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

"Enabling Technology – Decentralized Clinical Trial – Home Focus"

RPP #: RRPV-24-02-HomeFocus

Original Issue Date: November 30, 2023

Amendment No. 2 Issue Date: December 22, 2023

Due: January 19, 2024 – 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 10 January 2024 to 19 January 2024 at Noon Eastern

All other terms and conditions remain unchanged.

Contents

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 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.

1.2 Purpose

As the COVID-19 pandemic evolves, characterization of correlates of protection (CoPs) are critical for ongoing vaccine development and optimization as variants and subvariants continue to emerge. As part of Project NextGen, BARDA intends to leverage immunogenicity data from multiple clinical trials of investigational next-generation COVID-19 vaccines and FDA licensed or authorized COVID-19 vaccines to inform a broader understanding of immunologic correlates of vaccine protection. In addition to interventional clinical trials of investigational products, establishing a paradigm that allows for the capture of real-world data on both immunologic and clinical endpoints is critical for a continual assessment of thresholds of protection in an immunologically heterogeneous and geographically diverse cross-section of the United States.

The Biomedical Advanced Research and Development Authority (BARDA), Administration for Strategic Preparedness and Response (ASPR), US Department of Health and Human Services (HHS) is requesting project proposals to conduct a study designed to assess potential CoP using humoral immunogenicity data correlated to symptomatic COVID-19 following vaccination with an FDA licensed/authorized COVID-19 vaccine. To be eligible for funding, Awardees must have a successful history of conducting clinical trials for medical countermeasures as appropriate for and aligned with the project.

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 statement of 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 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 and Type of Funding Instrument Issued

The anticipated Period of Performance for this effort is estimated to be five years for the proposed program. 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.

The U.S. Government (USG) may apply additional dollars for follow-on efforts with appropriate modification of the Project Award.

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 sometime in February 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.

2.5 Anticipated Proposal Selection Notification

As the basis of selection 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.

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 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**:

- A successful history of conducting clinical trials for medical countermeasures as appropriate for and aligned with the project.
- A successful history of conducting multi-center, longitudinal, FDA regulated and non-regulated vaccine clinical trials
- Capability or demonstrated ability with examples and references to home-based collection studies involving blood draws (intravenous and self-collected capillary systems)
- Demonstrated coordination of sites capable of digital and remote-based patient data capture and collection
- Capability or demonstrated partnership with CAP/CLIA collection laboratories for the analysis of blood specimens for determination of Correlates of Protection for vaccines Demonstrated coordination of or within a clinical network structure

Note – if available, examples should provide National Clinical Trial (NCT) identifier or ClinicalTrial.gov reference

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

2.8 Cost Sharing

Removed via Amendment #1

2.9 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 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 1, Technical Proposal, 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 1 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 Question and Answer Period

Date	Event
30 Nov 2023	RPP released
07 Dec 2023	Questions due from proposers
12 Dec 2023	Questions & Answers released (date is approximate)
19 Jan 2024 (noon eastern)	Proposals due

Please submit questions to rrpv-contracts@ati.org

3.2 Proposal General Instructions
Offerors who submit Proposals in response to this RPP must submit by the date on the cover page of this RPP. Proposals received after the time and date specified 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.

3.3 Proposal Submission
Proposals shall be submitted by the date and time specified on the cover page to the following website. Include this RRPV Solicitation Number on each Proposal submitted.

Do not submit any classified information in the Proposal submission.

Offerors shall submit files in Microsoft Word, Microsoft Excel, or Adobe Acrobat (PDF – portable 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.**

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

3.5 Submission Format
Proposals shall reference this RPP number. 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 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, cost realism*, 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 3.5 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.

3.6 Cost Proposal

The Cost Proposal must include two sections, a Cost Proposal Narrative, and a Cost Proposal Format. Offerors are encouraged to use their own cost formats such that the necessary detail is provided. The RRPV CMF will make optional cost proposal formats available on the Members-Only RRPV website. The 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.

3.7 Restrictions on Animal and Human Subjects

Performer 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:

- Support and maintain regulatory submissions throughout life of the project.
- For research involving human subjects, HHS human subject protection regulations and policies require that any institution engaged in non-exempt human subjects research conducted or supported by HHS must submit a written assurance of compliance to Office for Human Research Protections (OHRP). Under an Federal Wide Assurance, an institution commits to HHS that it will comply with the requirements set forth in 45 CFR part 46, as well as the Terms of Assurance.

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

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

4 Technical Requirements

4.1 Project Objectives (Attachment A)

This project aims to develop, execute, and analyze a study designed to assess the potential vaccine correlates of protection (CoP) using humoral immunogenicity data correlated to symptomatic COVID-19 following vaccination with an FDA licensed/authorized COVID-19 vaccine. Additionally, the proposed study would randomize participants into two groups to either undergo phlebotomy for venous specimens or self-collect capillary blood specimens. This allows for the assessment of the feasibility of remote self-collected specimens to inform CoP analyses as well as a comparison of immunologic data obtained from venous and capillary specimens. The Offeror is expected to collaborate, to include humoral immunogenicity analyses for correlates of protection, at a central laboratory determined by USG.

A successful offeror should assume a companion task order will be released to the BARDA Clinical Studies Network Statistical and Data Coordinating Center (SDCC).

A successful offeror may be required to collaborate with the CSN SDCC following the roles and responsibilities matrix as per the BARDA Clinical Studies Network (CSN) Governance Plan (Attachment D). Offeror is expected to describe in its response plans how this cross collaboration will be achieved, assuming the performer will fulfill the Clinical Trial Planning and Execution (CTPE) role as described in the BARDA Clinical Studies Network (CSN) Governance Plan (v. 1.0 02Sep21).

Work may include all aspects of clinical study planning and execution from development through analysis (with the exception of full clinical data management and statistical analysis; see Attachment C).

4.2 Solution Requirements

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

Study Execution

- Program Management and Administration
  - Perform all aspects of task order project management as per the Project Management Plan and as specified in other performer plans. This includes program coordination; implementation; Quality Assurance/Quality Control (QA/QC) oversight for the entire program; risk management and mitigation.
  - Schedule, develop create agendas for, and lead team meetings. Author and distribute meeting minutes documenting key discussions, decisions, action items and persons responsible.

- Provide Secure (21 CFR Part 11 compliant validated), study-specific internet-based portal that is password protected with managed user access roles.
- Develop a Project Management Plan (PMP) that describes the relationships, accountabilities, communications, and oversight of coordination of the collaborative activities of the Project Awardee as well as the vendors, and subPerformers during study planning, start-up, execution, and close-out.
- Collaborate with other vendors to develop the overall PMP, and comprehensive study timelines in MS Project.
- Provide written project status reports according to pre-specified schedules.

- Planning and Pre-Study Activities
  - Provide protocol development and medical writing support, including the development of protocol-related documents such as sample informed consents. Protocol development and subsequent study enrollment should take into consideration:
    - Diversity of the clinical study population, taking into account applicable principles outlined in "Enhancing the Diversity of Clinical Trial Populations — Eligibility Criteria, Enrollment Practices, and Trial Designs Guidance for Industry" https://www.fda.gov/regulatory-information/search-fda-guidance-documents/enhancing-diversity-clinical-trial-populations-eligibility-criteria-enrollment-practices-and-trial.
  - Other FDA Guidance Documents including and not limited to:
    - Draft, "Decentralized Clinical Trials for Drugs, Biological Products and Devices" https://www.fda.gov/regulatory-information/search-fda-guidance-documents/decentralized-clinical-trials-drugs-biological-products-and-devices, and
    - Draft, "Digital Health Technologies for Remote Data Acquisition in Clinical Investigations" https://www.fda.gov/regulatory-information/search-fda-guidance-documents/digital-health-technologies-remote-data-acquisition-clinical-investigations
  - Provide a Diversity Plan for enrollment of participants based on "Diversity Plans to Improve Enrollment of Participants from Underrepresented Racial and Ethnic Populations in Clinical Trials Guidance for Industry" (Draft April 2022) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/diversity-plans-improve-enrollment-participants-underrepresented-racial-and-ethnic-populations. The Diversity Plan must include proposed targets to achieve deliverable. If necessary, the USG may pause enrollment to ensure diversity in the study.

- Negotiate and execute all clinical trial agreements and site budgets. This should include all necessary elements to implement all aspects of a clinical study.
- Author, as needed, project-specific Standard Operating Procedures (SOPs) associated with processes necessary to comply with the FDA and Sponsor-established requirements. Provide BARDA access to SOPs for review upon request.
- Develop study procedures manual and other manuals as necessary.
- Perform site feasibility and site selection including evaluation of investigator and research staff qualifications, facilities, and laboratory capabilities, site logistics, and infrastructure.
- Determine what type of Institutional Review Board (IRB)/ Ethics Committee (EC) as per Federal and local regulations can be utilized and coordinate all aspects of selecting the IRB.
- Have current access to a network of sites/investigators available to perform clinical studies including sites with access to normal healthy adults aged 18 years and above.
- Secure clinical trial insurance appropriate for the study and population.
- Purchase all necessary clinical/laboratory supplies. This includes all supplies necessary to implement a clinical study.
- Provide sites with study supplies and materials. This includes all supplies necessary to implement all aspects of a clinical study.
- Identify and establish contractual agreements with clinical research vendors to support studies as needed, including but not limited to clinical laboratories for biological sample management and analysis, chain of custody, and clinical sites inclusive of participant remuneration.
- Pre-qualify central laboratories for validated assays.
- Establish a validated research specimen tracking and reporting system.
- Establish processes in a study-specific manual for handling of specimens: collection, processing, shipping and receipt, final specimen disposition and reconciliation. The appended Specimen Guidelines for Transfer of Specimens for Secondary use to Biological Specimen and Investigational Product Storage Facility should be followed.
- Coordinate sample management and shipping. This includes all sample management supplies necessary to implement all aspects of a clinical study.
- Obtain local clinical laboratory ranges, qualifications, and certifications, including College of American Pathologists (CAP) and Clinical Laboratory Improvement Amendments (CLIA).

    - Obtain necessary approvals for export of biological specimens as allowed by regulatory authorities.
    - Develop and implement a study supplies procurement and management plan.
    - Medical and Safety Monitoring/Pharmacovigilance
    - Develop and implement plans for providing medical monitoring support with qualified medical monitors trained in the appropriate therapeutic area.
    - Develop and implement plans for safety assessment and safety monitoring/pharmacovigilance activities.
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    - Develop and implement plans for providing medical monitoring support with qualified medical monitors trained in the appropriate therapeutic area.
    - Develop and implement plans for safety assessment and safety monitoring/pharmacovigilance activities.
- Regulatory Services
    - Collect and review Regulatory Essential Document Packet for site activation and provide the package to BARDA for approval prior to activation as requested. Manage site activation process.
    - Manage electronic Trial Master File (eTMF) during the active study and transfer eTMF for archiving to BARDA performer upon task order closure. Activities include: create eTMF index; set up and maintain eTMF; conduct periodic eTMF audits; and final eTMF Quality Control, archiving, and document return.
    - As directed by BARDA, register and/or provide information for the clinical study to ClinicalTrials.gov Protocol Registration and Results System (PRS).
    - Obtain approval and annual renewals from Institutional Review Board (IRB)/Independent Ethics Committee (IEC) as required.
- Quality Assurance and Audits
    - Development and implementation of an effective internal Quality Assurance and Quality Control Plan ensuring compliance with federal and local regulations and approved protocol.
    - Have an established internal system to measure, monitor and improve the level of performance of the personnel responsible for direct management of the sites (e.g., on site and central monitoring activities, clinical trial agreement (CTA) essential records management) and the performer/subperformer staff.
    - Provide capabilities for on-site auditing of clinical study sites and vendors (subperformer) including drafting and submission of audit plans and reports.

- Maintain inspection readiness state.
- The Performer shall undergo independent quality audits initiated at the discretion of the USG for review of Performer processes, procedures, and operations at the Performer's site to ensure regulatory compliance.
    - The Performer shall ensure that designated staff and all necessary information/documents are available.
    - For cause audits may also be performed at any time and without advance notice to the Performer, in instances of non-performance and/or suspected non-compliance with federal and/or local regulatory requirements.

- Clinical Site Selection, Management, and Monitoring
    - Ensure the conduct of the study is in compliance with approved protocol; all applicable federal and local regulations, Good Clinical Laboratory Practices (GCLP) and Good Clinical Practices (GCP).
    - Organize and provide all site training.
    - Perform protocol-specific clinical site monitoring, identification, assessments and develop site selection plans.
    - Perform on-site and remote risk-based monitoring visits to ensure the conduct of the study is in compliance with approved protocol; federal and local regulations; and GCP.
    - Develop and implement a robust risk-based monitoring plan with quality metric deliverables on an ongoing basis to evaluate site status.
    - Ensure clinical sites, have documentation of proficiency in: GCP, Investigator Responsibilities, Protection of Human Subjects, HHS/ASPR Performer Information Security Awareness, Privacy, and Records Management training, Role-based training commensurate with their roles and responsibilities in accordance with HHS policy and the HHS Role-Based Training of Personnel with Significant Security Responsibilities Memorandum, and read and adhere to the HHS Information Technology General Rules of Behavior before performing any work under this contract.
    - Ensure site(s) and IRB/IEC are in compliance with Federal wide Assurance (FWA).
    - Assist sites with the development of recruitment and retention plans, monitor site recruitment and retention as well as subject visit compliance.
    - Initiate enrollment of eligible subjects in accordance with institutional and regulatory guidelines to complete studies.
    - Monitor participant enrollment and quality metrics. Establish and maintain centralized monitoring reporting systems to track individual site activities such as

numbers of subjects screened, enrolled, withdrawn, and completed by gender and ethnicity.

- Develop and implement risk management contingency plans for slow enrollment and gender/ethnicity distribution such as frequent meetings with the clinical sites and identification and prequalification of back-up clinical sites.
- Manage investigator site payments, inclusive of subject remuneration, vendor payments, and other indirect/direct costs per contract and budget.
- Provide ongoing and active vendor management of all subPerformers.
- Review site performance on an ongoing basis and work directly with site staff to improve processes and achieve best practices.
- Develop and implement clinical site quality management programs including data quality assessments, source data verification and quality audits.
- Develop and maintain a system to monitor all clinical site items that require expiration dates such as site personnel professional licensures, IRB initial approval and periodic IRB status reports, Federal wide Assurance certification, equipment inspections, temperature monitoring or calibration, laboratory license(s) and site staff training.
- Coordinate biological specimen management with the central clinical laboratory or other designated facilities, and coordinate shipment and storage to a research lab.
- Procure study supplies, manage kitting, shipment, delivery, proper storage, and inventory at clinical sites.

- Transition Plan
  - Maintain contract operations at full staffing of key processes and activities until completion of final clinical study report and transfer of applicable files, and/or specimens (including specimen-associated metadata) to BARDA/BARDA designated performer.
  - Coordinate and collaborate with the BARDA/BARDA designated performer to transfer all applicable files, and/or specimens (including specimen-associated metadata).

4.3 Project Management Objectives

It is anticipated that the Project Awardee will be required to submit a number of documents to capture the progression of the project, post-award. 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 including a master schedule. Annual reports shall also be provided. At the end of the effort, the Offeror shall provide a detailed clinical study report, and a final technical and business report.
2. Additional deliverables will include:
    a. Those as described in the Deliverables Table below
    b. Draft and final nonclinical and clinical study reports.
    c. Inclusion of the U.S. Government in FDA meetings.
    d. Submission of all read-ahead packages for FDA meetings ahead of time.
    e. Records of any and all communications with the FDA.

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

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

Performance Requirements

Submission and maintenance of clinical documentation for compliance with Institutional Review Board (IRB)/ Ethics Committee (EC) as per Federal and local regulations to support execution and completion of the clinical study.

The successful Offeror shall provide deliverables as included in Attachment 3, Statement of Work.

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. Where appropriate, the USG will employ non-disclosure agreements to protect information contained in the RPP. An Offeror's submission of a Proposal under this RPP indicates concurrence with the aforementioned use of contractors and SMEs.

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

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 – Cost/Price: (See Section 5.4 below)

Factor 3 – 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.

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 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 to 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 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. Cost Realism*
6. Current & Pending Support
7. Data Rights*
8. Resumes of Key Personnel*

***Excluded from page limitation**

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), 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.]

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

- A successful history of conducting clinical trials for medical countermeasures as appropriate for and aligned with the project.
- A successful history of conducting multi-center, longitudinal, FDA regulated and non-regulated vaccine clinical trials
- Capability or demonstrated ability with examples and references to home-based collection studies involving blood draws (intravenous and self-collected capillary systems)
- Demonstrated coordination of site capable of digital and remote-based patient data capture and collection

Capability or demonstrated partnership with CAP/CLIA collection laboratories for the analysis of blood specimens for determination of Correlates of Protection for vaccines
Note – if available, examples should provide National Clinical Trial (NCT) identifier or ClinicalTrial.gov reference

Proposals found to not meet minimum eligibility criteria(s) as detailed above may 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 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. **Relevant Experience:** [Describe relevant 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. **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 (HIPPA) 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 International Conference on Harmonisation (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			%
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. **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*	*Not applicable if cost share proposed*
Total Cost to Government	*$2,852,400*	
Total Project Value	***$2,852,400.00***	

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. Data Rights

[Failure to complete this attachment in its entirety (including a failure to provide the required signature) may result in removal from the competition and the proposal determined to be ineligible for award]

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.

☐ If Offeror WILL be asserting data rights for the proposed effort, check this box and complete the table below, adding rows as necessary.

Technical Data to Be Furnished with Restrictions	Basis for Assertion	Asserted Rights Category	Name of Asserting Organization	Milestone Affected

☐ If the Offeror will NOT be asserting data rights for the proposed effort, check this box.

_____ _____

Signature of responsible party for the proposing Prime Offeror DATE

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

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

Section I: Cost Proposal Narrative

a. Cover Page
b. Overview
c. Cost Information

Section II: Cost Proposal Format

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

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

1. Cost Proposal Cover Page

[Name of Offeror]
[Address of Offeror]

RPP Number 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/ (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 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.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

Submitted under Request for Project Proposals (*RPP NUMBER***)**
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 (Attachment B):

1. Meetings

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
		Meetings	
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 with all parties - SDCC to coordinate meeting	The Performer must complete a Kickoff meeting after the initiation of the agreement period of performance.	• To be agreed upon by BARDA and Performer must submit agenda and itinerary, if applicable, at least 5 business days in advance of in-person meeting or teleconference. • PAR edits/approves and instructs Performer to distribute agenda at least 3 business days prior to meeting. • Performer submits meeting minutes to PAR within 3 business days after the meeting. • PAR reviews, comments, and approves minutes within 10 business days.
1.3	Routine project/ad hoc meetings - SDCC to coordinate meetings	The Performer must participate in teleconferences weekly with BARDA and stakeholders 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. SDCC to coordinate project specific meetings.	• 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 - SDCC to coordinate meetings	At the discretion of the USG, the Performer must hold up to four per year recurring Project Review Meetings, held by teleconference or face-to face either in Washington, D.C. or at work sites of the Performer or sub-Performers. Face-to-face meetings shall alternate between Washington, D.C. and Performer, sub-Performer sites. The meetings will be used to discuss agreement progress in relation to the Program Management deliverables described in this agreement as well as clinical, technical, regulatory, and ethical aspects of the program.	• Performer must submit an agenda and itinerary, if applicable, at least 5 business days, and Performer must provide presentation materials at least 3 business days, in advance of the meeting. • PAR edits/approves and instructs Performer to distribute agenda prior to meeting by at least 3 business days. • Performer provides meeting minutes to PAR within 3 business days after the meeting. • PAR reviews, comments, and approves minutes within 10 business days.

1.6	Daily check in with BARDA	Upon request of the USG, the Performer must participate in a daily check-in update with the project staff (via teleconference or email). The updates will address key cost, schedule, and technical updates. Daily updates may be shared with senior USG leaders and should be provided on a non-confidential basis, unless the update includes confidential information in which case Performer must provide the update in both confidential and non-confidential formats. Daily check-ins may occur on weekdays, excluding federal holidays. Upon request of the USG, check-ins may also occur on weekends and on federal holidays, provided at least 24 hours' notice.	• A standing agenda must be used, to include key cost, schedule, technical updates, as well as updates on ad hoc communications between the USG and the Performer. • No meeting minutes are required. • Performer must provide bulleted email updates following any call or in lieu of a call by 2:00PM ET for that day.

2. Technical Reporting: General

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
2.1	Project-specific Project Management Plan (PMP) – SDCC to lead this effort	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	Performer must submit a Project Management Plan (PMP): ○ Within 30 calendar days after the initiation of the agreement period of performance. ○ Updates should be provided to reflect any key changes and reviewed at least annually.

		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.	
2.2	Project-specific Gantt Chart/timeline – SDCC to lead this effort	The Protocol-specific 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	Project-specific Communication Plan – SDCC to lead this effort	The Performer must develop and implement an effective Communication Plan that details the flow of information between BARDA, Performer, collaborators, vendors, and other organizations, including communications with regarding label contents, expiry dating, healthcare provider educational materials. The Communication Plan must also include a press release review process.	• Performer must submit a Communication Plan: ○ Within 30 calendar days after the initiation of the agreement period of performance. ○ Updates should be provided to reflect any key changes and reviewed at least annually.

2.4	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 Agreement Performance Report (CPR) – or as applicable: 1. An Executive Summary highlighting the progress, issues, and relevant clinical and regulatory activities. The Executive Summary should highlight all critical issues for that reporting period and resolution approach; limited to 2 pages. 2. BARDA Performer Clinical Studies Information Sheet – covering ongoing BARDA- funded clinical studies. This form must provide data on relevant activities during the period covered, by study site, including: cumulative enrollment; new enrollments; screen failures; patients dropped from study; AE and SAEs; study initiation visits; activation or inactivation of study sites; investigator appointments or changes; and status of IRB/IEC review/approval/renewal review/approval/renewal. 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.	• 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. 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.

		4. A three-month rolling forecast of the key planned activities, referencing the WBS/IMS. 5. Estimated and Actual Expenses:	
		a. 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 SubPerformers' expenses from the previous month if the SubPerformer 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 subPerformers If the PAR and AO are satisfied that the Performer's reporting is sufficient to convey this information, this section may be waived.	

2.5	Draft and Final Technical Progress Report	A draft Final Technical Progress Report must contain a summation of the work performed and the results obtained over the entire agreement. This report must be in sufficient detail to fully describe the progress achieved under all milestones. Report must contain a timeline of originally planned and baselined activities and milestones overlaid with actual progress attained during the agreement. Descriptions and rationale for activities and milestones that were not completed as planned should be provided. The draft report must be duly marked as 'Draft'. The Final Technical Progress Report incorporating feedback received from BARDA and containing a summation of the work performed and the results obtained for the entire agreement PoP. The final report must document the results of the entire agreement. The final 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. Final Report shall NOT be marked proprietary and shall have Distribution Statement.	The Performer must submit the Draft Final Technical Progress Report 75 calendar days before the end of the PoP and the Final Technical Progress Report on or before the completion date of the PoP. • PAR will provide feedback on draft report within 21 calendar days of receipt, which the Performer must consider incorporating into the Final Report.

2.6	Final Transition Plan	Inclusive of transfer of study documents and study specimens to BARDA/BARDA Performer.	• No later than 6 months of first subject enrollment.
2.7	Transfer of study documents and study specimens	As per Final Transition Plan.	• No later than six months after Final Clinical Study Report submission to BARDA.

3. Physical Inventory Deliverables

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates
3.1	Clinical Study Protocols - SDCC to lead this effort	The Performer must submit draft and final clinical study protocols to AO and PAR.	• The Performer must submit Draft study protocols to PAR electronically prior to finalization: ○ BARDA will provide comments within 10 business days of receipt of draft protocol. ○ Performer must respond in writing to BARDA comments and recommendations within 10 business days of receipt and must

			be addressed prior to finalization of protocol. o PAR must approve the final protocol. • The Performer must submit Final study protocols to PAR electronically no later than 10 business days prior to IRB submission.
3.2	Clinical Study Documentation	The Performer must provide the following documents for any portion of a study funded under this agreement: • Study Supplies Procurement Plan • Site selection questionnaire • Overall Recruitment and Retention plan • Informed Consent Form (ICF) template • Specimen Management Plan • Diversity inclusion plan to enroll based on US demographic based on most recent census and ensure equitable subject distribution in market research calls	• The Performer must submit Draft study documents to PAR electronically prior to finalization: o BARDA will provide comments within 10 business days of receipt of draft document. o Performer must respond in writing to BARDA comments and recommendations prior to finalization of protocol. • The Performer must submit Final study documents to PAR electronically no later than 10 business days prior to IRB submission. • Performer must submit final version Clinical Supplies Management Plan at least 6 weeks prior to shipments to clinical sites. Performer 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.

		• Community engagement materials, posters, media advertisements, animations, graphics, etc. • Clinical Trial Agreements • Monitoring Plan • Essential Regulatory Documents The Performer must make arrangements for up to four (4) BARDA representative(s) to be present during clinical site monitoring visits.	
3.3	ClinicalTrials.Gov posting and results reporting	Per clinicaltrials.gov registration and reporting requirements.	Per clinicaltrials.gov registration and reporting requirements.
3.4	Project-specific first site activated for first subject first visit	Performer should have all pre-study planning complete and be ready to enroll subjects.	Within five working days of IRB approval.
3.5	Clinical Report during Active Enrollment Periods[4]	The Performer must submit daily detailed clinical reports during active clinical study enrollment to include at a minimum: • Site IRB approval status (Central IRB; Site IRB if applicable) • Site information (FWA number, site type (e.g., commercial site, academic site), site activation status) • Status of ancillary supplies e.g., PPE, swabs, syringes, tubes on site • Specimen status report	• Performer must submit Clinical Reports on a daily basis starting when first subject is enrolled and ending when last subject is enrolled. • Performer must provide notification of designated safety events to the AO, PAR and PAR designee(s)within 24 hours of Performer notification. • Performer and USG to discuss and agree on format.

		Clinical Report submission must be by electronic transfer, e.g., from Performer EDC/IVRS/CTMS to a USG database or dashboard and/or provided to BARDA (outside of the Performer access-controlled web-based document/content management system). The Performer must inform BARDA of any upcoming site visits and/or audits of CRO facilities funded under this effort. BARDA reserves the right to accompany the Performer on site visits and/or audits of CROs as BARDA deems necessary.	
3.6	Access to electronic systems used in study conduct	The Performer must provide access to systems used in study conduct.	Due within 20 calendar days of PAR request, no later than ten calendar days prior to first site activated.
3.7	Specimen Collection for Future Use[5]	The Performer must collect and store serum samples at key immune time points for future use. These samples and associated clinical data will be transferred to a BARDA-managed repository at a date to be determined. The intended use of these samples is to establish a serum repository of samples from the vaccine arm(s) at multiple time points for future use. The samples and associated clinical data (metadata) must be transferred	Performer must provide weekly specimen inventory reports during the course of the clinical study. Specimens and associated clinical data must be transferred to BARDA upon request from the AO or PAR.

		to a BARDA-managed repository upon request at a date to be mutually agreed with the USG. The Performer must remove any personal identifying information (PII) from the samples and assign each with a unique subject identification number before transferring to BARDA. The Performer must provide	
		A specimen disposition report prior to transferring the material to the repository. The repository will be used to store samples to support development and evaluation of medical countermeasures. Testing on samples can include but will not be limited to in vitro biochemical, biophysical, and cell-based assays. BARDA will establish a Deliverables Table, Technology Transfer and Evaluation Agreement (TTEA) and Data Distribution Agreement (DDA) with appropriate partners as applicable (i.e., vaccine manufacturer, repository, testing labs, data analysis services), necessary to secure execution, timelines, materials and preserve intellectual property.	

[4] Note that this may be modified to daily, weekly, monthly, etc., reporting as required by the PCT.
[5] The volume of sera per timepoint should be defined in the study protocol. For example, the volume of sera per time point should be 3 milliliters (mL). Smaller volumes from a larger number of subjects are acceptable (minimum of 1 mL per subject per time point) if larger volumes are unavailable.

4. Technical Reporting: Manufacturing

#	Deliverable	Deliverable Description	Reporting Procedures and Due Dates

4.1	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 GCP. All quality management plans must include subPerformer quality management plans specifically addressing how subPerformer quality will managed. All subPerformers must have a current quality agreement with the Performer and a recent vendor qualification audit.	• 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.
4.2	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 clinical study.	• 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.

4.3	FDA Inspections/Site Visits	In the event of an FDA inspection that occurs r for any other reason that has the reasonable potential to impact the performance of this agreement, including, but not limited to clinical studies 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 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 also provide redacted copies of any FDA inspection reports received from subPerformers that occur as a result of this agreement. 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.	• 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 subPerformers that occur as a result of this agreement 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.
4.4	Quality Assurance Audits and SubPerformer 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	• Performer must notify AO and PAR a minimum of 10 business days in advance of upcoming, audits/site visits of subPerformers. • Performer must notify the PAR and AO within 5 business days of report completion and provide Draft Report. • PAR and AO will review the report and provide a response to the

		GLP or GCP guidelines, as identified in the audit report, must be provided to BARDA. The Performer must provide responses from the subPerformers to address these concerns and plans for corrective action. The Performer must allow for up to four (4) USG representative(s) to be present during the audit as necessary for appropriate oversight, including at clinical sites, CROs, and any other clinical vendor involved in the conduct of the clinical study under agreement.	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.
4.5	Project-specific Risk Management Plan (RMP) - SDCC to lead this effort	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 USG 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.

Publications			
4.6	Publications	The Performer must submit any manuscript or scientific meeting abstract containing data generated under this agreement to BARDA for review prior to submission. Acknowledgment of BARDA funding must be included as noted in Base agreement.	• 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 or posters. • 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.
4.7	Performer Clinical Publication Timeline and USG Right to Publish Data	The Performer and USG are committed to transparent and timely publication of clinical study data to ensure rapid distribution of information during a Public Health Emergency. Within 30 days of the primary analysis, results from clinical studies funded in whole or in part under this agreement and consistent with Good Publications Practices. Sponsor must submit clinical study primary endpoint analysis for publication to a peer reviewed journal. Within 90 days of 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, Sponsor must submit clinical study data for publication to a peer reviewed journal. If the Performer does not elect to publish data, Performer must provide AO and PAR with clinical study data to support the USG	• Performer must notify AO and PAR within 30 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 AO, the Performer must provide AO with requested data, information and materials in the form(s) requested by the USG, to support the USG publication of the clinical study data funded in part or whole under this agreement.

		publication of data as deemed appropriate by the USG, without the Performer involvement. The USG reserves the right to publish a counter-analysis of the data.	

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.. 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.

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)	1/25/2020	$ -		$ -
3	N/A	Monthly Report (Technical and Business Reports)	2/25/2020	$ -		$ -
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)	3/25/2020	$ -		$ -
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	$210,757	$187,457	$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		$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		$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	$150,000	$187,457	$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	$ 157,829	$ 187,457	$ 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		$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	$350,000	$187,457	$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	$315,658	$187,457	$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	$315,658	$187,457	$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		$157,829
50	N/A	Final Reports (POP End)	11/30/2022	$ -		$ -
			Total	$2,025,240	$1,124,742	$3,149,982

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 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.

ATTACHMENT SUMMARY

Attachment A – Project Objectives (see Section A, page 10)
Attachment B – Minimum Required Deliverables (see Attachment 3, Section 4, page 40)
Attachment C – BARDA CSN Governance Plan V1.0_2021-09-02 (See Separate File)
Attachment D – Assumptions, Constraints, and Limitations (See Separate File)
Attachment E – Protocol Synopsis_Final_16Jun23 (See Separate File)
Attachment F - NIAIDDMID SOP PBMC And Associated Plasma Collection (See Separate File)
Attachment G - Specimen Guidelines for Transfer of Specimens for Secondary use to CSN BSIP (See Separate File)
Attachment H - Possible Options for Biometric Devises, status FDA Cleared (See Separate File)
Attachment I – Example Data Visualization (See Separate File)