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

"NextGen Vaccines: Immune Assays"

RPP #: 24-04-NGVxAssays

Original Issue Date: February 15, 2024

Amendment No. 2 Issue Date: 12 March 2024

Due: March 22, 2024, 1PM ET – This solicitation is closed

Biomedical Advanced Research Development Authority (BARDA)
Contracts Management & Acquisition (CMA)
400 7th Street, SW, Washington, DC 20024

MedicalCountermeasures.gov

Amendment No. 02 does the following:
Extends the proposal due date from March 18, 2024, to March 22, 2024, at 1pm Eastern.
All other terms and conditions remain unchanged.

Contents

1 Executive Summary

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

Purpose

BARDA, Administration for Strategic Preparedness and Response (ASPR), US Department of Health and Human Services (HHS) is requesting project proposals for immune assays to support the advanced clinical development and assessment of next-generation vaccines for COVID-19. BARDA has previously identified a capability gap for COVID-19 vaccines that, when compared to current vaccines, offer improved durability, breadth of protection, and/or transmission blocking in the face of new SARS-CoV-2 variants. A key part of development for the Project NextGen vaccine trials is harmonized immune assays that will enable analysis of vaccine-generated immune responses across trials as well as meta-analysis. The purpose of this project is to partner with performers to establish multiparameter intracellular staining (ICS) assays as part of a centralized testing resource for Project NextGen vaccine trials.

The goal of this project is to establish multiparameter ICS assays to identify and quantify SARS-CoV-2-specific T-cell subsets in peripheral blood mononuclear cell (PBMC) samples. **To be eligible for funding, performers must:**

1. Demonstrate a successful history of developing, qualifying, and validating ICS assays.
2. Demonstrate a successful history of testing of human clinical samples to appropriate quality standards in multiparameter ICS assays.

Offerors should also describe the following in their proposals in order to maximize their potential for award:

1. Offerors should describe their available resources, proposed ICS panels, controls, and prior experience validating flow cytometry panels to assess vaccine immunogenicity.

2. Offerors proposing to perform laboratory ICS assay testing should describe their internal quality systems and statistical analyses capabilities. Offerors that utilize or are proposing teaming arrangements should describe how these will flow through to the subrecipients.

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

2 Administrative Overview

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.***

RPP Approach

It is expected that there will be a total of one or more qualified respondents to accomplish the statement of objectives.

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

At the time of the submission, Offerors must certify on the cover page of their Proposal that, if selected for award, they will abide by the terms and conditions of the latest version of the RRPV Base Agreement. Base Agreements are typically not executed until Offeror is selected for award.

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.

Period of Performance and Type of Funding Instrument Issued

The anticipated Period of Performance for this effort is up to five (5) years from date of award for development (qualification/validation) and testing of clinical trial samples. Specific dates are to be negotiated. It is anticipated that the primary place of performance will be the performers' facilities, however, this aspect can be negotiated as part of each Performers' submission.

Expected Award Date

Offeror should plan on the period of performance beginning sometime in the third quarter of fiscal year 2024. 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.

Anticipated Proposal Selection Notification

As the basis of selections is completed, the Government will forward their selections 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.

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.

Eligibility Criteria

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

Additionally, in order to respond to this RPP, Offerors must show evidence they satisfy the following **minimum eligibility criteria**:

- Demonstrated successful history of developing, qualifying, and validating ICS assays
- Demonstrated successful history of testing of human clinical samples to appropriate quality standards in multiparameter ICS assays

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

History of Successful ICS Assays

While not required, a demonstrated history of successful ICS assays in FDA-regulated clinical trials will improve the competitiveness of an Offeror's proposal.

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 would be delivered consistent with terms of the base OT 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 Section 6 of the SOW, for any items to be furnished to the Government with restrictions. An example is provided below.

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

Question and Answer Period

Date	Event
15 Feb 2024	RPP released
28 Feb 2024 COB	Questions due from proposers
5 Mar 2024 COB	Questions & Answers released (can be approx.)
22 Mar 2024 1PM ET	Proposals due

Please submit questions to rrpv-contracts@ati.org.

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 Other Transaction Agreements Officer, is legally authorized to contractually bind or otherwise commit funding for selected Project Awards as result of this RPP.

Proposal Submission

Proposals shall be submitted by the date and time specified on the cover page.

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.

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.**

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.

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 (50-page limit, with all attachments limited to a total of no more than 70 pages)** – **See Attachment 1:** One signed 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, and key personnel resumes.

- **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 3.6 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.

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 Cost Proposal formats are **NOT** mandatory.

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

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:

- Effective July 17, 2023, BARDA will automatically issue a Certificate to all BARDA funded research commenced on or after July 17, 2023, that is within the scope of the BARDA Policy Notice No. BARDA-CoC-001-2023 – Issuing Certificates
- Support and maintain applicable regulatory submissions throughout life of the project.
- The Project 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.

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

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

4 Technical Requirements

Introduction

This project supports assay development and qualification/validation, as well as testing of human clinical PBMCs in multiparameter ICS assay for vaccine-generated T cell response assessments. Offerors shall develop the assay(s) to analyze clinical study samples to evaluate immune responses to COVID-19 vaccines, licensed or under development. Assays shall quantify responses relevant to ancestral SARS-CoV-2 and circulating variant(s) of concern.

For scheduling and pricing purposes, Offerors should assume that all activities may occur concurrently to support cost and schedule savings.

Solution Requirements

- Stage 1. Develop multiparameter ICS assays to identify and quantify SARS-CoV-2 -specific T-cell subsets in PBMC samples. Offerors shall also address the following requirements in the development of assay:
- Focus on T cell lineage, Th1, Th2 and Th 17 response, memory, regulatory, cytotoxicity markers, homing markers understood to direct cells to the airway or other mucosal surfaces.
- Performers shall include plans to update the assay target virus as requested based on SARS-CoV-2 variant emergence and evolution within 3 months of BARDA request (and availability of appropriate reagents).
- Validation studies shall be performed for analysis of Th1/Th2 CD4+ T cells and CD8+ T cells
- Qualification and validation studies shall include precision, sensitivity, specificity and dilutional linearity, as defined by ICH guidelines[1].
- Data cleaning, processing, visualization and cell population identification.

Stage 2. Establish laboratory testing capability using the assays developed under Stage 1 (including rapid establishment of testing using updated assays for variants) at the organization developing the assay or a subcontractor. Data from these assays should meet regulatory requirements. Data may be used to support a U.S. Food and Drug Administration (FDA) Emergency Use Authorization (EUA) or Biological License application (BLA) for COVID-19 vaccines. Laboratory testing capability should include:

[1] ICH Q2(R1) guidance document "Validation of Analytical Procedures". De Rosa, S Methods. 2012; 57(3):383-391. Kagina, B et al. J Immunol Methods. 2015; 417:22-33.

- Establish laboratory testing capability for multiparameter ICS assay to identify and quantify SARS-CoV-2 -specific T cells in PBMC samples.
- Perform vaccine-product specific partial assay validation, if requested.
- Sample throughput of 200 samples/week
- The total number of tests to be performed is an estimated 35,000-40,000

In addition to the minimum eligibility criteria (identified in Section 2), Offerors should also describe the following in their proposals in order to maximize their potential for award:

1. Offerors should describe their available resources, proposed ICS panels, controls, and prior experience validating flow cytometry panels to assess vaccine immunogenicity.
2. Offerors proposing to perform laboratory ICS assay testing should describe their internal quality systems and statistical analyses capabilities. Offerors that utilize or are proposing teaming arrangements should describe how these will flow through to the subrecipients.

Project Management Objectives

It is anticipated that the performer will be required to submit a number of documents to capture the progression of the project, post-award. Offerors shall provide deliverables as included in Attachment 3, Statement of Work. Requirements may include, but are not limited to, the following:

Reporting

1. The performer shall deliver monthly technical and financial reports and progress reports, to include a master schedule. Annual reports shall also be provided. At the end of the effort, a detailed draft Technical Progress Report shall be submitted 75 calendar days before the end of the Period of Performance (PoP) and the Final Technical Progress Report on or before the completion date of the PoP.

Meetings

1. The performer shall schedule regular, recurring progress meetings with the Government.
2. The meeting agenda shall be submitted to the Government in advance and meeting minutes will be submitted following meetings.

Logistics Objectives

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

Performance Requirements

a) The Contractor shall qualify and/or validate (as required by BARDA) the variant-specific ICS assay for PBMC samples.

b) If requested, the Contractor shall perform partial (vaccine-specific) validation of the ICS assay for PBMC samples. BARDA will provide vaccine study-derived incurred samples to the Contractor for partial validation.
c) The Contractor must generate, oversee, and manage validation protocols, execution and reports as required by the FDA and per guidance of the Clinical and Laboratory Standards Institute (CLSI) CLSI H62 Validation of Assays Performed by Flow Cytometry, 1st Edition. ISBN: 978-1-68440-129-1.
d) Within three months of BARDA request (and availability of appropriate antigen panels), Contractor shall update the assay as needed based on SARS-CoV-2 variant emergence and/or evolution.
e) The Contractor shall source appropriate positive and negative quality control samples, as well as reference sera and proficiency panel sera or other reagents, as appropriate.
f) The ICS assay qualification/validation protocol(s) shall be approved by BARDA prior to execution.
g) The Contractor shall generate, oversee, and manage qualification/validation protocol(s) and study report(s).
h) The contractor shall provide ICS raw assay qualification/validation data and the final qualification/validation report(s). These reports must include the source and lot information for all assay reagents and components, including biologicals. Assay qualifications/validations must assess precision, dilutional linearity, sensitivity, and specificity. The immunoassays must include appropriate routine quality control samples.
i) The final assay qualification/validation report(s) to BARDA shall also include results and performance parameters of assay quality control samples and proficiency panel sample testing. The report must be in electronic Common Technical Document (eCTD) submission ready format as required by the FDA.
j) The Contractor shall submit method qualification/validation plans, protocols, and reports to FDA/Center for Biologics Evaluation and Research (CBER) through the Drug Master File (DMF) that the Contractor will establish with the FDA and get feedback from FDA indicating that the assay is acceptable for use.
k) Testing of the clinical samples on ICS assays shall be conducted under appropriate quality management system (QMS); e.g., Clinical and Laboratory Standards Institute (CLSI) QMS01: A Quality Management System Model for Laboratory Services, 5th Edition.
l) The contactor shall report assay data results to the sponsor and BARDA to conduct immunogenicity and correlates of protection studies.
m) The Contractor shall coordinate quality and data transfer agreements (DTA) and data transfer as required with vaccine sponsor(s) and BARDA. The Contractor shall make the data transfer in formats compatible with the vaccine sponsor and BARDA statistics team (or designee).
n) The Contractor shall perform regular testing of internal and/or external quality control(s) (QC) along with clinical testing and provide a biweekly report to BARDA that includes results and performance parameters of assay quality control sample panels. Results of periodic proficiency panel sample testing will also be reported to BARDA, as appropriate.

5 Selection/Evaluation

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.

Proposal Evaluation Process

Following the preliminary screening, the Government sponsor will perform source selection 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. The USG will employ non-disclosure agreements to protect information contained in the RPP. An Offeror's submission of a Proposal under this RPP indicates concurrence with the aforementioned use of contractors and SMEs.

Evaluation of proposals will be based on an independent, comprehensive review and assessment of the work proposed against stated source selection criteria and evaluation factors. The Government will evaluate each proposal against the evaluation factors detailed below and assign adjectival ratings to the non-cost/price factor(s) as discussed below. The Offeror shall clearly state how it intends to meet and, if possible, exceed the RPP requirements. Mere acknowledgement or restatement of a RPP requirement is not acceptable, unless specifically stated otherwise.

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:

- Outstanding
- Good
- Acceptable
- Marginal
- 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.

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.

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

Factor 3 – Cost/Price: (See Cost/Price Evaluation below)

Evaluation factors are listed in descending order of importance.

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 for potential future award if funding currently is unavailable; or*
3. *Reject the proposal (will not be considered for award and will not be placed in the Basket)*

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.

Best Value

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

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

Basket Provision

The electronic "Basket" is an innovative acquisition tool. Proposals rated as Acceptable through Outstanding, but not immediately selected for award, may be placed in the Basket (at the Government's sole discretion) for 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 rrpv-contracts@ati.org.

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 50 pages, with all attachments limited to a total of no more than 70 pages. Pages in excess of this limitation may not be considered**.** Offerors are advised that the number of pages should be commensurate with the degree of complexity of the proposed effort.

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

1. Cover Page
2. RRPV Member Organization Information Sheet
3. Executive Summary & Minimum Eligibility Criteria
4. Technical Approach
5. Current & Pending Support
6. Resumes of Key Personnel

1. Technical Proposal Cover Page

[Name of Offeror]
[Address of Offeror]

RPP Number XXXXXX

[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).]

_____ _____
Signature of responsible party for the Offeror DATE

2. Member Information Sheet

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

OFFEROR NAME:	
ALL PLACES OF PERFORMANCE:	
TITLE OF PROPOSED EFFORT:	
UEI # (if applicable):	
CAGE CODE (if applicable):	
SMALL BUSINESS (YES/NO):	
SMALL/ DISADVANTAGED BUSINESS (YES/NO): SOCIOECONOMIC CATEGORY?	
CONFLICT OF INTEREST (YES/NO):	
TOTAL COST OF PROPOSAL:	
PROPOSED PERIOD OF PERFORMANCE IN MONTHS:	
PREFERRED PAYMENT METHOD (FFP, CPFF, Cost Reimbursable (CR):	
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.]

[Additionally, this section must address how the Offeror currently satisfies the following minimum eligibility requirement:]

- Demonstrated successful history of developing, qualifying, and validating ICS assays, and
- Demonstrated successful history of testing of human clinical samples to appropriate quality standards in multiparameter ICS assays

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 overarching approach and framework addressing the requirements set forth in the RPP. Include relevant background data and information on your platform or solution and listing the current status of your approach.]
3. **Objectives:** [Specify the objectives of the proposed effort.]
4. **Past Experience:** [Describe relative past experience, as well as the technical and management experience of the proposed team, to perform the proposed work]
5. **Technical Strategy**: [Provide a detailed and stepwise approach on how your organization intends to address the requirements set forth in the RPP and show a clear course of action.]
6. **Anticipated Outcomes**: [Provide a description of the anticipated outcomes from the proposed work.]
7. **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.]
8. **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			%
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]

9. **Schedule:** [Identify key technical, schedule, and cost risks, their potential impact and mitigation.]
10. **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.]
11. **Government Resources**: [Identify any key Government facilities, Government equipment, Government property, etc. that your organization requests to use for the effort.]
12. **Cost Realism:** [This section provides technical evaluators with high-level cost data in order for the evaluators to determine if the costs proposed are realistic as compared to the scope of work proposed. This information must be consistent with the Cost Proposal. The information must be provided in this section of the Technical Proposal. Include the following table as a summary of the costs by cost element.]

Cost Realism Form EXAMPLE This form is to be completed by Offeror and evaluated by Technical Evaluators. Items in italics are provided as samples only. Offeror must complete table with the applicable information.		
Cost Element	**Total Proposed Cost**	**Description/Explanation**
Labor	*$1,475,000*	*5000 hrs of senior scientist; 3000 hours of program management; 3000 of hours of contracts management; 3750 hours of scientist*
Labor Hours	*$14,750*	
Subcontractors	*$300,000*	*Sub A - $150,000; 1500 legal advisor hours* *Sub B - $150,000; 1500 hours of Testing*
Subcontractor Hours	*$3,000*	

Consultants	*$60,000*	*Financial consultant supporting all phases*
Consultant Hours	*$600*	
Material/Equipment	*$500,000*	*pipettes, gloves, computer software*
Other Direct Costs	*$12,000*	*ship testing materials to lab*
Travel	*$30,000*	*12 trips for 2 people for 2 days to Washington, DC from Charleston, SC for program meetings*
Indirect Costs	*$475,400*	*approved by DHHS 30 Sept 23*
Fee	*$0*	
Total Cost to Government	*$2,852,400*	
Total Project Value	***$4,592,400***	

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 pending 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. The Principal Investigator must be identified.

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, dates, etc.). Proposals that deviate substantially from these guidelines or that omit substantial parts or sections may be found non-responsive and may be eliminated from further review and funding consideration.

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

Section I: Cost Proposal Narrative

a. Cover Page
b. Overview
c. Cost Information

Section II: Cost Proposal Format

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

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

1. Cost Proposal Cover Page

[Name of Offeror]
[Address of Offeror]

RPP Number XXXXXX

[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).]

_____ _____
Signature of responsible party for the Offeror DATE

2. Cost Proposal Section I: Cost Proposal Narrative Template

1. Cost Proposal Narrative Overview

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

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

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 facilities and administrative [F&A] costs).

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

   See the salaries and wages pay tables on the 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, catalogue 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 rational used to derive the rate.

   Only in extraordinary circumstances will government funds be used to purchase equipment. Examples of acceptable equipment might include special test equipment, special tooling, or other specialized equipment specific to the 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 Agreements 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. 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.]

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

Request for Project Proposals (*RPP NUMBER***)**
Project Identifier: RRPV24-04-NGVxAssays-XXX
Member Organization Name:
Proposed Project Title:

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

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

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

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

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

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

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

Below are the following minimum deliverables for this RPP:

1. Meetings

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
1.1	Post Award Teleconference	The Performer must complete an initial teleconference after the initiation of the agreement period of performance. 1. Outline activities for the next 30 days 2. Discuss agenda items for the post-award Kickoff Meeting	• Within 5 business days after the initiation of the agreement period of performance • Performer must submit agenda and establish a teleconference number at least 3 business days in advance of the teleconference unless notified that BARDA will supply a teleconference number • PAR edits/approves and instructs Performer to distribute agenda at least 2 business days prior to meeting • Performer submits meeting minutes to PAR within 3 business days after the meeting • PAR reviews, comments, and approves minutes within 10 business days
1.2	Kickoff Meeting	The Performer must complete a Kickoff meeting after the initiation of the agreement period of performance.	• Within 10 business days after the initiation of the agreement period of performance, pending concurrence by the Agreements Officer • Performer must submit agenda and itinerary, if applicable, at least 5 business days in advance of in-person meeting or teleconference • PAR edits/approves and instructs Performer to distribute agenda at

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
			least 3 business days prior to meeting • Performer submits meeting minutes to PAR within 3 business days after the meeting • PAR reviews, comments, and approves minutes within 10 business days
1.3	Weekly Teleconference	The Performer must participate in teleconferences weekly with BARDA to discuss the technical performance on the agreement. Meeting frequency may be increased or decreased as needed during the course of the project.	• Performer must submit agenda to PAR no later than 2 business days in advance of meeting • PAR edits/approves and instructs Performer to distribute agenda prior to meeting • Performer must distribute agenda and presentation materials at least 2 calendar days in advance of meeting • Performer must submit meeting minutes to PAR within 3 business days of the meeting • PAR reviews, comments, and approves minutes within 10 business days
1.4	Technical, Subgroup, Ad Hoc Teleconference(s)	The Performer must participate in technical, subgroup, or ad hoc teleconferences as needed or upon BARDA request to discuss the technical performance on the agreement. Meeting frequency may be defined as needed during the course of the project.	• Performer must submit agenda to PAR no later than 2 business days in advance of Technical or Subgroup meeting • PAR edits/approves and instructs Performer to distribute agenda prior to meeting • Performer must distribute agenda and presentation materials at least 24 hours in advance of meeting • Performer must submit meeting minutes to PAR within 3 business days of the meeting • PAR reviews, comments, and approves minutes within 6 business days
1.5	Periodic Review Meetings	At the discretion of the Government, the Performer must hold up to four recurring Project Review Meetings per year, held by teleconference or face-to face either in Washington,	• Performer must submit an agenda and itinerary, if applicable, at least 5 business days, and Performer must provide presentation

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		D.C. or at work sites of the Performer or sub-performers. Face-to-face meetings shall alternate between Washington, D.C. and Performer, sub-contractor sites. The meetings will be used to discuss agreement progress in relation to the Program Management deliverables described in this agreement as well as nonclinical, technical, regulatory, and ethical aspects of the program.	materials at least 3 business days, in advance of the meeting • PAR edits/approves and instructs Performer to distribute agenda at least 3 business days prior to meeting • Performer provides meeting minutes to PAR within 3 business days after the meeting • PAR reviews, comments, and approves minutes within 10 business days after the meeting

2. Technical Reporting: General

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
2.1	Project Management Plan (PMP)	The Project Management Plan should define the overall plan for how the project will be executed, monitored and controlled and must include a Study Responsibility Assignment Matrix for Performer and subperformer team(s). The PMP may be a single detailed document or composed of one or more subsidiary planning documents. These additional planning documents provide guidance and direction for specific management, planning, and control activities such as schedule, cost, risk, staffing, change control, communications, quality, procurement, deployment, etc. Each of the subsidiary planning documents should be detailed to the extent required by the specific project.	• Performer must submit a Project Management Plan (PMP) o Within 30 calendar days after the initiation of the agreement period of performance o 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.	• At first project meeting and as updated no later than every 30 calendar days. Provided in pdf.
2.3	Communication Plan	The Performer must develop and implement an effective	• Performer must submit a Communication Plan

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		Communication Plan that details the flow of information between BARDA, Performer, collaborators, vendors, and other organizations. The Communication Plan must also include a press release review process.	○ Within 30 calendar days after the initiation of the agreement period of performance ○ Updates should be provided to reflect any key changes and reviewed at least annually.
2.4	Performer Locations	The Performer must submit detailed data regarding locations where work will be performed under this agreement, including addresses, points of contact, and work performed per location, to include sub-contractors and critical vendors of reagents and supplies. Contractors must include vendors for critical infrastructure protection.	• Performer must submit Work Locations Report: ○ Within 5 business days after the initiation of the agreement 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
2.5	Pandemic/Public Health Emergency Facility and Operational Management Plan	Performer must develop a Pandemic Facility and Operational Management Plan, including change procedures from normal to pandemic operations and continuity of operations in the event of a declared pandemic emergency. Performer must identify critical infrastructure.	• Performer must submit Pandemic Management Plan: ○ Draft within 15 days of award ○ Final within 30 days of award
2.6	Request for Information (RFI) Responses	Upon request of the Government, the Performer must provide complete responses to ad hoc RFIs. RFIs may address key cost, schedule, and technical updates. Responses may be shared with senior Government leaders and should be provided on a non-confidential basis, unless the response includes confidential information in which case Performer must provide the	• Performer must submit an RFI response to BARDA by email within 24 hours (or whatever response time is designated by the Government) after Performer receipt of the RFI.

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		response in both confidential and non-confidential formats.	
2.7	Monthly & Annual Technical Progress Reports/Annual Meeting	The Monthly and Annual Technical Progress reports must address each of the below items and be cross-referenced to the Work Breakdown Structure (WBS), Statement of Work (SOW), Integrated Master Schedule (IMS), and Contract Performance Report (CPR) – or as applicable. 1. An Executive Summary highlighting the progress, issues and relevant manufacturing, nonclinical, regulatory, and publication activities. The Executive Summary should highlight all critical issues for that reporting period and resolution approach; limited to 2 pages 2. Progress in meeting agreement milestones organized by WBS, overall project assessment, problems encountered and recommended solutions. The reports must detail the planned and actual progress during the period covered, explaining any differences between the two and the corrective steps 3. A three-month rolling forecast of the key planned activities, referencing the WBS/IMS 4. A tracking log of progress on regulatory submissions with the FDA number, description of submission, date of	• The Performer must submit monthly reports on the 25th day of the month covering the preceding month; Annual Reports submitted on the last calendar day of the month after each agreement anniversary. Monthly progress reports are not required for the months when the Annual Report(s) are due, and Monthly/Annual Report(s) are not due during a month when the Final Report (final version, not draft) is due (see deliverable 2.8). The PAR and AO will review the monthly reports with the Performer and provide feedback • Performer must provide FINAL versions of reports within 10 business days after receiving BARDA comments/edits • Performer must provide notification of designated safety events to the AO and PAR within 24 hours of being notified of the event

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		submission, status of submission, and next steps 5. Estimated and Actual Expenses • This report must also contain a narrative or table detailing whether there is a significant discrepancy (>10%) at this time between the % of work completed and the cumulative costs incurred to date. Monthly and actual expenses should be broken down to the appropriate WBS level. This section of the report should also contain estimates for the Subcontractors' expenses from the previous month if the Subcontractor did not submit a bill in the previous month. If the subperformer(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 subcontractors. If the PAR and AO are satisfied that the Performer's reporting is sufficient to convey this information, this section may be waived. 6. Publication activities and progress for any manuscript, scientific meeting abstract, poster, presentation, and other public-facing material or information containing data generated under this agreement.	
2.8	Draft and Final Technical Progress Report	A draft Final Technical Progress Report must contain a summation of the work performed and the results	• The Performer must submit the Draft Final Technical Progress Report 75 calendar days before the

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		obtained over the entire agreement. This report must be in sufficient detail to fully describe the progress achieved under all milestones. Report must contain a timeline of originally planned and baselined activities and milestones overlaid with actual progress attained during the agreement. Descriptions and rationale for activities and milestones that were not completed as planned should be provided. The draft report must be duly marked as 'Draft.' The Final Technical Progress Report incorporating feedback received from BARDA and containing a summation of the work performed and the results obtained for the entire agreement PoP. The final report must document the results of the entire agreement. The final 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.	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 Performer must consider incorporating into the Final Report

3. Quality Assurance

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
3.1	Quality Management Plan (QMP)	Performer must develop an overall project Quality Management Plan to include a description of all quality activities and personnel involved in ensuring all activities are conducted and data are maintained under cGXP, and all products are managed to ensure that GMP requirements are met. All quality management plans must include subperformer quality	• Performer must submit a Quality Management Plan ○ Within 30 calendar days after the initiation of the agreement period of performance ○ On the 6th month agreement anniversary to include any updates.

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		management plans specifically addressing how subperformer quality will managed. All subcontractors must have a current quality agreement with the Performer and a recent vendor qualification audit.	
3.2	BARDA Audit	Performer must accommodate periodic or ad hoc site visits, auditing, inspection and review of release documents, test results, equipment and facilities when requested by HHS. If BARDA, the Performer, or other parties identify any issues during an audit, the Performer must capture the issues, identify potential solutions and submit a report to BARDA detailing the finding and corrective action(s). HHS reserves the right to conduct an audit, either by HHS and/or HHS designee(s), of the facilities used under this agreement and all records related to the manufacture, testing (including but not limited to analytical testing, nonclinical study), and storage of the product.	• If issues are identified during the audit, Performer must submit a report to BARDA detailing the finding and corrective action(s) within 10 business days of the audit • PAR and AO will review the report and provide a response to the Performer with 10 business days • Once corrective action is completed, the Performer will provide a final report to BARDA
3.3	FDA Inspections/Site visits	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 manufacturing facilities, the Performer must provide the USG with an exact copy (non-redacted) of the FDA Form 483 or summary and the Establishment Inspection Report (EIR). The Performer must provide the PAR and AO 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	• Performer must notify AO 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 • Performer must provide copies of any FDA inspection report received from subcontractors that occur as a result of this agreement or for this product within 1 business day of receiving correspondence from the FDA, a subperformer, or third party • Within 10 business days of inspection report, Performer must provide AO with a plan for addressing areas of nonconformance, if any are identified

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		Performer must also provide redacted copies of any FDA inspection reports received from subcontractors that occur as a result of this agreement or for this product. The Performer 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.	
3.4	Quality Assurance Audits and Subcontractor Monitoring Visits	BARDA reserves the right to participate in QA audits performed by the Performer. Upon completion of the audit/site visit the Performer must provide a report capturing the findings, results and next steps in proceeding with the subperformer. If action is requested of the subperformer, detailed concerns for addressing areas of non-conformance to FDA regulations for GLP, GMP, or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Performer must provide responses from the subcontractors to address these concerns and plans for corrective action. The Performer must allow for up to four (4) USG representative(s) to be present during the audit as necessary for appropriate oversight, including manufacturing person in plant, at nonclinical sites, CROs, and any other vendor involved in the conduct of the nonclinical study under agreement.	• Performer must notify AO and PAR a minimum of 10 business days in advance of upcoming, audits/site visits of subcontractors • Performer must notify the PAR and AO within 5 business days of report completion and provide Draft Report. • PAR and AO will review the report and provide a response to the Performer with 10 business days before audit can be finalized. • Performer must provide a final audit report and corrective and preventive actions (CAPAs) to address all findings in the report. • Performer must provide a final closeout report that all CAPAs were addressed to PAR and AO • Performer must notify BARDA within 24 hours of any critical and/or major findings
3.5	Risk Management Plan (RMP)	The Performer must provide an RMP that outlines the impacts of each risk in relation to the cost, schedule, and performance objectives. The plan must include risk mitigation strategies. Each risk mitigation strategy will capture how the corrective action will reduce impacts on cost, schedule, and performance.	• A Draft is due within 45 calendar days after the initiation of the agreement period of performance; updates to the RMP are due concurrent with Monthly Technical Progress Reports, but may be communicated more frequently. The Performer may choose to notify the government

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
			up to two times every three months if there are no changes from the prior submission, and not submit an update • BARDA will provide Performer with a list of concerns in response plan submitted • Performer must address, in writing, all concerns raised by BARDA within 20 business days of Performer's receipt of BARDA's concerns • The Performer must submit updates at minimum of every three months.
3.6	Integrated Master Schedule (IMS)	The Performer must provide an IMS that illustrates project tasks, dependencies, durations throughout the period of performance, and milestones (GO/NO-GO). The IMS must map to the WBS, and provide baseline, and actual or forecast dates for completion of tasks.	• The Performer must submit the IMS in both PDF and an agreed-upon electronic format (e.g., Microsoft Project) to the PAR • The first Draft of the IMS is due within 30 business days after the initiation of the agreement period of performance • The Government will request revisions within 10 business days, at which point the schedule baseline for the period of performance will be set • Thereafter an updated IMS is due concurrent with Monthly Technical Progress Reports • During a declared Public Health Emergency, the Performer must submit the IMS within 10 business days after the initiation of the agreement period of performance, updates are due weekly, and any significant change (i.e., a change which would impact the schedule by greater than one week) must be reported immediately to the PAR and/or designee.
3.7	Deviation Notification	Process for changing IMS activities associated with cost and schedule as	• The Performer must submit Deviation Notification and

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
	and Mitigation Strategy	baselined. Performer must notify BARDA of significant proposed changes the IMS defined as increases in cost above 5% or schedule slippage of more than 30 days, which would require a PoP extension. Performer must provide a high-level management strategy for risk mitigation.	Mitigation Strategy at least 10 business days prior to the Performer anticipating the need to implement changes
3.8	Incident Report	Performer must communicate to BARDA and document all critical programmatic concerns, issues, or probable risks that have or are likely to significantly impact project schedule and/or cost and/or performance. "Significant" is defined as a 10% or greater cost or schedule variance within a control account, but should be confirmed in consultation with the PAR. Incidents that present liability to the project even without cost/schedule impact.	• Due within 48 hours of activity or incident or within 24 hours for a security activity or incident • Email or telephone with written follow-up to PAR and AO • Additional updates due to PAR and AO within 48 hours of additional developments • Performer must submit within 5 business days a Corrective Action Plan (if deemed necessary by either party) to address any potential issues • If corrective action is deemed necessary, Performer must address in writing, its consideration of concerns raised by BARDA within 5 business days of receiving such concerns

4. Advanced R&D Products

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
4.1	Technical Documents	Upon request, Performer must provide AO and PAR with deliverables from the following activities: quality agreements between Contractors and sub-contractors, process Development Reports, Assay Qualification Plan/Report, Assay Validation Plan/Report, Assay Technology Transfer Report, Batch Records, SOPs, Master Production Records, Certificate of Analysis. The AO and PAR reserve the right to request within the PoP a non-	• Performer must provide technical document within 10 business days of AO or PAR request. Performer can request additional time on an as needed basis • If corrective action is recommended, the Performer must address, in writing, concerns raised by BARDA in writing

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		proprietary technical document for distribution within the Government.	
4.2	Publications	The Performer must submit any manuscript, scientific meeting abstract, poster, presentation, and any other public-facing material or information disseminated outside the purview of other deliverables, containing data generated under this agreement, to BARDA for review prior to submission. An acknowledgment of BARDA funding must be included.	• Performer must submit all manuscript or scientific meeting abstracts to PAR and AO prior to submission/presentation by 30 business days for manuscripts and 15 business days for abstracts, posters, or any other material • Performer must address in writing all concerns raised by BARDA in writing • Final submissions must be submitted to BARDA concurrently or no later than within one (1) calendar day of its submission • Performer must list all publication material in the Monthly Technical Progress Report

5. Regulatory Deliverables

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
5.1	FDA Correspondence	The Performer must memorialize all original and unredacted correspondence between Performer and FDA and submit to BARDA, including formal and informal emails, correspondence, telephone calls, and official information requests (IRs).	• Performer must provide copies of all original and unredacted FDA correspondence within 2 business days of correspondence
5.2	FDA Submissions	The Performer must provide BARDA the opportunity to review and comment upon all draft submissions before submission to the FDA. Performer must provide BARDA with an electronic copy of the final FDA submission. All documents must be duly marked as either “Draft” or “Final.”	• Performer must submit draft FDA submissions to BARDA at least 15 business days prior to FDA submission • BARDA will provide feedback to Performer within 10 business days of receipt • The Performer must address, in writing, its consideration of all concerns raised by BARDA prior to FDA submission • The Performer must submit Final FDA submissions to BARDA concurrently or no

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
			later than five (5) calendar days of submission

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, and the monetary value for that deliverable.. 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 25th of each month), Annual Technical Report, Final Technical Report, and Final Business Status Report. Reports shall have no funding associated with them.

Milestone Number	Task Number	Milestone Description	Due Date	Total Funding
1	N/A	Project Kickoff	12/1/2019	$20,000

2	N/A	Monthly Report (Technical and Business Reports)	1/25/2020	$ -
3	N/A	Monthly Report (Technical and Business Reports)	2/25/2020	$ -
4	1	Protocol Synopsis	2/28/2020	$21,075
5	2	Submission for Program Office Approval	2/28/2020	$21,075
6	N/A	Monthly Report (Technical and Business Reports)	3/25/2020	$ -
7	N/A	Monthly Report (Technical and Business Reports)	4/25/2020	$ -
8	3	Submission of Investigational New Drug application to the US FDA	4/30/2020	$398,214
9	N/A	Monthly Report (Technical and Business Reports)	5/25/2020	$ -
10	N/A	Monthly Report (Technical and Business Reports)	6/25/2020	$ -
11	N/A	Monthly Report (Technical and Business Reports)	7/25/2020	$ -
12	N/A	Monthly Report (Technical and Business Reports)	8/25/2020	$ -
13	N/A	Monthly Report (Technical and Business Reports)	9/25/2020	$ -
14	4	Toxicity Studies	10/1/2020	$63,227
15	N/A	Annual Report 1	10/25/2020	$ -
16	N/A	Monthly Report (Technical and Business Reports)	11/25/2020	$ -
17	5	FDA authorization trial	11/30/2020	$84,303
18	6	Research staff trained	11/30/2020	$ -
19	7	Data Management system completed	11/30/2020	$ -

20	N/A	Monthly Report (Technical and Business Reports)	12/25/2020	$ -
21	8	1st subject screened, randomized, and enrolled in study	1/1/2021	$337,457
22	N/A	Monthly Report (Technical and Business Reports)	1/25/2021	$ -
23	N/A	Monthly Report (Technical and Business Reports)	2/25/2021	$ -
24	9	Completion of dip molding apparatus	3/1/2021	$ 345,286
25	N/A	Monthly Report (Technical and Business Reports)	3/25/2021	$ -
26	N/A	Monthly Report (Technical and Business Reports)	4/25/2021	$ -
27	N/A	Monthly Report (Technical and Business Reports)	5/25/2021	$ -
28	10	Assess potential toxicology	6/1/2021	$157,829
29	N/A	Monthly Report (Technical and Business Reports)	6/25/2021	$ -
30	N/A	Monthly Report (Technical and Business Reports)	7/25/2021	$ -
31	N/A	Monthly Report (Technical and Business Reports)	8/25/2021	$ -
32	N/A	Monthly Report (Technical and Business Reports)	9/25/2021	$ -
33	11	Complete 50% patient enrollment	10/1/2021	$537,457
34	N/A	Annual Report 1	10/25/2021	$ -
35	N/A	Monthly Report (Technical and Business Reports)	11/25/2021	$ -
36	N/A	Monthly Report (Technical and Business Reports)	12/25/2021	$ -

37	N/A	Monthly Report (Technical and Business Reports)	1/25/2022	$ -
38	N/A	Monthly Report (Technical and Business Reports)	2/25/2022	$ -
39	12	Electronic Report Forms Developed	3/1/2022	$503,115
40	N/A	Monthly Report (Technical and Business Reports)	3/25/2022	$ -
41	N/A	Monthly Report (Technical and Business Reports)	4/25/2022	$ -
42	N/A	Monthly Report (Technical and Business Reports)	5/25/2022	$ -
43	N/A	Monthly Report (Technical and Business Reports)	6/25/2022	$ -
44	N/A	Monthly Report (Technical and Business Reports)	7/25/2022	$ -
45	13	Complete 100% patient enrollment	8/1/2022	$503,115
46	N/A	Monthly Report (Technical and Business Reports)	8/25/2022	$ -
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
50	N/A	Final Reports (POP End)	11/30/2022	$ -
			Total	$3,149,982
			Period of Performance (Months)	**XX Months**
			Contract Type	**FFP/CPFF/CR**

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 (i.e., Quarterly, Annual and Final Reports should not have an assigned Government Funded 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**