

Request for Project Proposals



Solicitation Number: MTEC 19-10-MID-PIP

“Military Infectious Disease - Prototype Innovation Program (MID-PIP)”

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

Request Issue Date: August 15, 2019

***Proposal Due Date: September 16, 2019
Noon Eastern Time***

White Papers Are NOT Required

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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 Development Command (USAMRDC) 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 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 USAMRDC Military Infectious Disease Research Program (MIDRP). 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 MIDRP staff and Joint Program Committee (JPC)-2.

The goal of this “Military Infectious Disease - Prototype Innovation Program (MID-PIP)” is to develop the following 4 prototypes:

- FOCUS AREA #1 (Diagnostic): A point-of-care device to detect the presence of microbial infection.
- FOCUS AREA #2 (mAbs): Generation of high affinity monoclonal antibodies to four bacterial antigens for the prevention and treatment of bacterial wound infections and sepsis.
- FOCUS AREA #3 (HIV): A single administration escape-resistant therapy for HIV control.

- FOCUS AREA #4 (Biofilm): Clinical evaluation of products to treat biofilm-mediated antibiotic-resistant infections in non-healing chronic wounds.

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 Proposal Preparation Guide (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 within the first two 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. Department of Defense (DoD) currently has available approximately the following Defense Health Program (DHP) Fiscal Year 2019 (FY19) Restoral Funds for each focus area:

- 1) FOCUS AREA #1 (Diagnostic): \$2.57 M
- 2) FOCUS AREA #2 (mAb): \$1.84 M
- 3) FOCUS AREA #3 (HIV): \$3.68 M
- 4) FOCUS AREA #4 (Biofilm): \$2.57 M

The U.S. Government (USG) may apply additional dollars for follow-on efforts with appropriate modification after the evaluation and acceptance of work and cost plan.

The anticipated Period of Performance (PoP) for each focus area is as follows:

- 1) FOCUS AREA #1 (Diagnostic): 4 years
- 2) FOCUS AREA #2 (mAb): 2 years
- 3) FOCUS AREA #3 (HIV): 1 year
- 4) FOCUS AREA #4 (Biofilm): 3 years

Dependent on the results and deliverables, additional time may be added to the period of performance for follow-on tasks.

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

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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 a total of 4 awards (a single award for each focus area) to qualified teams to accomplish the statement of work. If a single proposal is unable to sufficiently address the entire scope of a specific focus area (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 once selected for award. 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 website and 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 MTEC Member Teaming

While teaming is not required for this effort, Offerors are encouraged to consider teaming during the proposal preparation period (prior to proposal submission) if they cannot address the full scope of technical requirements of the RPP or otherwise believe a team may be beneficial to the Government.

MTEC members are encouraged to use the MTEC Database Collaboration Tool. The purpose of the tool is to help MTEC member organizations identify potential teaming partners by providing a quick and easy way to search the membership for specific technology capabilities, collaboration interest, core business areas/focus, R&D highlights/projects, and technical expertise. The Primary Point of Contact for each member organization is provided access to the collaboration database

tool to make edits and populate their organization's profile. There are two sections as part of the profile relevant to teaming:

- "Collaboration Interests" - Select the type of teaming opportunities your organization would be interested in. This information is crucial when organizations need to search the membership for specific capabilities/expertise that other members are willing to offer.
- "Solicitation Collaboration Interests" - Input specific active solicitations that you are interested in teaming on. This information will help organizations interested in a specific funding opportunities identify others that are interested to partner in regards to the same funding opportunity. Contact information for each organization is provided as part of the member profile in the collaboration database tool to foster follow-up conversations between members as needed.

The Collaboration Database Tool can be accessed via the "MTEC Profiles Site" tab on the MTEC members-only website.

2.5 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 organizations. 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.

2.6 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 extent* includes:

1. Supplying a new key technology, product or process
 2. Supplying a novel application or approach to an existing technology, product or process
 3. Providing a material increase in the performance, efficiency, quality or versatility of a key technology, product or process
 4. Accomplishing a significant amount of the prototype Project
 5. Causing a material reduction in the cost or schedule of the prototype project
- Provide for a material increase in performance of the prototype project

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.

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.

2.11 Intellectual 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.

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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 February 1, 2020 (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 may 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 5.

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 **September 11, 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-19-10-MID-PIP). 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

Program Description:

The Joint Program Committee (JPC)-2/MIDRP is one of six major Defense Health Program (DHP) core research program areas within the DHP medical Research Development Test & Evaluation (RDT&E). JPC-2 is a committee of DoD and non-DoD medical and military technical experts in infectious disease-related program areas. Per the program's mission statement, JPC-2/MIDRP seeks to plan, coordinate and oversee for the DOD, a focused and responsive world class infectious diseases Science and Technology (S&T) program, leading to fielding of effective, improved means of protection and treatment to maintain effective global operational capability by maximizing Warfighter readiness and performance.

Technical Background:

The MIDRP has identified four focus areas for funding under the MID-PIP. To meet the intent of this RPP, each proposal ***MUST*** specifically address only ***ONE*** of the four MID-PIP Focus Areas described below. Offerors are not limited to a single proposal submission. Projects not aligned to at least one of these Focus Areas will not be considered for funding. It is expected that MTEC will make a total of 4 awards - a single award for each focus area.

1) FOCUS AREA #1 (Diagnostic): A point-of-care device to detect the presence of microbial infection.

OBJECTIVE: Delivery of a diagnostic device to detect physiological status as related to medical readiness in an individual.

PERIOD OF PERFORMANCE: Not to exceed 4 years

DESCRIPTION: A Point-of-Care (PoC) device that performs real-time monitoring of an individual's physiological status using minimally-invasive techniques. The physiological status is to be monitored for "active microbial infection" status. The device should be painless, easy to apply and remove from the skin, and should use no power source. The device and associated reagents should be shelf stable for at least one year at ambient temperatures and should have a low footprint. The device should be coupled to a lateral flow assay or a similar low-complexity (potentially CLIA-waived) device to detect molecules that provide reliable information on the infection status of the individual. The device should provide results within 30 minutes, with the results being easy to interpret by non-laboratory personnel. Information obtained from the device would be used to determine the status of medical readiness of deployable/deployed personnel.

During the PoP, the Awardee will be expected to develop a working prototype, perform testing in animals, and perform a preliminary evaluation in humans.

2) FOCUS AREA #2 (mAb): Generation of high affinity monoclonal antibodies to four bacterial antigens for the prevention and treatment of bacterial wound infections and sepsis

OBJECTIVE: Generation of at least four monoclonal antibody products against two *Staphylococcus aureus* and two *Pseudomonas aeruginosa* targets ready for testing in preclinical wound models.

PERIOD OF PERFORMANCE: Not to exceed 2 years

DESCRIPTION: A cocktail of monoclonal antibodies against at a minimum of two antigens of *Staphylococcus aureus* and two antigens of *Pseudomonas aeruginosa*, engineered to be stable in blood no less than 4 months, intended to be used for therapeutic use post-exposure to limit disease progression at Role of Care 1 and Role of Care 2.

During the PoP, the Awardee will be expected to conduct all relevant prototype development work and testing. At the end of the PoP, the Awardee will be expected to deliver the four end products to the Walter Reed Army Institute of Research (WRAIR)/Naval Medical Research Center (NMRC) team for testing in animal infection models.

3) FOCUS AREA #3 (HIV): A single administration escape-resistant therapy for HIV control

OBJECTIVE: Development of a novel therapeutic for the treatment of HIV.

PERIOD OF PERFORMANCE: Not to exceed 1 year

DESCRIPTION: An HIV therapeutic to reduce and control systemic viral loads, halt viral transmission and disease progress is required. Efficacy of the proposed HIV therapeutic should have previously been demonstrated in small animal models of HIV.

During the PoP, the Awardee will be expected to perform studies that assess dose, time of treatment, biodistribution, genotoxicity, and transmission potential of therapeutics in humanized mice models and non-human primates (NHPs). Simian immunodeficiency virus (SIV)-infected Rhesus macaques (RM) animal models used for testing safety and efficacy of experimental HIV interventions should be used to test therapeutic safety (genotoxicity and immunogenicity).

4) FOCUS AREA #4 (Biofilm): Clinical evaluation of products to treat biofilm-mediated antibiotic-resistant infections in non-healing chronic wounds

OBJECTIVE: Development of a safe and efficacious topical product that inhibits and disrupts biofilms formed by multiple drug resistant (MDR) pathogens for the management of chronic wound infections.

PERIOD OF PERFORMANCE: Not to exceed 3 years

DESCRIPTION:

- Prototype for the treatment of biofilm-containing infected wounds to be used topically.
- Prototype must be capable of eradicating bacterial pathogens from infected wounds containing biofilms formed by MDR pathogens. Examples of target wound-associated bacteria are: *Acinetobacter baumannii*, *Staphylococcus aureus*, *E. coli*, and *Klebsiella pneumoniae*.
- Prototype should cause biofilm destabilization by specifically hydrolyzing the glycosidic linkages of poly-beta 1,6 N-acetyl glucosamine (PNAG), a major matrix polysaccharide of biofilms.
- Offerors must have a prototype at a minimum technology readiness level (TRL) of 3 at the time of submission [for definitions of TRLs: <https://mtec-sc.org/wp-content/uploads/2016/12/TRL-definitions.pdf>]. Offerors must already have the following preliminary data on the topical prototype formulation before submitting a proposal:
 - Demonstrated non-cytotoxicity to multiple human cells lines *in vitro*
 - Completed and passed a 3-month biocompatibility and toxicity test *in vivo*

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- Demonstrated long-term stability
- Demonstrated that the topical prototype potentiates the activity of antibiotics and antimicrobials in preclinical (animal) wound models

During the PoP, the Awardee will be expected to:

- Develop a prototype formulation for topical application to infected wounds.
- Demonstrate stability of prototype formulation across a range of temperatures (20°C to 45°C) for a minimum of 6 months.
- Conduct pre-clinical (*in vivo*) biocompatibility studies by a good laboratory practice (GLP)-compliant contract research organization (CRO).
- Conduct proof of concept study in a large animal model (e.g., porcine) by a GLP-compliant CRO to demonstrate efficacy, safety, drug distribution and penetration into the tissue, and drug pharmacokinetics.
- Conduct safety study in human subjects with chronic wounds.
- Obtain feedback on usability of topical prototype formulation from potential users.

Potential Follow-on Tasks:

There is the potential for award of one or more follow-on tasks based on the success of the project (subject to change depending upon Government review of completed work):

- Clinical evaluation of monoclonal antibodies for prevention and treatment of wound infections
- Clinical evaluation of point-of-care device to detect the presence of microbial infection

4.3 Preparation of the Proposal

The Technical Proposal format provided in the MTEC PPG is mandatory. Proposals shall reference this RPP number (MTEC-19-10-MID-PIP). 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 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 Formats either in Excel (.xlsx or .xls) or PDF format is required.

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- **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 6, "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 USAMRDC Office of Research Protections (ORP) provides authorization that the research may proceed. The USAMRDC ORP will issue written approval to begin research under separate notification. Written approval to proceed from the USAMRDC 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.

4.7 Freedom of Information Act (FOIA)

To request protection from FOIA disclosure as allowed by 10 U.S.C. §2371(i), Offerors shall mark business plans and technical information with a legend identifying the documents as being submitted on a confidential basis. For more information, please refer to Section 6.1.1 of the MTEC PPG.

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 2.7). The Cost Sharing/Nontraditional Contractor determination will be made as shown in Table 1:

TABLE 1- COST SHARING/NONTRADITIONAL CONTRACTOR ASSESSMENTS	
RATING	DESCRIPTION
PASS	<p>Offeror proposing an MTEC research project meets at least ONE of the following:</p> <ul style="list-style-type: none"> • 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 • 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. • Offeror provides at least one third of the total project cost as acceptable cost share
FAIL	<p>Offeror proposing an MTEC research project does NOT meet any of the following:</p> <ul style="list-style-type: none"> • Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution

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	<ul style="list-style-type: none">• Offeror's proposal has at least one Nontraditional Defense Contractor or Nonprofit Research Institution participating to a significant extent• 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.• Offeror provides at least one third of the total project cost as acceptable cost share
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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 2.5.

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 and Feasibility
2. Potential for Transition and Commercialization
3. Cost/Price

Evaluation factors are listed in descending order of importance.

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Table 2 explains the adjectival merit ratings that will be used for the Technical Approach and Feasibility 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 and Feasibility

The Technical Approach and Feasibility 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 solution’s maturity. 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 and membership questions should be directed to the MTEC Director of Research, Dr. Lauren Palestrini, Ph.D., lauren.palestrini@officer.mtec-sc.org
- All other questions should be directed to the MTEC Interim Executive Director and 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
CAS	Contract Accounting System
CM	Consortium Manager

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CMA	Consortium Member Agreement
CRO	Contract research organization
DHP	Defense Health Program
DoD	Department of Defense
FAQ	Frequently Asked Questions
F&A	Facilities and Administrative Costs
FDA	Food and Drug Administration
FOIA	Freedom of Information Act
FY	Fiscal Year
G&A	General and Administrative Expenses
GLP	Good laboratory practice
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IR&D	Independent Research and Development
JPC	Joint Program Committee
M	Millions
mAbs	Monoclonal antibodies
MDR	Multiple drug resistant
MID-PIP	Military Infectious Disease – Prototype Innovation Program
MIDRP	Military Infectious Disease Research Program
MTEC	Medical Technology Enterprise Consortium
NDA	Nondisclosure Agreement
NHPs	Non-human primates
NMRC	Naval Medical Research Center
OCI	Organizational Conflict of Interest
ODC	Other Direct Charges
ORP	Office of Research Protections, USAMRDC
pOTA	Prototype Other Transaction Agreement
POC	Point-of-Contact
PoC	Point-of-Care
PoP	Period of Performance
PPG	Proposal Preparation Guide
R&D	Research and Development
RDT&E	Research Development Test & Evaluation
RM	Rhesus macaques
RPP	Request for Project Proposals
SME	Subject Matter Expert
SOW	Statement of Work
TRL	Technology Readiness Level
USAMRDC	United States Army Medical Research and Development Command
USG	U.S. Government
WRAIR	Walter Reed Army Institute of Research

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.*)

Proposal Number:

Organization:

Title:

ACURO and/or HRPO approval needed:

1. 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. 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. 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. 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.

- 5. 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

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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	1 st 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	\$ -		\$ -

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		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 (<u>Prior to the POP End</u>)	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 must invoice for actual costs incurred against a milestone. Invoicing should be monthly.

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

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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.

6. 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

7. 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

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

Report Months	Due Date
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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)
-