Request for Project Proposals

Solicitation Number: MTEC-21-07-iACT

"interoperable Medical Automated Systems (iMAS) Data Analytics and Artificial Intelligence (AI) Algorithm Development for interoperable Algorithms for Care and Treatment (iACT)"

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: March 16, 2021
Amendment No. 01 Issue Date: April 8, 2021

White Paper Due Date: April 27, 2021
Noon Eastern Time

Amendment No. 01 does the following:
Extends the proposal due date from April 15, 2021 to April 27, 2021.
Extends the date by which Offerors must be members in good standing in Section 2.7.

All other terms and conditions remain unchanged.

White Papers are Required

Table of Contents

Table of Contents 2
1 Executive Summary 4
1.1. Medical Technology Enterprise Consortium 4
1.2. Purpose 4
2 Administrative Overview 5
2.1. Request for Project Proposals (RPP) 5
2.2. Funding Availability and Period of Performance 5
2.3. Acquisition Approach 6
2.4. Proposers Conference 7
2.5. Proprietary Information 7
2.6. MTEC Member Teaming 7
2.7. Offeror Eligibility 8
2.8. Cost Sharing Definition 8
2.9. Cost Share Requirements 8
2.10. MTEC Assessment Fee 9
2.11. Intellectual Property and Data Rights 9
2.12. Expected Award Date 10
2.13. White Paper Selection Notification 10
3 Technical Requirements 10
3.1. Background 10
3.2. Solution Requirements 11
3.3. Potential Follow-on Tasks 13
3.4. Restrictions on Animal and Human Subjects 13
3.5. Guidance related to DOD-affiliated personnel for participation 14
4 White Paper Preparation 14
4.1. General Instructions 14
4.2. Instructions for the Preparation & Submission of the Stage 1 White Paper 14
4.3. Stage 2 Full Proposal (for Only Those Offerors Recommended for Stage 2) 16
4.4. White Paper and Full Proposal Preparation Costs 18
4.5. Freedom of Information Act (FOIA) 18
4.6. Telecommunications and Video Surveillance 18
5 Selection 18
5.1. Preliminary Screening 18
5.2. White Paper (Stage 1) Evaluation 19
5.3. Full Proposal (Stage 2) Evaluation (for Only Those Offerors Recommended for Stage 2) 21
5.4. Cost/Price Evaluation by the Consortium Manager 23
5.5. Definitions of General Terms Used in Evaluations 25
6 Points-of-Contact 25
7 Acronyms/Abbreviations 25
8 White Paper Template 27

Attachment A – Cost Share 30
Attachment B – Statutory Requirements for the Appropriate Use of Other Transaction Authority 31
Attachment C – Intellectual Property and Data Rights 32
Attachment D – Statement of Work Template 34
Attachment E – Warranties and Representations Template 40
Attachment F – Current & Pending Support Template 45
Attachment G – BIDS Instructions 46

1 Executive Summary

1.1. 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 at https://mtec-sc.org/.

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

1.2. Purpose

This solicitation, issued by the MTEC Consortium Manager (CM), Advanced Technology International (ATI), represents a Request for Project Proposals (RPP) for MTEC support of the DOD U.S. Army Medical Materiel Development Activity (USAMMDA). Proposals selected for award as a result of this RPP will be awarded under the authority of 10 U.S.C. § 2371b. Strategic

oversight for the award(s) supported by this RPP will be provided by the Warfighter, Health, Performance and Evacuation (WHPE) Project Management Office (PMO).

This Request for Project Proposals (RPP) is focused on providing soldiers and military medic personnel with Artificial Intelligence (AI) and Machine-Learning based decision support software to enhance their ability to provide short and long term patient care in all domain operation (ADO) environments.

2 Administrative Overview

2.1. Request for Project Proposals (RPP)

MTEC is utilizing a two-staged approach for this RPP. In Stage 1, current MTEC members are invited to submit White Papers using the mandatory format contained in this RPP (Section 8). The Government will evaluate White Papers submitted and will select White Papers that best meet their current technology priorities using the criteria in Section 5 of this RPP. Offerors whose proposed solution is selected for further consideration based on White Paper evaluation will be invited to submit a proposal in Stage 2. Notification letters will contain specific Stage 2 proposal submission requirements.

2.2. Funding Availability and Period of Performance

The U.S. Government (USG) currently has available a total of approximately **$5.8 million (M)** for this effort.

Award and funding from the Government is expected to be limited to the funding specified above and is contingent upon the availability of federal funds for this program. Awards resulting from this RPP are expected to be made under the authority of 10 U.S.C. § 2371b.

Cost sharing, including cash and in kind (e.g., personnel or product) contributions are strongly encouraged, have no limit, and are in addition to the Government funding to be provided under the resultant award(s).

MTEC expects to make a **single award** to a qualified Offeror to accomplish the scope of work. If a single proposal is unable to sufficiently address the entire scope of the RPP, several Offerors may be asked to work together in a collaborative manner.

Award funding will be structured incrementally and based upon completion of Milestones and Deliverables to include formal Product Review meetings and Critical Decision points incorporated as milestones within the Milestone Payment Schedule (MPS).

The Period of Performance (PoP) is **not to exceed five years.**

Dependent on the results and deliverables under any resultant award(s), the USG may apply additional dollars and/or allow for additional time for non-competitive follow-on efforts with appropriate modification of the award. See Section 3.3. for additional details.

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.

2.3. Acquisition Approach

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

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

Stage 1: White Papers submitted under this RPP shall follow the MTEC White Paper Template provided in Section 8.

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

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

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

The Government-selected prototype project(s) awarded as a result of this solicitation will be funded under the Other Transaction Agreement for prototype projects (OTA) Number W81XWH-15-9-0001 with MTEC administered by the CM, ATI. The CM will negotiate and execute a Base Agreement with MTEC members (if not yet executed). The same provisions will govern this Base Agreement as the OTA for prototype projects between the Government and MTEC. Subsequently, any proposal that is selected for award will be funded through a Research Project

Award issued under the member's Base Agreement. A sample of the MTEC Base Agreement can be found on the MTEC website at www.mtec-sc.org.

2.4. Proposers Conference

MTEC will host a Proposers Conference that will be conducted via webinar within two (2) weeks after the release of the RPP. The intent of the Proposers Conference is to provide an administrative overview of this RPP process to award and present further insight into the specific areas of interest outlined in Section 3. 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.

2.5. Proprietary Information

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

2.6. MTEC Member Teaming

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

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

tool to make edits and populate their organization's profile. There are two sections as part of the profile relevant to teaming:

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

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

2.7. Offeror Eligibility

Offerors must be MTEC Members in good standing. Offerors submitting White Papers as the prime contractor must be MTEC members of good standing **by April 22, 2021**. To join MTEC, please visit http://mtec-sc.org/how-to-join/.

2.8. Cost Sharing Definition

Cost sharing is defined as the resources expended by the award recipients on the proposed statement of work (SOW). *Cost sharing above the statutory minimum is not required in order to be eligible to receive an award under this RPP.* If cost sharing is proposed, then the Offeror shall state the amount that is being proposed and whether the cost sharing is a cash contribution or an in-kind contribution (see Attachment A for definitions); provide a description of each cost share item proposed; the proposed dollar amount for each cost share item proposed; and the valuation technique used (e.g., vendor quote, historical cost, labor hours and labor rates, number of trips, etc.).

2.9. Cost Share Requirements

In order to be compliant with 10 U.S.C. §2371b, Research Projects selected for funding under this RPP are required to meet at least one of the conditions specified in Attachment B ("Statutory Requirements for the Appropriate Use of Other Transaction Authority"). Beyond that, cost sharing is encouraged if possible, as it leads to stronger leveraging of Government-contractor collaboration. For more information regarding cost share, please see Attachment A.

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

2.10. MTEC Assessment Fee

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

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. Awardees must select one of the two methods:

(1) 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.

(2) 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.

2.11. Intellectual Property and Data Rights

Baseline Intellectual Property (IP) and Data Rights for MTEC Research Project Awards are defined in the terms of an awardee's Base Agreement, and specifically-negotiated terms are finalized in any resultant Research Project Award. Due to this project's unique requirements, the Government is identifying in this RPP the level of specifically-negotiated IP and data rights required by the Government for this project. Proposals will be evaluated on a pass/fail basis for the inclusion of IP and data rights terms as outlined in this section (i.e. section 2.11) of the RPP. MTEC reserves the right to assist in the negotiation of IP, royalties, licensing, future development, etc., between the Government and the individual performers during the entire award period.

The Offeror shall comply with the terms and conditions contained in their Base Agreement regarding IP and data rights, as modified by the specifically-negotiated IP and data rights terms herein. Specifically, the Awardee shall grant to and/or obtain for the Government, Government Purpose Rights to all Category A and Category B Data **including all documents, software, and materials developed under this award, and those developed prior to award by the Awardee or other entity, which are needed for full functionality and maintenance of the project deliverables, to include the source codes, algorithms, libraries and additional files required to compile and run the software developed under this award. The documents, software, and**

materials developed under this award, as well as those developed prior to award as mentioned in the preceding sentence (such as libraries needed for full functionality and maintenance of the project deliverables), shall be Offeror owned, with the Government receiving Government Purpose Rights therein. Any Commercial Computer Software and/or Data needed for the full functionality and maintenance of the project deliverables must be delivered with a commercial license granting to the Government rights equivalent to the Government Purpose Rights described herein. The documents, software and materials produced under the Award shall not be sold back to a different Government entity as the Government is receiving Government Purpose Rights therein. All documents, materials and software supplied to the Government under this Award shall be conveyable to other government entities and third parties within the limitations of a Government Purpose Rights license as mentioned above, with no notice to or authorization from the Offeror needed. This right does not abrogate any other Government rights. For purposes of this this section (i.e. paragraph 2.11.), the terms "developed" and "government purpose" shall have the same definition as utilized in DFARS 252.227-7014.

Note that as part of the Stage 1 of the RPP process (submission of a white paper), Offerors shall complete and submit Attachment C with the signature of responsible party for the proposing Prime Offeror.

2.12. Expected Award Date

Offerors should plan on the period of performance beginning September 15, 2021 (subject to change). The Government reserves the right to change the proposed period of performance start date through negotiations via the CM and prior to issuing a Research Project Award.

2.13. White Paper Selection Notification

As the basis of selections is completed, the Government will forward their selections to MTEC CM to notify Offerors. Proposers will be notified by email from the MTEC CM of the results of the evaluation. Those successful will move forward to the next phase of the process while those not selected will gain evaluation rationale for non-selection.

3 Technical Requirements

3.1. Background

The overall objective of interoperable Algorithms for Care and Treatment (iACT) is to provide the enhanced medical knowledge, skills, and abilities for combat life savers and military medical personnel to care for injured warfighters in Prolonged Field Care (PFC) or deployed clinical settings. These capabilities are imperative not only to support injuries sustained from military munitions, but also the enduring threat of disease during Multi-Domain Operations (MDO). The effective implementation of the platform will enable a larger portion of the Joint force to quickly and accurately assess and treat injuries sustained from a variety of mechanisms. The goal of iACT is to provide warfighters with access to an inclusive database which will utilize AI algorithms to

generate indications, warnings, and suggestions to support their ability to monitor, diagnose, triage, and treat injured warfighters.

3.2. Solution Requirements

The iACT prototype is a software system utilizing AI and Machine Learning based Clinical Decision Support algorithms to be used to support military medical personnel in their duties. The system will be developed with a Graphical User Interface (GUI) and Application Program Interface (API) to enable military personnel to input data and provide military personnel with AI-based alerts for their patients. The prototype shall include the development and integration of the medical database and AI based algorithms that are free of errors and minimizes the risks of data fitting and dimensionality through scalable data subsets. AI capabilities include, but are not limited to, predicting point of patient decompensation, predicting injury patterns, assessing patient status, identifying treatments and medications relating to the initial assessments, and providing medical alerts for personnel based on patient medical data. The system will receive patient data both manually entered and automatically collected from vital signs monitors, analyze the data received, and provide recommendations for medical treatment. The prototype must enable the development of specific AI-based algorithms that are free of errors and minimize the risks of data fitting and dimensionality through scalable data subsets.

Offerors are expected to provide the following information in their submissions:

- Prior experience developing and integrating machine learning algorithms.
- Strategy for large-scale dataset management.
- Identification of pitfalls and decision factors that should be considered when making short-term and long-term decisions.
- Description of the types of AI/Machine Learning algorithms for medical purposes that will be developed in addition to any potential algorithms that could be developed and the types of data/amount of data necessary for developing those algorithms, as well as the strategy and feasibility of successfully developing each algorithm.
- Strategy and recommended software to store large-scale datasets and how they will be optimized to build machine learning algorithms.
- Strategy for managing query costs.
- Strategy and recommended software for the processing of large-scale data sets.
- Strategy for handling different types of data and what those data types may include.

- Description of how the proposed algorithms will provide Joint Warfighters and military medical personnel with machine learning-based decision support algorithms that can be implemented in DOD tactical medical software applications to enhance their ability to monitor, diagnose, triage, and treat injured warfighters during tactical combat casualty care.

- Description of how the proposed algorithms will provide inclusive assessments and treatment procedures, indications, warnings, or suggestions for consideration in prolonged field care and deployed clinical environments.

- Description of how the complete database will be capable of storing large amounts of real world medical trauma cases, including patient diagnoses, complete vital signs sets, medications given, medical treatments performed, and patient outcomes.

- Description of how the proposed database will enable their development of AI-based medical Clinical Decision Support algorithms and evaluate machine learning that will ultimately be used to recommend diagnoses, treatments, and medications to care providers in Medical Treatment Facilities.

- Strategy to collaborate and cooperate with the joint effort between WHPE PMO subject matter experts and stakeholders, including but not limited to the U.S. Army Combat Capabilities Development Command Aviation & Missile Center (CCDC AvMC) Systems Simulation, Software and Integration Directorate (S3i).

- Technical support to establish and maintain a Risk Management Framework assessment to obtain an Authority to Operate (ATO) at Sensitive But Unclassified (SBU) and Secret levels.

Additional Points of Consideration:

- Offerors shall propose an appropriate number of FTEs to accomplish the full scope of work.

- Awardees will provide updates through Technical and Business Status Reports to the Government point of contact chosen by the WHPE PMO. This report shall indicate the current work completed, work in progress, man hours required, funds expended, and program status. The report shall include configuration and change management revision, control documentation for hardware and software, major accomplishments, work to be accomplished in the next month, performance, schedule, and cost updates. It shall also rate and document risks, risk mitigation activities, and issues raised by the Integrated Product Team. The format of the Technical and Business Status Report is at the discretion of the Awardee. The report is due the 10th working day of each month after award until contract conclusion (Offerors should include this in the SOW, see Attachment D of this

RPP). The Government will review the submissions of the Technical and Business Status Reportfor compliance with the Statement of Work and other contract provisions.

- Awardees shall schedule an Initial Baseline Review with WHPE PMO within 60 days of contract award (include this in the SOW, see Attachment D of the RPP).

- Offerors shall arrange two (2) Product Reviews per year to provide the WHPE PMO with updates regarding the status of the contract and prototype (include this in the SOW, see Attachment D of the RPP). Product Reviews shall occur:
    - Within 150-180 days from the contract award date, repeated annually.
    - 30 to 60 days prior to the end of the performing year, repeated annually.

  Following these Product Reviews, the Milestone Payment Schedule within the SOW **shall** include distinct **Critical Decision Points** (30 days following the Product Reviews). The Critical Decision Points will serve as discrete programmatic decision points which will allow the Government to assess the progress to date, considering cost, schedule, and performance, and make a determination to proceed with subsequent milestones as awarded, renegotiate any aspect of the SOW/MPS, or end the project.

- A Technical Data Package (TDP) shall be delivered seven (7) calendar days prior to the end of each year (Offerors shall include this in the SOW, see Attachment D of this RPP). The Technical Data Package (TDP) shall consist of all technical data and documentation necessary for the development, manufacturing, and support of the device, for all software and hardware. This shall include but is not limited to the TDP, Product Master Data File, system / network architectures, system / network architectures, data points / formats, transmission protocols, cybersecurity test plan, RMF package submission plan, and Interface Control Documents to include the source codes, algorithms, libraries and additional files required to compile and run the software, Requirement Traceability Matrix, User Manuals and Quick Setup Guides, New Equipment Training Briefs and Guides, Bill of Materials (BOM), component manufacturer and part numbers, Test Measurement & Diagnostic Equipment (TMDE), Product Maintenance Plan and Schedule.

3.3. Potential Follow-on Tasks

There is potential for award of one or more follow-on tasks based on the success of any resultant Research Project Awards (subject to change depending upon Government review of work completed). Note that any potential follow-on work is expected to be awarded non-competitively to resultant project awardees.

3.4. Restrictions on Animal and Human Subjects

White Papers and proposals must comply with restrictions and reporting requirements for the use of animal and human subjects, to include research involving the secondary use of human biospecimens and/or human data. The Awardee shall ensure local Institutional Animal Care and

Use Committee (IACUC) and Institutional Review Board (IRB) approvals, continuing review (in the intervals specified by the local IACUC and IRB, but at a minimum, annually), and approval by the U.S. Army Medical Research and Development Command Animal Care and Use and Review Office (ACURO) and the USAMRDC Human Research Protections Office (HRPO). Offerors shall include IACUC, ACURO, IRB and HRPO review and approval in the SOW/Milestones Table submitted with the Stage 2 full proposal (if invited), as applicable.

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

3.5. Guidance related to DOD-affiliated personnel for participation

Compensation to DOD-affiliated personnel for participation:
Please note that compensation to DOD-affiliated personnel for participation in research while on duty is prohibited with some exceptions. For more details, see Department of Defense Instruction 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DOD-Conducted and Supported Research. You may access a full version of the DODI by accessing the following link: https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf

4 White Paper Preparation

4.1. General Instructions

White Papers should be submitted by the date and time specified on the cover page using BIDS: https://ati2.acqcenter.com/ATI2/Portal.nsf/Start?ReadForm. Include the MTEC Solicitation Number (**MTEC-21-07-iACT**) on each white paper submitted. See RPP Attachment G for further information regarding BIDS registration and submission.

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

The White Paper format provided in this MTEC RPP is mandatory and shall reference this RPP number (**MTEC-21-07-iACT**). Note that Cost Proposals are only required for Stage 2 and are not part of the initial White Paper submission. Offerors are encouraged to contact the Points-of-Contact (POCs) identified herein up until the White Paper submission date/time to clarify requirements (both administrative and technical in nature).

All eligible Offerors may submit White Papers for evaluation according to the criteria set forth herein. Offerors are advised that only ATI as the MTEC's CM, with the approval of the DOD Agreements Officer, is legally authorized to contractually bind MTEC into any resultant awards.

4.2. Instructions for the Preparation & Submission of the Stage 1 White Paper

Offerors submitting White Papers in response to this RPP should prepare all documents in accordance with the following instructions:

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

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

Required Submission Documents (1): Submitted via BIDS

- **White Paper: One PDF document 5MB or lower.**
- **Data Rights as one signed Word or PDF document.**

The following information provides additional information related to each of the required documents for the full proposal submission.

- **White Paper (template provided in Section 8 of the RPP):** Each White Paper is limited to five pages plus a cover page (6 pages total). The White Paper shall be in 11 point (or larger) type font, single-spaced, single-sided, on 8.5 inches x 11 inches paper. Smaller font may be used in figures and tables, but must be clearly legible. Margins on all sides (top, bottom, left, and right) should be at least 1 inch. The MTEC staff will share white papers with various potential public and private sector sponsors. ***Please do not include confidential or proprietary information.*** White Papers exceeding the page limits specified above may not be accepted.

- **Data Rights Assertions (template provided in Attachment C):**
    - The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding data rights. It is anticipated that anything delivered under this proposed effort would be delivered to the Government in accordance with Section 2.11 of this RPP unless otherwise asserted in the proposal and agreed to by the Government.
    - If this is not the intent, then you should discuss any restricted data rights associated with any proposed deliverables. If applicable, complete the table

within the Attachment for any items to be furnished to the Government with restrictions. An example is provided.

4.3. Stage 2 Full Proposal (for Only Those Offerors Recommended for Stage 2)

MTEC members who are invited to participate in Stage 2 will be required to submit the following information.

Required Submission Documents (8): Submit via BIDS (5MB or lower)

- **Technical Proposal as one word or PDF document.**
- **Statement of Work (SOW)/Milestone Payment Schedule (MPS) as one Word (.docx or .doc)**
- **Section I: Cost Proposal Narrative as one Word or PDF document.**
- **Section II: Cost Proposal Formats as one Excel or PDF document.**
- **Royalty <u>or</u> Additional Research Project Award Assessment as one signed Word or PDF document.**
- **Warranties and Representations for all proposals as one Word or PDF document.**
- **Current and Pending Support as one Word or PDF document.**
- **Data Rights as one signed Word or PDF document.**

The following information provides additional information related to each of the required documents for the full proposal submission. <u>The Technical Proposal and Cost Proposal must be submitted in two separate volumes</u>, 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. **<u>Each document will be uploaded to BIDS separately (see Attachment G of RPP for BIDS instructions).</u>**

- **Technical Proposal:** <u>The Technical Proposal format provided in the MTEC PPG is mandatory.</u> Proposals shall reference this RPP number (**MTEC-21-07-iACT**). If your proposal addresses more than one focus area, please ensure that your technical proposal clearly delineates your approach separated by focus area. Refer to section 6.2 of the PPG for instruction regarding the preparation of the Technical Proposal (also referred to as Volume 1).

- **Statement of Work (SOW)/Milestone Payment Schedule (MPS) (template provided in Attachment D)**: The Offeror is required to provide a detailed SOW/Milestone Payment Schedule using the format provided herein (Attachment D). 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. [Note: Although the SOW/MPS is already included as Appendix B of the Technical Proposal (Volume 1), <u>it must be uploaded into the BIDS system again as a separate file in either the *.docx or *.doc format.]</u>

- **Cost Proposal:** The Cost Proposal should clearly delineate your costs separated by focus area (if applicable), where possible. Each cost proposal should include direct costs and other necessary components as applicable, for example, fringe, General & Administrative Expense (G&A), Facilities & Administrative (F&A), Other Direct Costs (ODC), etc. Offerors shall provide a breakdown of material and ODC costs as applicable. The Cost Proposal shall be submitted in two separate sections Section I: Cost Proposal Narrative (see Attachment 1 of the PPG) is required. Separately, Section II: Cost Proposal Formats. Refer to Section 7 of the PPG for instruction regarding the preparation of the Cost Proposal (also referred to as Volume 2).] **Offerors are encouraged to use their own cost formats such that the necessary detail is provided.** MTEC will make cost proposal formats available on the Members-Only MTEC website. The Cost Proposal formats provided in the MTEC PPG are **NOT** mandatory. Refer to the MTEC PPG for additional details.

- **Warranties and Representations (template provided in Attachment E):** one Word (.docx or .doc) or PDF file that contains all Warranties and Representations is required for each proposal. Refer to Attachment E 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 **<u>or</u>** the Royalty Payment Agreement (available on the MTEC members only website), **not both**, and submit a signed copy with the proposal. [Note: As per section 7.1 of the PPG, you must indicate your choice of either the MTEC Additional Research Project Award Assessment Fee or the Royalty Payment Agreement as part of Section I of the Cost Proposal (Cost Proposal Narrative). For more information regarding the Royalty Payment Agreement or Additional Research Project Award Assessment, refer to Section 8.8 of the PPG.]

- **Current and Pending Support (template provided in Attachment F):** 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), role, 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."

- **Data Rights Assertions (template provided in Attachment C):** Although this was already provided at Stage 1 of the RPP process, Offerors are required to either re-submit or provide an updated version at Stage 2 of the RPP process.
    - The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding data rights. The Government will retain Government Purpose Rights to all property and software produced in the course of developing,

deploying, training, using and supporting this effort. See Section 2.11 for more detail.

- If this is not the intent, then you should discuss any restricted data rights associated with any proposed deliverables. If applicable, complete the table within the Attachment for any items to be furnished to the Government with restrictions. An example is provided.
- Note: This document is no longer required as part of the Technical Proposal (Volume 1) and will be uploaded as a separate attachment into the BIDS system.

Evaluation: The Government will evaluate and determine which proposal(s) to award based on criteria described in **Section 5, "Selection,"** of this RPP. The Government reserves the right to negotiate with Offerors.

4.4. White Paper and Full Proposal Preparation Costs

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

4.5. Freedom of Information Act (FOIA)

To request protection from FOIA disclosure as allowed by 10 U.S.C. §2371(i), Offerors shall mark business plans and technical information with a legend identifying the documents as being submitted on a confidential basis. For more information, please refer to Section 6.1.1 of the MTEC PPG.

4.6. Telecommunications and Video Surveillance

Per requirements from the Acting Principal Director of Defense Pricing and Contracting dated 13 August 2020, the provision at FAR 52.204-24, "Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment" is incorporated in this solicitation. If selected for award, the Offeror(s) must complete and provide the representation as required by the provision to the CM.

5 Selection

5.1. Preliminary Screening

The CM will conduct a preliminary screening of submitted White Papers to ensure compliance with the RPP requirements. As part of the preliminary screening process, White Papers that do not meet the requirements of the RPP may be eliminated from the competition or additional information may be requested by the CM. The Government reserves the right to request additional information or eliminate proposals that do not meet these requirements from further consideration. One of the primary reasons for non-compliance or elimination during the initial screening is the lack of significant nontraditional defense contractor participation, nonprofit research institution participation, or cost share (see Attachment B). Proposal Compliance with

the statutory requirements regarding the appropriate use of Other Transaction Authority (as detailed within Attachment B) will be determination based upon the ratings shown in Table 1:

TABLE 1- COST SHARING/NONTRADITIONAL CONTRACTOR ASSESSMENTS	
RATING	**DESCRIPTION**
PASS	Offeror proposing an MTEC research project meets at least ONE of the following: • Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution • Offeror's White Paper has at least one Nontraditional Defense Contractor or Nonprofit Research Institute participating to a significant extent • All significant participants in the transaction other than the Federal Government are small businesses or nontraditional defense contractors • Offeror provides at least one third of the total project cost as acceptable cost share
FAIL	Offeror proposing an MTEC research project does **NOT** meet at least ONE of the following: • Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution • Offeror's White Paper 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

5.2. White Paper (Stage 1) Evaluation

The CM will distribute all White Papers that pass the preliminary screening (described above) to the Government for evaluation. The Government will evaluate White Papers submitted under this RPP using the following equally important criteria:

1. Technical Feasibility
2. Potential for Transition

Factor 1 – Technical Feasibility: The Offeror's white paper will be assessed for relevancy, thoroughness, and completeness of the proposed approach (e.g., the technical merit). The following information will be considered as part of this factor:

a) Feasibility: Feasibility of the proposed solution and its alignment with the RPP's topic area;
b) Study Design: The Offeror's study design to include the strategies and concepts for the proposed work as they relate to the objectives; and
c) Budget: The Offeror's estimated budget.

Factor 2 - Potential for Transition: The Offeror's white paper will be assessed for its potential to transition to the Government. This factor will assess how well the Offeror complies with the IP and data rights considerations described in Section 2.11.

Table 2 explains the adjectival merit ratings that will be used for the evaluation factors.

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

Upon review and evaluation of the White Papers, Offerors who are favorably evaluated will be invited to participate in Stage 2 for further consideration. Offerors whose White Papers were not favorably evaluated will be provided feedback on the evaluation. Note that Offerors should receive an overall rating of at least "Acceptable" or higher in order to be considered for Stage

2; however, the Government reserves the right to make final evaluation decisions based upon programmatic relevancy and overall best value solutions determined to be in the Government's best interest.

The RPP review and award process may involve the use of contractor subject matter experts serving as nongovernmental advisors. All members of the technical evaluation panel, to include contractor SMEs, will agree to and sign a Federal Employee Participation Agreement or a Nondisclosure/Nonuse Agreement, as appropriate, to protect information contained in the RPP as outlined in Section 2.5.

5.3. Full Proposal (Stage 2) Evaluation (for Only Those Offerors Recommended for Stage 2)

To the maximum extent practicable the evaluation criteria found here are anticipated for all (Stage 2) Full Proposal submissions (subject to change).

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

Full proposals that pass the preliminary compliance screening will be evaluated by the Government technical evaluation panel who will make recommendations to a Source Selection Authority.

Evaluation will be based on an independent, comprehensive review and assessment of the work proposed against stated source selection criteria and evaluation factors. The Government will evaluate against the technical evaluation factors detailed below and assign adjectival ratings to the non-cost/price factor(s) consistent with those defined in Table 2 (General Merit Ratings Assessments). As detailed below, the Cost Reasonableness factor will be evaluated based upon the ratings defined in Table 3. The Offeror shall clearly state how it intends to meet and, if possible, exceed the RPP requirements. Mere acknowledgement or restatement of a RPP requirement is not acceptable. The CM will evaluate the cost proposals for those Offerors recommended for award, as detailed below, for The CM will evaluate the cost proposals for realism, reasonableness, and completeness .

Evaluation Factors

1. Technical Approach and Strategy
2. Project Team and Relevant Experience
3. Cost Reasonableness

Technical Approach and Project Team and Relevant Experience will be evaluated with equal importance; however, when combined are significantly more important than cost/price.

Factor 1 – Technical Approach and Strategy: The Offeror's full proposal will be assessed for:

a) How well the specific aims and proposed methodology support the technical objectives and the development of the prototype.
b) An approach which effectively demonstrates the Offeror's understanding of the overall requirement and inclusion of complete and clear processes to execute the effort.
c) How well the submission defines a prototype that meets the requirements set forth in this RPP. Whether the prototype is based on promising preliminary data, sound scientific rationale, and demonstrated proof-of-concept.
d) How well the Offeror addresses the following:
    a. Description of the types of Artificial Intelligence/Machine Learning algorithms for medical purposes that could be developed and the types of data/amount of data necessary for developing those algorithms, as well as the strategy and feasibility of successfully developing each algorithm.
    b. Strategy and software recommended to store large-scale datasets and how they will be optimized to build machine learning algorithms.
    c. Strategy and software recommended for the processing of large-scale data sets.
    d. Strategy for handling different types of data and what those data types may include.

Factor 2 – Project Team and Relevant Experience: The Offeror's Full Proposal will be assessed for how the background and expertise of the personnel and organizations are appropriate to execute the proposed research. The following information will be considered as part of this factor:

a) <u>Strength of Team:</u> Strength of the organization/team, considering the qualifications of the personnel, facilities, equipment, supplies, services, and subcontractors proposed to complete the work.

b) <u>Experience:</u> Relevance of the Offeror's prior experience developing and integrating machine learning algorithms; Strength of proposed strategy for large-scale dataset management.

c) <u>Schedule:</u> The degree to which the Offeror demonstrates a realistic, achievable performance schedule with a plan to address potential pitfalls and decision factors that must be considered when making short-term and long-term decisions.

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

With the exception of "Cost Reasonableness," the Stage 2 evaluation factors will be rated based upon the adjectival merit ratings detailed in Table 2. See Table 3 for the definitions of the "Cost Reasonableness" factor ratings.

Table 3 - "Cost Reasonableness" Factor Ratings Definitions	
RATING	**DESCRIPTION**
SUFFICIENT	The estimate is within the available funding limits and considered appropriate to successfully complete the proposed project
INSUFFICIENT	The estimate is lower than what is considered appropriate to successfully complete the proposed project.
EXCESSIVE	The estimate is higher than what is considered appropriate to successfully complete the proposed project and may be outside of the available funding limits.

Please also refer to Section 5.5 for definitions of general terms used in technical evaluations.

5.4. Cost/Price Evaluation by the Consortium Manager

After completion of the technical evaluation performed by the Government sponsors, the MTEC CM will evaluate the total estimated cost proposed by the Offeror(s) recommended for funding. Evaluation will include analysis of the proposed cost together with all supporting information. The Offeror's cost and rationale will be evaluated for realism, reasonableness, and completeness. If a proposal is selected for award, the MTEC CM will review the original cost proposal and the Offeror's response to a Proposal Update Letter, if applicable. The MTEC CM will request additional information or clarification as necessary. The MTEC CM will assess the reasonableness, realism, 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.

The Cost Proposal(s) will be evaluated using the understanding of cost realism, reasonableness and completeness as outlined below:

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

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

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

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

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

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

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

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

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

Best Value

The Government will conduct the source selection based on the evaluation criteria and ratings contained within this RPP. The overall award decision will be based upon a Best Value determination and the final award selection(s) will be made to the most advantageous offer(s) by considering and comparing factors in addition to cost or price, including programmatic relevancy and overall best value solutions determined to be in the Government's best interest. Based on the results of the Stage 2 Technical Evaluation, the Government reserves the right to negotiate and request changes to any or all parts of the proposal to include the SOW. Offerors will have the opportunity to concur with the requested changes and revise cost proposals as necessary.

5.5. Definitions of General Terms Used in Evaluations

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

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

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

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

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

6 Points-of-Contact

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

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

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

7 Acronyms/Abbreviations

ACURO	Animal Care and Use Review Office
ADO	All Domain Operation
AI	Artifical Intelligence
API	Application Program Interface
ATI	Advanced Technology International
ATO	Authority to Operate
AvMC	Aviation & Missile Center

BOM	Bill of Materials
CAS	Contract Accounting System
CBRN	Chemical, biological, radiological, and nuclear
CCDC	Combat Capabilities Development Command
CM	Consortium Manager
CMA	Consortium Member Agreement
CT	Computed Tomography
DHA	Defense Health Agency
DHP	Defense Health Program
DOD	Department of Defense
ER	Emergency Room
EUD	End User Devices
FAQ	Frequently Asked Questions
F&A	Facilities and Administrative Costs
FTE	Full-Time Equivalents
FY	Fiscal Year
G&A	General and Administrative Expenses
GUI	Graphical User Interface
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
iACT	Interoperable Algorithms for Care and Treatment
iMAS	Interoperable Medical Automated Systems
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IRB	Institutional Review Board
IR&D	Independent Research and Development
ITN	Integrated Tactical Network
JADC2	Joint-All-Domain Command and Control
JBC-P	Joint Battle Command - Platform
JPC	Joint Program Committee
M	Millions
MDO	Multi-Domain Operations
MPS	Milestone Payment Schedule
MRI	Magnetic Resonance Imaging
MTEC	Medical Technology Enterprise Consortium
MTF	Medical Treatment Facilities
NDA	Nondisclosure Agreement
NW	Nett Warrior
OCI	Organizational Conflict of Interest
ODC	Other Direct Costs
OTA	Other Transaction Agreement
OR	Operating Room
HRPO	Human Research Protection Office, USAMRDC

PFC	Prolonged Field Care
PMO	Project Management Office
POC	Point-of-Contact
PoP	Period of Performance
PORTAL	Patient Operational Remote Tele-monitoring Advanced Layout
PPE	Personal protection equipment
PPG	Proposal Preparation Guide
R&D	Research and Development
RDT&E	Research, Development, Test and Evaluation
RPP	Request for Project Proposals
S3i	Systems Simulation, Software and Integration Directorate
SBU	Sensitive But Unclassified
SME	Subject Matter Expert
SOW	Statement of Work
TDP	Technical Data Package
TMDE	Test Measurement & Diagnostic Equipment
USAMMDA	U.S. Army Medical Materiel Development Activity
USAMRDC	U.S. Army Medical Research and Development Command
USG	U.S. Government
WHPE	Warfighter, Health, Performance and Evacuation

8 White Paper Template

See the following page for the mandatory White Paper Template.

<u>Cover Page (1 page)</u>
Title of White Paper

Principal Investigator and Institution

Statement that "This White Paper is submitted pursuant to the RPP MTEC-21-07-iACT"

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

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

Willingness to allow MTEC Officers access to your White Paper for the purposes of engaging in outreach activities with private sector entities: Indicate YES or NO
[As part of MTEC's mission to incorporate philanthropic donations, MTEC frequently makes contact with private sector entities (e.g., foundations, organizations, individuals) that award grants or otherwise co-fund research, and/or operate in research areas that are aligned with those of MTEC. Additional private entities may be interested in reviewing certain White Papers

within their program areas, allowing opportunities to attract supplemental funding sources. Please indicate your willingness to allow MTEC access to your White Paper for the purposes of engaging in outreach activities with these private sector entities. MTEC staff has signed Nondisclosure Agreements (NDAs) and Organizational Conflict of Interest statements.]

White Paper (5 pages)

Title: [Insert descriptive title of project]

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

Approach: [Briefly describe your approach to solving the problem. Include relevant background/preliminary data about your approach. Describe the existing or proposed solution. Indicate the technology or knowledge readiness level (TRL/KRL) at the time of submission and at end of the PoP. Full definitions of TRLs can be found here. More information regarding KRLs can be found here. Note: References are included within the page limit. There is no required format for the inclusion of references.]

Objectives: [Specify the objectives of the proposed effort.]

Technical Strategy: [Outline the proposed methodology in sufficient detail to show a clear course of action that addresses the technical requirements described in this RPP. Be sure to include all information requested in Section 3.2]

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

Potential for Transition: [Provide a brief description and justification of the maturity of the proposed solution and your plan to transition the prototype to the Government. Include information about IP/data rights Assertions. Refer to Section 2.11 for the Government's requirements related to IP and data rights.]

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

Project Team: [Briefly state the qualifications and relevant prior experience of the Principal Investigator, key personnel, and organizations that will perform the SOW.]

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

Period of Performance: [Indicate the total proposed PoP.]

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

Rough Order of Magnitude (ROM) Pricing: [The Offeror must provide an estimate based on the technical approach proposed in the White Paper. The following ROM pricing shall be included in the White Paper. (**NOTE: If invited to Stage 2, it is preferred that the total cost to the Government proposed in the ROM not substantially deviate from the proposed cost presented in the Stage 2 full proposal (unless otherwise directed by the Government) as this may result in an unacceptable rating.) Use the example table format and template below to provide the ROM pricing.** The labor, travel, material costs, other direct costs, and indirect costs, information should be entered for Offeror (project prime) only. Subcontractors and/or consultants should be included only in the "Subcontractor" section of the table. If selected for award, a full cost proposal will be requested.

Labor	*$200,000.00*
Subcontractors	*$100,000.00*
Consultants	*$20,000.00*
Material/Equipment	*$150,000.00*
Other Direct Costs	*00*
Travel	*,000.00*
Indirect costs	*$96,400.00*
Total	*$578,400.00*
Fee ***(applicable if cost share is proposed)***	*$0.00*
Total Cost (plus Fee)	*$578,400.00*
Cost Share (if cost share is proposed then fee is un-allowable)	*$580,000.00*
Total Project Cost	*$1,158,400.00*

EXAMPLE

***Offerors are reminded to refer to the Selection Criteria under Section 5 of the RPP to ensure that all required information is provided.**

Attachment A – Cost Share

Cost Sharing includes any costs a reasonable person would incur to carry out (necessary to) proposed projects' statements of work (SOW) not directly paid for by the Government. There are two types of cost sharing: Cash Contribution and In-Kind Contribution. If a proposal includes cost share then it cannot include fee. Cost Share may be proposed only on cost type agreements. Prior Independent Research and Development IR&D funds will not be considered as part of the Consortium Member's cash or In-Kind contributions, except when using the same procedures as those that authorize Pre-Award Costs, nor will fees be considered on a Consortium Member's cost sharing portion.

Cash Contribution

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

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

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

In-Kind Contribution

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

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

Nontraditional Defense Contractor Definition

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

Significant Extent Requirements

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

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

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

Conditions for use of Prototype OT Authority

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

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

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

(C) At least one third of the total cost of the prototype project is to be paid out of funds provided by sources other than the Federal Government.

This requirement is a statutory element of the Other Transaction Authority and will be regarded as a pass/fail criterion during the Compliance Screening in order to ensure compliance with 10 U.S.C. §2371b.

Attachment C – Intellectual Property and Data Rights

Stage 1 and 2 Requirement

Definitions

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

- **Data Rights:** It is anticipated that anything delivered under a Research Project Award would be delivered to the Government with **Government Purpose Rights to all Category A and Category B Data including all documents, software, and materials developed under this award, and those developed prior to award by the Awardee or other entity, which are needed for full functionality and maintenance of the project deliverables, to include the source codes, algorithms, libraries and additional files required to compile and run the software developed under this award. The documents, software, and materials developed under this award, as well as those developed prior to award as mentioned in the preceding sentence (such as libraries needed for full functionality and maintenance of the project deliverables), shall be Offeror owned, with the Government receiving Government Purpose Rights therein. Any Commercial Computer Software and/or Data needed for the full functionality and maintenance of the project deliverables must be delivered with a commercial license granting to the Government rights equivalent to the Government Purpose Rights described herein. The documents, software and materials produced under the Award shall not be sold back to a different Government entity as the Government is receiving Government Purpose Rights therein. All documents, materials and software supplied to the Government under this Award shall be conveyable to other government entities and third parties within the limitations of a Government Purpose Rights license as mentioned above, with no notice to or authorization from the Offeror needed. This right does not abrogate any other Government rights.**If this is not the intent, **then the White Paper (and Proposal if invited to Stage 2 of the RPP process) should discuss data rights associated with each item**, and possible approaches for the Government to gain unlimited data rights as referenced in the Base Agreement. Rights in technical data in each Research Project Award shall be determined in accordance with the provisions of MTEC Base Agreement.

Directions to the Offeror

If applicable, complete the below table for any items to be furnished to the Government with restrictions. An example is provided. If the Offeror does not assert data rights on any items, a negative response is required by checking the applicable box below.

Failure to complete this attachment in its entirety (including a failure to provide the required signature) may result in removal from the competition and the proposal determined to be ineligible for award

If the Offeror intends to provide technical data or computer software which existed prior to or was produced outside of the proposed effort, to which the Offeror wishes to maintain additional rights, these rights should be asserted through the completion of the table below.

Note that this assertion is subject to negotiation prior to award.

☐ If Offeror WILL be asserting data rights for the proposed effort, check this box and complete the table below, adding rows as necessary.

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

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

_____ _____

Signature of responsible party for the proposing Prime Offeror DATE

Attachment D – Statement of Work Template

For Information Only - Stage 2 Requirement

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.

Proposal Number:
Organization:
Title:
ACURO and/or HRPO approval needed:

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

Scope/Project Objective (*To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.)*
This section includes a statement of what the project covers. This should include the 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. Early phases in which the performance definition is known shall be detailed by subtask with defined work to be performed. Planned incrementally funded phases will require broader, more flexible tasks that are priced up front, and adjusted as required during execution and/or requested by the Government to obtain a technical solution. Tasks will need to track with established adjustable cost or fixed price milestones for payment schedule. Each major task included in the SOW should be priced separately in the cost proposal. Subtasks need not be priced separately in the cost proposal.

Deliverables (*To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.)*
Results of the technical effort are contractually binding and shall be identified herein. Offerors are advised to read the Base Agreement carefully. Any and all hardware/software to be provided to the Government as a result of this project shall be identified. Deliverables should be submitted in PDF or MS Office format. It must be clear what information will be included in a deliverable either through a descriptive title or elaborating text.

Milestone Payment Schedule (*To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding. The milestone schedule included should be in editable format (i.e., not a picture))*
The Milestone Payment Schedule should include all milestone deliverables that are intended to be delivered as part of the project, a planned submission date, the monetary value for that deliverable and any cost share, if applicable. For fixed price agreements, when each milestone is submitted, the MTEC member will submit an invoice for the exact amount listed on the milestone payment schedule. For cost reimbursable agreements, the MTEC member is required to assign a monetary value to each milestone. In this case, however, invoice totals are based on cost incurred and will not have to match exactly to the amounts listed on the milestone payment schedule.
The milestones and associated deliverables proposed should, in general:

- be commensurate in number to the size and duration of the project (i.e., a $5M multi-year project may have 20, while a $700K shorter term project may have only 6);
- not be structured such that multiple deliverables that might be submitted separately are included under a single milestone;
- be of sufficient monetary value to warrant generation of a deliverable and any associated invoices;
- include on the 10th working day of each month a Report which includes Technical and Business Status Reports, Final Technical Report, and Final Business Status Report. Reports shall have no funding associated with them.

iACT MTEC Sample Milestone Payment Schedule						
MTEC Milestone Number	**Task Number**	**Significant Event/Accomplishments**	**Due Date**	**Govt Funds**	**Cost Share**	**Total Funding**
1	N/A	Project Kickoff	7/15/2021	$ -		$ -
2	N/A	Monthly Technical & Business Status Report 1	8/10/2021	$ -		$ -
3	N/A	Initial Baseline Review	9/1/2021	$ -		$ -
4	N/A	Monthly Technical & Business Status Report 2	9/10/2021	$ -		$ -
5	N/A	Monthly Technical & Business Status Report 3	10/10/2021	$ -		$ -
6	N/A	Monthly Technical & Business Status Report 4	11/10/2021	$ -		$ -

7	N/A	Monthly Technical & Business Status Report 5	12/10/2021	$ -		$ -
8	N/A	Product Review 1	12/15/2021	$ -		$ -
9	N/A	Monthly Technical & Business Status Report 6	1/10/2022	$ -		$ -
10	N/A	Monthly Technical & Business Status Report 7	2/10/2022	$ -		$ -
11	N/A	Monthly Technical & Business Status Report 8	3/10/2022	$ -		$ -
12	N/A	Monthly Technical & Business Status Report 9	4/10/2022	$ -		$ -
13	N/A	Monthly Technical & Business Status Report 10	5/10/2022	$ -		$ -
14	N/A	Monthly Technical & Business Status Report 11	6/10/2022	$ -		$ -
15	N/A	Product Review 2	6/15/2022	$ -		$ -
16	N/A	Plans for HRPO/IACUC/ACURO/IRB/FDA Approval	7/1/2022	$ -		$ -
17	N/A	(Annual) Monthly Technical & Business Status Report 12	7/10/2022	$ -		$ -
18	N/A	Annual Technical Data Package Submission 1	7/10/2022	$ -		$ -
19	N/A	Critical Decision Point 1	7/15/2022	N/A		$ -
20	N/A	Monthly Technical & Business Status Report 13	8/10/2022	$ -		$ -
21	N/A	Monthly Technical & Business Status Report 14	9/10/2022	$ -		$ -
22	N/A	Monthly Technical & Business Status Report 15	10/10/2022	$ -		$ -
23	N/A	Monthly Technical & Business Status Report 16	11/10/2022	$ -		$ -
24	N/A	Monthly Technical & Business Status Report 17	12/10/2022	$ -		$ -
25	N/A	Product Review 3	12/15/2022	$ -		$ -
26	N/A	Submission for HRPO/IACUC/ACURO/IRB/FDA Approval	1/1/2023	$ -		$ -
27	N/A	Monthly Technical & Business Status Report 18	1/10/2023	$ -		$ -
28	N/A	Monthly Technical & Business Status Report 19	2/10/2023	$ -		$ -
29	N/A	Monthly Technical & Business Status Report 20	3/10/2023	$ -		$ -
30	N/A	Monthly Technical & Business Status Report 21	4/10/2023	$ -		$ -
31	N/A	Monthly Technical & Business Status Report 22	5/10/2023	$ -		$ -
32	N/A	Monthly Technical & Business Status Report 23	6/10/2023	$ -		$ -
33	N/A	Product Review 4	6/15/2023	$ -		$ -
34	N/A	Receive HRPO/IACUC/ACURO/IRB/FDA Approval	7/1/2023	$ -		$ -
35	N/A	(Annual) Monthly Technical & Business Status Report 24	7/10/2023	$ -		$ -
36	N/A	Annual Technical Data Package Submission 2	7/10/2023	$ -		$ -
37	N/A	Critical Decision Point 2	7/15/2023	N/A		$ -
38	N/A	Monthly Technical & Business Status Report 25	8/10/2023	$ -		$ -
39	N/A	Monthly Technical & Business Status Report 26	9/10/2023	$ -		$ -
40	N/A	Monthly Technical & Business Status Report 27	10/10/2023	$ -		$ -
41	N/A	Monthly Technical & Business Status Report 28	11/10/2023	$ -		$ -
42	N/A	Monthly Technical & Business Status Report 29	12/10/2023	$ -		$ -
43	N/A	Product Review 5	12/15/2023	$ -		$ -
44	N/A	HRPO/IACUC/ACURO/IRB/FDA Update	1/1/2024	$ -		$ -
45	N/A	Monthly Technical & Business Status Report 30	1/10/2024	$ -		$ -
46	N/A	Monthly Technical & Business Status Report 31	2/10/2024	$ -		$ -
47	N/A	Monthly Technical & Business Status Report 32	3/10/2024	$ -		$ -

48	N/A	Monthly Technical & Business Status Report 33	4/10/2024	$ -		$ -
49	N/A	Monthly Technical & Business Status Report 34	5/10/2024	$ -		$ -
50	N/A	Monthly Technical & Business Status Report 35	6/10/2024	$ -		$ -
51	N/A	Product Review 6	6/15/2024	$ -		$ -
52	N/A	(Annual) Monthly Technical & Business Status Report 36	7/10/2024	$ -		$ -
53	N/A	Annual Technical Data Package Submission 3	7/10/2024	$ -		$ -
54	N/A	Critical Decision Point 3	7/15/2024	N/A		$ -
55	N/A	Monthly Technical & Business Status Report 37	8/10/2024	$ -		$ -
56	N/A	Monthly Technical & Business Status Report 38	9/10/2024	$ -		$ -
57	N/A	Monthly Technical & Business Status Report 39	10/10/2024	$ -		$ -
58	N/A	Monthly Technical & Business Status Report 40	11/10/2024	$ -		$ -
59	N/A	Monthly Technical & Business Status Report 41	12/10/2024	$ -		$ -
60	N/A	Product Review 7	12/15/2024	$ -		$ -
61	N/A	HRPO/IACUC/ACURO/IRB/FDA Update	1/1/2025	$ -		$ -
62	N/A	Monthly Technical & Business Status Report 42	1/10/2025	$ -		$ -
63	N/A	Monthly Technical & Business Status Report 43	2/10/2025	$ -		$ -
64	N/A	Monthly Technical & Business Status Report 44	3/10/2025	$ -		$ -
65	N/A	Monthly Technical & Business Status Report 45	4/10/2025	$ -		$ -
66	N/A	Monthly Technical & Business Status Report 46	5/10/2025	$ -		$ -
67	N/A	Monthly Technical & Business Status Report 47	6/10/2025	$ -		$ -
68	N/A	Product Review 8	6/15/2025	$ -		$ -
69	N/A	(Annual) Monthly Technical & Business Status Report 48	7/10/2025	$ -		$ -
70	N/A	Annual Technical Data Package Submission 4	7/10/2025	$ -		$ -
71	N/A	Critical Decision Point 4	7/15/2025	N/A		$ -
72	N/A	Monthly Technical & Business Status Report 49	8/10/2025	$ -		$ -
73	N/A	Monthly Technical & Business Status Report 50	9/10/2025	$ -		$ -
74	N/A	Monthly Technical & Business Status Report 51	10/10/2025	$ -		$ -
75	N/A	Monthly Technical & Business Status Report 52	11/10/2025	$ -		$ -
76	N/A	Monthly Technical & Business Status Report 53	12/10/2025	$ -		$ -
77	N/A	Product Review 9	12/15/2025	$ -		$ -
78	N/A	HRPO/IACUC/ACURO/IRB/FDA Update	1/1/2026	$ -		$ -
79	N/A	Monthly Technical & Business Status Report 54	1/10/2026	$ -		$ -
80	N/A	Monthly Technical & Business Status Report 55	2/10/2026	$ -		$ -
81	N/A	Monthly Technical & Business Status Report 56	3/10/2026	$ -		$ -
82	N/A	Monthly Technical & Business Status Report 57	4/10/2026	$ -		$ -
83	N/A	Monthly Technical & Business Status Report 58	5/10/2026	$ -		$ -
84	N/A	Monthly Technical & Business Status Report 59	6/10/2026	$ -		$ -
85	N/A	Product Review 10	6/15/2026	$ -		$ -
86	N/A	(Final) Monthly Technical & Business Status Report 60	7/10/2026	$ -		$ -
87	N/A	(Final) Annual Technical Data Package Submission 5	7/10/2026	$ -		$ -

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. Monthly, 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 Status Reports (separate).
5. Final Report due date must be prior to PoP end noted in Research Project Award.
6. MTEC Milestone Numbers are used for administrative purposes and should be sequential.
7. Task Numbers are used to reference the statement of work if they are different from the MTEC Milestone Number.
8. Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.
9. Allow at least 2 to 3 months for HRPO regulatory review and approval processes.

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

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

Reporting

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

Annual Reports - The MTEC research project awardee shall prepare an Annual Report which will include Technical and Business Status Reports in accordance with the terms and conditions of the Base Agreement. (Required)

Final Technical Status Report – At the completion of the Research Project Award, the awardee will submit a Final Technical Status 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)

*Please refer to Section 3.2 of the RPP for additional reporting requirements.

Attachment E – Warranties and Representations Template

For Information Only - Stage 2 Requirement

Section 815 of the National Defense Authorization Act (NDAA) for Fiscal Year 2018, authorizes Department of Defense organizations to carry out prototype projects that are directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or to improvement of platforms, systems, components, or materials in use by the armed forces. The law also requires at least one of the following:

(A) There is at least one nontraditional defense contractor or nonprofit research institution participating to a significant extent in the prototype project.

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

(C) At least one third of the total cost of the prototype project is to be paid out of funds provided by sources other than the Federal Government.

A. Prime Contractor: The prime contractor must complete the following table.

1. Legal Name:		**2. DUNS #:**	
3. Point of Contact: Name, Title, Phone #, Email			
4. Prime Contractor is a nontraditional (Y/N)?			
5. Prime Contractor is a nonprofit research institution (Y/N)?			
6. Prime Contractor will provide at least one third of the total cost of the prototype project out of funds provided by sources other than the Federal Government (Y/N)?			
7. Prime Contractor is a small business (Y/N)?			

If the prime contractor has answered "Y" to question 4, 5, or 6, skip Section B and proceed to Section C.

B. Subcontractor(s)/Vendor(s): If the prime contractor is a **traditional** defense contractor and proposes the use of one or more nontraditional defense contractors or nonprofit research institutions, the following information is required **for each** participating nontraditional defense contractor or nonprofit research institution.

8. Legal Name:		**9. DUNS #:**	
10. Dollar Value to be Awarded to Subcontractor:			
11. Point of Contact: (Name, Title, Phone #, Email)		**12. Task/Phase:**	
13. Subcontractor/Vendor is a nontraditional (Y/N)?			
14. Subcontractor/Vendor is a nonprofit research institution (Y/N)?			
15. Subcontractor/Vendor is a small business (Y/N)?			
16. Significant Contribution:			

☐	**A - The significant contribution involves developing, demonstrating or providing a key technology.** *Please describe what the key technology is; why it is key to the medical technology community, and what makes it key.*
☐	**B - The significant contribution involves developing, demonstrating or providing a new technology that is not readily available.** *Please describe what the new part or material is and why it is not readily available.*
☐	**C - The significant contribution involves use of skilled personnel (such as modeling & simulation experience, medical technology design experience, etc.), facilities and/or equipment that are within the capabilities of the designated nontraditional and required to successfully complete the program.** *Please describe the personnel, facilities and/or equipment involved in the proposed program and why they are required to successfully complete the program.*
☐	**D - The use of this designated subcontractor/vendor will cause a material reduction in the cost or schedule.** *Please describe the specific cost or schedule impact to be realized*
☐	**E - The use of this designated subcontractor/vendor will increase medical technology performance.** *Please describe what the performance increase will be attained by the use of this designated nontraditional defense contractor*
1	**In addition to the above please provide the following information:**
Q1	**What additional capability beyond those described in A through E above does this subcontractor/vendor have that is necessary for this specific effort?**
A1	
Q2	**In which task/phase(s) of the effort will the subcontractor/vendor be used?**
A2	
Q3	**What is the total estimated cost associated with the subcontractor/vendor included in the proposal?** *Note: While cost is an indicator for the level of nontraditional defense contractor participation, there is no particular cost threshold required.*
A3	

C. Signature

_____ _____

Signature of authorized representative of proposing Prime Contractor Date

Warranties and Representations Instructions

Section A must be completed for the Prime Contractor.

1. Insert prime contractor's legal name.
2. Insert prime contractor's DUNS #.
3. Insert the Point of Contact (Name, Title, Phone #, Email) for the prime contractor.
4. Indicate Yes (Y) or No (N) if the prime contractor is a nontraditional defense contractor (Note: A nontraditional defense contractor means an entity that is not currently performing and has not performed, for at least the one-year period preceding the issue date of the solicitation, any contract or subcontract for the Department of Defense that is subject to full coverage under the cost accounting standards prescribed pursuant to Section 1502 of Title 41 and the regulations implementing such section.).
5. Indicate Yes (Y) or No (N) if the prime contractor is a nonprofit research institution.
6. Indicate Yes (Y) or No (N) if the prime contractor will provide at least one third of the total cost of the prototype project out of funds provided by sources other than the Federal Government (i.e. will the project contain at least 1/3 cost share).
7. Indicate Yes (Y) or No (N) if the prime contractor is a small business (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)).

Section B must be completed if the Prime Contractor is **traditional** and has proposed nontraditional defense contractors, nonprofit research institutions, or small businesses. Copy, paste, and complete the table found in Section B **for each** participating nontraditional defense contractor, nonprofit research institutions, or small business.

8. Insert subcontractor/vendor's legal name.
9. Insert subcontractor/vendor's DUNS #.
10. Insert the dollar value (cost and fee) to be awarded to the subcontractor/vendor.
11. Insert the Point of Contact (Name, Title, Phone #, Email) for the subcontractor/vendor.
12. Indicate in which specific task/phase(s) of the effort will the subcontractor/vendor be used.
13. Indicate Yes (Y) or No (N) if the subcontractor/vendor is a nontraditional defense contractor (Note: A nontraditional defense contractor means an entity that is not currently performing and has not performed, for at least the one-year period preceding the issue date of the solicitation, any contract or subcontract for the Department of Defense that is subject to full coverage under the cost accounting standards prescribed pursuant to Section 1502 of Title 41 and the regulations implementing such section.).
14. Indicate Yes (Y) or No (N) if the subcontractor/vendor is a nonprofit research institution.
15. Indicate Yes (Y) or No (N) if the subcontractor/vendor is a small business (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)).
16. Explain the subcontractor/vendor's Significant Contribution to the project by answering the questions below.

A - The significant contribution involves developing, demonstrating or providing a key technology. ***Please describe what the key technology is; why it is key to the medical technology community, and what makes it key***.

B - The significant contribution involves developing, demonstrating or providing a new technology that is not readily available. ***Please describe what the new part or material is and why it is not readily available.***

C - The significant contribution involves use of skilled personnel (such as modeling & simulation experience, medical technology design experience, etc.), facilities and/or equipment that are within the capabilities of the designated nontraditional and required to successfully complete the program. ***Please describe the personnel, facilities and/or equipment involved in the proposed program and why they are required to successfully complete the program.***

D - The use of this designated subcontractor/vendor will cause a material reduction in the cost or schedule. ***Please describe the specific cost or schedule impact to be realized.***

E - The use of this designated subcontractor/vendor will increase medical technology performance. ***Please describe what the performance increase will be attained by the use of this designated nontraditional defense contractor.***

Q1 - What additional capability beyond those described in A through E above does this subcontractor/vendor have that is necessary for this specific effort?

Q2 - In which task/phase(s) of the effort will the subcontractor/vendor be used?

Q3 - What is the total estimated cost associated with the subcontractor/vendor included in the proposal? Note: While cost is an indicator for the level of nontraditional defense contractor participation, there is no particular cost threshold required.

Section C must be signed by an authorized representative of the prime contractor.

General Guidance

- Nontraditional defense contractors can be at the prime level, team members, subcontractors, lower tier vendors, or "intra-company" business units, provided that the business unit makes a significant contribution to the prototype project.
- All nontraditional defense contractors must have a DUNS number.
- A foreign business can be considered a nontraditional if it has a DUNS number and can comply with the terms and conditions of the MTEC Base Agreement.

Attachment F – Current & Pending Support Template

For Information Only - Stage 2 Requirement

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

Current
Award Number:
Title:
Funding Agency/Requiring Activity:
Dates of Funding:
Total Awarded Costs:
Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*
Brief summary of the scope of work:

Award Number:
Title:
Funding Agency/Requiring Activity:
Dates of Funding:
Total Awarded Costs:
Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*
Brief summary of the scope of work:

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

Pending
Title of Proposal:
Funding Agency/Requiring Activity:
Estimated Dates of Funding:
Proposed Total Direct Costs:
Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*
Brief summary of the scope of work:

Title of Proposal:
Funding Agency/Requiring Activity:
Estimated Dates of Funding:
Proposed Total Direct Costs:
Role: *(i.e., Principal Investigator, Co-Investigator, etc.)*
Brief summary of the scope of work:

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

Attachment G – BIDS Instructions

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

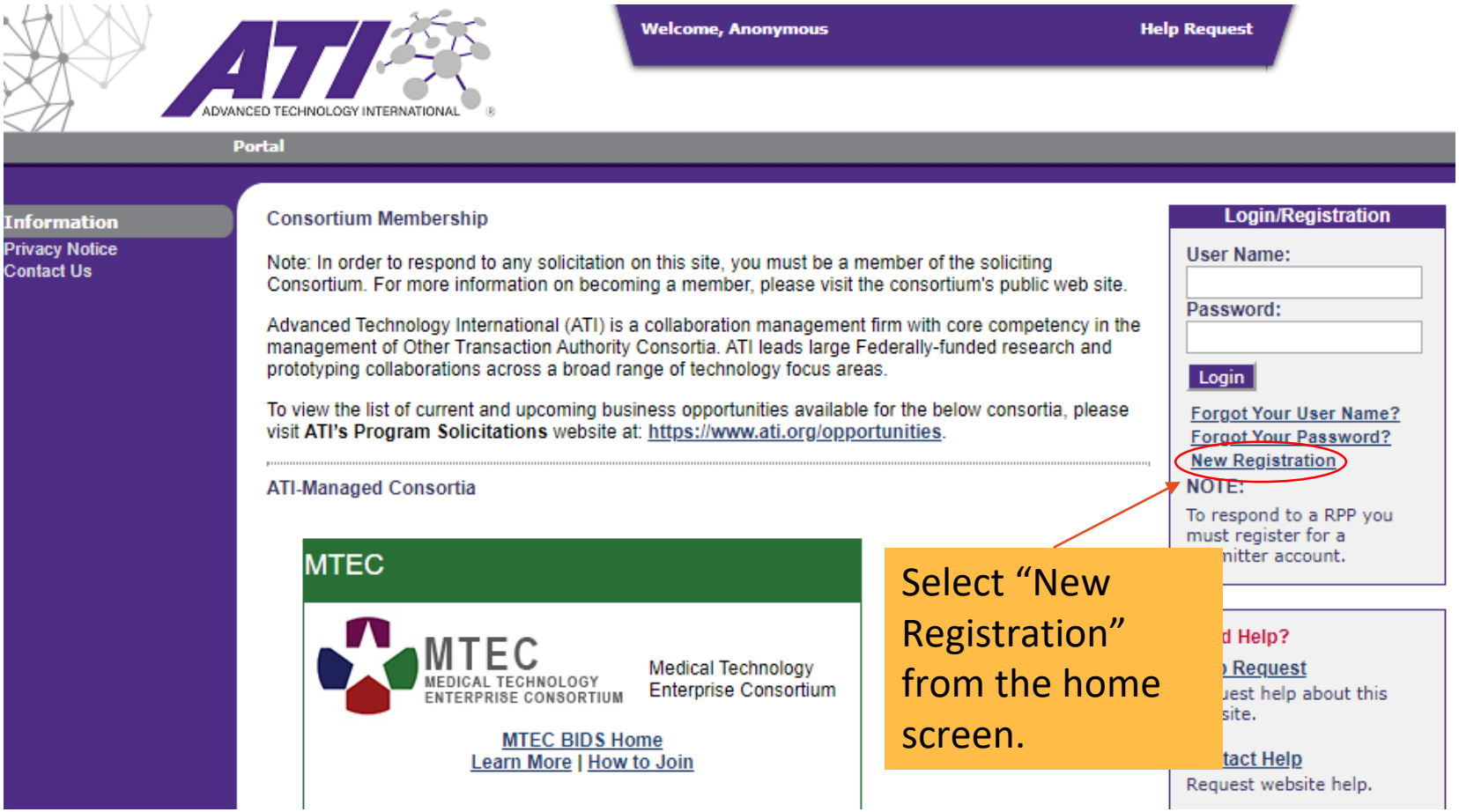
MTEC BIDS REGISTRATION

MTEC BIDS URL:

HTTPS://ATI2.ACQCENTER.COM

BIDS New Registration

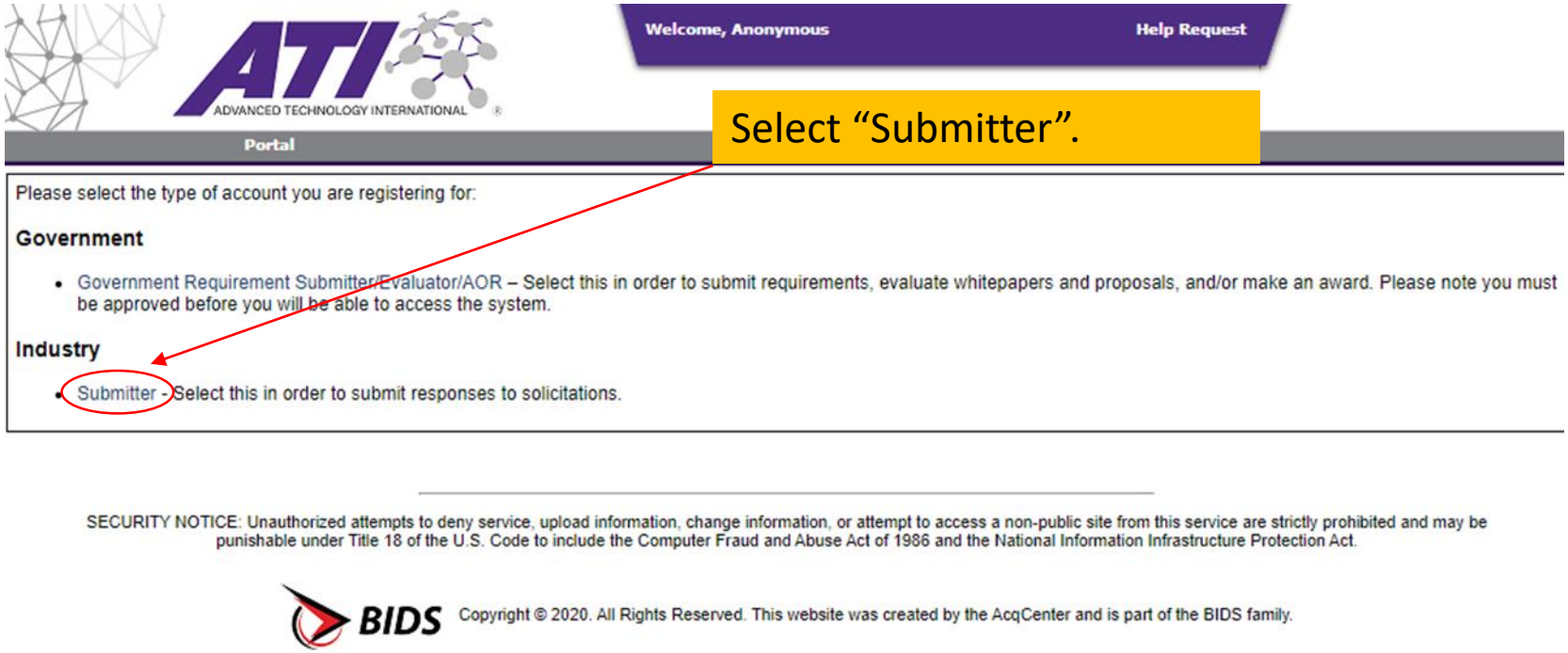
Navigate to the MTEC BIDS website and select “New Registration”



Select “New Registration” from the home screen.

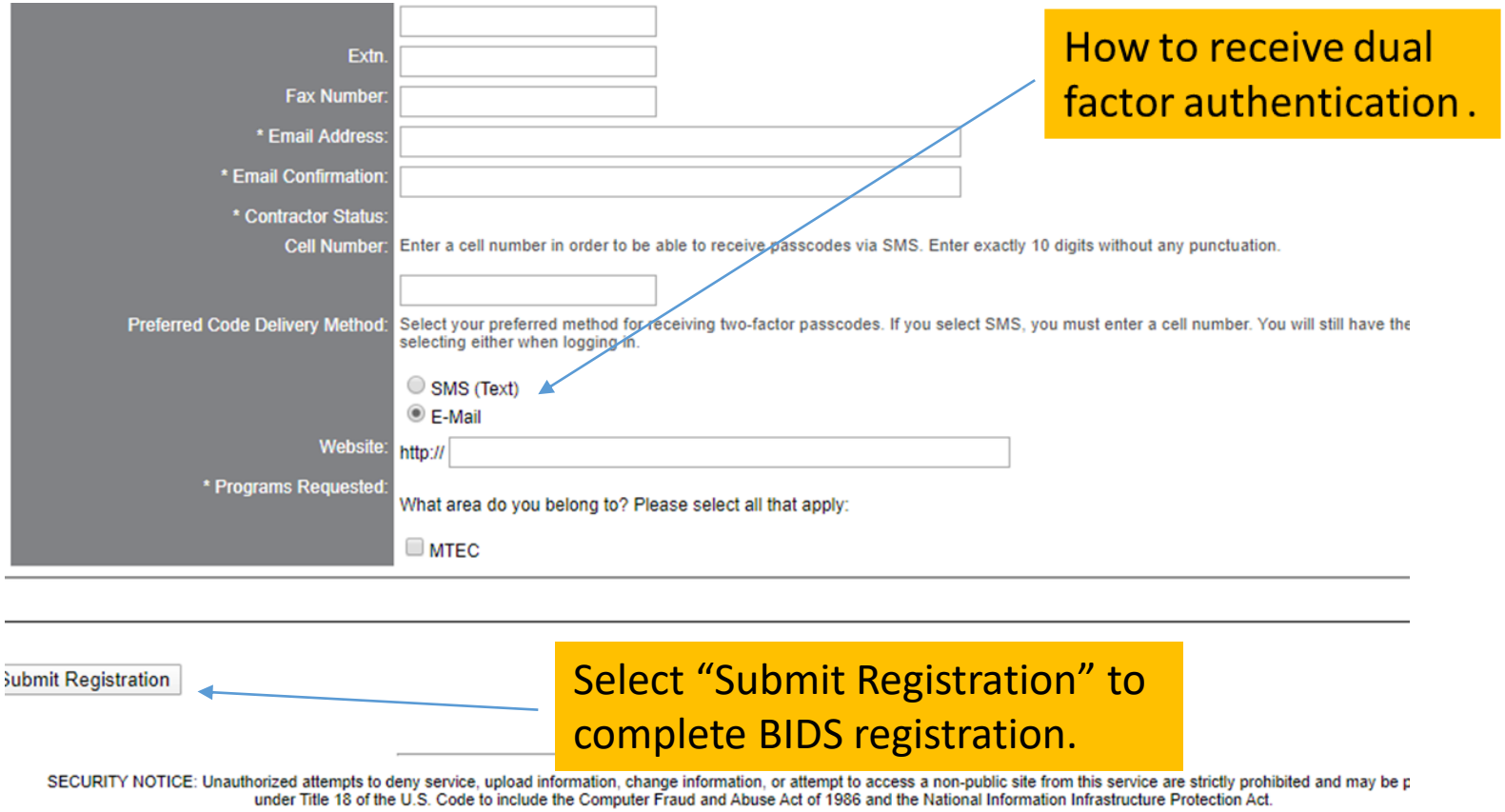
BIDS New Registration

Select “Submitter”



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).



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:

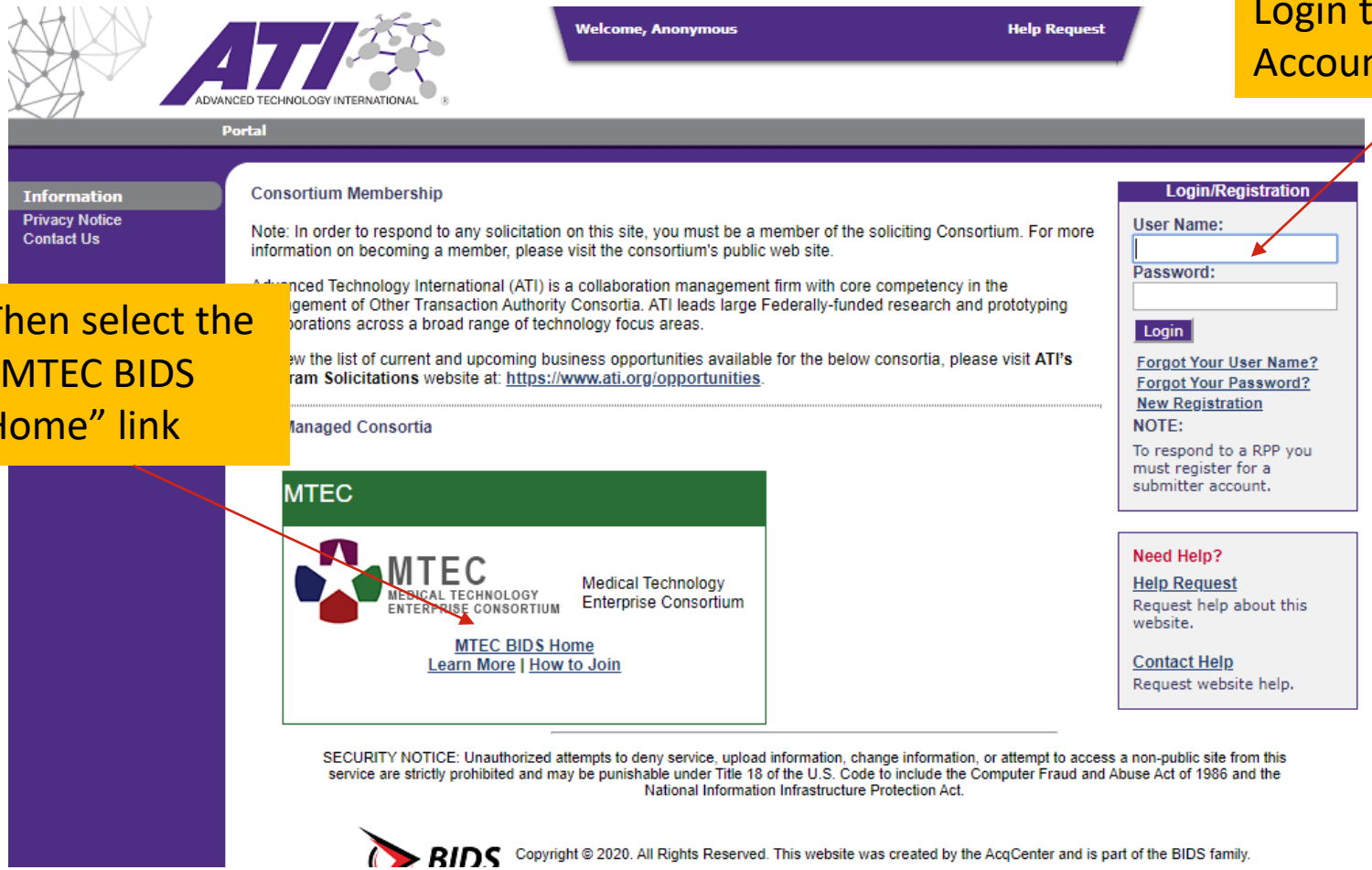
HTTPS://ATI2.ACQCENTER.COM

Proposal Submission BIDS

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

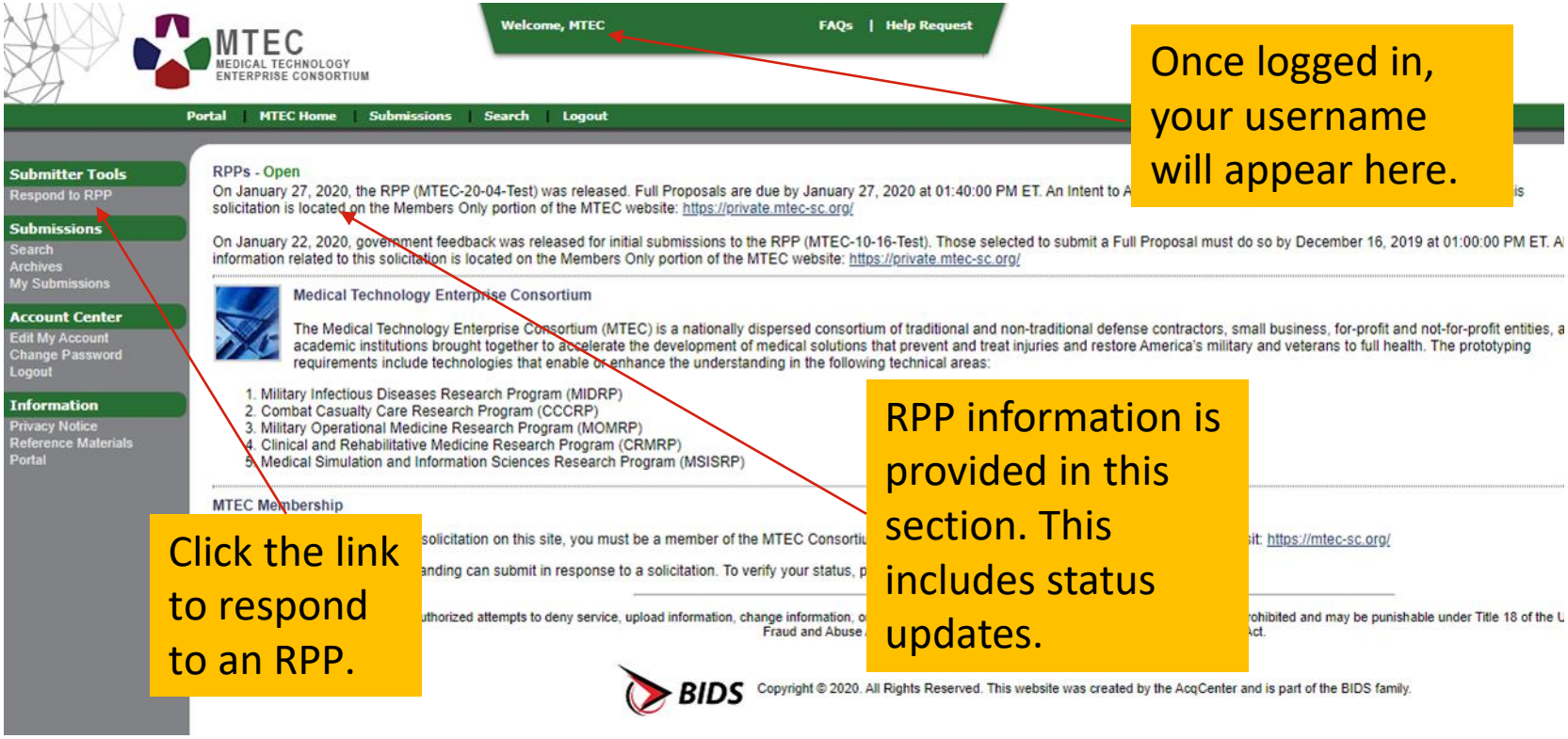
Login to your BIDS Account.

Then select the “MTEC BIDS Home” link



Proposal Submission BIDS

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



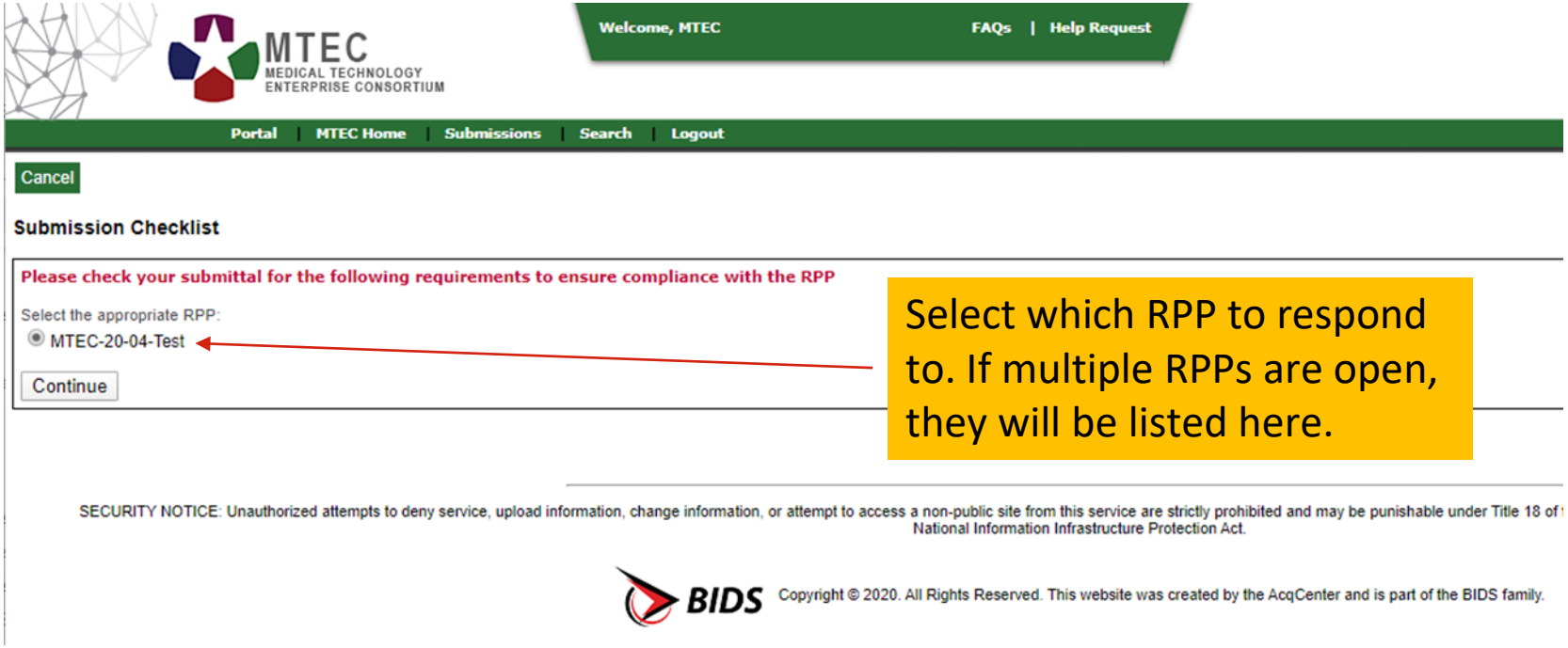
Once logged in, your username will appear here.

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

Click the link to respond to an RPP.

Proposal Submission BIDS

Select which RPP you will be responding to.



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

Proposal Submission BIDS

Complete the submission form.

MTEC
MEDICAL TECHNOLOGY ENTERPRISE CONSORTIUM

Welcome, MTEC FAQs | Help Request

Portal | MTEC Home | Submissions | Search | Logout

Cancel

New MTEC White Paper for MTEC

Time remaining before submission deadline: 03:31:59

PLEASE NOTE: Your web session will expire automatically if you are idle for more than 60 minutes.

*Denotes Required Field.

Submission Information

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

Contact Information

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

Shows remaining time before submission close.

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

Proposal Submission BIDS

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

File Attachments

Required Files: **White Paper** No file uploaded Upload White Paper (Allowed file types: pdf, doc, docx; Size Limit: 5mb)

Agreements

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

☐ 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 Subr
indicates concurrence with the aforementioned CMF responsibilities. Additionally, the Governmer
(CSP) to assist in the submitted proposals' evaluation. The CSP will be required to submit to the
reflecting the effort they will supply to support this RPP. The Submitter's submission of a proposa
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.

☐ Agree

Submit

Upload documents in this section.

Once the submission form is completed select submit.

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

BIDS Copyright © 2020. AcqCenter and is part of the BIDS family.

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 <u>two stages</u> (i.e. White Paper to Full Proposal) <u>only the account that submitted the stage 1 proposal</u> (the White Paper) <u>will be allowed to submit for stage 2</u> (the Full Proposal), if selected.

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