

## Request for Project Proposals



**Solicitation Number: MTEC-20-15-TBI**

**“Candidate Acute Traumatic Brain Injury (TBI) Management Capabilities (CATMC) and Acute TBI Diagnostics and Monitoring (ATDM) in Austere Environments”**

Issued by:

Advanced Technology International (ATI),

MTEC Consortium Manager (CM)

315 Sigma Drive

Summerville, SC 29486

for the

Medical Technology Enterprise Consortium (MTEC)

***Request Issue Date: July 30, 2020***

***Solutions Brief Due Date: September 1, 2020***

***Noon Eastern Time Zone***

***White Papers Are NOT Required***

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## **1 Executive Summary**

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### **1.1. The Medical Technology Enterprise Consortium**

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

- (a) biomedical research and prototyping;
- (b) exploration of private sector technology opportunities;
- (c) technology transfer; and
- (d) deployment of intellectual property (IP) and follow-on production.

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 Proposal Preparation Guide (PPG) and MTEC website.

MTEC operates under an Other Transaction Agreement (OTA) for prototypes with USAMRDC. As defined in the OTA Guide dated November 2018, a prototype project addresses a proof of concept, model, reverse engineering to address obsolescence, pilot, novel application of commercial technologies for defense purposes, agile development activity, creation, design, development, demonstration of technical or operational utility, or combinations of the foregoing. A process, including a business process, may be the subject of a prototype project. Although assistance terms are generally not appropriate in OT agreements, ancillary work efforts that are necessary for completion of the prototype project, such as test site training or limited logistics support, may be included in prototype projects. A prototype may be physical, virtual, or conceptual in nature. A prototype project may be fully funded by 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.

### **1.2. Purpose**

This solicitation, issued by the MTEC Consortium Manager (CM), Advanced Technology International (ATI), represents a Request for Project Proposals (RPP) for MTEC support of the USAMRDC Combat Casualty Care Research Program (CCCRP). Strategic oversight for the award(s) supported by this RPP will be provided by USAMRDC. Project management will be

conducted by the Congressional Directed Medical Research Program (CDMRP). Portfolio management will be conducted by CCCRP.

This program aims to support the acute diagnostic, therapeutic and management technologies across the spectrum of traumatic brain injury (TBI) severities capable of being used in a far-forward operational environment:

- FOCUS AREA #1 (Treatments): Development of an acute treatment (pharmaceutical, technology, etc.) for TBI.
- FOCUS AREA #2 (Diagnostics): Diagnostic, prognostic and management technologies for acute, early intervention for TBI.

## **2 Administrative Overview**

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### **2.1. Request for Project Proposals (RPP)**

Each MTEC Solution Brief submitted must be in accordance with the mandatory format provided in the MTEC PPG, which is available on the Members-Only MTEC website at [www.mtec-sc.org](http://www.mtec-sc.org). **White papers are not required for this RPP.** The Government reserves the right to award Solution Briefs received from this RPP on a follow-on prototype OTA or other stand-alone OTAs as necessary to meet mission requirements.

### **2.2. Proposers Conference**

MTEC will host a Proposers Conference within two weeks after the release of the RPP that will be conducted via webinar. 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.

### **2.3. Funding Availability and Type of Funding Instrument Issued**

The Government currently has available the following **for the base period of performance (PoP1)** of up to 24 months (18 months or less is preferable):

- FOCUS AREA #1 (Treatments): Approximately \$12 Million
- FOCUS AREA #2 (Diagnostics): Approximately \$9.2 Million

The maximum request for Government funding for each Solution Brief should not exceed \$2 million for projects proposing to achieve TRL 5 and \$3 million to achieve TRL 6. **Cost sharing, including cash and in kind (e.g., personnel or product) contributions are strongly encouraged and have no limit.**

MTEC anticipates that one or more awards will be made to qualified Offerors to accomplish the statement of work. It is possible that a single Offeror could receive an award for more than one Focus Area.

Additional 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 6 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 the completion of milestones.

#### **2.4. Acquisition Approach & Rolling Down-Selection**

This RPP will be conducted using a multi-staged approach. In Stage 1, current MTEC members are invited to submit Solution Briefs using the mandatory format contained in this RPP (see Section 6 of this RPP). The Government will evaluate Solution Briefs submitted and will select the Solution Briefs that best meet their current technology priorities using the criteria in Section 7 of this RPP. Offerors whose proposed solution is selected for further consideration based on the Solution Brief evaluation will be invited to submit a "pitch" in Stage 2. Notification letters will contain specific Stage 2 proposal submission requirements. See Section 6 below for additional details regarding the Stage 2 solicitation process.

Offerors are hereby notified that the Government intends to utilize a **rolling down-select** approach **during the performance** of prototype projects awarded as a result of this RPP. Using this approach, the Government intends to award projects, structured into two different 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 to occur 20 months into PoP1). See the proposal format requirements and instructions to Offerors detailed under Section 6 ("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.

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

The Government-selected Research Project Awards will be funded under the Other Transaction Agreement for prototype projects (OTA) Number W81XWH-15-9-0001 with MTEC administered by the CM, ATI. The CM will negotiate and execute a Base Agreement with MTEC members (if not yet executed). The same provisions will govern this Base Agreement as the OTA for prototype projects between the Government and MTEC. Subsequently, any proposal that is selected for award will be funded through a Research Project Award issued under the member's Base Agreement. A sample of the MTEC Base Agreement can be found on the MTEC website and Members-Only website at [www.mtec-sc.org](http://www.mtec-sc.org).

**At the time of the submission, if Offerors have not yet executed a Base Agreement, then Offerors must certify on the cover page of their Solution Brief that, if selected for award, they will abide by the terms and conditions of the latest version of the MTEC Base Agreement.** If the Offeror already has executed an MTEC Base Agreement with the MTEC CM, then the Offeror must state on the cover page of its Solution Brief that, if selected for award, it anticipates the proposed effort will be funded under its executed MTEC Base Agreement.

## **2.5. MTEC Member Teaming**

While teaming is not required for this effort, Offerors are encouraged to consider teaming during the proposal preparation period (prior to Solution Brief submission) if they cannot address the full scope of technical requirements of the RPP or otherwise believe a team may be beneficial to the Government. MTEC members are encouraged to use the MTEC Database Collaboration Tool. The purpose of the tool is to help MTEC member organizations identify potential teaming partners by providing a quick and easy way to search the membership for specific technology capabilities, collaboration interest, core business areas/focus, Research and Development (R&D) highlights/projects, and technical expertise. The Primary Point of Contact for each member organization is provided access to the collaboration database tool to make edits and populate their organization's profile. There are two sections as part of the profile relevant to teaming:

- "Collaboration Interests" - Select the type of teaming opportunities your organization would be interested in. This information is crucial when organizations need to search

the membership for specific capabilities/expertise that other members are willing to offer.

- “Solicitation Collaboration Interests” - Input specific active solicitations that you are interested in teaming on. This information will help organizations interested in a specific funding opportunities identify others that are interested to partner in regards to the same funding opportunity. Contact information for each organization is provided as part of the member profile in the collaboration database tool to foster follow-up conversations between members as needed.

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

## **2.6. Proprietary Information**

The MTEC CM will oversee submission of Solution Briefs submitted in response to this RPP. The MTEC CM shall take the necessary steps to protect all proprietary information and shall not use such proprietary information for purposes other than the evaluation of an Offeror’s Solution Brief and the subsequent agreement administration if the Solution Brief is selected for award. In accordance with the PPG, please mark all Confidential or Proprietary Information as such. An Offeror’s submission of a Solution Brief under this RPP indicates concurrence with the aforementioned CM responsibilities.

Also, as part of MTEC’s mission to incorporate philanthropic donations, MTEC frequently makes contact with private entities (e.g., foundations, investor groups, organizations, individuals) that award grants or otherwise co-fund research, and/or operates in research areas that are aligned with those of MTEC. These private entities may be interested in reviewing certain Proposals within their program areas, allowing opportunities to attract supplemental funding sources. On your Proposal Cover Page, please indicate your willingness to allow MTEC Officers and Directors access to your Proposal for the purposes of engaging in outreach activities with these private organizations. MTEC Officers and Directors granted Proposal access have signed Non-disclosure Agreements (NDAs) and Organizational Conflict of Interest (OCI) statements. Additionally, all Technical Evaluation Panel participants will agree to, and sign a nonproprietary information and a conflict of interest document.

## **2.7. Federal Interagency Traumatic Brain Injury Research (FITBIR) Data Sharing**

The DoD requires that awardees make TBI research data generated by this award mechanism available to the research community through the FITBIR Informatics System. The FITBIR Informatics System is a free resource designed to accelerate research progress by allowing the storage, re-analysis, integration, and rigorous comparison of multiple datasets. Currently FITBIR eligible research include all studies generating prospectively collected human TBI subject data (e.g., clinical, demographic, phenotypic, imaging, and genomic).

Data reporting to FITBIR is an opportunity for investigators to facilitate their own research and to collaborate with others engaged in similar research. While there is no direct charge to users of the FITBIR Informatics System, a project estimation tool (<https://fitbir.nih.gov/jsp/contribute/fitbir-costs.jsp>) is available to help estimate costs and manpower needs that may be associated with data submission. FITBIR guidance and policies, as well as the considerable advantages of FITBIR participation to the researcher, are detailed at <http://fitbir.nih.gov/>.

In order to share data with FITBIR, three elements must be included in the proposed research:

1. Updated informed consent language that includes FITBIR data sharing. Sample consent language is included in Appendix III.
2. Global Unique Identifier (GUID): FITBIR encourages collaboration between laboratories, as well as interconnectivity with other informatics platforms. Such community-wide sharing requires common data definitions and standards. FITBIR allows for de-identification and storage of data (medical imaging clinical assessment, environmental and behavioral history, etc.) of various types (text, numeric, image, time series, etc.). Use of FITBIR's GUID system facilitates repeated and multi-user access to data without the need to personally identify data sources. In order to generate a GUID for a subject, the following personally identifiable information (PII) must be collected in the proposed research:
  - a. Complete legal given (first) name of subject at birth
  - b. Complete legal additional name of subject at birth (if subject has a middle name)
  - c. Complete legal family (last) name of subject at birth
  - d. Day of birth
  - e. Month of birth
  - f. Year of birth
  - g. Name of city/municipality in which subject was born
  - h. Country of birth

Note that this PII is never sent to the FITBIR system. PII cannot be extracted from the GUID. Information on GUID compliance with Health Insurance Portability and Accountability Act (HIPAA) regulations can be found at <https://fitbir.nih.gov/content/global-unique-identifier>.

3. Common Data Elements (CDEs): Research data elements must be reported using the National Institute of Neurological Disorders and Stroke (NINDS) TBI CDEs or entered into the FITBIR data dictionary as new, unique data elements (UDEs). For the most current version of the NINDS TBI CDEs, go to <http://www.commondataelements.ninds.nih.gov>. Assistance will be available to help the researchers map their study variables to specific CDEs and ensure the formats of the CDEs collected are compatible with the FITBIR Informatics System. Use of the TBI CDEs is required wherever possible in an effort to create standardized definitions and guidelines about the kinds of data to collect and the

data collection methods that should be used in clinical studies of TBI. Use of UDEs is strongly discouraged and subject to program approval.

## **2.8. Offeror Eligibility**

Offerors must be MTEC Members in good standing. Offerors submitting Solution Briefs as the prime contractor must be MTEC members of good standing by August 27, 2020.

## **2.9. Inclusion of Nontraditional Defense Contractors or Nonprofit Research Institutions**

Proposals that do not include Nontraditional Defense Contractor or Nonprofit Research Institution participation to a significant extent, or do not propose at least one third acceptable cost sharing, will not be eligible for award.

This requirement is a statutory element of the Other Transaction Authority. Please see the MTEC PPG and RPP (Section 5) for additional details.

## **2.10. Nontraditional Defense Contractor Definition**

A nontraditional defense contractor is a business unit that has not, for a period of **at least one year prior to the issue date of the Request for Project Proposals**, entered into or performed on any contract or subcontract that is subject to full coverage under the cost accounting standards (CAS) prescribed pursuant to section 26 of the Office of Federal Procurement Policy Act (41 U.S.C. 422) and the regulations implementing such section.

## **2.11. Requirements**

Research Projects selected for funding under this RPP are required to meet at least one of the following conditions:

- Have at least one nontraditional defense contractor or nonprofit research institution participating to a significant extent
- 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).
- Provide at least 1/3 of the Research Project cost as cost share.

Beyond that, cost sharing is encouraged if possible, as it leads to stronger leveraging of Government-Contractor collaboration.

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 (see PPG)** 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:

- a. Supplying a new key technology, product or process;
- b. Supplying a novel application or approach to an existing technology, product or process;
- c. Providing a material increase in the performance, efficiency, quality or versatility of a key technology, product or process;
- d. Accomplishing a significant amount of the prototype project;
- e. Causing a material reduction in the cost or schedule of the prototype project; and,
- f. Provide for a material increase in performance of the prototype project

## **2.12. Cost Sharing Definition**

Cost sharing is defined as the resources expended by the award recipients on the proposed statement of work (SOW). If cost sharing is proposed, then the Offeror shall state the amount that is being proposed and whether the cost sharing is a cash contribution or in-kind contribution; provide a description of each cost share item proposed; the proposed dollar amount for each cost share item proposed; and the valuation technique used (e.g., vendor quote, historical cost, labor hours and labor rates, number of trips, etc.). Cost sharing is encouraged if possible, as it leads to stronger leveraging of Government-contractor collaboration.

### **Cash Contribution**

Cash Contribution means the Consortium and/or the Research Project Awardee (or Awardees' lower tier sub-awards) financial resources expended to perform a Research Project. The cash contribution may be derived from the Consortium's or Research Project Awardee (or Awardees' sub-awards) 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 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' sub-award efforts expended on the SOW of a Research Project, and restocking the parts and material consumed.

### **In-Kind Contribution**

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

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

See the MTEC PPG for additional details. If the offer contains multiple team members, this information shall be provided for each team member providing cost share.

### **2.13. MTEC Assessment Fee**

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

### **2.14. Intellectual Property**

Intellectual Property (IP) rights for MTEC Research Project Awards will be defined in the terms of an awardee's Base Agreement and resultant Task Orders. MTEC reserves the right to assist in the negotiation of IP, royalties, licensing, future development, etc., between the Government and the individual performers during the entire award period.

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

#### **Royalty Payment Agreements**

Government-funded research projects awarded through MTEC will be subject to a 10% royalty on all Net Revenues received by the Research Project Award recipient resulting

from the licensing/commercialization of the technology, capped at 200% of the Government funding provided.

#### **Additional Research Project Award Assessment**

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

#### **2.15. Data Rights**

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

See Attachment E for more detail.

#### **2.16. Expected Award Date**

Offeror should plan on the period of performance beginning May 1, 2021 (subject to change). The Government reserves the right to change the proposed period of performance start date through negotiations via the CM and prior to issuing a Research Project Award.

#### **2.17. Anticipated Solutions Brief Selection Notification**

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

### **3 Solution Brief**

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#### **3.1. Solution Brief**

The MTEC will use a streamlined, interactive approach for this RPP. Because of the nature of the requirements set forth in this RPP, this streamlined, interactive approach is anticipated to be a better means to highlight company methodologies and skills that should allow the Government to gain a fuller appreciation of the work required to be completed. It provides more freedom and initiative to the Offeror to describe how the Offeror would approach and solve such an action. The following sections describe the formats and requirements of the Solution Brief.

*Offerors who submit Solution Briefs in response to this RPP must submit by the date on the cover page of this RPP. Solution Briefs received after the time and date specified will not be evaluated.*

### **3.2. Solution Brief Submission**

Solution Briefs shall be submitted by the date and time specified on the cover page using BIDS: <https://ati2.acgcenter.com/ATI2/Portal.nsf/Start?ReadForm>. Include the **MTEC-20-15-TBI Solicitation Number** on each Solution Brief submitted. See RPP Attachment F for further information regarding BIDS registration and submission.

Do not submit any classified information in the Solution Brief submission.

### **3.3. Submission Format**

Offerors should submit files in Microsoft Office formats or Adobe Acrobat (PDF – portable document format) as indicated below. ZIP files and other application formats are not acceptable. All files must be print-capable and without a password required. Filenames must contain the appropriate filename extension (.docx, .doc, .pptx, .ppt, .xlsx, .xls or .pdf). Filenames should not contain special characters. Apple users must ensure the entire filename and path are free of spaces and special characters.

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

## **4 Solution Brief Preparation Instructions**

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### **4.1. General Instructions**

The Solution Brief and Cost Proposal format provided in this MTEC RPP are mandatory and shall reference this RPP number (MTEC-20-15-TBI). Offerors are encouraged to contact the Point-of-Contact (POC) identified herein up until the Solution Brief submission date/time to clarify requirements.

All eligible Offerors may submit Solution Briefs for evaluation according to the criteria set forth herein. Offerors are advised that only ATI as the MTEC's CM, with the approval of the DoD Agreements Officer, is legally authorized to contractually bind or otherwise commit funding for selected awards as result of this RPP.

## 5 Technical Requirements

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### 5.1. Introduction

Current wartime operations assume that the United States and our allies will maintain air, land, maritime, space and cyber superiority. Future conflicts against peer and near-peer adversaries are expected to be layered stand-offs, fought across multiple domains (Multi-Domain Operations, MDO). Mission success will be determined by our ability to compete to expand the competitive space, penetrate both strategic and operationally, disintegrate enemy's defenses, exploit enemy weaknesses and re-compete to consolidate gains. Medical plays a critical role in each aspect of MDO and must modernize rapidly to maintain Force readiness and increase soldier lethality. Diagnosis, treatment, monitoring, and maintenance of TBI casualties in the acute setting can significantly improve long-term functional outcomes and reduce injury severity. Development of diagnosis and treatment interventions to reduce injury severity and improve casualty maintenance that can be employed at Role 1 (far-forward medical care), over the course of the subsequent 1-3 days following injury, will facilitate reductions in permanent brain damage, better Warfighter care and improved return-to-duty times.

For additional information on JPC-6/CCCRP, the program's previous and current successes, and other documents related to the program's long-term planning efforts, please visit the CCCRP official website at <https://ccc.amedd.army.mil/Pages/default.aspx>

### 5.2. Technical Focus Area

Traumatic brain injury (TBI) is a major health burden in both military and civilian populations. In the last two decades, there have been approximately 420,000 documented incidents of Service members sustaining at least one TBI. Future combat operations are expected to result in an increase in time to evacuation, delaying TBI diagnosis and treatment during the most critical period after injury. **This MTEC RPP is aimed at acute diagnostic, therapeutic and management technologies across the spectrum of TBI severities capable of being used in a far-forward operational environment.**

The CCCRP has identified two focus areas for funding. To meet the intent of this RPP, each Solution Brief **MUST** specifically address only **ONE** of the two Focus Areas described below. Offerors are not limited to a Solution Brief submission. Projects not aligned to at least one of these Focus Areas will not be considered for funding.

**FOCUS AREA #1 (Treatments):** Development of a treatment (pharmaceutical, technological, etc.) for traumatic brain injury.

The intent of this focus area is to enable the advancement of candidate treatments (pharmaceutical, technological, etc.) to TRL 6 for the treatment of TBI, for eventual evaluation by the TBI Clinical Trial Network as appropriate. Despite the enormous burden of TBI on Service members and their family, there is no effective FDA-approved

therapeutic intervention. In addition to the complexities of treating TBI, future operational environments pose an addition barrier to the treatment of TBI: time and location. Through MTEC, the DoD U.S. Army Medical Materiel Development Activity (USAMMDA) has recently made an award and established a contractual relationship with a competent and experienced TBI Clinical Trial Network to enable the rapid clinical testing of several TBI drug candidates. The intent of this prior award was to establish an experienced and funded infrastructure that could be made available to drug sponsors/industry partners for the evaluation of candidate TBI drugs in Phase 2 clinical trials. The awarded TBI Clinical Trial Network (<https://tracktbinet.ucsf.edu/>) brings 18 potential clinical sites and staff that are very familiar with TBI diagnosis, studies and treatment. The already awarded TBI Clinical Trial Network is now poised and ready to collaborate with several drug sponsors/industry partners to design and execute focused Phase 2 clinical trials on TBI drug candidates, with the goal to reduce the overall risk of future investment in a Phase 3 clinical trial for TBI.

**FOCUS AREA #2 (Diagnostics):** Diagnostic, prognostic and management technologies for TBI, most likely requiring FDA clearance.

The intent of this focus area is to enable the advancement of candidate technologies to TRL 6 for the objective diagnosis, prognosis, and/or management of TBI. Currently, TBI severity is stratified by Glasgow Coma Scale (GCS)- mild (GCS 14-15), moderate (GCS 9-13), and severe (GCS 3-8); however, a more thorough classification of TBI based on endophenotypic characterization of the injury (neurological exam, imaging, blood-based biomarkers, symptomology, etc.) would provide a more comprehensive picture of the overall injury burden. Additionally, in future combat operations, delayed evacuation times will create a prolonged care scenario that will require TBI casualty management for periods in excess of 24 hours. Examples of these technologies include non-invasive and portable TBI diagnosis and neurocritical care parameter monitoring technology.

**Offerors should only propose technology solutions that meet the following two criteria:**

1. Currently be at Technology Readiness Level (TRL) of 4 or 5 [definition of TRLs – <https://mtec-sc.org/wp-content/uploads/2016/12/TRL-definitions.pdf>]; and,
2. Currently be in development or commercially available.

**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. [NOTE: This RPP allows for proposed solutions to be currently at TRL 4 of 5 at the time of submission. It is the goal that proposed projects should achieve TRL

6 by the end of the total program (which may include potential follow-on funding and PoP beyond the initial base PoP of 24 months (Phase 1)).]

- **Industry Partners:** It is expected that the eventual goal of projects funded by this RPP will transition to organizations for the preparation for (e.g., advanced development of the prototype) and execution of Phase 2 clinical trials with the ultimate goal to reach market. While not a requirement, Offerors are strongly encouraged to include industry partnerships as appropriate.
- **Cost Share:** The Government funds provided for this initiative are not anticipated to be the sole funding resource for the efforts. Because the RPP is focused on prototyping activities, rather than basic science and discovery, it is anticipated that the Government funds would provide incentive for industry funding to join the project. While not a requirement, Offerors are strongly encouraged to include Cost Share as appropriate.
- **Military Impact:** Priority will be given to technologies that can be utilized for all injury severities and can be scaled to fit the needs of DoD. Offerors need to demonstrate the capability to complete TRL 6 with an appreciation of the military and commercial markets for TBI interventions, and demonstrate an understanding of the military need for far forward diagnostic and therapeutic interventions for TBI.

### 5.3. Scope of Work

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

The initial, maximum of 24-month base PoP1 should be focused on tasks relevant to advance the prototype to the next TRL. Project scope should be proposed based on the prototype's maturity (TRL 4 vs. 5) at the time of submission. The work in the base PoP1 could include, but is not limited to:

- Prototype refinement/maturation progressing towards clinical product
- Pre-clinical work (as needed) to support an Investigational Device Exemption (IDE) or Investigational New Drug (IND) application (or other appropriate FDA) submission
- Animal studies under Good Laboratory Practice (GLP) (as needed) to support the IDE or IND (or other appropriate FDA) submission
- IDE or IND (or other appropriate FDA) submission
- Clinical safety studies (as needed) to support regulatory approval/clearance
- 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, considering military-relevant environments
- Establishment of Good Manufacturing Practice (GMP) manufacturing for clinical trials and for market release
- Interoperability and open-source technology

- 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:**

Prior to the end of the base PoP (tentatively projected to occur 20 months into PoP1), the Government will conduct an **in process review (IPR)**, in which the Awardees will attend and participate in, to assess the work completed for each PoP1 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 two weeks prior to the date of the IPR). This deliverable will be reviewed and evaluated as part of the Go/No-Go decision point during which time the Government will make award recommendations for the subsequent 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 Step 1 (Solution Brief) submission.

**Potential for Follow-on Work:**

Potential follow-on work for PoP2 and subsequent PoPs may be awarded based on the advancement in prototype maturity during the base PoP1. Potential follow-on work may include tasks related to advancement of prototype maturity to achieve TRL 7, and/or to expand the use or utility of the prototype.

**5.4. Restrictions on Animal and Human Subjects:**

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

***These restrictions include mandatory Government review and reporting processes that will impact the Offeror's schedule.***

For example, the clinical studies under this RPP shall not begin until the USAMRDC Office of Research Protections (ORP) provides authorization that the research may proceed. The USAMRDC ORP will issue written approval to begin research under separate notification. Written approval to proceed from the USAMRDC ORP is also required for any Research Project Awardee (or lower tier sub-awards) that will use funds from this award to conduct research involving human subjects. Offerors must allow at least 60 days in their schedule for the ORP review and authorization process.

## **6 Solution Brief Preparation**

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### **6.1. Preparation of the Solution Brief**

Offerors submitting Solution Briefs in response to this RPP will be required to submit using the following steps outlined below:

#### ***Step 1: Solution Brief***

##### **Required Submission Documents (1): Submitted via BIDS**

- **Solution Brief: One PDF document 5MB or lower.**

The Offeror will submit a Solution Brief, which describes the overall technical concept and approach along with the viability toward the Offeror's specific effort. The following sections must be included in the Solution Brief:

- **Cover Page** (included in the page limit) must include the following information:
  - Title of Solution Brief
  - Offeror's name and contact information (such as name of the organization, point of contact's name, email address, phone number, mailing address, etc.)
  - Statement that "This Solution Brief is submitted pursuant to the RPP MTEC-20-15-TBI"
  - Indicate which Focus Area this proposal is addressing (only 1 focus area may be selected per Solution Brief):
    - Focus Area #1: Treatments
    - Focus Area #2: Diagnostics
  - Dates of submission and signature of official authorized to obligate the institution contractually

- Willingness to allow MTEC Officers access to your Solution Brief 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 Solution Briefs and Cost Proposals within their program areas, allowing opportunities to attract supplemental funding sources. Please indicate your willingness to allow MTEC access to your Solution Brief for the purposes of engaging in outreach activities with these private sector entities. MTEC staff has signed NDAs and OCI statements.]
- **Approach:** [Briefly describe your approach to solving the problem. Include relevant background 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.]
- **Regulatory Pathway:** [Provide a brief description of the anticipated regulatory pathway for the base PoP1 and proposed follow-on work to achieve TRL 6.]
- **Commercialization Strategy:** [Provide a brief description of the commercialization plans.]
- **Military Impact:** [Offeror should demonstrate an appreciation of the DoD and demonstrate an understanding of the DoD need for far-forward diagnostic and therapeutic interventions for TBI.]
- **Participants:** [Briefly state the qualifications of the Principal Investigator, key personnel, and organizations that will perform the SOW proposed in the base PoP1.]

- **Base POP:** [Indicate the proposed base PoP1. Provide an estimated Gantt Chart of the major activities proposed.]
- **Project Management Plan:** [The Solution Brief shall describe the overall project management plan.]
- **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.]
- **Non-traditional defense contractor, 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. Refer to Sections 2.5-2.8 for more information.]
- **Rough Order of Magnitude (ROM) Pricing:** [Refer to Attachment B.]
- **Technical Addendum for Potential Follow-On Work for PoP2:** [Refer to Attachment C, limited to three pages, included in the 15 page Solution Brief page limitation. This technical addendum is a critical component of the Solution Brief submission. Please provide a well-thought out response. This addendum should be indicative of the work that you propose to conduct in PoP2.]
- **Technical Addendum for Expansion of Use or Utility (if applicable):** [Refer to Attachment D, limited to two pages, included in the 15 page Solution Brief page limitation. This technical addendum is a critical component of the Solution Brief submission. Please provide a well-thought out response.]
- **IP and Data Rights:** [Refer to Attachment E, included in the 15 page Solution Brief page limitation. IP and data rights are a critical component of the Solution Brief submission. Please provide a well-thought out response.]

The Solution Brief is limited to fifteen pages (including cover page), 12 point font (or larger), Single-spaced, single-sided, 8.5 inches x 11 inches). Smaller type may be used in figures and tables, but must be clearly legible. Margins on all sides (top, bottom, left, and right) should be at least 0.5 inch. Solution Briefs **exceeding the 15-page limit will not be accepted.**

***Solution Brief Evaluation:***

The CM will distribute all Solution Briefs to the Government for evaluation. The Government will evaluate and determine which proposal(s) to award based on the following criteria:

- **Factor 1 – Technical Feasibility:** Feasibility of the proposed solution and its alignment with the RPP’s topic area, including access to human subject population if applicable.
- **Factor 2 – Potential for Transition:** Soundness of regulatory strategy and potential to achieve TRL 6 with success. Military impact will also be considered as part of this factor.
- **Factor 3 – Project Team:** Strength of the organization/team proposed to complete the work and its financial stability to potentially continue the maturation of the system beyond the scope of this RPP. Includes experience with animal research for IND, and human research, study population recruitment and sustainment.
- **Factor 4 – Cost/Price:** Estimated ROM costs represent reasonable value for proposed solution offered.
- **Factor 5 – OTA Compliance Requirement:** Inclusion of nontraditional or small business participation, nonprofit research institution, or a 1/3 cost share.

***Upon review of the Solution Briefs, Offerors may be invited into Step 2 of the Solution Brief process. Offerors who are not invited to proceed into Step 2 will be provided feedback.***

***Step 2: Solution Brief Pitch:***

**Required Submission Documents (2): Submitted via BIDS**

- **Solution Brief Pitch: One PDF document 5MB or lower.**
- **Statement of Work and Milestone Payment Schedule: One PDF or word document 5MB or lower.**

In Step 2, the Offeror(s) will provide a virtual or in-person “pitch” of the proposed project along with a SOW/Milestone Payment Schedule (MPS) and ROM Pricing (see Attachment A) during a meeting with the Government sponsors for the research. The solution brief pitch should provide more details about the technical and business viability of the proposed work outlined in Phase 1. Specifically, the pitch should include the following:

- **Description:** The Offeror will provide a more robust description of their approach and emphasize why this approach is expected to result in a successful outcome. This approach should follow the SOW/MPS provided with the pitch.
- **Progress:** The Offeror will describe the milestones provided with objective, quantifiable, and measurable metrics that will be used to measure progress during the period of

performance/delivery schedule and describe the oversight managerial methods that will be employed to maintain a quality and timely performance.

- **Relevant Experience:** The Offeror will convey details related to key personnel and past performance(s) that demonstrate relevance to the scope of the proposed work and build confidence in the team's capabilities.
- **Effectiveness (Opportunity and Risk):** The Offeror will identify, assess, evaluate, and clearly convey items (for known-knowns; known-unknowns and potential unknown-unknowns) for opportunities (e.g., reduction in cost or schedule, and/or improvement in performance) and risks within each appropriate project Cost, Schedule, Performance measure of effectiveness. The Offeror will identify objective measures and metrics used to assess each item, the triggering event(s), the expected result of Opportunities and Risk (if risk is unmitigated) item, and the mitigation plan for each identified risk item.
- **Data Rights Assertions:** The Solution Brief will identify any and all proprietary and/or intellectual property involved in the efforts and any associated restrictions that may possibly affect the Government's use of the property in any way whatsoever. Offeror must describe pathway to developing this into a product that can be used by the DoD and other potential customers (if applicable). Include relevant information about existing royalty agreements. See Section 2.13 for format.
- **Cost:** The Solution Brief Pitch must present summarized costs at the task level.
- **Statement of Work and Milestone Payment Schedule submission:** Separately, a Word (.docx or .doc) version of the SOW and MPS and a Word (.docx or .doc) are required. See Attachment A for additional information.

If desired, the Government can request additional information related to specific areas of interest to be included in the pitch. The request for such information will be provided at the end of Step 1 and at the time of invitation to advance into Step 2.

The information discussed during the pitch provides a means for the Government to engage in a discussion with the Offeror to gain a greater understanding of the Solution Brief and the Offeror's capabilities. The pitch should be restricted to **a maximum of One hour** with a total time of two hours to include questions from the Government and discussion. Any materials that will be presented during the pitch or included as supplementary material must be provided in advance of the meeting date. If an in-person meeting cannot be accommodated by the Offeror, then a minimum of a telephonic discussion accompanied by written support material will be required. Briefing slides or documents or a combination thereof can be used to support this effort.

**Evaluation of Step 2:** The Government will evaluate the information provided in each Offeror's Solution Brief (Step 1) and the Solution Brief Pitch (Step 2) to determine which pitch(es) provide(s) the greatest value to the Government. Such a determination will be based on the following criteria:

- Most Important (of equal importance)
  - **Performance:** Overall technical approach and how well Offeror's solution enhances the DoD mission described in the RPP; including processes described to identify and manage risks/opportunities
  - **Schedule:** Suitability of the notional schedule, including processes described to identify and manage risks/opportunities.
  - **Cost:** The parity of the relationship between the Offeror's solution and ROM costs, and whether a superior technical approach is warranted at a higher estimated cost.
  - **Risk-Opportunity:** Identification of risks (with supportable mitigations) and opportunities with the Offeror's approach with objective measurable metrics.
  - Inclusion of nontraditional or small business participation, a nonprofit research organization, or 1/3 cost share.
  
- Less Important (of equal importance)
  - Relevant Experience.
  - Assessment of the potential impact of data rights assertions.

At the conclusion of the Step 2 evaluation, Offerors who are favorably evaluated will be invited to submit a final solution brief (which may be amended from the initial brief to incorporate discussion points from the government interaction) and a cost proposal.

### ***Step 3: Cost Proposal***

**Required Submission Documents (4): Submit to [mtec-contracts@ati.org](mailto:mtec-contracts@ati.org)**

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

The Offerors invited to submit a Cost Proposal are encouraged to contact the MTEC and/or Government with any questions so that all aspects are clearly understood by both parties. The full proposal should include the following and be completed in accordance with Section 3 of this RPP and the PPG.

- **Cost Proposal submission:** one Word (.docx or .doc) or PDF file for Section I: Cost Proposal Narrative (Appendix B) required. Separately, Section II: Cost Proposal Formats (by Task) either in Excel (.xlsx or .xls) or PDF format is required.
- **Warranties and Representations:** If Nontraditional Defense Contractor participation is proposed, Warranties and Representations are required. One Word (.docx or .doc) or PDF file that contains all Warranties and Representations is required.
- **Royalty or Additional Research Project Award Assessment:** Each Offeror will select either the MTEC Additional Assessment Fee or the Royalty Agreement (available on the MTEC members only website), **not both**, and submit a signed copy with the proposal.

## 6.2. Cost Proposal

**Offerors are encouraged to use their own cost formats such that the necessary detail is provided.** MTEC will make cost proposal formats available on the Members-Only MTEC website. The Cost Proposal formats provided in the MTEC PPG are **NOT** mandatory. Refer to the MTEC PPG for additional details.

Each cost should include direct costs and other necessary components as applicable, for example, fringe, General & Administrative Expense (G&A), Facilities & Administrative (F&A), Other Direct Costs (ODC), etc. Offerors shall provide a breakdown of material and ODC costs as applicable.

Please note that compensation to Federal personnel (civil servants or Service members) participating as human subjects (when “On-Duty”), whether or not the research is Federally funded, is **unallowable** (with the exception of some blood draws) in accordance with Department of Defense Instruction number 3216.02 (SUBJECT: Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research). You may access a full version of the DODI by accessing the following link:  
<https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf>

## 6.3. Solution Brief and Cost Proposal Preparation Costs

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

## 6.4. 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.

## 7 Selection

The CM will conduct a preliminary screening of submitted Solution Briefs to ensure compliance with the RPP requirements. As part of the preliminary screening process, Solution Briefs that do not meet the requirements of the RPP may be eliminated from the competition or additional information may be requested by the CM. The Government reserves the right to request additional information or eliminate proposals that do not meet these requirements from further consideration. One of the primary reasons for non-compliance or elimination during the initial screening is the lack of significant nontraditional defense contractor participation, nonprofit research institution participation, or cost share (see RPP Section 2.6). The Cost Sharing/Nontraditional Contractor determination will be made as shown in Table 1:

TABLE 1- COST SHARING/NONTRADITIONAL CONTRACTOR ASSESSMENTS	
RATING	DESCRIPTION
PASS	<p>Offeror proposing an MTEC research project meets at least ONE of the following:</p> <ul style="list-style-type: none"> <li>• Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution</li> <li>• Offeror's Solution Brief has at least one Nontraditional Defense Contractor or Nonprofit Research Institute participating to a significant extent</li> <li>• All significant participants in the transaction other than the Federal Government are small businesses or nontraditional defense contractors</li> <li>• Offeror provides at least one third of the total project cost as acceptable cost share</li> </ul>
FAIL	<p>Offeror proposing an MTEC research project does <b>NOT</b> meet at least ONE of the following:</p> <ul style="list-style-type: none"> <li>• Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution</li> <li>• Offeror's Solution Brief has at least one Nontraditional Defense Contractor or Nonprofit Research Institution participating to a significant extent</li> <li>• All significant participants in the transaction other than the Federal Government are small businesses or nontraditional defense contractors</li> <li>• Offeror provides at least one third of the total project cost as acceptable cost share</li> </ul>

Based on the results of the evaluation of the Solution Brief, the Solution Brief Pitch, and Cost Proposal, Offerors may be selected for funding, placed into the basket, or not selected.

The RPP review and award process may involve the use of contractors as subject-matter-experts or reviewers; where appropriate, the Government will employ NDAs to protect information contained in the RPP as outlined in Section 1.4.

## **8 Points-of-Contact**

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For inquiries, please direct your correspondence to the following contacts:

- Questions concerning contractual, cost or pricing related to this RPP should be directed to the MTEC Contracts Administrator, [mtec-contracts@ati.org](mailto:mtec-contracts@ati.org)
- Technical and membership questions should be directed to the MTEC Director of Research, Dr. Lauren Palestrini, Ph.D., [lauren.palestrini@officer.mtec-sc.org](mailto: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](mailto:kathy.zolman@ati.org)

**Once an Offeror has submitted a Solution Brief, the DoD and the MTEC CM will not discuss evaluation/status until the source selection process is complete.**

## **9 Acronyms/Abbreviations**

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ACURO	U.S. Army Animal Use and Review Office
ATI	Advanced Technology International
CAS	Cost accounting standards
CCCRP	Combat Casualty Care Research Program
CDMRP	Congressionally Directed Medical Research Program
CFR	Code of Federal Regulations
CM	Consortium Manager
CMA	Consortium Member Agreement
CSI	Congressional Special Interest
DHP	Defense Health Program
DoD	Department of Defense
FAQ	Frequently Asked Questions
F&A	Facilities and Administrative Costs
FDA	U.S. Food and Drug Administration
FITBIR	Federal Interagency Traumatic Brain Injury Research (FITBIR)
FOIA	Freedom of Information Act (FOIA)
FY	Fiscal Year

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G&A	General and Administrative Expenses
HRPO	Human Research Protections Office
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
JPC	Joint Program Committee
IND	Investigational New Drug
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IRB	Institutional Review Board
IR&D	Independent Research and Development
M	Millions
MPS	Milestone Payment Schedule
MTEC	Medical Technology Enterprise Consortium
NDA	Nondisclosure Agreement
OCI	Organizational Conflict of Interest
ODC	Other Direct Charges
ORP	Office of Research Protections, USAMRDC
POC	Point-of-Contact
POI	Point of Injury (POI)
POP	Period of performance
OTA	Other Transaction Agreement
PPG	Proposal Preparation Guide
RDA	Research, Development, and Acquisition
ROM	Rough Order of Magnitude
RPP	Request for Project Proposals
SOW	Statement of Work
TBI	Traumatic brain injury
USAMRDC	U.S. Army Medical Research and Development Command
Government	U.S. Government, specifically the DoD

## **Attachment A: Statement of Work (SOW)**

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The SOW developed by the Lead MTEC member organization and included in the Solution Brief Pitch is intended to be incorporated into a binding agreement if selected for award. If no SOW is submitted, there may be no award. The proposed SOW shall contain a summary description of the technical methodology as well as the task description, but not in so much detail as to make the contract inflexible. DO NOT INCLUDE ANY PROPRIETARY INFORMATION OR COMPANY-SENSITIVE INFORMATION IN THE SOW TEXT. The following is the required format for the SOW.

### **Statement of Work**

**Submitted under Request for Project Proposal** (*Insert current Request No.*)

**(Proposed Project Title)**

**Introduction/Background** (*To be provided initially by the Offeror at the time of Solution Brief Pitch submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.*)

**Scope/Project Objective** (*To be provided initially by the Offeror at the time of Solution Brief Pitch submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.*)

This section includes a statement of what the project covers. This should include the technology area to be investigated, the objectives/goals, and major milestones for the effort.

**Requirements** (*To be provided initially by the Offeror at the time of Solution Brief Pitch submission to be finalized by the Government based on negotiation of Scope/Project Objective*).

State the technology objective in the first paragraph and follow with delineated tasks required to meet the overall project goals. The work effort should be segregated into major phases, then tasks and identified in separately numbered paragraphs (similar to the numbered breakdown of these paragraphs). Early phases in which the performance definition is known shall be detailed by subtask with defined work to be performed. Planned incrementally funded phases will require broader, more flexible tasks that are priced up front, and adjusted as required during execution and/or requested by the Government to obtain a technical solution. Tasks will need to track with established adjustable cost or fixed price milestones for payment schedule. Each major task included in the SOW should be priced separately in the cost proposal. Subtasks need not be priced separately in the cost proposal.

**Deliverables** *(To be provided initially by the Offeror at the time of Solution Brief Pitch submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.)*

Results of the technical effort are contractually binding and shall be identified herein. Offerors are advised to read the Base Agreement carefully. Any and all hardware/software to be provided to the Government as a result of this project shall be identified. Deliverables should be submitted in PDF or MS Office format. It must be clear what information will be included in a deliverable either through a descriptive title or elaborating text.

**Milestone Payment Schedule** *(To be provided initially by the Offeror at the time of Solution Brief Pitch submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding. The milestone schedule included should be in editable format (i.e., not a picture))*

The Milestone Payment Schedule should include all milestone deliverables that are intended to be delivered as part of the project, a planned submission date, the monetary value for that deliverable and any cost share, if applicable. For fixed price agreements, when each milestone is submitted, the MTEC member will submit an invoice for the exact amount listed on the milestone payment schedule. For cost reimbursable agreements, the MTEC member is required to assign a monetary value to each milestone. In this case, however, invoice totals are based on cost incurred and will not have to match exactly to the amounts listed on the milestone payment schedule.

The milestones and associated deliverables proposed should, in general:

- be commensurate in number to the size and duration of the project (i.e., a \$5M multi-year project may have 20, while a \$700K shorter term project may have only 6);
- not be structured such that multiple deliverables that might be submitted separately are included under a single milestone;
- be of sufficient monetary value to warrant generation of a deliverable and any associated invoices;
- include at a minimum Quarterly Reports which include both Technical Status and Business Status Reports (due the 25th of Apr, Jul, Oct, Jan), Annual Technical Report, Final Technical Report, and Final Business Status Report. Reports shall have no funding associated with them.

### MTEC Milestone Payment Schedule Example

MTEC Milestone Number	Task Number	Significant Event/ Accomplishments	Due Date	Government Funds	Cost Share	Total Funding
1	N/A	Project Kickoff	12/1/2019	\$20,000		\$20,000
2	N/A	Quarterly Report 1 (October - December, Technical and Business Reports)	1/25/2020	\$ -		\$ -
3	1	Protocol Synopsis	2/28/2020	\$21,075		\$21,075
4	2	Submission for HRPO Approval	2/28/2020	\$21,075		\$21,075
5	3	Submission of Investigational New Drug application to the US FDA	4/30/2020	\$210,757	\$187,457	\$398,214
6	N/A	Quarterly Reports 2 (January - March, Technical and Business Reports)	4/25/2020	\$ -		\$ -
7	N/A	Quarterly Report 3 (April - June, Technical and Business Reports)	7/25/2020	\$ -		\$ -
8	4	Toxicity Studies	10/1/2020	\$63,227		\$63,227
9	N/A	Annual Report 1	10/25/2020	\$ -		\$ -
10	5	FDA authorization trial	11/30/2020	\$84,303		\$84,303
11	6	Research staff trained	11/30/2020	\$ -		\$ -
12	7	Data Management system completed	11/30/2020	\$ -		\$ -
13	8	1 <sup>st</sup> subject screened, randomized and enrolled in study	1/1/2021	\$150,000	\$187,457	\$337,457
14	N/A	Quarterly Report 4 (October - December, Technical and Business Reports)	1/25/2021	\$ -		\$ -
15	9	Completion of dip molding apparatus	3/1/2021	\$ 157,829	\$ 187,457	\$ 345,286

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16	N/A	Quarterly Reports 5 (January - March, Technical and Business Reports)	4/25/2021	\$ -		\$ -
17	10	Assess potential toxicology	6/1/2021	\$157,829		\$157,829
18	N/A	Quarterly Report 6 (April - June, Technical and Business Reports)	7/25/2021	\$ -		\$ -
19	11	Complete 50% patient enrollment	10/1/2021	\$350,000	\$187,457	\$537,457
20	N/A	Annual Report 1	10/25/2021	\$ -		\$ -
21	N/A	Quarterly Report 7 (October - December, Technical and Business Reports)	1/25/2022	\$ -		\$ -
22	12	Electronic Report Forms Developed	3/1/2022	\$315,658	\$187,457	\$503,115
23	N/A	Quarterly Reports 8 (January - March, Technical and Business Reports)	4/25/2022	\$ -		\$ -
24	N/A	Quarterly Report 9 (April - June, Technical and Business Reports)	7/25/2022	\$ -		\$ -
25	13	Complete 100% patient enrollment	8/1/2022	\$315,658	\$187,457	\$503,115
26	N/A	Annual Report 1	10/25/2022	\$ -		\$ -
27	14	Report results from data analysis	11/1/2022	\$157,829		\$157,829
28	N/A	Final Reports ( <b><u>Prior to the POP End</u></b> )	11/30/2022	\$ -		\$ -
			<b>Total</b>	<b>\$2,025,240</b>	<b>\$1,124,742</b>	<b>\$3,149,982</b>

**Please Note:**

1. Firm Fixed Price Contracts – Milestone must be complete before invoicing for fixed priced contracts.
2. Cost Reimbursable Contracts – You may invoice for costs incurred against a milestone. Invoicing should be monthly.

3. Cannot receive payment for a report (i.e. Quarterly, Annual and Final Reports should not have an assigned Government Funded or Cost Share amount.)
4. Quarterly and Annual Reports include BOTH Technical and Business Reports (separate).
5. Final Report due date must be prior to POP end noted in subcontract.
6. MTEC Milestone Numbers are used for administrative purposes and should be sequential.
7. Task Numbers are used to reference the statement of work if they are different from the MTEC Milestone Number.

**Shipping Provisions** *(The following information, if applicable to the negotiated SOW, will be finalized by the Government and the MTEC Consortium Manager based on negotiations)*

- The shipping address is:  
Classified Shipments:  
Outer Packaging  
Inner Packaging

**Data Rights** *(see Section 8.4 of PPG for more information)*

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

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

<b>Report Months</b>	<b>Due Date</b>
January – March	25 April
April - June	25 July
July - September	25 October
October - December	25 January

- Quarterly Reports – The MTEC research project awardee shall prepare a Quarterly Report, which will include a Technical Status Report and a Business Status Report in accordance with the terms and conditions of the Base Agreement. (Required)
  - Annual Technical Report – The project awardee shall prepare an Annual Technical Report for projects whose periods of performances are greater than one year in accordance with the terms and conditions of the Base Agreement. (Required)
  - Final Technical Report – At the completion of the Research Project Award, the awardee will submit a Final Technical Report, which will provide a comprehensive, cumulative, and substantive summary of the progress and significant accomplishments achieved during the total period of the Project effort in accordance with the terms and conditions of the Base Agreement. (Required)
  - Final Business Status Report – At the completion of the Research Project Award, the awardee will submit a Final Business Status Report, which will provide summarized details of the resource status of the Research Project Award, in accordance with the terms and conditions of the Base Agreement. (Required)
-

**Attachment B: Rough Order of Magnitude (ROM) Pricing**

---

Sufficient cost information to substantiate the proposed cost as realistic and reasonable for the proposed effort must be provided to ensure that a complete and fair evaluation of the cost or price can be conducted. **Use the example table format and template below to provide an initial ROM.** 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.

<b>Labor</b>	<i>\$ 100,000.00</i>
<b>Labor Hours</b>	<i>1,000.0 hrs</i>
<b>Subcontractors</b>	<i>\$ 50,000.00</i>
<b>Subcontractors Hours</b>	<i>500.0 hrs</i>
<b>Consultants</b>	<i>\$ 10,000.00</i>
<b>Consultants Hours</b>	<i>100.0 hrs</i>
<b>Material/Equipment</b>	<i>\$ 75,000.00</i>
<b>Other Direct Costs</b>	<i>\$ 1,000.00</i>
<b>Travel</b>	<i>\$ 5,000.00</i>
<b>Indirect cost</b>	<i>\$ 48,200.00</i>
<b>Total Cost</b>	<i>\$ 289,200.00</i>
<b>Fee</b> <i>(Not applicable if cost share is proposed)</i>	<i>\$ 0.00</i>
<b>Total Cost (plus Fee)</b>	<i>\$ 289,200.00</i>
<b>Cost Share</b> <b>(if cost share is proposed then fee is unallowable)</b>	<i>\$ 290,000.00</i>
<b>Total Project Cost</b>	<i>\$ 579,200.00</i>

**Attachment C: Technical Addendum for Potential Follow-On Work**

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**General Instruction:** As noted in Section 5.3 of the RPP, additional funding may be available for potential follow-on work for the continuation of prototype development to TRL 7. Potential follow-on work will be dependent on the maturity of the deliverable at the end of the base POP. Although awards in response to this RPP will initially focus on the scope of work for the first 24 months, this addendum is intended to provide the Sponsor with information on the Offeror's plan for potential follow-on work beyond the base POP. The word discussed in this addendum should be limited to the continued development and advancement of the currently proposed prototype. See Attachment D for potential follow-on work that involved the expansion of use or utility of the proposed prototype. The following template is required as part of the Solution Brief submission. This part of the Solution Brief is limited to three pages. It is included within the Solution Brief page limitation of 15 pages. This is a critical component of the Solution Brief submission, so please provide a well thought-out response.

**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 for the potential follow-on work in total.]

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

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

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

**Rough Order of Magnitude (ROM) Pricing:** [Indicate the ROM pricing (including indirect costs) **using the table format below**. The ROM table should include a column for each potential follow-on task. This information will be used to provide the Sponsor with a reasonable representation of the amount of funding required for each potential follow-on task required to advance the project toward FDA clearance. The labor, travel, material costs, other direct costs, and indirect costs, information should be entered for Offeror (project prime) only. Subcontractors and/or consultants should be included only in the "Subcontractor" section of the table.]

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<b>Labor</b>	<b>\$200,000.00</b>
<b>Subcontractors</b>	<b>\$100,000.00</b>
<b>Consultants</b>	<b>\$20,000.00</b>
<b>Material/Equipment</b>	<b>\$150,000.00</b>
<b>Other Direct Costs</b>	<b>\$2,000.00</b>
<b>Travel</b>	<b>\$10,000.00</b>
<b>Indirect costs</b>	<b>\$96,400.00</b>
<b>Total Cost</b>	<b>\$578,400.00</b>
<b>Fee (Not applicable if cost share is proposed)</b>	<b>\$0.00</b>
<b>Total Cost (plus Fee)</b>	<b>\$578,400.00</b>
<b>Cost Share (if cost share is proposed then fee is un-allowable)</b>	<b>\$580,000.00</b>
<b>Total Project Cost</b>	<b>\$1,158,400.00</b>

**Attachment D: Technical Addendum for Expansion of Use or Utility (if applicable)**

---

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

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

- is NOT applicable  
 is applicable (following the instructions below)

**General Instruction (complete only if the box for “is applicable” is checked):** As noted in Section 5.3 of the RPP, additional funding may be available for potential follow-on work for the expansion of use or utility of the proposed prototype. Although awards in response to this RPP will initially focus on the scope of work for the first 24 months, this addendum is intended to provide the Sponsor with information on the Offeror’s plan for potential follow-on work beyond the base POP. The following template is required as part of the Solution Brief submission. This part of the Solution Brief is limited to two pages (if applicable). It is included within the Solution Brief page limitation of 15 pages. Some examples may include but are not limited to:

- FOCUS AREA #1: a widget that can be added to or complements the diagnostic proposed to be developed during the base POP
- FOCUS AREA #2: an alternative route of administration, or broader clinical indications

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

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

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

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

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

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

**Rough Order of Magnitude (ROM) Pricing:** [Indicate the ROM pricing (including indirect costs) using the table format below. The ROM table should include a column for each potential follow-on task. This information will be used to provide the Sponsor with a reasonable representation of the amount of funding required to advance the project toward FDA clearance. The labor, travel, material costs, other direct costs, and indirect costs, information should be entered for Offeror (project prime) only. Subcontractors and/or consultants should be included only in the “Subcontractor” section of the table.]

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

**Attachment E: IP and Data Rights**

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**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 Solution Brief 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.

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	Restricted	Organization XYZ	Milestones 1, 3, and 6

Request for Project Proposals MTEC-20-15-TBI  
Number W81XWH-15-9-0001

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	exclusively at private expense			
Technical Data Description	Previously developed exclusively at private expense	Limited	Organization XYZ	Milestone 2
Technical Data Description	Previously developed with mixed funding	Government Purpose Rights	Organization XYZ	Milestone 2

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

---

Signature of responsible party for the proposing Prime Offeror

---

DATE

**Attachment F: BIDS Instructions**

---

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

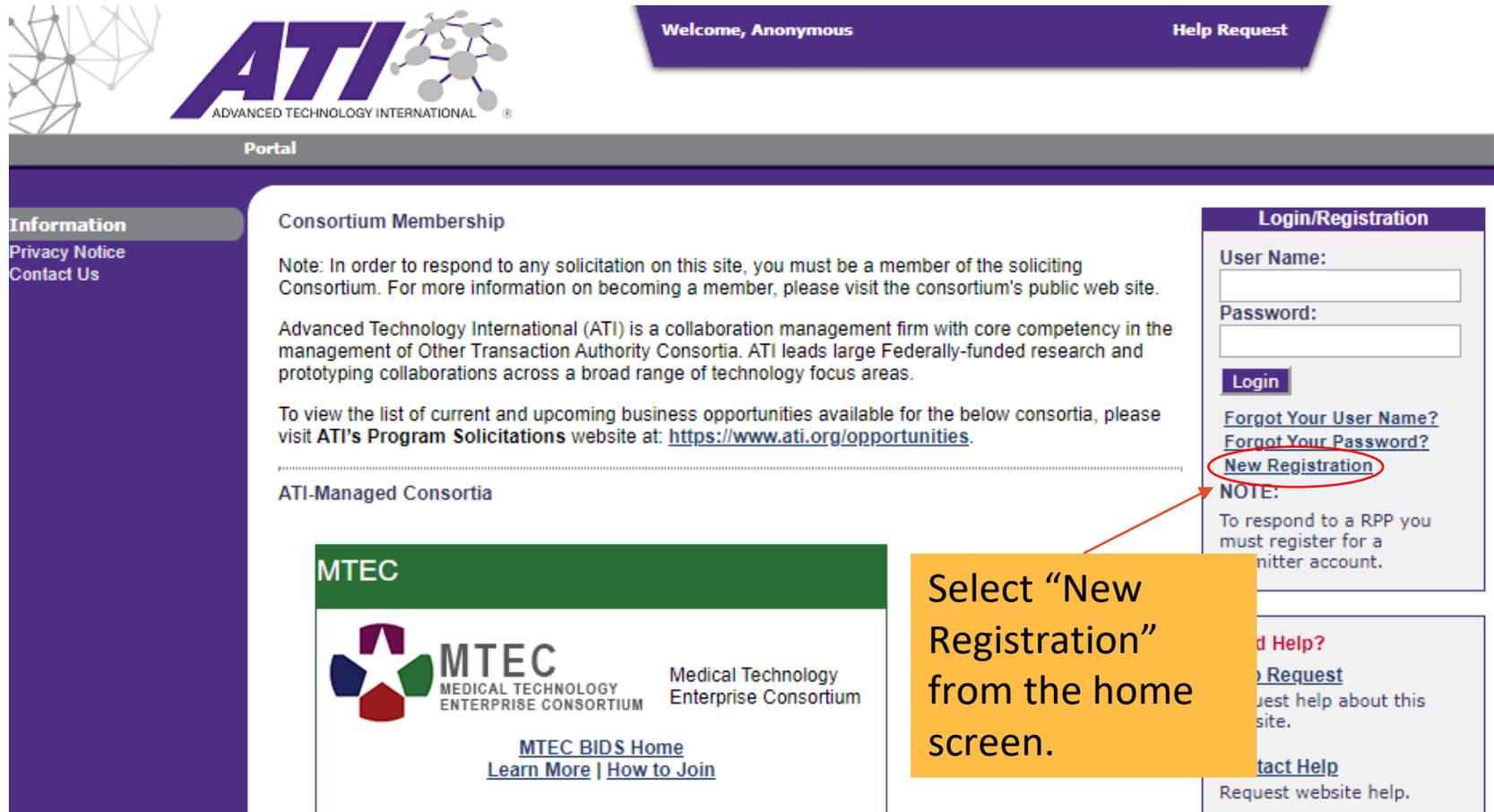
# MTEC BIDS REGISTRATION

*MTEC BIDS URL:*

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

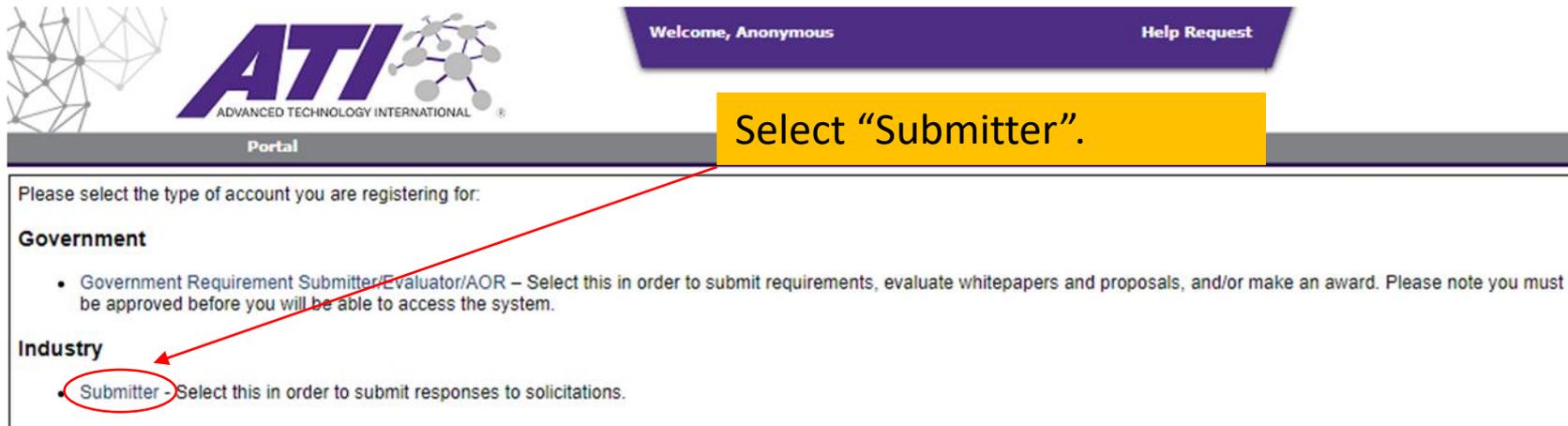
# BIDS New Registration

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



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

## Select “Submitter”



Portal

Welcome, Anonymous Help Request

Select “Submitter”.

Please select the type of account you are registering for:

**Government**

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

**Industry**

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

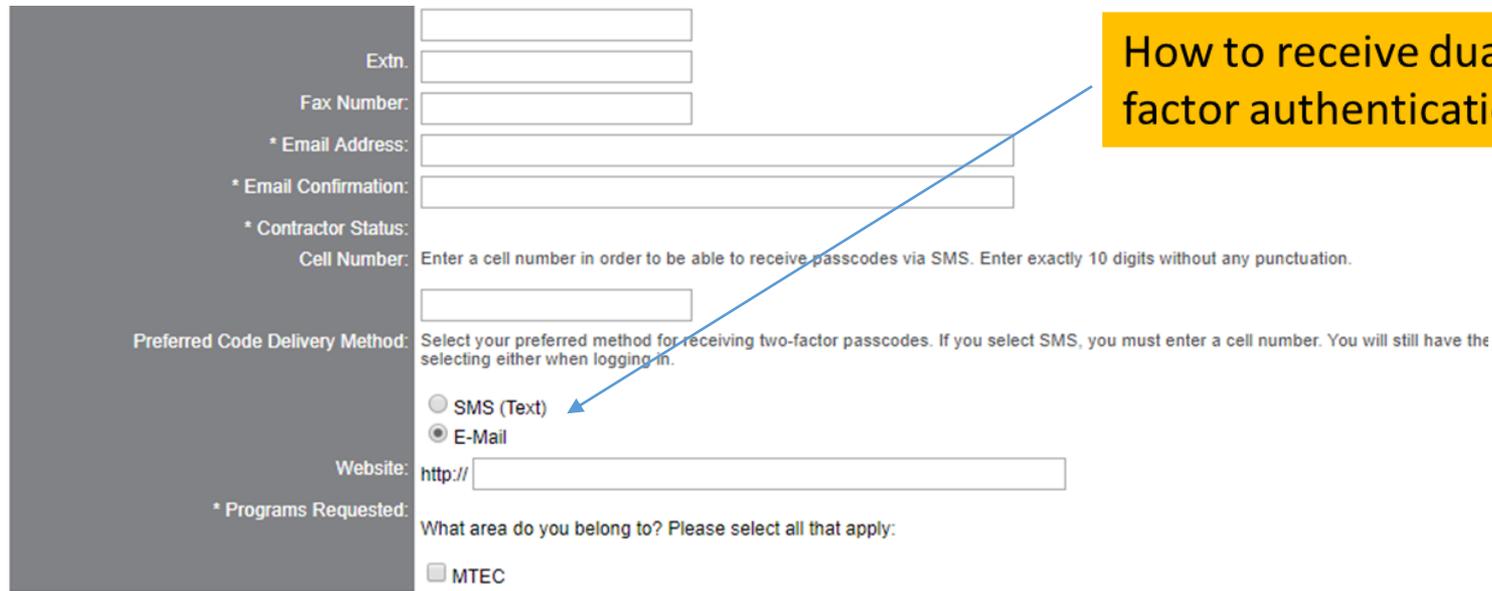
SECURITY NOTICE: Unauthorized attempts to deny service, upload information, change information, or attempt to access a non-public site from this service are strictly prohibited and may be punishable under Title 18 of the U.S. Code to include the Computer Fraud and Abuse Act of 1986 and the National Information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



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# BIDS New Registration

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



Extn.

Fax Number:

\* Email Address:

\* Email Confirmation:

\* Contractor Status:

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

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

SMS (Text) ←

E-Mail

Website: http://

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

MTEC

How to receive dual factor authentication .

Select "Submit Registration" to complete BIDS registration.

# BIDS New Registration

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

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

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

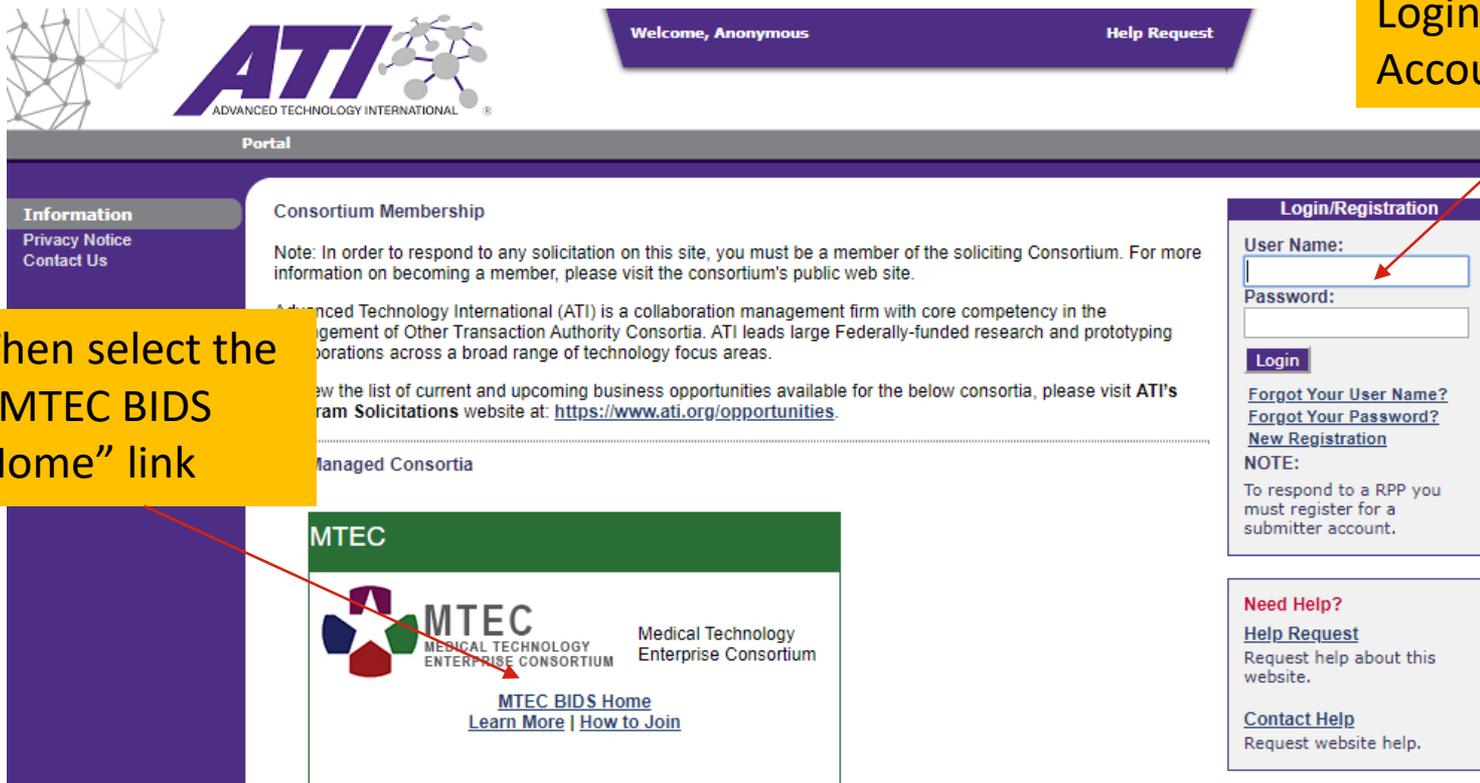
**ALL PROPOSALS MUST BE SUBMITTED BEFORE THE SUBMISSION DUE DATE AND TIME. LATE PROPOSALS CAN NOT BE ACCEPTED.**

# MTEC BIDS PROPOSAL SUBMISSION

*MTEC BIDS URL:*

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

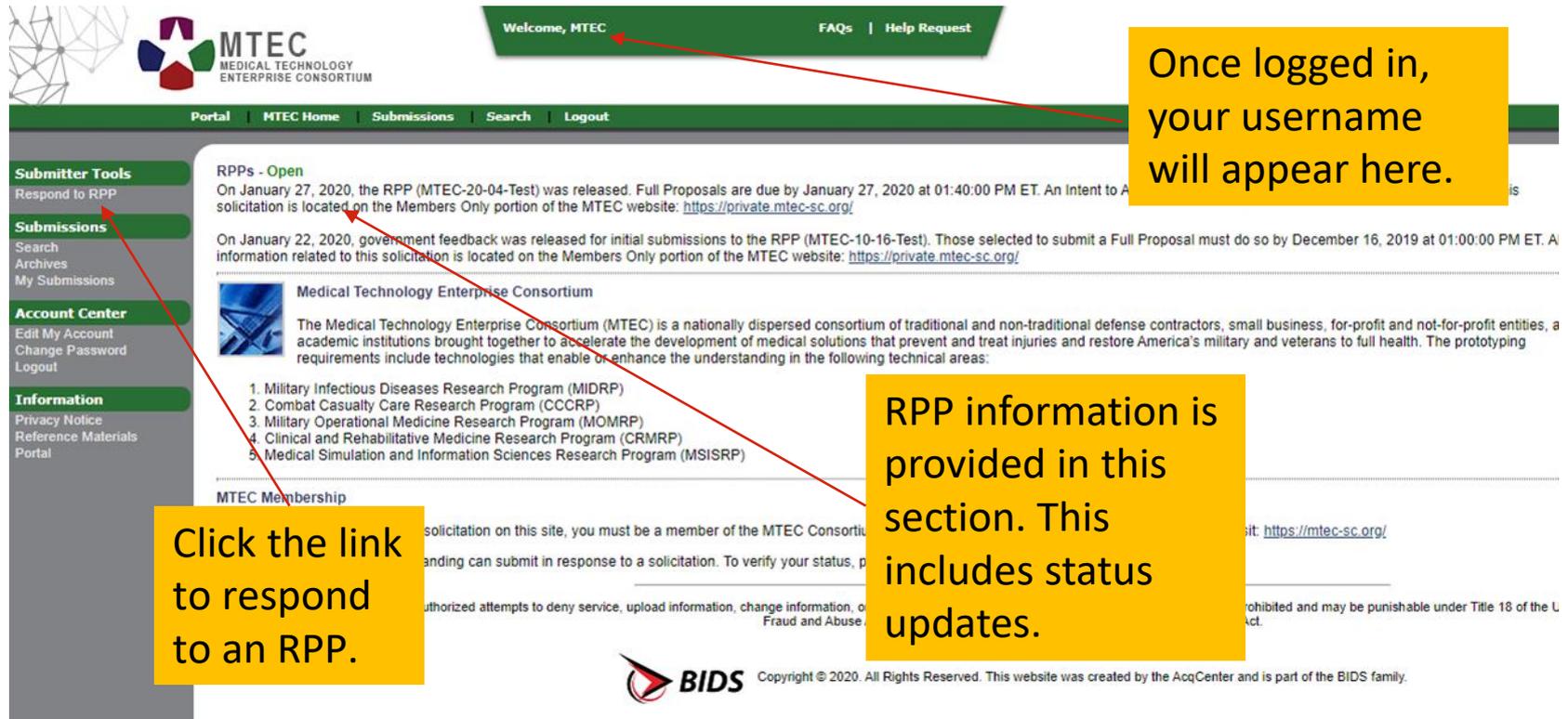
Navigate to the MTEC BIDS site and login. After login select the “MTEC BIDS Home” link.



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

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

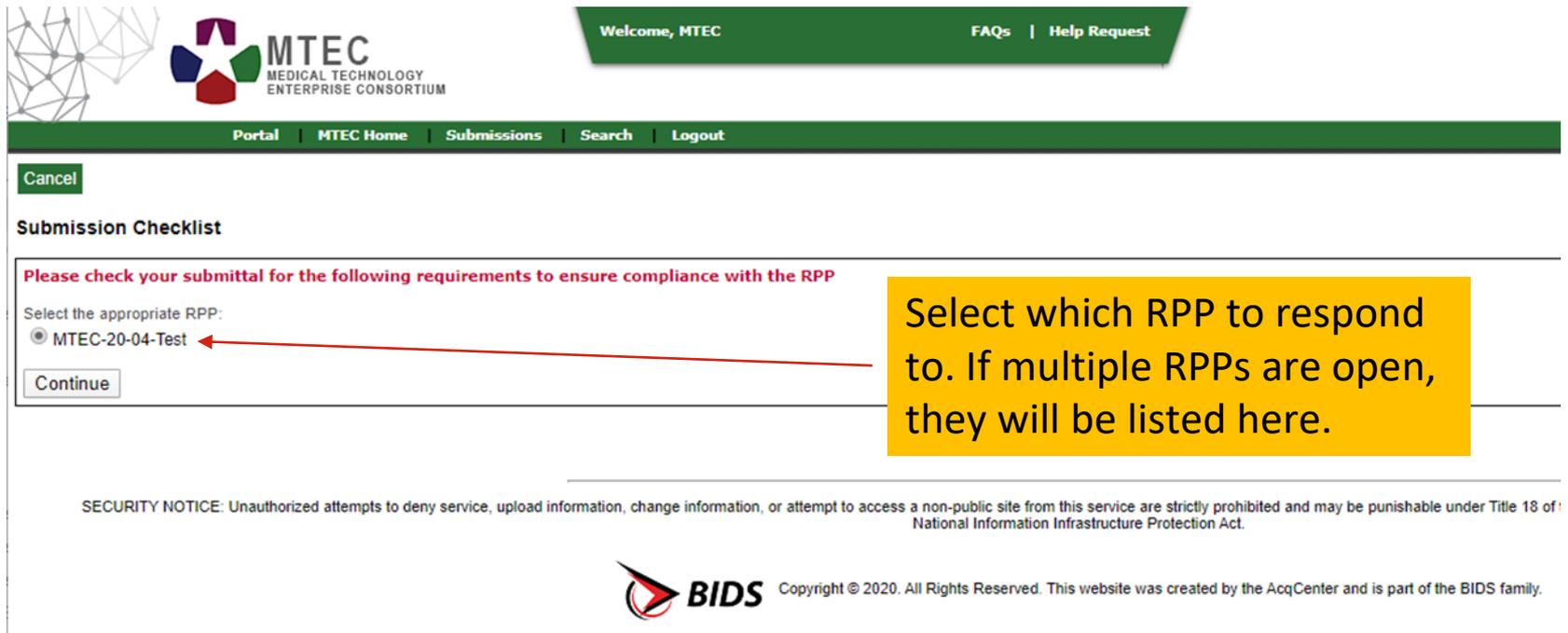
solicitation on this site, you must be a member of the MTEC Consortium. To verify your status, please visit: <https://mtec-sc.org/>

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 page. 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". Below this, it says "Select the appropriate RPP:" and lists "MTEC-20-04-Test" with a radio button that is selected. 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

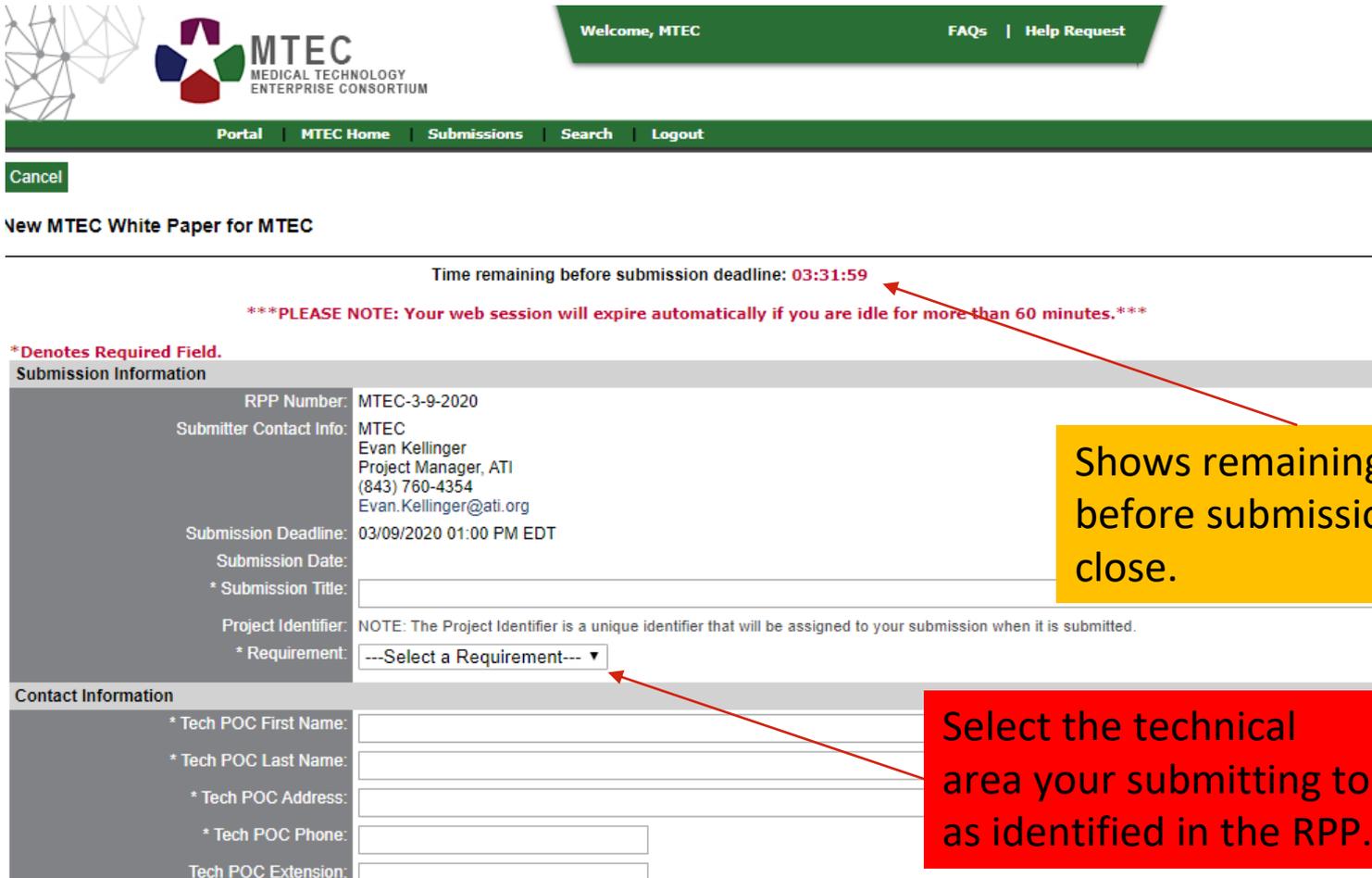
Continue

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

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

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Complete the submission form.



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

<b>File Attachments</b>	
Required Files:	White Paper No file uploaded <a href="#">Upload White Paper</a> (Allowed file types: pdf, doc, docx; Size Limit: 5mb)
<b>Agreements</b>	
*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.**