** assume 3,000 samples per year.
  - The Offeror must test clinical or nonclinical samples in a qualified or validated assay (as developed in Workstreams 1 and 2 for Capability 1) Assay data will be transferred to BARDA (or its assignee) to support its programmatic goals.
  - Samples for testing may include serum, mucosal secretions (e.g., nasal/salivary mucosal matrices), or novel-assay-appropriate panels in any combination.
  - The Offeror is required to source/provide all critical reagents, including appropriate positive and negative quality control sera/samples, as well as reference sera/samples and trending panel sera/samples, as appropriate.
  - Samples may be provided to the Offeror in a blinded manner (e.g., barcoded), and QC'd/QA'd assay result data will be transmitted to the clinical trial Sponsor or designee such as BARDA's Clinical Study Network (CSN) Standard Data Coordinating Center (SDCC) in a mutually agreed-upon format (e.g., csv file). A Data Transfer Agreement (DTA) must be in place prior to data transfer. Clinical trial analyses will be performed by the clinical trial Sponsor.
  - At completion of testing, the Offeror must ship all remaining study or clinical trial samples, at appropriate temperature, to a BARDA-determined location.
  - The Offeror must provide a final report to BARDA that includes sample test results and performance parameters of assay quality control samples and trending panel sample testing.
  - The Offeror must provide a Project Management Plan (PMP) that defines the overall plan for how the project will be executed, monitored, and controlled and must include a Study Responsibility Assignment Matrix for Performer and sub-performer teams. The Performer must submit the PMP within 30 calendar days after the initiation of the agreement period of performance.

- The Offeror must provide a Gantt Chart/timeline at first project meeting and as updated no later than every 30 calendar days. The Gantt Chart/timeline should be detailed to the extent required by the specific project.

- **Capability 3:** Prepare and develop vaccine potency reagents as required. The Offeror will prepare antigen reagents for generating animal antisera or antibodies, which may be used in immunoassays and vaccine release testing, including potency measurement.

  - **Workstream 1**: Propagate, purify, and characterize influenza viral hemagglutinin (HA) for antiserum production.

    The Offeror will prepare purified influenza viral HAs that will be used for generating animal antisera for calibrating reference antigens and release testing bulk influenza vaccine antigens and/or influenza vaccine products.

    BARDA will advise the Offeror on influenza virus strains for preparing the viral HA antigens. **For planning and costing purposes,** assume up to two (2) strains annually. Influenza virus subtypes may include, but are not limited to, H5Nx (e.g., H5N1, H5N6, H5N8, etc.), H7Nx (e.g., H7N3 H7N9), H9N2, H10Nx (e.g., H10N3, H10N8, etc.), H3N2(v), H1N1(v), H2Nx (e.g., H2N2, H2N3, etc.), B, or other emerging subtypes.
  - Technical requirements:
    - The Offeror will propagate virus (e.g., A/Puerto Rico/8/1934 (PR8)-based reassortant influenza viruses) in embryonated chicken eggs or Madin-Darby canine kidney (MDCK) cells. The viruses will be sourced by the Offeror in collaboration with BARDA or influenza virus laboratories (e.g., international regulatory laboratory, academia, etc.) as appropriate.
    - The Offeror will inactivate (e.g., β-Propiolactone, BPL) and purify influenza viruses, e.g., by sucrose gradient centrifugation.
    - The Offeror will cleave HAs from the purified viruses, e.g., using bromelain, and then isolate the HA properly, e.g., by sucrose gradient centrifugation or lectin-based affinity chromatography, etc.
    - The purified viral HAs will preferably be in PBS, pH 7.0-7.2.
    - The Offeror must test the purified viral HAs at a minimum for: protein concentration, purity, hemagglutination function, oligomer status, sterility, endotoxin.
    - The Offeror will store the purified viral HAs at 2-8°C and will ship 5-8mg of purified viral HAs including certificate of analysis to a BARDA-designated location (e.g., FDA) upon completion of the viral HA purification and characterization.
  - Quality standards:
    - The Offeror will characterize the purified viral HAs and make sure they meet the following requirements at minimum:
    - A purity of 95% or higher.
    - The majority of HA molecules are trimers or oligomers of trimers as indicated by polyacrylamide gel electrophoresis (PAGE) or size exclusion chromatography (SEC).
    - HAs are functionally active, i.e., positive in hemagglutination assay. Requirements are subject to change based on the downstream need, and Protocol(s) must be approved by BARDA prior to start of the workstream.
  - Timelines:
    - The Offeror must provide purified viral antigens to a BARDA designee within 60

calendar days of the time of BARDA request, or as negotiated with BARDA.

- Documentation:
  - The Offeror must provide a certificate of analysis to BARDA that includes a minimum for: volume, protein concentration, purity, hemagglutination unit (e.g., per 50µl), sterility, endotoxin.
  - The Offeror must provide a Project Management Plan (PMP) that defines the overall plan for how the project will be executed, monitored, and controlled and must include a Study Responsibility Assignment Matrix for Performer and sub-performer teams. The Performer must submit the PMP within 30 calendar days after the initiation of the agreement period of performance.
  - The Offeror must provide a Gantt Chart/timeline at first project meeting and as updated no later than every 30 calendar days. The Gantt Chart/timeline should be detailed to the extent required by the specific project.

- **Workstream 2:** Express, purify, and characterize recombinant influenza HA for antiserum production.
  - This will be an alternative to Capability 3-Workstream 1.
  - Except as indicated below, other specific items included in this workstream are identical to those indicated above for Workstream 1.
  - Based on the HA nucleotide sequences provided and/or approved by BARDA, the Offeror will design and prepare plasmid constructs or recombinant baculoviruses for expressing full-length or soluble, secreted recombinant HAs in mammalian cells (e.g., human embryo kidney 293F cells) or insect cells (e.g., Sf9 or High Five cells, etc.).
  - The Offeror will transfect mammalian cells with plasmids containing the target HA sequences or infect insect cells with recombinant baculoviruses.
  - The Offeror will purify the HAs via an appropriate process, e.g., metal ion affinity chromatography, ion-exchange chromatography, etc.

- **Workstream 3:** Reagent development, purification, and characterization as required.
  - The Offeror will prepare reagents (viral or recombinant proteins) specific to influenza antigens other than HA or pathogens other than influenza viruses, or for alternative potency testing as requested by BARDA. The number of pathogen strains for preparing reagents as well as the amount of and quality requirements for the reagents will be at the discretion of BARDA. **For planning and costing purposes,** assume two strains for viral protein and two strains for recombinant protein will be required.

- **Capability 4:** Develop, optimize, and perform exploratory assays to support clinical and/or nonclinical studies. In particular, test clinical samples for potentially cross-reactive immune responses to non-seasonal (including zoonotic or animal-origin) virus strains as determined by BARDA with fit-for-purpose HAI and/or MN assay. In addition, other exploratory assays may include but are not limited to: Antibody-Dependent Cell Cytotoxicity (ADCC), Antibody-Dependent Cellular Phagocytosis (ADCP), Antibody-Dependent Natural Killer Cell Activation (ADNKA), Antibody-Dependent Complement Deposition (ADCD), Antibody-Dependent Neutrophil Phagocytosis (ADNP), Antibody-Dependent Dendritic Cell Phagocytosis (ADDCP), Fc receptor array, antibody sub-classing and isotyping, systems serology, whole genome phage display libraries, surface plasmon resonance, biolayer interferometry, and B and T cell epitope repertoire analysis. BARDA will advise the Offeror on specific assays and pathogens.

- **Workstream 1:**
  - The Offeror will optimize HAI and MN assays for testing clinical samples for potentially cross-reactive immune responses to virus strains.
  - Items included in this workstream are identical to those indicated above for Capability 1, Workstream 1 except the assays are to be optimized not qualified, and a panel of assays with up to 6 virus strains will be required for this purpose.

- **Workstream 2:** Optimize other exploratory assays to test clinical or nonclinical samples including animal samples from studies/clinical trials with influenza and emerging infectious diseases vaccine candidates, as needed.
  - Technical requirements, documentation requirements, regulatory compliance, and technology transfer requirements for assay development and optimization will be provided by BARDA when the option is exercised.
  - At minimum, the Offeror must provide a Project Management Plan (PMP) that defines the overall plan for how the project will be executed, monitored, and controlled and must include a Study Responsibility Assignment Matrix for Performer and sub-performer teams. The Performer must submit the PMP within 30 calendar days after the initiation of the agreement period of performance.
  - The Offeror must provide a Gantt Chart/timeline at first project meeting and as updated no later than every 30 calendar days. The Gantt Chart/timeline should be detailed to the extent required by the specific project.

- **Workstream 3:** Test clinical or nonclinical samples including animal samples from studies/clinical trials with influenza or emerging infectious disease vaccine candidates with any of these exploratory assays, as needed. Samples for testing may include serum, plasma, PBMC, mucosal secretions (e.g., nasal/salivary mucosal matrices), or novel-assay-appropriate panels in any combination.
  - For all assay types, the number of samples required for testing will be determined by BARDA.
  - Cross-reactivity testing with HAI and MN assays will include an assay panel of 6-12 influenza viruses.
  - The Offeror must provide a final report to BARDA that includes sample test results and performance parameters of assay quality control samples and trending panel sample testing.
  - The Offeror must provide a Project Management Plan (PMP) that defines the overall plan for how the project will be executed, monitored, and controlled and must include a Study Responsibility Assignment Matrix for Performer and sub-performer teams. The Performer must submit the PMP within 30 calendar days after the initiation of the agreement period of performance.
  - The Offeror must provide a Gantt Chart/timeline at first project meeting and as updated no later than every 30 calendar days. The Gantt Chart/timeline should be detailed to the extent required by the specific project.

- **Capability 5:** Perform concordance assays as required.
  - **Workstream 1:**

- The Offeror must perform inter-laboratory assay **concordance** study(ies) for qualified and/or validated assay(s), as requested.
  - The concordance assay protocol(s) must be reviewed and approved by BARDA prior to execution.
  - Samples for testing may include serum, plasma, PBMC, mucosal secretions (e.g., nasal/salivary mucosal matrices), or novel-assay-appropriate panels in any combination.
  - The Offeror is required to source appropriate positive and negative quality control samples, as well as reference sera, as appropriate.
  - The Offeror must provide a Project Management Plan (PMP) that defines the overall plan for how the project will be executed, monitored, and controlled and must include a Study Responsibility Assignment Matrix for Performer and sub-performer teams. The Performer must submit the PMP within 30 calendar days after the initiation of the agreement period of performance.
  - The Offeror must provide a Gantt Chart/timeline at first project meeting and as updated no later than every 30 calendar days. The Gantt Chart/timeline should be detailed to the extent required by the specific project.

- **Capability 6:** Conduct technology transfer of any of the above assays to (or from) other laboratories to support the USG programs.

  - **Workstream 1:**
    - The Offeror must conduct technology transfer of (i) any of the assays developed in their laboratory to another laboratory as designated by BARDA, or (ii) assays developed in another laboratory to the Offeror's laboratory. The technology transfer is intended to maintain the development state (e.g., qualified or validated) of the assay(s) as in the originator laboratory.
    - The Offeror must generate a technology transfer plan or protocol, as well as projected timelines, that must be reviewed and approved by BARDA prior to its commencement.
    - After completion of the technology transfer experiments, the Offeror will generate a final technology transfer report that includes experimental test results and analyses for all assay parameters assessed. BARDA must review and approve the technology transfer data and analyses in the report for the technology transfer to be deemed complete.
    - The Offeror must provide a Project Management Plan (PMP) that defines the overall plan for how the project will be executed, monitored, and controlled and must include a Study Responsibility Assignment Matrix for Performer and sub-performer teams. The Performer must submit the PMP within 30 calendar days after the initiation of the agreement period of performance.
    - The Offeror must provide a Gantt Chart/timeline at first project meeting and as updated no later than every 30 calendar days. The Gantt Chart/timeline should be detailed to the extent required by the specific project.

4.3 Project Management Objectives

It is anticipated that the Performer will be required to submit a number of documents to capture the progression of the project, post-award. See Attachment C for full listing of anticipated deliverables. Requirements may include but are not limited to the following:

- **Reporting:** The Performer shall deliver monthly technical and financial reports including estimate to complete (ETC) and progress reports. Annual reports shall also be provided.

At the end of the effort, the Performer shall provide a detailed final report of Central Influenza and Emerging Infectious Diseases Vaccine Immunoassay Laboratory Services efforts. The Performer must provide a Project Management Plan (PMP) that defines the overall plan for how the project will be executed, monitored, and controlled and must include a Study Responsibility Assignment Matrix for Performer and sub-performer teams. The Performer must submit the PMP within 30 calendar days after the initiation of the agreement period of performance. The Performer must provide a Gantt Chart/timeline at first project meeting and as updated no later than every 30 calendar days. The Gantt Chart/timeline should be detailed to the extent required by the specific project.

Meetings: The Performer shall schedule regular, recurring progress meetings with the Government. The meeting agenda shall be submitted to the Government in advance and meeting minutes will be submitted following meetings.

The successful Offeror shall provide deliverables as included in Attachment C, Statement of Work.

4.4 Logistics Objectives

The Performer shall be responsible for (sub) contracting or executing all intellectual property, material, and sample shipments and maintenance of all associated records and permits.

5 Selection/Evaluation

5.1 Compliance Screening

The RRPV CMF will conduct a preliminary screening of submitted Proposals to ensure compliance with the RPP requirements. As part of the preliminary screening process, proposals that are not accompanied by a completed mandatory eligibility criteria table in Attachment A and documentation of Offeror meeting the mandatory eligibility criteria may be removed from consideration, no further evaluation will be performed, and feedback will not be provided. Proposals that do not meet the requirements of the RPP may be eliminated from the competition or additional information may be requested by the RRPV CMF. The Government reserves the right to request additional information, perform a pre-award audit, or eliminate proposals that do not meet these requirements from further consideration.

5.2 Proposal Evaluation Process

Proposals that meet the mandatory eligibility criteria will undergo a technical evaluation. Evaluators will assign adjectival rating to Factors 1 through 3 listed in Section 5.3 below. Proposals that fail to meet the Special Requirements specified in Section 3.7 should expect less favorable ratings for Factor 1. The individual merit ratings will be consolidated by the Technical Evaluation Panel members into one overall adjectival rating for each evaluation criterion.

This process may involve the use of contractors as subject matter expert (SME) consultants or reviewers. Where appropriate, the USG will employ non-disclosure agreements to protect information contained in the RPP. An Offeror's submission of a Proposal under this RPP indicates concurrence with the aforementioned use of contractors and SMEs.

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 adjectival ratings to the non-cost/price factor(s) as discussed below. The Offeror shall clearly state how it intends to meet and, if possible, exceed the RPP requirements. Mere acknowledgement or restatement of a RPP requirement is not acceptable, unless specifically stated otherwise.

For each evaluated proposal, the non-cost/price factors will each be assigned one of the following adjectival ratings:

- **Outstanding**
- **Good**
- **Acceptable**
- **Marginal**
- **Unacceptable**

5.3 Evaluation Factors

The U.S. Government will evaluate the information provided in each Offeror's Proposal to determine which Proposal(s) provide(s) the best value to the U.S. Government. Such a determination will be based on the following criteria and rated in descending order of importance:

Factor 1 – Technical Approach: This factor evaluates the relevancy, thoroughness, completeness, and feasibility of the proposed approach.

Factor 2 – Relevant Experience: This factor evaluates the offeror's demonstrated organizational experience, as well as the technical and management experience of the proposed team to perform the proposed work. The U.S. Government may also consider information in Contractor Performance Assessment Reporting System (CPARS), and the Federal Awardee Performance and Integrity Information System (FAPIIS) or similar systems.

Factor 3 – Program Management Plan: This factor evaluates the quality, thoroughness, completeness and feasibility of the proposed Program Management approach.

Factor 4 – Cost/Price: The Offeror(s) cost/price proposal will be evaluated for reasonableness. For a price to be reasonable, it must represent a price to the U.S. 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.

5.4 Cost/Price Evaluation

The Cost Proposal will receive a narrative rating to determine whether costs are realistic, reasonable, and complete.

If a proposal is selected for award, the RRPV CMF will evaluate the estimated cost proposed by the Offeror for performing all requirements outlined in this RPP. Evaluation will include analysis of the proposed cost together with all supporting information. The RRPV CMF will request additional information or clarification as necessary. The RRPV CMF will assess the reasonableness and completeness of the cost estimates and then provide a formal assessment to the Government. The Government will review this assessment and make the final determination that the project value is fair and reasonable, subject to final Government negotiations.

Proposals will be evaluated using the understanding of cost realism, reasonableness and completeness as outlined below:

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

Estimates are "realistic" when they are neither excessive nor insufficient for the effort to be accomplished. Estimates must also be realistic for each phase of the proposed project when compared to the total proposed cost.

The RRPV CMF will make a determination by directly comparing proposed costs with comparable current and historical data, evaluator experience, available estimates, etc. Proposed estimates will be compared with the corresponding technical proposals for consistency.

b) Reasonableness. The Offeror's cost proposal will be evaluated to determine if it is reasonable. For a price to be reasonable, it must represent a price to the Government that a prudent person would pay in the conduct of competitive business. Normally, price reasonableness is established through cost and price analysis.

To be considered reasonable, the Offeror's cost estimate should be developed from applicable historic cost data. The Offeror should show that sound, rational judgment was used in deriving and applying cost methodologies. Appropriate narrative explanation and justification should be provided for critical cost elements. The overall estimate should be presented in a coherent, organized, and systematic manner.

Costs provided shall be clearly attributable to activities or materials as described by the Offeror. Costs should be broken down in the Cost Proposal Format. An optional template is located on the Members-Only RRPV website.

c) Completeness. The RRPV CMF will evaluate whether the proposal clearly and thoroughly documents the rationale supporting the proposed cost and is compliant with the requirements of the solicitation.

The proposal should clearly and thoroughly document the cost/price information supporting the proposed cost in sufficient detail and depth. The RRPV CMF will evaluate whether the Offeror's cost proposal is complete with respect to the work proposed. The RRPV CMF will consider substantiation of proposed cost (i.e., supporting data and estimating rationale) for all elements.

Rate and pricing information is required to properly perform the cost analysis of the proposal. If the Offeror is unwilling to provide this information in a timely manner, its proposal will be lacking information that is required to properly evaluate the proposal and the proposal may not be selected for award.

5.5 Best Value

The Government will conduct the source selection based on the evaluation criteria and ratings listed above. The overall award decision will be based upon a Best Value determination by considering and comparing factors in addition to cost or price. Funding recommendations depend on various factors and programmatic relevance. Based on the evaluation of the Technical Approach, Relevant Experience, and Cost/Price, the Government reserves the right to negotiate and request changes to any or all parts of the

SOW. Offerors will have the opportunity to concur with the requested changes, propose further changes and revise cost proposals, as necessary.

5.6 Evaluation Results

Following the evaluation, the Source Selection Authority may:

1. Select the proposal (or some portion of the proposal) for award;
2. Place the proposal in the Basket if funding currently is unavailable; or
3. Reject the proposal (will not be considered for award and will not be placed in the Basket)

The Government does not guarantee a minimum or maximum number of awards resulting from this solicitation.

5.7 Basket Provision

The electronic "Basket" is an innovative acquisition tool. Proposals rated as Acceptable through Outstanding, but not immediately selected for award, may be placed in the Basket (at the Government's sole discretion) for two (2) years and eligible for award during that time. Proposals rated as Unacceptable will not be placed in the Basket and will not be eligible for future award. If awarding from the Basket, the Government reserves the right to award whichever proposal best meets its needs.

6 Points of Contact

Questions related to this RPP should be directed to Ms. Rebecca Harmon (rrpv-contracts@ati.org).

All technical questions must be submitted by April 24, 2025, at 12:00 PM Eastern Time**,** to allow for Government response. The Government will respond to questions at its discretion. All questions and responses will be posted to the RRPV Solicitation webpage https://www.rrpv.org/opportunities/. Questions received after the stated deadline are not guaranteed a response.

Once an Offeror has submitted a Proposal, the Government and the RRPV CMF will not discuss evaluation/status until the evaluation results have been provided to the Offerors.

ATTACHMENT A – TECHNICAL PROPOSAL TEMPLATE

General Instructions

The Technical Proposal must address the technical requirements described in the RPP in sufficient detail to permit evaluation from a technical perspective in accordance with the evaluation factors set forth in the RPP. The Technical Proposal shall be single-spaced, single-sided, and 8.5 x 11 inches, and 12-point font. Smaller type may be used in figures and tables but must be clearly legible. Margins on all sides (top, bottom, left, and right) should be at least 1 inch. Offerors are strongly encouraged to use pictures and graphics to succinctly represent proposed ideas, organization, etc.

The Technical Proposal shall be limited to 35 pages excluding all attachments (unless otherwise noted below). Pages in excess of this limitation may not be considered**.** Offerors are advised that the number of pages should be commensurate with the degree of complexity of the proposed effort.

To ensure Technical Proposals receive proper consideration, **the Technical Proposal format shown below is mandatory**. If there are any items which are not applicable to a specific proposal, include the section topic in the proposal with a short explanation as to why it is not applicable.

1. Cover Page*
2. RRPV Member Organization Information Sheet*
3. Executive Summary & Eligibility
    - Mandatory Eligibility Criteria Table* (supporting documentation as separate attachments)
    - Executive Summary
4. Technical Approach
5. Program Management Plan (See Attachment D)
6. Cost Realism
7. Current Government Support
8. Data Rights*

*Excluded from page limitation

1. Technical Proposal Cover Page

[Name of Offeror]
[Address of Offeror]

RPP Number RRPV 24-07- CentralIEIDLab

[Proposal Title]

[Offeror] certifies that, if selected for award, the Offeror will abide by the terms and conditions of the RRPV Base Agreement.

[Offeror] certifies that this Proposal is valid for 180 days from the close of the applicable RPP, unless otherwise stated.

[As detailed in Section 2.6 of the Request for Project Proposals, Offerors are to include a proprietary data disclosure statement/legend if proprietary data is included. Sample: *This Proposal includes data that shall not be disclosed outside the RRPV Consortium Management Firm and the Government. It shall not be duplicated, used, or disclosed, in whole or in part, for any purpose other than proposal evaluation and agreement administration. The data subject to this restriction is (clearly identify) and contained on pages (insert page numbers).*]

2. Member Information Sheet

If an item is not applicable, then that section should be listed as “not applicable.”

OFFEROR NAME:	
ALL PLACES OF PERFORMANCE:	
TITLE OF PROPOSED EFFORT:	
UEI # (if applicable):	
CAGE CODE (if applicable):	
SMALL BUSINESS (YES/NO):	
SMALL/DISADVANTAGED BUSINESS (YES/NO): SOCIOECONOMIC CATEGORY?	
CONFLICT OF INTEREST (YES/NO):	
TOTAL COST OF PROPOSAL:	
PROPOSED PERIOD OF PERFORMANCE IN MONTHS:	
PREFERRED PAYMENT METHOD (FFP, CPFF, Cost Reimbursable (CR), CR/COST SHARE):	
REQUESTED USE OF GOVERNMENT RESOURCES, PROPERTY, LABS, ETC. (YES/NO):	
CONTRACT/NEGOTIATION CONTACT (NAME, ADDRESS, PHONE, EMAIL):	
TECHNICAL/PRINCIPAL INVESTIGATOR CONTACT (NAME, ADDRESS, PHONE, EMAIL):	
COGNIZANT RATE AUDIT AGENCY OFFICE (IF KNOWN, INCLUDE POC, ADDRESS, PHONE #, E-MAIL):	

3. Executive Summary & Eligibility

Mandatory Eligibility Criteria

Clearly indicate if your organization and proposal address each of the "Mandatory Eligibility Criteria" listed in Section 2.7 of this RPP. Supporting documents for meeting the mandatory eligibility criteria must be provided as attachments to the proposals, and other evidence must reference the section and page number within the proposal.

	Criterion	Meets?	Reference (Section and Page #)	Supporting Documentation provided? (If Yes, provide document/File Name)
1.	Offerors submitting proposals must be RRPV members when the proposal is submitted.	Yes/No		
2.	Offerors must provide supporting documents that demonstrate their immunoassay laboratory previously qualified and/or validated hemagglutination inhibition (HAI) assay and microneutralization (MN) assay for seasonal or zoonotic (specifically non-H1, non-H3, non-B) influenza virus strains.	Yes/No		Yes/No
3.	i. Offeror must provide evidence of relevant experience that supports organizational capacity and technical expertise to serve as the central influenza and emerging infectious diseases immunoassay laboratory	Yes/No		Yes/No
	ii. Offeror must, at minimum, qualify and validate influenza virus HAI and MN assays and conduct assay concordance studies	Yes/No		Yes/No
	iii. Offeror must perform influenza virus HAI and MN testing to support clinical trials	Yes/No		Yes/No
4.	The Offeror must provide a list of existing or proposed partnerships to address capability areas three (3) through six (6) if the Offeror does not have the in-house expertise. The Offeror must provide a letter of commitment from the proposed partner indicating a willingness to perform the specific duties under the capability area under which they will perform to fulfill the Government's needs.	Yes/No		Yes/No
5.	The central influenza and emerging infectious diseases immunoassay laboratory must be based in the continental U.S.	Yes/No		

Failure to address each mandatory eligibility criteria may result in your submission being removed from further consideration with no further evaluation being performed nor feedback being provided.]

[The Executive Summary allows Offerors to briefly and concisely present the important aspects of their proposals to evaluators. The summary should present an organized progression of the work to be accomplished, without the technical details, such that the reader can grasp the core concepts of the proposed project.]

4. Technical Approach

[Provide sufficient technical detail and analysis to support the technical solution being proposed for the project. Clearly identify the core of the intended approach. It is not effective simply to address a variety of possible solutions to the technology problems. Provide the following information:]

1. **Background:** [Describe the problem that the proposal is addressing.]
2. **General Approach:** [Briefly describe your overarching approach and framework addressing the requirements set forth in the RPP. Include relevant background data and information on your platform or solution and list the current status of your approach.]
3. **Objectives:** [Specify the objectives of the proposed effort.]
4. **Relevant Experience:** [Identify relevant experience, as well as the technical and management experience of the proposed team, to perform the proposed work. **Offeror should also describe any history of utilizing standardization plans to ensure that teaming partners follow the same structure.]**
5. **Technical Strategy**: [Thoroughly describe the detailed and stepwise approach on how your organization intends to address each technical requirement set forth in the RPP and show a clear course of action to also include standardization plans.]
6. **Risk & Mitigation:** [Identify key technical, schedule, and cost risks, their potential impact and mitigation.]
7. **Organizational Conflict of Interest:** [An Organizational Conflict of Interest can occur, but is not limited to, when an individual or an entity is unable, or potentially unable, to provide impartial advice or service to the Government or separate entity because of other business activities or relationships. Disclose any potential conflict of interest pertaining to this opportunity. If none, state as such.]
8. **Period of Performance:** [Identify the proposed Period of Performance (PoP) in months from award.]
9. **Offeror Resources**: [Identify any key facilities, equipment and other resources proposed for the effort. Identified facilities, equipment and resources should be available and relevant for the technical solution being proposed.]
10. **Government Resources**: [Identify any key Government facilities, Government equipment, Government property, etc. that your organization requests to use for the effort.]

11. **Cost Realism:** [This section provides technical evaluators with high-level cost data in order for the evaluators to determine if the costs proposed are realistic as compared to the scope of work proposed. This information must be consistent with the Cost Proposal. The information must be provided in this section of the Technical Proposal. Include the following table as a summary of the costs by cost element.]
12. **Proposed Cost Share:** [If applicable, this section provides technical evaluators with information on any additional cost share proposed by the Offeror. If proposing cost share, identify deliverables that are associated with cost shared resources as well as the technical benefit resulting from this resource.]

5. Program Management Plan

[Please include completed Program Management Plan (Attachment D). Not to exceed 5 pages.]

Cost Realism Form EXAMPLE This form is to be completed by Offeror and evaluated by Technical Evaluators. Items in italics are provided as samples only. Offeror must complete table with the applicable information.			
Cost Element	**Tasks**	**Total**	**Description/Explanation**
Labor	*$XXXX*	*$XXXX*	*XXX hrs of XXX; XXX hrs of XXX; XXX hrs of XXX; XXX hrs of XXX*
Labor Hours	*XXX*	*XXX*	
Sub-performers	*$XXXX*	*$XXXX*	*Sub A - $$$$; XXX hrs of XXX* *Sub B - $$$; XXX hrs of XXX*
Sub-performer Hours	*XXX*	*XXX*	
Consultants	*$XXXX*	*$XXXX*	*____ consultant supporting all phases*
Consultant Hours	*XXX*	*XXX*	
Material/Equipment	*$XXXX*	*$XXXX*	*XXX, YYY, ZZZ*
Other Direct Costs	*$XXXX*	*$XXXX*	*YYYYY*
Travel	*$XXXX*	*$XXXX*	*## trips for # people for # days from _____ to ____ for _____*
Indirect Costs	*$XXXX*	*$XXXX*	*approved by DHHS 30 Sept 23*
Fee	*$XXXX*	*$XXXX*	*Not applicable if cost share proposed*
Total Cost to Government	*$XXXXXX*	*$XXXXXX*	
Additional Offeror-Provided Cost Share	*$XXXX*	*$XXXX*	
Total Project Value	***$XXXXXX***	***$XXXXXX***	

7. Current Government Support

Current
Award Number:
Title:
Funding Agency/Requiring Activity:
Dates of Funding:
Total Direct Costs:
Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*
Brief summary of the scope of work:

Award Number:
Title:
Funding Agency/Requiring Activity:
Dates of Funding:
Total Direct Costs:
Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*
Brief summary of the scope of work:

[Add additional fields, if needed, to report all current support]

8. Resumes of Personnel

Include the resumes of personnel from the Offeror's organization, as well as sub-performers or consultants, who will work on this project if selected (each no greater than 3 pages).

Submit to BARDA appropriate qualified scientific, technical, managerial personnel information (e.g., curricula vitae (CVs), current training certificates or records (each no greater than 3 pages).

ATTACHMENT B – COST PROPOSAL TEMPLATE

General Instructions

The objective of the Cost Proposal is to provide sufficient cost information to substantiate that the proposed cost is realistic, reasonable, and complete for the proposed work. The Cost Proposal should provide enough information to ensure that a complete and fair evaluation of the reasonableness and realism of cost or price can be conducted and reflect the best estimate of the costs for the project. The Cost Proposal must be consistent with information provided in the Technical Proposal (i.e., costs, cost share, dates, etc.). Proposals that deviate substantially from these guidelines or that omit substantial parts or sections may be found non-responsive and may be eliminated from further review and funding consideration.

To ensure Cost Proposals receive proper consideration, it is mandatory that the Cost Proposal include the information below.

Section I: Cost Proposal Narrative

a. Cover Page
b. Overview
c. Cost Information

Section II: Cost Proposal Format

The Cost Proposal Narrative is used to assess various criteria. This section will be used to determine reasonableness, allowability, and allocability of costs. The Cost Proposal Narrative section should provide a more detailed breakdown of the figures that are contained in the Cost Proposal Format. The Cost Proposal Narrative section also should give substantiation and written explanation of proposed costs. Breakdowns should be as accurate and specific as possible. Ensure that any figures presented in this part are consistent with the figures in the Cost Proposal Format.

Separately, the Cost Proposal Format must be provided in Excel, with working formulas to the maximum extent practicable. Optional formats are available on the Members-Only website. However, Offerors are encouraged to use their own formats so long as the required level of detail is provided.

1. Cost Proposal Cover Page

[Name of Offeror]
[Address of Offeror]

RPP Number RRPV-24-07- CentralIEIDLab

[Proposal Title]

[Offeror] certifies that, if selected for award, the Offeror will abide by the terms and conditions of the RRPV Base Agreement.

[Offeror] certifies that this Proposal is valid for 180 days from the close of the applicable RPP, unless otherwise stated.

[As detailed in Section 2.6 of the Request for Project Proposals, Offerors are to include a proprietary data disclosure statement/legend if proprietary data is included. Sample: *This Proposal includes data that shall not be disclosed outside the RRPV Consortium Management Firm and the Government. It shall not be duplicated, used, or disclosed, in whole or in part, for any purpose other than proposal evaluation and agreement administration. The data subject to this restriction is (clearly identify) and contained on pages (insert page numbers).*]

2. Cost Proposal Section I: Cost Proposal Narrative Template

1. Cost Proposal Narrative Overview

[The Cost Proposal Narrative must include sufficient information to evaluate the proposed value through cost information. This information is required to properly perform the cost and/or price analysis of a proposal. Proposals without this information cannot be properly evaluated and may be eliminated from selection for award. All Proposals must provide the following information as part of the Cost Proposal Narrative Overview:]

1. **Overall Approach.** [Provide an overall and succinct explanation of how this Proposal is justified.]
2. **Assumptions.** [Provide any assumptions. Note that assumptions should be limited to cost or pricing. Technical assumptions are better captured in the Statement of Work.]
3. **Preferred Payment Method.** [Identify which of the payment methods is preferred. The methods are (1) Cost Reimbursable Milestones (with ceiling), (2) Cost Reimbursable/Cost Share (with ceiling), (3) Cost Plus Fixed Fee Milestones (with ceiling) and (4) Fixed Price Milestones (with ceiling).]
4. **Total Cost Elements by Stage.** [Include a cost-by-cost element breakout of the costs]

2. Cost Proposal Narrative Cost Data

[The Cost Proposal Narrative must include the following cost categories and details, at a minimum.]

1. **Labor Rates**. [Portions of labor information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Identify the position title of all personnel, the labor category description, the hourly rate for each individual, and estimated hours for each labor category proposed. If an approved organizational estimating procedure uses average labor rates for specific labor categories, this would be acceptable.

   It is recognized that an organization may not be able to identify all of the personnel to be assigned to the project several years in advance. Where this cannot be done, use generic position titles such as “scientist.” If direct labor costs include allocated direct costs or other direct costs in accordance with established accounting and estimating practices and systems, identify these costs separately and provide an explanation and basis for proposed costs.

   Provide an explanation for any proposed labor escalation.

Offerors are expected to avoid overtime as much as practicable, except when lower overall costs to the Government will result or when it is necessary to meet urgent program needs. If overtime is proposed, provide an explanation as to why.]

2. **Salary Rate Limitation.** [Payment of the direct salary of an individual at a rate in excess of the Federal Executive Schedule Level II is an unallowable cost under the RRPV OTA and shall be addressed in accordance the RRPV Base Agreement.

   For purposes of the salary rate limitation, the terms "direct salary," "salary," and "institutional base salary" have the same meaning and are collectively referred to as "direct salary." An individual's direct salary is the annual compensation that the entity pays for an individual's direct effort (costs). Direct salary excludes any income that an individual may be permitted to earn outside of duties to the entity. Direct salary also excludes fringe benefits, overhead, and general and administrative expenses (also referred to as indirect costs or facilities and administrative [F&A] costs).

   The salary rate limitation does not restrict the salary that an entity may pay an individual; it merely limits the portion of that salary that may be paid with Federal funds.

   See the salaries and wages pay tables on the US Office of Personnel Management website for Federal Executive Schedule salary levels that apply to the current period. See the RRPV Base Agreement for further details.]

3. **Fringe Benefits.** [Identify whether or not the proposed labor rates include fringe costs. If so, then identify the percentage rate. If not, then provide a statement to that effect and include the fringe costs in the indirect section instead.]

4. **Travel.** [Portions of travel information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Identify the total travel amount proposed. Provide an estimate of the cost per trip; number of trips; number of days; number of persons; departure city, destination city; approximate travel time frames; and the purpose of the travel. The key is to apply best estimating techniques that are auditable. Include a brief explanation of the methodology used to estimate travel costs. If exact destination is unknown at time of proposal, for pricing purposes use a potential location using best known information. Note that RRPV project awardees are expected to be cost-conscious regarding travel (e.g., using coach rather than first class accommodations and, whenever possible, using Government per diem, or similar regulations, as a guideline for lodging and subsistence costs). If travel is estimated based on an approved methodology, then state as such.]

5. **Sub-performers/Consultants.** [Portions of sub-performer/consultant information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical.

Provide a list of all sub-performers/consultants and a total cost for each. If a cost and/or price analysis has been performed, provide a copy or summary of results.

Support is required for each sub-performer/consultant as follows:

- If a sub-performer/consultant is based on commercial pricing, provide an explanation of the commerciality determination and supporting documentation (e.g., website pricing, catalogue pricing, etc.)
- For a sub-performer /consultant less than $250,000, provide a brief explanation of the work to be performed.
- For a sub-performer/consultant greater than $250,000 and less than or equal to $2,000,000, provide a supporting quote and confirmation of compliance with the Salary Rate Limitation.
- If a sub-performer /consultant over $2,000,000 was competitively solicited, provide the price analysis showing how the price was determined reasonable, summary of competition, and copies of the competitive quotes.
- Absent any of the above, if relying on cost data for a sub-performer /consultant greater than $2,000,000, a cost-by-cost element breakout must be provided to the same level of detail as the Offeror.]

6. **Material/Equipment/Other Direct Costs.** [Portions of the material/equipment/other direct cost information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Provide an itemized list of the material/equipment/other direct costs, including the itemized unit cost and quantity. Identify the supplier/manufacturer and basis of cost (i.e., vendor quote, catalog pricing data, past purchase orders, etc.) for each item, if known. Additionally, a copy of the basis of cost documentation for each piece of proposed material/equipment/other direct cost with a unit cost greater than or equal to $25,000, or total cost greater than or equal to $150,000, must be provided. If material/equipment/other direct cost is estimated based on an approved methodology, then state as such.

   If any sort of usage cost is determined by a rate, identify the basis and rational used to derive the rate.

   Only in extraordinary circumstances will government funds be used to purchase equipment. Examples of acceptable equipment might include special test equipment, special tooling, or other specialized equipment specific to the effort. This award is not an assistance agreement/instrument and Offerors should normally have the required equipment to perform. The value of equipment should be prorated according to the share of total use

dedicated to carrying out the proposed work. Include a brief explanation of the prorating methodology used.]

7. **Indirect Costs.** [Portions of the indirect cost information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Provide an estimate of the total indirect costs, identify each rate used in the proposal, and provide documentation to support the indirect cost rates by one of the below methods.
    a. Provide a copy of certification from a Federal agency indicating these indirect rates are approved by the Federal agency;
    b. Provide a letter from the Offeror's Administrative Contracting Officer, in lieu of a rate certificate, stating these indirect rates are approved by a Federal agency;
    c. Provide a copy of current forward pricing rate proposal with date proposal was submitted to the Administrative Contracting Officer; or
    d. Absent Government-approved rates, provide detailed supporting data to include (1) indirect rates and all pricing factors that were used; (2) methodology used for determining the rates (e.g., current experience in the organization or the history base used); and (3) all factors, by year, applied to derive the proposed rates.

    Alternately, in lieu of providing indirect rates, if the Offeror can obtain appropriate Government assistance, it may provide a letter from the cognizant Federal audit agency stating that, based upon their review of the Offeror's proposal, the indirect rates used in the proposal are approved by a Federal agency and were applied correctly in this specific proposal. If the Offeror elects to rely on these Government inputs, it is responsible for ensuring any Government agency cooperation is obtained so that the proposal is complete when submitted.]

8. **Fee/Profit.** [State the fee/profit percentage, if proposed. Fee/Profit is allowable for the effort being conducted. The fees shall be specific to the individual RRPV project and negotiated on a project-by-project basis.]

9. **Cost Share.** [Identify if any Cost Share is proposed. Cost Share includes any costs a reasonable person would incur to carry out (necessary to) proposed project's Statement of Work not directly paid for by the Government. If a proposal includes cost share, then it cannot include fee. Cost Share may be proposed only on cost-type agreements. There are two types of cost sharing, Cash Contribution and In-Kind Contribution:

    Cash Contribution:
    Cash Contribution means the Project Awardee (or Awardees' lower tier subawards) financial resources expended to perform a Project Award. The cash contribution may be derived from the Project Awardee (or Awardees' subawards) funds or outside sources, from nonfederal contract or grant revenues, or from profit or fee on a federal procurement contract.

An Offeror's own source of funds may include corporate retained earnings, current or prospective Independent Research and Development (IR&D) funds, or any other indirect cost pool allocation. New or concurrent IR&D funds may be utilized as a cash contribution provided those funds identified by the Offeror will be spent on performance of the Statement of Work (SOW) of a Project Award or specific tasks identified within the SOW of a Project Award. Prior IR&D funds will not be considered as part of the Offeror's Cost Share.

Cash contributions include the funds the Offeror will spend for labor (including benefits and direct overhead), materials, new equipment (prorated if appropriate), awardees' subaward efforts expended on the SOW of a Project Award, and restocking the parts and material consumed.

In-Kind Contribution:
In-Kind Contribution means the Offeror's non-financial resources expended to perform a Project Award such as wear and tear on in-place capital assets like machinery or the prorated value of space used for performance of the Project Award, and the reasonable fair market value (appropriately prorated) of equipment, materials, IP, and other property used in the performance of the SOW of the Project Award.

Prior IR&D funds will not be considered as part of the Consortium Member's cash or In-Kind contributions, except when using the same procedures as those that authorize Pre-Award Costs, nor will fees be considered on cost share.

If cost share is proposed, the following must be provided:

- A description of each cost share item proposed;
- Proposed dollar value of each cost share item proposed; and
- The valuation technique used to derive the cost share amounts (e.g., vendor quote, historical cost, labor hours and labor rates, number of trips, etc.).]

10. **Small Business Utilization:** Small businesses utilization is encouraged to the maximum extent practicable under the RRPV OTA. To be a small business, an organization must first be a for-profit legal structure. Next, it must qualify with the Small Business Association's (SBA) size standards, which are structured by NAICS Code (see https://www.sba.gov/document/support-table-size-standards for more details). Lastly, some small businesses participate in one or more additional programs with the Small Business Administration (see https://www.hhs.gov/grants-contracts/small-business-support/programs-supporting-small-businesses/index.html for more details).

As part of the Cost Narrative, provide details on any significant small business utilization proposed, similar to the below chart. Participation can include the Offeror, sub-performers, consultants, material providers, service providers, etc.

Small Business Name	NAICS Code	Proposed $ Value	Task Involvement	SBA Program*

*[*Can include: 8(a) Business Development; HUBZone; Service-disabled-veteran-owned; small-disadvantaged-business; and/or Women-owned-small-business. Otherwise, list N/A.]*

3. Cost Proposal Section II: Cost Proposal Format

[The Cost Proposal Format must be provided as a separate Excel document. Offerors are encouraged to use their own Excel cost formats so long as the necessary cost detail is provided. Working formulas should be included to the maximum extent possible. The Cost Proposal Formats provided on the RRPV Members-Only website are ***NOT*** mandatory.

The Cost Proposal Format section must include cost-by-element detail broken out by the Offeror's fiscal year. **As required by the RPP, costs must also be broken out by Capability to match the technical requirements and objectives**.

Supporting data and justification for labor, equipment/material, team member/sub-performer, consultants, travel, other direct costs, indirect costs, and profit used in developing the cost breakdown also must be included. The Offeror must provide sufficient details to allow a full understanding of and justification for the proposed costs. Offerors must refer to the RPP for a start date for cost estimating purposes.]

ATTACHMENT C – STATEMENT OF WORK (SOW) TEMPLATE

[The SOW developed by the Lead RRPV member organization and included in the proposal (also submitted as a separate document) is intended to be incorporated into a binding agreement if the proposal is selected for award. If no SOW is submitted with the proposal, there may be no award. The proposed SOW shall contain a summary description of the technical methodology as well as the task description, but not in so much detail as to make the contract inflexible. The following is the required format for the SOW.]

Statement of Work

Submitted under Request for Project Proposals (RRPV 24-07- CentralIEIDLab**)**
Proposed Project Title:
RRPV Member Organization Name:
RRPV Member Primary Place of Performance:

1.0 Introduction/Background (*To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.)*

2.0 Scope/Project Objective (*To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.)*

This section includes a statement of what the project covers. This should include the technology area to be investigated, the objectives/goals, and major milestones for the effort.

3.0 Requirements *(To be provided initially by the Offeror at the time of proposal submission to be finalized by the Government based on negotiation of Scope/Project Objective.)*

State the technology objective in the first paragraph and follow with delineated tasks required to meet the overall project goals. The work effort should be segregated into major phases, then tasks and identified in separately numbered paragraphs (similar to the numbered breakdown of these paragraphs). Early phases in which the performance definition is known shall be detailed by subtask with defined work to be performed. Planned incrementally funded phases will require broader, more flexible tasks that are priced up front, and adjusted as required during execution and/or requested by the Government to obtain a technical solution. Tasks will need to track with established adjustable cost or fixed price milestones for payment schedule. Each major task included in the SOW should be priced separately in the cost proposal. Subtasks need not be priced separately in the cost proposal.

4.0 Deliverables (*To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.)*

Results of the technical effort are contractually binding and shall be identified herein. Offerors are advised to read the Base Agreement carefully. Any and all hardware/software to be provided to the Government as a result of this project shall be identified. Deliverables should be submitted in PDF or MS Office format. It must be clear what information will be included in a deliverable either through a descriptive title or elaborating text.

Below are the following minimum deliverables for this RPP:

1.0 Meetings		
1.1 Kickoff Meeting	**Deliverable Description**	• The Performer must complete a Kickoff meeting after the initiation of the agreement period of performance.
	Reporting Procedures and Due Dates	•Within 10 business days after the initiation of the agreement period of performance, pending concurrence by the Agreements Officer •Performer must submit agenda and itinerary, if applicable, at least 5 business days in advance of in-person meeting or teleconference •PAR edits/approves and instructs Performer to distribute agenda at least 3 business days prior to meeting •Performer submits meeting minutes to PAR within 3 business days after the meeting •PAR reviews, comments, and approves minutes within 10 business days
1.2 Monthly Teleconference	**Deliverable Description**	The Performer must participate in teleconferences monthly with BARDA to discuss the technical performance on the agreement. Meeting frequency may be increased or decreased as needed during the course of the project.
	Reporting Procedures and Due Dates	•Performer must submit agenda to PAR no later than 2 business days in advance of meeting •PAR edits/approves and instructs Performer to distribute agenda prior to meeting •Performer must distribute agenda and presentation materials at least 2 business days in advance of meeting •Performer must submit meeting minutes to PAR within 3 business days of the meeting •PAR reviews, comments, and approves minutes within 10 business days
1.3 Technical, Subgroup, Ad Hoc Teleconference (s)	**Deliverable Description**	The Performer must participate in technical, subgroup, or ad hoc teleconferences as needed or upon BARDA request to discuss the technical performance on the agreement. Meeting frequency may be defined as needed during the course of the project.
	Reporting Procedures and Due Dates	•Performer must submit agenda to PAR no later than 2 business days in advance of Technical or Subgroup meeting •PAR edits/approves and instructs Performer to distribute agenda prior to meeting •Performer must distribute agenda and presentation materials at least 24 hours in advance of meeting •Performer must submit meeting minutes to PAR within 3 business days of the meeting •PAR reviews, comments, and approves minutes within 6 business days

1.0 Meetings		
1.4 Periodic Review Meetings	Deliverable Description	At the discretion of the Government, the Performer 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 Performer or sub-performers. Face-to-face meetings shall alternate between Washington, D.C. and Performer, sub-performer sites. The meetings will be used to discuss agreement progress in relation to the Program Management deliverables described in this agreement as well as non-clinical, technical, regulatory, and ethical aspects of the program.
	Reporting Procedures and Due Dates	•Performer must submit an agenda and itinerary, if applicable, at least 5 business days, and Performer must provide presentation materials at least 3 business days, in advance of the meeting •PAR edits/approves and instructs Performer to distribute agenda prior to meeting by at least 3 business days •Performer provides meeting minutes to PAR within 3 business days after the meeting •PAR reviews, comments, and approves minutes within 10 business days
1.5 Reporting of New and Departing Employees	Deliverable Description	The Performer must disclose to the PAR and AO staffing changes for positions that require suitability investigations within 7 days.
	Reporting Procedures and Due Dates	Performer updates PAR and AO within 7 days following staffing changes for positions that require suitability investigations.

2.0 Technical Reporting: General		
2.1 Project Management Plan (PMP)	Deliverable Description	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 Performer and sub-performer team(s). 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.
	Reporting Procedures and Due Dates	•Performer must submit a Project Management Plan (PMP) • Within 30 calendar days after the initiation of the agreement period of performance • Updates should be provided to reflect any key changes and reviewed at least annually.
2.2 Gantt Chart/Timeline	Deliverable Description	The Gantt Chart/Timeline should be detailed to the extent required by the specific project.
	Reporting Procedures and Due Dates	•At first project meeting and as updated no later than every 30 calendar days. •The Performer must submit in both PDF and an agreed-upon electronic format (e.g., Microsoft Project) to the PAR

2.0 Technical Reporting: General		
2.3 **Communication Plan**	**Deliverable Description**	The Performer must develop and implement an effective Communication Plan that details the flow of information between BARDA, Performer, collaborators, vendors, and other organizations. The Communication Plan must also include a press release review process.
	Reporting Procedures and Due Dates	•Performer must submit a Communication Plan • Within 30 calendar days after the initiation of the agreement period of performance • Updates should be provided to reflect any key changes and reviewed at least annually.
2.4 **Performer Locations**	**Deliverable Description**	The Performer must submit detailed data regarding locations where work will be performed under this agreement, including addresses, points of contact, and work performed per location, to include sub-Performers and critical vendors of reagents and supplies. Performers must include vendors for critical infrastructure protection.
	Reporting Procedures and Due Dates	•Performer must submit Work Locations Report: • Within 5 calendar days after the initiation of the agreement period of performance • 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 threat that has been declared a Public Health Emergency by the HHS Secretary
2.5 **Request for Information (RFI) Responses**	**Deliverable Description**	Upon request of the Government, the Performer must provide complete responses to ad hoc RFIs. RFIs 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 Performer must provide the response in both confidential and non-confidential formats.
	Reporting Procedures and Due Dates	Performer must submit an RFI response to BARDA by email within 24 hours after Performer receipt of the RFI.

2.0 Technical Reporting: General		
2.6 **Monthly & Annual Technical Progress Reports/Annual Meeting**	**Deliverable Description**	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. 1. An Executive Summary highlighting the progress, issues and relevant, non-clinical, regulatory, and publication activities. The Executive Summary should highlight all critical issues, risks, and mitigations for that reporting period and resolution approach; limited to 2 pages 2. Progress in meeting agreement milestones organized by WBS, overall project assessment, problems encountered and recommended solutions. The reports must detail the planned and actual progress during the period covered, explaining any differences between the two and the corrective steps 3. A three-month rolling forecast of the key planned activities, referencing the WBS/IMS 4. An 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 Sub-Performers' expenses from the previous month if the Sub-performer did not submit a bill in the previous month. If the sub-performer(s) 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 sub-Performers. If the PAR and AO are satisfied that the Performer's reporting is sufficient to convey this information, this section may be waived. 5. Publication activities and progress for any manuscript, scientific meeting abstract, poster, presentation, and other public-facing material or information containing data generated under this agreement
	Reporting Procedures and Due Dates	•The Performer must submit monthly reports on the 15th day of the month covering the preceding month; Annual Reports submitted on the last calendar day of the month after each agreement 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 PAR and AO will review the monthly reports with the Performer and provide feedback •Performer must provide FINAL versions of reports within 10 business days after receiving BARDA comments/edits Performer must provide notification of designated safety events to the AO and PAR within 24 hours of being notified of the event
2.7 **Draft and Final Technical Progress Report**	**Deliverable Description**	A draft Final Technical Progress Report must contain a summation of the work performed and the results obtained over the entire agreement. This report must be in sufficient detail to fully describe the progress achieved under all milestones. Report must contain a timeline of originally planned and baselined activities and milestones overlaid with actual progress attained during the agreement. 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 agreement PoP. The final report must document the results of the entire agreement. The final

2.0 Technical Reporting: General		
		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 agreement.
	Reporting Procedures and Due Dates	•The Performer must submit the Draft Final Technical Progress Report 75 calendar days before the end of the PoP and the Final Technical Progress Report on or before the completion date of the PoP •PAR will provide feedback on draft report within 21 days of receipt, which the Performer must consider incorporating into the Final Report
2.8 **Pandemic/Public Health Emergency Facility and Operational Management Plan**	**Deliverable Description**	Performer must develop a Pandemic Facility and Operational Management Plan, including change procedures from normal to pandemic operations and continuity of operations in the event of a declared pandemic emergency. Performer must identify critical infrastructure.
	Reporting Procedures and Due Dates	•Performer must submit Pandemic Management Plan: • Draft within 15 days of award • Final within 30 days of award
2.9 **Technical Documents**	**Deliverable Description**	Upon request, Performer must provide AO and PAR with deliverables from the following activities: quality agreements between Performers and sub-Performers, process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, Certificate of Analysis. The AO and PAR reserve the right to request within the PoP a non-proprietary technical document for distribution within the Government
	Reporting Procedures and Due Dates	•Performer must provide technical document within 10 calendar days of AO or PAR request. Performer can request additional time on an as needed basis If corrective action is recommended, the Performer must address, in writing, concerns raised by BARDA in writing
2.10 **Draft and Final Technology Transfer Package**	**Deliverable Description**	The Performer must provide 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 the USG support
	Reporting Procedures and Due Dates	•Performer must provide a draft package within 20 business days Performer must revise the package within 20 business days after receiving BARDA comments to address BARDA's concerns, recommendations and/or requests for additional detail
2.11 **Raw Data, Tabulation Data (e.g., CDISC-compliant SDTM SAS XPT datasets), or Data Analysis (e.g., CDISC-compliant ADaM SAS XPT datasets) or FASTQ files**	**Deliverable Description**	Performer must provide raw data, Tabulation Data (e.g., CDISC-compliant SDTM SAS XPT datasets), or Data Analysis (e.g., CDISC-compliant ADaM SAS XPT datasets), or FASTQ files, to BARDA upon request
	Reporting Procedures and Due Dates	Performer must provide raw data, Tabulation Data (e.g., CDISC-compliant SDTM SAS XPT datasets), or Data Analysis (e.g., CDISC-compliant ADaM SAS XPT datasets), or FASTQ files to CO and COR within 20 business days after submission of the draft study report

2.0 Technical Reporting: General		
2.12 Publications	**Deliverable Description**	The Performer must submit any manuscript, scientific meeting abstract, poster, presentation, and any other public-facing material or information disseminated outside the purview of other deliverables, containing data generated under this agreement, to BARDA for review prior to submission.
	Reporting Procedures and Due Dates	• Performer must submit all manuscript or scientific meeting abstracts to PAR and AO prior to submission/presentation by 35 business days for manuscripts and 30 business days for abstracts, posters, or any other material • Performer must address in writing 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 Performer must list all publication material in the Monthly Technical Progress Report
2.13 USG Right to Publish Data	**Deliverable Description**	The Performer and Government are committed to transparent and timely publication of nonclinical data to ensure rapid distribution of information, particularly during a Public Health Emergency. Performer must provide AO and PAR with data as deemed appropriate by the government, to support publication.
	Reporting Procedures and Due Dates	Within 10 business days of a request for data from the AO, the Performer must provide AO and PAR with requested data, information and materials in the form(s) requested by the US Government, to support the US Government publication of the data funded in part or whole under this contract
2.14 Press Releases	**Deliverable Description**	Performer must provide electronically to ATI, PAR, and AO
	Reporting Procedures and Due Dates	• Not less than 10 business days prior to the issuance
2.15 Annual Licensure/Registration Documentation		• Licensure/registration or regional equivalents for, applicable USDA licenses/registration, and CDC Select Agent Registration as applicable to work proposed will be provided to AO and PAR. • Performer must provide current documentation to support each relevant accreditation, licensure, or registration annually within 30 calendar days of contract anniversary date.

3.0 Quality Assurance		
3.1 Quality Management Plan (QMP)	**Deliverable Description**	Performer 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 GCLP requirements are met. All quality management plans must include sub-performer quality management plans specifically addressing how sub-performer quality will be managed. All subPerformers must have a current quality agreement with the Performer and a recent vendor qualification audit.

3.0 Quality Assurance		
	Reporting Procedures and Due Dates	•Performer must submit a Quality Management Plan • Within 30 calendar days after the initiation of the agreement period of performance • On the 6th month agreement anniversary to include any updates.
3.2 BARDA Audit	**Deliverable Description**	Performer must accommodate periodic or ad hoc site visits, auditing, inspection and review of release documents, test results, equipment and facilities when requested by HHS. If BARDA, the Performer, or other parties identify any issues during an audit, the Performer must capture the issues, identify potential solutions, and submit a report to BARDA detailing the finding and corrective action(s). HHS reserves the right to conduct an audit, either by HHS and/or HHS designee(s), of the facilities used under this agreement and all records related to testing (including but not limited to analytical testing, nonclinical study), and storage.
	Reporting Procedures and Due Dates	•If issues are identified during the audit, Performer must submit a report to BARDA detailing the finding and corrective action(s) within 10 business days of the audit •PAR and AO will review the report and provide a response to the Performer with 10 business days •Once corrective action is completed, the Performer will provide a final report to BARDA
3.3 Quality Assurance Audits and subPerformers Monitoring Visits	**Deliverable Description**	BARDA reserves the right to participate in QA audits performed by the Performer. Upon completion of the audit/site visit the Performer must provide a report capturing the findings, results and next steps in proceeding with the subperformer. If action is requested of the subperformer, detailed concerns for addressing areas of non-conformance to FDA regulations for GCLP guidelines, as identified in the audit report, must be provided to BARDA. The Performer must provide responses from the subperformers to address these concerns and plans for corrective action. The Performer must allow for up to four (4) USG representative(s) to be present during the audit as necessary for appropriate oversight, including any other vendor involved in the conduct of the study under agreement.
	Reporting Procedures and Due Dates	•Performer must notify AO and PAR a minimum of 10 business days in advance of upcoming, audits/site visits of subperformers •Performer must notify the PAR and AO within 5 business days of report completion and provide Draft Report. •PAR and AO will review the report and provide a response to the Performer with 10 business days before audit can be finalized. •Performer must provide a final audit report and corrective and preventive actions (CAPAs) to address all findings in the report. •Performer must provide a final closeout report that all CAPAs were addressed to PAR and AO •Performer must notify BARDA within 24 hours of any critical and/or major findings

3.0 Quality Assurance		
3.4 Risk Management Plan (RMP)	**Deliverable Description**	The Performer must provide an RMP that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan must include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule, and performance.
	Reporting Procedures and Due Dates	• A Draft is due within 45 calendar days after the initiation of the agreement period of performance; updates to the RMP are due concurrent with Monthly Technical Progress Reports, but may be communicated more frequently. The Performer may choose to notify the government up to two times every three months if there are no changes from the prior submission, and not submit an update • BARDA will provide Performer with a list of concerns in response plan submitted • Performer must address, in writing, all concerns raised by BARDA within 20 business days of Performer's receipt of BARDA's concerns • The Performer must submit updates at minimum of every three months.
3.5 Integrated Master Schedule (IMS)	**Deliverable Description**	The Performer 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.
	Reporting Procedures and Due Dates	• The Performer must submit the IMS in both PDF and an agreed-upon electronic format (e.g., Microsoft Project) to the PAR • The first Draft of the IMS is due within 30 business days after the initiation of the agreement period of performance • The Government will request revisions within 10 business days, at which point the schedule baseline for the period of performance will be set • Thereafter an updated IMS is due concurrent with Monthly Technical Progress Reports • During a declared Public Health Emergency, the Performer must submit the IMS within 10 business days after the initiation of the agreement 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 PAR and/or designee.
3.6 Deviation Notification and	**Deliverable Description**	Process for changing IMS activities associated with cost and schedule as baselined. Performer must notify BARDA of significant proposed changes the IMS defined as increases in cost above 5% or schedule slippage of more than 30 days, which would require a PoP extension. Performer must provide a high-level management strategy for risk mitigation.

3.0 Quality Assurance		
Mitigation Strategy	**Reporting Procedures and Due Dates**	The Performer must submit Deviation Notification and Mitigation Strategy at least 10 business days prior to the Performer anticipating the need to implement changes
3.7 Incident Report	**Deliverable Description**	Performer 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 control account, but should be confirmed in consultation with the PAR. Incidents that present liability to the project even without cost/schedule impact.
	Reporting Procedures and Due Dates	•Due within 48 hours of activity or incident or within 24 hours for a security activity or incident •Email or telephone with written follow-up to PAR and AO •Additional updates due to PAR and AO within 48 hours of additional developments •Performer must submit within 5 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues If corrective action is deemed necessary, Performer must address in writing, its consideration of concerns raised by BARDA within 5 business days of receiving such concerns

5.0 Milestone Payment Schedule (*To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding. The milestone schedule included should be in editable format (i.e., not a picture).)*

The Milestone Payment Schedule should include all milestone deliverables that are intended to be delivered as part of the project, a planned submission date, the monetary value for that deliverable and any cost share, if applicable. For fixed price agreements, when each milestone is submitted, the RRPV member will submit an invoice for the exact amount listed on the milestone payment schedule. For cost reimbursable agreements, the RRPV member is required to assign a monetary value to each milestone. In this case, however, invoice totals are based on cost incurred and will not have to match exactly to the amounts listed on the milestone payment schedule.

The milestones and associated deliverables proposed should, in general:

- be commensurate in number to the size and duration of the project (i.e., a $5M multi-year project may have 20, while a $700K shorter term project may have only 6);
- not be structured such that multiple deliverables that might be submitted separately are included under a single milestone;

- be of sufficient monetary value to warrant generation of a deliverable and any associated invoices;
- include at a minimum Monthly Reports which include both Technical Status and Business Status Reports (due the 15th of each month), Annual Technical Report, Final Technical Report, and Final Business Status Report. Reports shall have no funding associated with them.

RRPV Milestone Payment Schedule Example						
RRPV Milestone Number	Stage #	Significant Event/ Accomplishments	Due Date	Government Funds	Cost Share	Total Funding
1	#	Kick-Off Meeting	XX/XX/XXXX	$ -	$ -	$ -
2	#	Monthly Report (Technical and Business Reports)	XX/15/XXXX	$ -	$ -	$ -
4	#		XX/XX/XXXX	$ -	$ -	$ -
5	#	Final Reports (PoP End)	XX/XX/XXXX	$ -	$ -	$ -
			Total	**$ -**	**$ -**	**$ -**
					Period of Performance (Months)	**XX Months**
					Contract Type	

Please Note:
1. Firm Fixed Price Contracts – Milestone must be complete before invoicing for fixed priced contracts.
2. Expenditure Based Contracts – You may invoice for actual costs incurred and providing a progress report on technical milestones.
3. Monthly and Annual Reports include BOTH Technical and Business Reports (separate).
4. Final Report due date must be the PoP end noted in Project Award.
5. RRPV Milestone Numbers are used for administrative purposes and should be sequential.
6. Task Numbers are used to reference the Statement of Work if they are different from the RRPV Milestone Number.

6.0 INTELLECTUAL PROPERTY, DATA RIGHTS, AND COPYRIGHTS

If the Offeror intends to provide technical data which existed prior to, or was produced outside of the proposed effort, to which the Offeror wishes to maintain additional rights, these rights should be asserted through the completion of the table below.

Note that this assertion is subject to negotiation prior to award.

Rights in such Data shall be as established under the terms of the Base Agreement, unless otherwise asserted in the proposal and agreed to by the Government. The below table lists the Awardee's assertions.

Technical Data or Computer Software to be Furnished with Restrictions	Basis for Assertion	Asserted Rights	Name of Organization Asserting Restrictions	Deliverables Affected

ATTACHMENT D – PROGRAM MANAGEMENT PLAN TEMPLATE

[The Offeror is required to provide details on their proposed approach for Program Management and sub performer management, to include:

1. **Program Management:** Provide details on proposed Program Management approach.
2. **Sub performer Management:** Provide details on proposed Sub performer Management Approach.
3. **Personnel:** Provide resumes of management and technical personnel (including proposed consultants) who possess the necessary education, training, and experience to successfully perform the work. A summary of related activities must also be provided for personnel. Include the resumes of personnel from the Offeror's organization, as well as sub-performers or consultants, who will work on this project if selected (each no greater than 3 pages. Resumes do not count toward the technical proposal page limit.) Identify the proposed management and technical personnel for the project using a summary table in the below format. Principal Investigator must be identified.

Personnel	**Organization**	**Role and Key Contribution**	**Level of Effort**
Name (Principal Investigator)			%
Name			%
Name			%
Name			%
Name			%

4. **Organizational Chart**: Organizational chart for the project with affiliations (who will report to whom).
5. **Offeror-Provided Facilities**: Details on infrastructure and other resources, such as:
    a. Overview of the management of Quality Systems at the facility;
    b. List of capabilities in house and at sub performer's facility;
    c. List of key vendors or service providers, locations, and brief description of their expertise/experience.

References:

1. CSN Clinical Related Documents for eCTD Formatting BARDA Held INDs (v. 2.0 14Jan22)
2. BARDA's Document QC Guide: A copy of this document will be provided after award and kick-off meeting, BARDA's Regulatory Operations will share and train on "BARDA's Document QC Guide", which has direct impact on FDA submissions.