

Request for Project Proposals



Solicitation Number: MTEC-20-14-Ocular
“Temporary Corneal Repair Solution”

Issued by:
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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) 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. Proposed prototype projects should not be exploratory in nature and do require a foundation of preliminary data. 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 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 Department of Defense (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 Temporary Corneal Repair 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 a prototype that allows for temporary stabilization of corneal and corneoscleral injuries at a Role 1 battalion aid station. The desired prototype should be simple enough for a medic or physician's assistant to administer it under austere circumstances with little to no additional equipment, safe enough to use on any suspected corneal or corneoscleral injuries, and effective at stabilizing the eye such that it preserves the Soldier's eyesight.

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 White Papers that best meet their current technology priorities 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 contain specific Stage 2 proposal submission requirements. 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 the RPP. Using this approach, the Government intends to award 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 PoP 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 PoP (PoP2) work will be completed during the Go/No-go Decision Point which is expected to occur prior to the end of the base PoP (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 PoP 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 PoP (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 USC 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 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 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 available approximately **\$3.5 million (M) for the base period of performance (PoP1)** of up to 24 months. MTEC anticipates that **multiple awards** will be made.

An additional \$6.3M 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 PoP (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 PoP (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 PoP 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. 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 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; provide a description of each cost share item proposed; the proposed dollar amount for each cost share item proposed; and the valuation technique used (e.g., vendor quote, historical cost, labor hours and labor rates, number of trips, etc.). Cost sharing above the statutory minimum is encouraged if possible, as it leads to stronger leveraging of Government-contractor collaboration.

1.10 Cost Share Requirements

Research Projects selected for funding under this RPP are required to meet at least one of the following conditions in accordance with 10 U.S.C. § 2371b section (d) with regards to the Appropriate Use of Authority:

- There is at least one nontraditional defense contractor or nonprofit research institution participating to a significant extent in the prototype project.
- All significant participants 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.

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- 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.

Beyond that, cost sharing is encouraged if possible, as it leads to stronger leveraging of Government-contractor collaboration. More information regarding nontraditional defense contractor requirements can be found in Attachment 2. 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 listed above, 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 are defined in the terms of an awardee's Base Agreement and resultant Task Orders. MTEC reserves the right to assist in the negotiation of IP, royalties, licensing, future development, etc., between the government and the individual performers during the entire award period.

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.

1.12 White Paper Submission

White Papers shall 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-20-14-Ocular) 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 **Monday, August 3, 2020**.

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

1.13 Submission Format

See Attachment 1 for the White Paper template. Files should be submitted 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, or .pdf). Filenames should not contain 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.

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.

2 Technical Requirements

2.1 Background

In future combat scenarios where the U.S. could face a peer or near-peer adversary, the ability to evacuate casualties from the battlefield, and even out of theater, will be severely hampered. Large-scale combat operations will put high numbers of Soldiers into a fight where tactical areas are highly contested and operationally degraded. Freedom of movement, whether by air or land, will be difficult such that moving supplies and casualties to/from the front lines could take days or weeks.

Unfortunately, blasts will continue to be a significant source of ocular trauma in the future fight. Without surgical intervention by an ophthalmologist, seriously injured ocular tissue is not viable after 24-36 hours. Given protracted evacuation timelines and a lack of specialists in theater, it will be impossible for the necessary specialists to treat these ocular injuries early enough to preserve the eyesight of these wounded Soldiers.

In order to address corneal and corneoscleral injuries earlier and in a way that is relevant to the future fight, a product that allows for temporary stabilization of corneal and corneoscleral injuries at a Role 1 battalion aid station is needed. The desired product should be simple enough for a medic or physician's assistant to administer it under austere circumstances with little to no additional equipment, safe enough to use on any suspected corneal or corneoscleral injuries, and effective at stabilizing the eye such that it preserves the Soldier's eyesight.

2.2 Solution Requirements

This program is intended to support the development of prototype technologies that allow temporary stabilization of corneal and corneoscleral injuries at a Role 1 battalion aid station.

Offerors should only propose technology solutions that meet the following two criteria as the following specifications define the minimum prototype requirements that all proposals must demonstrate:

1. Currently at a Technology Readiness Level (TRL) of 4 or above [definition of TRL – <https://mtec-sc.org/wp-content/uploads/2016/12/TRL-definitions.pdf>]
 - a. A prototype is at a TRL 4 if has completed the following: “Non-GLP laboratory research to refine hypothesis and identify relevant parametric data required for technological assessment in a rigorous (worst case) experimental design. Exploratory study of candidate device(s)/systems (e.g., initial specification of device, system, and subsystems). Candidate devices/systems are evaluated in laboratory and/or animal models to identify and assess potential safety problems, adverse events, and side effects. Procedures and methods to be used during non-clinical and clinical studies in evaluating candidate devices/systems are identified. The design history file, design review, and, when required, a Device Master Record (DMR), are initiated to support either a 510(k) or Premarket Approval (PMA).”
2. Currently in development or commercially available.

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

Although White Papers that propose to meet all of the solution requirements outlined below 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):

- A product that will ***temporarily*** stabilize suspected full-thickness corneal and corneoscleral injuries that is capable of obtaining approval/clearance by the U.S. Food and Drug Administration (FDA) for this indication
 - Preserves ocular tissues
 - Effective at preserving ocular tissues in a clinical model (with intent to restore vision) such that they can be surgically repaired in 25-50% of cases, or greater

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- Capable of stabilizing suspected full-thickness corneal and corneoscleral wounds of various shapes and sizes, with or without prolapse of other ocular structures, contributing to the preservation of ocular tissue. Some examples could include:
 - Creates a watertight seal over the corneal or corneoscleral injury
 - Is oxygen permeable
 - Safe to use even in presence of intraocular foreign body(ies)
 - Prevents infection
 - Enables maintenance of intraocular pressure in safe ranges (product itself does not need to re-establish intraocular pressure)
- A non-surgical solution that can be applied to the surface of the injured eye that does not require any specialized equipment (beyond an included applicator)
 - Topically administered to the eye
 - Simple to use/apply (based on design of applicator, process for administration, time to prepare, etc.)
 - Can be administered by non-licensed medical personnel quickly and easily (see attributes of Role 1 medical setting below)
 - Doesn't require a surgical microscope, surgical loupes, specula, etc.
 - Can be left in place or reapplied for up to 3 days (even higher durations are ideal)
- Removable and/or reversible
 - Does not cause disproportionate damage to eye when removed
 - Either sloughs off/is resorbed into the body; or can be safely removed by ophthalmologist in preparation for/during definitive repair surgery
 - Could be reapplied, if needed
- Appropriate for use at Role 1 (unit-level medical care, i.e., Battalion Aid Station) [Refer to the Emergency War Surgery for Roles of Care definitions:
<https://www.cs.amedd.army.mil/FileDownloadpublic.aspx?docid=6f9e0685-1290-4e92-8277-c1e7b0f2fef0>]
 - Purpose of Role 1:
 - Provides primary healthcare, specialized first aid, triage, resuscitation, and stabilization
 - Casualty collection
 - Providers:
 - Treatment provided by medics
 - Expanded medical treatment provided by physician assistant, physician (if available), independent duty corpsman/medical technician, pararescueman
 - Role 1 facilities include:
 - Tent
 - Limited power
 - Limited space

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- Highly mobile
- Not substantially climate controlled, if at all
- Capable of achieving a shelf life of at least two years at room temperature
- Doesn't require climate-controlled transit or storage
- Commercially viable product or technology that will be brought to market (can be marketed for different indication in civilian market than what DoD is seeking)

Project Scope (PoP1 & PoP2) and non-competitive Follow-on Work:

The Government and MTEC expect that Offerors' proposed project scope and maturity will vary based on the initial maturity of the proposed prototype and the ability to meet the solution requirements listed above. Therefore, Government decisions regarding both the rolling down select and potential non-competitive follow-on work will be based on the advancement in prototype maturity (among other considerations), as it applies to each resultant award(s) during the performance of the prototype project(s). The Government may consider funding any of the following (but not necessarily limited to the) work listed below during any period (i.e., PoP1, PoP2) of the awarded prototype project(s) to include any non-competitive follow on work (which may proceed PoP2 tasks):

- Prototype refinement/maturation progressing towards clinical product
- Pre-clinical work (as needed) to support an Investigational Device Exemption (IDE) (or other appropriate FDA) submission
- Animal studies under Good Laboratory Practice (GLP) (as needed) to support IDE (or other appropriate FDA) submission
- IDE (or other appropriate FDA) submission
- 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 PoP (tentatively projected at t = 20 months), 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 Awardees. The IPR will be 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. Each Awardee shall submit full details of the tasks proposed for the subsequent PoP (PoP2) phase, in separate technical and cost volumes, as a deliverable to the Government. The exact due date for this deliverable is TBD (anticipated on or about 2 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 PoP 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).

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.

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.

3 Selection/Evaluation Criteria

3.1 Stage 1: White Papers

3.1.1 Compliance Screening

The CM will conduct a preliminary screening of received 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 (at the discretion of the CM and/or the Government). One of the primary reasons for elimination from further consideration is noncompliance with the statutory requirements with regards to the Appropriate Use of Authority as summarized under Section 1.10 of this RPP.

3.1.2 Selection Criteria

The Government will evaluate White Papers submitted under this RPP using the following criteria listed in descending order of importance:

- (1) Factor 1 - Technical Approach:** Reviewers will assess the technical approach based on:
- a. How well the white paper defines and describes a prototype that can already meet or be modified to meet the requirements of the ideal solution as set forth in this RPP, including:
 - i. How the prototype works, how it is administered and by whom
 - 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. 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.

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The reviewers may also consider the Offeror’s high level description of subsequent Period of Performance tasks (PoP2) for the continuation of prototype development 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, and evaluation.

(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 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 2 under Attachment 4 of the RPP. See below for the definitions of the “Cost Reasonableness” factor ratings:

“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 subsequent submissions beyond the Stage 1 process, including Full Proposals.

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 requirements in addition to any Stage 2 proposal requirements:

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. Current and Pending Support (no page limit) for each person who will contribute significantly to the proposed research project – See Attachment 8
 - a. For all current and pending research support (to include government and non-government), include the award number and title, funding agency and requiring activity's names, period of performance (dates of funding), level of funding (total direct costs only), brief description of the project's goals, and list of specific aims. If applicable, identify where the proposed project overlaps with other existing and pending research projects. Clearly state is there is no overlap.
 - b. If there is no current and/or pending support, enter "None."
5. IP Rights (no page limit) – See Attachment 7
6. Technical Addendum for Potential Follow-On Work – See Attachment 9

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 source selection process is complete.

6 Acronyms/Abbreviations

ACURO	Animal Care and Use Review Office, USAMRDC
AMEDD	Army Medical Department
ATI	Advanced Technology International
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
FOC	Full Operating Capability
FY	Fiscal Year
G&A	General and Administrative Expenses
GLP	Good Laboratory Practice
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
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
PMA	Pre-market Approval
PMO	Project Management Office
POC	Point-of-Contact
POP	Period of Performance
PPG	Proposal Preparation Guide
Q&A	Questions and Answers

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RDT&E	Research, Development, Test, and Evaluation
ROM	Rough Order of Magnitude
RPP	Request for Project Proposals
SOW	Statement of Work
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

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. The MTEC staff will share white papers with various potential public and private sector sponsors. ***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-20-14-Ocular”

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.]

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

Technical Maturity and Commercialization Strategy: [Provide a brief description and justification of the maturity of the proposed technology, anticipated regulatory pathway and commercialization plans. 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.]

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 proposed 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.

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

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 – Nontraditional Defense Contractor

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.

Nontraditional Defense Contractor Requirements

If the Offeror asserts either (1) it is a nontraditional defense contractor or (2) proposes a nontraditional defense contractor as a team member/subcontractor, the Offeror shall submit Warranties and Representations (Attachment 5) specifying the critical technologies being offered and/or the significant extent of participation of the nontraditional defense contractor. The nontraditional defense contractor can be an individual so long as he/she has a DUNS Number and meets the requirements in the Warranties and Representations. The significance of the nontraditional defense contractor's participation must be explained in detail in the signed Warranties and Representations. Inadequate detail can cause delay in award.

Per the DoD OT Guide, rationale to justify a *significant contribution* 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

Inclusion of Nontraditional Defense Contractors

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.

(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.

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This requirement is a statutory element of the Other Transaction Authority and will be regarded as a pass/fail criterion during the Compliance Screening.

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 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.

*There is a statutory requirement for proposals to include either 1) significant participation of a Nontraditional Defense Contractor (NDC) or Nonprofit Research Institution (NRI), 2) all significant participants other than the Federal Government being Small Businesses or 3) 1/3 cost share on projects. One of the primary reasons for elimination from further consideration is noncompliance with this statutory requirement.

Evaluation Process

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

This process may involve the use of contractors as SME (e.g., system experts, scientists, and/or clinicians) consultants or reviewers. Where appropriate, the USG will employ non-disclosure agreements 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 evaluation factors detailed below and assigned adjectival ratings to the noncost/price factor(s) consistent with those defined in Table 2 (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.

Evaluation Factors

1. Technical Approach

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

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

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

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

Evaluation Factor 1. Technical Approach

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

- a. The Offeror’s proposed solution will be assessed for the likelihood of successfully achieving the requirements of the technology as defined above in order to meet the government’s needs. The likelihood of success will be determined by considering the soundness and clarity of the technical approach. Additional consideration will be given to the degree to which any preliminary existing data supports the proposed project plan.

- 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 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 and the austere environment in which treatment is performed.
- e. A description of the project team's expertise, key personnel, and corporate expertise should demonstrate an ability to execute the SOW.
- f. The proposal will also be evaluated on the soundness of the proposed scope of work for a Subsequent Period of Performance and how that work builds upon the proposed work under the Base Period of Performance 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 using the merit rating as shown in Table 2.

The Offeror's proposal will be assessed for:

- a. How well the Offeror provides sufficient evidence that the effort is ready to move into the proposed stage of 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 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.
- 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.

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.

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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 listed above. 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 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.

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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:			

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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

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 – IP 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 and resultant Task Orders. 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 White Papers 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.

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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 \$6.3M of funding may be available for the performer(s) that is selected for the continuation of prototype development under the subsequent PoP 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 POP 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 PoP (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-20-14-Ocular
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

EXAMPLE

Attachment 10 – BIDS Instructions

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

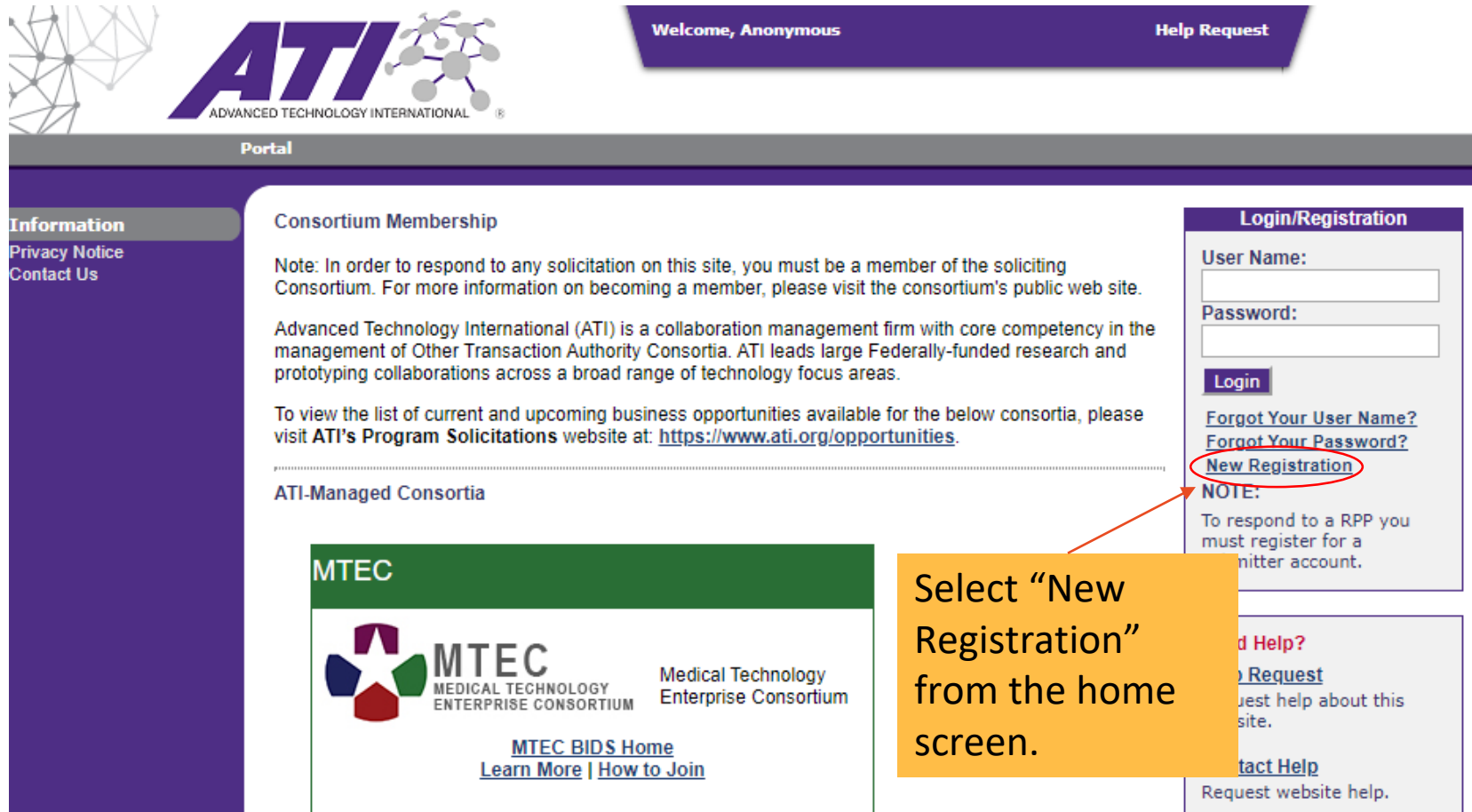
MTEC BIDS REGISTRATION

MTEC BIDS URL:

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

BIDS New Registration

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



ATI
ADVANCED TECHNOLOGY INTERNATIONAL

Welcome, Anonymous [Help Request](#)

Portal

Information
[Privacy Notice](#)
[Contact Us](#)

Consortium Membership

Note: In order to respond to any solicitation on this site, you must be a member of the soliciting Consortium. For more information on becoming a member, please visit the consortium's public web site.

Advanced Technology International (ATI) is a collaboration management firm with core competency in the management of Other Transaction Authority Consortia. ATI leads large Federally-funded research and prototyping collaborations across a broad range of technology focus areas.

To view the list of current and upcoming business opportunities available for the below consortia, please visit ATI's Program Solicitations website at: <https://www.ati.org/opportunities>.

ATI-Managed Consortia

MTEC
MEDICAL TECHNOLOGY
ENTERPRISE CONSORTIUM

Medical Technology
Enterprise Consortium

[MTEC BIDS Home](#)
[Learn More | How to Join](#)

Login/Registration

User Name:

Password:

[Login](#)

[Forgot Your User Name?](#)
[Forgot Your Password?](#)
[New Registration](#)

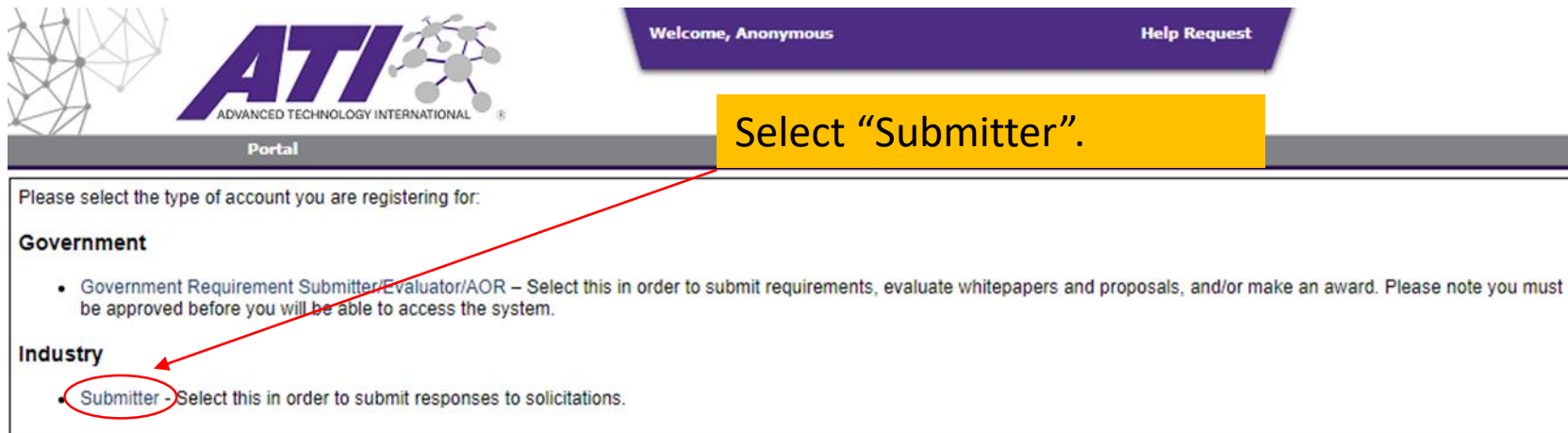
NOTE:
To respond to a RPP you must register for a twitter account.

[Request Help?](#)
[Request Help](#)
Request help about this site.

[Contact Help](#)
Request website help.

Select “New Registration” from the home screen.

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.

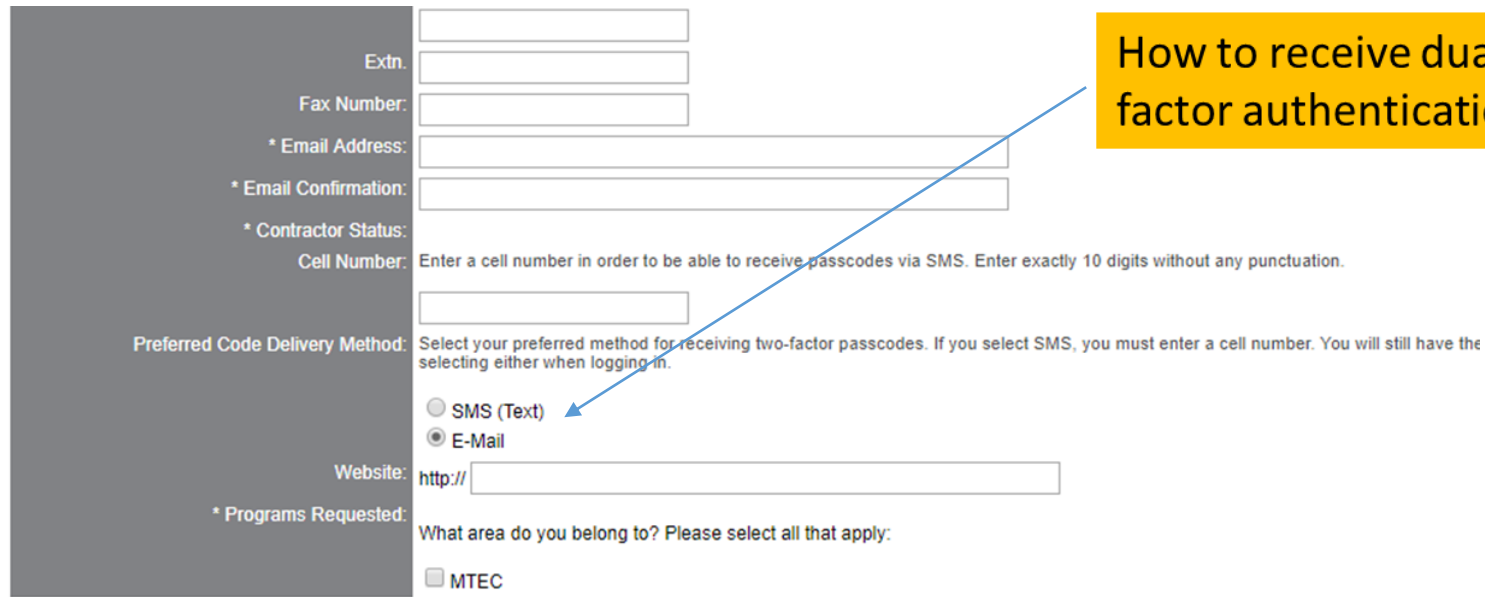
SECURITY NOTICE: Unauthorized attempts to deny service, upload information, change information, or attempt to access a non-public site from this service are strictly prohibited and may be punishable under Title 18 of the U.S. Code to include the Computer Fraud and Abuse Act of 1986 and the National Information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

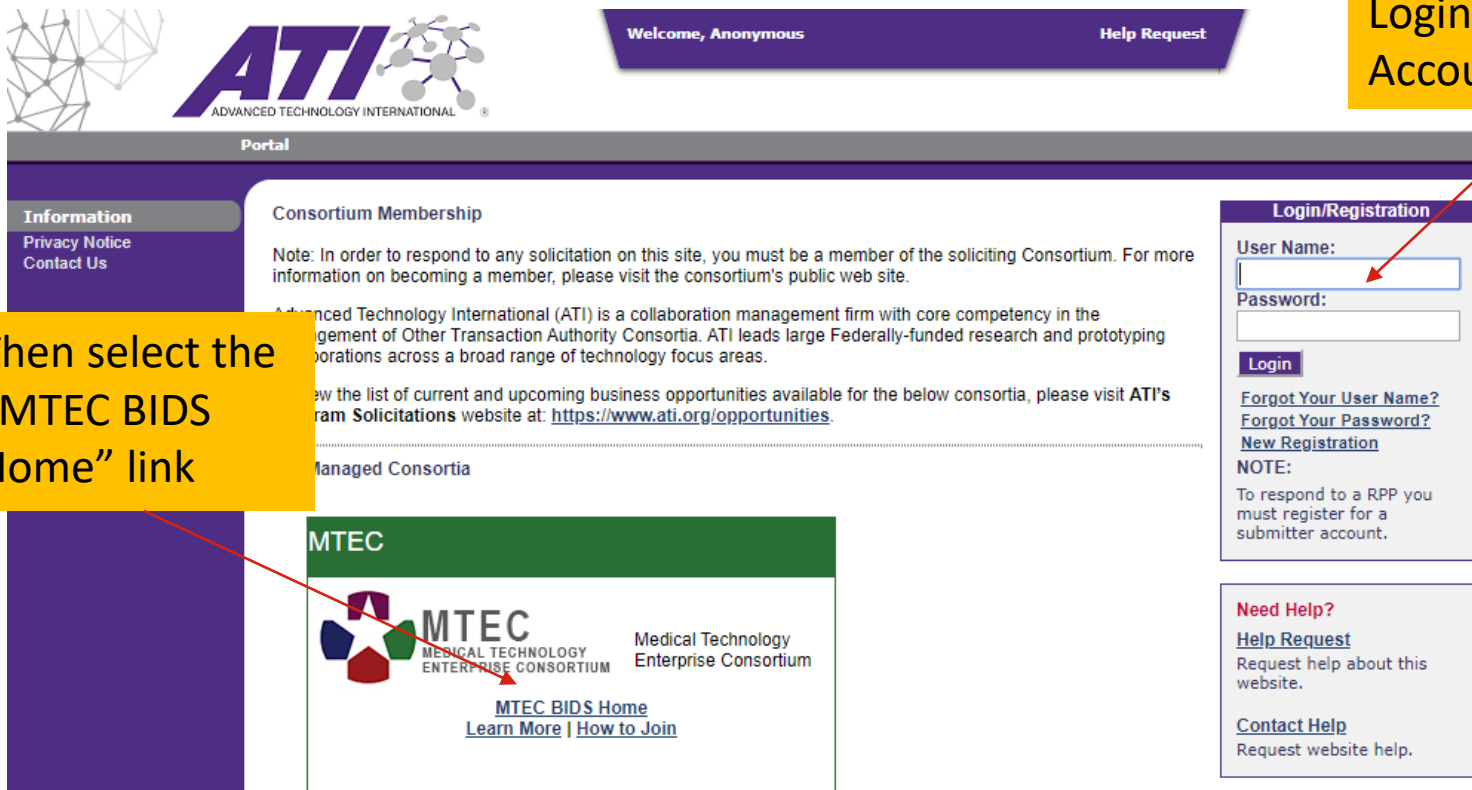
ALL PROPOSALS MUST BE SUBMITTED BEFORE THE SUBMISSION DUE DATE AND TIME. LATE PROPOSALS CAN NOT BE ACCEPTED.

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.



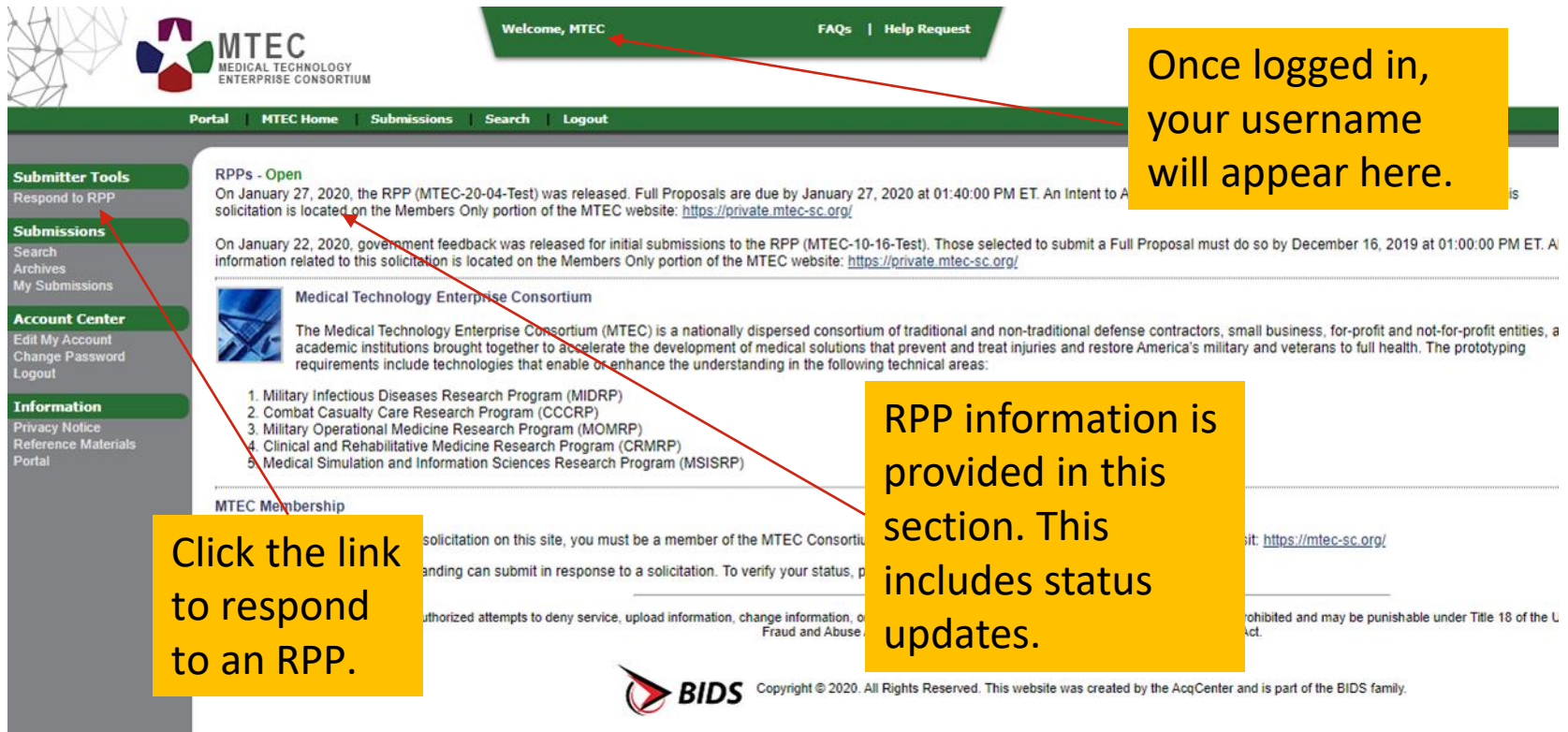
The screenshot shows the MTEC BIDS website interface. At the top, there is a navigation bar with "Welcome, Anonymous" and a "Help Request" link. Below this is a "Portal" header. The main content area is divided into several sections: "Information" (Privacy Notice, Contact Us), "Consortium Membership" (Note: In order to respond to any solicitation on this site, you must be a member of the soliciting Consortium. For more information on becoming a member, please visit the consortium's public web site. Advanced Technology International (ATI) is a collaboration management firm with core competency in the management of Other Transaction Authority Consortia. ATI leads large Federally-funded research and prototyping operations across a broad range of technology focus areas. View the list of current and upcoming business opportunities available for the below consortia, please visit ATI's Program Solicitations website at: <https://www.ati.org/opportunities>), and "Managed Consortia". A prominent feature is the "MTEC" section, which includes the MTEC logo and the text "Medical Technology Enterprise Consortium". Below this, there is a link for "MTEC BIDS Home" with sub-links for "Learn More" and "How to Join". On the right side, there is a "Login/Registration" section with input fields for "User Name:" and "Password:", a "Login" button, and links for "Forgot Your User Name?", "Forgot Your Password?", and "New Registration". A "NOTE:" section below this states: "To respond to a RPP you must register for a submitter account." At the bottom right, there is a "Need Help?" section with links for "Help Request" (Request help about this website.) and "Contact Help" (Request website help.).

Login to your BIDS Account.

Then select the “MTEC BIDS Home” link

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.

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

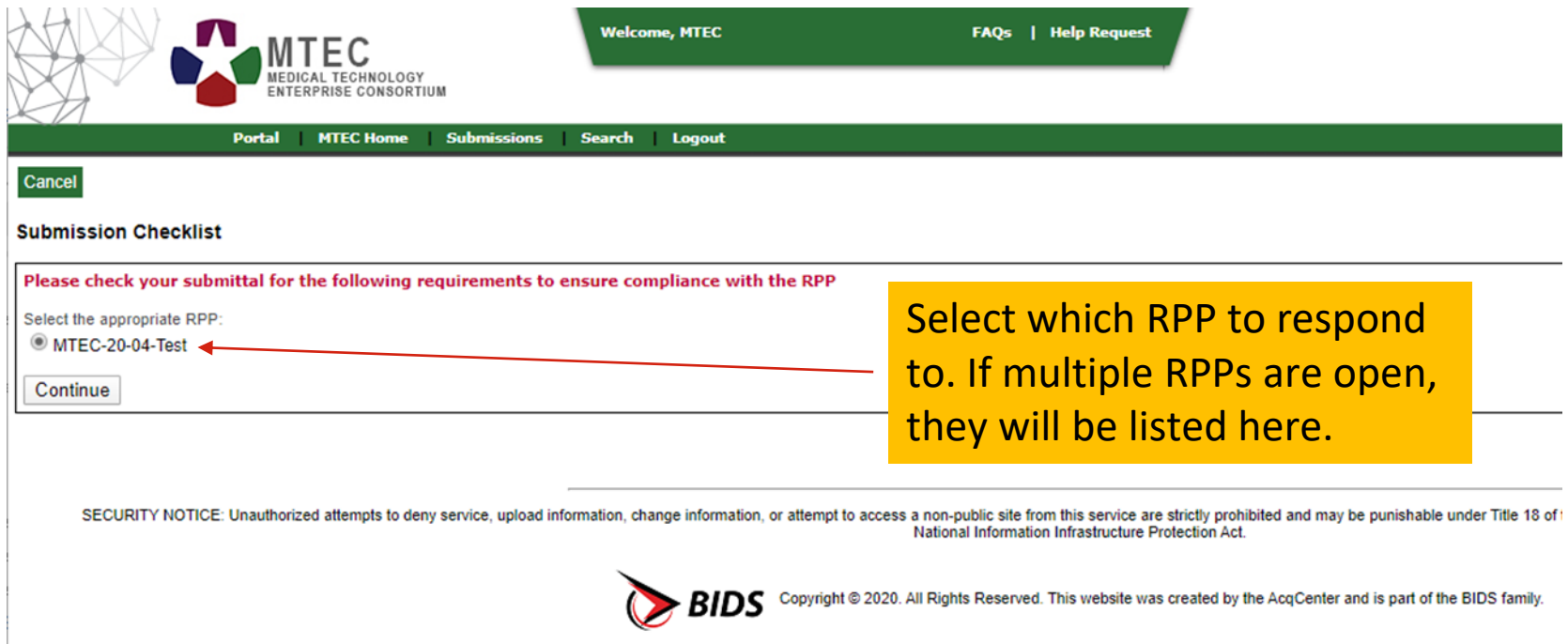
solicitation on this site, you must be a member of the MTEC Consortium. To verify your status, please visit: <https://mtec-sc.org/>

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 has a "Cancel" button and a "Submission Checklist" section. The checklist contains the text "Please check your submittal for the following requirements to ensure compliance with the RPP" and "Select the appropriate RPP:". Below this, there is a radio button selected 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 radio button. 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

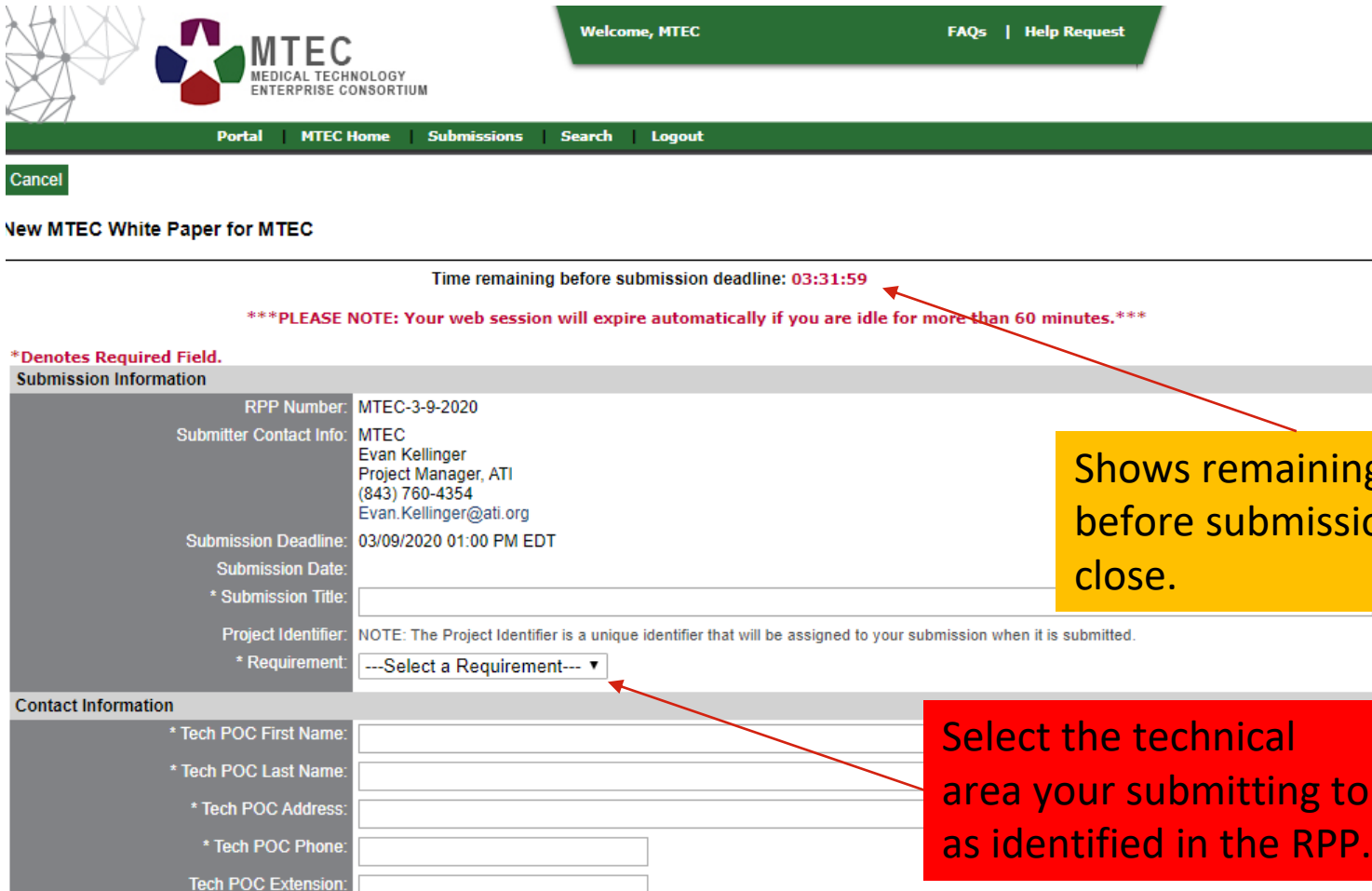
Continue

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

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.***". A section titled "*Denotes Required Field." contains the "Submission Information" form. This form includes fields for "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" (empty text input), "Project Identifier" (NOTE: The Project Identifier is a unique identifier that will be assigned to your submission when it is submitted.), and "* Requirement" (dropdown menu showing "---Select a Requirement---"). Below this is the "Contact Information" section with fields for "* Tech POC First Name", "* Tech POC Last Name", "* Tech POC Address", "* Tech POC Phone", and "Tech POC Extension". Two callout boxes provide instructions: a yellow box points to the timer with the text "Shows remaining time before submission close.", and a red box points to the requirement dropdown with the text "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.