

Request for Project Proposals



Solicitation Number: MTEC 20-11-PTSD-DT

“Posttraumatic Stress Disorder-Drug Treatment (PTSD-DT) Adaptive Platform Trial (APT)”

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: April 24, 2020

***Proposal Due Date: May 21, 2020
Noon Eastern Time***

White Papers Are NOT Required

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1 Executive Summary

1.1 The Medical Technology Enterprise Consortium

The Medical Technology Enterprise Consortium (MTEC) is an enterprise partnership in collaboration with industry and academia to facilitate research and development activities, in cooperation with the U.S. Army Medical Research and Development Command (USAMRDC) and other 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 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 the Department of Defense (DOD), jointly funded by multiple federal agencies, cost-shared, funded in whole or part by third parties, or involve a mutual commitment of resources other than an exchange of funds.

1.2 Purpose

This solicitation, issued by the MTEC Consortium Manager (CM), Advanced Technology International (ATI), represents a Request for Project Proposals (RPP) for MTEC support of the DOD US Army Medical Materiel Development Activity (USAMMDA). Strategic oversight for the award(s) supported by this RPP will be provided USAMMDA’s Warfighter Brain Health Project Management Office (WBH PMO).

This RPP aims to support the development and maintenance of clinical trial infrastructure for the simultaneous and sequential testing of drug interventions to treat post-traumatic stress disorder (PTSD) in an adaptive platform trial (APT) design. The requirement for this RPP includes three focus areas. Offerors are not limited to a single proposal submission. It is expected that MTEC will make up to 3 awards - a single award for each focus area. It is possible that a single Offeror could receive an award for more than one Focus Area.

- **Focus Area #1 (Statistical Modeling):** Trial design, simulation, initiation, and execution, including drafting of key documents (e.g., statistical sections of Master Protocol, Statistical Analysis Plan, Operational Plan).
- **Focus Area #2 (Drug Selection):** Operationalization and execution of a drug selection process for initial and continual selection of interventions to be tested in the APT.
- **Focus Area #3 (Clinical and Clinical Operations):** Completion of the APT design, development of clinical trial infrastructure, and execution of the APT.

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

2 Administrative Overview

2.1 Request for Proposals (RPP)

Each MTEC research project proposal submitted shall contain both a Technical and Cost Proposal Volume as described in Section 5 of this request and shall be submitted in accordance with the mandatory format provided in the ***“Technical Proposal and Cost Proposal Preparation Instruction Manual,”*** which is available on the MTEC website via the following link: <https://www.mtec-sc.org/wp-content/uploads/2020/04/MTEC-20-11-PTSD-DT-Proposal-Instruction-Manual.pdf>. ***White papers are not required for this RPP.*** The Government reserves the right to award Proposals received from this RPP on a follow-on Other Transaction Agreement for prototype projects or other stand-alone OTAs as necessary to meet mission requirements.

2.2 Proposers Conference

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

2.3 Funding Availability, Period of Performance, and Type of Funding Instrument Issued

The U.S. Government (USG) Department of Defense (DOD) anticipates funding the focus areas with Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) funds.

The anticipated Period of Performance (PoP) and estimated funding available for each focus area is as follows:

- Focus Area #1 (Statistical Modeling): 5 years (FY2021 – FY2025), \$630K

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- Focus Area #2 (Drug Selection): 6 months (FY2021), \$250K
- Focus Area #3 (Clinical and Clinical Operations): 5 years (FY2021 – FY2025), \$25.5M

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 anticipates that award funding will be structured incrementally.

2.4 Acquisition Approach

It is expected that MTEC will make up to 3 awards (a single award for each focus area) 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.

If a single proposal is unable to sufficiently address the entire scope of a specific focus area (outlined in Section 5), several Offerors may be asked to work together in a collaborative manner. However, if an optimal team is not identified, then MTEC may make multiple, individual awards to Offeror(s) to accomplish subset(s) of the key tasks.

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 USG and MTEC. Subsequently, any proposal that is selected for award will be funded through a Research Project Award issued under the member's Base Agreement. A sample of the MTEC Base Agreement can be found on the MTEC website and Members-Only website at www.mtec-sc.org.

At the time of the submission, if Offerors have not yet executed a Base Agreement, then Offerors must certify on the cover page of their Proposal 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 Proposal that, if selected for award, it anticipates the proposed effort will be funded under its executed MTEC Base Agreement.

Offerors are advised to check the MTEC website periodically during the proposal preparation period for any changes to the MTEC Base Agreement terms and conditions as well as clarifications found in Frequently Asked Questions (FAQ) responses.

2.5 MTEC Member Teaming

While teaming is not required for this effort, Offerors are encouraged to consider teaming during the proposal preparation period (prior to submission of Full Proposals) if they:

- Cannot address the full scope of a specific Focus Area (see Section 5 of RPP);
- Need to partner to satisfy the mandatory statutory conditions (see Section 2.8 of RPP);
or,
- Otherwise believe a team may be beneficial to the Government.

The Government intends to have direct interactions with both prime contractors and subcontractors for each Focus Area.

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

There are two sections as part of the profile relevant to teaming:

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

The Collaboration Database 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 Full Proposals 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 Full Proposal and the subsequent agreement administration if the Proposal is selected for award. Please mark all Confidential or Proprietary Information as such. An Offeror's submission of a Full Proposal under this RPP indicates concurrence with the aforementioned CM responsibilities.

Also, as part of MTEC's mission to incorporate philanthropic donations, MTEC frequently makes contact with private entities (e.g., foundations, investor groups, organizations, individuals) that

award grants or otherwise co-fund research, and/or operates in research areas that are aligned with those of MTEC. These private entities may be interested in reviewing certain Proposals within their program areas, allowing opportunities to attract supplemental funding sources. On your Proposal Cover Page, please indicate your willingness to allow MTEC Officers and Directors access to your Proposal for the purposes of engaging in outreach activities with these private organizations. MTEC Officers and Directors granted Proposal access have signed Non-disclosure Agreements (NDAs) and Organizational Conflict of Interest (OCI) statements. Additionally, these MTEC Officers and Staff represent organizations that currently are not MTEC members, and therefore their parent organizations are not eligible to submit Proposals or receive any research project funding through MTEC. Additionally, all Technical Evaluation Panel participants will agree to, and sign a nonproprietary information and conflict of interest document.

2.7 Offeror Eligibility

Offerors must be MTEC Members in good standing.

2.8 Inclusion of Nontraditional Defense Contractors, Nonprofit Research Institutions, or Small Business Participation

Proposals that fail to meet the mandatory statutory conditions with regard to the appropriate use of Other Transaction Authority, as listed below, will not be evaluated and will be determined ineligible for award. Please see the RPP Section 6 for additional details.

Mandatory statutory conditions (the Offeror shall assert that at least one of the following conditions is met):

- (1) There is at least one nontraditional defense contractor or nonprofit research institution participating to a significant extent in the prototype project.
- (2) All significant participants in the transaction other than the Federal Government are small businesses (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)) or nontraditional defense contractors.
- (3) At least one third of the total cost of the prototype project is to be paid out of funds provided by sources other than the Federal Government.

The Offeror shall submit Warranties and Representations (see Section 13 of the *“Technical Proposal and Cost Proposal Preparation Instruction Manual”*) specifying the critical technologies being offered and/or the significant extent of participation of the nontraditional defense contractor, small business or nonprofit research institution. 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, small business’ or nonprofit research institution’s participation shall be

explained in detail in the signed Warranties and Representations. Inadequate detail can cause delay in award.

Per the DOD OT Guide, rationale to justify a *significant extent* includes:

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

2.9 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.

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

Cash Contribution

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

An Offeror's own source of funds may include corporate retained earnings, current or prospective Independent Research and Development (IR&D) funds or any other indirect cost pool allocation. New or concurrent IR&D funds may be utilized as a cash contribution provided those funds identified by the Offeror will be spent on performance of the

Statement of Work (SOW) of a Research Project or specific tasks identified within the SOW of a Research Project.

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

In-Kind Contribution

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

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

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

2.11 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 award. Such deposits shall be due no later than 90 days after the research project award is executed. Awardees are not allowed to use MTEC funding to pay for their assessment fees.

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.

2.12 Intellectual Property & Data Rights

Intellectual Property (IP) rights for MTEC Research Project Awards will be defined in the terms of an awardee's Base Agreement, specially negotiated IP and data rights, which take precedence over the terms of the Base Agreement, and resultant Task Orders. MTEC reserves the right to facilitate the discussions and negotiation of IP, royalties, licensing, future development, etc., between the government and the individual performers during the entire award period.

Rights in technical data in each Research Project Award shall be determined in accordance with the provisions of MTEC Base Agreement. However, Offerors are hereby advised that the Government intends to specially negotiate the rights in intellectual property and technical data developed under this agreement. These specially negotiated rights will take precedence over and shall differ from the MTEC Base Agreement terms.

It is anticipated that the government will have exclusive ownership of all IP and exclusive rights in all Research Project Awardee data developed in the course of performing the work defined under this Research Project, including the infrastructure, biological samples and data, and clinical trial data (see definitions below), as permitted under Category D of the MTEC Base Agreement.

- "Data" means computer software, computer software documentation, form, fit and function data, and technical data, including infrastructure.
- "Technical data" means recorded information, regardless of the form or method of the recording, of a scientific or technical nature (including computer software documentation). The term does not include computer software or data incidental to contract administration, such as financial and/or management information. "Form, fit and function data" means technical data that describes the required overall physical, functional and performance characteristics (along with the qualification requirements, if applicable) of an item, component, or process to the extent necessary to permit identification of physically and functionally interchangeable items.
- "Infrastructure" includes, but is not limited to, the governance structure and associated charters; information produced by or with input from governance structure bodies; information and materials produced by or with Research Project Awardee subcontractors including agreements and budgets; study documents developed with or without input from governance structure bodies (e.g. protocols, statistical analysis plans, data flow

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plans, site feasibility documents, site and rater training plans and materials, investigator meeting presentations); site lists, intelligence relationships, contracts and database; program standard operating procedures (SOPs) including those developed with quality assurance (QA) vendor; all study materials, presentations, brochures, logos, and trademark; all statistical Research Project Awardee outputs including, simulations and analysis plans for this study.

The Awardees for each focus area will not own the IP developed during the PoP. The Focus Area Awardees’ rights to the data (as defined above) will be restricted to use during the active agreement PoP solely for this effort. The Government may negotiate different IP ownership or data rights, including exclusive licensing thereof, as called for in MTEC Base Agreement sections 9.3.4 and 10.7, with to-be-determined partners for the development of and regulatory approval of biological markers or drugs resulting from the research herein.

If applicable, the Offeror shall complete the below table for any items to be furnished to the Government with restrictions and include this table as a separate document of the proposal submission. See Section 11 of the RPP for additional information. An example is provided below.

| 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 |

2.13 Expected Award Date

Offeror should plan on the period of performance beginning September 30, 2020 (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.

2.14 Anticipated Proposal Selection Notification

As the basis of selections is completed, the Government will forward their selections to MTEC CM to notify Offerors.

3 Proposal

3.1 Proposal Preparation Guidance Documents

Offerors who submit proposals in response to this RPP must submit by the date on the cover page of this RPP. Proposals received after the time and date specified may not be evaluated.

The MTEC “Technical Proposal and Cost Proposal Preparation Instruction Manual” is specifically designed to assist Offerors in preparing their Technical Proposals and Cost Proposals for this specific RPP #MTEC-20-11-PTSD-DT.

The proposal format outlined in the ***“Technical Proposal and Cost Proposal Preparation Instruction Manual”*** is mandatory. MTEC will post any general questions received and corresponding answers (without including questioners’ proprietary data) on the Members-Only MTEC website. The Government will evaluate Proposals submitted and will select Proposals that best meet their current technology priorities using the criteria in RPP Section 5.

3.2 Proposal Submission

Proposals shall be submitted by the date and time specified on the cover page using BIDS: <https://ati2.acqcenter.com/ATI2/Portal.nsf/Start?ReadForm>. Include the MTEC Solicitation Number (MTEC-20-11-PTSD-DT) on each proposal submitted. See RPP Section 12 for further information regarding BIDS registration and submission.

MTEC membership is required for the submission of a Proposal. Offerors submitting Proposals as the prime contractor must be MTEC members of good standing by May 18, 2020.

Do not submit any classified information in the proposal submission.

3.3 Submission Format

Offerors shall submit files in Microsoft Word or Microsoft Excel or Microsoft Project. 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). Filenames should not contain special characters. Apple users must ensure the entire filename and path are free of spaces and special characters.

An automated BIDS receipt confirmation will be provided by email. Offerors may submit in advance of the deadline and update (or replace any of the files) up until the submission deadline. **Neither MTEC nor ATI will make allowances/exceptions for submission problems encountered by the Offeror using system-to-system interfaces. If the Offeror receives errors and fails to**

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

4 Proposal Preparation Instructions

4.1 General Instructions

The Technical Proposal and Cost Proposal shall be submitted in two separate volumes, and shall remain valid for 180 days unless otherwise specified by the Offeror in the proposal. The Proposal format provided in this MTEC RPP is mandatory and shall reference this RPP number (MTEC 20-11-PTSD-DT). Offerors are encouraged to contact the POC identified herein up until the proposal submission date/time to clarify requirements.

Offerors shall propose a Milestone Payment Schedule (MPS), which shall include all significant event/accomplishments that are intended to be accomplished as part of the project, a planned completion date (based on months post award), the expected research funding expended towards completing that milestone (based on the expected cost of doing the work), and any cost share, if applicable. See the example in "Section 9: Statement of Work (SOW)" within this RPP. The Milestones and associated accomplishments proposed should, in general, be commensurate in number to the size and duration of the project. A milestone is not necessarily a physical deliverable; it is typically a significant R&D event. Monthly technical reports may be considered deliverables, but they are not milestones. Please include monthly and final technical reports as part of the Milestone Payment Schedule, without an associated cost.

Offerors shall also propose a project schedule. Submitted information is subject to change through negotiation if the Government recommends the proposal for funding.

All eligible Offerors may submit proposals 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 Government Agreements Officer, is legally authorized to contractually bind or otherwise commit funding for selected Research Project Awards as result of this RPP.

5 Technical Requirements

5.1 Program Description

The Government will have oversight of all Research Project Awardees' technical work, and shall be the prime integrator of all three of the focus areas (Figure 1). Interactions among the three focus areas is not anticipated without DOD coordination and oversight. The DOD will be responsible for the composition and development of working groups via agreements outside of MTEC. The DOD Product Manager (PM) or PM DOD-team designee(s) will ensure that the work by the Research Project Awardees is coordinated in alignment with the APT governance

structure. **It is expected that the PM or PM DOD-team designee(s) will have direct interactions with the Research Project Awardees subcontractors to coordinate technical work.**

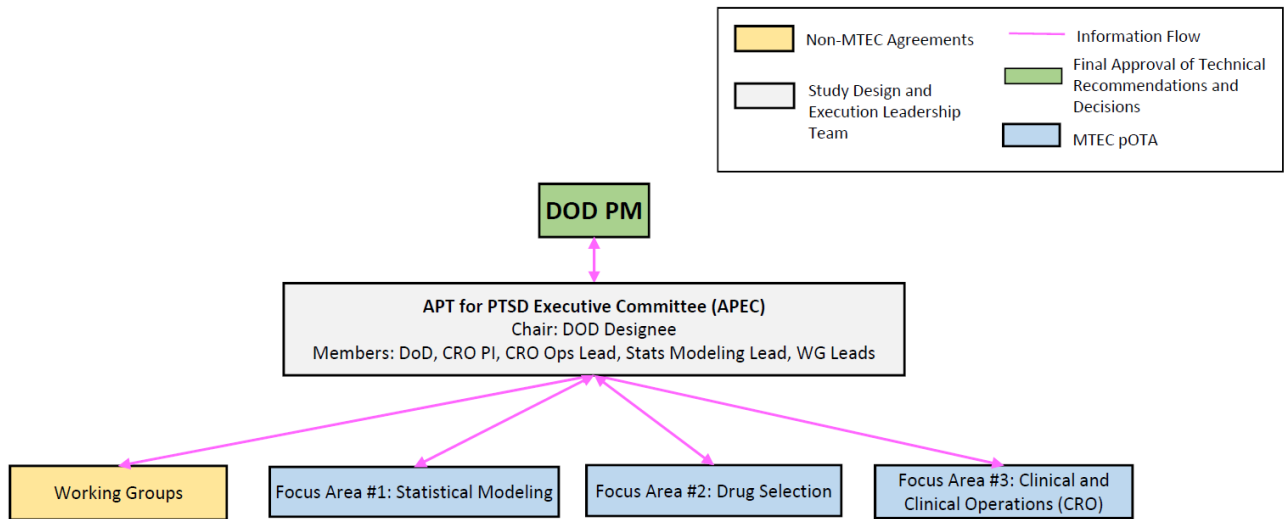


Figure 1. Adaptive Platform Trial Communication Schema for MTEC and Working Groups

5.2 Project End Goals

Focus Area #1 (Statistical Modeling): The end goal for each step of focus area #1 is as follows:

- STEP #1 (Trial design): A platform trial structure that will include patient subgroups, multiple arms, outcomes, etc. that will meet the goals of the DOD.
- STEP #2 (Trial simulation): A detailed trial design software that will allow simulation of the trial skeleton design created above.
- STEP #3 (Trial initiation): Documents and meetings for trial initiation.
- STEP #4 (Trial execution): Execution of the adaptive analyses needed during the course of the trial including interim and final analyses.

Focus Area #2 (Drug Selection): The end goal is a prioritized list of drugs recommended for inclusion in the APT. **NOTE: Focus Area #2 is for the drug selection process only. Focus Area #2 is not seeking proposals from Offerors that bring forth PTSD drugs for evaluation.*

Focus Area #3 (Clinical and Clinical Operations): The end goal is a functioning adaptive platform trial built to DOD specifications allowing for efficient testing of a minimum of two interventions simultaneously to treat military-related PTSD, including discovery and validation of biological markers to identify patients with highest likelihood to respond to specific treatments.

5.3 Scope of Work

The DOD has identified three focus areas for funding under this RPP. To meet the intent of this RPP, each proposal ***MUST*** specifically indicate which of the three Focus Areas described below are addressed. Offerors are not limited to a single proposal submission. If proposals include teaming across focus areas, Offerors are allowed to submit a single proposal that addresses more than one Focus Area, otherwise one proposal per focus area is preferred. Projects not aligned to at least one of these Focus Areas will not be considered for funding. It is expected that MTEC will make up to 3 awards - a single award for each focus area. It is possible that a single Offeror could receive an award for more than one Focus Area.

- 1) Focus Area #1 (Statistical Modeling): Trial design, simulation, initiation, and execution, including drafting of key documents (e.g., statistical sections of Master Protocol, Statistical Analysis Plan, Operational Plan).**

OBJECTIVE: Finalization and implementation of the APT statistical design to meet DOD requirements.

DESCRIPTION: The PTSD APT will test a minimum of two drugs versus a placebo in a platform design, which allows for replacement of drugs based on pre-defined rules for success or futility. Adaptive platform trials are often based on Bayesian statistical models with multiple features that improve trial efficiency and decision-making. In collaboration with key personnel from the DOD, DOD-specified subject matter experts (SMEs), and a contract research organization (CRO) [Focus Area #3], the Offeror is expected to develop statistical models to inform an optimal statistical design that will meet DOD requirements to evaluate multiple drugs and biomarkers to enable a precision medicine approach to the treatment of PTSD. The Offeror will be expected to perform trial simulations and contribute to the writing of the master protocol, intervention appendices, statistical analysis plan, and operational plans, in collaboration with the DOD, DOD-specified SMEs, and the CRO **via DOD coordination**. The Offeror will interact with regulators, members of the study team, and institutional review boards (IRBs), as determined by the DOD. The Offeror will also execute the adaptive analyses during the course of the trial.

The required scope of work for Focus Area #1 is outlined in the four steps below. All parts of the work will be transparent, documented, quality controlled, and communicated to the DOD.

STEP 1: Trial Skeleton and Goals

The statistical Offeror will create a platform trial structure. This will include possible patient subgroups, handling of multiple arms (doses and agents), the randomization scheme, the generic behavior of a variable number of experimental agents, the modeling of patient outcomes and different endpoints, the addition or removal of different arms seamlessly, decision rules, and trial outcomes. These initial discussions will be respectful of the potential operational and ethical burden of the trial as well as the goals of the DOD.

STEP 2: Trial Simulation and Iteration

The Offeror will create detailed trial design software that allows the full simulation of the trial skeleton design. This simulation software will allow:

- Simulation of virtual patients, allowing a wide range of assumptions about the behavior of a possible common control arm and all experimental arms to be explored;
- Simulation of a range of execution variables, including accrual rate, variation in types of patients, dropout rates, adjustment of randomization ratios, and delay in data availability;
- Full chronological mirroring of the exact trial design, including the timing of all trial updates with exact data availability at these trial updates;
- Fitting of the statistical modeling identical to the model fitting in the actual platform trial design; and
- Capturing of all trial results and decision points reached by the platform trial. This includes the ability to create example trials, movies of the trial process and results, summarizing the results across repeated trials.

The simulation results will be presented to the DOD and DOD-specified team members. These explorations of the results lead to iterating all aspects of the platform trial design, including all rules, structure, models, decision points, sample size, number of sites, etc.

This iteration and exploration process, all driven by continuous simulations creates the strongest, most efficient trial design and leads to much deeper understanding by all stakeholders. The iteration will lead to a final trial design skeleton allowing complete specification and writing of a master protocol and appendices. The deliverable at the conclusion of this step is a quality-controlled adaptive design report, including the trial design, statistical modeling, analysis methods, operating characteristics, and example trials. This report will describe the design, adaptations, models, and simulation results in complete detail.

STEP 3: Help with Writing the Master Protocol, at least two appendices, and the statistical analysis plan. Helping to identify the operational plan, the interactions with regulators, the DOD, and IRBs.

Once the design has been vetted and explored and a final design has been created, the Offeror will work on the documentation and interactions needed for trial initiation.

STEP 4: Trial Execution

The Offeror will execute the adaptive analyses during the course of the trial. Data flow will be mapped out in Step 3, but the actual implementation of the adaptations and interims will take place prior to or during the trial conduct, including:

- Preparation of the modeling and reports that will be generated during the execution of the interim analyses;
- Execution of the interim analyses, interim report generation; and
- Preparation of the final analyses for each of the first two interventions in the trial.

2) Focus Area #2 (Drug Selection): Operationalization and execution of a DOD-provided drug selection process for initial and continual selection of interventions to be tested in the APT.

OBJECTIVE: To gather data related to clinical efficacy, safety, mechanism of action, etc. from public and commercial databases for drugs tested in PTSD and related conditions. Data will be analyzed according to DOD-provided pre-defined selection criteria to yield a prioritized list of drug candidates for testing in the APT.

**NOTE: Focus Area #2 is for the drug selection process only. Focus Area #2 is not seeking proposals from Offerors that bring forth PTSD drugs for evaluation.*

DESCRIPTION: The PTSD APT will test a minimum of two drugs versus a placebo in a platform design, which allows for replacement of drugs based on pre-defined rules for success or futility. The Offeror will utilize publically available and commercial databases to acquire necessary information to execute the DOD-provided drug selection process. **Focus Area #2 requires an objective process and must avoid conflicts of interest.** Data generated during each step of the down-selection process, and the outcomes will be reviewed by the DOD. All parts of the work will be transparent, documented, quality controlled, and communicated to the DOD.

The complete, detailed drug selection process will be provided by the Government following Award, however high-level steps to be performed within the overall process are outlined below:

1. Acquire and extract clinical trial data from public and commercial databases.
2. Filter compounds based on defined criteria (e.g., indication/population tested, trial design)
3. Score trial-level results against defined criteria (e.g., statistical significance, responder rate characteristics, target engagement)
4. Map filtered drug list to corresponding mechanisms of action (MOA)
5. Prioritize MOAs with highest weight of evidence from trial-level results
6. Score and weight drugs within MOAs based on defined criteria (e.g., safety profile, regulatory risk, military population and operational considerations)
7. Compile prioritized list of drugs for consideration by the DOD to include in the APT

POTENTIAL FOLLOW-ON WORK (subject to the availability of funding and timing within the PoP): The initial PoP for Focus Area #2 is 6 months (FY2021), however there is the potential for additional rounds of drug selection subject to the timing of drug substitution within the APT.

3) Focus Area #3 (Clinical and Clinical Operations): Completion of the APT design, development of clinical trial infrastructure, execution of the APT.

OBJECTIVE: Perform all major activities of a Contract Research Organization (CRO), except for data management, to build the infrastructure for, and implement testing of the PTSD APT.

DESCRIPTION: The PTSD APT will test a minimum of two drugs versus a placebo in a platform design, which allows for replacement of drugs based on pre-defined rules for success or futility. Beyond standard clinical trial operations, APTs require additional flexibility in various aspects to run as planned. The Offeror will identify a principal investigator (PI) for the study and will perform all major functions of a contract research organization for this Phase 2 APT, except Data Management. This includes protocol and appendix drafting and finalization, study initiation, regulatory services, site selection and recruitment, site initiation, clinical study management, study monitoring, medical monitoring, safety monitoring, data monitoring committee, statistics, clinical study reporting, vendor management, meeting and teleconferences, clinical trial supplies and logistics, quality assurance, patient recruitments and retention, protocol amendments, and interactive voice response systems (IVRS). The PI and other necessary members within the CRO will provide technical and administrative support to the DOD to manage the APT governance bodies. The Offeror should have experience with Master Protocols and will work closely with key DOD team members and, via coordination by the DOD, members of the statistical modeling group and the drug selection vendor to perform the scope of the project. All parts of the work will be transparent, documented, quality controlled, and communicated to the DOD.

For the purposes of the project schedule and cost proposal, assume the following:

- Drugs to be tested will be generic with a cost of \$6.00 per dose and one dose per day.
- Four total in-clinic visits
- Acquisition of the following biomarker data and samples at two of the in-clinic visits (potential options for additional future work may include analyses, however analyses should not be included in the proposal):
 - Functional and structural magnetic resonance imaging (fMRI, sMRI), in collaboration with an Imaging CRO, if expertise for the acquisition of fMRI and sMRI is not an internal resource.
 - 64-channel Electroencephalography (EEG)
 - In addition to standard safety laboratory testing, assume biofluid biomarker collection, including blood and saliva, to be managed by a qualified biorepository. Blood collection should include four standard blood collection tubes and one PAXgene tube.

- Physiological measures, including skin conductance, heart rate variability, and startle response using Biopac equipment
- Clinician-administered assessments will be conducted by central raters, not by individual site personnel.

5.4 Potential Follow-on Work:

There is the potential for award of one or more follow-on tasks based on the success of the project (subject to change depending upon Government review of completed work). These tasks may include, but are not limited to:

- Planning and conduct of Phase 3 clinical studies
- Development of complimentary or companion diagnostics
- Development of qualified biomarkers, clinical outcome assessments, or patient reported outcomes
- Development of an amended drug selection process based on emerging data from the APT
- Continued use of the APT infrastructure for Phase 2 testing

5.5 Preparation of the Proposal

Proposals shall reference this RPP number (MTEC-20-11-PTSD-DT). The Technical Proposal and Cost Proposal must be submitted in two separate volumes, and shall remain valid for 180 days unless otherwise specified by the Offeror in the proposal. Offerors are encouraged to contact MTEC with any questions so that all aspects are clearly understood by both parties. The full proposal should include the following. Each document will be uploaded to BIDS separately.

- **Technical Proposal by Focus Area submission:** one signed Technical Proposal (.doc or .docx). The Technical Proposal requirements and format provided in the ***“Technical Proposal and Cost Proposal Preparation Instruction Manual”*** is mandatory (<https://www.mtec-sc.org/wp-content/uploads/2020/04/MTEC-20-11-PTSD-DT-Proposal-Instruction-Manual.pdf>).
- **Statement of Work (SOW)/Milestone Payment Schedule by Focus Area:** one document in Word (.docx or .doc). The Offeror is required to provide a detailed SOW/Milestone Payment Schedule using the format provided herein (Section 9 of RPP). The Government reserves the right to negotiate and revise any or all parts of SOW/Milestone Payment Schedule. Offerors will have the opportunity to concur with revised SOW/Milestone Payment Schedule as necessary.
- **Project Schedule:** one document in Excel (.xlsx or .xls) or Microsoft Project format. The Offeror is required to provide a project schedule, including assumptions, broken out either monthly or quarterly. The project schedule is a detailed illustration of the timing of initiation, duration, and completion of project activities over the course of the PoP. The project schedule does not include costs, and is not limited to milestones. (*Submitted*

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information is subject to change through negotiation if the Government recommends the proposal for funding.) There is no template required for the project schedule.

- **Cost Proposal by Focus Area submission:** one Word (.docx or .doc) for Section I: Cost Proposal Narrative, including all assumptions, by Focus Area (see Section 12.1 of the *“Technical Proposal and Cost Proposal Preparation Instruction Manual”*) is required. Separately, Section II: Cost Proposal Formats by Focus Area in Excel (.xlsx or .xls) is required. The Cost Proposal format outlined in the *“Technical Proposal and Cost Proposal Preparation Instruction Manual”* is mandatory (<https://www.mtec-sc.org/wp-content/uploads/2020/04/MTEC-20-11-PTSD-DT-Proposal-Instruction-Manual.pdf>). [Note: Each major task included in the SOW should be priced separately in the cost proposal. For Focus Areas #1 and #2, subtasks need not be priced separately in the cost proposal. For Focus Area #3, subtasks should be priced separately in the cost proposal.]
- **Warranties and Representations:** one Word (.docx or .doc) that contains all Warranties and Representations is required. See Section 13 of the *“Technical Proposal and Cost Proposal Preparation Instruction Manual”* for the template.
- **Royalty Payment Agreement or Additional Research Project Award Assessment:** Each Offeror will select either the MTEC Additional Research Project Award Assessment Fee **or** the Royalty Payment Agreement (available on the MTEC members only website), **not both**, and submit a signed copy with the proposal.
- **Current and Pending Support (no page limit)**
 - For all current and pending research support (to include government and non-government), include the award number and title, funding agency and requiring activity’s names, period of performance (dates of funding), level of funding (total direct costs only), brief description of the project’s goals, and list of specific aims. If applicable, identify where the proposed project overlaps with other existing and pending research projects. Clearly state if there is no overlap.
 - If there is no current and/or pending support, enter “None.”
 - See Section 10 of RPP for template
- **Data Rights (no page limit)**
 - Please reference RPP Section 2.12 for details
 - See Section 11 of RPP for template

Evaluation: The Government will evaluate and determine which proposal(s) to award based on criteria described in **Section 6, “Selection,”** of this RPP. The Government reserves the right to negotiate with Offerors.

5.6 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 *“Technical Proposal and Cost Proposal Preparation Instruction Manual”* are **NOT** mandatory. Refer to the MTEC *“Technical Proposal and Cost Proposal Preparation Instruction Manual”* 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.

5.7 Proposal Preparation Costs

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

5.8 Restrictions on Human Subjects, Cadavers, and Laboratory Animal Use

Proposals must comply with important restrictions and reporting requirements for the use of human subjects, to include research involving the secondary use of human biospecimens and/or human data, human cadavers, or laboratory animals. For a complete description of these mandatory requirements and restrictions and others, Offerors must refer to the accompanying Section 14 of the *Technical Proposal and Cost Proposal Preparation Instruction Manual*, “Additional Requirements.”

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’s Human Research Protection Office (HRPO) provides authorization that the research may proceed. The USAMRDC HRPO will issue written approval to begin research under separate notification. Written approval to proceed from the USAMRDC HRPO is also required for any Research Project Awardee (or lower tier subawards) that will use funds from this award to conduct research involving human subjects. Offerors must allow at least 90 days in their schedule for the HRPO review and authorization process. Similar authorization from USAMRDC’s Animal Care and Use Review Office (ACURO) is required for work involving animal subjects. **For proposals that include use of animal or human subjects, proposals shall account for requirements related to obtaining these approvals to include Institutional Animal Use and Care Committee (IACUC) and ACURO and/or Institutional Review Board (IRB) and HRPO review and approval in the SOW/Milestones Payment Schedule (Section 9 of the RPP).**

5.9 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 3 of the *“Technical Proposal and Cost Proposal Preparation Instruction Manual.”*

6 Selection

The CM will conduct a preliminary screening of submitted proposals to ensure compliance with the RPP requirements. As part of the preliminary screening process, proposals that do not meet the requirements of the RPP may be eliminated from the competition or additional information may be requested by the CM. The Government reserves the right to request additional information or eliminate proposals that do not meet these requirements from further consideration. One of the primary reasons for elimination from further consideration is the lack of significant nontraditional defense contractor participation, nonprofit research institution participation, all small business participation, or cost sharing (see RPP Sections 2.8-2.10). 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"> • Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution • Offeror's proposal has at least one Nontraditional Defense Contractor or Nonprofit Research Institution participating to a significant extent • All significant participants in the transaction other than the Federal Government are small businesses or nontraditional defense contractors • Offeror provides at least one third of the total project cost as acceptable cost share |
| FAIL | <p>Offeror proposing an MTEC research project does NOT meet any of the following:</p> <ul style="list-style-type: none"> • Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution • Offeror's proposal has at least one Nontraditional Defense Contractor or Nonprofit Research Institution participating to a significant extent • All significant participants in the transaction other than the Federal Government are small businesses or nontraditional defense contractors |

| | |
|--|--|
| | <ul style="list-style-type: none">• Offeror provides at least one third of the total project cost as acceptable cost share |
|--|--|

Following the preliminary screening, the Government sponsor will perform proposal source selection. This will be conducted using the evaluation factors detailed below. The Government will conduct an evaluation of all qualified proposals. The Source Selection Authority may:

1. *Select the proposal (or some portion of the proposal) for award*
2. *Place the proposal in the Basket for potential future award if needed, as determined by the Government; or*
3. *Reject the proposal (will not be considered for award and will not be placed in the Basket)*

6.1 Proposal Evaluation Process

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

This process may involve the use of contractors as SME consultants or reviewers. Where appropriate, the USG will employ non-disclosure agreements to protect information contained in the RPP as outlined in Section 2.6.

Evaluation of proposals will be based on an independent, comprehensive review and assessment of the work proposed against stated source selection criteria and evaluation factors. The Government will evaluate each proposal against the evaluation factors detailed below and assigned adjectival ratings to the non-cost/price factor(s) consistent with those defined in Table 2 (General Merit Ratings Assessments). The Offeror shall clearly state how it intends to meet and, if possible, exceed the RPP requirements. Mere acknowledgement or restatement of a RPP requirement is not acceptable.

The evaluation factors and evaluation criteria are described below.

6.2 Evaluation Factors

1. Technical Approach
2. Project Management
3. Cost/Price

Evaluation factors 1 and 2 are of equal importance. Evaluation factor 3 is of lesser importance than both factors 1 and 2.

Table 2 explains the adjectival merit ratings that will be used for the Technical Approach factor and Project Management factor.

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

Evaluation Factor 1. Technical Approach

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

The Offeror’s proposed solution will be assessed for the likelihood of successfully achieving the requirements of the technology of interest as defined in Section 5 above. The likelihood of success will be determined by considering the soundness and clarity of the technical approach. The SOW should provide a succinct approach for achieving the project’s objectives. The SOW will be evaluated based on the degree to which the proposed work supports the technical requirements.

Evaluation Factor 2. Project Management

The Project Management factor will be evaluated using the merit rating as shown in Table 2. A description of the project team’s expertise, key personnel, and corporate experience shall demonstrate an ability to execute the SOW. The schedule will be evaluated to determine whether the proposed work is realistic and reasonable within the proposed period of performance.

Evaluation Factor 3. Cost/Price

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The Cost/Price area will receive a narrative rating to determine whether costs are realistic, reasonable, and complete.

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

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

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

Estimates are "realistic" when they are neither excessive nor insufficient for the effort to be accomplished. Estimates must also be realistic for each task of the proposed project when compared to the total proposed cost.

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

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

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

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

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

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

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

6.3 Best Value

The Government will conduct the source selection based on the evaluation criteria and ratings listed above. The overall award decision will be based upon a Best Value determination by considering and comparing factors in addition to cost or price. Based on the results of the Technical Approach and Project Management Evaluation, the Government reserves the right to negotiate and request changes to any or all parts of the SOW. Offerors will have the opportunity to concur with the requested changes, proposed further changes and revise cost proposals, as necessary.

6.4 Definition of General Terms Used in Evaluations:

Strength - An aspect of an Offeror's proposal that has merit or exceeds specified performance or capability requirements in a way that will be advantageous to the Government during award performance.

Weakness - A flaw in the proposal that increases the risk of unsuccessful award performance.

Significant Strength - An aspect of an Offeror's proposal that has appreciable merit or appreciably exceeds specified performance or capability requirements in a way that will be appreciably advantageous to the Government during award performance.

Significant Weakness - A flaw that appreciably increases the risk of unsuccessful award performance.

Deficiency - A material failure of a proposal to meet a Government requirement or a combination of weaknesses in a proposal that increases the risk of unsuccessful award performance to an unacceptable level.

7 Points-of-Contact

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

- Questions concerning contractual, cost or pricing related to this RPP should be directed to the MTEC Contracts Administrator, mtec-contracts@ati.org
- Technical and membership questions should be directed to the MTEC Director of Research, Dr. Lauren Palestrini, Ph.D., lauren.palestrini@officer.mtec-sc.org
- All other questions should be directed to the MTEC Director of Program Operations, Ms. Kathy Zolman, kathy.zolman@ati.org

Once an Offeror has submitted a Proposal the Government and the MTEC CM will not discuss evaluation/status until the source selection process is complete.

8 Acronyms/Abbreviations

| | |
|-------|--|
| ACURO | Animal Care and Use Review Office |
| APEC | APT for PTSD Executive Committee |
| APT | Adaptive Platform Trial |
| ATI | Advanced Technology International |
| CAS | Contract Accounting System |
| CM | Consortium Manager |
| CMA | Consortium Member Agreement |
| CRO | Contract Research Organization |
| DHP | Defense Health Program |
| DOD | Department of Defense |
| EEG | Electroencephalogram |
| FAQ | Frequently Asked Questions |
| F&A | Facilities and Administrative Costs |
| fMRI | Functional Magnetic Resonance Imaging |
| FOIA | Freedom of Information Act |
| FY | Fiscal Year |
| G&A | General and Administrative Expenses |
| HRPO | Human Research Protection Office |
| IACUC | Institutional Animal Care and Use Committee |
| IP | Intellectual Property (e.g., patents, copyrights, licensing, etc.) |
| IRB | Institutional Review Board |
| IR&D | Independent Research and Development |

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|---------|--|
| IVRS | Interactive Voice Response System |
| M | Millions |
| MOA | Mechanism of Action |
| MTEC | Medical Technology Enterprise Consortium |
| NDA | Nondisclosure Agreement |
| OCI | Organizational Conflict of Interest |
| ODC | Other Direct Costs |
| OTA | Other Transaction Agreement |
| ORP | Office of Research Protections, USAMRDC |
| PI | Principal Investigator |
| PM | Product Manager |
| POC | Point-of-Contact |
| PoP | Period of Performance |
| PTSD | Post-traumatic Stress Disorder |
| QA | Quality Assurance |
| R&D | Research and Development |
| RDT&E | Research, Development, Test and Evaluation |
| RPP | Request for Project Proposals |
| SME | Subject Matter Expert |
| sMRI | Structural Magnetic Resonance Imaging |
| SOP | Standard Operating Procedure |
| SOW | Statement of Work |
| USAMMDA | US Army Medical Materiel Development Activity |
| USAMRDC | U.S. Army Medical Research and Development Command |
| USG | U.S. Government |
| WBH PMO | Warfighter Brain Health Project Management Office |
| WG | Working Group |

9 Statement of Work (SOW)

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

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 proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.*)

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

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

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

State the technology objective in the first paragraph and follow with delineated tasks required to meet the overall project goals. The work effort should be segregated into major phases, then tasks and identified in separately numbered paragraphs (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. Tasks will need to track with the milestone schedule. Each major task included in the SOW should be priced separately in the cost proposal. For Focus Areas #1 and #2, subtasks need not be priced separately in the cost proposal. For Focus Area #3, subtasks should be priced separately in the cost proposal.

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

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

At a minimum, the following deliverables will be required:

- **Deliverable 1: Spend Plan.** The awardee shall provide a Spend Plan which details how they expect to incur and invoice for costs against the contract. Include detailed costs to be incurred monthly by fiscal year (1 October – 30 September) through the PoP, starting at the award date. The Spend Plan total shall match the total costs proposed for the entire award in the Cost/Pricing Sheet. The Spend Plan shall be updated as necessary throughout the duration of the project/award. The awardee shall report actual progress against the Spend Plan in the Monthly Report.
- **Deliverable 2: Quality Control Plan.** A Quality Control Plan shall document how the awardee will meet and comply with the quality standards established in this proposal.
- **Deliverable 3: Communication Plan.** A Communication Plan shall define who should be given specific information, when that information should be delivered and what communication channels will be used to deliver the information.
- **Deliverable 4: Responsibility Assignment Matrix.** A Responsibility Assignment Matrix in the form of a RACI matrix shall clarify individual or group roles for project tasks by assigning one of four roles: Responsible (R), Accountable (A), Consult (C), and Inform (I).
- **Deliverable 5: Non-Disclosure/Non-Use Agreement.** The awardee shall sign and submit Non-Disclosure Statement(s) among members and shall also ensure that all staff including all subcontractors and consultants performing on any task/delivery order execute and adhere to the terms of the non-disclosure statement, protecting the procurement sensitive information of the DoD and proprietary information.

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

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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 solely on cost incurred and will not have to match exactly to, but shall not exceed, 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 Monthly Reports which include both Technical Status and Business Status Reports (due the 25th of each month), 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 |

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| | | | | | | |
|----|-----|---|------------|------------|------------|------------|
| 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 st 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 |
| 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, | 1/25/2022 | \$ - | | \$ - |

Request for Project Proposals MTEC-20-11-PTSD-DT
Number W81XWH-15-9-0001

| | | | | | | |
|----|-----|---|--------------|--------------------|--------------------|--------------------|
| | | Technical and Business Reports) | | | | |
| 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 (<u>Prior to the POP End</u>) | 11/30/2022 | \$ - | | \$ - |
| | | | Total | \$2,025,240 | \$1,124,742 | \$3,149,982 |

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. Monthly 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.

Request for Project Proposals MTEC-20-11-PTSD-DT
Number W81XWH-15-9-0001

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 11 of this RPP 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)*

- Monthly Reports – The MTEC research project awardee shall prepare a Monthly Report, which will include a Technical Status Report and a Business Status Report in accordance with the terms and conditions of the Base Agreement, and will be submitted with the monthly invoice. (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)

Request for Project Proposals MTEC-20-11-PTSD-DT
Number W81XWH-15-9-0001

- 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)
-

10 Current & Pending Support Template

Current

Award Number:

Title:

Funding Agency/Requiring Activity:

Dates of Funding:

Total Direct Costs:

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

Brief summary of the scope of work:

Award Number:

Title:

Funding Agency/Requiring Activity:

Dates of Funding:

Total Direct Costs:

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

Brief summary of the scope of work:

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

Pending

Title of Proposal:

Funding Agency/Requiring Activity:

Estimated Dates of Funding:

Proposed Total Direct Costs:

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

Brief summary of the scope of work:

Title of Proposal:

Funding Agency/Requiring Activity:

Estimated Dates of Funding:

Proposed Total Direct Costs:

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

Brief summary of the scope of work:

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

11 Data Rights Template

The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding Data Rights.

It is anticipated that all data developed and delivered under this proposed effort would be classified as specially negotiated data rights under Category D, as specified in 9.3.4 of the MTEC Base Agreement, and shall be owned and exclusively controlled by the Government, so as, at a minimum, to provide the Government with the ability to convey the needed rights in data to whomever may be a sponsor in a future FDA regulatory application, and to prevent use of the prototype and/or data for potentially competing efforts during the PoP. If this is not the intent, then the proposal should discuss the alternative proposed IP ownership and data rights associated with each item, and explain how such alternative proposed IP ownership and Data Rights will allow the Government to meet its objectives as stated above.

As discussed above, if the proposal includes such an alternative classification of IP and data, and/or includes IP and data defined under Categories A-C of the MTEC Base Agreement, please complete the below table for said items to be furnished to the Government with restrictions. An example is provided.

| 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 |

12 BIDS Instructions

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

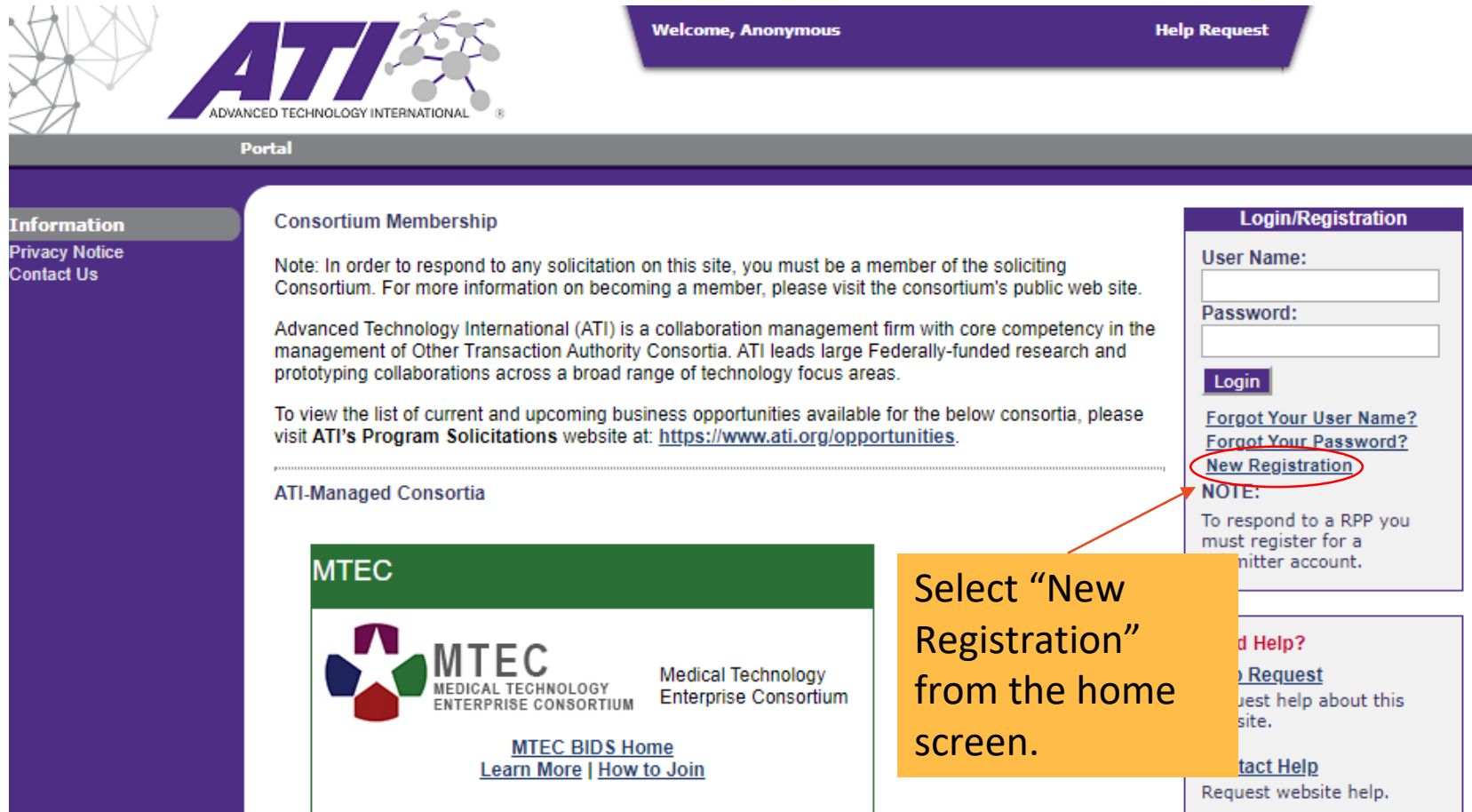
MTEC BIDS REGISTRATION

MTEC BIDS URL:

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

BIDS New Registration

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



ATI
ADVANCED TECHNOLOGY INTERNATIONAL

Welcome, Anonymous [Help Request](#)

Portal

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

Consortium Membership

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

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

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

ATI-Managed Consortia

MTEC
MEDICAL TECHNOLOGY
ENTERPRISE CONSORTIUM

Medical Technology
Enterprise Consortium

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

Login/Registration

User Name:

Password:

[Login](#)

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

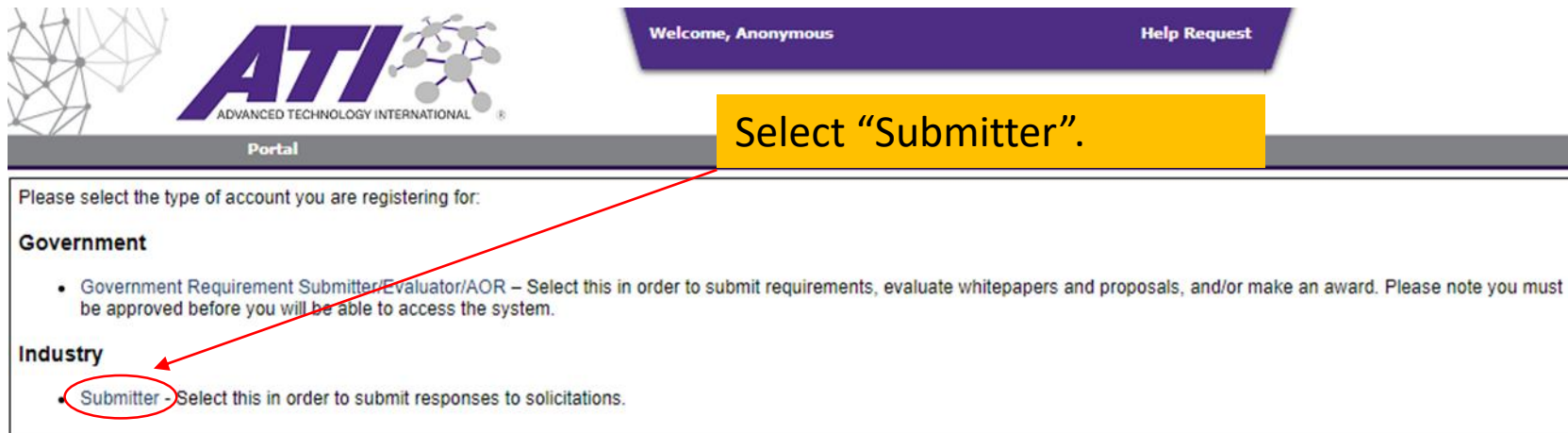
NOTE:
To respond to a RPP you must register for a twitter account.

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

[Contact Help](#)
Request website help.

Select “New Registration” from the home screen.

Select “Submitter”



Portal

Welcome, Anonymous Help Request

Select “Submitter”.

Please select the type of account you are registering for:

Government

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

Industry

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

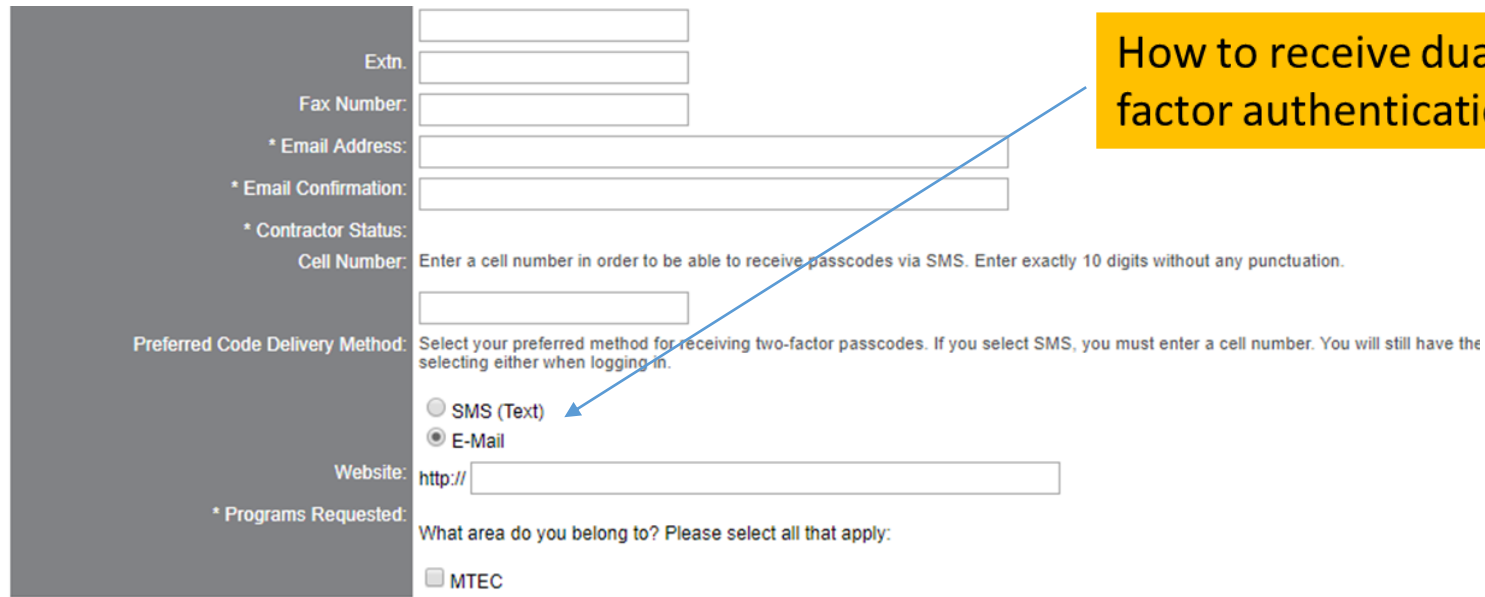
SECURITY NOTICE: Unauthorized attempts to deny service, upload information, change information, or attempt to access a non-public site from this service are strictly prohibited and may be punishable under Title 18 of the U.S. Code to include the Computer Fraud and Abuse Act of 1986 and the National Information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



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BIDS New Registration

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



Extn.

Fax Number:

* Email Address:

* Email Confirmation:

* Contractor Status:

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

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

SMS (Text) ← **How to receive dual factor authentication .**

E-Mail

Website: http://

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

MTEC

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.

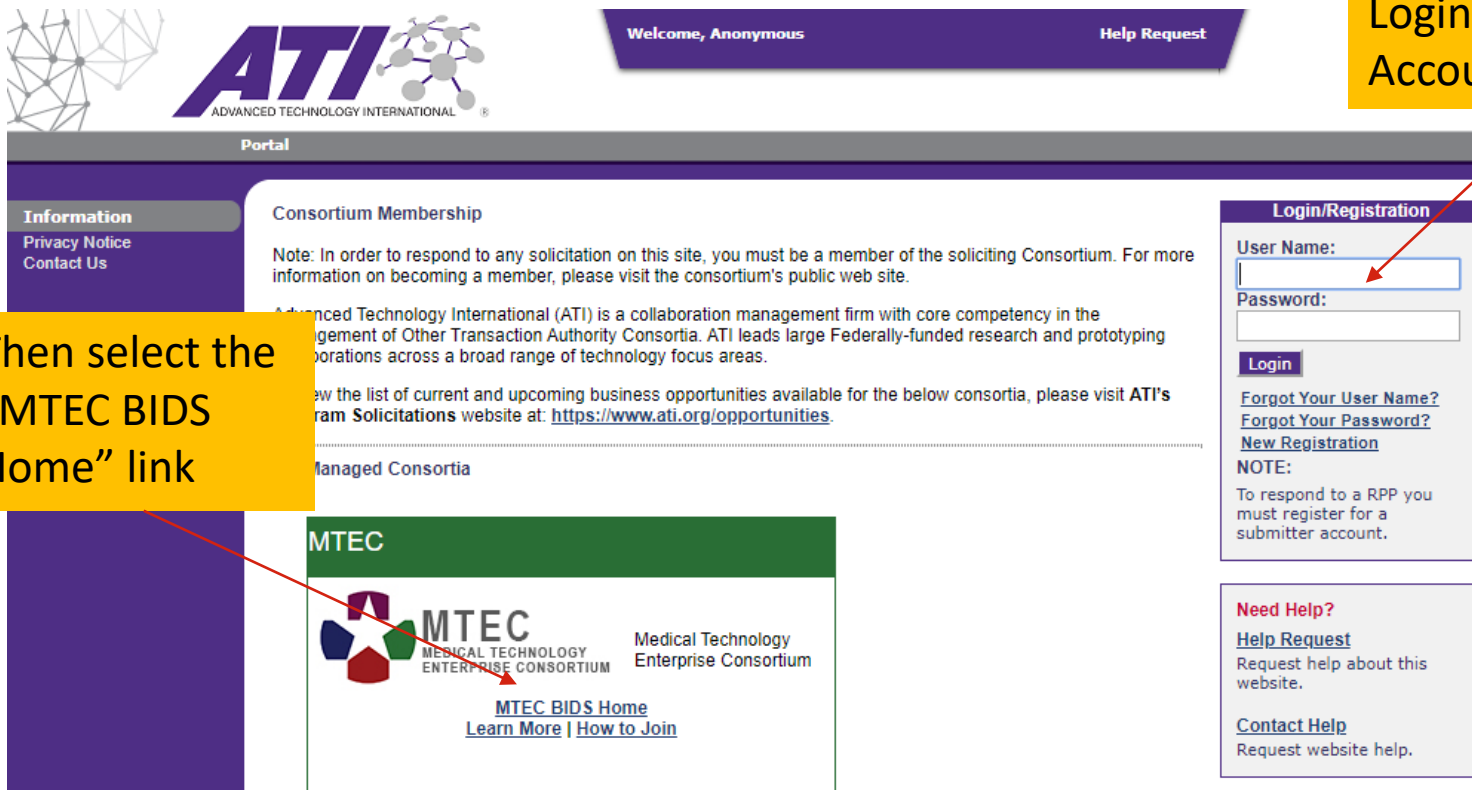
ALL PROPOSALS MUST BE SUBMITTED BEFORE THE SUBMISSION DUE DATE AND TIME. LATE PROPOSALS CAN NOT BE ACCEPTED.

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.



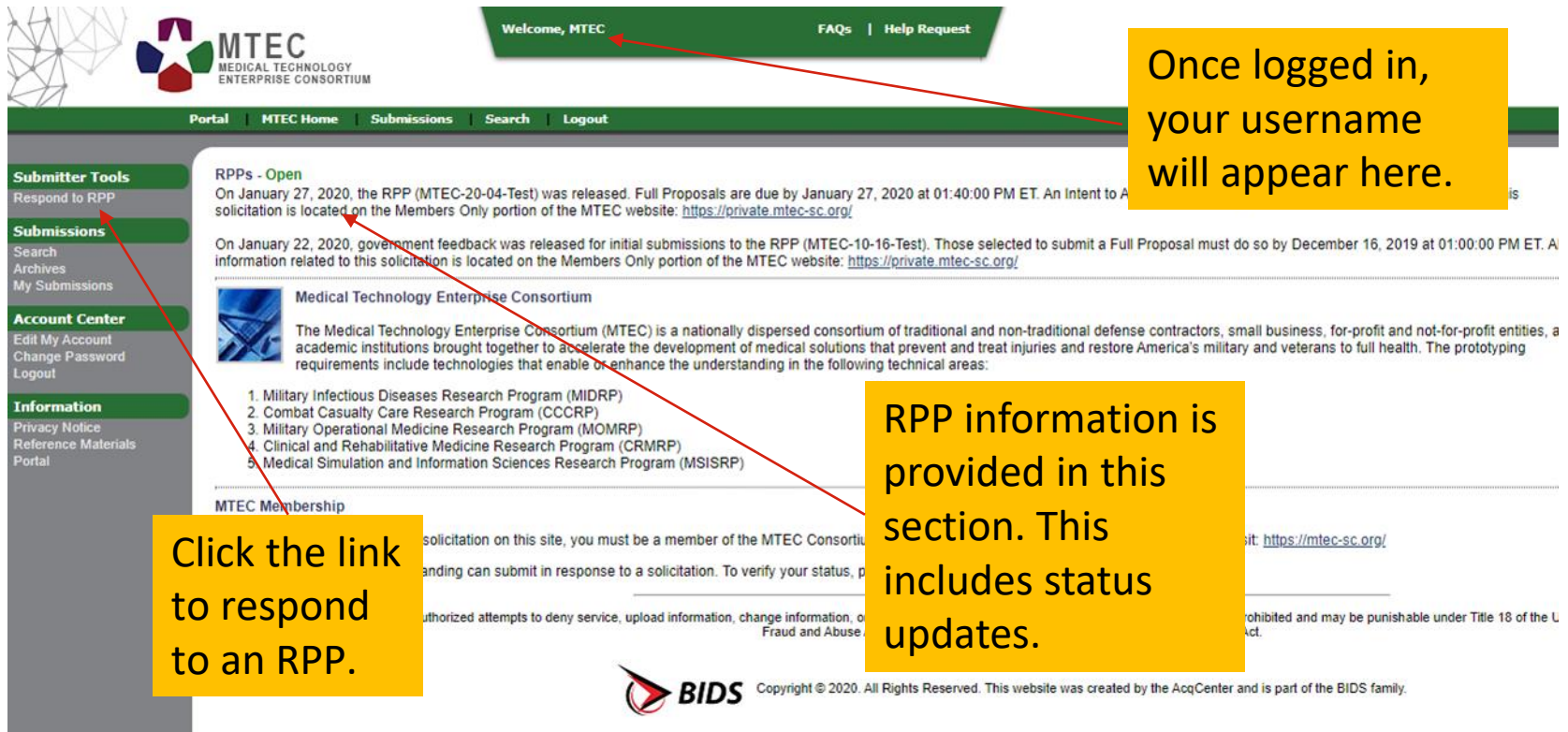
The screenshot shows the MTEC BIDS website interface. At the top, there is a navigation bar with "Welcome, Anonymous" and "Help Request" links. Below this is a "Portal" header. The main content area is divided into several sections: "Information" (Privacy Notice, Contact Us), "Consortium Membership"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

Login to your BIDS Account.

Then select the “MTEC BIDS Home” link

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

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



Once logged in, your username will appear here.

Click the link to respond to an RPP.

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

Welcome, MTEC FAQs | Help Request

Portal | MTEC Home | Submissions | Search | Logout

Submitter Tools
Respond to RPP
Submissions
Search
Archives
My Submissions
Account Center
Edit My Account
Change Password
Logout
Information
Privacy Notice
Reference Materials
Portal

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

On January 22, 2020, government feedback was released for initial submissions to the RPP (MTEC-10-16-Test). Those selected to submit a Full Proposal must do so by December 16, 2019 at 01:00:00 PM ET. All information related to this solicitation is located on the Members Only portion of the MTEC website: <https://private.mtec-sc.org/>

Medical Technology Enterprise Consortium
The Medical Technology Enterprise Consortium (MTEC) is a nationally dispersed consortium of traditional and non-traditional defense contractors, small business, for-profit and not-for-profit entities, and academic institutions brought together to accelerate the development of medical solutions that prevent and treat injuries and restore America's military and veterans to full health. The prototyping requirements include technologies that enable or enhance the understanding in the following technical areas:


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

MTEC Membership

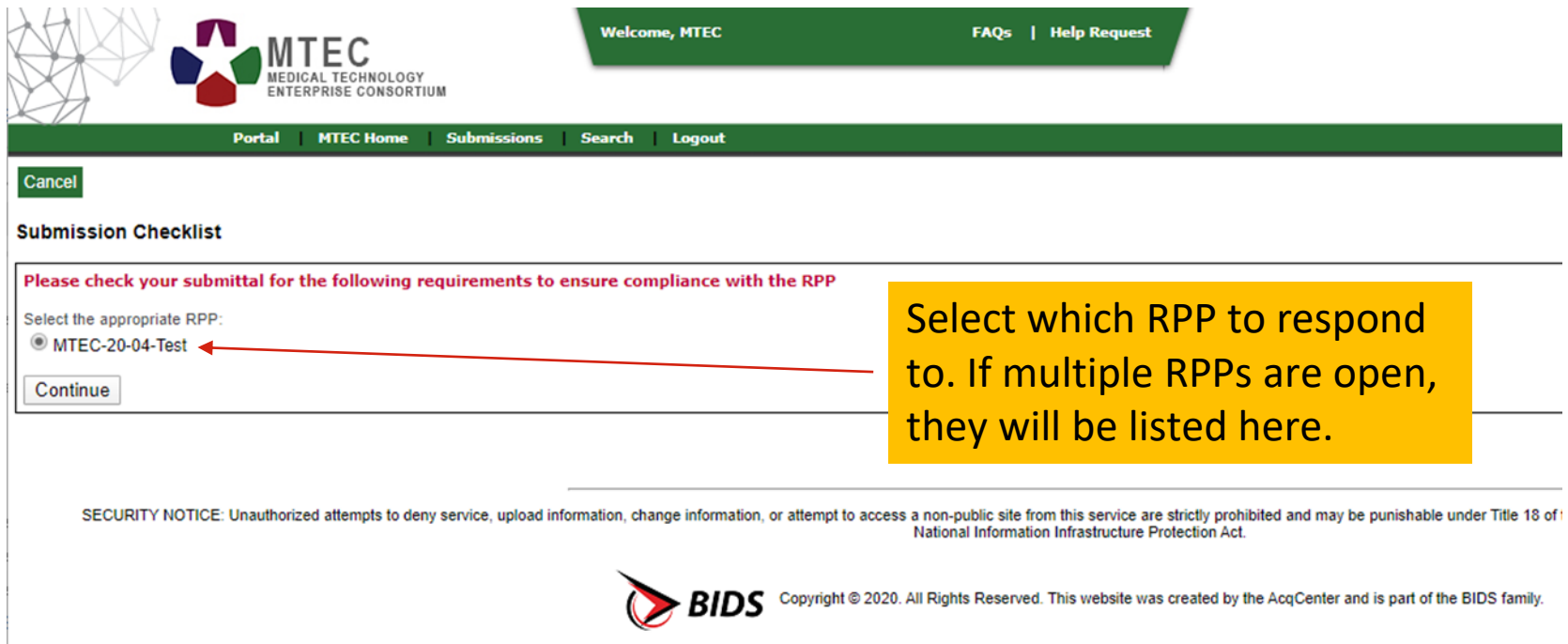
solicitation on this site, you must be a member of the MTEC Consortium. To verify your status, please visit: <https://mtec-sc.org/>

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

authorized attempts to deny service, upload information, change information, or engage in any activity prohibited and may be punishable under Title 18 of the U.S. Code, Chapter 115, Section 2385, Fraud and Abuse of Computer Resources.

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Select which RPP you will be responding to.



The screenshot shows the MTEC submission checklist interface. At the top, there is a navigation bar with the MTEC logo and the text "Welcome, MTEC" and "FAQs | Help Request". Below this is a secondary navigation bar with "Portal | MTEC Home | Submissions | Search | Logout". The main content area is titled "Submission Checklist" and contains a "Cancel" button. The checklist instructions read: "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 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

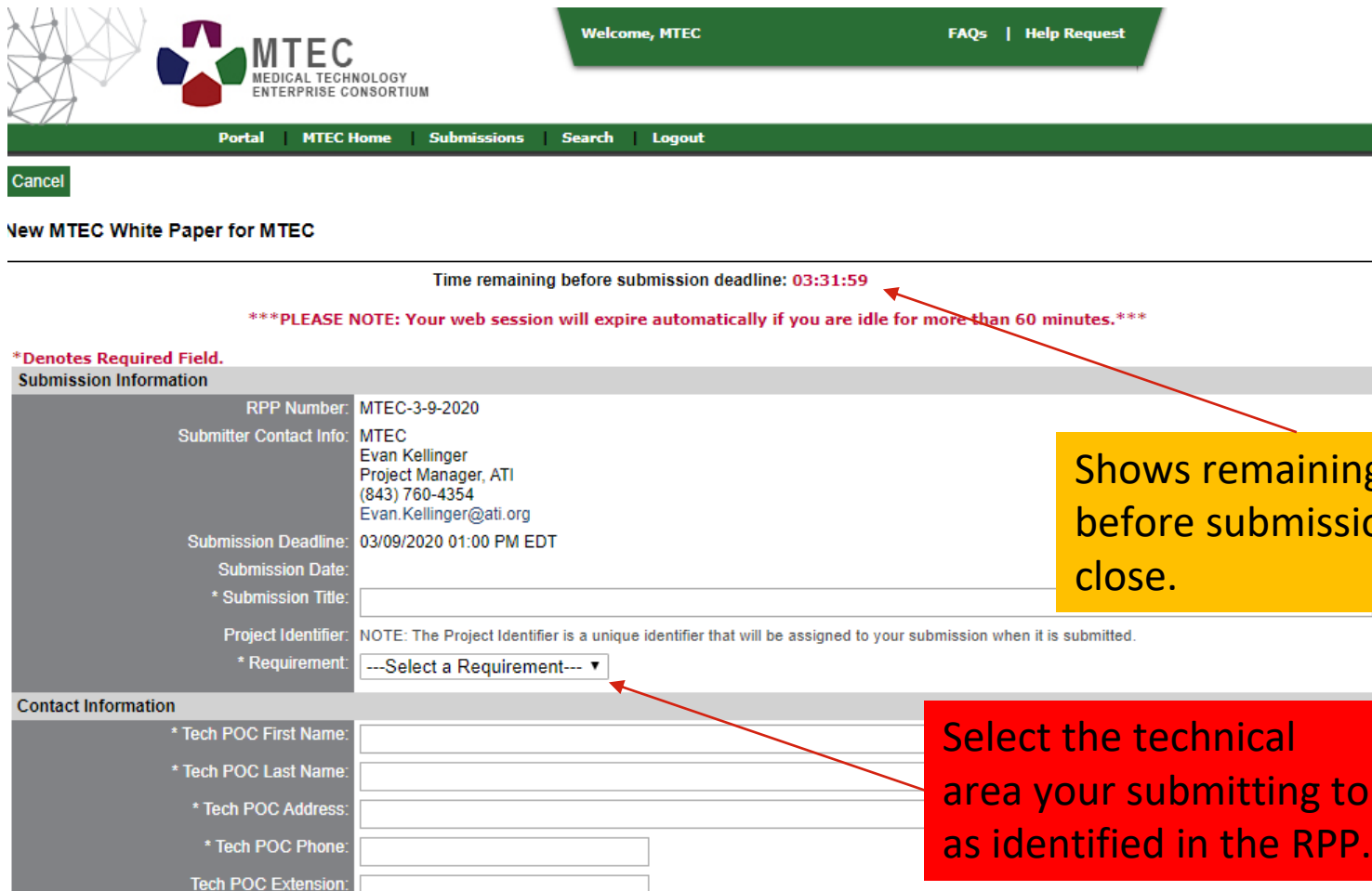
Continue

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

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

Complete the submission form.



The screenshot shows the MTEC submission form interface. At the top, there is a green navigation bar with the MTEC logo and text: "Welcome, MTEC" and "FAQs | Help Request". Below this is a dark 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." is followed by "Submission Information" and "Contact Information" sections. The "Submission Information" section 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), Project Identifier (NOTE: The Project Identifier is a unique identifier that will be assigned to your submission when it is submitted.), and * Requirement (---Select a Requirement---). The "Contact Information" section includes fields for * Tech POC First Name, * Tech POC Last Name, * Tech POC Address, * Tech POC Phone, and Tech POC Extension.

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

| Contact Information | |
|------------------------|----------------------|
| * Tech POC First Name: | <input type="text"/> |
| * Tech POC Last Name: | <input type="text"/> |
| * Tech POC Address: | <input type="text"/> |
| * Tech POC Phone: | <input type="text"/> |
| Tech POC Extension: | <input type="text"/> |

Shows remaining time before submission close.

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

Proposal Submission BIDS

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

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

Upload documents in this section.

Submit

Once the submission form is completed select submit.

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

Proposal Submission BIDS

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

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

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

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