

Request for Project Proposals



**Solicitation Number: MTEC-21-03-Wound_Infections
“Prevention of Combat Wound Infections”**

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: November 10, 2020

***Enhanced White Paper Due Date: December 17, 2020
Noon Eastern Time Zone***

Request for Project Proposals MTEC-21-03-Wound_Infections
Number W81XWH-15-9-0001

Table of Contents

1	Executive Summary.....	3
1.1.	The Medical Technology Enterprise Consortium.....	3
1.2.	Purpose.....	3
2	Administrative Overview	4
2.1.	Request for Project Proposals (RPP)	4
2.2.	Funding Availability and Period of Performance	4
2.3.	Acquisition Approach	5
2.4.	MTEC Member Teaming.....	6
2.5.	Proprietary Information	6
2.6.	Offeror Eligibility	7
2.7.	Cost Sharing Definition.....	7
2.8.	Cost Share Requirements.....	7
2.9.	MTEC Assessment Fee.....	8
2.10.	Intellectual Property and Data Rights	8
2.11.	Expected Award Date.....	9
2.12.	Anticipated Enhanced White Paper Selection Notification	9
3	Technical Requirements	9
3.1.	Background.....	9
3.2.	Overall Requirement	9
3.3.	Scope of Work	9
3.4.	Potential Follow-on Tasks:	11
3.5.	Restrictions on Animal and Human Subjects	11
4	Enhanced White Paper Preparation	11
4.1.	General Instructions.....	11
4.2.	Instructions for the Preparation & Submission of the Stage 1 Enhanced White Paper	12
4.3.	Stage 2: Cost Proposal (for Only Those Offerors Recommended for Funding)	13
4.4.	Enhanced White Paper and Cost Proposal Preparation Costs.....	14
4.5.	Freedom of Information Act (FOIA)	14
4.6.	Telecommunications and Video Surveillance	14
5	Selection.....	14
6	Points-of-Contact	17
7	Acronyms/Abbreviations	18
8	Enhanced White Paper Template	19
	Attachment A – Cost Share.....	25
	Attachment B – Statutory Requirements for the Appropriate Use of Other Transaction Authority	26
	Attachment C – Intellectual Property and Data Rights.....	27
	Attachment D – Statement of Work Template.....	29
	Attachment E – Warranties and Representations Template.....	34
	Attachment F – BIDS Instructions	39

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 DoD 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) engage in 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.

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” defense contractors, academic research institutions and not-for-profit organizations; for more information on the MTEC mission, see the MTEC website at <https://mtec-sc.org/>.

MTEC operates under an Other Transaction Agreement (OTA) for prototypes with USAMRDC. As defined in the OTA Guide dated November 2018, a prototype project addresses a proof of concept, model, reverse engineering to address obsolescence, pilot, novel application of commercial technologies for defense purposes, agile development activity, creation, design, development, demonstration of technical or operational utility, or combinations of the foregoing. A process, including a business process, may be the subject of a prototype project. Although assistance terms are generally not appropriate in OT agreements, ancillary work efforts that are necessary for completion of the prototype project, such as test site training or limited logistics support, may be included in prototype projects. A prototype may be physical, virtual, or conceptual in nature. A prototype project may be fully funded by the Department of Defense (DoD), jointly funded by multiple federal agencies, cost-shared, funded in whole or part by third parties, or involve a mutual commitment of resources other than an exchange of funds. Proposed prototype projects should not be exploratory in nature and do require a foundation of preliminary data.

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’s Military Infectious Diseases Research Program (MIDRP). Military relevance is a critical component of Enhanced White Paper submission. Strategic and tactical oversight for the award(s) supported by this RPP will be provided by the MIDRP.

The goal of this RPP is to develop prototype solutions for the prevention of infection of combat wounds. This RPP seeks a non-surgical, definitive solution(s) for a moderate to severe dermal disruption (penetrating wounds) with a focus on averting infection, with the ultimate goal of returning the Service Member to full functional duty without the need for evacuation. The proposed solution(s) may also be used as a temporary treatment when surgical capability is unavailable.

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

2 Administrative Overview

2.1. Request for Project Proposals (RPP)

MTEC is utilizing an accelerated approach to award for this RPP. This streamlined approach is anticipated to be a better means to highlight Offeror methodologies and skills required to address the technical requirements described herein. The Enhanced White Paper process requires quick turnaround times by Offerors. The following sections describe the formats and requirements of the Enhanced White Paper.

Offerors who submit Enhanced White Papers in response to this RPP should submit by the date on the cover page of this RPP. Enhanced White Papers may not be considered under this RPP unless received on or before the due date specified on the cover page.

Each MTEC Enhanced White Paper submitted must be in accordance with the mandatory format provided in Section 8 of the RPP. Enhanced White Papers that fail to follow the mandatory format may be eliminated from the competition during the preliminary screening stage. The Government reserves the right to award Enhanced White Papers received from this RPP on a follow-on prototype OTA or other stand-alone OTAs as necessary to meet mission requirements.

*Note that the terms “Enhanced White Paper” and “Proposal” are used interchangeably throughout this RPP.

2.2. Funding Availability and Period of Performance

The Government Department of Defense (DoD) currently has approximately **\$4 Million (M)** available for a period of performance (PoP) for **up to 24 months**. Award and funding from the Government of proposals received in response to this RPP is expected to be limited to \$4M and is contingent upon the availability of federal funds for this program. Awards resulting from this RPP are expected to be made in Fiscal Year 2021 under the authority of 10 U.S.C. § 2371b.

Cost sharing, including cash and in kind (e.g., personnel or product) contributions are strongly encouraged, have no limit, and are in addition to the \$4M in Government funding to be provided under the resultant award(s).

It is expected that MTEC will make **up to two awards** to qualified Offerors to accomplish the statement of work. If a single Enhanced White Paper is unable to sufficiently address the entire scope of this RPP's technical requirements (outlined in Section 3), 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.

Award funding will be structured incrementally and based upon completion of Milestones and Deliverables.

Dependent on the results and deliverables under any resultant award(s), the U.S. Government (USG) may apply additional dollars and/or allow for additional time for follow-on efforts with appropriate modification of the award. See Section 3.4. for additional details.

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 Enhanced White Papers received in response to this RPP is contingent upon the availability of federal funds for this program.

2.3. Acquisition Approach

This RPP will be conducted using the enhanced white paper approach. In Stage 1, current MTEC members are invited to submit Enhanced White Papers using the mandatory format contained in this RPP (see Section 8 of this RPP). The Government will evaluate Enhanced White Papers submitted and will select those that best meet their current technology priorities using the criteria in Section 5 of this RPP. Offerors whose proposed solution is selected for further consideration based on the Enhanced White Paper evaluation will be invited to submit a full cost proposal in Stage 2. Notification letters will contain specific Stage 2 proposal submission requirements.

Pending successful completion of the total effort, the Government may issue a non-competitive follow-on production contract or transaction pursuant to 10 U.S.C. § 2371b section f.

The Government-selected prototype project(s) awarded as a result of this solicitation will be funded under the Other Transaction Agreement for prototype projects (OTA) Number W81XWH-15-9-0001 with MTEC administered by the CM, ATI. The CM will negotiate and execute a Base Agreement with MTEC members (if not yet executed). The same provisions will govern this Base Agreement as the OTA for prototype projects between the Government and MTEC. Subsequently, any proposal that is selected for award will be funded through a Research Project

Award issued under the member's 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 Enhanced White Paper 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 Enhanced White Paper that, if selected for award, it anticipates the proposed effort will be funded under its executed MTEC Base Agreement.

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 Enhanced White Paper 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, Research and Development (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 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 Enhanced White Papers 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 Enhanced White Paper and the subsequent agreement administration if the Proposal is selected for award. Please mark all Confidential or Proprietary Information as such. 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 who are 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. Offeror Eligibility

Offerors must be MTEC Members in good standing. Offerors submitting Enhanced White Papers as the prime contractor must be MTEC members of good standing by December 14, 2020. To join MTEC, please visit <http://mtec-sc.org/how-to-join/>.

2.7. Cost Sharing Definition

Cost sharing is defined as the resources expended by the award recipients on the proposed statement of work (SOW). *Cost sharing above the statutory minimum is not required in order to be eligible to receive an award under this RPP.* If cost sharing is proposed, then the Offeror shall state the amount that is being proposed and whether the cost sharing is a cash contribution or an in-kind contribution (see Attachment A for definitions); 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.).

2.8. Cost Share Requirements

In order to be compliant with 10 U.S.C. §2371b, Research Projects selected for funding under this RPP are required to meet at least one of the conditions specified in Attachment B ("Statutory Requirements for the Appropriate Use of Other Transaction Authority"). Beyond that, cost sharing is encouraged if possible, as it leads to stronger leveraging of Government-contractor collaboration. For more information regarding cost share, please see Attachment A.

Proposals that fail to meet the mandatory statutory conditions with regard to the appropriate use of Other Transaction authority, as detailed in Attachment B, will not be evaluated and will be determined ineligible for award.

2.9. 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 awarded. 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.

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. Awardees must select one of the two methods:

(1) 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.

(2) 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.

2.10. Intellectual Property and Data Rights

Intellectual Property (IP) rights for MTEC Research Project Awards (RPAs) are defined in the terms of an awardee's Base Agreement and, if applicable, in the resultant RPA. However, MTEC reserves the right to assist in the negotiation of IP, royalties, licensing, future development, etc., between the government and the individual performers prior to final award decision and during the entire award period.

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 unlimited data rights unless otherwise asserted in the proposal and agreed to by the Government.** Rights in technical data shall be determined in accordance with the provisions of MTEC Base Agreement.

See Attachment C for more detail. Note that as part of the Stage 1 of the RPP process (submission of an Enhanced White Paper), **Offerors shall complete and submit Attachment C as an appendix to the Enhanced White Paper** with the Signature of responsible party for the proposing Prime Offeror.

2.11. Expected Award Date

Offeror should plan on the period of performance beginning April 15, 2021 (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.

2.12. Anticipated Enhanced White Paper Selection Notification

As the basis of selections is completed, the Government will forward their selections to MTEC CM to notify Offerors. Proposers will be notified by email from the MTEC CM of the results of the evaluation. Those successful will move forward to the next phase of the process while those rejected will gain evaluation rationale for non-selection.

3 Technical Requirements

3.1. Background

The Joint Program Committee (JPC)-2/Military Infectious Diseases Research Program (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 MIDRP'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.

3.2. Overall Requirement

Combat wound infections in a prolonged care environment are a major risk to Warfighter survivability and their ability to return to competition, posing a significant burden to an Army Health System that has little to no capacity for significant periods of time during Multi-Domain Operations. Research has shown that greater than 30% of all combat wounds become infected. That percentage is expected to rise in a prolonged care environment, hence integrated interventions provided by Tactical Combat Casualty Care (TCCC) providers at the point of injury are critically important to diminish the occurrence of infection in battlefield wounds.

3.3. Scope of Work

The goal of this RPP is to develop prototype solutions that enable prevention of Warfighter wound infections on the battlefield as close to the point of injury as possible without requiring evacuation to higher roles of care and to enable speedy return of Warfighters to duty. Therefore, this requirement is focused on a multi-layered approach to protecting Warfighters against wound infections. The proposed solution(s) is expected to be part of a system to provide an adequate response to complex traumatic penetrating injuries that can lead to wound infections.

Minimum Requirements for Submission of an Enhanced White Paper:

- The expected Technology Readiness Level (TRL) at start of the period of performance (PoP) is 3/4 and at the end of the PoP is TRL 6/7 [definition of TRLs can be found here: <https://mtec-sc.org/wp-content/uploads/2016/12/TRL-definitions.pdf>]
- At the time of submission, the Offeror is expected to have a candidate solution with non-clinical data (in vitro, toxicology, pre-clinical animal data, etc.) indicating safety and/or efficacy.
- The Offeror shall have demonstrated manufacturing feasibility of the candidate solution.

In addition to these minimum requirements, it is strongly **preferred** that Offerors have had at least one meeting with the FDA to discuss the regulatory strategy for their candidate(s). Therefore, proposals demonstrating evidence of the FDA engagement may receive a higher rating.

An ideal solution would meet the following requirements (not listed in order of importance):

[Note: Although Enhanced White Papers that propose to meet all of the product requirements outlined below are **preferred**, the Government may consider responses demonstrating only a portion of the final product attributes if the team's approach can address how the remaining requirements can be met over time. Therefore, it is expected that an Offeror's White Paper will describe in detail what they plan to accomplish and how they plan to satisfy all of the product requirements either during the proposed PoP or beyond that period (Offerors should specify the projected timeline), as applicable.]

1. Broad and rapid microbicidal (bacterial and/or fungal) activity with a shelf life of at least a year. For proposed solutions that may have to be opened multiple times, it is preferred that the "use within" period is at least one year.
2. Ease of use, small and lightweight (i.e., should fit in a combat medic's medical bag) without the need for additional logistic considerations, e.g., cold/warm storage, impact protection, additional supplies/products to enable use.
3. When placed into a wound, the product should not stain the skin or surrounding exposed underlying tissue and should be easily removable (i.e., washed out of the site of placement with sterile water or saline).
4. The product should be usable and efficacious in austere environment conditions, as well as packaging that maintains integrity in wide temperature ranges (between 0-45°C), and also in conditions of high and low humidity.
5. Demonstrable efficacious use of the product on the wound for at least three days in austere environmental conditions referenced above.

At the end of the PoP, the performer(s) is expected to have successfully achieved the following milestones:

- Completed Good Laboratory Practice (GLP)-compliant study demonstrating acceptable safety and efficacy profile in relevant animal model(s), human dose equivalent, and route of administration as intended for human use.

- Completed a Phase 1 clinical trial demonstrating adequate safety and preliminary efficacy profile in optimized dose and schedule.
- A Defined Regulatory Pathway: An adequately defined, detailed regulatory pathway towards a Medical Device, Biologics License or New Drug Application, including (but not limited to) Phase 2 and 3 study plans validated by formal communication with the FDA.
- Evidence that production is capable of scale up and available quantities of the product are adequate to support the remainder of clinical development.
- Demonstrated stability of product(s) for at least one year at 0-45°C and under conditions of high humidity.

3.4. Potential Follow-on Tasks:

There is potential for award of one or more follow-on tasks based on the success of any resultant Research Project Awards (subject to change depending upon Government review of work completed). Note that any potential follow on work is expected to be awarded non-competitively to resultant project awardees. Such follow on work may include (but is not limited to) the following:

- Manufacturing of prototypes for further clinical testing
- Further clinical testing of candidate prototypes

3.5. Restrictions on Animal and Human Subjects

Enhanced White Papers must comply with restrictions and reporting requirements for the use of animal and human subjects, to include research involving the secondary use of human biospecimens and/or human data. The Awardee shall ensure local Institutional Animal Care and Use Committee (IACUC) and Institutional Review Board (IRB) approvals, continuing review (in the intervals specified by the local IACUC and IRB, but at a minimum, annually), and approval by the U.S. Army Animal Use and Review Office (ACURO) and U.S. Army Human Research Protections Office (HRPO). Offerors shall include IACUC, ACURO, IRB and HRPO review and approval in the SOW/Milestones Table.

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 HRPO provides authorization that the research may proceed. The USAMRDC HRPO will issue written approval to begin research under separate notification. Written approval to proceed from the USAMRDC HRPO 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 Enhanced White Paper Preparation

4.1. General Instructions

Enhanced White Papers should be submitted by the date and time specified on the cover page using BIDS: <https://ati2.acgcenter.com/ATI2/Portal.nsf/Start?ReadForm>. Include the MTEC Solicitation Number (**MTEC-21-03-Wound_Infections**) on each Enhanced White Paper submitted. See RPP Attachment F for further information regarding BIDS registration and submission.

Do not submit any classified information in the Enhanced White Paper submission.

The Enhanced White Paper and Cost Proposal format provided in this MTEC RPP are mandatory and shall reference this RPP number (MTEC-21-03-Wound_Infections). Note that Cost Proposals are only required for Stage 2 and are not part of the initial Enhanced White Paper submission. Offerors are encouraged to contact the Points-of-Contact (POCs) identified herein up until the Enhanced White Paper submission date/time to clarify requirements.

All eligible Offerors may submit Enhanced White Papers 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 DoD Agreements Officer, is legally authorized to contractually bind MTEC into any resultant awards.

4.2. Instructions for the Preparation & Submission of the Stage 1 Enhanced White Paper

Offerors submitting Enhanced White Papers in response to this RPP should prepare all documents in accordance with the following instructions:

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. If the Offeror receives errors and fails to upload the full submission prior to the submission deadline, the submission may not be accepted. It is the Offeror's responsibility to ensure a timely and complete submission.**

Required Submission Documents (4): Submitted via BIDS

- **Enhanced White Paper: One PDF document 5MB or lower.**
- **Appendix 1 - Statement of Work: One Word document 5MB or lower.**
- **Appendix 2 - Data Rights Assertions: One PDF document 5MB or lower.**
- **Appendix 3 - Warranties and Representations: One Word (.docx or .doc) or PDF document 5MB or lower.**

Page Limitation: The Enhanced White Paper is limited to ten (10) pages (including cover page). The following Appendices are **excluded** from the page limitation: (1) *Statement of Work*, (2) *Data Rights*, and (3) *Warranties and Representations*

The Enhanced White Paper and its Appendices must be in 12 point font (or larger), single-spaced, single-sided, 8.5 inches x 11 inches. Smaller type may be used in figures and tables, but must be clearly legible. Margins on all sides (top, bottom, left, and right) should be at least 0.5 inch. **Enhanced White Papers and Appendices exceeding the page limits specified above may not be accepted. Each document will be uploaded to BIDS separately (see Attachment F of RPP for BIDS instructions).**

Enhanced White Papers **exceeding the page limit specified in Section 8 of the RPP may not be accepted.**

Please note a full Cost Proposal will be requested if the Enhanced White Paper is selected for funding.

4.3. Stage 2: Cost Proposal (for Only Those Offerors Recommended for Funding)

Offerors that are recommended for funding will receive notification letters which will serve as the formal request for a full Cost Proposal (and may contain a request for Enhanced White Papers revisions based on the results of the technical evaluation). These letters will contain specific submission requirements if there are any changes to those contained in this RPP. However, it is anticipated that the following will be required:

Required Submission Documents (3): Submit to mtec-contracts@ati.org

- **Section II: Cost Proposal Narrative as one word or PDF document.**
- **Section II: Cost Proposal Formats as one excel or PDF document.**
- **Royalty or Additional Research Project Award Assessment: One signed word or PDF document.**

See below for additional instructions:

The Cost Proposal shall be submitted in two separate sections. One Word (.docx or .doc) or PDF file for **Section I: Cost Proposal Narrative** (the MTEC Proposal Preparation Guide will be provided by MTEC to Offerors invited to Stage 2). Separately, **Section II: Cost Proposal Formats** either in Excel (.xlsx or .xls) or PDF format is required.

Each offeror selected for Stage 2 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 full proposal. Please see RPP Section 2.9 for additional information.

The MTEC Cost Proposal format is required. MTEC will make cost proposal formats available to Offerors invited to Stage 2.

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.

Please note that compensation to DoD-affiliated personnel for participation in research while on duty is prohibited with some exceptions. For more details, see Department of Defense Instruction 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research. You may access a full version of the DODI by accessing the following link:
<https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf>

The Offerors invited to submit a Cost Proposal are encouraged to contact the MTEC CM and/or Government with any questions so that all aspects are clearly understood by both parties.

4.4. Enhanced White Paper and Cost Proposal Preparation Costs

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

4.5. 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.

4.6. Telecommunications and Video Surveillance

Per requirements from the Acting Principal Director of Defense Pricing and Contracting dated 13 August 2020, the provision at FAR 52.204-24, "Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment" is incorporated in this solicitation. If selected for award, the Offeror(s) must complete and provide the representation as required by the provision to the CM.

5 Selection

The CM will conduct a preliminary screening of submitted Enhanced White Papers to ensure compliance with the RPP requirements. As part of the preliminary screening process, Enhanced White Papers that do not meet the requirements of the RPP may be eliminated from the competition or additional information may be requested by the CM. 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 non-compliance or elimination during the initial screening is the lack of significant nontraditional defense contractor participation, nonprofit research institution participation, or cost share (see Attachment B). Proposal Compliance with the statutory requirements regarding the appropriate use of Other

Request for Project Proposals MTEC-21-03-Wound_Infections
Number W81XWH-15-9-0001

Transaction Authority (as detailed within Attachment B) will be determination based upon the ratings 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 Enhanced White Paper has at least one Nontraditional Defense Contractor or Nonprofit Research Institute participating to a significant extent • All significant participants in the transaction other than the Federal Government are small businesses 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 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 Enhanced White Paper has at least one Nontraditional Defense Contractor or Nonprofit Research Institute participating to a significant extent • All significant participants in the transaction other than the Federal Government are small businesses or nontraditional defense contractors • Offeror provides at least one third of the total project cost as acceptable cost share

Enhanced White Paper (Stage 1) Evaluation:

The CM will distribute all Enhanced White Papers that pass the preliminary screening (described above) to the Government for evaluation. The Government will then conduct the source selection and determine which Offerors will be invited to submit a Stage 2 cost proposal based on the following Stage 1 criteria. The overall award decision will be based upon a best value determination by considering factors in addition to cost/price.

- **Factor 1 - Scientific Plan:** Relevancy, thoroughness, and completeness of the proposed approach (e.g., the technical merit). As part of this factor, the Government may consider:
 - Hypothesis and objectives;

Request for Project Proposals MTEC-21-03-Wound_Infections
Number W81XWH-15-9-0001

- Scientific rationale with supporting preliminary data;
 - Scientific study design and feasibility;
 - How well the white paper defines and describes a prototype that can meet the requirements and preferred attributes as set forth in this RPP under Section 3 (3.1-3.3);
 - Project management plan, expertise, and experience of personnel; and/or
 - SOW and estimated budget.
- **Factor 2 - Programmatic Relevance:** Relevance of the proposed solution and its alignment with the RPP’s topic area and the program objective described in Section 3 (3.1-3.3). How well the proposed methodology aligns with the program’s technical requirements and the overall intent of the announcement.
 - **Factor 3 - Regulatory and Commercialization Plan:** Feasibility of the Offeror’s regulatory strategy, including FDA pathway, indication of use and designation, strategy for obtaining FDA approvals or clearances. Feasibility of the commercialization strategy including the degree to which the Offeror demonstrates potential commercial use, including a description of the market (civilian and military) and sustainability.

Table 2 explains the adjectival merit ratings that will be used for the Scientific Plan, Programmatic Relevance, and Regulatory and Commercialization Plan factors.

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.
--------------	---

Upon review of the Enhanced White Papers, Offerors who are favorably evaluated may be invited for informal discussions with the Government. Upon completion of the Stage 1, Offerors may be selected for funding, placed into the basket, or not selected. Offerors who are recommended for award will be required to submit a full Cost Proposal. See RPP Section 4.3 for additional details. Offerors who are not invited to proceed into Stage 2 will be provided feedback.

The RPP review and award process may involve the use of contractor subject-matter-experts serving as nongovernmental advisors. All members of the technical evaluation panel, to include contractor SMEs, will agree to and sign a Federal Employee Participation Agreement or a Nondisclosure/Nonuse Agreement, as appropriate, to protect information contained in the RPP as outlined in Section 2.5.

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, mtec-contracts@ati.org
- Technical and membership questions should be directed to the MTEC Director of Research, Dr. Lauren Palestrini, Ph.D., lauren.palestrini@tunnellgov.com

- All other questions should be directed to the MTEC Director of Program Operations Ms. Kathy Zolman, kathy.zolman@ati.org

Once an Offeror has submitted an Enhanced White Paper, the Government and the MTEC CM will not discuss evaluation/status until the source selection process is complete.

7 Acronyms/Abbreviations

ACURO	U.S. Army Animal Use and Review Office
ATI	Advanced Technology International
CAS	Cost accounting standards
CFR	Code of Federal Regulations
CM	Consortium Manager
CMA	Consortium Member Agreement
DHP	Defense Health Program
DoD	Department of Defense
FAQ	Frequently Asked Questions
F&A	Facilities and Administrative Costs
FDA	U.S. Food and Drug Administration
FOIA	Freedom of Information Act (FOIA)
FY	Fiscal Year
G&A	General and Administrative Expenses
GLP	Good Laboratory Practice
Government	U.S. Government, specifically the DoD
HRPO	Human Research Protections Office
IACUC	Institutional Animal Care and Use Committee
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IRB	Institutional Review Board
IR&D	Independent Research and Development
JPC	Joint Program Committee
M	Millions
MIDRP	Military Infectious Diseases Research Program
MPS	Milestone Payment Schedule
MTEC	Medical Technology Enterprise Consortium
NDA	Nondisclosure Agreement
OCI	Organizational Conflict of Interest
ODC	Other Direct Charges
POC	Point-of-Contact
PoP	Period of performance
OTA	Other Transaction Agreement
PPG	Proposal Preparation Guide
RDT&E	Research Development Test & Evaluation

Request for Project Proposals MTEC-21-03-Wound_Infections
Number W81XWH-15-9-0001

ROM	Rough Order of Magnitude
RPP	Request for Project Proposals
S&T	Science and Technology
SOW	Statement of Work
TCCC	Tactical Combat Casualty Care
TRL	Technology Readiness Level
USAMRDC	U.S. Army Medical Research and Development Command

8 Enhanced White Paper Template

See the following page for the mandatory Enhanced White Paper Template

Cover Page

[Name of Offeror]
[Address of Offeror]
[Phone Number and Email Address of Offeror]

DUNS #: [DUNS #]
CAGE code: [CAGE code]

[Title of Enhanced White Paper]

[Offeror] certifies that, if selected for award, the Offeror will abide by the terms and conditions of the MTEC Base Agreement.

[Offeror] certifies that this Enhanced White Paper is valid for 3 years from the close of the applicable RPP, unless otherwise stated.

[A proprietary data disclosure statement if proprietary data is included. Sample:

This Enhanced White Paper includes data that shall not be disclosed outside the MTEC Consortium Management Firm and the Government and shall not be duplicated, used, or disclosed, in whole or in part, for any purpose other than to evaluate this Enhanced White Paper and negotiate any subsequent award. If, however, an agreement is awarded as a result of, or in connection with, the submission of this data, the MTEC Consortium Management Firm and the Government shall have the right to duplicate, use, or disclose these data to the extent provided in the resulting agreement. This restriction does not limit the MTEC Consortium Management Firm and the Government's right to use the information contained in these data if they are obtained from another source without restriction. The data subject to this restriction is (clearly identify) and contained on pages (insert page numbers).]

[Title of Enhanced White Paper]

Programmatic Relevance

- Provide the background and the Offeror's understanding of the problem and/or technology gap/process deficiency.
- Provide a description of how the proposed technology meets the needs specified in this RPP.

Scope Statement

- Define the scope of the effort and clearly state the hypothesis and objectives of the project.

Scientific Rationale / Preliminary Data

- Describe the scientific rationale for the project, including a brief description of the previous studies or preliminary data that support the feasibility of proposed work.
- Describe relevant non-clinical data and/or clinical preliminary data.
- Describe your demonstration of the manufacturing feasibility of the prototype.

Technical Approach

- Describe the experimental design, methods, and materials required to accomplish the proposed approach. Describe the proposed methodology in sufficient detail to show a clear course of action
- Clinical Trials: Clinical trials should be described in adequate detail to assess conformance with FDA regulations, guidance, and the requirements related to its appropriate pathway for development and testing.
 - Provide a description of the purpose and objectives of the study.
 - Describe the clinical intervention, medical drug, biologic, device or human exposure model to be tested. Document the availability and accessibility of the drug/compound, device, or other materials needed for the proposed research.
 - Include a description of study variables, appropriate controls and the endpoints to be tested.
 - Outline the proposed methodology (e.g., study design, data analysis, etc.) in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate.
 - Describe current status of interactions with the U.S. Food and Drug Administration and your plan to meet all regulatory sponsor responsibilities.

Anticipated Outcomes/Impact

- Provide a description of the anticipated outcomes from the proposed work. List milestones and deliverables from the proposed work.
- Describe the impact that the proposed project would have, if successful.

Team

- Describe the qualifications and expertise of the key personnel and organizations that will perform the proposed work.

Project Management Plan

- Describe the overall project management plan that clearly defines roles and responsibilities.

Regulatory and Commercialization Plan

- Describe previous interactions with the FDA related to this proposed prototype solution (e.g., pre-submission meeting).
- Briefly describe the regulatory plan, including FDA pathway and designation, strategy for obtaining FDA approvals or clearances.
- Briefly describe the transition and commercialization plan, including a description of the market (civilian and military) and sustainability.

Resources

- Identify any key facilities, equipment and other resources proposed for the effort. Identified facilities, equipment and resources should be available and relevant for the technical solution being proposed.

Schedule

- Period of Performance: Indicate the proposed period of performance in months from award.
- Proposed Schedule: Provide a schedule (e.g. Gantt chart) that clearly shows the plans to perform the program tasks in an orderly, timely manner. Provide each major task as a separate line.

Risk Identification and Mitigation

- Identify key technical, schedule, and cost risks. Discuss the potential impact of the risks, as well as potential mitigations.

Rough Order Magnitude (ROM) Pricing

- The Offeror must provide an estimate based on the technical approach proposed in the Enhanced White Paper. The following ROM pricing shall be included in the Enhanced White Paper. **[NOTE: If invited to Stage 2, the total cost to the Government proposed in the ROM must not deviate from the proposed cost presented in the Stage 2 full cost proposal (unless otherwise directed by the Government) as this may result in an unacceptable rating.] Use the example table format and template below to provide the ROM pricing.** The labor, travel, material costs, other direct costs, and indirect costs, information should be entered for Offeror (project prime) only. Subcontractors and/or

consultants should be included only in the “Subcontractor” section of the table. If selected for award, a full cost proposal will be requested.

Labor	\$ 100,000.00
Labor Hours	1,000.0 hrs
Subcontractors	\$ 50,000.00
Subcontractors Hours	500.0 hrs
Consultants	\$ 0.00
Consultants Hours	0.0 hrs
Material/Equipment	\$ 75,000.00
Other Direct Costs	\$ 1,000.00
Travel	\$ 5,000.00
Indirect costs	\$ 48,200.00
Total Cost	\$ 289,200.00
Fee (Not applicable if cost share is proposed)	\$ 0.00
Total Cost (plus Fee)	\$ 289,200.00
Cost Share (if cost share is proposed then fee is unallowable)	\$ 290,000.00
Total Project Cost	\$ 579,200.00

Estimate Rationale

- The Offeror must provide a **brief** rationale describing how the estimate was calculated and is appropriate for the proposed scope or approach.

APPENDICES (excluded from the page limit, and must be uploaded to BIDS as separate documents)

Appendix 1: Statement of Work (template provided in Attachment D)

- Provide a draft Statement of Work as a separate Word document to outline the proposed technical solution and demonstrate how the contractor proposes to meet the Government objectives. Submitted information is subject to change through negotiation if the Government selects the Enhanced White Paper for award. The format of the proposed Statement of Work shall be completed in accordance with the template provided below.

- 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.

Appendix 2: Data Rights Assertions (template provided in Attachment C)

- 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 Unlimited Data Rights.
- If this is not the intent, then you should discuss any restricted data rights associated with any proposed deliverables. If applicable, complete the table within the Attachment for any items to be furnished to the Government with restrictions. An example is provided.

Appendix 3: Warranties and Representations: (template provided in Attachment E)

- Warranties and Representations are required. One Word (.docx or .doc) or PDF file that contains all Warranties and Representations is required.

Attachment A – Cost Share

Cost Sharing includes any costs a reasonable person would incur to carry out (necessary to) proposed projects' statements of work (SOW) not directly paid for by the Government. There are two types of cost sharing: Cash Contribution and In-Kind Contribution. If a proposal includes cost share then it cannot include fee. Cost Share may be proposed only on cost type agreements. Prior Independent Research and Development 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.

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 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.

Attachment B – Statutory Requirements for the Appropriate Use of Other Transaction Authority

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. 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.

Significant Extent Requirements

All Offerors shall submit Warranties and Representations (See Attachment E) specifying the critical technologies being offered and/or the **significant extent** of participation of the nontraditional defense contractor and/or nonprofit research institution. The significance of the nontraditional defense contractor's and/or nonprofit research institution's participation shall 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* include:

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
6. Provide for a material increase in performance of the prototype project

Conditions for use of Prototype OT Authority

Proposals that do not include one of the following will not be eligible for award:

- (A) At least one nontraditional defense contractor or nonprofit research institution participating to a significant extent in the prototype project; or
- (B) 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; or
- (C) 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.

This requirement is a statutory element of the Other Transaction Authority and will be regarded as a pass/fail criterion during the Compliance Screening in order to ensure compliance with 10 U.S.C. §2371b.

Attachment C – Intellectual Property and Data Rights

Definitions

- **Intellectual Property (IP) Rights** for MTEC Research Project Awards will be defined in the terms of an awardee’s Base Agreement, unless specifically negotiated at the RPA level. MTEC Base Agreements are issued by the MTEC CM to MTEC members receiving Research Project Awards. Base Agreements include the applicable flow down terms and conditions from the Government’s Other Transaction Agreement with MTEC, including the IP terms and conditions.
- **Data Rights:** It is anticipated that anything delivered under a Research Project Award would be delivered to the Government with unlimited data rights. If this is not the intent, **then the Enhanced White Paper should discuss data rights associated with each item**, and possible approaches for the Government to gain unlimited data rights as referenced in the Base Agreement. Rights in technical data in each Research Project Award shall be determined in accordance with the provisions of MTEC Base Agreement.

Directions to the Offeror

If applicable, complete the below table for any items to be furnished to the Government with restrictions. An example is provided. If the Offeror does not assert data rights on any items, a negative response is required by checking the applicable box below.

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

If the Offeror intends to provide technical data or computer software which existed prior to or was produced outside of the proposed effort, to which the Offeror wishes to maintain additional rights, these rights should be asserted through the completion of the table below.

Note that this assertion is subject to negotiation prior to award.

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

Technical Data 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	Restricted	Organization XYZ	Milestones 1, 3, and 6

Request for Project Proposals MTEC-21-03-Wound_Infections
Number W81XWH-15-9-0001

	software funded exclusively at private expense			
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

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

Signature of responsible party for the proposing Prime Offeror

DATE

Attachment D – Statement of Work Template

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.

Proposal Number:

Organization:

Title:

ACURO and/or HRPO approval needed:

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. 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 Bimonthly Reports (submitted every other month) which include both Technical Status and Business Status Reports (due the 25th of the respective month), 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

Request for Project Proposals MTEC-21-03-Wound_Infections
Number W81XWH-15-9-0001

2	N/A	Bimonthly Report 1 (November - 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	3/14/2020	\$210,757	\$187,457	\$398,214
6	N/A	Bimonthly Reports 2 (January - February, Technical and Business Reports)	3/25/2020	\$ -		\$ -
7	4	Toxicity Studies	4/1/2020	\$63,227		\$63,227
8	5	FDA authorization trial	4/1/2020	\$84,303		\$84,303
9	6	Research staff trained	4/15/2020	\$ -		\$ -
10	7	Data Management system completed	4/30/2020	\$ -		\$ -
11	8	1 st subject screened, randomized and enrolled in study	5/15/2020	\$150,000	\$187,457	\$337,457
12	N/A	Bimonthly Report 3 (March - April, Technical and Business Reports)	5/25/2020	\$ -		\$ -
13	9	Completion of dip molding apparatus	6/1/2020	\$157,829	\$187,457	\$ 345,286
14	10	Assess potential toxicology	6/1/2020	\$157,829		\$157,829
15	11	Complete 50% patient enrollment	6/15/2020	\$350,000	\$187,457	\$537,457
16	12	Electronic Report Forms Developed	6/15/2020	\$315,658	\$187,457	\$503,115
17	13	Complete 75% patient enrollment	7/1/2020	\$157,829	\$93,728	\$251,55

Request for Project Proposals MTEC-21-03-Wound_Infections
Number W81XWH-15-9-0001

18	N/A	Bimonthly Report 4 (May - June, Technical and Business Reports)	7/25/2020	\$ -		\$ -
19	14	Complete 100% patient enrollment	8/1/2020	\$157,829	\$93,728	\$251,557
20	15	Report results from data analysis	8/5/2020	\$157,829		\$157,829
21	N/A	Final Reports (<u>Prior to the POP End</u>)	8/31/2020	\$ -		\$ -
			Total	\$2,025,240	\$1,124,741	\$3,149,981

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 Research Project Award.
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

Reporting

Bimonthly Reports – The MTEC research project awardee shall prepare a Bimonthly 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)

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)

Attachment E – Warranties and Representations Template

Section 815 of the National Defense Authorization Act (NDAA) for Fiscal Year 2018, authorizes Department of Defense organizations to carry out prototype projects that are directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or to improvement of platforms, systems, components, or materials in use by the armed forces. The law also requires at least one of the following:

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

(B) 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.

(C) 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.

A. Prime Contractor: The prime contractor must complete the following table.

1. Legal Name:		2. DUNS #:	
3. Point of Contact: Name, Title, Phone #, Email			
4. Prime Contractor is a nontraditional (Y/N)?			
5. Prime Contractor is a nonprofit research institution (Y/N)?			
6. Prime Contractor will provide at least one third of the total cost of the prototype project out of funds provided by sources other than the Federal Government (Y/N)?			
7. Prime Contractor is a small business (Y/N)?			

If the prime contractor has answered “Y” to question 4, 5, or 6, skip Section B and proceed to Section C.

B. Subcontractor(s)/Vendor(s): If the prime contractor is a **traditional** defense contractor and proposes the use of one or more nontraditional defense contractors or nonprofit research institutions, the following information is required **for each** participating nontraditional defense contractor or nonprofit research institution.

8. Legal Name:		9. DUNS #:	
10. Dollar Value to be Awarded to Subcontractor:			
11. Point of Contact: (Name, Title, Phone #, Email)		12. Task/Phase:	
13. Subcontractor/Vendor is a nontraditional (Y/N)?			
14. Subcontractor/Vendor is a nonprofit research institution (Y/N)?			
15. Subcontractor/Vendor is a small business (Y/N)?			
16. Significant Contribution:			

Request for Project Proposals MTEC-21-03-Wound_Infections
Number W81XWH-15-9-0001

<input type="checkbox"/>	A - The significant contribution involves developing, demonstrating or providing a key technology. <i>Please describe what the key technology is; why it is key to the medical technology community, and what makes it key.</i>
<input type="checkbox"/>	B - The significant contribution involves developing, demonstrating or providing a new technology that is not readily available. <i>Please describe what the new part or material is and why it is not readily available.</i>
<input type="checkbox"/>	C - The significant contribution involves use of skilled personnel (such as modeling & simulation experience, medical technology design experience, etc.), facilities and/or equipment that are within the capabilities of the designated nontraditional and required to successfully complete the program. <i>Please describe the personnel, facilities and/or equipment involved in the proposed program and why they are required to successfully complete the program.</i>
<input type="checkbox"/>	D - The use of this designated subcontractor/vendor will cause a material reduction in the cost or schedule. <i>Please describe the specific cost or schedule impact to be realized</i>
<input type="checkbox"/>	E - The use of this designated subcontractor/vendor will increase medical technology performance. <i>Please describe what the performance increase will be attained by the use of this designated nontraditional defense contractor</i>
1 In addition to the above please provide the following information:	
Q1	What additional capability beyond those described in A through E above does this subcontractor/vendor have that is necessary for this specific effort?
A1	
Q2	In which task/phase(s) of the effort will the subcontractor/vendor be used?
A2	
Q3	What is the total estimated cost associated with the subcontractor/vendor included in the proposal? Note: While cost is an indicator for the level of nontraditional defense contractor participation, there is no particular cost threshold required.
A3	

C. Signature

Signature of authorized representative of proposing Prime Contractor

Date

Warranties and Representations Instructions

Section A must be completed for the Prime Contractor.

1. Insert prime contractor's legal name.
2. Insert prime contractor's DUNS #.
3. Insert the Point of Contact (Name, Title, Phone #, Email) for the prime contractor.
4. Indicate Yes (Y) or No (N) if the prime contractor is a nontraditional defense contractor (Note: A nontraditional defense contractor means an entity that is not currently performing and has not performed, for at least the one-year period preceding the issue date of the solicitation, any contract or subcontract for the Department of Defense that is subject to full coverage under the cost accounting standards prescribed pursuant to Section 1502 of Title 41 and the regulations implementing such section.).
5. Indicate Yes (Y) or No (N) if the prime contractor is a nonprofit research institution.
6. Indicate Yes (Y) or No (N) if the prime contractor will provide at least one third of the total cost of the prototype project out of funds provided by sources other than the Federal Government (i.e. will the project contain at least 1/3 cost share).
7. Indicate Yes (Y) or No (N) if the prime contractor is a small business (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)).

Section B must be completed if the Prime Contractor is **traditional** and has proposed nontraditional defense contractors, nonprofit research institutions, or small businesses. Copy, paste, and complete the table found in Section B **for each** participating nontraditional defense contractor, nonprofit research institutions, or small business.

8. Insert subcontractor/vendor's legal name.
9. Insert subcontractor/vendor's DUNS #.
10. Insert the dollar value (cost and fee) to be awarded to the subcontractor/vendor.
11. Insert the Point of Contact (Name, Title, Phone #, Email) for the subcontractor/vendor.
12. Indicate in which specific task/phase(s) of the effort will the subcontractor/vendor be used.
13. Indicate Yes (Y) or No (N) if the subcontractor/vendor is a nontraditional defense contractor (Note: A nontraditional defense contractor means an entity that is not currently performing and has not performed, for at least the one-year period preceding the issue date of the solicitation, any contract or subcontract for the Department of Defense that is subject to full coverage under the cost accounting standards prescribed pursuant to Section 1502 of Title 41 and the regulations implementing such section.).
14. Indicate Yes (Y) or No (N) if the subcontractor/vendor is a nonprofit research institution.
15. Indicate Yes (Y) or No (N) if the subcontractor/vendor is a small business (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)).
16. Explain the subcontractor/vendor's Significant Contribution to the project by answering the questions below.

- A - The significant contribution involves developing, demonstrating or providing a key technology. ***Please describe what the key technology is; why it is key to the medical technology community, and what makes it key.***
- B - The significant contribution involves developing, demonstrating or providing a new technology that is not readily available. ***Please describe what the new part or material is and why it is not readily available.***
- C - The significant contribution involves use of skilled personnel (such as modeling & simulation experience, medical technology design experience, etc.), facilities and/or equipment that are within the capabilities of the designated nontraditional and required to successfully complete the program. ***Please describe the personnel, facilities and/or equipment involved in the proposed program and why they are required to successfully complete the program.***
- D - The use of this designated subcontractor/vendor will cause a material reduction in the cost or schedule. ***Please describe the specific cost or schedule impact to be realized.***
- E - The use of this designated subcontractor/vendor will increase medical technology performance. ***Please describe what the performance increase will be attained by the use of this designated nontraditional defense contractor.***
- Q1 - What additional capability beyond those described in A through E above does this subcontractor/vendor have that is necessary for this specific effort?
- Q2 - In which task/phase(s) of the effort will the subcontractor/vendor be used?
- Q3 - What is the total estimated cost associated with the subcontractor/vendor included in the proposal? Note: While cost is an indicator for the level of nontraditional defense contractor participation, there is no particular cost threshold required.

Section C must be signed by an authorized representative of the prime contractor.

General Guidance

- Nontraditional defense contractors can be at the prime level, team members, subcontractors, lower tier vendors, or "intra-company" business units, provided that the business unit makes a significant contribution to the prototype project.
- All nontraditional defense contractors must have a DUNS number.
- A foreign business can be considered a nontraditional if it has a DUNS number and can comply with the terms and conditions of the MTEC Base Agreement.

Attachment F – BIDS Instructions

THIS PAGE IS INTENTIONALLY LEFT BLANK. PLEASE SEE THE PRESENTATION BELOW.