Request for Project Proposals

Solicitation Number: MTEC 19-06-Phage
"Development of Personalized Bacteriophage Therapeutic for the treatment of Bacterial Infections"

Issued by:
Advanced Technology International (ATI),
MTEC Consortium Manager (CM)
315 Sigma Drive
Summerville, SC 29486
for the
Medical Technology Enterprise Consortium (MTEC)

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Proposal Due Date: February 25, 2019
Noon Eastern Time

White Papers Are NOT Required

Table of Contents

1 Executive Summary

1.1 The Medical Technology Enterprise Consortium

The Medical Technology Enterprise Consortium (MTEC) is an enterprise partnership in collaboration with industry and academia to facilitate research and development activities, in cooperation with the U.S. Army Medical Research and Materiel Command (USAMRMC) and other Government agencies in the biomedical sciences (including but not limited to drugs, biologics, vaccines, medical software and medical devices) to protect, treat and optimize the health and performance of U.S. military personnel. MTEC is a nonprofit corporation with the following principal objectives:

(a) biomedical research and prototyping;

(b) exploration of private sector technology opportunities;

(c) technology transfer; and

(d) deployment of intellectual property (IP) and follow-on production.

*Note: Pending successful completion of this effort, the Government may issue a non-competitive follow-on production contract or transaction pursuant to 10 USC 2371b section f.

MTEC is openly recruiting members to join a broad and diverse biomedical consortium that includes representatives from large businesses, small businesses, contract research organizations, "nontraditional" government contractors, academic research institutions and not-for-profit organizations; for more information on the MTEC mission, see the Proposal Preparation Guide (PPG) and MTEC website.

1.2 Purpose

This solicitation, issued by the MTEC Consortium Manager (CM), Advanced Technology International (ATI), represents a Request for Project Proposals (RPP) for MTEC support of the Naval Medical Research Center (NMRC). Military relevance is a critical component of the Proposal submission. Strategic oversight for the award(s) supported by this RPP will be provided by the NMRC Naval Advanced Medical Development (NAMD) program through a Defense Health Agency Component Acquisition Executive (DHA J4) chartered (DHA) Integrated Product Team (IPT) for Bacteriophage Therapeutics.

The goal of this research is to develop and optimize all aspects of practical precision bacteriophage therapy treatment(s) through clinical development to the submission of a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA). As understood, a "precision bacteriophage therapy treatment" refers to achieving reliable efficacy of a phage therapy by treating bacterial infections with phage therapeutics that are in some way customized to the individual cases being treated. As elaborated below, aspects of a bacterial infection that might require individual customization include the genetic diversity of circulating

pathogens, and the potential for phage-resistant variant subcultures to arise in the course of treatment. Clinical questions to be addressed include determination of the ability of precision bacteriophage therapy to avoid or overcome emergence of bacterial resistance to therapeutic bacteriophages and assessment of systemic responses in human subjects following treatment with antimicrobial bacteriophage therapy. Practical questions to be addressed include assessment and improvement of the clinical feasibility of delivering a precision bacteriophage therapeutic, in terms of timely and high-quality design, production, and delivery of the characterized phage therapeutic; and development and demonstration of Current Good Manufacturing Practice (cGMP) production for clinical-grade bacteriophages suitable for use as a precision bacteriophage investigational / clinical therapeutic.

2 Administrative Overview

2.1 Request for Proposals

Each MTEC research project proposal submitted must contain both a Technical and Cost Proposal Volume as described in Section 3 of this request and must be in accordance with the mandatory format provided in the MTEC PPG, which is available on the Members-Only MTEC website at www.mtec-sc.org. ***White papers are not required for this RPP.*** The Government reserves the right to award Proposals received from this RPP on a follow-on prototype Other Transaction Agreement (pOTA) or other stand-alone OTAs as necessary to meet mission requirements.

2.2 Proposers Conference

MTEC will host a Proposers Conference that will be conducted via webinar approximately 1-2 weeks after the release of the RPP. Further instructions will be forthcoming via email.

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

The U.S. Government (USG) potentially has available $3-6 Million (M) Defense Health Program (DHP) Research, Development, Test and Engineering (RDT&E) and other RDT&E dollars. The U.S. Government may apply additional dollars for follow-on efforts with the evaluation and acceptance of work and cost plan with appropriate contract modification.

The Period of Performance (POP) is 24 months for Task 1.

As of the release date of this RPP, future year Defense Appropriations Bills have not been passed and there is no guarantee that any additional funds will be made available to support this program. The funding estimated for this RPP is approximate and subject to realignment. Funding of proposals received in response to this RPP is contingent upon the availability of federal funds for this program. Award funding will be structured incrementally and based upon completion of milestones.

It is expected that MTEC will make one award to a qualified team to accomplish all tasks. If a single proposal is unable to sufficiently address the entire scope of this RPP's technology objectives (outlined in section 4), several Offerors may be asked to work together in a collaborative manner. However, if an optimal team is not identified, then MTEC may make multiple, individual awards to Offeror(s) to accomplish subset(s) of the key tasks.

The Government-selected Research Project Awards will be funded under the Other Transaction Agreement (pOTA) Number W81XWH-15-9-0001 (or subsequent OTAs in support of MTEC) with MTEC administered by the CM, ATI. The CM will negotiate and execute a Base Agreement with MTEC members. This Base Agreement will be governed by the same provisions as the pOTA between the USG and MTEC. Subsequently, any proposal that is selected for award will be funded through a Research Project Award issued under the Base Agreement. A sample of the MTEC Base Agreement can be found on the MTEC Members-Only website at www.mtec-sc.org.

At the time of the submission, if Offerors have not yet executed a Base Agreement, then 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 MTEC Base Agreement. If the Offeror already has executed an MTEC Base Agreement with the MTEC CM, then the Offeror must state on the cover page of its Proposal that, if selected for award, it anticipates the proposed effort will be funded under its executed MTEC Base Agreement.

Offerors are advised to check the MTEC website periodically during the Proposal preparation period for any changes to the MTEC Base Agreement terms and conditions as well as clarifications found in Frequently Asked Questions (FAQ) responses.

2.4 Proprietary Information

The MTEC CM will oversee submission of Proposals submitted in response to this RPP. The MTEC CM shall take the necessary steps to protect all proprietary information and shall not use such proprietary information for purposes other than the evaluation of an Offeror's Proposal and the subsequent agreement administration if the Proposal is selected for award. An Offeror's submission of a Proposal under this RPP indicates concurrence with the aforementioned CM responsibilities.

Also, as part of MTEC's mission to incorporate philanthropic donations, MTEC frequently makes contact with private entities (e.g., foundations, investor groups, organizations, individuals) that award grants or otherwise co-fund research, and/or operates in research areas that are aligned with those of MTEC. These private entities may be interested in reviewing certain Proposals within their program areas, allowing opportunities to attract supplemental funding sources. On your Proposal Cover Page, please indicate your willingness to allow MTEC Officers and Directors access to your Proposal for the purposes of engaging in outreach activities with these private foundations. MTEC Officers and Directors granted Proposal access have signed Non-disclosure

Agreements (NDAs) and Organizational Conflict of Interest (OCI) statements. Additionally, these MTEC Officers and Staff represent organizations that currently are not MTEC members, and therefore their parent organizations are not eligible to submit Proposals or receive any research project funding through MTEC. Additionally, all Technical Evaluation Panel participants will agree to, and sign a nonproprietary information and conflict of interest document.

2.5 Offeror Eligibility

Offerors must be MTEC Members in good standing.

2.6 Inclusion of Nontraditional Defense Contractors or Nonprofit Research Institutions

Proposals that do not include Nontraditional Defense Contractor or Nonprofit Research Institution participation to a significant extent, or do not propose at least one third acceptable cost sharing, will not be eligible for award.

This requirement is a statutory element of the Other Transaction Authority.Please see the MTEC PPG and RPP (Section 5) for additional details.

2.7 Nontraditional Defense Contractor Definition

A nontraditional defense contractor is a business unit that has not, for a period of **at least one year prior to the issue date of the Request for Project Proposals**, entered into or performed on any contract or subcontract that is subject to full coverage under the cost accounting standards (CAS) prescribed pursuant to section 26 of the Office of Federal Procurement Policy Act (41 U.S.C. 422) and the regulations implementing such section.

2.8 Requirements

If the Offeror asserts either:

(1) There is at least one nontraditional defense contractor or nonprofit research institution participating to a significant extent in the prototype project.

(2) All significant participants in the transaction other than the Federal Government are small businesses (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)) or nontraditional defense contractors.

(3) At least one third of the total cost of the prototype project is to be paid out of funds provided by sources other than the Federal Government.

The Offeror must submit Warranties and Representations (see Attachment 2 of the PPG) specifying the critical technologies being offered and/or the significant extent of participation of the nontraditional defense contractor or nonprofit research institution. The nontraditional defense contractor can be an individual so long as he/she has a DUNS Number and meets the requirements in the Warranties and Representations. The significance of the nontraditional

defense contractor's or nonprofit research institution's participation must be explained in detail in the signed Warranties and Representations. Inadequate detail can cause delay in award.
Per the DoD OT Guide, rationale to justify a *significant contribution* includes:

1. Supplying a key technology or products
2. Accomplishing a significant amount of the effort
3. Use of unique skilled personnel, facilities and/or equipment
4. Causing a material reduction in cost or schedule, and/or Improvement in performance

2.9 Cost Sharing Definition

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

Cash Contribution

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

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

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

In-Kind Contribution

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

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

See the MTEC PPG for additional details. If the offer contains multiple team members, this information shall be provided for each team member providing cost share.

2.10 MTEC Assessment Fee

Per Section 3.4 of the Consortium Member Agreement (CMA), each recipient of a Research Project Award under the MTEC OTA shall pay MTEC an amount equal to 1% of the total funded value of each research project award. Such deposits shall be due no later than 90 days after the research project award is executed. Awardees are not allowed to use MTEC funding to pay for their assessment fees.

2.11Intellectual Property

Intellectual Property (IP) rights for MTEC Research Project Awards will be defined in the terms of an awardee's Base Agreement and resultant Task Orders. MTEC reserves the right to assist in the negotiation of IP, royalties, licensing, future development, etc., between the government and the individual performers during the entire award period.

Additionally, MTEC has established two methods of payment to be made to MTEC surrounding the licensing/commercialization of Intellectual Property developed with funding received from MTEC Research Project Awards:

Royalty Payment Agreements

Government-funded research projects awarded through MTEC will be subject to a 10% royalty on all Net Revenues received by the Research Project Award recipient resulting from the licensing/commercialization of the technology, capped at 200% of the Government funding provided.

Additional Research Project Award Assessment

In lieu of providing the royalty payment agreement described above, members receiving Research Project Awards may elect to pay an additional assessment of 2% above the standard assessment percentage described in Section 3.4 of the CMA. This additional assessment applies to all research project awards, whether the award is Government funded or privately funded.

2.12 Data Rights

The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding Data Rights. **It is anticipated that anything delivered under this proposed effort would be delivered to the Government with Government purpose data rights or unlimited data rights**

unless otherwise asserted in the proposal and agreed to by the Government. Rights in technical data in each Research Project Award shall be determined in accordance with the provisions of MTEC Base Agreement.

If applicable, complete the below table for any items to be furnished to the Government with restrictions. An example is provided.

Technical Data or Computer Software to be Furnished with Restrictions	Basis for Assertion	Asserted Rights Category	Name of Organization Asserting Restrictions	Milestone # Affected
Software XYZ	Previously developed software funded exclusively at private expense	Restricted	Organization XYZ	Milestones 1, 3, and 6
Technical Data Description	Previously developed exclusively at private expense	Limited	Organization XYZ	Milestone 2
Technical Data Description	Previously developed with mixed funding	Government Purpose Rights	Organization XYZ	Milestone 2

2.13 Expected Award Date

Offeror should plan on the period of performance beginning May 1, 2019 (subject to change). The Government reserves the right to change the proposed period of performance start date through negotiations via the CM and prior to issuing a Research Project Award.

2.14 Anticipated Proposal Selection Notification

As the basis of selections is completed, the Government will forward their selections to MTEC CM to notify Offerors.

3 Proposal

3.1 Proposal

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

The MTEC PPG is specifically designed to assist Offerors in understanding the proposal preparation process. The proposal format outlined in the PPG is mandatory. MTEC will post any general questions received and corresponding answers (without including questioners' proprietary data) on the Members-Only MTEC website. The Government will evaluate Proposals submitted and will select Proposals that best meet their current technology priorities using the criteria in Section 6.

3.2 Proposal Submission

Instructions on how to submit are included in the RPP version that is posted on MTEC Members Only Site.

MTEC membership is required for the submission of a Proposal. Offerors must be MTEC Members in good standing. Offerors submitting Proposals as the prime contractor must be MTEC members of good standing by February 20, 2019.

Do not submit any classified information in the proposal submission.

3.3 Submission Format

Offerors should submit files in Microsoft Office formats or Adobe Acrobat (PDF – portable document format) as indicated below. ZIP files and other application formats are not acceptable. All files must be print-capable and without a password required. Filenames must contain the appropriate filename extension (.docx, .doc, .pptx, .ppt .xlsx, .xls or .pdf). Filenames should not contain special characters. Apple users must ensure the entire filename and path are free of spaces and special characters.

MTEC will email receipt confirmations to Offerors upon submission. Offerors may submit in advance of the deadline**. Neither MTEC nor ATI will make allowances/exceptions for submission problems encountered by the Offeror using system-to-system interfaces with MTEC's submission form. If the Offeror receives errors and fails to upload the full submission prior to the submission deadline, the submission will not be accepted.**

4 Proposal Preparation Instructions

4.1 General Instructions

The Technical Proposal and Cost Proposal must be submitted in two separate volumes, and shall remain valid for 180 days unless otherwise specified by the Offeror in the proposal. The Proposal format provided in this MTEC RPP is mandatory and shall reference this RPP number (MTEC-19-06-Phage). Offerors are encouraged to contact the POC identified herein up until the proposal submission date/time to clarify requirements. Offerors are to propose a Milestone Payment Schedule which should include all significant event/accomplishments that are intended to be accomplished as part of the project, a planned completion date (based on months post award),

the expected research funding expended towards completing that milestone, and any cost share, if applicable.

The Milestones and associated accomplishments proposed should, in general, be commensurate in number to the size and duration of the project. A milestone is not necessarily a physical deliverable; it is typically a significant R&D event. Quarterly and final technical reports may be considered deliverables, but they are not milestones. Please include quarterly and final technical reports as part of the Milestone Payment Schedule, without an associated cost.

All eligible Offerors may submit proposals for evaluation according to the criteria set forth herein. Offerors are advised that only ATI as the MTEC's CM, with the approval of the Government Agreements Officer, is legally authorized to contractually bind or otherwise commit funding for selected Research Project Awards as result of this RPP.

4.2 Technical Requirements

Technical Background:

Recent conflicts in Iraq and Afghanistan have seen a notable rise in the survival of combat casualties. These patients with anatomically complex wounds and extended, invasive treatment regimens are vulnerable to combat extremity wound infections. Furthermore, those infections are often clinically complicated or multidrug resistant and thus difficult to treat effectively. The bacterial species responsible for these types of infections often include the group called 'ESKAPE' pathogens (*Enterococcus faecium*, *Staphylococcus aureus*, *Klebsiella pneumoniae*, *Acinetobacter baumannii*, *Pseudomonas aeruginosa* and *Enterobacter* spp), which cause the majority of infections within the nosocomial environment and are noted for prevalence of antibiotic resistance.

Multidrug antibiotic resistance is an emerging medical challenge that is reaching crisis proportions. Existing antimicrobials are losing their efficacy, and the drug development pipeline for traditional small molecule antimicrobials (antibiotics) is limited in new alternative candidates. One alternative to traditional antibiotics for treatment of bacterial infections is bacteriophage therapy.

Bacteriophages (phages) are viruses that specifically attack bacteria. Since their discovery a century ago, phages have been contemplated as potential therapeutic agents. However, the immature science of bacteriophage microbiology at the time, followed by the discovery and development of conventional antibiotics, diverted attention from bacteriophages. Now with the growing failure of antibiotics, bacteriophages are being reconsidered as therapeutic agents.

One key feature of bacteriophages is their host specificity. Any given bacteriophage typically will infect only a single species of bacteria, and indeed often has a restricted host range within that species, where naturally occurring genetic diversity of the host limits the bacteriophage to a

subset of bacterial strains. Furthermore, it is common in a susceptible bacterial population for genetic variants to occur that gain resistance to the bacteriophage. These two points can significantly constrain the efficacy of a bacteriophage therapeutic: a single bacteriophage or defined combination of bacteriophages is unlikely to work against all clinically presented infections, and infections against which a bacteriophage therapeutic might initially be effective can ultimately overcome treatment through the emergence of a resistant subclone.

This program seeks to overcome both these failure points by using a precision medicine approach for delivering bacteriophage therapy. A submitted proposal should recognize and include means to overcome the genetic diversity of MDR bacterial clinical pathogens, and the possible emergence of phage-resistant bacterial variants during the course of precision bacteriophage treatment. At a minimum, a successful precision strategy will address both these concerns and thus help enable bacteriophage therapy to become a practical solution to the treatment of bacterial infections.

This precision medicine approach to bacteriophage therapeutics also faces a challenging product development and production pathway. Given the complexity of phages themselves and the inherent novelty of clinical, bacteriophage-based precision therapeutic approaches, US FDA requirements, including Pharmaceutical Quality/Chemistry, Manufacturing, and Controls (CMC), will entail demanding characterization and production procedures. The regulatory environment for licensure of a precision phage product is incompletely defined and as yet untested. The logistics of case-by-case design of a precision phage therapeutic and delivery to bedside in a clinically useful timeframe needs to be established. The prototyping effort sought here is intended to help resolve all these aspects of the clinical development of precision bacteriophage therapeutics for antimicrobial applications.

Program Description:
The goal of this program is to support the RDT&E activities required for the clinical development of a precision bacteriophage therapeutic. The ultimate objective is to support submission of a BLA for FDA approval, and thus any submitted proposal should have a defined and feasible pathway to licensure.

This MTEC RPP focuses on the execution of clinical trial(s) for the treatment of bacterial infections, for example, treating appropriate ESKAPE infection indication(s), to most effectively advance a precision bacteriophage product toward FDA licensure. Objectives of the program include:

- Clinical and scientific:
    - Clinical evaluation of the ability to safely and effectively treat bacterial infections via design and administration of a precision bacteriophage therapeutic.
    - Assessment of the safety and efficacy of a precision bacteriophage therapeutic approach across relevant model populations of affected patients.

  - Testing of the practical ability to adapt the phage therapeutic to dynamic changes in the patients' pathogens in the course of investigational clinical treatment. The successful therapeutic should prevent or overcome the emergence of bacteriophage resistance in the infection.
  - Assessment of the effect of bacteriophage therapy on changes in antibiotic susceptibility over the course of treatment, and on the outcomes of surgical intervention.
  - Assessment of the pharmacokinetics and pharmacodynamics of phage administration.
- Logistical:
  - Assessment and improvement of the feasibility of delivering a precision bacteriophage therapeutic, in terms of timely and high-quality design, production, and delivery of the characterized phage therapeutic.
  - Development and demonstration of cGMP production for clinical-grade bacteriophages suitable for use as a precision bacteriophage investigational/ clinical therapeutic.

Work Plan:

The goal of this MTEC award is to evaluate human safety and efficacy of a bacteriophage prototype for treatment of bacterial infections. Examples of bacterial infection diagnoses relevant for testing of bacteriophage therapy can include asymptomatic bacteriuria, symptomatic refractory MDR genitourinary (GU) infections, and potentially other clinically relevant infections suitable to support development and evaluation of precision phage interventions for bacterial infections.

This program seeks to test precision bacteriophage therapy using a suitable clinical indication that will maximize the probability of assessing efficacy. The Government may pursue optional follow-on tasks to continue product development through additional clinical trials for relevant supplemental FDA marketing approval/licensure.

Specifically, the intent of this effort is to support the prototyping of a precision bacteriophage antimicrobial therapeutic to complete all requisite FDA-compliant manufacturing and packaging development, complete the Phase 1 / 2 clinical trials (Task 1 and potential Follow-on Task 2, as denoted below); conduct (potential) Phase 2 clinical trials (potential Follow-on Task 3), conduct Phase 3 clinical trial(s), and to complete all other developmental requirements to support a BLA application to FDA to ultimately support FDA licensure (potential Follow-on Task 4).

Offerors, as the regulatory sponsor for the eventual submission to FDA, will be expected to conduct all manner of development, test and evaluation activities (as necessary) toward achievement of an FDA-licensed precision bacteriophage product that is suitable for use by the U.S. Military. It is expected that the Offeror will work in close coordination with the DoD in the design of the trial, and the Offeror is encouraged to partner with one or more medical treatment

facilities such as the Veteran's Administration (VA) and/or Department of Defense (DoD) medical treatment facilities for the conduct of the clinical trial. For proposal submission, the Offeror is expected to identify aspects of the proposed work which may be done in collaboration with DoD and VA clinical trial sites. Once selected for award, the Awardee can coordinate with the Government sponsor to identify and establish formal collaborations with the DoD / VA site(s).

The full spectrum of work is expected to be conducted in several tasks over a minimum of a 6 year period of performance (PoP), as follows. Offerors must have cGMP capability for production of the test material (to include aseptic fill capability) that is at least sufficient for a Phase 1 clinical trial, in both quality and output capacity. Task 1 is the basis for the upcoming award but Tasks 2, 3, and 4 may be added as follow-on work dependent on the technical progress and/or outcome of Task 1, and therefore, may be of interest to potential Offerors. **Potential Offerors are expected to propose a clinical trial in response to Task 1, only, and to include in their proposal a realistic regulatory strategy and development framework for ultimate BLA approval of a precision bacteriophage therapeutic that would encompass the follow-on Tasks 2-4 (or equivalent).**

Task 1 (PoP up to 2 years): Conduct Phase 1 / 2 clinical trial(s) for ESKAPE pathogen or other relevant, strategically selected indications as a part of a full-spectrum FDA-compliant clinical development to support a BLA submission to FDA. Task 1 is expected to be completed within two (2) years. Proposals may request support for Task 1 that includes, but is not limited to, subject matter expertise, appropriate consultation for regulatory strategy, and ensuring reproducibility of the manufacturing process at scale for the ultimate fielding of the innovative biologic bacteriophage product to DoD stakeholders and to commercial market. Anticipated Task 1 activities include (but are not limited to):

- Manufacture (cGMP) of bacteriophage therapeutic product suitable for clinical investigation in Phase 1 / 2 clinical trials;
- Conception and execution of appropriate regulatory strategy (e.g., submission of Investigational New Drug [IND] application and other FDA-compliant responsibilities); conduct of Phase 1 / 2 clinical trial as the regulatory sponsor (accordingly, the development partner bears the legal responsibilities of sponsor under 21 CFR 312 Subpart D).
- Establishment and management of clinical trial sites;
- Enrollment and clinical monitoring at all enrollment sites;
- Provisions of all aspects of data configuration, data management, analysis, and reporting in compliance with all applicable regulatory guidance and Code of Federal Regulations (CFRs).

Potential Follow-on Task 2: Prepare for and conduct additional FDA compliant Phase 1 / 2 clinical trial(s).

Potential Follow-on Task 3: Prepare for and conduct FDA compliant Phase 2 clinical trial(s).

Potential Follow-on Task 4: Prepare for and conduct FDA complaint Phase 3 clinical trial(s) and submission of BLA for FDA licensure.

4.3 Preparation of the Proposal

The Technical Proposal format provided in the MTEC PPG is mandatory. Proposals shall reference this RPP number (MTEC-19-06-Phage). The Technical Proposal and Cost Proposal must be submitted in two separate volumes, and shall remain valid for 180 days unless otherwise specified by the Offeror in the proposal. Offerors are encouraged to contact MTEC with any questions so that all aspects are clearly understood by both parties. The full proposal should include the following:

- **Technical Proposal submission:** one signed Technical Proposal (.pdf, .doc or .docx).

- **Statement of Work/Milestone Payment Schedule**: one Word (.docx or .doc). The Offeror is required to provide a detailed SOW/Milestone Payment Schedule using the format provided herein (Attachment A). The Government reserves the right to negotiate and revise any or all parts of SOW/Milestone Payment Schedule. Offerors will have the opportunity to concur with revised SOW/Milestone Payment Schedule as necessary.

- **Cost Proposal for Task 1 only submission:** one Word (.docx or .doc) or PDF file for Section I: Cost Proposal Narrative (see Attachment 1 of the PPG) required. Separately, Section II: Cost Proposal **by Task** Formats either in Excel (.xlsx or .xls) or PDF format is required.

- **Warranties and Representations:** one Word (.docx or .doc) or PDF file that contains all Warranties and Representations is required.

- **Royalty Payment Agreement or Additional Research Project Award Assessment:** Each Offeror will select either the MTEC Additional Research Project Award Assessment Fee **or** the Royalty Payment Agreement (available on the MTEC members only website), **not both**, and submit a signed copy with the proposal.

Evaluation: The Government will evaluate and determine which proposals to award based on criteria described in **Section 5, "Selection,"** of this RPP. The Government reserves the right to negotiate with Offerors.

4.4 Cost Proposal

Offerors are encouraged to use their own cost formats such that the necessary detail is provided. MTEC will make cost proposal formats available on the Members-Only MTEC website.

The Cost by Task Proposal formats provided in the MTEC PPG are **NOT** mandatory. Refer to the MTEC PPG for additional details

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.

4.5 Proposal Preparation Costs

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

4.6 Restrictions on Human Subjects, Cadavers, and Laboratory Animal Use

Proposals must comply with important restrictions and reporting requirements for the use of human subjects, to include research involving the secondary use of human biospecimens and/or human data, human cadavers, or laboratory animals. For a complete description of these mandatory requirements and restrictions and others, Offerors must refer to the accompanying MTEC PPG, "Additional Requirements."

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

For example, the clinical studies under this RPP shall not begin until the USAMRMC Office of Research Protections (ORP) provides authorization that the research may proceed. The USAMRMC ORP will issue written approval to begin research under separate notification. Written approval to proceed from the USAMRMC ORP is also required for any Research Project Awardee (or lower tier subawards) that will use funds from this award to conduct research involving human subjects. Offerors must allow at least 30 days in their schedule for the ORP review and authorization process.

5 Selection

The CM will conduct a preliminary screening of submitted proposals to ensure compliance with the RPP requirements. The Government reserves the right to request additional information or eliminate proposals that do not meet these requirements from further consideration. One of the primary reasons for elimination from further consideration is the lack of significant nontraditional defense contractor participation, nonprofit research institution participation, all small business participation, or cost share (see RPP Section 2.8). The Cost Sharing/Nontraditional Contractor determination will be made as shown in Table 1:

TABLE 1- COST SHARING/NONTRADITIONAL CONTRACTOR ASSESSMENTS

RATING	DESCRIPTION
PASS	Offeror proposing an MTEC research project meets at least ONE of the following: • Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution • Offeror's proposal has at least one Nontraditional Defense Contractor or Nonprofit Research Institution participating to a significant extent • Offeror provides at least one third of the total project cost as acceptable cost share
FAIL	Offeror proposing an MTEC research project does **NOT** meet any of the following: • Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution • Offeror's proposal has at least one Nontraditional Defense Contractor or Nonprofit Research Institution participating to a significant extent • Offeror provides at least one third of the total project cost as acceptable cost share

Following the preliminary screening, the Government sponsor will perform proposal source selection. This will be conducted using the evaluation factors detailed below. The Government will conduct an evaluation of all qualified proposals. 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 placed in the Basket)*

5.1 Proposal Evaluation Process

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

This process may involve the use of contractors as SME consultants or reviewers. Where appropriate, the USG will employ non-disclosure-agreements to protect information contained in the RPP as outlined in Section 2.4.

Evaluation of proposals shall be based on an independent, comprehensive review and assessment of the work proposed against stated source selection criteria and evaluation factors. A rating consistent with these evaluation factors will be derived from the ability of the Offeror to perform the work in accordance with all aspects of requirements outlined in this RPP. The Offeror

shall clearly state how it intends to meet the RPP requirements. Mere acknowledgement or restatement of a RPP requirement is not acceptable.
The evaluation factors and evaluation criteria are described below.

5.2 Evaluation Factors

1. Technical Approach
2. Potential for Transition and Commercialization
3. Cost/Price

Evaluation factors are listed in descending order of importance.

Table 2 explains the adjectival merit ratings that will be used for the Technical Approach Factor, and Potential for Transition and Commercialization factor.

TABLE 2- GENERAL MERIT RATING ASSESSMENTS	
RATING	**DESCRIPTION**
OUTSTANDING	Proposal meets requirements and indicates an exceptional approach and understanding of the requirements. Strengths far outweigh any weaknesses. Risk of unsuccessful performance is very low.
GOOD	Proposal meets requirements and indicates a thorough approach and understanding of the requirements. Proposal contains strengths which outweigh any weaknesses. Risk of unsuccessful performance is low.
ACCEPTABLE	Proposal meets requirements and indicates an adequate approach and understanding of the requirements. Strengths and weaknesses are offsetting or will have little or no impact on contract performance. Risk of unsuccessful performance is no worse than moderate.
MARGINAL	Proposal does not clearly meet requirements and has not demonstrated an adequate approach and understanding of the requirements. The proposal has one or more weaknesses which are not offset by strengths. Risk of unsuccessful performance is high.
UNACCEPTABLE	Proposal does not meet requirements and contains one or more deficiencies. Proposal is not awardable.

5.2.1 Evaluation Factor 1. Technical Approach

The Technical Approach factor will be evaluated using the merit rating as shown in Table 2.

The Offeror's proposed solution will be assessed for the likelihood of successfully achieving the requirements of the technology of interest as defined in Section 4.2 above. The likelihood of

success will be determined by considering the soundness and clarity of the technical approach. Additional consideration will be given to the degree to which any preliminary existing data supports the proposed project plan and the suitability of the proposed statistical plan. The SOW should provide a succinct approach for achieving the project's objectives. The SOW will be evaluated for how well the rationale, objectives, and specific aims support the proposed research. The effort will be assessed for the extent to which the solution is technologically innovative and how the proposed deliverable advances the TRL Military relevance is a critical component of proposal submission. This relevance includes the health care needs of military Service members, Veterans, and/or other Military Health System beneficiaries and the extent to which the proposal offers a joint Service solution. A description of the project team's expertise, key personnel, and corporate experience should demonstrate an ability to execute the SOW.

5.2.2 Evaluation factor 2: Potential for Transition and Commercialization

The Potential for Transition and Commercialization factor will be evaluated using the merit rating as shown in Table 2.

The Offeror's proposal will be assessed for:

a) How well the Offeror provides sufficient evidence that the effort is ready to move into the proposed stage of research, development, or clinical testing.
b) How well the project will translate promising, well-founded basic or clinical research findings into clinical applications for military Service members and or their beneficiaries.
c) How well the funding strategy described will advance the technology to the next level of development and/or delivery to the military or civilian market.
d) How well the proposal identifies intellectual property ownership, describes any appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development.
e) How well the regulatory strategy is described, if applicable.

5.2.3 Evaluation Factor 3. Cost/Price

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

The MTEC CM will evaluate the estimated cost proposed by the Offeror for performing all requirements outlined in this RPP and the MTEC PPG. Evaluation will include analysis of the proposed cost together with all supporting information. The Offeror's cost and rationale will be evaluated for realism, reasonableness, and completeness. If a proposal is selected for award, the MTEC CM will review the original cost proposal and the Offeror's response to a Proposal Update Letter, if applicable. The MTEC CM will request additional information or clarification as necessary. The MTEC CM 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 negotiated project value is fair and reasonable.

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 task of the proposed project when compared to the total proposed cost. For more information on cost realism, please refer to the MTEC PPG.

The MTEC CM 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 using the Cost Proposal Formats that are located on the Members-Only MTEC website.

c) Completeness. The MTEC CM 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 MTEC CM will evaluate whether the Offeror's cost proposal is complete with respect to the work proposed. The MTEC CM 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 cannot be selected for award.

5.3 Best Value

The Government will conduct the source selection and MTEC CM will award the projects in Best Value sequence. If applicable, the Government will invoke a best value process to evaluate the most advantageous offer by considering and comparing factors in addition to cost or price. Based on the results of the Technical Approach Evaluation, the Government reserves the right to negotiate and request changes to any or all parts of the SOW. Offeror's will have the opportunity to concur with the requested changes and revise cost proposals as necessary.

5.4 Definition of General Terms Used in Evaluations:

Strength - An aspect of an Offeror's proposal that has merit or exceeds specified performance or capability requirements in a way that will be advantageous to the Government during award performance.

Weakness - A flaw in the proposal that increases the risk of unsuccessful award performance.

Significant Strength - An aspect of an Offeror's proposal that has appreciable merit or appreciably exceeds specified performance or capability requirements in a way that will be appreciably advantageous to the Government during award performance.

Significant Weakness - A flaw that appreciably increases the risk of unsuccessful award performance.

Deficiency - A material failure of a proposal to meet a Government requirement or a combination of weaknesses in a proposal that increases the risk of unsuccessful award performance to an unacceptable level.

6 Points-of-Contact

For inquiries, please direct your correspondence to the following contacts:

- Questions concerning contractual, cost or pricing related to this RPP should be directed to the MTEC Contracts Administrator, Ms. Rebecca Harmon, mtec-contracts@ati.org
- Technical related questions should be directed to the MTEC Director of Research, Dr. Lauren Palestrini, Ph.D., lauren.palestrini@officer.mtec-sc.org

- Questions concerning membership should be directed to the MTEC Executive Director, Ms. Stacey Lindbergh, execdirect@officer.mtec-sc.org
- All other questions should be directed to the MTEC Program Manager, Ms. Kathy Zolman, kathy.zolman@ati.org

Once an Offeror has submitted a Proposal the Government and the MTEC CM will not discuss evaluation/status until the source selection process is complete.

7 Acronyms/Abbreviations

ATI	Advanced Technology International
BLA	Biologics License Application
CAS	Contract Accounting System
CFRs	Code of Federal Regulations
cGMP	Current Good Manufacturing Practice
CM	Consortium Manager
CMA	Consortium Member Agreement
CMC	Chemistry, Manufacturing, and Controls
DHA	Defense Health Agency
DHP	Defense Health Program
FAQ	Frequently Asked Questions
F&A	Facilities and Administrative Costs
FDA	Food and Drug Administration
FY	Fiscal Year
G&A	General and Administrative Expenses
GU	Genitourinary
HIPPA	Health Insurance Portability and Accountability Act
IND	Investigational New Drug
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IPT	Integrated Product Team
IR&D	Independent Research and Development
MDR	Multidrug resistant
MTEC	Medical Technology Enterprise Consortium
M	Millions
NAMD	Naval Advanced Medical Development
NDA	Nondisclosure Agreement
NMRC	Naval Medical Research Center
OCI	Organizational Conflict of Interest
ODC	Other Direct Charges
ORP	Office of Research Protections, USAMRMC

pOTA	Prototype Other Transaction Agreement
POC	Point-of-Contact
POP	Period of Performance
PPG	Proposal Preparation Guide
R&D	Research and Development
RDT&E	Research, Development, Test and Engineering
RPP	Request for Project Proposals
SME	Subject Matter Expert
SOW	Statement of Work
TRL	Technology Readiness Level
USAMRMC	U.S. Army Medical Research and Materiel Command
USG	U.S. Government
VA	Veteran's Administration

Attachment A: Statement of Work (SOW)

The SOW developed by the Lead MTEC 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. DO NOT INCLUDE ANY PROPRIETARY INFORMATION OR COMPANY-SENSITIVE INFORMATION IN THE SOW TEXT. The following is the required format for the SOW.

Statement of Work

Submitted under Request for Project Proposal (*Insert current Request No.***)**

(Proposed Project Title)

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.)*

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.

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.

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.

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

The Milestone Payment Schedule should include all milestone deliverables that are intended to be delivered as part of the project, a planned submission date, the monetary value for that deliverable and any cost share, if applicable. For fixed price agreements, when each milestone is submitted, the MTEC member will submit an invoice for the exact amount listed on the milestone payment schedule. For cost reimbursable agreements, the MTEC 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 Quarterly Reports which include both Technical Status and Business Status Reports (due the 25th of Apr, Jul, Oct, Jan), Annual Technical Report, Final Technical Report, and Final Business Status Report. Reports shall have no funding associated with them.

MTEC Milestone Payment Schedule Example

MTEC 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	Quarterly Report 1 (October - December, Technical and Business Reports)	1/25/2020	$ -		$ -
3	1	Protocol Synopsis	2/28/2020	$21,075		$21,075
4	2	Submission for HRPO Approval	2/28/2020	$21,075		$21,075
5	3	Submission of Investigational New Drug application to the US FDA	4/30/2020	$210,757	$187,457	$398,214
6	N/A	Quarterly Reports 2 (January - March, Technical and Business Reports)	4/25/2020	$ -		$ -
7	N/A	Quarterly Report 3 (April - June, Technical and Business Reports)	7/25/2020	$ -		$ -
8	4	Toxicity Studies	10/1/2020	$63,227		$63,227
9	N/A	Annual Report 1	10/25/2020	$ -		$ -
10	5	FDA authorization trial	11/30/2020	$84,303		$84,303
11	6	Research staff trained	11/30/2020	$ -		$ -
12	7	Data Management system completed	11/30/2020	$ -		$ -
13	8	1st subject screened, randomized and enrolled in study	1/1/2021	$150,000	$187,457	$337,457
14	N/A	Quarterly Report 4 (October - December, Technical and Business Reports)	1/25/2021	$ -		$ -
15	9	Completion of dip molding apparatus	3/1/2021	$ 157,829	$ 187,457	$ 345,286
16	N/A	Quarterly Reports 5 (January - March,	4/25/2021	$ -		$ -

		Technical and Business Reports)				
17	10	Assess potential toxicology	6/1/2021	$157,829		$157,829
18	N/A	Quarterly Report 6 (April - June, Technical and Business Reports)	7/25/2021	$ -		$ -
19	11	Complete 50% patient enrollment	10/1/2021	$350,000	$187,457	$537,457
20	N/A	Annual Report 1	10/25/2021	$ -		$ -
21	N/A	Quarterly Report 7 (October - December, Technical and Business Reports)	1/25/2022	$ -		$ -
22	12	Electronic Report Forms Developed	3/1/2022	$315,658	$187,457	$503,115
23	N/A	Quarterly Reports 8 (January - March, Technical and Business Reports)	4/25/2022	$ -		$ -
24	N/A	Quarterly Report 9 (April - June, Technical and Business Reports)	7/25/2022	$ -		$ -
25	13	Complete 100% patient enrollment	8/1/2022	$315,658	$187,457	$503,115
26	N/A	Annual Report 1	10/25/2022	$ -		$ -
27	14	Report results from data analysis	11/1/2022	$157,829		$157,829
28	N/A	Final Reports **(Prior to the 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. Cost Reimbursable Contracts – You may invoice for costs incurred against a milestone. Invoicing should be monthly.

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. Quarterly and Annual Reports include BOTH Technical and Business Reports (separate).

5. Final Report due date must be prior to POP end noted in subcontract.

6. MTEC 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 MTEC Milestone Number.

Shipping Provisions (*The following information, if applicable to the negotiated SOW, will be finalized by the Government and the MTEC Consortium Manager based on negotiations)*

- The shipping address is:
  Classified Shipments:
  Outer Packaging
  Inner Packaging

Data Rights *(see Section 8.4 of PPG for more information)*

Technical Data or Computer Software to be Furnished with Restrictions	Basis for Assertion	Asserted Rights Category	Name of Organization Asserting Restrictions	Milestone # Affected
Software XYZ	Previously developed software funded exclusively at private expense	Restricted	Organization XYZ	Milestones 1, 3, and 6
Technical Data Description	Previously developed exclusively at private expense	Limited	Organization XYZ	Milestone 2
Technical Data Description	Previously developed with mixed funding	Government Purpose Rights	Organization XYZ	Milestone 2

Reporting (*The following information, if applicable to the negotiated SOW, will be provided by the Government based on negotiation)*

Report Months	Due Date
January – March	25 April
April - June	25 July
July - September	25 October
October - December	25 January

- Quarterly Reports – The MTEC research project awardee shall prepare a Quarterly Report which will include a Technical Status Report and a Business Status Report in accordance with the terms and conditions of the Base Agreement. (Required)

- Annual Technical Report – The project awardee shall prepare an Annual Technical Report for projects whose periods of performances are greater than one year in accordance with the terms and conditions of the Base Agreement. (Required)

- Final Technical Report – At the completion of the Research Project Award, the awardee will submit a Final Technical Report, which will provide a comprehensive, cumulative, and substantive summary of the progress and significant accomplishments achieved during the total period of the Project effort in accordance with the terms and conditions of the Base Agreement. (Required)

- Final Business Status Report – At the completion of the Research Project Award, the awardee will submit a Final Business Status Report, which will provide summarized details of the resource status of the Research Project Award, in accordance with the terms and conditions of the Base Agreement. (Required)