

Request for Project Proposals



Solicitation Number: MTEC-21-02-FFBT
"Far Forward Burn Treatment"

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for the
Medical Technology Enterprise Consortium (MTEC)

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White Papers are Required

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1 Request for Project Proposal Overview

1.1 Medical Technology Enterprise Consortium

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

- (a) engage in biomedical research and prototyping;
- (b) exploration of private sector technology opportunities;
- (c) technology transfer; and
- (d) development 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 <https://mtec-sc.org/>.

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

1.2 Purpose

This solicitation, issued by the MTEC Consortium Manager (CM), Advanced Technology International (ATI), represents a Request for Project Proposals (RPP) for MTEC support of the DoD, U.S. Army Medical Materiel Development Activity (USAMMDA). Proposals selected for award as a result of this RPP will be awarded under the authority of 10 U.S.C. § 2371b. The award(s) will be managed by the Warfighter Expeditionary Medicine and Treatment (W-EMT)

Project Management Office (PMO), specifically by the chairperson of the Burn Treatment Skin Repair (BTSR) Integrated Product Team (IPT). The IPT will provide consultative input into the project as needed in preparation for their annual in-progress reviews with the Milestone Decision Authority, as well as interim reviews if needed more frequently.

This Request for Project Proposals (RPP) is focused on the development of treatments for severe burn injuries in a far-forward, austere environment to address the harmful sequelae of the burn injury during prolonged care, which could extend for several weeks post-injury. This RPP addresses the following four capability gaps: burn conversion prevention, infection prevention, non-surgical debridement, and temporizing cover.

1.3 Acquisition Approach & Rolling Downselection

This RPP will be conducted using a two-staged approach. In Stage 1, current MTEC members are invited to submit White Papers using the mandatory format contained in this RPP (Attachment 1). The Government will evaluate White Papers submitted and will select those that best meet the Government's current technology priorities for further consideration using the criteria in Section 3 of this RPP. Offerors whose proposed solution is selected for further consideration based on White Paper evaluation will be invited to submit a proposal in Stage 2. Notification letters will be sent upon completion of the Government's Stage 1 technical evaluation and will contain specific Stage 2 proposal submission requirements for those Offerors selected for further consideration. See Section 1.6 below for additional details regarding the solicitation process.

Offerors are hereby notified that the Government intends to utilize a **rolling downselect** approach **during the performance** of prototype projects awarded as a result of this RPP. Using this approach, the Government intends to award prototype projects, structured into two Periods of Performance (PoPs), with an initial base period (PoP1) (see period of performance and funding details under Section 1.7 below) reflecting ***the first of the two PoPs***. After an In-Process Review (IPR), an evaluation of project deliverables and other considerations to include progress towards completion of the base PoP1 tasks, the Government intends to award a second PoP, referred to as the subsequent PoP (PoP2), to the performer(s) that demonstrates a best value approach for follow-on tasks. Award decisions for the subsequent PoP2 work will be made during the Go/No-go Decision Point which is expected to occur prior to the end of the base PoP1 (tentatively projected at t = 20 months). See the proposal format requirements and instructions to Offerors detailed under Section 2 ("Technical Requirements") of this RPP for additional details.

The Government reserves the right to end all awarded projects after the initial base period and award no subsequent PoP2 tasks depending on project outcomes, availability of funding, and changing Government requirements. Additionally, the Government reserves the right to negotiate with performers (selected for award under this RPP), on a noncompetitive basis, to award additional scope to successful projects. While this is anticipated to occur after the subsequent PoP2, this may occur at any time following award of OTA for prototype projects.

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

1.4 Proposers Conference

MTEC will host a Proposers Conference that will be conducted via webinar within two (2) weeks after the release of the RPP. Further instructions will be forthcoming via email. Offerors are advised to check the MTEC website periodically during the proposal preparation period for any clarifications found in Frequently Asked Questions (FAQ) responses.

1.5 MTEC Member Teaming

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

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

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

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

1.6 Request for White Papers and Process Stages

MTEC recognizes that considerable effort is required to prepare a competitive proposal to MTEC. The two-stage approach for this RPP is intended to streamline the initial proposal preparation time and effort for MTEC members. Based on the Government's evaluation of White Papers in Stage 1, select Offerors will be invited to participate in Stage 2 and will be required to submit a

full proposal for more a detailed evaluation.

The due date for White Papers is found on the cover page of this RPP. White Papers may not be considered under this RPP unless the White Paper was received on or before the due date specified on the cover page.

Stage 1: White Papers submitted under this RPP shall follow the MTEC White Paper Template provided in Attachment 1.

Stage 2: Offerors whose technology solutions are selected for further consideration based on White Paper evaluation will be invited to submit a proposal in Stage 2. Notification letters will contain specific Stage 2 proposal submission requirements. An example of the proposal submission requirements is (subject to change):

- **Technical Proposal** according to the format provided in the Proposal Preparation Guidelines (PPG) available on the MTEC members-only website.
- Detailed **Statement of Work (SOW)** according to the format provided in the notification letter.
- **Cost Proposal** according to the format provided in the PPG.

1.7 Potential Funding Availability and Period of Performance

The U.S. Government (USG) currently has approximately **\$7.5 million (M) available for the base period of performance (PoP1)** of up to 24 months. MTEC anticipates that **multiple awards** will be made. Awards resulting from this RPP are expected to be made as early as Fiscal Year 2021 or in Fiscal Year 2022.

An additional \$7M of funding is anticipated for the performer(s) that is selected for the continuation of prototype development under the subsequent PoP (PoP2) of the resultant award(s), after the Go/No-go Decision Point. Note, however, that as of the release date of this RPP, future year Defense Appropriations Bills have not been passed and there is no guarantee that any additional funds will be made available to support this program. The funding estimated for this RPP is approximate and subject to realignment. Funding of proposals received in response to this RPP is contingent upon the availability of federal funds for this program. The Government reserves the right to reduce the scope/funding of the subsequent PoP2 for the continuation of prototype development as part of the rolling down-select, if the Offeror's technology after the initial base period (PoP1) excels only in a limited number of the solutions requirements detailed in Section 2 of this RPP. Furthermore, the Government reserves the right to encourage teaming arrangements between any or all of the base PoP1 awardees/performers to collaborate in the subsequent PoP award phase (PoP2) to maximize performance across the greatest number of the solutions requirements, and may allocate the subsequent PoP2 funds in accordance with participation in such a collaboration.

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

1.8 Proprietary Information

The MTEC CM will oversee submission of proposals and analyze cost proposals submitted in response to this RPP. The MTEC CM shall take the necessary steps to protect all proprietary proposal information and shall not use such proprietary information for purposes other than the evaluation of an Offeror's proposal and the subsequent agreement administration if the proposal is selected for award. **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 foundations that award grants for research and operate in research areas that are aligned with those of MTEC. These private foundations may be interested in reviewing proposals within their program areas, allowing for opportunities to attract supplemental funding sources. Therefore, on your White Paper Cover Page, please indicate your willingness to allow MTEC Officers and Directors access to your Technical Proposal for the purposes of engaging in outreach activities with these private foundations. MTEC Officers and Directors who are granted proposal access have signed Nondisclosure Agreements (NDAs) and Organizational Conflict of Interest (OCI) statements. Additionally, all Technical Evaluation Panel participants, which may include contractor support personnel serving as nongovernmental advisors, will agree to and sign a Federal Employee Participation Agreement or a Nondisclosure/Nonuse Agreement, as applicable.

1.9 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 3 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.).

1.10 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 2 ("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 3.

Proposals that fail to meet the mandatory statutory conditions with regard to the appropriate use of Other Transaction authority, as detailed in Attachment 2, will not be evaluated and will be determined ineligible for award.

1.11 Intellectual Property and Data Rights

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

The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding Data Rights. **It is anticipated that anything delivered under this proposed effort would be delivered to the Government with unlimited data rights unless otherwise asserted in the proposal and agreed to by the Government.** Rights in technical data shall be determined in accordance with the provisions of MTEC Base Agreement.

Note that as part of the Stage 2 of the RPP proposal (submission of a full proposal), Offerors shall complete and submit Attachment 7 with the Signature of responsible party for the proposing Prime Offeror. If the Offeror does not assert data rights on any items, a negative response on Attachment 7 is required.

1.12 White Paper Submission

White Papers should be submitted by the date and time specified on the cover page using BIDS: <https://ati2.acqcenter.com/ATI2/Portal.nsf/Start?ReadForm>. Include the MTEC Solicitation Number (MTEC-21-02-FFBT) on each white paper submitted. See RPP Attachment 10 for further information regarding BIDS registration and submission.

MTEC membership is required for the submission of a White Paper. Offerors must be MTEC Members in good standing. Offerors submitting White Papers as the prime contractor must be MTEC members of good standing by **March 4, 2021**.

Do not submit any classified information in the White Paper or Full Proposal submission.

1.13 Submission Format

See Attachment 1 for the White Paper template. 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.

Please follow the format and page requirements contained in Attachment 1 carefully. White Papers that do not meet these requirements are subject to disqualification at the sole discretion of the Government.

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

1.14 White Paper Preparation Cost

No project awards will be made based on White Paper submissions, nor will any reimbursement be provided for the information requested. Submission of a White Paper is voluntary and does not obligate the Government, the MTEC or the MTEC CM to pay or entitle the submitter to payment. Respondents are solely responsible for all expenses associated with preparing and submitting this White Paper.

1.15 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.

1.16 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.

2 Technical Requirements

2.1 Background

It is anticipated in future conflicts that the Army will have to fight and win across multiple domains in contested locations where air, ground, and nautical evacuations of casualties will be extremely challenging. Evacuating casualties within theater may take days or weeks. Additionally, the explosive weapons that will likely be used against US forces will be more powerful than what has been used to date, resulting in higher numbers of casualties with significant burn injuries including larger, more severe burns. Only minimal burn wound management tools are available in the pre-hospital environment, consisting primarily of silver-

containing wound dressings to prevent/minimize infection until the casualties' expedient evacuation to the San Antonio Military Medical Center Burn Center for definitive treatment. Unfortunately, the future burn casualty may not have the benefit of the early evacuation to the burn center that was available during recent conflicts. As such, there is a significant need to push burn treatment capabilities much farther forward in order to begin burn treatment as early as possible. By closing the time gap between burn injury and burn treatment with solutions that can be reasonably provided by non-medical personnel (i.e., buddy care) or medical first responders (e.g., medics) in a pre-hospital setting, morbidity and mortality rates can be significantly decreased.

The Government is seeking burn interventions that are simple and effective enough to be used in a pre-hospital setting. These tools will need to enable providers from the point of injury through Role 3 Hospital Centers to treat severe burn injury for up to several weeks post-injury. It is imperative that these solutions be simple enough that non-licensed medical providers (e.g., medics) can administer them, and effective enough to decrease morbidity and mortality rates and improve outcomes over current in-theater burn treatment options.

It is expected that multiple burn treatment solutions will be needed, and may be used in concert with one another, to provide the needed burn treatment capabilities in theater. These solutions will need to address: burn conversion prevention, infection prevention, non-surgical debridement, and temporizing coverage/dressings that protect the burn wound and may promote early healing. Technological advances that contribute to product solutions that meet these requirements will be considered as possible candidates for fielding by the Burn Treatment Skin Repair acquisition program, which is managed by the Burn Treatment Skin Repair (BTSR) Integrated Product Team (IPT).

2.2 Detailed Requirements

Simple and effective solutions are required to treat severe burn injuries as early as the point of injury and throughout in-theater care. While there are desired solution characteristics unique to each of the burn treatment capability areas being sought, there are some characteristics that are common to them all. These common characteristics (which apply to all treatment capabilities) are strongly preferred at the time of proposal submission. However, the Government will consider proposals that thoroughly demonstrate the ability to achieve these common characteristics (a demonstrated ability to achieve this during PoP1 or PoP2 under a prototype project resulting from this RPP is strongly preferred). It is also anticipated that some product solutions may satisfy, or have the potential to satisfy, more than one of these burn treatment capability areas. In instances where a product has sufficient data supporting its use in one area (e.g., infection prevention), but there is evidence that it may also be useful in another area (e.g., burn conversion prevention), optional tasks can be incorporated into any award to address indications for additional areas where the product solution may have utility. The Government reserves the right to negotiate any proposed optional tasks with the Offeror and/or award under only one burn treatment capability area.

Offerors should only propose technology solutions that are currently at a Technology Readiness Level (TRL) of 4 or above and currently in development or commercially available.

The definition of TRL 4 is summarized below [full definitions of all TRLs – <https://mtec-sc.org/wp-content/uploads/2016/12/TRL-definitions.pdf>]:

- TRL 4 Decision Criterion for Medical Devices - Proof-of-concept and safety of candidate devices/systems demonstrated in defined laboratory/animal models
- TRL 4 Decision Criterion for Pharmaceuticals - Proof-of-concept and safety of candidate drug formulation(s) demonstrated in defined laboratory/animal model(s).
- TRL 4 Decision Criterion for Biologics - Proof-of-concept and safety of candidate biologic constructs demonstrated in defined laboratory/animal model(s).

Common Characteristics for All Capabilities (not listed in order of importance):

In the far forward environment, it is important for interventions to be as simple, safe and effective as possible. As such, the following characteristics apply to all four desired capabilities:

1. Prototype must be capable of achieving an indication for use on large (>20% total body surface area (TBSA)) burns.
2. Prototype must be capable of achieving an indication for use on full-thickness burns. Regulatory strategies can include a seeking a deep-partial thickness indication as a bridge to a full-thickness burn indication.
3. Prototype must not negatively impact use of other downstream burn or lifesaving treatments in the care of burn-injured individuals, specifically those treatments being sought after within this RPP. (Most casualties will have polytrauma beyond their burn injuries.)
4. Prototype must be capable of being administered by a medic quickly and easily at the point of injury and Role 1. Care at the point of injury and Role 1 can include providing care under fire. Prototype should require minimal preparation time (no more than five minutes) prior to administration. Topical solutions are preferred, but not required. Products that could be administered by a non-medical responder (a “buddy” or even self-administration) are encouraged but not required.
 - a. Purpose of Role 1:
 - i. Provides immediate lifesaving measures that do not require the knowledge and skills of a physician
 - ii. Casualty collection and evacuation from supported units to supporting military treatment facilities
 - b. Role 1 Providers:
 - i. Treatment provided by designated combat medics or treatment squads
 - ii. Expanded medical treatment may be provided by single physician assistant or physician, if available
 - c. Role 1 Facilities:
 - i. Tent
 - ii. Limited power

- iii. Limited space
- iv. Highly mobile
- v. Not substantially climate controlled, if at all
- d. Point of Injury Characteristics:
 - i. Combat medics carry a Combat Medic Aid Bag (bag dimension 20" x 13" x 3"; 0.45ft³) to treat casualties at the point of injury.
 - ii. The Combat Medic Aid Bag already contains approximately 57 other items (some in multiple quantities). Therefore solutions for point of injury must fit in the bag along with these items. Proposed solutions may replace items currently in the Combat Medic Aid bag.
 - iii. Average cube of an item in Combat Medic Aid Bag: 0.2ft³; average weight of an item in Combat Medic Aid Bag: 0.72oz.
- 5. Prototype must be capable of achieving a shelf life of at least two years at room temperature.
- 6. Prototype must not require climate controlled transit or storage at maturity.
- 7. Prototype must eventually become a commercially viable product or technology that will be brought to market. (NOTE: can be marketed for the same or a different indication in civilian market than what DoD is seeking. If a different indication will be sought for the civilian market, FDA approval for the military's intended use/indication will still need to be secured.)

Capability-specific Characteristics:

In addition to the *Common Characteristics for All Capabilities* listed above, each capability has specific desired characteristics listed below.

- A. Burn conversion prevention
 - 1) Prevents conversion of partial-thickness burns to deep partial-thickness or full-thickness burns, ideally within 24 hours of being administered
 - 2) Single dose/application per 24 hours is preferred, but not required
 - 3) Shows efficacy in limiting the expansion and/or depth progression of burns
- B. Infection prevention
 - 1) Topically administered product that can be applied immediately after a burn to prevent infection and/or after infection has set in as a treatment
 - 2) Control broad range of bacterial infections; control of fungal infections and resistant pathogens preferred
 - 3) Low risk of causing resistance
- C. Non-surgical debridement in pre-hospital setting
 - 1) Complete procedure/course of treatment is 24 hours or less
 - 2) Does not require sedation or anesthesia for pain management; causes minimal pain per FDA-approved scales preferred
 - 3) Fully mitigates the toxicity of eschar
 - 4) Requires minimal ancillary equipment such as batteries, power supply, etc.
- D. Temporizing coverage/dressing for burn wounds that may promote healing

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- 1) Can be used to cover/dress burn wounds both at initial treatment and also after debridement
- 2) Provides a barrier over the burn wound in the absence of grafting
- 3) Coverage material is thin, conformable, breathable, able to move with patient and non-toxic; preference for coverage materials that are bio-absorbable, and enable healing of the burn wound preferred but not required
- 4) Can be left in place for up to 5 days, preferably longer
- 5) Does not require multiple dressing changes and/or mitigates/eliminates the deleterious effects of dressing changes

Additional points of consideration:

- Project Maturity: This solicitation is not meant to support development of a new prototype, but should focus on fine tuning and optimization of existing prototypes or other technologies.
- Industry Partners: MTEC considers that a white paper involving an industry partner (or alternative organizations) to serve as the regulatory sponsor and commercialization partner 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.
- Military Impact: Offerors must demonstrate an understanding of the military need for far forward burn treatment.
- Technical Characteristics: An ideal solution would meet the characteristics described above. Although White Papers that propose to meet all of the solution characteristics outlined above are preferred, we encourage you to submit even if you cannot currently meet all these specifications within the project period of performance. The Government may consider lesser responses based upon the specifications that could be met and the team's approach to meeting the other requirements over time. However, it is expected that an Offeror's White Paper will describe in detail what they plan to accomplish and how they plan to satisfy all of the solution requirements either during the performance of the resultant award or beyond that period (Offerors should specify the projected timeline).
- Training Requirements: Offerors must describe the anticipated training requirements for their prototype to be used by end users described above, e.g., medics and other non-licensed medical personnel and potentially non-medical responders, if appropriate.

2.3. Scope of Work

Scope Work of Base PoP1 (up to 24 months):

The initial base PoP1 (which is limited to a period not to exceed 24 months), should be focused on tasks relevant to advance the prototype to the next TRL. Project scope should be proposed based on the prototype's maturity at the time of submission. The work in the base PoP1 could include, but is not limited to:

- 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 at US Army Institute of Surgical Research (USAISR)
 - Testing of prototypes at Army Medical Department (AMEDD)
 - Product demonstrations
- 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

Go/No-Go Decision Point for Downselect:

Prior to the end of the base PoP1 (tentatively projected to occur 20 months into PoP1), the Government will conduct an **in process review (IPR)**, in which the Awardees will attend and participate in, to assess the work completed for each PoP1 Awardee. The IPR will be either a virtual or an in-person meeting at USAMRDC at Fort Detrick, MD. Following the IPR, the Government intends to down-select Awardees to a smaller number for continuation of funding for the conduct of follow-on work representing PoP2 or the subsequent PoP of the prototype project. This down-select represents the **Go/No-Go Decision point** between PoP1 (base) and PoP2 (subsequent).

In preparation for the IPR, all awardees shall submit a **deliverable** to the Government. Specifically, each Awardee shall submit full details of the tasks proposed for the subsequent PoP2 phase, in separate technical and cost volumes. The exact due date for this deliverable is TBD (anticipated on or about two weeks prior to the date of the IPR). This deliverable will be reviewed and evaluated as part of the Go/No-Go decision point during which time the Government will make award recommendations for the subsequent PoP2 selections.

All Offerors responding to this RPP **shall account for the IPR requirement and associated deliverable requirement** by identifying these as a milestone(s) in the Stage 1 (White Paper) proposal submission (under the “Anticipated Outcomes” section of the white Paper and elsewhere, as appropriate).

Potential for Follow-on Work:

Potential follow-on work to include PoP2 (but may also include additional, non-competitive tasks negotiated after OTA award) may be awarded based on the advancement in prototype maturity during the base PoP1. Potential follow-on work may include tasks related to advancement of prototype maturity, and/or to expand the use or utility of the prototype.

2.4. Restrictions on Animal and Human Subjects

White Papers and proposals must comply with restrictions and reporting requirements for the use of animal and human subjects, to include research involving the secondary use of human biospecimens and/or human data. The Awardee shall ensure local Institutional Animal Care and Use Committee (IACUC) and Institutional Review Board (IRB) approvals, continuing review (in the intervals specified by the local IACUC and IRB, but at a minimum, annually), and approval by the U.S. Army Medical Research and Development Command Animal Care and Use and Review Office (ACURO) and the USAMRDC Human Research Protections Office (HRPO). Offerors shall include IACUC, ACURO, IRB and HRPO review and approval in the SOW/Milestones Table submitted with the Stage 2 full proposal (if invited), as applicable.

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

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>

3 Selection/Evaluation Criteria

3.1 Stage 1: White Papers

3.1.1 Compliance Screening

The CM will conduct a preliminary screening of submitted White Papers to ensure compliance with the RPP requirements. As part of the preliminary screening process, White Papers that do not meet the requirements of the RPP may be eliminated from the competition or additional information may be requested by the CM. The Government reserves the right to request additional information or eliminate White Papers that do not meet these requirements from further consideration. One of the primary reasons for non-compliance or elimination during the

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initial screening is the lack of significant nontraditional defense contractor participation, nonprofit research institution participation, or cost share (see Attachment 2). Proposal Compliance with the statutory requirements regarding the appropriate use of Other Transaction Authority (as detailed within Attachment 2) will be determined based on the ratings shown in Table 1:

TABLE 1- COST SHARING/NONTRADITIONAL CONTRACTOR ASSESSMENTS	
RATING	DESCRIPTION
PASS	<p>Offeror proposing an MTEC research project meets at least ONE of the following:</p> <ul style="list-style-type: none"> • Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution • Offeror's Solution Brief 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 Solution Brief 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

3.1.2 Selection Criteria

The Government will evaluate those White Papers that pass the preliminary screening (described above) using the following criteria listed in descending order of importance:

(1) Factor 1 - Technical Approach: Reviewers will assess the technical approach based on:

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- a. How well the white paper defines and describes a prototype that can already meet or be modified to meet the requirements of the common characteristics and capability-specific characteristics as set forth in this RPP, including:
 - i. How the prototype works, how it is administered, and by whom. The degree to which the Offeror successfully addressed the training requirements in order for the prototype to be used by end users.
 - ii. Preliminary data, sound scientific rationale, and demonstrated proof-of-concept that supports the prototype's current or proposed ability to meet the requirements.
 - iii. Identification of regulatory pathway, description of intended indication, and any work done to date to support regulatory clearance / approval of the prototype.
- b. How well the white paper proposes work and a methodology that supports achieving the technical objectives and further development of the prototype to meet the requirements.
- c. The appropriateness of the intended commercialization strategy for the prototype.

The reviewers may also consider the Offeror's high level description of subsequent Period of Performance tasks (PoP2) for the continuation of prototype development or expansion of use as an aspect of Technical Approach.

(2) Factor 2 - Project Management: The soundness of the proposed schedule that shows that the project can be completed within the proposed timeline, and whether the background and expertise of the personnel are appropriate to accomplish the proposed development, test, evaluation, and commercialization.

(3) Factor 3 – Cost Reasonableness: Assessment of the cost of the project to determine i) whether the project cost is within the available funding limits, and ii) the ability and/or likelihood of the offeror to successfully execute the proposed project within the financial resources proposed. The proposed cost will be based on the following ratings: Sufficient, Insufficient or Excessive. See the definitions of these ratings in Table 2 below.

Those White Papers that are favorably evaluated will be invited to participate in Stage 2 for further consideration. Offerors whose White Papers were not favorably evaluated will be provided feedback on the evaluation. Note that Offerors should receive an overall rating of at least "Acceptable" or higher in order to be considered for Stage 2; however, the Government reserves the right to make final evaluation decisions based upon programmatic relevancy and overall best value solutions determined to be in the Government's best interest.

With the exception of “Cost Reasonableness,” the Stage 1 evaluation factors will be rated based upon the adjectival merit ratings detailed in Table 3 under Attachment 4 of the RPP. See Table 2 below for the definitions of the “Cost Reasonableness” factor ratings:

TABLE 2 - “COST REASONABLENESS” FACTOR RATINGS DEFINITIONS	
RATING	DESCRIPTION
SUFFICIENT	The estimate is within the available funding limits and considered appropriate to successfully complete the proposed project
INSUFFICIENT	The estimate is lower than what is considered appropriate to successfully complete the proposed project.
EXCESSIVE	The estimate is higher than what is considered appropriate to successfully complete the proposed project and may be outside of the available funding limits.

Please also refer to Attachment 4 for definition of general terms used in technical evaluations.

3.2 Stage 2: Full Proposal Evaluation

To the maximum extent practicable the evaluation criteria found in Attachment 4 are anticipated for all (Stage 2) Full Proposal submissions.

4 Other Factors to Consider

Please note that MTEC members who are invited to participate in Stage 2 will be required to comply with the following general requirements in addition to any additional Stage 2 proposal requirements detailed elsewhere in this RPP:

1. If Offerors have not yet executed a MTEC Base Agreement, then Offerors must certify on the cover page of their full proposal that, if selected for award, they will abide by the terms and conditions of the latest version of the MTEC Base Agreement.
2. Warranties and Representations for all proposals - See Attachment 5.
3. MTEC Additional Research Project Award Assessment or Royalty Payment Agreement – See Attachment 6.
4. IP and Data Rights (no page limit) – See Attachment 7
5. Current & Pending Support Template – See Attachment 8
6. Technical Addendum for Potential Follow-On Work – See Attachment 9
7. Technical Addendum for Expansion of Use or Utility – See Attachment 10

5 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 at mtec-contracts@ati.org
- Technical and membership related questions should be directed to the MTEC Director of Research, Dr. Lauren Palestrini, Ph.D., lauren.palestrini@officer.mtec-sc.org
- All other questions should be directed to Ms. Kathy Zolman, MTEC Director of Program Operations, kathy.zolman@ati.org

Once an Offeror has submitted a White Paper, neither the Government nor the MTEC CM will discuss evaluation/proposal status until the evaluation results have been provided to all Offerors.

6 Acronyms/Abbreviations

ACURO	Animal Care and Use Review Office, USAMRDC
AMEDD	Army Medical Department
ATI	Advanced Technology International
BIDS	BAA Information Delivery System (Proposal submission site)
CAS	Cost accounting standards
CM	Consortium Manager
CMA	Consortium Member Agreement
CMO	Contract Manufacturing Organization
DoD	Department of Defense
DUNS	Data Universal Numbering System
F&A	Facilities and Administrative Costs
FAQ	Frequently Asked Questions
FDA	Food and Drug Administration
FFBT	Far Forward Burn Treatment
FOC	Full Operating Capability
FY	Fiscal Year
G&A	General and Administrative Expenses
GMP	Good Manufacturing Practice
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IPR	In process review
IPT	Integrated Product Team
IRB	Institutional Review Board

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IR&D	Independent Research and Development
M	Million
MTEC	Medical Technology Enterprise Consortium
NDA	Nondisclosure Agreement
NDC	Nontraditional Defense Contractor
NRI	Nonprofit Research Institution
OCI	Organizational Conflict of Interest
ODC	Other Direct Costs
OTA	Other Transaction Agreement
PMO	Project Management Office
POC	Point-of-Contact
PoP	Period of Performance
PPG	Proposal Preparation Guide
Q&A	Questions and Answers
RDT&E	Research, Development, Test, and Evaluation
ROM	Rough Order of Magnitude
RPP	Request for Project Proposals
SOW	Statement of Work
TBSA	Total Body Surface Area
TRL	Technology Readiness Level
USAISR	U.S. Army Institute of Surgical Research
USAMMDA	U.S. Army Medical Materiel Development Activity
USAMRDC	U.S. Army Medical Research and Development Command
USG	U.S. Government
W-EMT	Warfighter Expeditionary Medicine and Treatment

Attachment 1 – MTEC White Paper Template

Required Submission Documents (1): Submitted via BIDS

- White Paper - One PDF document 5MB or lower.

General Requirements: Each White Paper is limited to five pages plus a cover page (6 pages total). The White Paper must be in 11 point (or larger) type font, single-spaced, single-sided, on 8.5 inches x 11 inches paper. Smaller font may be used in figures and tables, but must be clearly legible. Margins on all sides (top, bottom, left, and right) should be at least 1 inch. *Please do not include confidential or proprietary information.*

Cover Page (1 page)

Title of White Paper

Principal Investigator and Institution

Statement that “This White Paper is submitted pursuant to the RPP MTEC-21-02-FFBT”

Dates of submission and signature of official authorized to obligate the institution contractually

Nontraditional Defense Contractor or Nonprofit Research Institution % - (See Attachment 2)

Willingness to allow MTEC Officers access to your White Paper for the purposes of engaging in outreach activities with private sector entities: Indicate YES or NO

[As part of MTEC’s mission to incorporate philanthropic donations, MTEC frequently makes contact with private sector entities (e.g., foundations, organizations, individuals) that award grants or otherwise co-fund research, and/or operate in research areas that are aligned with those of MTEC. Additional private entities may be interested in reviewing certain White Papers within their program areas, allowing opportunities to attract supplemental funding sources. Please indicate your willingness to allow MTEC access to your White Paper for the purposes of engaging in outreach activities with these private sector entities. MTEC staff has signed Nondisclosure Agreements (NDAs) and Organizational Conflict of Interest statements.]

White Paper (5 pages)

Title: [Insert descriptive title of project]

Principal Investigator: [Insert name, organization, email address, phone number]

Approach: [Briefly describe your approach to solving the problem. Include relevant background/preliminary data about your approach. Describe the existing technology, including

the TRL. Note: References are included within the page limit. There is no required format for the inclusion of references.]

Objectives: [Specify the objectives of the proposed effort for the base PoP1 of up to 24 months.]

Technical Strategy: [Outline the proposed methodology for the base PoP1 of up to 24 months **by task** in sufficient detail to show a clear course of action that addresses the technical requirements described in this RPP.]

Training Requirements: [Briefly describe the anticipated training requirements for the proposed prototype to be used by end users (e.g., medics and other non-licensed medical personnel and potentially non-medical responders), if appropriate. The intent of this section is to provide insight into the proposed solution's ease of use at Role 1. If invited to Stage 2 of the RPP process, Offerors will have an opportunity to elaborate on this section as necessary.]

Anticipated Outcomes: [Provide a description of the anticipated outcomes from the proposed work. List milestones and deliverables from the proposed work of PoP1. Also provide a high-level summary of follow-on tasks that would be a part of a PoP2 award, if made, to continue the development of the prototype.]

Potential for Expansion of Use or Utility: [Additional funding in PoP2 may be available for potential follow-on work for the expansion of use or utility of the proposed prototype. This section is intended to provide the Sponsor with information on the Offeror's plan for potential follow-on work beyond the base PoP1 related to expansion of use or utility of the proposed prototype. Examples may include but are not limited to:

- an alternative route of administration, or broader clinical indications
- expanding to address more than 1 capability gap.]

Technical Maturity and Commercialization Strategy: [Provide a brief description and justification of the maturity of the proposed technology, anticipated regulatory pathway and commercialization plans (including any work done to date to support regulatory clearance / approval of the prototype). Include information about Intellectual Property/Data Rights Assertions.]

Schedule: [Provide an overview of the timing of initiation, duration, and completion of project activities over the course of the PoP1.]

Participants: [Briefly state the qualifications of the Principal Investigator, key personnel, and organizations that will perform the SOW.]

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Non-traditional defense contract, nonprofit research institution, or 1/3 cost sharing: [Describe the plan to include significant participation of a non-traditional defense contractor, nonprofit research institution, or the ability to meet 1/3 cost sharing requirement.]

Period of Performance: [Indicate the total duration proposed for PoP1.]

Cost Share: [It is anticipated that Government funds would provide incentive for industry funding to join the project. While not a requirement, Offerors are strongly encouraged to discuss the ability to bring leveraged funding/cost share to complete the project goals.]

Rough Order of Magnitude (ROM) Pricing:

[Indicate the ROM pricing (including indirect costs) **using the table format below**. This information will be used to provide the Sponsor with a reasonable representation of the amount of funding required for PoP1 of up to 24 months to advance the project. 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.

Labor	<i>\$200,000.00</i>
Subcontractors	<i>\$100,000.00</i>
Consultants	<i>\$20,000.00</i>
Material/Equipment	<i>\$150,000.00</i>
Other Direct Costs	<i>00</i>
Travel	<i>0,000.00</i>
Indirect costs	<i>\$96,400.00</i>
Total	<i>\$578,400.00</i>
Fee (Not applicable if cost share is proposed)	<i>\$0.00</i>
Total Cost (plus Fee)	<i>\$578,400.00</i>
Cost Share (if cost share is proposed then fee is unallowable)	<i>\$580,000.00</i>
Total Project Cost	<i>\$1,158,400.00</i>

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Offerors are reminded to refer to the Selection Criteria under section 3.1.2. of the RPP to ensure that all required information is provided

Attachment 2 – Statutory Requirements for the Appropriate Use of Other Transaction Authority

Nontraditional Defense Contractor Definition

A nontraditional defense contractor is a business unit that has not, for a period of **at least one year prior to the issue date of the Request for Project Proposals**, entered into or performed on any contract or subcontract that is subject to full coverage under the cost accounting standards (CAS) prescribed pursuant to section 26 of the Office of Federal Procurement Policy Act (41 U.S.C. 422) and the regulations implementing such section. The nontraditional defense contractor can be an individual so long as he/she has a DUNS Number and meets the requirements in the Warranties and Representations.

Significant Extent Requirements

All Offerors shall submit Warranties and Representations (See Attachment 5) specifying the critical technologies being offered and/or the **significant extent** of participation of the nontraditional defense contractor and/or nonprofit research institution. The significance of the nontraditional defense contractor's and/or nonprofit research institution's participation shall be explained in detail in the signed Warranties and Representations. Inadequate detail can cause delay in award.

Per the DoD OT Guide, rationale to justify a *significant extent* include:

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

Conditions for use of Prototype OT Authority

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

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

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

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(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 3 – 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.

Cash Contribution

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

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

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

In-Kind Contribution

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

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

Attachment 4 – Stage 2 Evaluation Criteria

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

Stage 2

Compliance Screening

The CM will conduct a preliminary screening of received proposals to ensure compliance with the Stage 2 RPP requirements. As part of the preliminary screening process, proposals that do not meet the requirements of the RPP may be eliminated from the competition or additional information may be requested by the CM. The Government reserves the right to request additional information or eliminate proposals that do not meet these requirements from further consideration.

Evaluation Process

Full proposals that pass the preliminary compliance screening will be evaluated by the Government technical evaluation panel who will make recommendations to a Source Selection Authority. This process may involve the use of contractor Subject Matter Experts (e.g., system experts, scientists, and/or clinicians) 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 applicable, to protect information contained in the RPP as outlined in RPP Section 1.8.

Evaluation will be based on an independent, comprehensive review and assessment of the work proposed against stated source selection criteria and evaluation factors. The Government will evaluate against the technical evaluation factors detailed below and assign adjectival ratings to the non-cost/price factor(s) consistent with those defined in Table 3 (General Merit Ratings Assessments). The Offeror shall clearly state how it intends to meet and, if possible, exceed the RPP requirements. Mere acknowledgement or restatement of a RPP requirement is not acceptable. The CM will evaluate the cost proposals for those Offerors recommended for award, as detailed below, for realism, reasonableness, and completeness.

Evaluation Factors

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

Technical Approach and Potential for Transition and Commercialization will be evaluated with equal importance; however, when combined are significantly more important than cost/price.

Table 3 explains the adjectival merit ratings that will be used for the Technical Approach Factor, and Potential for Transition and Commercialization factor.

TABLE 3- 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.

Evaluation Factor 1. Technical Approach

The Technical Approach factor will be evaluated based upon the following:

- a. The Offeror’s proposed solution will be assessed for the likelihood of successfully achieving the requirements of the technology as defined in Section 2 of the RPP in order to meet the government’s needs. The likelihood of success will be determined by considering the soundness and clarity of the scientific rationale and technical approach, including technical merit of proposed research experiments. Additional consideration will be given to the degree to which any preliminary existing data supports the proposed project plan.
- b. The SOW should provide a succinct approach for achieving the project’s objectives. The SOW will be evaluated for how well the rationale, objectives, and specific aims support the proposed work and, as needed, meet Animal Care and Use Review Office (ACURO), Human Research Protection Office (HRPO), and FDA regulations.

- c. The proposed effort will be assessed for the extent to which the solution is technologically innovative and how the proposed deliverable(s) advance the TRL.
- d. Military relevance is a critical component of proposal submission. This relevance includes the health care needs of military Service members, enhanced capabilities of their care providers, training requirements, and the austere environment in which treatment is performed.
- e. A description of the project team's experience, key personnel, and corporate experience should demonstrate an ability to execute the SOW. Any relevant experience commercializing medical products should also be included.
- f. The proposal will also be evaluated on the soundness of the proposed scope of work for a Subsequent Period of Performance (PoP2) and how that work builds upon the proposed work under the Base Period of Performance (PoP1) and furthers the prototype's maturity towards regulatory clearance, commercialization, and military relevance.

Evaluation factor 2: Potential for Transition and Commercialization

The Potential for Transition and Commercialization factor will be evaluated based upon the following:

- a. How well the Offeror provides sufficient evidence that the effort is ready to move into the proposed stage of development and clinical testing.
- b. How well the project will translate from promising, well-founded basic or clinical research findings into clinical applications for military Service members.
- c. How well the funding strategy described will advance the technology to the next level of development and/or delivery to the military or civilian market.
- d. How well the proposal identified intellectual property ownership, describes any appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development.
- e. How well the regulatory strategy is described (including intended indication being sought) and how well the Offeror provides sufficient evidence of their progression through their identified regulatory pathway as well as how the proposed work advances their prototype towards regulatory clearance for the intended use by the military.
- f. How well the manufacturing and commercialization strategies are described, including current or potential use of contract manufacturing organizations (CMOs), intended quality management systems, sales and distribution channels, etc.

Evaluation Factor 3. Cost/Price

The Cost/Price area will receive a narrative rating to determine whether costs are realistic, reasonable, and complete. However, please note that the Government technical evaluation panel may provide an additional cost reasonableness review (based upon the same ratings as detailed in Table 2 of this RPP) for the purposes of informing the CM's detailed cost analysis, specifically with regards to the cost realism analysis.

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

Proposals will be evaluated using the understanding of cost realism, reasonableness and completeness as outlined below:

a) Realism. Proposals will be evaluated to determine if Costs are realistic for the work to be performed, reflect a clear understanding of the requirements, and are consistent with the various elements of the Offeror's schedule proposal.

Estimates are "realistic" when they are neither excessive nor insufficient for the effort to be accomplished. Estimates must also be realistic for each task of the proposed project when compared to the total proposed cost. For more information on cost realism, please refer to the MTEC PPG.

The MTEC CM will make a determination by directly comparing proposed costs with comparable current and historical data, evaluator experience, available estimates, etc. Proposed estimates will be compared with the corresponding technical proposals for consistency.

b) Reasonableness. The Offeror's cost proposal will be evaluated to determine if it is reasonable. For a price to be reasonable, it must represent a price to the Government that a prudent person would pay in the conduct of competitive business. Normally, price reasonableness is established through cost and price analysis.

To be considered reasonable, the Offeror's cost estimate should be developed from applicable historic cost data. The Offeror should show that sound, rational judgment was used in deriving and applying cost methodologies. Appropriate narrative explanation and justification should be provided for critical cost elements. The overall estimate should be presented in a coherent, organized and systematic manner.

Costs provided shall be clearly attributable to activities or materials as described by the Offeror. Costs should be broken down using the Cost Proposal Formats that are located on the Members-Only MTEC website.

c) Completeness. The MTEC CM will evaluate whether the proposal clearly and thoroughly documents the rationale supporting the proposed cost and is compliant with the requirements of the solicitation.

The proposal should clearly and thoroughly document the cost/price information supporting the proposed cost in sufficient detail and depth. The MTEC CM will evaluate whether the Offeror's cost proposal is complete with respect to the work proposed. The MTEC CM will consider substantiation of proposed cost (i.e., supporting data and estimating rationale) for all elements.

Rate and pricing information is required to properly perform the cost analysis of the proposal. If the Offeror is unwilling to provide this information in a timely manner, its proposal will be lacking information that is required to properly evaluate the proposal and the proposal cannot be selected for award.

Best Value

The Government will conduct the source selection based on the evaluation criteria and ratings contained within this RPP. The overall award decision will be based upon a 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. Based on the results of the Stage 2 Technical Evaluation, the Government reserves the right to negotiate and request changes to any or all parts of the proposal to include the SOW. Offerors will have the opportunity to concur with the requested changes and revise cost proposals as necessary.

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.

Attachment 5 – Warranties and Representations for Nontraditional Defense Contractors

For Information Only - Stage 2 Requirement

Authority to use Other Transaction Agreement

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.

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8. Legal Name:		9. DUNS #:	
10. Dollar Value to be Awarded:			
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:			
<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:			

Request for Project Proposal MTEC-21-02-FFBT
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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? <i>Note: While cost is an indicator for the level of nontraditional defense contractor participation, there is no particular cost threshold required.</i>
A3	

C. Signature

Signature of authorized representative of proposing Prime Contractor

Date

Attachment 6 – MTEC Requirements (Assessment Fee)

For Information Only - Stage 2 Requirement

As a tax-exempt 501(c)(3) entity, MTEC can accept contributions directly from the private sector, including industry partners who wish to co-fund a particular project, philanthropic entities who wish to co-fund a particular project, and/or philanthropic entities who wish to support the overall MTEC mission. Additional MTEC revenue streams for supporting entity operations are membership dues, research assessment fees, and royalty payments.

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

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

Royalty Payment Agreements

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

Additional Research Project Award Assessment

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

Attachment 7 – Intellectual Property and Data Rights

For Information Only - Stage 2 Requirement

Intellectual Property

Intellectual Property (IP) rights for MTEC Research Project Awards will be defined in the terms of an awardee’s Base Agreement, unless specifically negotiated at the RPA level. MTEC Base Agreements are issued by the MTEC CM to MTEC members receiving Research Project Awards. Base Agreements include the applicable flow down terms and conditions from the Government’s Other Transaction Agreement with MTEC, including the IP terms and conditions.

Data Rights

It is anticipated that anything delivered under a Research Project Award would be delivered to the Government with unlimited data rights. If this is not the intent, **then the Offeror’s proposal 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.

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.

Request for Project Proposal MTEC-21-02-FFBT
Number W81XWH-15-9-0001

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

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 8 – Current & Pending Support Template

For Information Only - Stage 2 Requirement

Include the requested information for each person who will contribute significantly to the proposed research project

Current

Award Number:

Title:

Funding Agency/Requiring Activity:

Dates of Funding:

Total Awarded Costs:

Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*

Brief summary of the scope of work:

Award Number:

Title:

Funding Agency/Requiring Activity:

Dates of Funding:

Total Awarded Costs:

Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*

Brief summary of the scope of work:

[Add additional fields, if needed, to report all current support]

Pending

Title of Proposal:

Funding Agency/Requiring Activity:

Estimated Dates of Funding:

Proposed Total Direct Costs:

Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*

Brief summary of the scope of work:

Title of Proposal:

Funding Agency/Requiring Activity:

Estimated Dates of Funding:

Proposed Total Direct Costs:

Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*

Brief summary of the scope of work:

[Add additional fields, if needed, to report all current support]

Attachment 9 – Technical Addendum for the Subsequent PoP Work (PoP2)

For Information Only - Stage 2 Requirement

General Instruction: As noted in Section 1.7 of the RPP, an additional \$7.4M of funding may be available for the performer(s) that is selected for the continuation of prototype development under the subsequent PoP2 after the Go/No-go Decision Point. The PoP2 work will be dependent on the advancement in prototype maturity of the prototype at the end of the base PoP1 of up to 24 months, as it applies to each resultant award(s). Examples of PoP2 tasks are listed in Section 2.2 of the RPP. Although awards in response to this RPP will initially focus on the scope of work for the first 24 months, this addendum is intended to provide the Sponsor with information on the Offeror’s plan for work beyond the base PoP1. The following template is required for Attachment 9 of the Stage 2 Proposal.

Technical Tasks: [Specify the objective of each proposed follow-on task. 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.]

PoP: [Indicate the proposed PoP (duration) for the potential follow-on work in total.]

Gantt Chart: [Include a Gantt chart that demonstrates the timeline for each proposed potential follow-on task.]

Anticipated Outcomes: [Provide a description of the anticipated outcomes from the proposed PoP2 work. List milestones and deliverables from the proposed PoP2 work.]

Participants: [Briefly state the qualifications of the Principal Investigator, key personnel, and organizations that will perform the proposed follow-on tasks.]

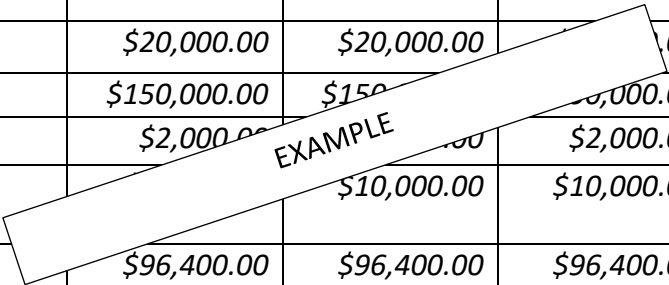
Rough Order of Magnitude (ROM) Pricing:

[Indicate the ROM pricing (including indirect costs) **using the table format below**. The ROM table should include a column for each potential PoP2 task. This information will be used to provide the Sponsor with a reasonable representation of the amount of funding required for each potential PoP2 task required to advance the project toward military fielding and/or production tasks. 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.]

	<i>Potential PoP2 Task 1</i>	<i>Potential PoP2 Task 2</i>	<i>Potential PoP2 Task 3</i>	<i>Potential PoP2 Task 4</i>
Labor	\$200,000.00	\$200,000.00	\$200,000.00	\$200,000.00

Request for Project Proposal MTEC-21-02-FFBT
Number W81XWH-15-9-0001

Subcontractors	\$100,000.00	\$100,000.00	\$100,000.00	\$100,000.00
Consultants	\$20,000.00	\$20,000.00	\$20,000.00	\$20,000.00
Material/Equipment	\$150,000.00	\$150,000.00	\$150,000.00	\$150,000.00
Other Direct Costs	\$2,000.00	\$2,000.00	\$2,000.00	\$2,000.00
Travel		\$10,000.00	\$10,000.00	\$10,000.00
Indirect costs	\$96,400.00	\$96,400.00	\$96,400.00	\$96,400.00
Total Cost	\$578,400.00	\$578,400.00	\$578,400.00	\$578,400.00
Fee (Not applicable if cost share is proposed)	\$0.00	\$0.00	\$0.00	\$0.00
Total Cost (plus Fee)	\$578,400.00	\$578,400.00	\$578,400.00	\$578,400.00
Cost Share (if cost share is proposed then fee is un-allowable)	\$580,000.00	\$580,000.00	\$580,000.00	\$580,000.00
Total Project Cost	\$1,158,400.00	\$1,158,400.00	\$1,158,400.00	\$1,158,400.00



Attachment 10 – Technical Addendum for Expansion of Use or Utility (if applicable)

For Information Only - Stage 2 Requirement

NOTE: Failure to complete this attachment may result in removal from the competition and the proposal determined to be ineligible for award

Check only one box if an expansion of use or utility of the proposed prototype:

is NOT applicable

is applicable (following the instructions below)

General Instruction (complete only if the box for “is applicable” is checked): As noted in Section 1.7 of the RPP, additional funding may be available for potential follow-on work for the expansion of use or utility of the proposed prototype. Although awards in response to this RPP will initially focus on the scope of work for the first 24 months, this addendum is intended to provide the Sponsor with information on the Offeror’s plan for potential follow-on work beyond the base PoP1. The following template is required as part of the full proposal submission. It is included within the full proposal page limitation. The following template is required for Attachment 10 of the Stage 2 Proposal. Some examples may include but are not limited to:

- an alternative route of administration, or broader clinical indications
- expanding to address more than 1 capability gap.

Description: [Describe the expansion of use or utility of the proposed prototype. Explain the clinical need and include relevant background/preliminary data that supports the approach to the expanded use or utility.]

Technical Tasks: [Specify the objective of each proposed follow-on task related to the expansion of use or utility of the proposed prototype. Outline the proposed methodology **by task** to the extent possible to demonstrate a course of action.]

PoP: [Indicate the proposed PoP for the potential follow-on work in total.]

Gantt Chart: [Include a Gantt chart that demonstrates the timeline for each proposed potential follow-on task.]

Anticipated Outcomes: [Provide a description of the anticipated outcomes from the proposed follow-on work. List milestones and deliverables from the proposed follow-on work.]

Additional Participants Required for Potential Follow-on Work: [Briefly state the qualifications of the key personnel/organizations that will perform the proposed follow-on tasks not already included earlier in the full proposal.]

Request for Project Proposal MTEC-21-02-FFBT
Number W81XWH-15-9-0001

Rough Order of Magnitude (ROM) Pricing: [Indicate the ROM pricing (including indirect costs) using the table format below. The ROM table should include a column for each potential follow-on task. This information will be used to provide the Sponsor with a reasonable representation of the amount of funding required to advance the project toward FDA clearance. 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.]

Labor	<i>\$200,000.00</i>
Subcontractors	<i>\$100,000.00</i>
Consultants	<i>\$20,000.00</i>
Material/Equipment	<i>\$50,000.00</i>
Other Direct Costs	<i>\$2,000.00</i>
Travel	<i>\$10,000.00</i>
Indirect costs	<i>\$96,400.00</i>
Total Cost	<i>\$578,400.00</i>
Fee (Not applicable if cost share is proposed)	<i>\$0.00</i>
Total Cost (plus Fee)	<i>\$578,400.00</i>
Cost Share (if cost share is proposed then fee is un-allowable)	<i>\$580,000.00</i>
Total Project Cost	<i>\$1,158,400.00</i>

Attachment 11 – BIDS Instructions

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

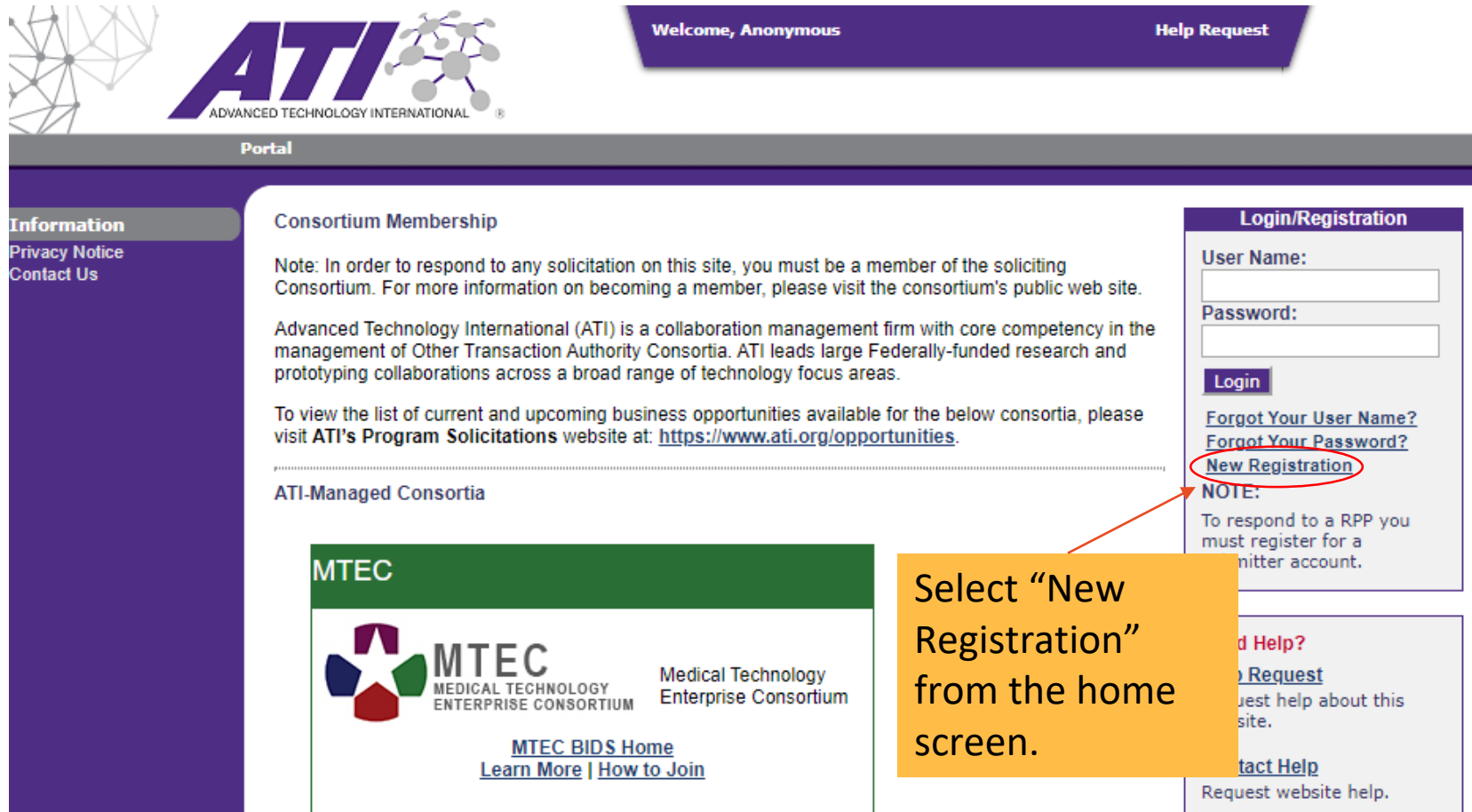
MTEC BIDS REGISTRATION

MTEC BIDS URL:

[HTTPS://AT12.ACQCENTER.COM](https://at12.acqcenter.com)

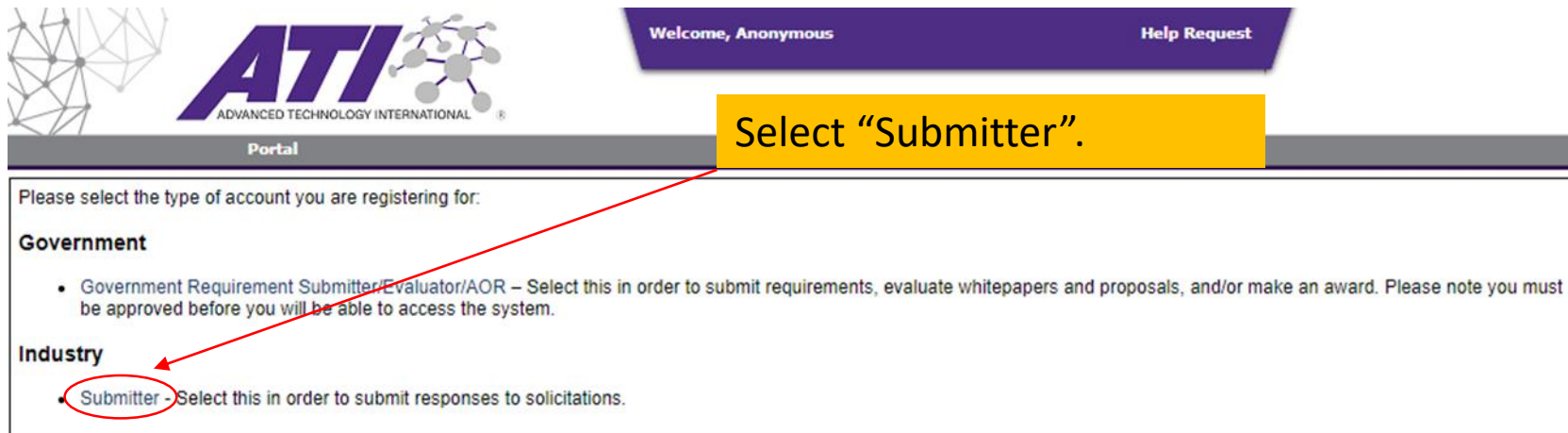
BIDS New Registration

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



The screenshot shows the MTEC BIDS website home page. At the top, there is a purple navigation bar with the text "Welcome, Anonymous" and a "Help Request" link. Below this is the ATI logo (Advanced Technology International) and a "Portal" header. On the left, there is a purple sidebar with "Information", "Privacy Notice", and "Contact Us" links. The main content area is titled "Consortium Membership" and contains a note about membership requirements, a paragraph about ATI's services, and a link to "ATI's Program Solicitations" website. Below this is a section for "ATI-Managed Consortia" featuring a green banner for "MTEC" with the MTEC logo and text: "MTEC MEDICAL TECHNOLOGY ENTERPRISE CONSORTIUM Medical Technology Enterprise Consortium". Underneath the banner are links for "MTEC BIDS Home" and "Learn More | How to Join". On the right side of the page, there is a "Login/Registration" box with input fields for "User Name:" and "Password:", a "Login" button, and links for "Forgot Your User Name?", "Forgot Your Password?", and "New Registration". The "New Registration" link is circled in red, and a red arrow points from a yellow callout box to it. The callout box contains the text: "Select 'New Registration' from the home screen." Below the "New Registration" link is a "NOTE:" section with text about registering for a RPP account. At the bottom right, there is a "Request Help?" section with a "Request" link and text about requesting help about the site, and a "Contact Help" link with text about requesting website help.

Select “Submitter”



Portal

Welcome, Anonymous Help Request

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.

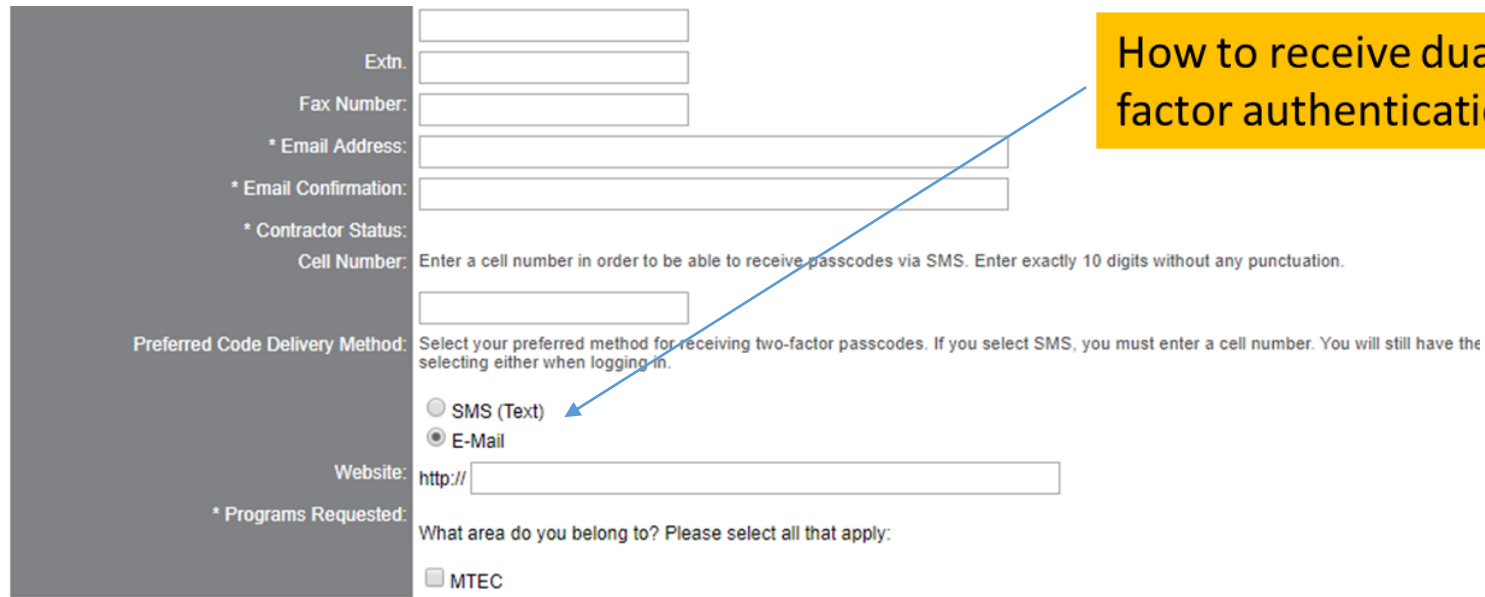
SECURITY NOTICE: Unauthorized attempts to deny service, upload information, change information, or attempt to access a non-public site from this service are strictly prohibited and may be punishable under Title 18 of the U.S. Code to include the Computer Fraud and Abuse Act of 1986 and the National Information Infrastructure Protection Act.



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BIDS New Registration

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



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 .

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.

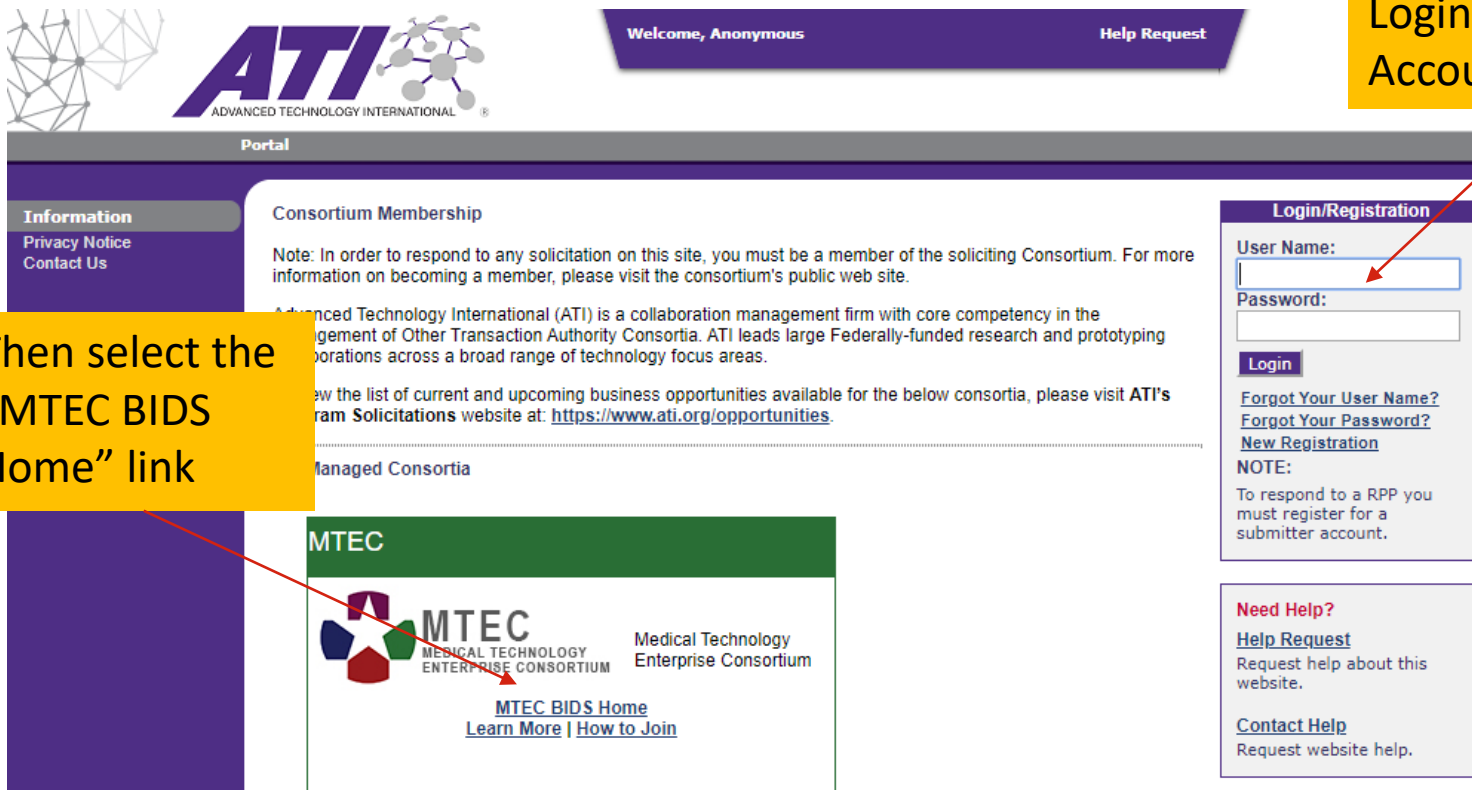
ALL PROPOSALS MUST BE SUBMITTED BEFORE THE SUBMISSION DUE DATE AND TIME. LATE PROPOSALS CAN NOT BE ACCEPTED.

MTEC BIDS PROPOSAL SUBMISSION

MTEC BIDS URL:

[HTTPS://AT12.ACQCENTER.COM](https://at12.acqcenter.com)

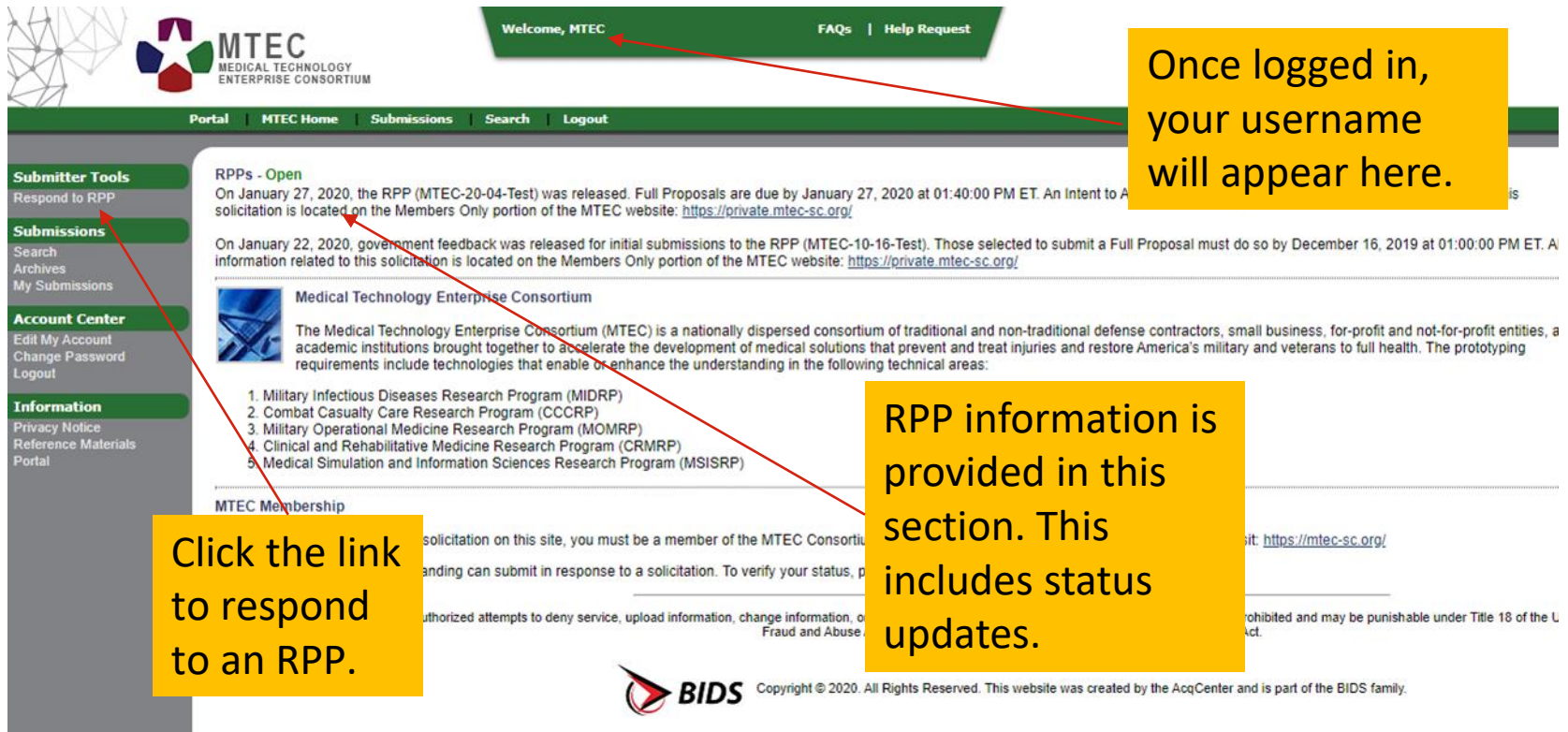
Navigate to the MTEC BIDS site and login. After login select the “MTEC BIDS Home” link.



The screenshot shows the MTEC BIDS website interface. At the top, there is a navigation bar with "Welcome, Anonymous" and "Help Request" links. Below this, the "Portal" section is visible. On the left, there is an "Information" sidebar with links for "Privacy Notice" and "Contact Us". The main content area features a "Consortium Membership" section with a note about solicitation requirements and a link to "MTEC BIDS Home". A yellow callout box points to this link with the text "Then select the 'MTEC BIDS Home' link". On the right side, there is a "Login/Registration" form with fields for "User Name:" and "Password:", a "Login" button, and links for "Forgot Your User Name?", "Forgot Your Password?", and "New Registration". Another yellow callout box points to the "Login" button with the text "Login to your BIDS Account." Below the login form, there is a "Need Help?" section with links for "Help Request" and "Contact Help".

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Select the “Respond to RPP” link under the submitter tools



Once logged in, your username will appear here.

Click the link to respond to an RPP.

RPP information is provided in this section. This includes status updates.

Welcome, MTEC FAQs | Help Request

Portal | MTEC Home | Submissions | Search | Logout

Submitter Tools
Respond to RPP

Submissions
Search
Archives
My Submissions

Account Center
Edit My Account
Change Password
Logout

Information
Privacy Notice
Reference Materials
Portal

RPPs - Open
On January 27, 2020, the RPP (MTEC-20-04-Test) was released. Full Proposals are due by January 27, 2020 at 01:40:00 PM ET. An intent to award solicitation is located on the Members Only portion of the MTEC website: <https://private.mtec-sc.org/>

On January 22, 2020, government feedback was released for initial submissions to the RPP (MTEC-10-16-Test). Those selected to submit a Full Proposal must do so by December 16, 2019 at 01:00:00 PM ET. All information related to this solicitation 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 contractors, small business, for-profit and not-for-profit entities, and academic institutions brought together to accelerate the development of medical solutions that prevent and treat injuries and restore America's military and veterans to full health. The prototyping requirements include technologies that enable or enhance the understanding in the following technical areas:


1. Military Infectious Diseases Research Program (MIDRP)
2. Combat Casualty Care Research Program (CCCRP)
3. Military Operational Medicine Research Program (MOMRP)
4. Clinical and Rehabilitative Medicine Research Program (CRM RP)
5. Medical Simulation and Information Sciences Research Program (MSISRP)

MTEC Membership

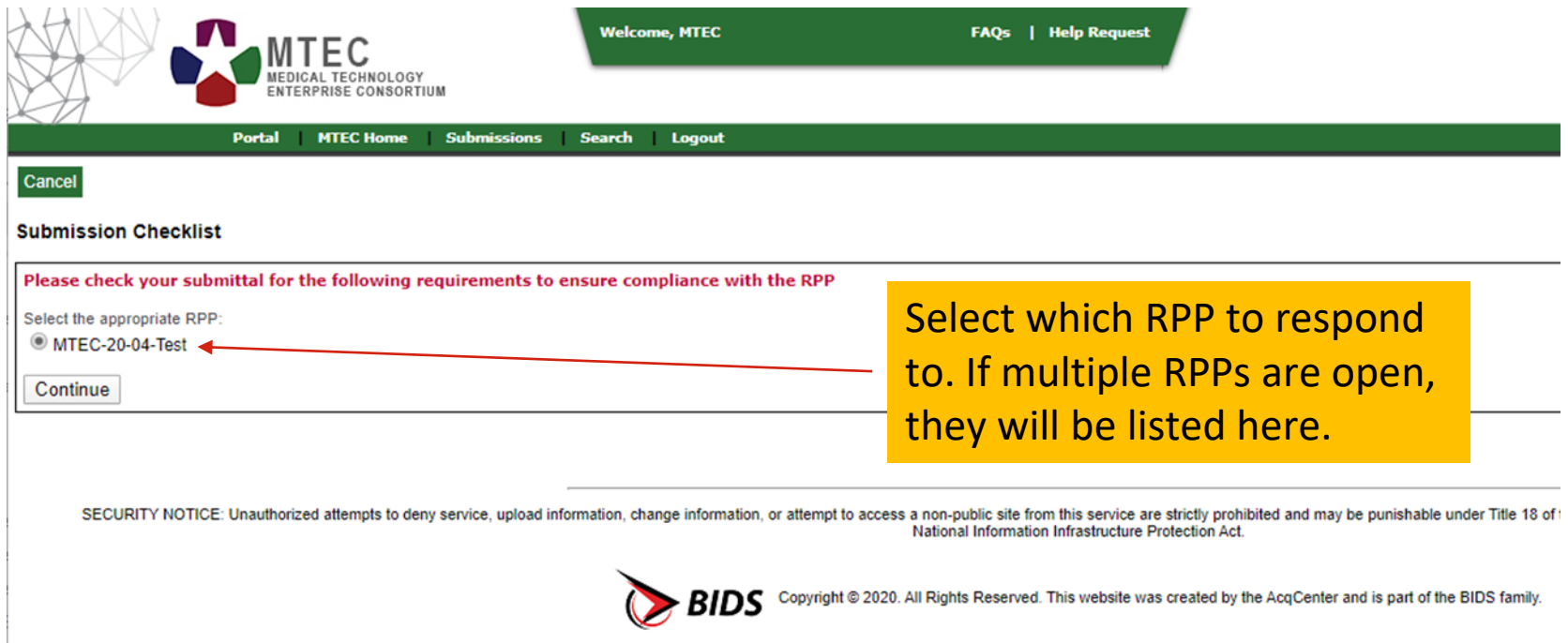
solicitation on this site, you must be a member of the MTEC Consortium. To verify your status, please visit: <https://mtec-sc.org/>

standing can submit in response to a solicitation. To verify your status, please visit: <https://mtec-sc.org/>

authorized attempts to deny service, upload information, change information, or engage in Fraud and Abuse. Prohibited and may be punishable under Title 18 of the U.S. Code, Section 1030.

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Select which RPP you will be responding to.



The screenshot shows the MTEC submission checklist interface. At the top, there is a green navigation bar with the MTEC logo and the text "Welcome, MTEC" and "FAQs | Help Request". Below this is a dark green bar with navigation links: "Portal", "MTEC Home", "Submissions", "Search", and "Logout". The main content area is titled "Submission Checklist" and contains a "Cancel" button. Below the title, there is a red heading: "Please check your submittal for the following requirements to ensure compliance with the RPP". Underneath, it says "Select the appropriate RPP:" followed by a radio button selection for "MTEC-20-04-Test". A red arrow points from a yellow callout box to this radio button. A "Continue" button is located below the selection. At the bottom of the page, there is a "SECURITY NOTICE" and the BIDS logo with the text "Copyright © 2020. All Rights Reserved. This website was created by the AcqCenter and is part of the BIDS family."

Cancel

Submission Checklist

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


Select the appropriate RPP:

MTEC-20-04-Test

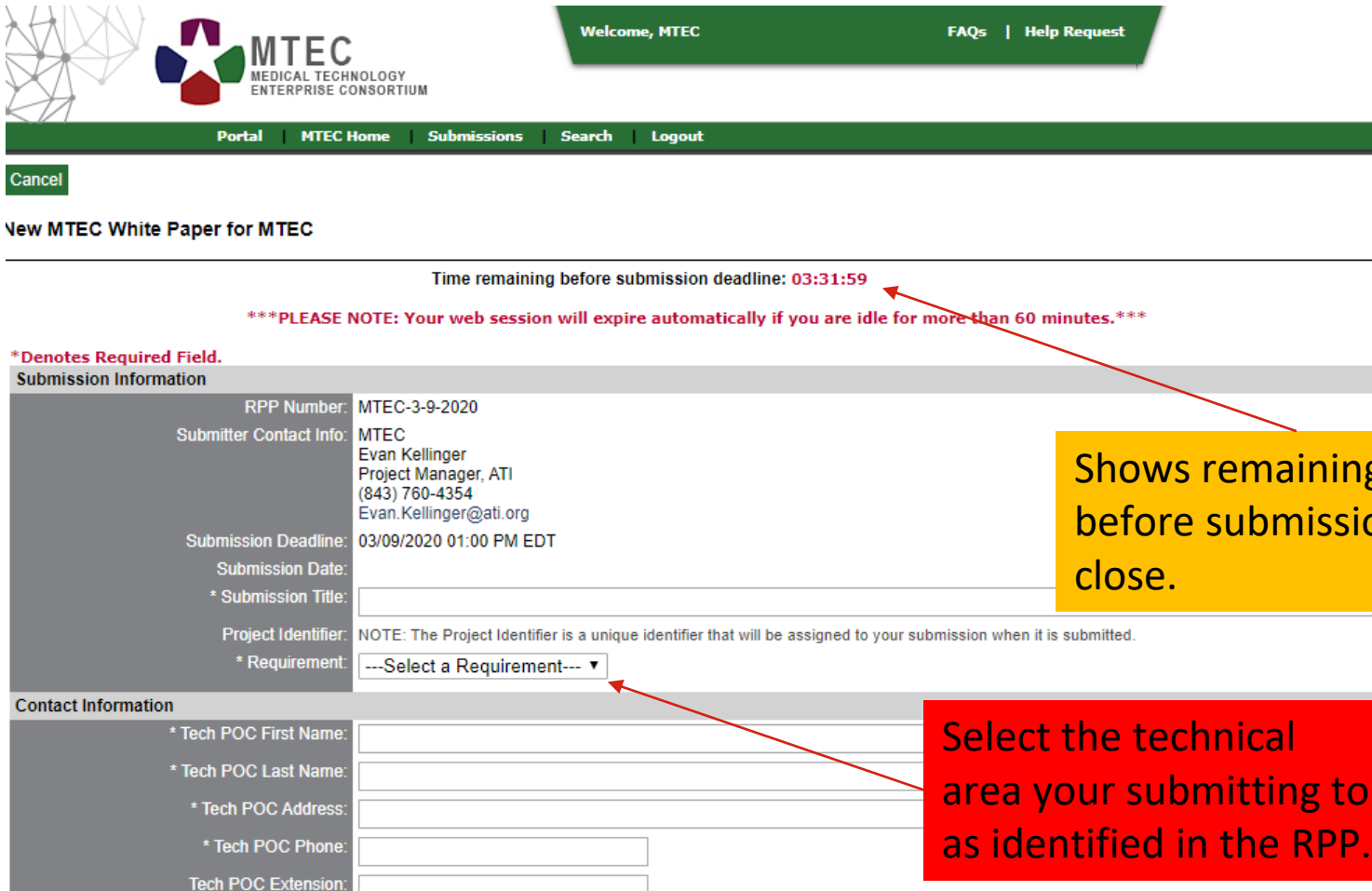
Continue

Select which RPP to respond to. If multiple RPPs are open, they will be listed here.

SECURITY NOTICE: Unauthorized attempts to deny service, upload information, change information, or attempt to access a non-public site from this service are strictly prohibited and may be punishable under Title 18 of National Information Infrastructure Protection Act.

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Complete the submission form.



The screenshot shows the MTEC submission form interface. At the top, there is a green navigation bar with the MTEC logo and text: "Welcome, MTEC" and "FAQs | Help Request". Below this is a secondary green bar with navigation links: "Portal | MTEC Home | Submissions | Search | Logout". A "Cancel" button is visible on the left. The main content area displays "New MTEC White Paper for MTEC" and a countdown timer: "Time remaining before submission deadline: 03:31:59". A red note states: "***PLEASE NOTE: Your web session will expire automatically if you are idle for more than 60 minutes.***". The form is divided into two sections: "Submission Information" and "Contact Information".

Submission Information

- RPP Number: MTEC-3-9-2020
- Submitter Contact Info: MTEC, Evan Kellinger, Project Manager, ATI, (843) 760-4354, Evan.Kellinger@ati.org
- Submission Deadline: 03/09/2020 01:00 PM EDT
- Submission Date:
- * Submission Title:
- Project Identifier: NOTE: The Project Identifier is a unique identifier that will be assigned to your submission when it is submitted.
- * Requirement: ---Select a Requirement---

Contact Information

- * Tech POC First Name:
- * Tech POC Last Name:
- * Tech POC Address:
- * Tech POC Phone:
- Tech POC Extension:

Shows remaining time before submission close.

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

Proposal Submission BIDS

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

File Attachments	
Required Files:	White Paper No file uploaded Upload White Paper (Allowed file types: pdf, doc, docx; Size Limit: 5mb)
Agreements	
*Classified Information:	I certify no classified information is contained in the information being submitted. <input type="checkbox"/> Agree
*Submitter Agreement:	I understand The Government intends to use the Consortium Management Firm, ATI, to assist in the processing of Submitter's proposals to this RPP as indicated in the MTEC Base Agreement. The Consortium Management Firm shall take the necessary steps to protect all proprietary proposal information and shall not use such proprietary information for purposes other than the evaluation of a Submitter's proposal and the subsequent contract administration if the proposal is selected for award. A Submitter indicates concurrence with the aforementioned CMF responsibilities. Additionally, the Government (CSP) to assist in the submitted proposals' evaluation. The CSP will be required to submit to the Submitter reflecting the effort they will supply to support this RPP. The Submitter's submission of a proposal with the aforementioned Consortium Management Firm responsibilities and the use of CSP. Finally, the Consortium leadership may be provided, at their request, top-level data and metrics on submissions for their use in monitoring the effectiveness of submission processes and the level of participation by members in the RPP. Information will only be released with Government approval. A Submitter's submission under this RPP indicated concurrence with the aforementioned release of information to the Consortium leadership. <input type="checkbox"/> Agree

Upload documents in this section.

Submit

Once the submission form is completed select submit.

SECURITY NOTICE: Unauthorized attempts to deny service, upload, or delete data on this non-public site from this service are strictly prohibited and may be punishable under Title 18 of the U.S. Code to include the National Information Infrastructure Protection Act.

Proposal Submission BIDS

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

- Submission documents can be modified anytime prior to the due date and time from your BIDS account.
- To make changes to your submission, prior to the due date/time, select the submission link from the home page and navigate to your submission.

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.