

Request for Project Proposals



Solicitation Number: MTEC-21-06-MPAI
"Military Prototype Advancement Initiative (MPAI)"

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

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Noon Eastern Time Zone

Amendment No. 02 incorporates the Enhanced White Paper BIDS Submission Instructions and revises language in Section 4.3 in accordance with the recent revisions to the Consortium Member Agreement and MTEC Assessment Fee.

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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 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) to solicit current MTEC members for a broad range of medical prototype technological and knowledge solutions related to the Focus Areas of Interest (also called “Focus Area(s)”) listed below. Proposed solutions may

include medical techniques, knowledge products, and materiel¹ (medical devices, drugs, and biologics).

- Focus Area #1: Prolonged Field Care
- Focus Area #2: Medical Readiness
- Focus Area #3: Emerging Technologies
- Focus Area #4: Maximizing Human Potential
- Focus Area #5: Applied Medical Robotics and Machine Perception and Intelligence Systems

2 Administrative Overview

2.1. Request for Project Proposals (RPP)

MTEC is utilizing a streamlined solicitation approach to award for this broad, multiple focus area RPP to solicit and fund a wide range of projects of varying scope and maturity levels under the Military Prototype Advancement Initiative (MPAI). This solicitation mechanism has been implemented for the following reasons and has several **unique features** noted below.

- *Increase information exchange between the MTEC membership and the military* – This solicitation mechanism provides the MTEC membership with an official way of sending information related to their military-relevant solutions through MTEC to the military, and potentially make the military aware of new solutions that can address unmet needs.
- *Provide feedback to the MTEC membership* – This solicitation mechanism differs from the previous MTEC “Open Concepts” Request for Project Information in that MTEC membership will receive feedback from the Government, which can help Offerors realign to better meet the Government/military need downstream, or even find out whether the Government/military would be interested at all (a “not interested” is valuable feedback as well). ***Having said that, due to the anticipated high number of submissions and the need for a compressed timeline for the review cycles, feedback provided may be VERY BRIEF. Although this may be disappointing, the Government has weighed the benefits vs. costs of this more open-ended type RPP, and in order to provide a mechanism that allows members to submit Enhanced White Papers any time during the lengthy submission period, the reviewers must be allowed the opportunity to provide more succinct feedback.*** To supplement these succinct reviews, MTEC has implemented an educational webinar series and through this, hopes to offer opportunities throughout the year for MTEC members to hear from and interact with the military Sponsors. While this will not allow for direct and specific feedback on Offerors’ proposals, it will allow for an open discussion regarding priorities and capability gaps within the Government’s portfolios.

¹ Materiel is defined as equipment and supplies of a military force.

- *Establish an open window for the military to make awards* – The solicitation mechanism is intended to provide MTEC members with an opportunity to propose solutions throughout the year. However, the open period of the MPAI RPP is ***initially established*** for a 3-month period with the intent to extend the deadline or issue a similar RPP to allow for submissions beyond the current due date. Offerors are advised that updates may be added via amendment at any time to reflect changes in Government requirements or other revisions, as appropriate. With an extended open submission period, awards may be made on a first-in, first-out basis. Additionally, the MTEC selection process for this solicitation includes a “basket” provision that permits holding proposed projects that have technical merit but unfunded for up to two years, which allows for efficient contracting as funding becomes available.
- *Solicit for key areas to support achievement of the USAMRDC strategic objectives* – The focus areas will allow MTEC members to propose innovative and relevant solutions to USAMRDC’s strategic objectives.
- *Diversity in potential Sponsors* – While USAMRDC is listed throughout this RPP, sponsoring offices from outside commands may also participate in the source selection process and select projects for award depending on interest, programmatic alignment, and funding availability.

Offerors who submit Enhanced White Papers in response to this RPP should submit by the date on the cover page of this RPP (see Section 4.1 for details on the submission period). Enhanced White Papers may not be considered under this RPP unless received on or before the due date specified on the cover page.

Each 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 CM’s preliminary screening stage (see Section 5 for more details on the Selection process). 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 (PoP)

The funding amount and PoP for this RPP is unspecified (with the exceptions detailed below), and the number of awards is indeterminate and contingent upon funding availability. Selection of prototype projects is a highly competitive process and is based on the evaluation of the proposal’s technical merit, programmatic considerations, and the availability of funds. The quantity of meaningful submissions received normally exceeds the number of awards that the available funding can support. Any funding that is received by the USAMRDC and is appropriate

for a Focus Area of Interest described within this RPP may be utilized to fund Enhanced White Papers. Awards resulting from this RPP are expected to be made in Fiscal Years 2021 and 2022 under the authority of 10 U.S.C. § 2371b.

A budget and PoP should be commensurate with the nature, scope and complexity of the proposed research. Offerors should submit budgets that include the entire PoP of the research project. Yearly budgets should include all direct and indirect costs, based on supportable, verifiable estimates. Offerors are encouraged to scope out their budgets in alignment with major deliverables of their proposed work so that large budgets are easier to evaluate and Sponsors can more easily allocate available funding. *The funding limitations per Enhanced White Paper are as follows:*

- Focus Area 1.10 - The maximum request for Government funding for each Enhanced White Paper should not exceed \$1.4 M for projects proposing in response to Focus Area 1.10.
- Focus Area 2.6 - The maximum request for Government funding for each Enhanced White Paper should not exceed \$511 K for projects proposing in response to Focus Area 2.6. The USG anticipates funding this focus area with (2-year) FY20 funds, where awards will be made no later than September 30, 2021.
- Focus Area 2.8 - The maximum request for Government funding for each Enhanced White Paper should not exceed \$781 K for projects proposing in response to Focus Area 2.8. The USG anticipates funding this focus area with FY20 funds, where awards will be made no later than September 30, 2021.
- Focus Area 2.9 - The maximum request for Government funding for each Enhanced White Paper should not exceed \$4.3 M for projects proposing in response to Focus Area 2.9. The USG anticipates funding this focus area with FY20 funds, where awards will be made no later than September 30, 2021.
- Focus Area 2.11 - The maximum request for Government funding for each Enhanced White Paper should not exceed \$3 M for projects proposing in response to Focus Area 2.11. The USG anticipates funding this focus area with FY20 funds, where awards will be made no later than September 30, 2021.
- Focus Area 2.12 - The maximum request for Government funding for each Enhanced White Paper should not exceed \$1.4 M for projects proposing in response to Focus Area 2.12. The USG anticipates funding this focus area with FY20 funds, where awards will be made no later than September 30, 2021.
- Focus Area 5 (all technical areas of interest) – The maximum request for Government funding for each Enhanced White Paper should not exceed \$600,000 for projects proposing in response to *any of the technical areas of interest* within Focus Area #5. Additional funding may be available for selected performer(s) for the continuation of prototype development under a subsequent period(s) of performance of the resultant award(s).
- For all other Focus Areas not explicitly listed above – There are no specified funding limitations identified for an Enhanced White Paper submitted under this RPP. For

informational purposes, the average award size of MTEC awards for the initial PoP is approximately \$1.5 – 3M over a 2 – 3 year PoP.

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 Government funding to be provided under the resultant award(s).

Award funding may 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 non-competitively award additional dollars and/or allow for additional time for scope increases and/or follow-on efforts with appropriate modification of the award. See Section 3.6. for additional details.

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 (and may be required to submit additional documentation or supplemental information such as those examples listed under Section 4.2). 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. 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. Proposers Conference

MTEC intends to host multiple Proposers Conferences that will be conducted via webinar within several weeks of the release of the RPP and may include up to six (6) separate sessions. Further instructions will be forthcoming via email. The intent of the MPAI Proposers Conference series is to provide an administrative overview of this RPP process to award (anticipated as a standalone session) and to present further insight into the Focus Areas of Interest outlined in Section 3. Offerors are advised to check the MTEC website periodically during the proposal preparation period for any clarifications found in Frequently Asked Questions (FAQ) responses.

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

2.6. 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. In accordance with the PPG, 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.

2.7. Offeror Eligibility

Offerors must be MTEC Members in good standing to be eligible to submit an Enhanced White Paper. Offerors submitting Enhanced White Papers as **the prime performer must be MTEC members of good standing at least 3 days prior to submission of the Enhanced White Papers.** Subcontractors (including all lower tier subawardees) do not need to be MTEC members. To join MTEC, please visit <http://mtec-sc.org/how-to-join/>.

2.8. 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.).

2.9. 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.

2.10. MTEC Assessment Fee

This RPP was initially issued on March 18, 2021. Effective on April 1, 2021 the Consortium Member Agreement was amended to implement a new Assessment Fee. This RPP is hereby amended to allow the proposer to elect either to pay the new, 2% Assessment Fee, or in the alternative pay a 1% Assessment Fee and to also execute a Royalty Agreement (one of the options that was available prior to the amendment of the CMA). Both options are described in more detail in the next two paragraphs. The proposer is required to indicate the option selected from below, as a part of their proposal.

2% FEE OPTION:

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 2% of the total funded value of each research project awarded. Payment 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.

1% FEE PLUS ROYALTY AGREEMENT OPTION:

Under this method, the Research Project Award recipient will pay MTEC an amount equal to 1% of the total funded value of the resulting research project award. Payment shall be due no later than 90-days after the research project award is executed. In addition, the 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. Royalties will be capped at 200% of the Government funding provided. A copy of the standard Royalty Agreement is available upon request. Should the proposer not accept the terms of the Royalty Agreement, or if there is no mutual agreement on any proposed modifications to the Royalty Agreement, MTEC will require the proposer to pay the 2% Fee Option.

2.11. Intellectual Property and Data Rights

Baseline Intellectual Property (IP) and Data rights for MTEC Research Project Awards (RPAs) are defined in the terms of a member's Base Agreement, and specifically-negotiated terms are finalized in any resultant RPA. 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 created 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 the 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 the responsible party for the proposing Prime Offeror.

2.12. Expected Award Date

Offeror should plan on the PoP beginning no sooner than 4 months after the submission deadline (subject to change). The Government reserves the right to change the proposed PoP start date through negotiations via the CM and prior to issuing a Research Project Award.

2.13. 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 not selected will gain evaluation rationale for non-selection.

Offerors are hereby notified that once an Enhanced White Paper has been submitted, neither the Government nor the MTEC CM will discuss evaluation/status until after the Offeror receives the formal notification with the results of this evaluation.

3 Technical Requirements

3.1. Background

In multi-domain operations, today's operating force will be overwhelmed with casualties, the ability to evacuate will be limited, first responders and medics will struggle with limited resources and ability to achieve the "Golden Day," resulting in operational units and commanders rapidly losing freedom of maneuver and combat effectiveness. Therefore, medical assets must be highly mobile and more dispersed (e.g., smaller, more modular medical units), Warfighters will require greater self-sufficiency and autonomy (e.g., may have more limited medical-related communications and re-supply), and there will be an increased cognitive and physical stress on Warfighters (they will need ways to maximize lethality and return to the fight quickly).

3.2. Minimum Requirements for Submission of an Enhanced White Paper

Enhanced White Papers submitted in response to this RPP shall meet the following minimum requirements:

1. **Military Relevance:** Proposed projects shall focus on providing medical solutions to support readiness and care in future battlefield scenarios.

2. Fit the prototype definition: Proposed prototype projects should not be exploratory in nature and do require a foundation of preliminary data. The definition of a "prototype" is as follows: 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.
3. Minimum Knowledge/Technology Readiness Level (KRL/TRL): The expected KRL/TRL **at the time of submission of the Enhanced White Paper** is at least KRL/TRL 3. Offerors have achieved KRL/TRL 3 if:
 - **Knowledge Products:** Offeror has validated hypotheses that suggest applications (e.g., prediction for prognosis, screening for diagnosis, or treatment for prevention)
 - **Pharmaceutical (Drugs):** Offeror has demonstrated initial proof-of-concept for candidate drug constructs in a limited number of in vitro and in vivo research models
 - **Pharmaceutical (Biologics, Vaccines):** Offeror has demonstrated initial proof-of-concept for biologic/vaccine constructs in a limited number of in vitro and in vivo research models.
 - **Medical Devices:** Offeror has demonstrated initial proof-of-concept for device candidates in a limited number of laboratory models (may include animal studies).
 - **Medical Information Management/Information Technology & Medical Informatics:** Medical Informatics data and knowledge representation schema are modeled.

*NOTE: Full definitions of TRLs can be found [here](#). More information regarding KRLs can be found [here](#).
4. New Submissions to MTEC: Focus on proposed solutions that have not been submitted to MTEC under previous RPPs within the past 2 years. The Government is already aware of concepts submitted in response to previous MTEC solicitations, and therefore, such projects are not allowed to be resubmitted here. This RPP is intended only for submission of new projects to MTEC, not direct resubmissions or modifications of projects previously submitted. Furthermore, Enhanced White Papers reflecting substantially the same technical approach submitted multiple times under this MPAI RPP may not be evaluated by the technical evaluators and determined ineligible for award, unless such a resubmission is directed by the Government.
5. Alignment to a Specified Focus Area of Interest: Enhanced White Papers shall align to a single Focus Area of Interest specified in Section 3.3 below. Failure to align to a single Focus Area of Interest may result in an "Unacceptable" rating and render the proposal ineligible for award.

****NOTE:** Failure to meet any or all of these minimum requirements may result in an overall “Unacceptable” rating of the Enhanced White Paper with minimum or no additional feedback provided.

3.3. Focus Areas of Interest

To meet the intent of this RPP, each enhanced white paper ***SHALL*** specifically address ***ONLY ONE*** Focus Area of Interest described below. Offerors are not limited to a single Enhanced White Paper submission. Projects not aligned to one of these Focus Areas of Interest may not be considered for funding.

- **FOCUS AREA #1: Prolonged Field Care (PFC):** A primary emphasis in 2021 is to identify and develop medical techniques, knowledge products, and materiel² (medical devices, drugs, and biologics) for early intervention in life-threatening battle injuries and prolonged field care³ (PFC). Because battlefield conditions impose severe constraints on available manpower, equipment, and medical supplies available for casualty care, there is a need for medical interventions that can be used within the battle area or as close to it as possible, before or during medical evacuation. Preferred medical techniques and materiel that can be used by combat medics must be easily transportable (i.e., small, lightweight, and durable in extreme environments and handling); devices must be easy to use and require low maintenance, with self-contained power sources as necessary. This focus area is also interested in solutions that include artificial intelligence (AI), with a focus on the employment of AI to support providing care at the point of need in remote and austere environments. **The following focus areas of interest are (not listed in order of importance):**
 - **FA1.1** Control & Sustainment of Critical Organ System & Metabolic Function
 - **FA1.2** Enabling Medical Capabilities to Support En Route and Prolonged Care in Remote, Austere Settings, & Extreme Environments
 - **FA1.3** Prophylactic to Prevent Infection in Battlefield Wounds
 - **FA1.4** Control of Wound Progression & Infection Prevention
 - **FA1.5** Enabling capabilities to increase patient movement capacity
 - **FA1.6** Blood and Blood Products – Next Generation Blood, Blood Products, Pharmaceuticals, Synthetic Replacements, & Delivery Systems
 - **FA1.7** Brain Trauma – Treatment and Objective Diagnosis, Prognosis and Assessment of Traumatic Brain Injury (TBI) in combat and prolonged care scenarios
 - **FA1.8** Tactical Combat Casualty Care – Point of Injury Control of Non-Compressible Hemorrhage & Immediate Cardiopulmonary Stabilization

² Materiel is defined as equipment and supplies of a military force.

³ Prolonged field care is defined as field medical care, applied beyond “doctrinal planning timelines” by a North Atlantic Treaty Organization (NATO) Special Operations Combat Medic (NSOCM) or higher, in order to decrease patient mortality and morbidity. PFC utilizes limited resources and is sustained until the patient arrives at an appropriate level of care. Rasmussen TE, Baer DG, Cap AP, et al. 2015. Ahead of the Curve. *J Trauma Acute Care Surg* 79: S61-64.

- **FA1.9** Cognition-sparing, long-duration pain control
 - **FA1.10** Large animal studies for the development of a portable non-pharmaceutical device that provides regional analgesia at the point of injury and/or during medical evacuation
 - **FA1.11** Automated Ultrasound Technology – An automated ultrasound that is field portable with the capability of imaging abdomen, thoracic cavity, extremities, and pelvis. The prototype will also be capable of interpreting images and providing diagnostic feedback as well as having a semi-autonomous/autonomous guidance feature for surgical procedures.
 - **FA1.12** Burns – Development of material and knowledge solutions to enable limited volume parenteral and/or enteral burn resuscitation in forward environments potentially under prolonged care
 - **FA1.13** Autonomy – use of autonomy solutions in austere environments in PFC to help with resuscitation, stabilization, airway management, reduce major bleeding, help MEDICs in degraded environments, etc. to support autonomous care, Decision Support Systems, and/or Intelligent Evacuation and Prolonged Care
- **FOCUS AREA #2: Medical Readiness:** This area focuses on developing technologies that maximize medical readiness and provide mobile health solution sets for the modern Warfighter. Efforts may include diagnostics, treatments, AI-based advanced telehealth technologies, and training solutions to prevent or reduce injury and improve physiological and psychological health and resilience. This objective includes environmental health and protection including the assessment and sustainment of health and the operational effectiveness of Service members exposed to harsh operational environments including altitude, cold, heat, and exposure to environmental health. This focus area also includes medical readiness in response to infectious diseases encountered by service members during deployment and those that can significantly impact performance. **The following focus areas of interest are (not listed in order of importance):**
 - **FA2.1** Leader and Provider Tools to Prevent, Reduce, Screen and Diagnose Musculoskeletal Injury in all Settings
 - **FA2.2** Solutions to Accelerate Return-to-Readiness following Musculoskeletal Injuries
 - **FA2.3** Solutions to Sustain Warfighter Performance in Arctic and Other Extreme Environments
 - **FA2.4** Far Forward Psychological Health Care
 - **FA2.5** Field Deployable Solutions to Prevent Degradation of Unit Performance and Soldier Psychological Health
 - **FA2.6** AI Platform for the Early Identification and/or Management of Symptoms Associated with Post-traumatic Stress Disorder (PTSD) – The platform should allow for the integration of physiological data collected from a wearable device that can be used at home and on-demand. It should utilize audio-visual stimulation aimed to manage PTSD symptoms, include a remote monitoring app, and provide real-

- time data to both users and monitoring physicians. Testing of the prototype should be performed in a military or veteran population suffering from PTSD.
- **FA2.7** Medical Strategies to Sustain Soldier Alertness & Performance in all Settings
 - **FA2.8** Guidelines and Recommendations on the Implementation of Human-Automation Teaming that Optimizes Human Performance and Increases Operational Effectiveness – The research should include a multi-day study in humans in a controlled environment to determine how task complexity, time on task, rest, and fatigue state (sleep loss and circadian misalignment) affect the Warfighter’s ability to perform and interact with automation.
 - **FA2.9** Pharmacological/Technological (P/T) Approaches to Measure & Manipulate the Glymphatic/Lymphatic (G/L) System in Humans during Sleep – Awardees will be expected to demonstrate that the G/L system can be reliably measured in humans during sleep and directly manipulated through P/T approaches; demonstrate efficacy of their approach to positively impact cognitive performance and psychological health outcomes; develop or adapt approaches to improve or enhance brain fluid movement in humans; and develop models that quantify the impacts of G/L clearance in the brain on short term impacts on the restorative effects of sleep.
 - **FA2.10** Medical Criteria and brain injury-based thresholds for Informing Development of New Tactical Headborne Systems and personal protection equipment against blast, ballistic, and blunt trauma threats
 - **FA2.11** Acute and Repetitive Blast Exposure Induced Brain Injury and Cognitive Health Models – The research should deliver blast-induced brain injury risk thresholds and probability risk curves for brain injury resulting from single and repetitive blast exposures. It should also lead to blast-induced brain injury criteria, test methodology, and an assessment tool that can be integrated into the Army’s Health Hazard Assessment Program non-auditory blast overpressure risk model.
 - **FA2.12** Medically-based Criteria for Body Armor Fielded for Future Development and Evaluation of Next Generation PPE – Awardees will be expected to develop and conduct, in cooperation with DoD laboratories, novel research to characterize physiological response (e.g., vital organ injury) and torso impact parameters under military-relevant exposures, using mechanical, cadaveric, or animal surrogates. The researchers should leverage existing computational models of the torso, as well as existing and emerging clinical data and emerging field data on torso injuries being collected by the DoD, law enforcement community, industry, academia, etc.
 - **FA2.13** Infectious Diseases – Rapid Diagnostic and Detection Devices
 - **FA2.14** Prophylactic for Endemic Diarrheal Diseases
 - **FA2.15** Broad Spectrum Antivirals
 - **FA2.16** Broadly protective vaccine platforms for Emerging Infectious Diseases
 - **FA2.17** Novel, adaptive, and tailored simulation education trainings that optimize practice and effectiveness (i.e., brain focused and learning retention)

- **FOCUS AREA #3: Emerging Technologies:** This area is focused on the Multi-Domain Battle, an operational environment involving greater dispersion and near isolation over great distances, which is likely to cause severe restrictions on mobility for medical missions and shortfalls in both human and materiel human resources due to area denial challenges. Combat units will need to be more self-sufficient and less dependent on logistical support. Combatant commanders with increased sick or wounded Soldiers will face degradation of medical resources and encumbered combat effectiveness without new combat casualty management and Force multiplication strategies. This focus area is searching for emerging technologies that will increase medical mobility while ensuring access to essential medical expertise and support regardless of the operating environment. **The following focus areas of interest are (not listed in order of importance):**
 - **FA3.1** AI for information and technology – focus on employment of AI to support medical resupply in theater to improve real-time information access, security and mobility; interoperable data capture and documentation technologies
 - **FA3.2** Synthetic Biology – general interest as well as cell & therapeutics, diagnostics, detection platforms
 - **FA3.3** Casualty Management – Next generation casualty management, medical logistics, training and education, and medical command and control in dispersed operations and other theater/operational environments.
 - **FA3.4** Human Machine Integration Best Practices and Trust – Efficacy of integrating robotics into the far forward mission that consider best practices to encourage trust by the user. Understanding the extent to which Warfighters may trust robots and how to achieve this capability.
 - **FA3.5** Nano, micro, and macro interoperable haptic platforms – This aspect of performing Live, Virtual, Augmented, and Gaming education tools is limited by the ability to experience force and real life tactile sensations especially in the medical field. The limiting factor in realistic environments is the ability to provide this factor to assist in cognitively remembering and understanding how the action should feel to be correct. Haptic gloves available utilize wires and limit the perimeter because the user is tethered.
- **FOCUS AREA #4: Maximizing Human Potential:** This area aims to develop effective countermeasures against military-relevant stressors and to prevent physical and psychological injuries during training and operations in order to maximize the human potential, in support of the Army Human Performance Optimization and Enhancement, Human Dimension, Multi-Domain Battle, and the DoD Total Force Fitness concepts. **The following focus areas of interest are (not listed in order of importance):**
 - **FA4.1** Maximizing Human Potential - cognitive, physical and emotional potential in multi-domain operations (MDO) by optimizing physical and psychological health and resilience and provide safe, impactful, and ethical human performance; optimizing the interactions between systems and Soldiers, leaders, and teams
 - **FA4.2** Solutions to Maximize Warfighter and Family Member Psychological Health and Resilience to Stressors

- **FA4.3** Repair, restore, preserve and maintain sensory system (e.g., vision, hearing, balance) function after combat related threats (including but not limited to directed energy exposure). Seeking research efforts to support the development of innovative strategies and technologies that may include medical devices, pharmaceuticals, rehabilitation strategies, and regenerative medicine-based approaches, to treat, restore, and preserve spared tissue and function, and/or rehabilitate patients due to neurosensory related trauma.
- **FOCUS AREA #5: Applied Medical Robotics and Machine Perception and Intelligence Systems:** This area focuses on investigation of novel technologies and methods of applying robotics to augment medical capability and capacity in forward care settings. The specific technologies include machine perception and intelligence systems, and advanced motion planning and control of semi-autonomous robotics. The target applications include the use of tele-surgical robotics to extend the reach of remote surgeons, and robotic-assisted casualty monitoring, diagnostics, and intervention to assist local care providers in combat casualty care situations. This area also focuses on leveraging unmanned air and ground systems to provide standoff detection and remote assessment of combat casualties to facilitate rapid casualty extraction, and to provide emergency medical resupply to support field care when evacuation is not possible. **The following focus areas of interest are (not listed in order of importance):**
 - **FA5.1** Machine Perception Systems for robotic-assisted diagnostics and interventions – The development and integration of computer vision techniques to locate, segment, and map key anatomical features that enable the use of robotic systems to assist in interventions. Applications include the development of safety protocols for telerobotic surgery and robotic-assisted diagnostic imaging.
 - **FA5.2** Standoff Casualty Detection, Assessment, Monitoring – the development and integration of image processing algorithms using common sensors as input to provide casualty detection and remote assessment at standoff distances. Applications include integration with vision systems on common robotic or manned vehicles platforms.
 - **FA5.3** Unmanned Aerial System (UAS) supply of critical medical supplies to the tactical edge – The use emerging unmanned vehicle platforms for medical resupply to support field care and other medical logistics missions in austere operating environments. Applications include the rapid distribution of vaccines and test kits to support pandemic response in remote and high-threat environments.
 - **FA5.4** Medic/Robot Teaming – The development and integration of techniques that allow forward care providers to effectively team with robotic or semi-autonomous systems. Applications include supervisory-level command and control of semi-autonomous robotics, or systems designed to automate data entry for existing or emerging Medic tools, e.g. patient documentation or clinical decision support systems.

3.4. Additional points of consideration

- Project Maturity: This solicitation is not meant to support development of a new prototype, and should meet the minimum TRL or KRL requirement of 3 (described in Section 3.3).
- Industry Partners: MTEC considers that an enhanced white paper involving an industry partner (or alternative organization(s)) to serve as the regulatory sponsor and commercialization partner (if applicable to the proposed project) may have the greatest level of success, especially considering that the eventual goal is to obtain FDA clearance/approval.
- Cost Share: It is anticipated that the Government funds would provide incentive for industry funding to join the project. While not a requirement, Offerors are strongly encouraged to include Cost Share as appropriate.

3.5. Examples of Proposed Tasks

The PoP should be focused on tasks relevant to advance the prototype to the next TRL or KRL. Project scope should be proposed based on the prototype's maturity at the time of submission.

Examples of the work that could be included in the PoP are **(but not limited to)**:

- Non-GLP laboratory research to refine hypothesis and identify relevant parametric data required for technological assessment in a rigorous (worst case) experimental design.
- Exploratory study of candidate devices/systems/drugs.
- Candidate devices/drugs/vaccines are evaluated in laboratory or animal model(s) to identify and assess potential safety problems, adverse events, and side effects.
- Prototype development, refinement, maturation
- Nonclinical and preclinical studies required for the technical data package for a regulatory application
- Preparation of regulatory packages (e.g., Investigational New Drug application, Investigational Device Exemption application), including regulatory consultant costs.
- Prototype refinement/maturation progressing towards clinical product
- Clinical feasibility studies (as needed) to support regulatory approval/clearance
- Clinical pivotal studies (as needed) to support regulatory approval/clearance
- Stability and shelf-life studies
- Prototype delivery for military-relevant testing
 - Testing of prototypes
 - System prototype demonstration in a relevant or operational environment
- Establishment of Good Manufacturing Practice (GMP) manufacturing for clinical trials and for market release
- Initial production runs; first article testing, etc.
- Low rate initial product runs to reach Full Operating Capability (FOC)

- Draft product support documentation (e.g., training guides, product inserts, etc.)
- Development of a business and/or commercialization plan for market release
- Integration of medical informatics system components and system is evaluated in a simulated environment/ Develop interfaces to supporting systems
- Advanced technical testing in a laboratory environment and ultimately in a relevant or simulated operational environment of an informatics system including actual interfaces to realistic supporting elements

3.6. Potential Follow-on Tasks

Under awards resulting from this RPP, there is the potential for award of one or more non-competitive follow-on tasks based on the success of the project (subject to change depending upon Government review of completed work and successful progression of milestones). Potential follow-on work may be awarded based on the advancement in prototype maturity during the PoP. Follow-on work may include tasks related to advancement of prototype maturity, and/or to expand the use or utility of the prototype. **Examples** of potential follow-on work are **(but not limited to)**:

- Prototype development, refinement, maturation
- Nonclinical and preclinical studies required for the technical data package for a regulatory application
- Clinical Studies
- Establish robust quality system
- Improve efficiency and reproducibility of manufacturing process for scale up
- Work towards FDA clearance/ approval
- Military environmental and operational assessments
- Ruggedization for operation in military environments
- Advanced technical testing in relevant or simulated operational environments
- Initial Procurement

Offerors are encouraged, as appropriate, to discuss potential follow-on work in the Enhanced White Paper submission to demonstrate the ability to further advance the project maturity beyond the proposed PoP. This will also allow the Offeror to highlight the potential capabilities that can be explored/achieved through short term and/or long-term advancement of the project in a way that is beneficial to the Government.

3.7. Restrictions on Animal and Human Subjects, Human Anatomical Substances, or Human Cadavers

All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC Office of Research Protections (ORP), Human Research Protection Office (HRPO), prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.

If the proposed research is cooperative (i.e., involving more than one institution), a written plan for single IRB review arrangements must be provided at the time of application submission or award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

Research Involving Animals: All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRDC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.

Enhanced White Papers must comply with the above mentioned 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. Under any resultant award(s), the Awardee(s) shall ensure local IACUC and IRB approvals, continuing review (in the intervals specified by the local IACUC and IRB, but at a minimum, annually), and approval by ACURO and 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.

3.8. Inclusion of Women and Minorities in Study

Consistent with the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects," and Congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRDC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Under any resultant awards, Offerors may be required to describe the strategy for the inclusion of women and minorities in the clinical trial appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, and ethnicity, and an accompanying rationale for the selection of subjects. Such strategy should provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The suggested Inclusion Enrollment

Report format is a one-page fillable PDF form, which can be downloaded from the Documents Library on the MTEC Public Site (mtec-sc.org) and the Members Only Site.

3.9. Guidance for research studies targeting DOD personnel for survey research

Protocols that target DoD personnel for research in which the primary data collection tool is a survey require additional administrative review per Department of Defense Instruction (DODI) 1100.13. Investigators will need to coordinate with HRPO to identify current submission requirements.

3.10. Guidance for research studies targeting military families and children

In accordance with DODI 1402.5 and Army Directive 2014-23, Child Care National Agency Check and Inquiries (CNACI) background investigations are required for all individuals who have regular contact with military dependents under 18 years of age. All individuals who regularly interact with children under 18 years of age in Army sponsored and sanctioned programs are required to undergo specific initial background checks and periodic re-verifications. Investigators who propose work involving contact with military dependents under 18 years of age should plan for the additional time and funds required for such investigations.

Per Department of Defense Education Activity (DODEA) Administrative Instruction 2071.3, DODEA approval is required for research studies involving DODEA school personnel, school facilities, students, sponsors, and/or data. Investigators proposing to conduct any research activities involving DODEA schools should plan for the additional time (~3-6 months) and effort required to obtain approval from DODEA to conduct such activities. Procedures and requirements for the review and approval of a research study request can be found at <http://www.dodea.edu/datacenter/research/requests.cfm>

Research studies that address Army Family Advocacy Program (FAP) concerns will need to be coordinated with the Family Advocacy Research Subcommittee (FARS) per Army Regulation 608-18.

3.11. Guidance for research studies involving US Army Special Operations Command

Per USASOC policy 24-18, studies involving US Army Special Operations Command (USASOC) Soldiers as human subjects require additional review by the USASOC Research Advisory Committee (RAC) and Human Subjects Research Board (HSRB).

3.12. Compensation to DOD-affiliated personnel for participation

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-Conducted and -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>

4 Enhanced White Paper Preparation

4.1. General Instructions

Enhanced White Papers may be submitted at any time during the submission period but no later than the due date and time specified on the cover page using BIDS: <https://ati2.acgcenter.com/ATI2/Portal.nsf/Start?ReadForm>. **The BIDS system will open for submissions on April 20, 2021.** Include the MTEC Solicitation Number (**MTEC-21-06-MPAI**) on each Enhanced White Paper submitted. See RPP Attachment G for further information regarding BIDS registration. Instructions regarding BIDS submissions will be forthcoming.

Evaluations and recommendations for award are expected to be conducted on a first-in, first-out basis. Therefore, we highly encourage Offerors to submit as soon as possible during the open submission period as this may increase the likelihood of available funding for your proposed project as awards will be made on a rolling basis.

Evaluations will be conducted individually on a submission by submission basis. The intent is to provide an evaluation on or about **75** days after the receipt of an Enhanced White Paper submission. **NOTE: Some Enhanced White Papers may be sent for external peer review** (for example, but not limited to, proposed projects that involve the use of human subjects), **which will result in an extended evaluation period (expected at a minimum of 60 days longer).** Please do not worry if you do not receive notification within 75 days as we may experience slower timelines dependent on the number of Enhanced White Papers submitted.

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

The Enhanced White Paper format provided in this MTEC RPP is **mandatory** and shall reference this RPP number (**MTEC-21-06-MPAI**). Offerors are encouraged to contact the Points-of-Contact (POCs) identified herein up until the Enhanced White Paper due 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.

An automated BIDS receipt confirmation will be provided by email. 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 and/or the specified file size above may not be accepted. **Each document shall be uploaded to BIDS separately (see Attachment G of RPP for BIDS instructions).**

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

FOR INFORMATION ONLY: Please note a full Cost Proposal will be requested if the Enhanced White Paper is selected for funding (see Section 4.3 for additional details). Furthermore, additional attachments/appendices (henceforth referred to as supplemental information) to this proposal submission may be requested after completion of the technical evaluation to include the following:

- **Previous, Current and Pending Support** summarizing other sponsored research for each person who will contribute significantly to the proposed prototype project. The information for previous support should include the past five (5) years, unless otherwise specified in the request.

- **Human Subject Recruitment and Safety Procedures** which details study population, inclusion/exclusion criteria, description of the recruitment process, description of the informed consent process, etc.
- **Letter(s) of Support**, as applicable, if the prototype project will require access to active duty military patient populations and/or DoD resource(s) or database(s).

The exact requirements of any such attachment/appendix is subject to change and will be provided at the time (or immediately following) the technical evaluation summary is provided.

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 Paper revisions and/or supplemental information, such as those examples listed in the section above, 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 I: Cost Proposal Narrative as one word or PDF document.**
- **Section II: Cost Proposal Formats as one excel or PDF document.**
- **Royalty Payment Agreement (if applicable): One signed word or PDF document.**

See below for additional instructions. Also refer to Attachment F for details on how the full Cost Proposals will be evaluated:

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 **2%** 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 2.10 for additional information.

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 Proposal formats provided in the MTEC website and within the PPG are **NOT** mandatory.

Each cost proposal 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. Refer to the MTEC PPG for additional details.

Those Offerors invited to submit a Cost Proposal are encouraged to contact the MTEC CM and/or Government with any questions so that all aspects of the Stage 2 requirements 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. For more information, please refer to Section 6.1.1. of the MTEC PPG.

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. Additionally, 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 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	Offeror proposing an MTEC research project meets at least ONE of the following:

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	<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. In some cases, to ensure scientific excellence, the Government may utilize an additional evaluation process to include an external peer review for the evaluation of Enhanced White Papers against established criteria to determine technical merit. Regardless of whether or not the evaluation includes a peer review, all proposals will be evaluated based on the following factors. The overall award decision will be based upon a best value determination by considering factors in addition to cost/price.

- **Factor 1 - Programmatic Relevance:** The Offeror's Enhanced White Paper will be assessed for how well the proposed prototype demonstrates alignment and relevancy to the RPP's Focus Areas of Interest described in Section 3 and overall military impact. The following information will be considered as part of this factor:
 - **The Clinical Problem:** The degree to which the Offeror demonstrates an innovative approach/solution and demonstrates an understanding of the research gap described in the RPP.

- **Minimum Requirements for Submission of an Enhanced White Paper:** The Offeror's ability to clearly and completely demonstrate that the following minimum requirements (as detailed in Section 3.2) have been met or exceeded:
 - **Military Relevance:** The degree to which the proposal demonstrates relevance by proposing medical solutions to support readiness and care in future battlefield scenarios.
 - **Fits within the prototype definition:** The degree to which the proposal describes a prototype as described in Section 3.2 of this RPP.
 - **KRL/TRL:** The Offeror's ability to clearly demonstrate that the proposed project meets the minimum KRL/TRL requirement at the time of submission (KRL/TRL 3).
 - **New Submission:** Whether the proposal represents a new proposal to MTEC and is not a direct resubmission or modification of a previously submitted proposal.
 - **Alignment to RPP:** The degree to which the proposed project meets the overall intent of this RPP and aligns to a single focus area of interest specified in Section 3.3.
- **Factor 2 – Technical Approach:** The Offeror's proposal will be assessed for relevancy, thoroughness, and completeness of the proposed approach (e.g., the technical merit). The Government's evaluation of this factor may include the degree to which the following are addressed:
 - Hypothesis and objectives;
 - Scientific rationale with supporting preliminary data;
 - Experimental design, feasibility, and risks;
 - Ability for the technical and management team to execute the proposed SOW in an efficient and effective manner(to include addressing USAMRDC's ORP approval requirements); and
 - SOW and estimated budget.
- **Factor 3 – Commercialization Readiness Advancement:** The Offeror's proposal will be assessed for its likelihood of achieving and advancing through the development milestones identified in its proposal, thus advancing the Offeror's commercialization readiness, analogous to Technology Readiness Levels. Examples of the information that may be assessed **(if applicable to the proposed project)**:
 - **Technical Maturity Advancement** - The degree to which the Offeror proposes to advance the technical maturity level during the performance of the project, and advance the technology to the next level of development, from a technical and financial perspective. As such, the Government may evaluation how well the funding strategy supports that advancement.
 - **Market and business model:** Clear articulation of value proposition, competitive position, market opportunity and business model for getting to

revenue through commercial use, including a description of the market (civilian and military) and sustainability.

- **Development Strategy (including timing and regulatory):** Feasibility of the Offeror's product development strategy, including regulatory and FDA pathway, indication of use and designation, strategy for obtaining FDA approvals or clearances. If commercialization is not relevant to the proposed project, then feasibility of the plan to transition the technology to the government may be assessed.

Table 2 explains the adjectival merit ratings that will be used for the Programmatic Relevance, Technical Approach and Commercialization Readiness Advancement 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 evaluations, Offerors may be selected for funding (receive an overall recommendation of "Award"), placed into the basket, or not selected. Selection of prototype projects is a highly competitive process and is based on the evaluation of the Enhanced White Paper's technical merit, programmatic considerations, and the availability of funds. Therefore, an Enhanced White Paper that demonstrates technical merit may receive a "Non-Select" recommendation as a result of funding priority decisions. All Offerors will receive feedback to include a summary

of the technical evaluation for their proposal submission. Additionally, Offerors who are recommended for award will be required to submit a full Cost Proposal. See RPP Section 4.3 for additional instructions and Attachment F for details regarding the anticipated Stage 2 evaluation. Offerors are advised that due to the anticipated high number of Enhanced White Paper submissions and the need for a compressed timeline for the review cycles, feedback provided may be VERY BRIEF. Although this may be disappointing, the Government has weighed the benefits vs. costs of this more open-ended type RPP, and in order to provide a mechanism that allows members to submit Enhanced White Papers any time during the lengthy submission period, the reviewers must be allowed the opportunity to provide more succinct 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, prior to accessing any proposal submission to protect information contained in the Enhanced White Paper as outlined in Section 2.6.

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@mtec-sc.org

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

7 Acronyms/Abbreviations

ACURO	U.S. Army Animal Care and Use Review Office
AI	Artificial Intelligence
ATI	Advanced Technology International
CAS	Cost Accounting Standards
CFR	Code of Federal Regulations
CM	Consortium Manager
CMA	Consortium Member Agreement
CNACI	Child Care National Agency Check and Inquiries
DoD	Department of Defense
DODEA	Department of Defense Education Activity
DODI	Department of Defense Instruction
EC	Ethics Committee
F&A	Facilities and Administrative Costs
FAP	Family Advocacy Program
FAQ	Frequently Asked Questions
FARS	Family Advocacy Research Subcommittee
FDA	U.S. Food and Drug Administration
FOIA	Freedom of Information Act (FOIA)
FY	Fiscal Year
G&A	General and Administrative Expenses
G/L	Glymphatic/Lymphatic
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
Government	U.S. Government, specifically the DoD
HRPO	U.S. Army Human Research Protections Office
HSRB	Human Subjects Research Board
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
KRL	Knowledge Readiness Level
M	Millions
MDO	Multi-Domain Operations
MPS	Milestone Payment Schedule

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MTEC	Medical Technology Enterprise Consortium
NDA	Nondisclosure Agreement
OCI	Organizational Conflict of Interest
ODC	Other Direct Costs
ORP	USAMRDC Office of Research Protections
POC	Point-of-Contact
PoP	Period of performance
PPE	Personal Protective Equipment
P/T	Pharmacological/Technological
PTSD	Post-Traumatic Stress Disorder
OTA	Other Transaction Agreement
PFC	Prolonged Field Care
PPG	Proposal Preparation Guide
RAC	Research Advisory Committee
ROM	Rough Order of Magnitude
RPP	Request for Project Proposals
SOW	Statement of Work
TBI	Traumatic Brain Injury
TRL	Technology Readiness Level
USAMRDC	U.S. Army Medical Research and Development Command
USASOC	US Army Special Operations Command

8 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]

Focus Area

- Indicate which focus area of interest this enhanced white paper is responding to [include only one area per submission], for example, **FA1.1** Control & Sustainment of Critical Organ System & Metabolic Function.

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.
- Describe the relevance of your proposed technology to the healthcare needs of military.
- Please indicate the KRL/TRL stage of the proposed solution at the time of submission of the enhanced white paper, as well as anticipated KRL/TRL at project completion. Full definitions of TRLs can be found [here](#). More information regarding KRLs can be found [here](#).

KRL/TRL at Time of Submission:

KRL/TRL at Project End:

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 Research and Trials (if applicable): Clinical trials should be described in adequate detail to assess conformance with IRB/HRPO and 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.
 - Provide a clear strategy for enrollment and attrition to include applicable risks and mitigation strategies.

- 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.

Potential Follow-On Work

- [As noted in Section 3.6 of the RPP, additional follow-on funding may become available for the continuation of prototype development. Offerors are encouraged as appropriate to discuss potential follow-on work to demonstrate the ability to further advance the project maturity beyond the proposed PoP. This will also allow the Offeror to highlight the potential capabilities that can be explored/achieved through short-term and/or long-term advancement of the project in a way that is beneficial to the Government. Although awards in response to this RPP may initially focus on the scope of work presented above, this section is intended to provide the Sponsor with information on the Offeror's plan for work beyond the initial proposed PoP.]
- Specify the objective of each proposed follow-on task.
- Briefly outline the proposed methodology **by task** to the extent possible to demonstrate a course of action that addresses the technical requirements described in this RPP.
- Indicate the proposed PoP (duration) for the potential follow-on work in total.
- Specify a total (including direct and indirect) cost for each task.

Technical and Management Team

- Describe the qualifications and expertise of the key personnel and organizations that will perform the proposed work.
- Describe the overall project management plan that clearly defines roles and responsibilities. This plan should include a communication and conflict resolution plan if the proposal involves more than one company/institution/organization.
- Describe the ability of the management team to advance the technology toward later TRLs beyond the scope of the proposed work described in the Enhanced White Paper.

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.

Market and Business Model

- Clearly articulate the value proposition, competitive position, market opportunity and business model for getting to revenue through commercial use, including a description of the market (civilian and military) and sustainability.

Product Development Strategy

- Describe the final vision of what the product would look like and how that product would be administered or delivered for military use (required) and civilian use (if applicable).
- 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.
- Briefly describe your funding strategy to advance the technology to the next level of development and/or delivery to the military or civilian market.
- If commercialization is not relevant to the proposed project, then describe the plan to transition the technology to the military market for government use/implementation.

Schedule

- PoP: Indicate the proposed PoP 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 (to include regulatory-specific tasks) as a separate line. Do not duplicate the level of detail presented in Appendix 1.

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 example format shall be included in the Enhanced White Paper (the number of columns should reflect the proposed PoP, i.e., add or delete the yearly budget columns as needed). **[NOTE: If invited to Stage 2, the total cost to the Government must not significantly increase from the estimate provided in the ROM (unless otherwise directed by the Government) as award recommendations**

may be based upon proposed costs within the Enhanced White Paper.] 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.

	Year 1	Year 2	Year 3	TOTAL
Labor	\$ 100,000.00	\$ 100,000.00	\$ 100,000.00	\$ 300,000.00
Labor Hours	1,000.0 hrs	1,000.0 hrs	1,000.0 hrs	3,000.0 hrs
Subcontractors	\$ 50,000.00	\$ 50,000.00	\$ 50,000.00	\$ 150,000.00
Subcontractors Hours	500.0 hrs	500.0 hrs	500.0 hrs	1,500.0 hrs
Government/Military Partner(s)/Subcontractor(s) (subKTR)*	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00
Gov’t/Military Prtnrs / subKTR Hours	0.0 hrs	0.0 hrs	0.0 hrs	0.0 hrs
Consultants	\$ 10,000.00	\$ 10,000.00	\$ 10,000.00	\$ 30,000.00
Consultants Hours	100.0 hrs	100.0 hrs	100.0 hrs	300.0 hrs
Material/Equipment	\$ 75,000.00	\$ 75,000.00	\$ 75,000.00	\$ 225,000.00
Other Direct Costs	\$ 1,000.00	\$ 1,000.00	\$ 1,000.00	\$ 3,000.00
Travel	\$ 5,000.00	\$ 5,000.00	\$ 5,000.00	\$ 15,000.00
Indirect costs	\$ 48,200.00	\$ 48,200.00	\$ 48,200.00	\$ 144,600.00
Total Cost	\$ 289,200.00	\$ 289,200.00	\$ 289,200.00	\$ 867,600.00
Fee (Not applicable if cost share is proposed)	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00
Total Cost (plus Fee)	\$ 289,200.00	\$ 289,200.00	\$ 289,200.00	\$ 867,600.00
Cost Share (if cost share is proposed then fee is unallowable)	\$ 290,000.00	\$ 290,000.00	\$ 290,000.00	\$ 870,000.00
Total Project Cost	\$ 579,200.00	\$ 579,200.00	\$ 579,200.00	\$ 1,737,600.00

*Use the rows above for “Government/Military Partner(s)/Subcontractor(s)” if the project involves one or more Government/Military Facilities (MHS facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) performing as a collaborator in performance of the project.

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 below table 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 for DoD 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. 1502) 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* 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
6. Providing 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:** The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding Data Rights. It is anticipated that anything created under a Research Project Award resulting from this RPP 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
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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

☐ 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 scope 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 focus/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 Focus Area of Interest 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

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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

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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.
8. Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.
9. Allow at least 2 to 3 months for HRPO regulatory review and approval processes.

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-21-06-MPAI
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 – Stage 2 Evaluation Criteria

For Information Only - Stage 2 Requirement (subject to change)

Stage 2

The MTEC Consortium Manager (CM) will evaluate the cost proposed together with all supporting information for realism, reasonableness, and completeness as outlined below. The MTEC CM will then provide a formal assessment to the Government at which time the Government will make the final determination that the negotiated project cost is fair and reasonable.

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 technical approach and Statement of Work.

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 (Enhanced White Papers) 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. If the MTEC template is not used, the Offeror should submit a format providing for a similar level of detail.

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.

Best Value

The overall award decision will be based upon the Government's Best Value determination and the final award selection(s) will be made to the most advantageous offer(s) by considering and comparing factors in addition to cost or price. The Government anticipates entering into negotiations with all Offerors recommended for funding with the MTEC CM acting on the Government's behalf and/or serving as a liaison. The Government reserves the right to negotiate and request changes to any or all parts of the proposal, to include the SOW.

Attachment G – BIDS Instructions

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

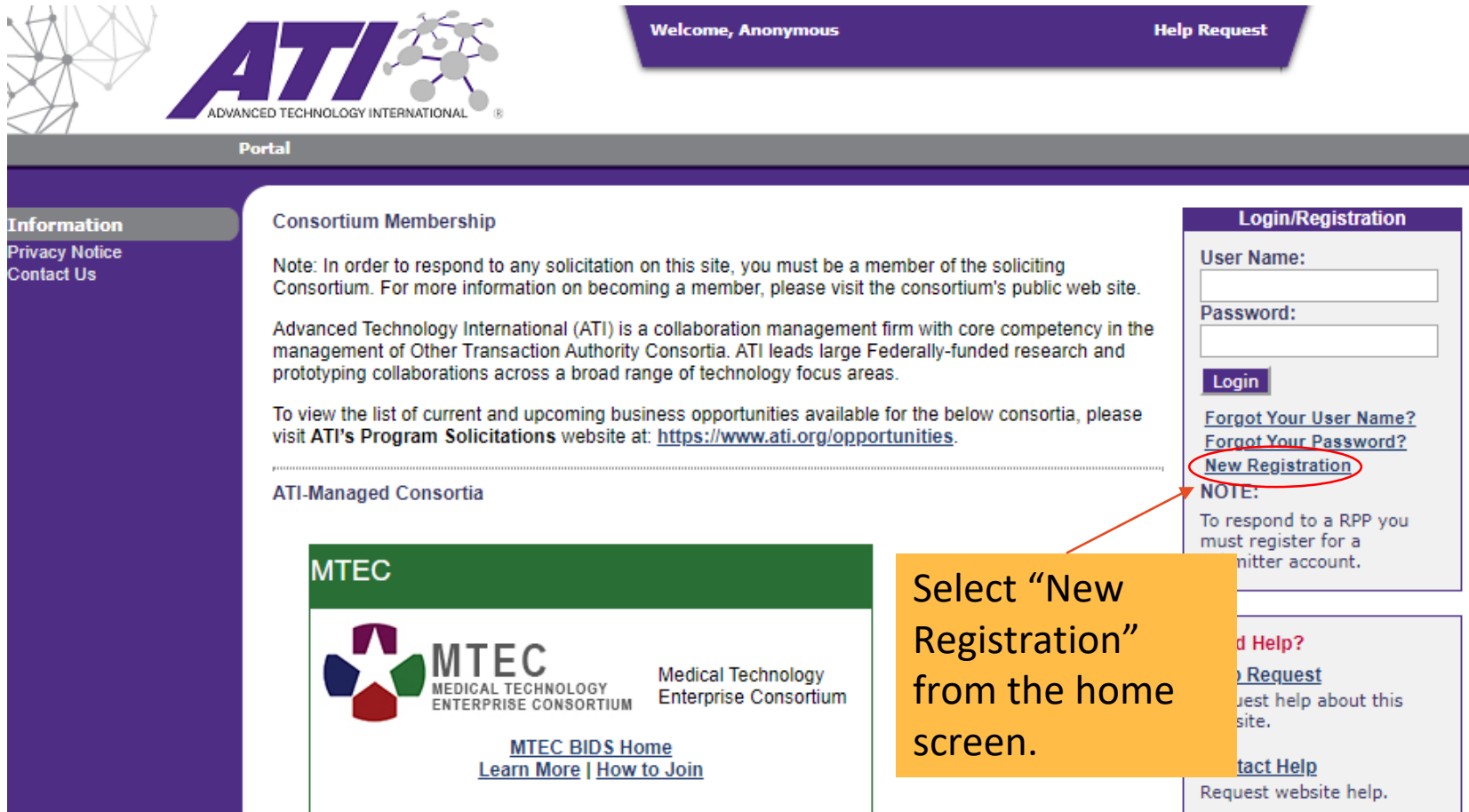
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Navigate to the MTEC BIDS website and select “New Registration”



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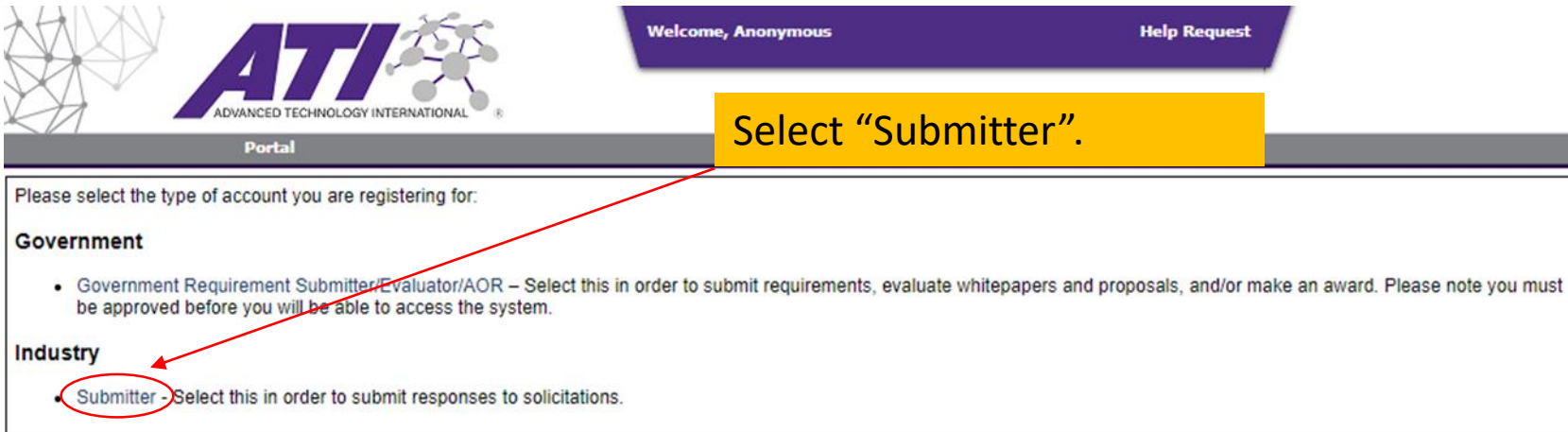
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Select “Submitter”



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Select “Submitter”.

Please select the type of account you are registering for:

Government

- Government Requirement Submitter/Evaluator/AOR – Select this in order to submit requirements, evaluate whitepapers and proposals, and/or make an award. Please note you must be approved before you will be able to access the system.

Industry

- Submitter** - Select this in order to submit responses to solicitations.

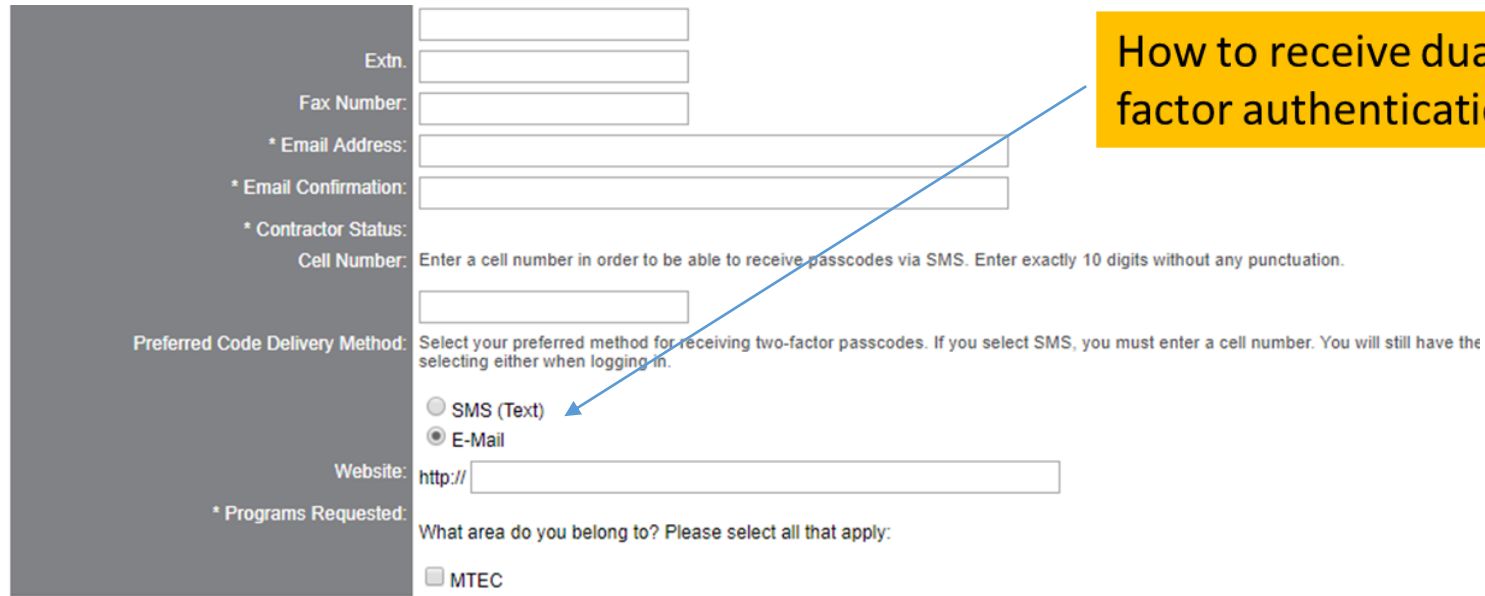
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Complete the registration form. Be sure to select how you want to receive the dual factor verification code (SMS text message is recommended).



The registration form is displayed on a dark grey background. It includes fields for 'Extn.', 'Fax Number', '* Email Address', '* Email Confirmation', '* Contractor Status', and 'Cell Number'. A note for the cell number field states: 'Enter a cell number in order to be able to receive passcodes via SMS. Enter exactly 10 digits without any punctuation.' The 'Preferred Code Delivery Method' section has two radio buttons: 'SMS (Text)' and 'E-Mail'. A blue arrow points from a yellow callout box to the 'SMS (Text)' option. Below this is a 'Website' field with a 'http://' prefix. The '* Programs Requested' section has a checkbox for 'MTEC'.

Extn.

Fax Number:

* Email Address:

* Email Confirmation:

* Contractor Status:

Cell Number: Enter a cell number in order to be able to receive passcodes via SMS. Enter exactly 10 digits without any punctuation.

Preferred Code Delivery Method: Select your preferred method for receiving two-factor passcodes. If you select SMS, you must enter a cell number. You will still have the selecting either when logging in.

☐ SMS (Text)

☒ E-Mail

Website: http://

* Programs Requested: What area do you belong to? Please select all that apply:

☐ MTEC

How to receive dual factor authentication .

Submit Registration

Select "Submit Registration" to complete BIDS registration.

BIDS New Registration

BIDS registration is instantaneous. It does not require any verification by the MTEC team. After successfully registering, you can submit proposals to any open MTEC RPP.

- MTEC Membership will be verified once a proposal is received and after the proposal deadline.
- Updates to submitted documents can be made anytime prior to the due date and time.
- MTEC RPP links will be opened, within BIDS, at least two weeks prior to the submission deadline.

Please note: For RPPs that are two stages (i.e. White Paper to Full Proposal) only the account that submitted the stage 1 proposal (the White Paper) will be allowed to submit for stage 2 (the Full Proposal), if selected.

ALL PROPOSALS MUST BE SUBMITTED BEFORE THE SUBMISSION DUE DATE AND TIME. LATE PROPOSALS CAN NOT BE ACCEPTED.



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Navigate to the MTEC BIDS site and login. After login select the “MTEC BIDS Home” link.

The screenshot shows the ATI website with a purple header. A yellow box on the right says "Login to your BIDS Account." with an arrow pointing to the "User Name:" field in the "Login/Registration" box. A yellow box on the left says "Then select the 'MTEC BIDS Home' link" with an arrow pointing to the "MTEC BIDS Home" link in the "Managed Consortia" section.

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RPPs - Open

The following RPPs have been published:

MTEC-20-02-NavyMultiTopic: released on March 13, 2020, White Papers due by March 24, 2021
test-13-20: released on March 13, 2020, Full Proposals due by August 13, 2020 at 03:25:00 PM ET

Intents to Announce are also posted on FBO. All information related to these solicitations is located on the Members Only portion of the MTEC website: <https://private.mtec-sc.org/>

Accepting follow-up submissions for the following RPPs:

back released on May 13, 2020, Full Proposals due by May 9, 2020 at 01:00:00 PM ET
feedback released on May 18, 2020, Full Proposals due by May 13, 2020 at 01:00:00 PM ET
back released on May 13, 2020, Full Proposals due by May 9, 2020 at 01:00:00 PM ET

Intents to Announce are also posted on FBO. All information related to these solicitations is located on the Members Only portion of the MTEC website: <https://private.mtec-sc.org/>

Initial submissions are currently being evaluated for 3-23-STAGE2. No fo

MPAs - Open

The following MPAs have been published:

MTEC-21-08-MPAI-Test1: released on April 2, 2021, responses due by May 2, 2021 at 01:00:00 PM ET
MTEC-21-08-MPAI-Test2: released on April 12, 2021, responses due by May 12, 2021 at 01:00:00 PM ET

Intents to Announce are also posted on FBO. All information related to these solicitations is located on the Members Only portion of the MTEC website: <https://private.mtec-sc.org/>



Medical Technology Enterprise Consortium

The Medical Technology Enterprise Consortium (MTEC) is a nationally dispersed consortium of traditional and non-traditional defense cont profit entities, and academic institutions brought together to accelerate the development of medical solutions that prevent and treat injuries

Once logged in,
your username
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Click the link to
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MPAA.

MPAA information
is provided in this
section.



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Select which RPP you will be responding to.

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Submission Checklist

Please check your submittal for the following requirements to ensure compliance with the RPP

Select the appropriate RPP:

☒ MTEC-20-04-Test

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Select which MPAI to respond to. If multiple MPAIs are open, they will be listed here.



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Complete the submission form.

New MTEC Enhanced Whitepaper for MTEC

***PLEASE NOTE: Your web session will expire automatically if you are idle for 15 minutes.

*Denotes Required Field.

Submission Information

MPAI Number: MTEC-21-08-MPAI-Test2

Submitter Contact Info: MTEC
Evan Kellinger
Project Manager, ATI
(843) 760-4354
Evan.Kellinger@ati.org

Submission Deadline: 05/12/2021 01:00 PM EDT

Submission Date:

* Submission Title:

Project Identifier:

*Requirement:

FA1.1

Requirement Customer: U.S. Army Medical Research and Development Command
Requirement Focus Area: FOCUS AREA 1 Prolonged Field Care

Select the focus area
your submitting to as
identified in the RPP.

Contact Information

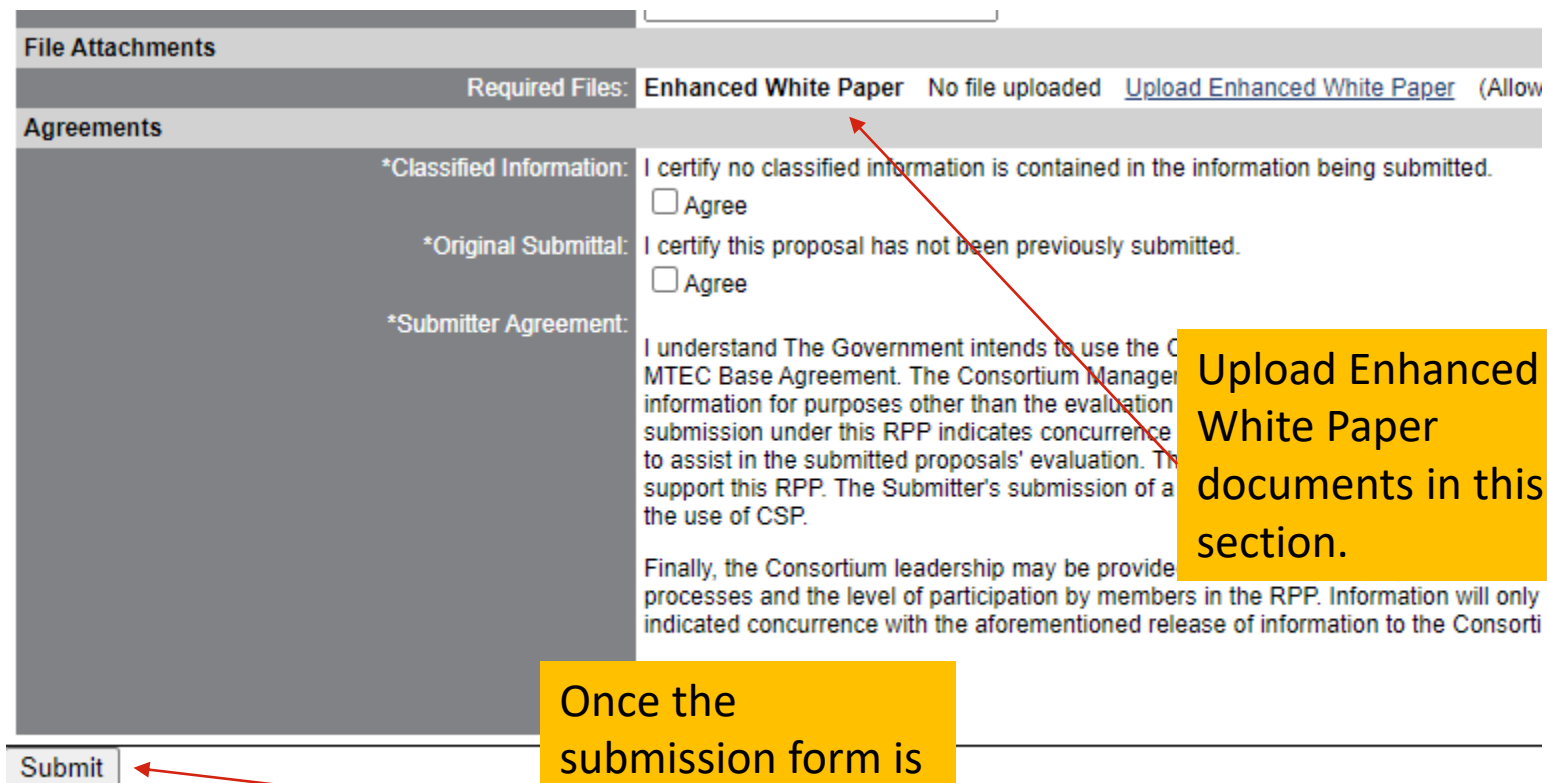
* Tech POC First Name:

* Tech POC Last Name:

* Tech POC Address:

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Complete the submission form by uploading the required documents and click submit.



File Attachments

Required Files: **Enhanced White Paper** No file uploaded [Upload Enhanced White Paper](#) (Allow

Agreements

*Classified Information: I certify no classified information is contained in the information being submitted.
☐ Agree

*Original Submittal: I certify this proposal has not been previously submitted.
☐ Agree

*Submitter Agreement: I understand The Government intends to use the C MTEC Base Agreement. The Consortium Manager information for purposes other than the evaluation submission under this RPP indicates concurrence to assist in the submitted proposals' evaluation. Th support this RPP. The Submitter's submission of a the use of CSP.
Finally, the Consortium leadership may be provide processes and the level of participation by members in the RPP. Information will only indicated concurrence with the aforementioned release of information to the Consorti

Submit

Upload Enhanced White Paper documents in this section.

Once the submission form is completed select submit.



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Once you have successfully submitted an enhanced white paper, you will receive a notification with your submission number (ex. MTEC-23-24-Everest-045).

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MTEC BIDS Submission Successful!

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MPAI Number:	MTEC-21-08-MPAI-Test2
Identifier:	MTEC-21-08-MPAI-Test2-001
Title:	Test

Click on this link to view your saved submission: [MTEC-21-08-MPAI-Test2-001](#)

NOTE: It is recommended that you click on the link(s) below to test your uploaded file(s):

 [Test.docx](#)

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