

**Biomedical Advanced Research and Development Authority (BARDA)
Rapid Response Partnership Vehicle (RRPV)**



**Request for Project Proposals (RPP)
Solicitation Number: RRPV 24-02-OralVx**

“NextGen Oral Formulation Vaccines for COVID-19”

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Questions Due: 20 September 2024 by 1pm Eastern

Amendment No. 2 Issue Date: 25 October 2024

Responses Due: 15 November 2024 by 1pm Eastern

Biomedical Advanced Research Development Authority (BARDA)
Contracts Management & Acquisition (CMA)
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Amendment No. 02 does the following:

Extends proposal due date from 1 November 2024 to 15 November 2024, at 1pm Eastern.

All other terms and conditions remain unchanged.

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SOLICITATION CLOSED

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 Biomedical Research and Development Authority (BARDA).

The RRPV will help fortify national health security by developing medical countermeasures products 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.

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 www.RRPV.org. For entities interested in joining the RRPV Consortium and responding to this solicitation, please visit www.rrpv.org/how-to-join.

1.2 Purpose

Project NextGen is supporting the development of next generation COVID-19 medical countermeasures, including vaccines and therapeutics, to protect Americans from health security threats, such as novel coronaviruses, with pandemic potential. The Project NextGen Enablers Program is focused on advancing innovative vaccines and vaccination strategies, therapeutic platforms, and pharmaceutical manufacturing strategies that enable faster and lower-cost production, as well as improved access to effective medical countermeasures during public health emergencies.

BARDA is requesting project proposals from developers to advance next generation oral vaccine formulations and technologies for COVID-19 into proof-of-concept Phase 1 trials. Oral delivery of vaccines offers several potential benefits for pandemic preparedness over traditional needle/syringe-based delivery, including: ease of administration from the perspective of both those administering vaccines and people receiving vaccines; generation of mucosal immunity at the site of infection; potential for reduced cold chain reliance; and improved distribution and administration logistics.

The purpose of this project is to advance oral vaccine platforms and technologies into a proof-of-concept Phase 1 clinical trial, improve our understanding of their potential, and to provide better COVID-19 solutions and bolster preparedness and response against future health security threats.

Strategic oversight for the Project Award(s) supported by this RPP will be provided by BARDA.

2 Administrative Overview

2.1 Request for Project Proposals (RPP)

Each response submitted to this RPP shall contain a Technical Proposal and a Cost Proposal, as well as additional documents described in Section 3 of this request. ***White papers are not required for this RPP.***

2.2 RPP Approach

It is expected that there will be a total of one or more qualified respondents to accomplish the technical objectives. If an optimal team is not identified, then BARDA may direct the RRPV CMF to make multiple, individual awards to Offeror(s) to accomplish subset(s) of the key tasks.

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 U.S. Government (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.

Offerors are advised to check the RRPV website periodically during the proposal preparation period for any changes to the RRPV Base Agreement terms and conditions.

2.3 Period of Performance, Place of Performance and Type of Funding Instrument Issued

The anticipated Period of Performance (PoP) is described below:

- The anticipated PoP for Stage 1 gap-filling activities for submission of an Investigational New Drug (IND) application to the U.S. Food and Drug Administration (FDA) is up to two (2) years.
- The anticipated PoP for Stage 2 execution and completion of a proof-of-concept Phase 1 trial is up to two (2) years.

The primary place of performance is anticipated to be the Project Awardee's facilities but remains negotiable as part of each offeror's submission.

The total Government funding anticipated to be available for Stage 1 is \$15M, and the Government anticipates making up to three awards for an estimated maximum value of \$5M each. The total Government funding anticipated to be available for Stage 2 is \$16M and the Government anticipates making up to two awards, after down selecting, if necessary, for an estimated maximum value of \$8M each.

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 FY2025 Q1. The 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 selections is completed, the Government will forward their recommendations to the RRPV CMF to notify Offerors. Proposers 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 Minimum Eligibility Criteria

Offerors submitting proposals will initially be reviewed for compliance with the following minimum eligibility criteria:

- a) Offerors 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.
- b) Offerors or their partner must have demonstrated experience in vaccine development.
- c) Offerors must have key personnel on their team that have proven experience in:
 - Developing oral formulations and technologies
 - Producing, characterizing, and releasing nonclinical and clinical lots of vaccines
 - Performing nonclinical vaccine studies (if relevant) in suitable animal model(s)
 - Executing stability testing of clinical trial material
 - Developing clinical/regulatory development plans
 - Submitting and maintaining INDs to FDA for clinical trials
- d) If proposing a partnership between a vaccine developer and a company with an oral formulation or technology, then all necessary partnership and intellectual property agreements must be in place prior to proposal submission, at a minimum as demonstrated by the submission of letters of intent i with the proposal.

Proposals found to not meet these minimum eligibility criteria as detailed above **will be** removed from consideration, no further evaluation will be performed, and feedback will not be provided to these Offerors.

2.8 In/Out of Scope Criteria

The following target, vaccine platforms, and oral delivery approaches/technologies are considered in or out of scope for this RPP. Proposals that include out of scope activities will be removed from consideration.

a. In Scope:

- Medical countermeasure type: vaccine
- Vaccine target: SARS-CoV-2
- Vaccine platform/technology:
 - Vaccine platforms: mRNA, recombinant protein, virus-like particle, nanoparticle, or viral vector
 - Oral delivery technologies and approaches:
 - Oral suspension or capsule containing food-grade yeast, probiotics, or algae expressing vaccine antigens
 - Oral suspension or capsule delivering target antigen via one of the noted in-scope vaccine platforms
 - Dissolvable thin films or strips combined with one of the noted in-scope vaccine platforms

b. Out of Scope:

- Medical countermeasure type: anything that is not a vaccine (e.g., over the counter products or sprays; therapeutics)
- Vaccine target: any target other than SARS-CoV-2
- Vaccine platform/technology:
 - Any approach including a live attenuated or inactivated whole virus vaccine
 - Adenovirus vector-based vaccines

2.9 Cost Sharing

Cost sharing is defined as the resources expended by the Project Awardee on the proposed statement of work (SOW). Cost sharing is encouraged; however, it is not required in order to be eligible to receive an award under this RPP.

If cost sharing is proposed, then the Offeror shall state the amount that is being proposed and whether the cost sharing is a cash contribution or an in-kind contribution; provide a description of each cost share item proposed; the proposed dollar amount for each cost share item proposed; and the valuation technique used (e.g., vendor quote, historical cost, labor hours and labor rates, number of trips, etc.). Cost sharing is encouraged, if possible, as it leads to stronger leveraging of Government-contractor collaboration.

For more information regarding cost share, please see Attachment 2.

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 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, including all technical data deliverables, would be delivered to the 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 Government review and approval. Rights in technical data agreed to by the Government will be incorporated into the Project Award.

The Offeror shall indicate in its Proposal submission its acceptance of the terms and conditions defined in the RRPV Base Agreement regarding intellectual property and data rights.

The Offeror shall complete the table provided in Attachment 3, Statement of Work, for any items to be furnished to the Government with restrictions. An example is provided below. If the Offeror does not assert data rights on any items, a negative response in Attachment 3 is required.

Technical Data to be Furnished with Restrictions	Basis for Assertion	Asserted Rights Category	Name of Organization Asserting Restrictions	Milestone # Affected
Technical Data Description	Previously developed exclusively at private expense	Limited	Organization XYZ	Milestone 2

3 Proposals

3.1 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 may not be evaluated.

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

The Government will evaluate Proposals submitted and will select the Proposal(s) 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 Government Other Transaction Agreements Officer, is legally authorized to contractually bind or otherwise commit funding for selected Project Awards as result of this RPP.

3.2 Proposal Submission

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

A BDR Portal account is required 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, offerors will be able to complete their account registration to be able to submit a proposal.

Failure to propose your submission on time for any reason (e.g., due to late registration in BDR Portal) will result in the submission not being considered for award. Respondents 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 without a password required. Filenames shall contain the appropriate filename extension (.docx, .doc, .xlsx, or .pdf). Filenames should not contain special characters. IOS users must ensure the entire filename and path are free of spaces and special characters. The file should not exceed 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 Government and the RRPV CMF will not discuss evaluation/status until the evaluation results have been provided to the Offerors.

A receipt confirmation will be provided by email. Offerors may submit, or re-submit, in advance of the deadline. **Neither the Government nor the RRPV CMF will make allowances/exceptions for submission problems encountered by the Offeror using system-to-system interfaces. If the Offeror fails to submit the full submission prior to the deadline, the submission may not be accepted. It is the Offeror's responsibility to ensure a timely and complete submission.**

3.3 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.

3.4 Submission Format

Proposals shall reference this RPP number. **Each document below (e.g., Technical Proposal, Cost Proposal Narrative, Cost Proposal Format, and Statement of Work) is mandatory and must each be submitted as separate files and 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:

- **Technical Proposal submission (30-page limit, unless noted*) – See Attachment 1:** One Technical Proposal (.pdf, .doc or .docx). The mandatory template is provided as Attachment 1, and includes mandatory sections for a cover page*, information sheet*, executive summary and minimum eligibility requirements, technical approach, current and pending support, data rights*, key personnel resumes*, Letters of Intent (if applicable*).
- **Cost Proposal submission (no page limit) – See Attachment 2:** 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 3.5 of this RPP for additional information.
- **Statement of Work/Milestone Payment Schedule (no page limit) – See Attachment 3:** One Word (.docx or .doc). The Offeror is required to provide a detailed SOW/Milestone Payment Schedule using the mandatory template provided as Attachment 3.
- **Program/Project Management submission (5-page limit) – See Attachment 4:** One Word (.docx or .doc) or PDF file. The Offeror is required to provide details on their proposed approach for Program Management and subcontractor management. Submission should include a listing of key personnel (including proposed consultants) who possess the necessary education, training, and experience to successfully perform the work identified in the technical proposal (Note: key personnel resumes to be included in the technical proposal). A summary of related activities must also be provided for key personnel. An organizational chart for the project with affiliations (who will report to whom). Details on Offeror-provided facilities, infrastructure, and other resources, such as:
 - Manufacturing capacity expansion plans to match the proposed manufacturing scale-up;

- Overview of the management of Quality Systems at the facility;
 - List of capabilities for clinical activities conducted in-house and at contract research organizations;
 - Qualified animal facilities where Good Laboratory Practice (GLP) studies would be conducted and appropriate certifications for humane care and use of vertebrate animals;
 - Commercial capabilities of the Offeror, including current products, and marketing, distribution, and customer support capabilities (as applicable); and
 - List of key vendors or service providers, locations, and brief description of their expertise/experience.
- **ASPR Security Requirements Attestation Statement (no page limit) – See Attachment 5.** One Word (.docx or .doc) or PDF file. Included with Project Proposals, Offerors must include a statement attesting to their intent and ability to comply with the deliverables and security requirements within the deadline dates stated in Attachment 5.

3.5 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 format provides 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, travel and ODC costs as applicable.

For scheduling and pricing purposes, Offerors should assume that all Base Period objectives and task may occur concurrently to support cost and schedule savings. If Optional tasks are included in the Project Award, Offerors should assume that a Project Award modification will be required to begin an optional task.

3.6 Restrictions on Animal and Human Subjects

Project Awardees must comply with restrictions and reporting requirements for the use of animal and human subjects, as addressed in further detail in the RRPV Base Agreement. It is anticipated that the Project Award(s) issued under this RPP will require the following:

- The Project Awardee shall serve as regulatory product sponsor and be responsible for any regulatory submissions to the US FDA.
- Support and maintain regulatory submissions throughout life of the project.
- The Project Awardee must submit to the Government all regulatory and supporting documentation related to therapeutic development, manufacturing, lot releasing, certificates of analysis, analytical development, stability, nonclinical and clinical testing as well as other related documentation.

- The Project Awardee shall cross-reference any applicable regulatory files, such as IND applications, Master Files, and Biologics License Applications (BLAs) prior to the conduct of the studies and shall allow cross-referencing of these documents associated with this effort.

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.

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4 Technical Requirements

4.1 Introduction

BARDA is seeking proposals for development of new technologies and other capabilities that decrease costs, speed production, increase efficacy, and/or improve access of vaccine platforms/technologies. BARDA has previously identified that response to an emerging infectious disease is enabled by robust and flexible platform technologies that can be pivoted to address the new pathogen. The purpose of this project is to partner with developers to advance flexible oral vaccine delivery platforms and technologies into a proof-of-concept Phase 1 trial. The goal of this project is to provide better COVID-19 solutions that also have the potential to be leveraged against future health security threats.

4.2 Scope

This project supports conducting limited, gap-filling studies or activities to enable submission of an IND application to the US FDA and execution of a proof-of-concept Phase 1 trial with an orally administered COVID-19 vaccine.

4.3 Objectives

A. Oral vaccine formulation/technology platforms

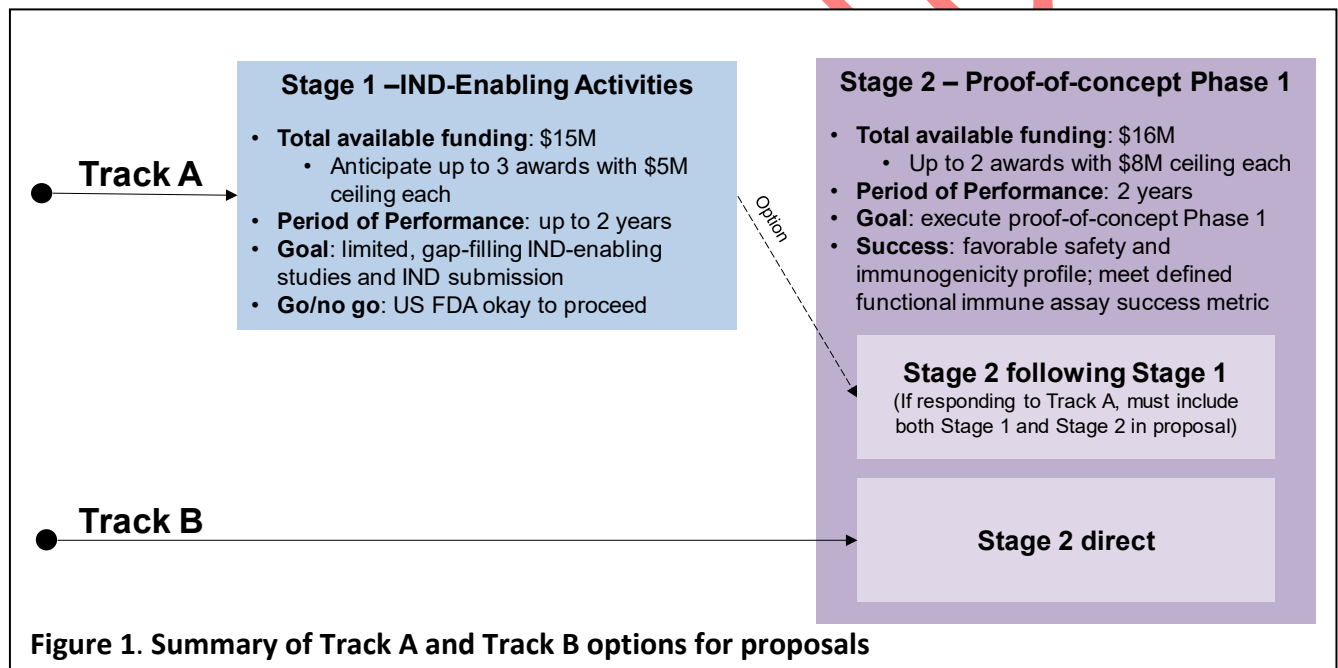
While this effort is focused on COVID-19 vaccines, the intention is to advance oral vaccine formulations/technologies into Phase 1 proof-of-concept clinical trials that have the potential to be leveraged for other health security threats. Proposed vaccine candidates and oral formulation approaches/technologies should have a technically justified potential, based on preclinical and/or clinical data, to have a favorable safety profile amenable to clinical testing and regulatory approval.

Proposals must respond to either Track A or Track B as described below and summarized in Figure 1. The intention is to fund up to three IND-Enabling Activities efforts (Stage 1). The intention is to fund two proof-of-concept Phase 1 trials (Stage 2), whether via down-selection following completion of Stage 1 (Track A) or directly (Track B).

- **Track A (Stage 1 & Stage 2).** Proposals responding to Track A must include, and cost for, both Stage 1 and Stage 2.
 - **Stage 1 – IND-Enabling Activities (Base).** The intention of Stage 1 is to support limited, gap-filling activities required for submission of an IND application to conduct a Phase 1 study under the US FDA; hence, vaccine candidates within the Technology Readiness Level (TRL) 5 space or higher (<https://medicalcountermeasures.gov/trl/integrated-trls/>) are preferred and will increase the competitiveness of a proposal. IND-enabling activities funded under Stage 1 must align with the period of performance and budget ceiling described in section 2.3; proposal evaluation will consider the realism of how the work proposed for Stage 1 aligns with noted limitations.
 - **Stage 2 – Proof-of-Concept Phase 1 (Option 1).** The intention of Stage 2 is to support the execution of a proof-of-concept Phase 1 clinical trial. The proposed study design, plans, and all required activities to execute and complete the proof-of-concept Phase 1 clinical

trial must align with the period of performance and budget described in section 2.4; proposal evaluation will consider the realism of how proposed work for Stage 2 aligns with noted limitations.

- **Track B (Stage 2 Direct).** Proposals responding to Track B must include, and cost for, only Stage 2.
- **Stage 2 – Proof-of-Concept Phase 1 (Base).** The intention of Stage 2 is to support the execution of a proof-of-concept Phase 1 clinical trial. The proposed study design, plans, and all required activities to execute and complete the proof-of-concept Phase 1 clinical trial must align with the period of performance and budget described in section 2.4; proposal evaluation will consider the realism of how proposed work for Stage 2 aligns with noted limitations.



B. Technical Requirements

- a. **Partnering.** Partnering is not a requirement for this RPP. However, partnership between COVID-19 vaccine developers and oral formulation/technology developers is encouraged. If proposing a partnership between a vaccine developer and a company with an oral formulation or technology, then all necessary partnership and intellectual property agreements must be in place at time of proposal submission.
- b. **Vaccine Candidate, Nonclinical, and Clinical Data.** The proposal should describe vaccine details, including antigen target, platform details, formulation, oral delivery approach/technology, candidate bioavailability, preclinical and clinical

data, and any other relevant details. Description of nonclinical and clinical data should include safety, immunogenicity (including, but not limited to systemic and mucosal responses, breadth of protection, and duration), efficacy, and any infection/transmission prevention data. Preclinical data demonstrating non-inferiority of oral administration to intramuscular administration will increase the competitiveness of the proposal.

- c. **Manufacturing.** The proposal should describe the status and/or readiness of clinical trial material manufacturing and plans to have material to support the proof-of-concept Phase 1 clinical trial. This includes, but is not limited to:
 - i. Information pertaining to the composition, manufacturer, stability, and controls used/planned for manufacturing clinical trial material
 - ii. Current demonstrated scale of manufacturing, including all in-process and release tests and validation status
- d. **Development/Regulatory Plan.** The proposal should describe the development and regulatory plan for successful IND application submission and acceptance to execute the proof-of-concept Phase 1 study under the US FDA.
 - i. Any feedback from the US FDA on the development and regulatory plan (i.e., nonclinical studies, clinical development, and/or manufacturing approach) should be noted and summarized within the technical proposal. The full US FDA feedback should be provided as an addendum, which will not count toward stated page limits.
 - ii. The proposal should describe, justify, and provide supportive data to support the development and regulatory plan. The proposed work must align with the period of performance and budget constraints described in section 2.4; this will be considered in proposal evaluation.
 - 1. Stage 1 – IND-Enabling Activities. The proposal should clearly list and define the nonclinical, manufacturing, clinical/regulatory, and other critical path planning activities and timeline for IND submission and acceptance to conduct a proof-of-concept Phase 1 trial under the US FDA. The proposal should note which activities are:
 - a. Complete; provide supporting data
 - b. Partially complete; provide supporting data as well as plans to complete missing elements
 - c. Not initiated; provide plans to initiate and complete
 - 2. Stage 2 – proof-of-concept Phase 1. The proposal should include, but is not limited to, the technical rationale for the proposed study design and include a draft clinical synopsis. The following should additionally be included in the proposal:
 - a. Functional immune assay. Study plan should include the use of a systemic antibody functional immune assay that has demonstrated correlation with protection from

symptomatic COVID-19. Proposal should propose a success metric (e.g., assay titer readout; percent seroconversion; etc.) that could reasonably demonstrate non-inferiority of this immunogenicity readout as compared to currently approved COVID-19 vaccines. Note that the actual study design does not require the use of an approved COVID-19 comparator arm but this can be proposed.

- b. Proposal should include additional immunogenicity readouts as aligned with proposed benefits of the candidate vaccine (e.g., mucosal immunity, T cells, etc.).

e. Sample Collection Plan for Clinical Immune Assays

- Developer-specific assays
 - Sample collection should align to guidelines provided in Attachment A (please refer specifically to Section 5, Immune Assay Sample Collection and Processing)
- BARDA-provided assays (notional and to be determined if available prior to award)
 - Include plans for additional sample collection for potential testing in a centralized immune assay resource provided by BARDA; costs should only account for additional sample collection and shipping to a central laboratory. Availability of this resource will be determined prior to finalization of award.
 - Awardee should agree to share clinical immune samples with BARDA and note as such in the proposal
- Proposal should describe the total proposed collection volumes across both the “developer-specific assays” and notional “BARDA-provided assays”
 - Note sample volumes required for the developer-specific assays
 - Note sample volumes that could be made available for the notional BARDA-specific assays

4.2.2 Project Tasks

A. Stage 1 – IND-Enabling Activities.

Stage 1 is intended to support limited, gap-filling IND-enabling activities necessary for submission of an IND application and acceptance to conduct a proof-of-concept Phase 1 clinical trial under the US FDA.

Stage 1 activities should directly support IND submission and pre-IND clinical trial preparation activities and may include, but are not limited to:

- Produce, characterize, and release nonclinical lots of the oral formulation vaccine candidate under appropriate quality standards for use in animal studies

as necessary.

- Perform nonclinical studies required for IND application submission in suitable model(s) to demonstrate safety (e.g., toxicology, biodistribution, etc.), immunogenicity, and efficacy data that support clinical trials
- Produce clinical trial material suitable for use in Phase 1 clinical trial
 - Execute stability testing of material in a manner consistent with the stability testing plan and as necessary for Phase 1 clinical trial
- Develop a clinical/regulatory development plan. Request and participate in regulatory meetings (e.g., Pre-IND, IND, etc.) with FDA, as needed.
- Submit and maintain INDs to US FDA for clinical trial.

Success at Stage 1 is defined as, but not limited to: (1) demonstration of nonclinical immunogenicity that represents a response reasonably predictive of clinical benefit that is non-inferior to currently approved COVID-19 vaccines and (2) IND submission to the US FDA with a package that aligns with previously received FDA feedback on plans.

Go/no go to progress to Stage 2 will minimally be based on, but not limited to, acceptance from the US FDA to proceed to the proof-of-concept Phase 1 trial.

B. Stage 2 – Proof-of-Concept Phase 1 Trial

Execute a proof-of-concept Phase 1 clinical trial of the oral COVID-19 vaccine. Stage 2 activities should directly support IND submission and may include, but are not limited to:

- Conduct trial readiness and execution activities, including but not limited to:
 - Conduct Site Readiness activities
 - IRB approval confirmed and if applicable sIRB
 - Confirm that materials and supplies are sourced and onsite
 - Execute Phase 1 clinical trial
 - Conduct study Close-out at sites
 - Conduct sample analysis for primary and secondary endpoints
 - Perform database lock
 - Perform data analysis
 - Produce Clinical Study Report within 3 months of database lock
 - Perform any required IRB/IND reporting
 - Provide Investigational Brochure
- Conduct immunogenicity assays
- Conduct safety and immunogenicity analysis
- Produce Clinical Study Report within 3 months of database lock

Success of stage 2 will be defined by (1) demonstration of a favorable safety and immunogenicity profile and (2) meeting the defined functional immune assay as described under Section 4.3(B)(d)(ii)(2), “Stage 2 – proof-of-concept Phase 1”.

C. Regulatory Objectives

- Awardee shall serve as regulatory product sponsor and be responsible for all regulatory submissions to the US FDA and continue to support and maintain regulatory submissions throughout the life of the project.
- Awardee shall submit to the Government all regulatory and supporting documentation related to candidate therapeutic development, manufacturing, lot releasing, certificates of analysis, analytical development, stability, nonclinical and clinical testing as well as other related documentation.
- Awardee shall cross-reference any applicable regulatory files, such as INDs, Master Files and New Drug Applications (NDAs) prior to the conduct of the studies and shall allow cross-referencing of these documents associated with this effort. All nonclinical (if required) and clinical studies should be approved in accordance with industry standards, and HHS Animal Welfare Assurance and HHS Office of Human Research Protection (OHRP) respectively.
- Awardee shall cross-reference any applicable regulatory files, such as INDs, Master Files, and BLA prior to the conduct of the studies, and shall allow cross-referencing of these documents associated with this effort.

4.2.3 Performance Requirements

Submission and maintenance of nonclinical and clinical documentation for regulatory filings (pre-IND/IND) that support a regulatory strategy to achieve FDA approval.

4.2.4 Special Requirements

4.2.4.1 Security and Classified Data: The security classification level for this effort will be *Unclassified*. If Controlled Unclassified Information is provided or must be generated under this agreement, it will be subject to the safeguarding provisions and reporting requirements of the RRPV Base Agreement and/or Project Award.

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 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 or eliminate proposals that do not meet these requirements from further consideration.

5.2 Proposal Evaluation Process

Following the preliminary screening, the Government sponsor will perform evaluations using the evaluation factors detailed below. The Government will conduct an evaluation of all qualified Proposals.

Qualified Proposals will be evaluated by a panel of subject matter experts (SMEs) who will make recommendations to a Source Selection Authority.

This process may involve the use of contractors as SME consultants or reviewers. Where appropriate, the USG will employ non-disclosure agreements to protect information contained in the RPP as outlined in Section 2.8. 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.

The evaluation factors and evaluation criteria are described below.

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

- Excellent
- Good
- Fair
- Poor
- Unacceptable

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.

5.3 Evaluation Factors

The Government will evaluate the information provided in each Offeror's Proposal to determine

which Proposal(s) provide(s) the best value to the Government. Such a determination will be based on the following criteria:

Factor 1 - Technical Approach: This factor evaluates the relevancy, thoroughness, completeness, and feasibility of the proposed approach in relation to the following subfactors:

- a. **General Technical Approach** including ability of proposal to meet all requirements as outlined in the Section 4 of this RPP.
- b. **Clinical and Regulatory Approach**
- c. **Development and Manufacturing Approach**

Factor 2 - Relevant Corporate and Capabilities Experience: This factor evaluates the offeror's demonstrated corporate experience and capabilities experience as well as the technical and program management experience of the proposed team to perform the proposed work, including management of personnel and subawardees. The Government may also consider information in Contractor Performance Assessment Reporting System (CPARS), and the Federal Awardee Performance and Integrity Information System (FAPIS) or similar systems.

Factor 3 - Cost/Price (See Section 5.4 below)

Non-Cost/Price Evaluation factors are listed in descending order of importance. Non-Cost/Price factors are more important than Cost/Price, collectively and individually. 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)

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. Proposals will be evaluated to determine if Costs are realistic for the work to be performed, reflect a clear understanding of the requirements, and are consistent with the various elements of the Offeror's schedule 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 evaluations and provide recommendations based on the evaluation criteria and ratings listed above. The Government does not guarantee a minimum or maximum

number of awards resulting from this solicitation. If an award is made, 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 Corporate and Capabilities Experience, Project Management Approach 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 Basket Provision

The electronic "Basket" is an innovative acquisition tool. Proposals rated as Fair through Excellent, but not immediately selected for award, will be placed in the Basket for 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 **1pm Eastern on 20 September 2024** 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/>).

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 1 – 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 30 pages (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. It is expected, and encouraged, that less complex, less expensive proposals will be significantly less than 30 pages in length.

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 & Minimum Eligibility Criteria
4. Technical Approach
5. Current & Pending Support
6. Data Rights*
7. Resumes of Key Personnel* (each not to exceed 3 pages)
8. Letters of Intent, if applicable*

*Excluded from page limitation

1. Technical Proposal Cover Page

[Name of Offeror]

[Address of Offeror]

RPP Number 24-02-OralVx

[Track: A or B]

[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):	
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):	
PROPOSED USE OF ANIMAL SUBJECTS (YES/NO):	
PROPOSED USE OF HUMAN SUBJECT (YES/NO):	
PROPOSED USE OF HUMAN SPECIMEN MATERIAL (YES/NO):	
PROPOSED USE OF HUMAN FETAL TISSUE (YES/NO):	
PROPOSED USE OF LIVE VERTABRATE ANIMALS (YES/NO):	
PROPOSED USE OF SELECT BIOLOGICAL AGENTS OR TOXINS (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 & Minimum Eligibility Requirements

[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.]

[As part of this section Offerors must provide yes/no answers to the below questions.]

- a) Is the Offeror an RRPV member at the time of proposal submission?
- b) Does the Offeror, or any of their key proposed partners, have experience in vaccine development?
- c) Does the Offeror have key personnel on their team that have proven experience in the following areas:
 - (i) developing oral formulations and technologies;
 - (ii) producing, characterizing, and releasing nonclinical and clinical lots of vaccines;
 - iii) performing nonclinical vaccine studies (if relevant) in suitable animal model(s);
 - (iv) executing stability testing of clinical trial material;
 - (v) developing clinical/regulatory development plans; and
 - (vi) submitting and maintaining INDs to FDA for clinical trial?
- d) If proposing a partnership between a vaccine developer and a company with oral formulation or technology, are all necessary partnership and intellectual property agreements in place at the time of proposal submission?

Proposals that include a negative answer (i.e. answer with “no”) to any of the above questions **will be** removed from consideration, no further evaluation will be performed, and feedback will not be provided to these offerors.

[Additionally, this section must address how the Offeror currently satisfies each aspect of the following minimum eligibility requirements:]

- a) Offerors 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.
- b) Explain how offerors or their partner(s) have successfully demonstrated experience in vaccine development in the past.
- c) Describe how offerors team key personnel have proven experience in:
 - Developing oral formulations and technologies
 - Producing, characterizing, and releasing nonclinical and clinical lots of vaccines

- Performing nonclinical vaccine studies (if relevant) in suitable animal model(s)
- Executing stability testing of clinical trial material
- Developing clinical/regulatory development plans
- Submitting and maintaining INDs to FDA for clinical trials

d) If proposing a partnership between a vaccine developer and a company with an oral formulation or technology, confirm that all necessary partnership and intellectual property agreements are in place prior to proposal submission, at minimum as demonstrated by letters of intent at proposal submission.

Proposals found to not meet these minimum eligibility criteria as detailed above **will be** removed from consideration, no further evaluation will be performed, and feedback will not be provided to these Offerors.

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. Include citation to each Deliverable identified in the Statement of Work throughout the Technical Approach (e.g. (1.1)). Provide the following information:]

1. **Background:** [Describe the problem that the proposal is addressing.]
2. **Approach:** [Describe your approach to solving the problem, broken out by Phase as outlined in Section 4.2 (Solution Requirements) of the RPP. Include relevant background data about your approach. Include the current status of your approach.]
3. **Objectives:** [Specify the objectives of the proposed effort.]
4. **Past Experience:** [Describe relative corporate and capabilities past experience, as well as the technical and management experience of the proposed team, to perform the proposed work. Past experience should be recent, relevant and similar in size and scope to offeror's proposed effort.]
5. **Technical Strategy:** [Describe the proposed methodology, including development and manufacturing approach, in sufficient detail to show a clear course of action.]
6. **Clinical Trial:** [If a clinical trial is proposed as part of Technical Strategy, then include the following information as part of the technical approach. Clinical trials should be described in adequate detail to assess conformance with FDA regulations, guidance, and the requirements related to development and testing of biologics. This will include compliance with applicable portions of Title 21 of the US Code of Federal Regulations (CFR) including Title 21 CFR Parts 11, 50, 54, 56, the Health Insurance Portability and Accountability Act (HIPAA) of 1996 (Pub.L. 104-191, 110 Stat. 1936, enacted August 21, 1996), and International Conference on Harmonisation (ICH) Guidelines for Good Clinical Practices (GCPs) (ICH Guidelines for Good Clinical Practice (E6), Published May 9, 1997).]

- **Clinical Trial History:** [If the proposed clinical trial/testing was initiated using other funding prior to this application, explain the history and background of the clinical trial/testing and declare the source of prior funding. Specifically identify the portions of the study that will be supported with funds from this award.]
- **On-Going Effort:** [If the proposed clinical trial/testing involves continuation or assumption of an ongoing effort then state the transition plan proposed (e.g., transfer of FDA Sponsorship). In the case of ongoing clinical trials, append or provide reference to previous FDA-regulated studies. Offeror must justify carefully any changes proposed to ongoing FDA-regulated protocols and provide specific rationale for alterations (e.g., FDA feedback, change in clinical resources or study sites, etc.)]
- **FDA Interactions:** [Describe plan to meet all regulatory sponsor responsibilities under ICH parts E6, E2A, E8, and 21 Code Federal Regulation parts 312, 11, 50, 54, 56 including regulatory writing and submissions support for clinical efforts, safety reporting, pharmacovigilance, clinical monitoring, data management, regulatory writing and submissions, etc.]
- **Test Materials:**
 - Describe the clinical intervention, medical drug, biologic, device or human exposure model to be tested and the projected outcomes or measures.
 - Document the availability and accessibility of the drug/compound, device, or other materials needed for the proposed research.
 - Describe the production/manufacturing plan for the test materials proposed.
- **Study Design/Clinical Protocol:**
 - Provide a description of the purpose and objectives of the study with detailed specific aims and/or study questions/ hypotheses to include the following details as applicable to the proposed work.
 - Describe the type of study to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action.
 - Describe potential challenges and alternative strategies where appropriate. Define the study variables, outline why they were chosen, and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.
 - Describe the study population, criteria for inclusion/exclusion, and the methods that will be used for recruitment/accrual of human subjects and/or samples (e.g., convenience, simple random, stratified random).
 - Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).
- **Statistical Plan and Data Analysis:** [Describe the data collection plan, statistical

model, and data analysis plan with respect to the study objectives. Specify the approximate number of human subjects to be enrolled or number of human samples to be studied. If multiple study sites are involved, state the approximate number to be enrolled or samples collected at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study. If a subpopulation of a sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study.]

- **Technical Risks:** [Identify and describe potential problem areas in the proposed approach and alternative methods and approaches that will be employed to mitigate any risks that are identified.]
- **Ethical Issues:** [Include a clear and detailed description of the potential ethical issues raised by the proposed study and provide a detailed plan for how the ethical issues will be addressed.]
- **Training/Proficiency Requirements:** [Determination to ensure that personnel have appropriate training/competency.]

7. Anticipated Outcomes: [Provide a description of the anticipated outcomes from the proposed work.]

8. Technical Maturity and Commercialization Strategy: [Provide a description and justification of the maturity of the proposed technology, anticipated regulatory pathway and commercialization plans. Include high-level information about Intellectual Property/Data Rights Assertions. Describe the planned indication for the product label, if appropriate, and include an outline of the development plan required to support that indication. The application should describe a transition plan (including potential funding and resources) showing how the product will progress to the next clinical trial phase and/or delivery to the market after the successful completion of this award.]

9. Organizational Conflict of Interest: [An Organizational Conflict of Interest can occur 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.]

10. Key Personnel: [Identify the proposed management and technical personnel for the project using a summary table in the below format. Principal Investigator must be identified].

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

[Address the qualifications, capabilities, and experience of the proposed personnel who will be assigned to carry out the project. Ensure resumes of key personnel are provided in the

“Resumes of Key Personnel” section. Resumes are excluded from page count limit]

11. **Schedule:** [Identify key technical, schedule, and cost risks, their potential impact and mitigation.]
12. **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.]
13. **Government Resources:** [Identify any key Government facilities, Government equipment, Government property, etc. that your organization requests to use for the effort.]
14. **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.]
15. **Cost Realism:** [This section provides technical evaluators with high-level cost data in order for them 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.]

Cost Realism Form EXAMPLE

This form is to be completed by Offeror and evaluated by Technical Evaluators. Items in italics are provided as examples only. Offeror must complete table with the applicable information. Add or delete columns to match optional tasks.

Cost Element	Total Proposed Cost	Description/Explanation
Labor	<i>\$750,000</i>	<i>3000 hours of senior scientist; 2500 hours of program management; 1000 of hours of contracts management; 1750 hours of scientist</i>
Labor Hours	<i>7,500</i>	
Subcontractors	<i>\$200,000</i>	<i>Sub A - \$25,000; 250 legal advisor hours – each task Sub B - \$25,000; 250 hours of Testing – each task</i>
Subcontractor Hours	<i>2,000</i>	
Consultants	<i>\$40,000</i>	<i>Financial consultant supporting all phases</i>
Consultant Hours	<i>400</i>	
Material/Equipment	<i>\$375,000</i>	<i>pipettes, gloves, computer software – each phase</i>
Other Direct Costs	<i>\$9,000</i>	<i>ship testing materials to lab – each phase</i>
Travel	<i>\$20,000</i>	<i>2 trips for 2 people for 2 days to Washington, DC from Charleston, for program meetings – each task</i>
Indirect Costs	<i>\$278,800</i>	<i>approved by DHHS 30 Sept 23</i>
Fee	<i>\$0</i>	<i>Not applicable if cost share proposed</i>
Total Cost to Government	<i>\$1,672,800</i>	
Cost Share	<i>\$1,160,000</i>	<i>5,000 hours of lab assistant – each task</i>
Total Project Value	<i>\$2,832,800</i>	

5. Current & Pending 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]

Pending

Title of Proposal:

Funding Agency/Requiring Activity:

Estimated Dates of Funding:

Proposed Total Direct Costs:

Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*

Brief summary of the scope of work:

Title of Proposal:

Funding Agency/Requiring Activity:

Estimated Dates of Funding:

Proposed 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]

6. Resumes of Key Personnel

Include the resumes of key personnel from the Offeror's organization, as well as subcontractors or consultants, who will work on this project if selected (each resume not to exceed 3 pages). The Principal Investigator must be identified.

SOLICITATION CLOSED

ATTACHMENT 2 – 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]

RRP Number 24-02-OralVx

[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) Expenditure-Based Milestones (with ceiling), (2) Expenditure-Based/Cost Sharing Milestones (with ceiling), (3) Expenditure-Based Plus Fixed Fee Milestones (with ceiling) and (4) Fixed Price Milestones (with ceiling).]
Note: Expenditure-Based agreements are agreements where the Project Awardee is paid based on actual expenditures incurred within the established ceiling and available funding.
4. **Total Cost by Phase Cost Elements.** [Include a list of each phase that is stated in the Statement of Work and its associated total cost by year. The sum of the phases must equal the total listed in the Cost Proposal Formats.]
5. **Cost Share.** [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 expenditure-based 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 or 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 s 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.).]

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 show estimated hours for each labor category proposed. If an approved organizational estimating procedure use 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 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 [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 U.S. Office of Personnel Management Web site 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. Subcontractors/Consultants.** [Portions of subcontractor/consultant information may be included in the Cost Proposal Format instead of this Cost Proposal Narrative if more practical. Provide a list of all subcontractor/consultant 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 subcontractor/consultant as follows:

- If a subcontractor/consultant is based on commercial pricing, provide an explanation of the commerciality determination and supporting documentation (e.g., website pricing, catalog pricing, etc.)
- For a subcontractor/consultant less than \$250,000, provide a brief explanation of the work to be performed.
- For a subcontractor/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 subcontractor/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 subcontractor/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 rationale 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 research 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; or
- 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. 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. Cost of Money. [If applicable, Cost of Money should be proposed separately from indirect costs.]

9. Fee/Profit. [State the fee/profit percentage, if proposed. Fee/Profit is allowable for the effort being conducted when cost share is not being contributed. The fees shall be specific to the individual RRPV project and negotiated on a project-by-project basis.]

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 Site are **NOT** mandatory.

The Cost Proposal Format section must include a breakout of the total cost proposed by cost element for each year of the program. If required by the RPP, costs must also be broken out by Phase stated in the Statement of Work. The sum of the Phases must equal the total.

Supporting data and justification for labor, equipment/material, team member/subcontractor, 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.]

SOLICITATION CLOSED

ATTACHMENT 3 – 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 (24-02-OralVx)

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. Track A proposals should include all deliverables; Track B proposal should include all deliverables, with the exclusion of the nonclinical section if not applicable.

Meetings

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
1.1	Post-Award Teleconference/ Kickoff Meeting	The Project Awardee must complete a Post-Award Teleconference/ Kickoff Meeting after the initiation of the Project Award period of performance. 1. Outline activities for the next 30 days	<ul style="list-style-type: none"> • Within 10 business days after the initiation of the Project Award period of performance, pending concurrence by the OTAO • Project Awardee 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 Project Awardee to distribute agenda at least 3 business days prior to meeting • Project Awardee submits meeting minutes to PAR within 3 business days after the meeting • PAR reviews, comments, and approves minutes within 10 business days
1.2	Bi-Weekly Teleconference	The Project Awardee must participate in teleconferences bi-weekly with BARDA to discuss the technical performance on the Project Award. Meeting frequency may be increased or decreased as needed during the course of the project.	<ul style="list-style-type: none"> • Project Awardee must submit agenda to PAR no later than 2 business days in advance of meeting • PAR edits/approves and instructs Project Awardee to distribute agenda prior to meeting • Project Awardee must distribute agenda and presentation materials at least 2 calendar days in advance of meeting • Project Awardee 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)	The Project Awardee must participate in technical, subgroup, or ad hoc teleconferences as needed or upon BARDA request to discuss the technical performance on the Project Award. Meeting frequency may be defined as needed during the course of the project.	<ul style="list-style-type: none"> • Project Awardee must submit agenda to PAR no later than 2 business days in advance of Technical or Subgroup meeting • PAR edits/approves and instructs Project Awardee to distribute agenda prior to meeting • Project Awardee must distribute agenda and presentation materials at least 24 hours in advance of meeting • Project Awardee must submit meeting minutes to PAR within 3 business days of the meeting • PAR reviews, comments, and approves minutes within 6 business days

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
1.4	Periodic Review Meetings	At the discretion of the Government, the Project Awardee must hold up to four (4) per year recurring Periodic Review Meetings, held by teleconference or face-to face either in Washington, D.C. or at work sites of the Project Awardee or subawardees. Face-to-face meetings shall alternate between Washington, D.C. and Project Awardee, subawardee sites. The meetings will be used to discuss Project Award progress as well as nonclinical, clinical, technical, regulatory, and ethical aspects of the program.	<ul style="list-style-type: none"> •Project Awardee must submit an agenda and itinerary, if applicable, at least 5 business days, and Project Awardee must provide presentation materials at least 3 business days, in advance of the meeting •PAR edits/approves and instructs Project Awardee to distribute agenda prior to meeting by at least 3 business days •Project Awardee provides meeting minutes to PAR within 3 business days after the meeting •PAR reviews, comments, and approves minutes within 10 business days

Technical Reporting: General

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
2.1	Project Management Plan (PMP)	<p>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 Project Awardee and subawardee team(s).</p> <p>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.</p>	<ul style="list-style-type: none"> •Project Awardee must submit a PMP: <ul style="list-style-type: none"> ○ Within 30 calendar days after the initiation of the Project Award period of performance ○ Updates should be provided to reflect any key changes and reviewed at least annually.
2.2	Gantt Chart/Timeline	The Gantt Chart/Timeline should be detailed to the extent required by the specific project.	<ul style="list-style-type: none"> •At first project meeting and as updated no later than every 30 calendar days. Provided in pdf.
2.3	Communication Plan	<p>The Project Awardee must submit an effective Communication Plan that details the flow of information between BARDA, Project Awardee, collaborators, vendors, and other organizations.</p> <p>The Communication Plan must also include a press release review process.</p>	<ul style="list-style-type: none"> •Project Awardee must submit a Communication Plan: <ul style="list-style-type: none"> ○ Within 30 calendar days after the initiation of the Project Award period of performance ○ Updates should be provided to reflect any key changes and reviewed at least annually.
2.4	Work Locations	<p>The Project Awardee 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 subawardees and critical vendors of reagents and supplies.</p> <p>Project Awardee must include vendors for critical infrastructure protection.</p>	<ul style="list-style-type: none"> •Project Awardee must submit Work Locations Report: <ul style="list-style-type: none"> ○ Within 5 business days after the initiation of the Project Award period of performance ○ Within 30 business 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 or a Public Health Emergency of International Concern (PHEIC) by the World Health Organization (WHO)

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
2.5	Pandemic/Public Health Emergency Facility and Operational Management Plan	Project Awardee 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. Project Awardee must identify critical infrastructure.	<ul style="list-style-type: none"> •Project Awardee must submit: <ul style="list-style-type: none"> ○ Draft within 15 days of award ○ Final within 30 days of award
2.6	Monthly & Annual Technical Progress Reports/Annual Meeting	<p>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.</p> <ol style="list-style-type: none"> 1. An Executive Summary highlighting the progress, issues and relevant manufacturing, nonclinical, clinical, regulatory, and publication activities. The Executive Summary should highlight all critical issues for that reporting period and resolution approach; limited to 2 pages 2. The Project Awardee must submit monthly detailed clinical reports during active clinical trial enrollment to include at a minimum: <ul style="list-style-type: none"> •Central IRB approval status •Site IRB approval status •Site information (FWA number, site type (e.g., commercial site, academic site), site activation status) •Number of subjects screened and enrolled by age, race, ethnicity, geographic distribution •Investigational Product status (receipt at depot and receipt on site) •Safety reporting (SAEs) •Protocol deviations •Database management •Status of ancillary supplies e.g., PPE, swabs, syringes, tubes on site •Specimen collection status •Pharmacy manuals <p>The Project Awardee must inform BARDA of any upcoming site visits and/or audits of Contract Research Organization (CRO) facilities funded under this effort. BARDA reserves the right to accompany the Project Awardee on site visits and/or audits of CROs as BARDA deems necessary.</p> 3. 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 4. A three-month rolling forecast of the key planned activities, referencing the WBS/IMS 5. A tracking log of progress on regulatory submissions with the FDA number, description of submission, date of submission, status of submission, and next steps 6. Estimated and Actual Expenses 	<ul style="list-style-type: none"> •Project Awardee 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 every 12 months. 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 (see deliverable 2.7). The PAR and OTAO will review the monthly reports with the Project Awardee and provide feedback •Project Awardee must provide FINAL versions of reports within 10 business days after receiving BARDA comments/edits •Project Awardee must provide notification of designated safety events to the OTAO and PAR within 24 hours of being notified of the event

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<ul style="list-style-type: none"> 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 Subawardees' expenses from the previous month if the Subawardee did not submit a bill in the previous month. If the subawardee(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 Subawardee. If the PAR and OTAO are satisfied that the Project Awardee's reporting is sufficient to convey this information, this section may be waived. 3 .Publication activities and progress for any manuscript, scientific meeting abstract, poster, presentation, and other public-facing material or information containing data generated under this Project Award 	
2.7	Draft and Final Technical Progress Report	<p>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.'</p> <p>1. 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 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.</p>	<ul style="list-style-type: none"> The Project Awardee 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 calendar days of receipt, which the Project Awardee must consider incorporating into the Final Report

Technical Reporting: Manufacturing

3.1	Product Development Source Material and Manufacturing Reports Projections	<p>If requested, the Project Awardee shall submit a detailed spreadsheet regarding critical project materials that are sourced from a location other than the United States, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing sites; and location and nature of non-clinical and clinical study sites.</p> <p>The Project Awardee will provide manufacturing reports and manufacturing projections/actuals on any agreement/agreement that is manufacturing product, including product for clinical trial use.</p>	<ul style="list-style-type: none"> • If requested, the Project Awardee will submit Product Development Source Material Report within 1 month after the initiation of the Project Award period of performance <ul style="list-style-type: none"> ○ Within 30 days of substantive changes are made to sources and/or materials ○ Or 6 months after the initiation of the Project Award period of performance • The Government will provide written comments to the Product Development Source Material and Manufacturing Report within 15 business days after the submission • If corrective action is recommended, Project Awardee must address all concerns raised by BARDA in writing • Product Development and Source Material report to be submitted via spreadsheet; Dose Tracking can be completed via spreadsheet or other format (e.g. XML or JSON) as agreed to by USG and Project Awardee
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Technical Reporting: Nonclinical Studies

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
4.1	Draft and Final Nonclinical Study Report(s)	Project Awardee must provide Draft and Final Nonclinical Study Reports to BARDA for review and comment.	<ul style="list-style-type: none"> • Draft report due within 45 calendar days after completion of analysis and at least 15 business days prior to submission to FDA • The Project Awardee must submit Subawardee-prepared reports received by the Project Awardee to the PAR and OTAO for review and comment no later than 5 business days after receipt by Project Awardee • The Government will provide written comments to the Draft Report for Nonclinical Study Reports within 15 business days after the submission • Final report due 30 calendar days after receiving comments on the Draft Final Report for Nonclinical Studies; If corrective action is recommended, Project Awardee must address all concerns raised by BARDA in writing • Project Awardee must consider revising reports to address BARDA's recommendations prior to FDA submission
4.2	Nonclinical Study Protocols	The Project Awardee must submit draft and final nonclinical study protocols to OTAO and PAR.	<ul style="list-style-type: none"> • The Project Awardee must submit Draft nonclinical study protocols to PAR electronically prior to finalization. <ul style="list-style-type: none"> ○ BARDA will provide comments within 10 business days of receipt of draft protocol ○ Project Awardee must respond in writing to BARDA comments and recommendations within 10 business days of receipt and must be addressed prior to finalization of protocol. ○ PAR must approve the final protocol • The Project Awardee must submit Final nonclinical study protocols to PAR electronically no later than 10 business days prior to FDA submission.

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
4.3	Nonclinical Study Final Data Submission Package	BARDA must have access to methods and reagents. BARDA must have unlimited rights to all nonclinical-related protocols, data generated from the execution of these protocols, and final reports, funded by BARDA under this agreement. At BARDA's request, the Project Awardee must provide any nonclinical-related agreement deliverable without any restrictive legends to ensure BARDA has the ability to review and distribute the nonclinical-related deliverables, as BARDA deems necessary.	<ul style="list-style-type: none"> Project Awardee must submit at least 15 business days prior to Project Award end date. Partial datasets may also be requested for delivery prior to submission of the Final Data Submission Package.

Technical Reporting: Clinical Trials

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
5.1	Clinical Trial Protocols	The Project Awardee must submit draft and final clinical study protocols to OTAO and PAR.	<ul style="list-style-type: none"> The Project Awardee must submit Draft study protocols to PAR electronically prior to finalization. <ul style="list-style-type: none"> BARDA will provide comments within 10 business days of receipt of draft protocol Project Awardee must respond in writing to BARDA comments and recommendations within 10 business days of receipt and must be addressed prior to finalization of protocol. PAR must approve the final protocol. The Project Awardee must submit Final study protocols to PAR electronically no later than 10 business days prior to FDA submission.
5.2	Clinical Trial Documentation ¹	<p>The Project Awardee must provide the following documents for any portion of a study funded under this agreement:</p> <ul style="list-style-type: none"> Investigational Product Accountability Plan Study Supplies Procurement Plan Site selection questionnaire Overall Recruitment and Retention plan Informed Consent Form (ICF) template eConsent Data Management Plan Data Validation/Quality Plan Statistical Analysis Plan Sample/Specimen Management Plan Diversity inclusion plan to enroll based on US demographic based on most recent census Investigator Brochure eCRF Community engagement materials, posters, media advertisements, animations, graphics, etc. Clinical Trial Agreements Monitoring Plan Safety Monitoring Plan (processes to provide 24-7 pharmacovigilance and safety monitoring) 	<ul style="list-style-type: none"> The Project Awardee must submit Draft study documents to PAR electronically prior to finalization. <ul style="list-style-type: none"> BARDA will provide comments within 10 business days of receipt of draft document Project Awardee must respond in writing to BARDA comments and recommendations prior to finalization of protocol. The Project Awardee must submit Final study documents to PAR electronically no later than 10 business days prior to FDA submission. Project Awardee must submit draft Statistical Analysis Plan no later than 20 business days after protocol is finalized. The final Statistical Analysis Plan must be submitted 5 business days prior to study database unblinding. Project Awardee must submit final version Investigational Product and Clinical Supplies Management Plan at least 6 weeks prior to investigational product shipments to clinical sites. Project Awardee must retain the capability to procure, ship, deliver, install, and train on the use of all required supplies, including, but not limited to, documents, files, and equipment.

¹ To be added at the discretion of the OTAO and the PAR as appropriate for the Project Award, e.g., if the clinical trial utilizes NIH-funded clinical sites: *The Project Awardee must participate in and provide information to a USG-oversight and review committee(s) outside of BARDA. The Project Awardee must submit protocol, ICF, and IB to a Protocol Science Review Committee (PSRC) four (4) business days before the review to the PSRC Chair and USG-designated reviewers.*

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		<ul style="list-style-type: none"> •SAE Reconciliation SOP (if safety database separate from clinical database) •Processes to manage and support an independent Data and Safety Monitoring Board (DSMB) •DSMB Charter •DSMB template reports and DSMB reports •Draft and Final Tables, Listings, and Figures (TLFs), ad hoc TLFs •Plan for notifying participants of his/her treatment assignment •Essential Regulatory Documents that demonstrate compliance with the standards of ICH E6 (R2) Good Clinical Practice and with all applicable regulatory requirements •Pharmacy Manual <p>The Project Awardee must make arrangements for up to four (4) BARDA representative(s) to be present during clinical site monitoring visits.</p>	<ul style="list-style-type: none"> •Final TLFs must be submitted to the PAR within 3 weeks after database lock.
5.3	ClinicalTrials.Gov Posting and Results Reporting	Per clinicaltrials.gov registration and reporting requirements.	<ul style="list-style-type: none"> •Project Awardee must post results: <ul style="list-style-type: none"> ○ 3 months from any interim analysis ○ 3 months from primary analysis ○ 3 months from final analysis
5.4	Draft and Final Clinical Study Report(s)	Project Awardee must provide Draft and Final Clinical Study Reports to BARDA for review and comment.	<ul style="list-style-type: none"> •Draft report due within 45 calendar days after completion of analysis and at least 15 business days prior to submission to FDA •The Project Awardee must submit Subawardee-prepared reports received by the Project Awardee to the PAR and OTAO for review and comment no later than 5 business days after receipt by Project Awardee •The Government will provide written comments to the Draft Report for Clinical Study Reports within 15 business days after the submission •Final report due 30 calendar days after receiving comments on the Draft Final Report for Clinical Trial; If corrective action is recommended, Project Awardee must address all concerns raised by BARDA in writing •Project Awardee must consider revising reports to address BARDA's recommendations prior to FDA submission
5.5	Project-Specific First Site Activated for First Subject First Visit	Project Awardee should have all pre-study planning complete and be ready to enroll subjects.	<ul style="list-style-type: none"> •After IND is in effect, within 5 calendar days of IRB approval
5.6	Clinical Report During Active Enrollment Periods ²	<p>The Project Awardee must submit daily the data specs during active clinical trial enrollment.</p> <p>Clinical Report submission must be by electronic transfer, e.g., from Project Awardee Electronic Data Capture (EDC) system/Interactive Voice Response System (IVRS) to USG.</p>	<ul style="list-style-type: none"> •Project Awardee must submit, in a format and to a location agreed to by BARDA, data specs on a daily basis starting when first subject is enrolled and ending when last subject is enrolled.

² Note that this may be modified to daily, weekly, monthly, etc., reporting as required by the PAR.

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
5.7	Access to Electronic Systems Used in Trial Conduct	The Project Awardee must provide access to systems used in trial conduct.	<ul style="list-style-type: none"> •Due within 20 calendar days of PAR request, no later than 10 calendar days prior to first site activated
5.8	Blinded Safety Reports, Medical Data Listing, CIOMS Report, Pharmacovigilance Database Listing	The Project Awardee must submit blinded safety data reports, medical data listings, CIOMS reports and listings from the Pharmacovigilance database.	<ul style="list-style-type: none"> •Project Awardee must provide weekly blinded safety data reports and medical data listings during the treatment period. •CIOMS reports and data listing from Pharmacovigilance database will be provided to the PSRT for review. Meeting frequency may be reduced during the follow up phase.
5.9	Clinical Trial Final Study Package	<p>BARDA must have unlimited rights to all clinical-related protocols, data generated from the execution of these protocols, and final reports, funded by BARDA under this Project Award</p> <p>At BARDA's request, the Project Awardee must provide any clinical-related agreement deliverable without any restrictive legends to ensure BARDA has the ability to review and distribute the clinical-related deliverables, as BARDA deems necessary.</p> <p>If clinical trial data is included, that data must be provided consistent with applicable privacy laws to protect personally identifiable information (PII).</p>	<ul style="list-style-type: none"> •Project Awardee must submit the Clinical Trial Final Study Package at least 15 business days prior to Project Award end date. Partial datasets may also be requested for delivery prior to submission of the Final Data Submission Package.
5.10	Data Exchange Package(s) Submitted to Regulatory Agency(s)	<p>As part of Final or Draft Submission Package(s), upon BARDA request, and also as part of deliverables, the Project Awardee must provide raw data, Tabulation Data (e.g., CDISC-compliant SDTM SAS XPT datasets), Analysis Datasets (e.g., CDISC-compliant ADaM SAS XPT datasets), and any additional documents including but not limited to Reviewer's Guide (PDF), SDTM annotated CRF(s) (PDF), and data definition file(s) (XML) to BARDA. Other data exchange standards or file formats might be used if discussed with and agreed by BARDA. The Project Awardee must provide the software programs (e.g., SAS programs, R programs) used to create any ADaM datasets and generate tables and figures associated with all analyses, including primary and secondary efficacy analyses.</p> <p><i>List of abbreviations: XPT = SAS Transport Format (XPORT) Version 5; PDF = Portable Document Format; XML = Extensible Mark-up Language; CDISC = Clinical Data Interchange Standards Consortium</i></p>	<ul style="list-style-type: none"> •Project Awardee must provide the Technical Documents and/or datasets within 20 business days of request from the OTAO or PAR
5.11	Clinical Trial Datasets	Project Awardee must make clinical trial datasets publicly available.	<ul style="list-style-type: none"> •Project Awardee must post clinical trial datasets on a web-based platform easily accessible by the public: <ul style="list-style-type: none"> ○ 3 months from any interim analysis supporting any action (e.g., regulatory filing, protocol change), if applicable ○ 3 months from primary analysis ○ 3 months from final analysis
5.12	Additional Data Package(s)	Upon request, the Project Awardee must provide raw data, tabulation Data and/or analysis data in a BARDA-agreed upon format and supporting documents that might be including but not limit to the list of files in package, technical specification documents, data analysis programs. Data exchange standards and file formats must be discussed and agreed upon with BARDA.	<ul style="list-style-type: none"> •Project Awardee must provide the data package(s) within 20 business days of request from the OTAO or PAR

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
6.1	Quality Management Plan (QMP)	<p>Project Awardee must develop an overall project Quality Management Plan to include a description of all quality activities and personnel involved in ensuring all activities are conducted and data are maintained under cGXP, and all products are managed to ensure that GMP requirements are met.</p> <p>All quality management plans must include subawardee quality management plans specifically addressing how subawardee quality will be managed. All subawardee must have a current quality agreement with the Project Awardee and a recent vendor qualification audit.</p>	<ul style="list-style-type: none"> Project Awardee must submit a Quality Management Plan <ul style="list-style-type: none"> Within 30 calendar days after the initiation of the Project Award period of performance 6 months after the initiation of the Project Award period of performance to include any updates.
6.2	BARDA Audit	<p>Project Awardee must accommodate periodic or ad hoc site visits, auditing, inspection and review of release documents, test results, equipment and facilities when requested by BARDA. If BARDA, the Project Awardee, or other parties identify any issues during an audit, the Project Awardee must capture the issues, identify potential solutions and submit a report to BARDA detailing the finding and corrective action(s).</p> <p>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 the manufacture, testing (including but not limited to analytical testing, nonclinical study, clinical trial), and storage of the product.</p>	<ul style="list-style-type: none"> If issues are identified during the audit, Project Awardee must submit a report to BARDA detailing the finding and corrective action(s) within 10 business days of the audit PAR and OTAO will review the report and provide a response to the Project Awardee with 10 business days Once corrective action is completed, the Project Awardee will provide a final report to BARDA
6.3	FDA Inspections/Site visits	<p>In the event of an FDA inspection that occurs in relation to this agreement and for the product, or for any other FDA inspection that has the reasonable potential to impact the performance of this agreement, including, but not limited to clinical trials and manufacturing facilities, the Project Awardee must provide the USG with an exact copy (non-redacted) of the FDA Form 483 or summary and the Establishment Inspection Report (EIR). The Project Awardee must provide the PAR and OTAO with copies of the plan and FDA submissions for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines as identified in the inspection report, status updates during the plan's execution and a copy of all final responses to the FDA. The Project Awardee must also provide redacted copies of any FDA inspection reports received from subawardee that occur as a result of this agreement or for this product.</p> <p>The Project Awardee must make arrangements for up to four (4) BARDA representative(s) to be present during the opening, any daily debriefs, and the final debrief by the regulatory inspector.</p>	<ul style="list-style-type: none"> Project Awardee must notify OTAO and PAR within 10 business days of the scheduling of a scheduled FDA inspection/site visit or within 24 hours after inspection/site visit if the FDA does not provide advanced notice Project Awardee must provide copies of any FDA inspection report received from subawardee that occur as a result of this agreement or for this product within 1 business day of receiving correspondence from the FDA, a subawardee, or third party Within 10 business days of inspection report, Project Awardee must provide OTAO with a plan for addressing areas of non-conformance, if any are identified
6.4	Quality Assurance (QA) Audits and Subawardee Monitoring Visits	<p>BARDA reserves the right to participate in QA audits performed by the Project Awardee. Upon completion of the audit/site visit the Project Awardee must provide a report capturing the findings, results and next steps in proceeding with the subawardee. If action is requested of the subawardee, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or</p>	<ul style="list-style-type: none"> Project Awardee must notify OTAO and PAR a minimum of 10 business days in advance of upcoming, audits/site visits of subawardee Project Awardee must notify the PAR and OTAO within 5 business days of report completion and provide Draft Report.

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		GCP guidelines, as identified in the audit report, must be provided to BARDA. The Project Awardee must provide responses from the subawardee to address these concerns and plans for corrective action. The Project Awardee must allow for up to four (4) USG representative(s) to be present during the audit as necessary for appropriate oversight, including manufacturing person in plant, at nonclinical sites, at clinical sites, CROs, and any other clinical vendor involved in the conduct of the nonclinical study or clinical trial under agreement.	<ul style="list-style-type: none"> • PAR and OTAO will review the report and provide a response to the Project Awardee with 10 business days before audit can be finalized. • Project Awardee must provide a final audit report and corrective and preventive actions (CAPAs) to address all findings in the report. • Project Awardee must provide a final closeout report that all CAPAs were addressed to PAR and OTAO • Project Awardee must notify BARDA within 24 hours of any critical and/or major findings
6.5	Risk Management Plan (RMP)	The Project Awardee 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.	<ul style="list-style-type: none"> • A Draft is due within 45 calendar days after the initiation of the Project Award period of performance; updates to the RMP are due concurrent with Monthly Technical Progress Reports, but may be communicated more frequently. The Project Awardee 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 Project Awardee with a list of concerns in response plan submitted • Project Awardee must address, in writing, all concerns raised by BARDA within 20 business days of Project Awardee's receipt of BARDA's concerns • The Project Awardee must submit updates at minimum of every three months.
6.6	Integrated Master Schedule (IMS)	The Project Awardee 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.	<ul style="list-style-type: none"> • The Project Awardee 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 • BARDA 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 Project Awardee 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.
6.7	Deviation Notification and Mitigation Strategy	Process for changing IMS activities associated with cost and schedule as baselined. Project Awardee 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. Project Awardee must provide a high-level management strategy for risk mitigation.	<ul style="list-style-type: none"> • The Project Awardee must submit Deviation Notification and Mitigation Strategy at least 10 business days prior to the Project Awardee anticipating the need to implement changes

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
6.8	Incident Report	<p>Project Awardee 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, such as breach of GCP during a clinical study, must also be reported.</p>	<ul style="list-style-type: none"> • 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 OTAO • Additional updates due to PAR and OTAO within 48 hours of additional developments • Project Awardee 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, Project Awardee must address in writing, its consideration of concerns raised by BARDA within 5 business days of receiving such concerns

Advanced R&D Products

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
7.1	Technical Documents	<p>Upon request, Project Awardee must provide OTAO and PAR with deliverables from the following activities: quality agreements between Project Awardees and subawardees, process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, Certificate of Analysis, Clinical Studies Data or Reports, clinical trial documents.</p> <p>The OTAO and PAR reserve the right to request within the PoP a non-proprietary technical document for distribution within the Government.</p>	<ul style="list-style-type: none"> • Project Awardee must provide technical document within 10 business days of OTAO or PAR request. Project Awardee can request additional time on an as needed basis • If corrective action is recommended, the Project Awardee must address, in writing, concerns raised by BARDA in writing
7.2	Publications	<p>The Project Awardee 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. Acknowledgment of BARDA funding must be included.</p>	<ul style="list-style-type: none"> • Project Awardee must submit all manuscript or scientific meeting abstracts to PAR and OTAO prior to submission/presentation by 30 business days for manuscripts and 15 business days for abstracts, posters, or any other material • Project Awardee must address in writing all concerns raised by BARDA in writing • Final submissions must be submitted to BARDA concurrently or no later than within 1 calendar day of its submission • Project Awardee must list all publication material in the Monthly Technical Progress Report
7.3	Project Awardee Clinical Publication Timeline and USG Right to Publish Data	<p>Within 30 days of the primary analysis, results from clinical studies funded in whole or in part under this agreement and consistent with Good Publications Practices. Project Awardee must submit clinical study primary endpoint analysis for publication to a peer reviewed journal.</p> <p>Within 90 days of the of study end date [last subject last visit] for studies funded in part or whole under this agreement and consistent with Good Publication Practices, Project Awardee must submit clinical study data for publication to a peer reviewed journal.</p> <p>If the Project Awardee does not elect to publish data, Project Awardee must provide OTAO and PAR with clinical trial data to support the government publication of data as deemed appropriate by the government, without the Project Awardee involvement. The government reserves the right to publish a counter-analysis of the data.</p>	<ul style="list-style-type: none"> • Project Awardee must notify OTAO and PAR within 30 calendar days of primary analysis results and study end date [last subject last visit] if they plan not to publish data. • Within 10 calendar days of a request for clinical data from the OTAO, the Project Awardee must provide OTAO with requested data, information and materials in the form(s) requested by the government, to support the government publication of the clinical trial data funded in part or whole under this Project Award

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
7.4	Project Awardee Nonclinical Publication Timeline and USG Right to Publish Data	<p>Within 90 days of the of study end date [audited or quality-controlled draft final report prepared and reviewed by the Government] for studies funded in part or whole under this agreement and consistent with Good Publication Practices, Project Awardee must submit nonclinical study data for publication to a peer reviewed journal.</p> <p>If the Project Awardee does not elect to publish data, Project Awardee must provide QAO (Quality Assurance Officer) and PAR with nonclinical data to support the government publication of data as deemed appropriate by the government, without the Project Awardee involvement. The government reserves the right to publish a counter-analysis of the data.</p>	<ul style="list-style-type: none"> • Project Awardee must notify OTAO within 30 calendar days of study end date [audited or quality-controlled draft final report prepared and submitted for Government review] if they plan not to publish data. • Within 10 calendar days of a request for nonclinical data from the OTAO, the Project Awardee must provide OTAO with requested data, information and materials in the form(s) requested by the government, to support the government publication of the nonclinical trial data funded in part or whole under this Project Award

Regulatory Deliverables

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
8.1	Regulatory Strategy/Plan	<p>The Project Awardee must provide a Regulatory Plan that outlines the regulatory strategy for the product.</p> <p>The plan must include information leading to the proof-of-concept Phase 1 trial.</p>	<ul style="list-style-type: none"> • Project Awardee must submit a Draft within 45 calendar days after the initiation of the agreement period of performance; updates to the Regulatory Strategy/Plan must be submitted concurrently with Monthly Technical Progress Reports. The Project Awardee 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 Project Awardee with a list of concerns in response to plan submitted • Project Awardee must address, in writing, all concerns raised by BARDA within 20 business days of Project Awardee's receipt of BARDA's concerns
8.2	FDA Correspondence	<p>The Project Awardee must memorialize all original and unredacted correspondence between Project Awardee and FDA and submit to BARDA, including formal and informal emails, correspondence, telephone calls, and official information requests (IRs).</p>	<ul style="list-style-type: none"> • Project Awardee must provide copies of all original and unredacted FDA correspondence within 2 business days of correspondence
8.3	FDA Submissions	<p>The Project Awardee must provide BARDA the opportunity to review and comment upon all draft submissions before submission to the FDA.</p> <p>Project Awardee must provide BARDA with an electronic copy of the final FDA submission. All documents must be duly marked as either "Draft" or "Final."</p>	<ul style="list-style-type: none"> • Project Awardee must submit draft FDA submissions to BARDA at least 15 business days prior to FDA submission • BARDA will provide feedback to Project Awardee within 10 business days of receipt • The Project Awardee must address, in writing, its consideration of all concerns raised by BARDA prior to FDA submission <p>The Project Awardee must submit Final FDA submissions to BARDA concurrently or no later than 5 calendar days of submission</p>
8.4	IND Filing	<p>The Project Awardee shall provide a copy of any request for IND submitted to the FDA</p>	<ul style="list-style-type: none"> • Within 7 calendar days after submission to the FDA

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	Task Number	Significant Event/Accomplishments	Due Date	Government Funds	Cost Share	Total Funding
1	N/A	Project Kickoff	12/1/2019	\$20,000		\$20,000
2	N/A	Monthly Report (Technical and Business Reports)	1/15/2020	\$ -		\$ -

3	N/A	Monthly Report (Technical and Business Reports)	2/15/2020	\$ -		\$ -
4	1	Protocol Synopsis	2/28/2020	\$21,075		\$21,075
5	2	Submission for Program Office Approval	2/28/2020	\$21,075		\$21,075
6	N/A	Monthly Report (Technical and Business Reports)	3/15/2020	\$ -		\$ -

47	N/A	Monthly Report (Technical and Business Reports)	9/25/2022	\$ -		\$ -
48	N/A	Annual Report 1	10/25/2022	\$ -		\$ -
49	14	Report results from data analysis	11/1/2022	\$157,829		\$157,829
50	N/A	Final Reports (POP End)	11/30/2022	\$ -		\$ -
Total				\$2,025,240	\$1,124,742	\$3,149,982
Period of Performance (Months)						XX Months
Contract Type						FFP

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. Cannot receive payment for a report. However, submission of a report may be used as a 'triggering event' indicating sufficient work has been completed to allow milestone payment.(i.e. Quarterly, Annual and Final Reports should not have an assigned Government Funded or Cost Share amount.)
4. Monthly, Quarterly, and Annual Reports include BOTH Technical and Business Reports (separate).
5. Final Report due date must be the POP end noted in Project Award.
6. RRPV Milestone Numbers are used for administrative purposes and should be sequential.

7. 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 4 – PROGRAM/PROJECT MANAGEMENT PLAN TEMPLATE

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

1. **Program Management:** Provide details on proposed Program Management approach.
2. **Subcontractor Management:** Provide details on proposed Subcontractor Management Approach.
3. **Key Personnel:** Key personnel (including proposed consultants) who possess the necessary education, training, and experience to successfully perform the work identified in the technical proposal (Note: key personnel resumes to be included in the technical proposal). A summary of related activities must also be provided for key personnel.
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:
 - Manufacturing capacity expansion plans to match the proposed manufacturing scale-up;
 - Overview of the management of Quality Systems at the facility;
 - List of capabilities for clinical activities conducted in house and at contract research organizations;
 - Qualified animal facilities where Good Laboratory Practice (GLP) studies would be conducted and appropriate certifications for humane care and use of vertebrate animals;
 - Commercial capabilities of the Offeror, including current products, and marketing, distribution, and customer support capabilities (as applicable); and
 - List of key vendors or service providers, locations, and brief description of their expertise/experience.]

ATTACHMENT 5 – ASPR SECURITY REQUIREMENTS

* This list of deliverables and ASPR-mandated security requirements may be required for any contract or agreement awarded by or on behalf of ASPR. ASPR shall be the sole determiner of the necessity of inclusion of these requirements, or subset thereof, on a case-by-case basis, as identified in the Deliverables Section of the RPP. Included with Project Proposals, Offerors must include a statement attesting to their intent and ability to comply with these deliverables and security requirements within the deadline dates stated in this attachment.

1. Security Reporting Requirements

The partner facility shall notify the Government Security Team within 24-72 hours of any activity or incident that is in violation of established security standards or indicates the loss or theft of government products associated with this Agreement. The facts and circumstances associated with these incidents will be documented in writing for government review.

2. Supply Chain Resiliency Plan - [Removed]

3. Manufacturing Data Requirements

The Project Awardee shall submit within 30 calendar days after project award detailed data regarding project materials, sources, and manufacturing sites, including but not limited to: physical locations of sources of raw and processed material by type of material; location and nature of work performed at manufacturing, processing, and fill/finish sites; and location and nature of non-clinical and clinical studies sites. The Government may provide a table in tabular format for Project Awardee to be used to submit such data which would include but not be limited to the following:

- Storage/inventory of ancillary materials (vials, needles, syringes, etc.)
- Shipment of ancillary materials (vials, needles, syringes, etc.)
- Disposal of ancillary materials (vials, needles, syringes, etc.)
- Seed development or other starting material manufacturing
- Bulk drug substance and/or adjuvant production
- Fill, finish, and release of product or adjuvant
- Storage/inventory of starting materials, bulk substance, or filled/final product or adjuvant
- Stability information of bulk substance and/or finished product
- Shipment of bulk substance of final product
- Disposal of bulk substance or final product

4. Work Locations

The Project Awardee shall submit detailed data regarding locations where work will be performed under this contract, including addresses, points of contact, and work performed per location, to include sub-contractors.

Project Awardee will submit a Work Locations Report:

- Within 5 business days after execution of Project Award
- Within 30 business 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 or a Public Health Emergency of International Concern (PHEIC) by the WHO

5. Operational Security (OPSEC)

The Project Awardee shall develop an OPSEC Standard Operating Procedure (SOP)/Plan within ninety (90) calendar days after project award to be reviewed and approved by the responsible Government OPSEC officer. This plan will be submitted to the PAR for coordination of approvals. This SOP/Plan will include identifying the critical information related to this Project Award, why it needs to be protected, where it is located, who is responsible for it, and how to protect it.

6. Security Plan

The Project Awardee shall develop a comprehensive security program that provides overall protection of personnel, information, data, and facilities associated with fulfilling the Government requirement. This plan shall establish security practices and procedures that demonstrate how the contractor will meet and adhere to the security requirements outlined below prior to the commencement of product manufacturing. The Draft Security Plan shall be delivered to the Other Transaction Agreements Officer (OTAO) and Project Award Representative (PAR) no later than 30 calendar days after award. The Project Awardee shall also ensure all subcontractors, consultants, researchers, etc. performing work on behalf of this effort, comply with all Government security requirements and prime contractor security plans.

- a) The Government will perform an internal review in detail and submit comments within ten (10) business days to the OTAO and PAR to be forwarded to the Project Awardee. The Project Awardee shall review the Draft Security Plan comments and submit a Final Security Plan to the U.S. Government within ten (10) calendar days after receipt of the comments.
- b) The Security Plan shall include a timeline for compliance of all the required security measures outlined by the Government.
- c) Upon completion of initiating all security measures, the Project Awardee shall supply to the OTAO and PAR a letter certifying compliance to the elements outlined in the Final Security Plan.

At a minimum, the Final Security Plan shall address the following items:

Security Requirements:

1. Facility Security Plan

Description: As part of the partner facility's overall security program, the Project Awardee shall submit a written security plan with their proposal to the Government for review and approval by Government security subject matter experts. The performance of work under the contract will be in accordance with the approved security plan. The security plan will include the following processes and procedures at a minimum:

Security
Administration

- organization chart and responsibilities
- written security risk assessment for site
- threat levels with identification matrix (High, Medium, or Low)
- enhanced security procedures during elevated threats
- liaison procedures with law enforcement

	<ul style="list-style-type: none"> • annual employee security education and training program
Physical Security Policies and Procedures	<ul style="list-style-type: none"> • internal/external access control • protective services • identification/badging • employee and visitor access controls • parking areas and access control • perimeter fencing/barriers • product shipping, receiving and transport security procedures • facility security lighting • restricted areas • signage • intrusion detection systems • alarm monitoring/response • closed circuit television • product storage security • other control measures as identified
Information Security	<ul style="list-style-type: none"> • identification and marking of sensitive information • access control • storage of information • document control procedures • retention/ destruction requirements
Information Technology/Cyber Security Policies and Procedures	<ul style="list-style-type: none"> • intrusion detection and prevention systems • threat identification • employee training (initial and annual) • encryption systems • identification of sensitive information/media • password policy (max days 90) • lock screen time out policy (minimum time 20 minutes) • removable media policy • laptop policy • removal of IT assets for domestic/foreign travel • access control and determination • VPN procedures • WiFi and Bluetooth disabled when not in use • system document control • system backup • system disaster recovery • incident response • system audit procedures • property accountability
2. Site Security Master Plan Description: The partner facility shall provide a site schematic for security systems which includes: main access points; security cameras; electronic access points; IT Server Room; Product Storage Freezer/Room; and bio-containment laboratories.	
3. Site Threat / Vulnerability / Risk Assessment	

Description: The partner facility shall provide a written risk assessment for the facility addressing: criminal threat, including crime data; foreign/domestic terrorist threat; industrial espionage; insider threats; natural disasters; and potential loss of critical infrastructure (power/water/natural gas, etc.) This assessment shall include recent data obtained from local law enforcement agencies. The assessment should be updated annually.

4. Physical Security

Description:

Closed Circuit Television (CCTV) Monitoring	<ul style="list-style-type: none"> a) Layered (internal/external) CCTV coverage with time-lapse video recording for buildings and areas where critical assets are processed or stored. b) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. c) Video recordings must be maintained for a minimum of 30 days. d) CCTV surveillance system must be on emergency power backup. e) CCTV coverage must include entry and exits to critical facilities, perimeters, and areas within the facility deemed critical to the execution of the contract. f) Video recordings must be maintained for a minimum of 30 days. g) CCTV surveillance system must be on emergency power backup.
Facility Lighting	<ul style="list-style-type: none"> a) Lighting must cover facility perimeter, parking areas, critical infrastructure, and entrances and exits to buildings. b) Lighting must have emergency power backup. c) Lighting must be sufficient for the effective operation of the CCTV surveillance system during hours of darkness.
Shipping and Receiving	<ul style="list-style-type: none"> a) Must have CCTV coverage and an electronic access control system. b) Must have procedures in place to control access and movement of drivers picking up or delivering shipments. c) Must identify drivers picking up Government products by government issued photo identification.
Access Control	<ul style="list-style-type: none"> a) Must have an electronic intrusion detection system with centralized monitoring. b) Responses to alarms must be immediate and documented in writing. c) Employ an electronic system (i.e., card key) to control access to areas where assets critical to the contract are located (facilities, laboratories, clean rooms, production facilities, warehouses, server rooms, records storage, etc.). d) The electronic access control should signal an alarm notification of unauthorized attempts to access restricted areas. e) Must have a system that provides a historical log of all key access transactions and kept on record for a minimum of 12 months. f) Must have procedures in place to track issuance of access cards to employees and the ability to deactivate cards when they are lost or an employee leaves the company.

	<ul style="list-style-type: none"> g) Response to electronic access control alarms must be immediate and documented in writing and kept on record for a minimum of 12 months. h) Should have written procedures to prevent employee piggybacking access i) to critical infrastructure (generators, air handlers, fuel storage, etc.) should be controlled and limited to those with a legitimate need for access. j) Must have a written manual key accountability and inventory process. k) Physical access controls should present a layered approach to critical assets within the facility.
Employee/Visitor Identification	<ul style="list-style-type: none"> a) Should issue company photo identification to all employees. b) Photo identification should be displayed above the waist anytime the employee is on company property. c) Visitors should be sponsored by an employee and must present government issued photo identification to enter the property. d) Visitors should be logged in and out of the facility and should be escorted by an employee while on the premises at all times.
Security Fencing	Requirements for security fencing will be determined by the criticality of the program, review of the security plan, threat assessment, and onsite security assessment.
5. Security Operations Description:	
Security Management	<ul style="list-style-type: none"> a) Designate a knowledgeable security professional to manage the security of the facility. b) Ensure subcontractor compliance with all Government security requirements.
6. Information Security Description:	
Physical Document Control	<ul style="list-style-type: none"> a) Applicable documents shall be identified and marked as procurement sensitive, proprietary, or with appropriate government markings. b) Sensitive, proprietary, and government documents should be maintained in a lockable filing cabinet/desk or other storage device and not be left unattended. c) Access to sensitive information should be restricted to those with a need to know.
Document Destruction	Documents must be destroyed using approved destruction measures (i.e, shredders/approved third party vendors / pulverizing / incinerating).
7. Information Technology & Cybersecurity Description:	
Identity Management	<ul style="list-style-type: none"> a) Physical devices and systems within the organization are inventoried and accounted for annually. b) Organizational cybersecurity policy is established and communicated. c) Asset vulnerabilities are identified and documented.

	<ul style="list-style-type: none"> d) Cyber threat intelligence is received from information sharing forums and sources. e) Threats, vulnerabilities, likelihoods, and impacts are used to determine risk. f) Identities and credentials are issued, managed, verified, revoked, and audited for authorized devices, users and processes. g) Users, devices, and other assets are authenticated (e.g., single-factor, multifactor) commensurate with the risk of the transaction (e.g., individuals' security and privacy risks and other organizational risks)
Access Control	<ul style="list-style-type: none"> a) Limit information system access to authorized users. b) Identify information system users, processes acting on behalf of users, or devices and authenticate identities before allowing access. c) Limit physical access to information systems, equipment, and server rooms with electronic access controls. d) Limit access to/ verify access to use of external information systems.
Training	<ul style="list-style-type: none"> a) Ensure that personnel are trained and are made aware of the security risks associated with their activities and of the applicable laws, policies, standards, regulations, or procedures related to information technology systems.
Audit and Accountability	<ul style="list-style-type: none"> a) Create, protect, and retain information system audit records to the extent needed to enable the monitoring, analysis, investigation, and reporting of unlawful, unauthorized, or inappropriate system activity. Records must be kept for minimum must be kept for 12 months. b) Ensure the actions of individual information system users can be uniquely traced to those users. c) Update malicious code mechanisms when new releases are available. d) Perform periodic scans of the information system and real time scans of files from external sources as files are downloaded, opened, or executed.
Configuration Management	<ul style="list-style-type: none"> a) Establish and enforce security configuration settings. b) Implement sub networks for publicly accessible system components that are physically or logically separated from internal networks.
Contingency Planning	<ul style="list-style-type: none"> a) Establish, implement, and maintain plans for emergency response, backup operations, and post-disaster recovery for information systems to ensure the availability of critical information resources at all times.
Incident Response	<ul style="list-style-type: none"> a) Establish an operational incident handling capability for information systems that includes adequate preparation, detection, analysis, containment, and recovery of cybersecurity incidents. Exercise this capability annually.

Media and Information Protection	<ul style="list-style-type: none"> a) Protect information system media, both paper and digital. b) Limit access to information on information systems media to authorized users. c) Sanitize and destroy media no longer in use. d) Control the use of removable media through technology or policy.
Physical and Environmental Protection	<ul style="list-style-type: none"> a) Limit access to information systems, equipment, and the respective operating environments to authorized individuals. b) Intrusion detection and prevention system employed on IT networks. c) Protect the physical and support infrastructure for all information systems. d) Protect information systems against environmental hazards. e) Escort visitors and monitor visitor activity.
Network Protection	Employ intrusion prevention and detection technology with immediate analysis capabilities.
8. Transportation Security Description: Adequate security controls must be implemented to protect materials while in transit from theft, destruction, manipulation, or damage.	
Drivers	<ul style="list-style-type: none"> a) Drivers must be vetted in accordance with Government Personnel Security Requirements. b) Drivers must be trained on specific security and emergency procedures. c) Drivers must be equipped with backup communications. d) Driver identity must be 100 percent confirmed before the pick-up of any Government product. e) Drivers must never leave Government products unattended, and two drivers may be required for longer transport routes or critical products during times of emergency. f) Truck pickup and deliveries must be logged and kept on record for a minimum of 12 months.
Transport Routes	<ul style="list-style-type: none"> a) Transport routes should be pre-planned and never deviated from except when approved or in the event of an emergency. b) Transport routes should be continuously evaluated based upon new threats, significant planned events, weather, and other situations that may delay or disrupt transport.
Product Security	<ul style="list-style-type: none"> a) Government products must be secured with tamper resistant seals during transport, and the transport trailer must be locked and sealed. <ul style="list-style-type: none"> • Tamper resistant seals must be verified as “secure” after the product is placed in the transport vehicle. b) Government products should be continually monitored by GPS technology while in transport, and any deviations from planned routes should be investigated and documented. c) Contingency plans should be in place to keep the product secure during emergencies such as accidents and transport vehicle breakdowns.
9. Security Reporting Requirements Description: The partner facility shall notify the Government Security Team within 24 hours of any activity or incident that is in violation of established security standards or indicates the loss or theft of	

government products. The facts and circumstances associated with these incidents will be documented in writing for government review.

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