Request for Project Proposals

Solicitation Number: MTEC-23-02-MSKI

"Solutions to Accelerate Return-to-Readiness following Musculoskeletal Injuries"

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Request Issue Date: January 4, 2023

Enhanced White Paper Due Date: February 28, 2023
Noon Eastern Time

Table of Contents

1 Executive Summary 3
1.1. The Medical Technology Enterprise Consortium 3
1.2. Orthopaedic Research and Education Foundation (OREF) 3
1.3. Purpose 4
2 Administrative Overview 4
2.1. Request for Project Proposals (RPP) 4
2.2. Funding Availability and Period of Performance 5
2.3. Acquisition Approach 5
2.4. Proposers Conference 6
2.5. Proprietary Information 6
2.6. MTEC Member Teaming 7
2.7. Offeror Eligibility 8
2.8. Cost Sharing Definition 8
2.9. Cost Sharing Requirements 8
2.10. MTEC Assessment Fee 8
2.11. Intellectual Property and Data Rights 8
2.12. Expected Award Date 9
2.13. Anticipated Enhanced White Paper Selection Notification 9
3 Technical Requirements 9
3.1. Background 9
3.2. Scope of Work 10
3.3. Potential Follow-on Tasks 11
3.4. Restrictions on Human Subjects 11
3.5. Guidance Related to DoD-Affiliated Personnel for Participation in research 12
4 Enhanced White Paper Preparation 12
4.1. General Instructions 12
4.2. Instructions for the Preparation & Submission of the Enhanced White Paper 12
4.3. Stage 2: Cost Proposal (for Only Those Offerors Recommended for Funding) 14
4.4. Enhanced White Paper and Cost Proposal Preparation Costs 15
4.5. Freedom of Information Act (FOIA) 15
4.6. Telecommunications and Video Surveillance 15
5 Selection 15
6 Points-of-Contact 19
7 Acronyms/Abbreviations 19
8 Enhanced White Paper Template 21
Addendum 1 – Warranties and Representations 26
Addendum 2 – Statement of Work (SOW)/Milestone Payment Schedule (MPS) 30
Addendum 3 – Intellectual Property and Data Rights Assertions 34
Addendum 4 – Biographical Sketch 36
Addendum 5 – Current and Pending Support 37
Addendum 6 – Stage 2 Evaluation Criteria 38
Addendum 7 – BIDS Instructions 40

1 Executive Summary

1.1. The Medical Technology Enterprise Consortium

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

(a) engage in biomedical research and prototyping;

(b) exploration of private sector technology opportunities;

(c) technology transfer; and

(d) deployment of intellectual property (IP) and follow-on production.

MTEC is 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 prototype projects with USAMRDC. In accordance with 10 USC 4022 (formerly 10 USC 2371b), the MTEC OTA enables the Government 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. As defined in the DoD 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. Orthopaedic Research and Education Foundation (OREF)

The **Orthopaedic Research and Education Foundation (OREF)** is an independent, 501(c)3 non-profit organization that raises funds to support research on diseases and injuries of bones, nerves, and muscles and to enhance clinical care leading to improved health, increased activity and a better quality of life for patients. To further its mission, OREF is committed to exploring ways to partner with others to support cutting-edge research that addresses musculoskeletal issues.

1.3. Purpose

This solicitation, issued by the MTEC Consortium Manager (CM), Advanced Technology International (ATI), represents a Request for Project Proposals (RPP) for MTEC in support of the Military Operational Medicine Research Program (MOMRP). Proposals selected for award as a result of this RPP will be awarded under the authority of 10 U.S.C. § 4022. Strategic oversight for the award(s) supported by this RPP will be provided by Military Operational Medicine Research Program (MOMRP).

The overall objective of effort is to identify and enable the development of solutions to accelerate recovery following acute or cumulative musculoskeletal injury. Prototypes may include developing medical technologies (e.g. drugs, biologics, and devices) and treatments or rehabilitative strategies (e.g. methods, guidelines, standards, knowledge products) for musculoskeletal injuries.

2 Administrative Overview

2.1. Request for Project Proposals (RPP)

MTEC is utilizing an accelerated approach to award for this RPP. This streamlined approach is anticipated to be a better means to highlight Offeror methodologies and skills required to address the technical requirements described herein. The Enhanced White Paper process requires quick turnaround times by Offerors. The following sections describe the formats and requirements of the Enhanced White Paper.

Offerors who submit Enhanced White Papers in response to this RPP should submit by the date on the cover page of this RPP. Enhanced White Papers may not be considered under this RPP unless received on or before the due date specified on the cover page.

Each MTEC Enhanced White Paper submitted must be in accordance with the mandatory format provided in Section 8 of the RPP. Enhanced White Papers that fail to follow the mandatory format may be eliminated from the competition during the CM's preliminary screening stage (see Section 5 for more details on the Selection process). The Government reserves the right to award Enhanced White Papers received from this RPP on a follow-on prototype OTA or other stand-alone OTAs as necessary to meet mission requirements.

*Note that the terms "Enhanced White Paper" and "Proposal" are used interchangeably throughout this RPP.

2.2. Funding Availability and Period of Performance

The U.S. Government (USG) currently has available a total of approximately $1.47 million (M) of Fiscal Year (FY) 2022 (FY22) research, development, testing, and evaluation (RDT&E) funds for this effort.

Please note that additional funds of at least $100,000 may be provided by the OREF to support a small portion/deliverable of the funded SOW. These additional funds are only available for use by academic or not-for-profit organizations based on OREF's guidelines. Therefore, the Offeror or one of its subcontractors should be an academic institution or a not-for-profit organization to be eligible for the additional funds to be provided by OREF. Please note, eligibility for the additional OREF funding is not required for submission of an enhanced white paper or consideration for award.

OREF gratefully acknowledges funding support from The Aircast Foundation.

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 **up to two awards** to a qualified Offeror to accomplish the scope of work with a Period of Performance not to exceed **36 months**.

2.3. Acquisition Approach

This RPP will be conducted using the Enhanced White Paper approach. In Stage 1, Offerors are invited to submit Enhanced White Papers using the mandatory format contained in this RPP (see Section 8 of this RPP). The Government and the OREF will evaluate Enhanced White Papers and will select those that represent the best value using the evaluation criteria in Section 5 of this RPP. Offerors whose proposed solution is selected for further consideration based on the Enhanced White Paper evaluation will be invited to submit a full cost proposal in Stage 2 (and may be required to submit additional documentation or supplemental information such as those examples listed under Section 4.2). Notification letters will contain specific Stage 2 proposal submission requirements.

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. § 4022 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 (RPA) issued under the member's Base Agreement. The MTEC Base Agreement can be found on the MTEC website and Members-Only website at www.mtec-sc.org.

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

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 Technical Requirements 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 Proposal Preparation Guide (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 entities (e.g., foundations, investor groups, organizations, individuals) that award grants or otherwise co-fund research, and/or operates in research areas that are aligned with those of MTEC. These private entities may be interested in reviewing certain Proposals within their program areas, allowing opportunities to attract supplemental funding sources. Therefore, on your Proposal Cover Page, please indicate your willingness to allow MTEC Officers and Directors access to your Proposal for the purposes of engaging in outreach activities with these private entities. MTEC Officers and Directors who are granted proposal access have signed Nondisclosure Agreements (NDAs) and Organizational Conflict of Interest (OCI) statements. Additionally, these MTEC Officers and Staff represent organizations that currently are not MTEC members, and therefore their parent organizations are not eligible to submit Proposals or receive any research project funding through MTEC. Additionally, all Technical Evaluation Panel participants, 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 Enhanced White Paper 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. The following two resources may help prime contractors provide a more complete team for this requested scope of work.

2.6.1. MTEC M-Corps

The MTEC M-Corps is a network of subject matter experts and service providers to help MTEC members address the business, technical, and regulatory challenges associated with medical product development. M-Corps offers members a wide variety of support services, including but not limited to: Business Expertise [i.e., business development, business and investment planning, cybersecurity, finance, intellectual asset management, legal, logistics/procurement, pitch deck coaching, transaction Advisory], and Technical Expertise [i.e., chemistry, manufacturing and controls (CMC), clinical trials, concepts and requirements development, design development and verification, manufacturing, process validation, manufacturing transfer quality management, regulatory affairs]. Please visit https://www.mtec-sc.org/m-corps/ for details on current partners of the M-Corps.

2.6.2. MTEC Database Collaboration Tool

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

- "Collaboration Interests" – Select the type of teaming opportunities your organization would be interested in. This information is crucial when organizations need to search the membership for specific capabilities/expertise that other members are willing to offer.

- "Solicitation Collaboration Interests" – Input specific active solicitations that you are interested in teaming on. This information will help organizations interested in a specific funding opportunities identify others that are interested to partner in regard 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.

2.6.3. Chat Forum

A dedicated chat forum has been established to facilitate direct interaction amongst MTEC members in relation to this active funding opportunity. The chat forum can be accessed via the "Team Portal" on the MTEC members-only website - https://private.mtec-sc.org/.

2.7. Offeror Eligibility

MTEC membership is **NOT** required for the submission of an Enhanced White Paper in response to this MTEC RPP. However, membership **WILL BE** required for Offerors recommended for award, prior to award being executed. Subcontractors (including all lower tier subawardees) do not need to be MTEC members. 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 **Section 7.4 of the PPG** 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 Sharing Requirements

In order to be compliant with the statute for awarding prototype projects, Research Projects selected for funding under this RPP are required to meet at least one of the conditions specified in **Section 3 of the PPG**. 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 **Section 7.4 of the PPG**. Proposals that fail to meet the mandatory statutory conditions with regard to the appropriate use of Other Transaction authority, as detailed in **Section 3 of the PPG**, 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 2% 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. The MTEC Assessment Fee is not allowable as a direct charge to any resulting award or any other contract. Therefore, Offerors shall not include this Assessment Fee as part of their proposed direct costs. Members who have not paid the assessment fee within 90 days of the due date are not "Members in good standing".

2.11. Intellectual Property and Data Rights

Baseline IP and Data Rights for MTEC Research Project Awards are defined in the terms of an awardee's Base Agreement and, if applicable, specifically-negotiated terms are finalized in any resultant Research Project Award. MTEC reserves the right to assist in the negotiation of IP,

royalties, licensing, future development, etc., between the Government and the individual performers prior to final award decision and during the entire award period.

The Offeror shall comply with the terms and conditions contained in their Base Agreement regarding IP and Data Rights, as modified by the specifically-negotiated IP and Data rights terms herein. **It is anticipated that anything created, developed, or delivered under this proposed effort will be delivered to the Government with Government Purpose Rights or unlimited data rights unless otherwise asserted in the proposal and agreed to by the Government.** Rights in technical data in each Research Project Award shall be determined in accordance with the provisions of MTEC Base Agreement.

See **Addendum 4 of this RPP** for more detail. Note that as part of the Stage 1 of the RPP process (submission of an Enhanced White Paper), **Offerors shall complete and submit Addendum 4 of this RPP (Intellectual Property and Data Rights) as an appendix to the Enhanced White Paper** with the Signature of the responsible party for the proposing Prime Offeror.

For more information, the CM has published a resource for Offerors entitled, "Understanding Intellectual Property and Data Rights" on the MTEC members-only website.

2.12. Expected Award Date

Offerors should plan on the period of performance beginning September of 2023 (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. Anticipated Enhanced White Paper Selection Notification

As the basis of selections is completed, the Government will forward its selections to the MTEC CM to notify Offerors. All Proposers will be notified by email from the MTEC CM of the results of the evaluation. Those successful will move forward to the next stage of the process.

Offerors are hereby notified that once an Enhanced White Paper has been submitted, neither the Government nor OREF nor the MTEC CM will discuss evaluation/status until after the Offeror receives the formal notification with the results of this evaluation.

3 Technical Requirements

3.1. Background

It is difficult to overstate the burden of musculoskeletal disease or the need for more research. According to the United States Bone and Joint Initiative's *The Burden of Musculoskeletal Diseases in the United States (fourth edition)*, more than a third of the population, over 107 million people, was affected by a musculoskeletal condition during the three-year period of 2012-2014. Moreover, the 2020 Health of the Force Report[1] shows a majority of Service member injuries (72%) being cumulative musculoskeletal overuse injuries, singling musculoskeletal injury as one of the largest threats to warfighter readiness. The threat relates

to both the operational and training environments. Battlefield orthopaedic injuries cause the majority of long-term disabilities. Moreover, while deployed, non-battle injuries account for 30% of all medical evacuations and more than 85% of Service members medically evacuated for musculoskeletal injury do not return to theater.[2] In the training environment, musculoskeletal injury accounts for up to 80% of causes for a Service member being medically non-deployable. Overall, fifty percent of soldiers can expect to sustain at least one musculoskeletal injury each year.[2]

This effort focuses on developing or advancing technologies that maximize medical readiness and provide orthopedic and rehabilitation solutions for the modern Warfighter to inform and/or accelerate recovery from musculoskeletal injury. It is believed that prototypes developed through this effort will be commercially applicable and improve the health and quality of life for the broader population of patients enduring orthopedic trauma.

[1] U.S. Army. 2020 Health of the Force Report. https://phc.amedd.army.mil/PHC%20Resource%20Library/2020-hof-report.pdf
[2] Malloy et al. 2020, Mil Med. Musculoskeletal Injuries and the United States Army Readiness Part I: Overview of Injuries and their Strategic Impact

3.2. Scope of Work

This RPP focuses on developing technologies that maximize medical readiness for the modern Warfighter. Efforts may include treatments and/or interventions to accelerate recovery following musculoskeletal injury including:

- Capability to treat, repair or regenerate functional muscle following acute injury.
- Capability to enable faster recovery timelines after soft tissue injury (e.g. strain/sprain)

Additional points of consideration:

- Project Maturity: Proposed prototypes must be at a minimum of a Technology Readiness Level (TRL) of 3, however, it is preferred that proposed prototypes are at a stage where they are ready for user testing. Studies involving human subject testing are highly encouraged. For TRL definitions: https://mtec-sc.org/wp-content/uploads/2016/12/TRL-definitions.pdf

- Proposed Scope: The proposed scope of work should be focused on tasks relevant to advance the prototype to the next TRL. Project scope should be based on the prototype's maturity at the time of submission. The work could include, but is not limited to:
    - Prototype refinement/maturation progressing towards clinical product
    - Clinical studies (as needed) to support regulatory approval/clearance
    - Prototype delivery for military-relevant testing (prototype testing or demonstrations)
    - First article testing

- Industry Partners: MTEC considers that a white paper involving an industry partner (or alternative organizations) to serve as the regulatory sponsor and commercialization partner may have the greatest level of success, especially considering that the eventual goal is to obtain clearance/approval by the U.S. Food and Drug Administration (FDA).

- Academic or Not-for-Profit Partners: MTEC is excited to bring forth OREF as a potential co-funder to this solicitation. OREF has committed $100,000 to support a portion of the proposed work that will be conducted by either an academic or not-for-profit partner organization. If the Offeror (prime contractor) is a for-profit organization, it is encouraged that the Offeror include an academic or not-for profit partner as a subcontractor who is capable and well poised to execute the OREF-funded portion of the work.

3.3. Potential Follow-on Tasks

Under awards resulting from this RPP, there is the potential for award of one or more non-competitive follow-on tasks based on the success of the project (subject to change depending upon Government review of completed work and successful progression of milestones). Potential follow-on work may be awarded based on the advancement in prototype maturity during the PoP. Potential follow-on work may include tasks related to advancement of prototype maturity, and/or to expand the use or utility of the prototype.

3.4. Restrictions on Human Subjects

Research Involving Humans: All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC Office of Human and Animal Research Oversight (OHARO) Office of Human Research Oversight (OHRO) prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Allow a minimum of 2 to 3 months for OHRO regulatory review and approval processes.

Enhanced White Papers must comply with the above-mentioned restrictions and reporting requirements for the use of human subjects, to include research involving the secondary use of human biospecimens and/or human data. The Awardee shall ensure local IRB approvals, continuing review (in the intervals specified by the local IRB, but at a minimum, annually), and approval by the USAMRDC OHRO. Offerors shall include IRB and OHRO review and approval in the SOW/Milestones Table submitted with the Proposal, as applicable.

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

The USAMRDC OHRO will issue written approval to begin research under separate notification. Written approval to proceed from the USAMRDC OHRO is also required for any Research Project Awardee (or lower tier subawards) that will use funds from this award to conduct research

involving human subjects. Offerors must allow at least 30 days in their schedule for the Office of Research Protections (ORP) review and authorization process.

3.5. Guidance Related to DoD-Affiliated Personnel for Participation in research

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 (DODI) 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 this link: https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf

4 Enhanced White Paper Preparation

4.1. General Instructions

Enhanced 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. See **Addendum 7 of this RPP** for further information regarding BIDS registration and submission. The Offeror shall include MTEC Solicitation Number (**MTEC-23-02-MSKI**) in the Enhanced White Paper.

The Enhanced White Paper format provided in this MTEC RPP (Section 8) is **mandatory**. Note that Cost Proposals are only required for Stage 2 and are not part of the initial Enhanced White Paper submission. Offerors are encouraged to contact the Points-of-Contact (POCs) identified herein up until the Enhanced White Paper due date/time to clarify requirements (both administrative and technical in nature).

All eligible Offerors may submit Enhanced 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 Enhanced White Paper

Offerors submitting an Enhanced White Paper, inclusive of a Rough Order of Magnitude cost/price estimate, in response to this RPP shall 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, searchable, 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 (6): Submitted via BIDS (5MB or lower per document)

- **Enhanced White Paper:** one PDF document **(Section 8 of this RPP)**
- **Warranties and Representations:** one Word or PDF document **(Addendum 1 of this RPP)**
- **Statement of Work (SOW)/Milestone Payment Schedule (MPS):** one Word or PDF document **(Addendum 2 of this RPP)**
- **Intellectual Property and Data Rights Assertions:** one Word or PDF document **(Addendum 3 of this RPP)**
- **Biographical Sketches:** one Word or PDF document **(Addendum 4 of this RPP)**
- **Current and Pending Support:** one Word or PDF document **(Addendum 5 of this RPP)**

Page Limitation: The Enhanced White Paper is limited to ten (10) pages (including cover page). The following Appendices are **excluded** from the page limitation: *(1) Warranties and Representations, (2) Statement of Work, (3) Intellectual Property and Data Rights Assertions, (4) Biographical Sketches, and (5) Current and Pending Support.*

The Enhanced White Paper and its Appendices must be in 12-point font (or larger), single-spaced, single-sided, 8.5 inches x 11 inches. Smaller type may be used in figures and tables but must be clearly legible. Margins on all sides (top, bottom, left, and right) should be at least 0.5 inch. **Enhanced White Papers and Appendices exceeding the page limitations and/or the file size specified above may not be accepted. Each document shall be uploaded to BIDS separately (see Addendum 7 of this RPP for BIDS instructions).**

Each Offeror will submit a **Current and Pending Support** document **(template provided in Addendum 5)** and a **Biographical Sketch (template provided in Addendum 4)**. The Offeror shall provide this information for all personnel who will contribute significantly to the proposed research project. Specifically, information shall be provided for all current and pending research support (to include Government and non- government) including 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."

FOR INFORMATION ONLY: Please note a full Cost Proposal will be requested if the Enhanced White Paper is recommended for funding (see Section 4.3 for additional details). Furthermore, additional attachments/appendices (henceforth referred to as supplemental information) to this proposal submission may be requested after completion of the technical evaluation to include the following:

- **Human Subject Recruitment and Safety Procedures** which details study population, inclusion/exclusion criteria, description of the recruitment process, description of the informed consent process, etc.
- **Letter(s) of Support**, as applicable, if the prototype project will require access to active-duty military patient populations and/or DoD resource(s) or database(s).

The exact requirements of any such attachment/appendix is subject to change and will be provided at the time (or immediately following) the technical evaluation summary is provided (as part of the Selection Notification described in 2.13).

4.3. Stage 2: Cost Proposal (for Only Those Offerors Recommended for Funding)

Offerors that are recommended for funding will receive notification letters which will serve as the formal request for a full Cost Proposal (and may contain a request for Enhanced White Paper revisions and/or supplemental information, such as those examples listed in the section above, based on the results of the technical evaluation). These letters will contain specific submission requirements if there are any changes to those contained in this RPP. However, it is anticipated that the following will be required:

Required Submission Documents (2): Submit to mtec-contracts@ati.org

- **Section I: Cost Proposal Narrative:** one Word or PDF document
- **Section II: Cost Proposal Formats:** one Excel or PDF document

See below for additional instructions. Also refer to **Addendum 6 of this RPP** for details on how the full Cost Proposals will be evaluated:

The Cost Proposal shall be submitted in two separate sections. One Word (.docx or .doc) or PDF file for **Section I: Cost Proposal Narrative** and one Excel (.xlsx or .xls) or PDF file for **Section II: Cost Proposal Formats** is required.

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 website and within the PPG are **NOT** mandatory.

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. Refer to the MTEC PPG for additional details.

Those Offerors invited to submit a Cost Proposal are encouraged to contact the MTEC CM and/or Government with any questions so that all aspects of the Stage 2 requirements are clearly understood by both parties.

4.4. Enhanced White Paper and Cost Proposal Preparation Costs

The cost of preparing Enhanced White Papers and Cost Proposals in response to this RPP is not allowable as a direct charge to any resulting award or any other contract. Additionally, the MTEC Assessment Fee (see Section 2.10 of this RPP) is not allowable as 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

As stated in Section 6.1.2 of the MTEC PPG, 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 Enhanced White Papers to ensure compliance with the RPP requirements. As part of the preliminary screening process, Enhanced 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. Additionally, 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 Section 3 of the PPG). Proposal Compliance with the statutory requirements regarding the appropriate use of Other Transaction Authority (as detailed within Section 3 of the PPG) will be determined 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 Proposal 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 Proposal has at least one Nontraditional Defense Contractor or Nonprofit Research Institution participating to a significant extent • All significant participants in the transaction other than the Federal Government are small businesses or nontraditional defense contractors • Offeror provides at least one third of the total project cost as acceptable cost share

5.2 Enhanced White Paper (Stage 1) Evaluation

The CM will distribute all Enhanced White Papers that pass the preliminary screening (described above and in Table 1) to both the Government and OREF for full evaluation. Evaluation of Enhanced White Papers will be based on an independent, comprehensive review and assessment of the work proposed against the stated source selection criteria and evaluation factors. This process may involve the use of contractors as subject matter expert (SME) consultants or reviewers. OREF will employ NDAs to protect information contained in submissions.

The Government and OREF will evaluate each Enhanced White Paper against the evaluation factors detailed below and assign adjectival ratings to the non-cost/price factor(s) consistent with those defined in Table 2 (General Merit Rating Assessments). The Offeror shall clearly state how it intends to meet and, if possible, exceed the RPP requirements. Mere acknowledgement or restatement of a RPP requirement is not acceptable. The overall award decision will be based upon a best value determination by considering factors in addition to cost/price.

The evaluation factors and evaluation criteria are described below.

Task 1 Evaluation Factors

1. **Technical Feasibility**
2. **Programmatic Relevance**
3. **Regulatory and Commercialization Plan**

Evaluation Factor 1 – Technical Feasibility: This factor will evaluate the relevancy, thoroughness, completeness, and feasibility of the proposed prototype demonstrates alignment and relevancy to Warfighter recovery and rehabilitation after MSKI. How well the proposal defines and describes a prototype that can meet the expected attributes/capabilities and technical requirements to be set forth in this RPP. Reviewers may also consider project management plan, expertise, experience of personnel, SOW and estimated budget as aspects of overall Technical Feasibility.

Evaluation Factor 2 – Programmatic Relevance: Relevance of the proposed solution and its alignment with the RPP's topic area and the program objective described in Section 3 (3.1-3.3). How well the proposed methodology aligns with the program's technical requirements and the overall intent of the announcement.

Evaluation Factor 3 – Regulatory and Commercialization Plan: Feasibility of the Offeror's regulatory strategy, including FDA pathway, indication of use and designation, strategy for obtaining FDA approvals or clearances. Feasibility of the commercialization strategy including the degree to which the Offeror demonstrates potential commercial use, including a description of the market (civilian and military) and sustainability.

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.

Please also refer to Section 5.3 for definitions of general terms used in technical evaluations.

Upon review and evaluation of the Proposals, the Government sponsor will perform proposal source selection. This will be conducted using the evaluation factors detailed above. The Government will conduct an evaluation of all qualified proposals. The Source Selection Authority may:

1. ***Select the proposal (or some portion of the proposal) for award***
2. ***Place the proposal in the Basket if funding currently is unavailable; or***
3. ***Reject the proposal (will not be placed in the Basket)***

In rare cases, the following recommendation may be provided: "Recommendation Undetermined." This is reserved for situations in which additional information/documentation is needed by the Government evaluators before finalizing a recommendation to one of those listed above and is intended to facilitate the release of all evaluator comments within the BIDS System.

The RPP review and award process may involve the use of contractor subject matter experts (SMEs) 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, prior to accessing any proposal submission to protect information contained in the Enhanced White Paper as outlined in Section 2.5.

5.3 Definition of General Terms Used in Evaluations

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.

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 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 Research Associate, Dr. Chuck Hutti, Ph.D., chuck.hutti@ati.org
- All other questions should be directed to the MTEC Chief of Consortium Operations, Ms. Kathy Zolman, kathy.zolman@ati.org

7 Acronyms/Abbreviations

ATI	Advanced Technology International
CM	Consortium Manager
CMA	Consortium Member Agreement
CMC	Chemistry, Manufacturing, and Controls
DCAA	Defense Contract Audit Agency
DCMA	Defense Contract Management Agency
DoD	Department of Defense
DODI	Department of Defense Instruction
EC	Ethics Committee
F&A	Facilities and Administrative Costs
FAQ	Frequently Asked Questions
FDA	U.S. Food and Drug Administration
FOIA	Freedom of Information Act
FY	Fiscal Year
G&A	General and Administrative Expenses
Government	U.S. Government, specifically the DoD
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IRB	Institutional Review Board
M	Millions
MOMRP	Military Operational Medicine Research Program
MPS	Milestone Payment Schedule
MTEC	Medical Technology Enterprise Consortium
NDA	Nondisclosure Agreement
NDAA	National Defense Authorization Act
OCI	Organizational Conflict of Interest
ODC	Other Direct Costs

OHARO	Office of Human and Animal Research Oversight
OHRO	Office of Human Research Oversight
OREF	Orthopaedic Research and Education Foundation
ORP	Office of Research Protections
OTA	Other Transaction Agreement
PDF	Portable Document Format
POC	Point-of-Contact
PoP	Period of Performance
PPG	Proposal Preparation Guide
R&D	Research and Development
RDT&E	Research, Development, Testing, and Evaluation
ROM	Rough Order of Magnitude
RPA	Research Project Award
RPP	Request for Project Proposals
SME	Subject Matter Expert
SOW	Statement of Work
TRL	Technology Readiness Level
USAMRDC	U.S. Army Medical Research and Development Command
USG	U.S. Government

8 Enhanced White Paper Template

Cover Page

[Name of Offeror]
[Address of Offeror]
[Phone Number and Email Address of Offeror]

Unique Entity ID: [UEI]
CAGE code: [CAGE code]

[Title of Enhanced White Paper]

[Offeror] certifies that, if selected for award, the Offeror will abide by the terms and conditions of the MTEC Base Agreement.

[Offeror] certifies that, if selected for award, the Offeror will become a member in good standing of the MTEC consortium prior to the Full Cost Proposal Submission.

[Offeror] certifies that this Enhanced White Paper is valid for 3 years from the close of the applicable RPP, unless otherwise stated.

[A proprietary data disclosure statement if proprietary data is included. Sample:
This Enhanced White Paper includes data that shall not be disclosed outside the MTEC Consortium Management Firm and the Government. If, however, an agreement is awarded as a result of, or in connection with, the submission of this data, the MTEC Consortium Management Firm and the Government shall have the right to duplicate, use, or disclose these data to the extent provided in the resulting agreement. This restriction does not limit the MTEC Consortium Management Firm and the Government's right to use the information contained in these data if they are obtained from another source without restriction. The data subject to this restriction is (clearly identify) and contained on pages (insert page numbers).]

[Title of Enhanced White Paper]

Programmatic Relevance

- Provide the background and the Offeror's understanding of the problem and/or technology gap/process deficiency.
- Describe how the proposed prototype meets the needs specified in this RPP.

Scope Statement

- Define the scope of the effort and clearly state the objectives of the project.

Scientific Rationale / Preliminary Data

- Describe the scientific rationale for the project, including a brief description of previous studies or preliminary data that support the feasibility of proposed work.
- Describe relevant non-clinical data and/or clinical preliminary data.

Technical Approach

- Describe the methods, organization, and staffing plan required to accomplish the proposed approach. Describe the proposed methodology in sufficient detail to show a clear course of action.
- Human Subject Testing (if applicable) should be described in adequate detail to assess conformance with U.S. FDA regulations, guidance, and the requirements related to its appropriate pathway for development and testing.
    - Provide a description of the purpose and objectives of the study.
    - Describe the clinical intervention, medical drug, biologic, device or human exposure model to be tested. Document the availability and accessibility of the drug/compound, device, or other materials needed for the proposed research.
    - Include a description of study variables, appropriate controls and the endpoints to be tested.
    - Outline the proposed methodology (e.g., study design, data analysis, etc.) in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate.
    - Describe current status of interactions with the U.S. FDA and your plan to meet all regulatory sponsor responsibilities.

Anticipated Outcomes/Impact

- Provide a description of the anticipated outcomes from the proposed work. List milestones and deliverables from the proposed work.
- Describe the impact that the proposed project would have, if successful.

Team and Management Plan

- Describe the qualifications and expertise of the key personnel and organizations that will perform the proposed work.
- Describe the overall project management plan that clearly defines roles and responsibilities.

Regulatory and Commercialization Plan

- Describe previous interactions with the FDA related to this proposed prototype solution
- (e.g., pre-submission meeting).
- Briefly describe the regulatory plan, including FDA pathway and designation, strategy for
- obtaining FDA approvals or clearances.
- Briefly describe the transition and commercialization plan, including a description of the market (civilian and military) and sustainability.

Resources

- Identify any key facilities, equipment and other resources proposed for the effort. Identified facilities, equipment and resources should be available and relevant for the technical solution being proposed.

Potential Follow-On Work

- Offerors are encouraged as appropriate to discuss potential follow-on work.

Schedule

- PoP: Indicate the proposed PoP in months from award.
- Proposed Schedule: Provide a schedule (e.g., Gantt chart) that clearly shows the plans to perform the program tasks in an orderly, timely manner. Provide each major task as a separate line. Do not duplicate the level of detail presented in the Statement of Work.

Risk Identification and Mitigation

- Identify key technical, schedule, and cost risks. Discuss the potential impact of the risks, as well as potential mitigations.

Rough Order Magnitude (ROM) Pricing and Estimate Rationale

- The Offeror must provide an estimate based on the technical approach proposed in the Enhanced White Paper.
- The Offeror must provide a **brief** rationale describing how the estimate was calculated and is appropriate for the proposed scope or approach.
- Describe the deployment of any cost share included to support the proposed scope of work.
- If OREF funding is to be utilized, the Offeror must provide a **brief** rationale describing the work to be done using OREF funding, including where that funding is to be deployed and what deliverables are expected to be funded.

The following ROM pricing example format shall be included in the Enhanced White Paper (the number of columns should reflect the proposed PoP, i.e., add or delete the yearly budget columns as needed). **[NOTE: If invited to Stage 2, the total cost to the Government must not significantly increase from the estimate provided in the ROM (unless otherwise directed by the Government) as award recommendations may be based upon proposed costs within the Enhanced White Paper.] 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.

	Proposed Federal Funding			***Proposed OREF Funding***	
	Year 1	***Year 2***	***Year 3***	***Years 1 - 3***	***TOTAL***
Labor	*$ 100,000.00*	*$ 100,000.00*	*$ 100,000.00*	*$ 45,000.00*	***$ 345,000.00***
Labor Hours	*1,000.0 hrs*	*1,000.0 hrs*	*1,000.0 hrs*	*450.0 hrs*	***3,450.0 hrs***
Subcontractors	*$ 50,000.00*	*$ 50,000.00*	*$ 50,000.00*	*$ 30,000.00*	***$ 180,000.00***
Subcontractors Hours	*500.0 hrs*	*500.0 hrs*	*500.0 hrs*	*300.0 hrs*	***1,800.0 hrs***
Government/Military Partner(s)/Subcontractor(s) (subKTR)*	*$0.00*	*$0.00*	*$0.00*	*$0.00*	***$0.00***
Gov't/Military Pa... subKTR Ho...	*0.0 hrs*	*0.0 hrs*	*0.0 hrs*	*0.0 hrs*	***0.0 hrs***
Consultants	*$ 10,000.00*	*$ 10,000.00*	*$ 10,000.00*	*$ 6,000.00*	***$ 36,000.00***
Consultants Hours	*100.0 hrs*	*100.0 hrs*	*100.0 hrs*	*60.0 hrs*	***360.0 hrs***
Material/Equipment	*$ 75,000.00*	*$ 75,000.00*	*$ 75,000.00*	*$ 9,000.00*	***$ 234,000.00***
Other Direct Costs	*$ 1,000.00*	*$ 1,000.00*	*$ 1,000.00*	*$ 5,000.00*	***$ 8,000.00***
Travel	*$ 5,000.00*	*$ 5,000.00*	*$ 5,000.00*	*$ 5,000.00*	***$ 20,000.00***
Indirect costs**	*$ 48,200.00*	*$ 48,200.00*	*$ 48,200.00*	*$ 0.00*	***$ 144,600.00***
Total Cost	*$ 289,200.00*	*$ 289,200.00*	*$ 289,200.00*	*$ 100,000.00*	***$ 967,600.00***
Fee (*Not applicable if cost share is proposed)*	*$ 0.00*	*$ 0.00*	*$ 0.00*	*$ 0.00*	***$ 0.00***
Total Cost (plus Fee)	*$ 289,200.00*	*$ 289,200.00*	*$ 289,200.00*	*$ 100,000.00*	***$ 967,600.00***
Cost Share (if cost share is proposed then fee is unallowable)	*$ 290,000.00*	*$ 290,000.00*	*$ 290,000.00*	*$ 0.00*	***$ 870,000.00***
Total Project Cost	*$ 579,200.00*	*$ 579,200.00*	*$ 579,200.00*	*$ 100,000.00*	***$ 1,837,600.00***

EXAMPLE

*Use the rows above for "Government/Military Partner(s)/Subcontractor(s)" if the project involves one or more Government/Military Facilities (Military Health System facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) performing as a collaborator in performance of the project.

**OREF funds may not be used to cover indirect costs.

APPENDICES (excluded from the page limit, and must be uploaded to BIDS as separate documents)

Appendix 1: Warranties and Representations: (template provided in Addendum 1 of this RPP)

- Warranties and Representations are required. One Word (.docx or .doc) or PDF file that contains all Warranties and Representations is required.

Appendix 2: Statement of Work (template provided in Addendum 2 of this RPP)

- Provide a draft Statement of Work as a separate Word document to outline the proposed technical solution and demonstrate how the contractor proposes to meet the Government objectives. Submitted information is subject to change through negotiation if the Government selects the Enhanced White Paper for award. The format of the proposed Statement of Work shall be completed in accordance with the template provided below.
- The Government reserves the right to negotiate and revise any or all parts of SOW/Milestone Payment Schedule (MPS). Offerors will have the opportunity to concur with revised SOW/Milestone Payment Schedule as necessary.

Appendix 3: Data Rights Assertions (template provided in Addendum 3 of this RPP)

- 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 the 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/milestones. If applicable, complete the table within the referenced attachment for any items to be furnished to the Government with restrictions.

Appendix 4: Biographical Sketches (template provided in Addendum 4 of this RPP)

- Provide a biographical sketch for all key personnel contributing to the proposed work.

Appendix 5: Current and Pending Support (template provided in Addendum 5 of this RPP)

Addendum 1 – Warranties and Representations

Warranties and Representations
Authority to Use Other Transaction Agreement

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

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

☐	**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 UEI #.
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 UEI #.
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 UEI number.
- A foreign business can be considered a nontraditional if it has a UEI number and can comply with the terms and conditions of the MTEC Base Agreement.

Addendum 2 – Statement of Work (SOW)/Milestone Payment Schedule (MPS)

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

Statement of Work

Proposal Number: (RPP Number)
Organization:
Title: (Proposed Project Title)
ACURO and/or HRPO approval needed: (If you're conducting any animal or human testing, you will need to submit for the appropriate Army Approvals)

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

Scope/Project Objective (*To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.)*
This section includes a statement of what the project covers. This should include the technology area to be investigated, the objectives/goals, and major milestones for the effort.

Requirements (*To be provided initially by the Offeror at the time of proposal submission to be finalized by the Government based on negotiation of Scope/Project Objective).*
State the technology objective in the first paragraph and follow with delineated tasks required to meet the overall project goals. The work effort should be segregated into major phases, then tasks and identified in separately numbered paragraphs (similar to the numbered breakdown of these paragraphs). Early phases in which the performance definition is known shall be detailed by subtask with defined work to be performed. 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.

Site Locations (Provide a list of site locations identifying where all project work is to be conducted. Site locations should be inclusive of the Prime Organization, Sub Contractors, Contract Research Organizations, Military Labs and/or Units. Only add information for an additional site if that site is receiving funding to conduct research as outline in the SOW. Delete "Site 2" header if not used.)

Site 1:	Institution Name	Site 2*:	Institution Name
	Address for primary site		Address for Org #2
	PI: John Doe		Partnering/Site PI/POC: Jane Smith

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 $1M shorter term project may have only 6);
- not be structured such that multiple deliverables that might be submitted separately are included under a single milestone;
- be of sufficient monetary value to warrant generation of a deliverable and any associated invoices;
- include, at a minimum, Quarterly Reports which include both Technical Reports and Business Status Reports (due the 25th of Apr, Jul, Oct, Jan), Annual Reports, Final Technical Report, and Final Business Status Report.

MTEC Milestone Payment Schedule Example

MTEC Milestone Number	Task Number	Significant Event/ Accomplishments	Due Date	Government Funds	OREF Funding	Cost Share	Total Funding
1	N/A	Project Kickoff	12/1/2019	$20,000			$20,000
2	N/A	Quarterly Report 1 (October - December, Technical and Business Reports)	1/25/2020	$ -			$ -

3	1	Protocol Synopsis	2/28/2020	$21,075	$25,000		$46,075
4	2	Submission for HRPO Approval	2/28/2020	$21,075			$21,075
5	3	Submission of Investigational New Drug application to the US FDA	4/30/2020	$210,757		$187,457	$398,214
6	N/A	Quarterly Reports 2 (January - March, Technical and Business Reports)	4/25/2020	$ -			$ -
7	N/A	Quarterly Report 3 (April - June, Technical and Business Reports)	7/25/2020	$ -			$ -
8	4	Toxicity Studies	10/1/2020	$63,227			$63,227
9	N/A	Annual Report 1	10/25/2020	$ -			$ -
10	5	FDA authorization trial	11/30/2020	$84,303	$25,000		$109,303
11	6	Research staff trained	11/30/2020	$ -			$ -
12	7	Data Management system completed	11/30/2020	$ -			$ -
13	8	1st subject screened, randomized and enrolled in study	1/1/2021	$150,000		$187,457	$337,457
14	N/A	Quarterly Report 4 (October - December, Technical and Business Reports)	1/25/2021	$ -			$ -
15	9	Completion of dip molding apparatus	3/1/2021	$157,829	$25,000	$187,457	$370,286
16	N/A	Quarterly Reports 5 (January - March, Technical and Business Reports)	4/25/2021	$ -			$ -
17	10	Assess potential toxicology	6/1/2021	$157,829	$25,000		$182,829
18	N/A	Quarterly Report 6 (April - June, Technical and Business Reports)	7/25/2021	$ -			$ -
19	11	Complete 50% patient enrollment	10/1/2021	$350,000		$187,457	$537,457
20	N/A	Annual Report 2	10/25/2021	$ -			$ -
21	N/A	Quarterly Report 7 (October - December, Technical and Business Reports)	1/25/2022	$ -			$ -
22	12	Electronic Report Forms Developed	3/1/2022	$315,658		$187,457	$503,115
23	N/A	Quarterly Reports 8 (January - March, Technical and Business Reports)	4/25/2022	$ -			$ -
24	N/A	Quarterly Report 9 (April - June, Technical and Business Reports)	7/25/2022	$ -			$ -
25	13	Complete 100% patient enrollment	8/1/2022	$315,658		$187,457	$503,115
26	N/A	Annual Report 3	10/25/2022	$ -			$ -
27	14	Report results from data analysis	11/1/2022	$157,829			$157,829
28	N/A	Final Reports (Prior to the POP End) – Final reports must have a milestone dollar amount.	11/30/2022	$50,000			$50,000

Total	**$2,075,240**	**$100,000**	**$1,124,742**	**$3,299,982**
Period of Performance				**XX Months**
Agreement Type				**CPFF/CR/FFP**

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. Quarterly and Annual Reports include BOTH Technical Reports and Business Status Reports (separate).
4. Final Report due date must be prior to POP end noted in Research Project Award and have an associated milestone dollar amount.
5. MTEC Milestone Numbers are used for administrative purposes and should be sequential.
6. Task Numbers are used to reference the statement of work if they are different from the MTEC Milestone Number.

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

Report Months	**Due Date**
January – March	25 April
April - June	25 July
July - September	25 October
October - December	25 January

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

- Annual Reports – The project awardee shall prepare an Annual Report which will include both a Technical Report and Business Status Report for projects whose periods of performances are greater than one year in accordance with the terms and conditions of the Base Agreement. (Required)
- Final Technical Report – At the completion of the Research Project Award, the awardee will submit a Final Technical Report, which will provide a comprehensive, cumulative, and substantive summary of the progress and significant accomplishments achieved during the total period of the Project effort in accordance with the terms and conditions of the Base Agreement. As part of the Final Technical Report, the awardee must submit a DD Form 882, Report of Inventions and Subcontracts. (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)

Addendum 3 – Intellectual Property and Data Rights Assertions

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 in any resultant Research Project Award. MTEC Base Agreements are issued by the MTEC CM to MTEC members receiving a Research Project Award. 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:** The Offeror shall comply with the terms and conditions contained in their Base Agreement regarding Data Rights, as modified by the specifically-negotiated Data rights terms herein. Refer to Section 2 of this RPP.

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.

☐ This award or sub-award contains federally-funded SBIR/STTR Data.

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

Addendum 4 – Biographical Sketch

Biographical Sketch

<table>
<tr><td colspan="4">Provide the following information for each individual included in the Research & Related Senior/Key Person Profile (Expanded) Form</td></tr>
<tr><td colspan="2">NAME</td><td colspan="2">POSITION TITLE</td></tr>
<tr><td colspan="4">EDUCATION/TRAINING (Begin with Baccalaureate or other initial professional education, such as nursing, and include postdoctoral training)</td></tr>
<tr><td>INSTITUTION AND LOCATION</td><td>DEGREE (IF APPLICABLE)</td><td>YEAR(S)</td><td>FIELD OF STUDY</td></tr>
<tr><td></td><td></td><td></td><td></td></tr>
<tr><td colspan="4">RESEARCH AND PROFESSIONAL EXPERIENCE: Concluding with present position, list in chronological order, previous employment, experience, and honors. Include present membership on any Federal Government public advisory committee. List in chronological order the titles, all authors, and complete references to all publications during the past 3 years and to representative earlier publications pertinent to this application. If the list of publications in the last 3 years exceeds 2 pages, select the most pertinent publications. PAGE LIMITATIONS APPLY. DO NOT EXCEED 5 PAGES FOR THE ENTIRE BIOGRAPHICAL SKETCH PER INDIVIDUAL.</td></tr>
</table>

Addendum 5 – Current and Pending Support

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

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

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

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

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

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

Addendum 6 – Stage 2 Evaluation Criteria

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

Stage 2

The MTEC Consortium Manager (CM) will evaluate the cost proposed together with all supporting information for realism (as applicable, dependent upon contract type, i.e., Firm Fixed Price, Cost Reimbursement), reasonableness, and completeness as outlined below. The MTEC CM will then provide a formal assessment to the Government at which time the Government will make the final determination that the negotiated project cost is fair and reasonable.

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 technical approach and Statement of Work.

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 (Enhanced White Papers) 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, in its nature and amount, 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 based upon verifiable techniques such as estimates developed from applicable and relevant 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. If the MTEC template is not used, the Offeror should submit a format providing for a similar level of detail.

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.

Government Access to Information
After receipt of the cost proposal and after the CM's completion of the cost analysis summarized above, the government may perform a supplemental cost and/or price analysis of the submitted cost proposal. For purposes of this analysis, the Agreement Officer and/or a representative of the Agreement Officer (e.g., DCAA, DCMA, etc.) shall have the right to examine the supporting records and/or request additional information, as needed.

Best Value
The overall award decision will be based upon the Government's 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. The Government anticipates entering into negotiations with all Offerors recommended for funding with the MTEC CM acting on the Government's behalf and/or serving as a liaison. The Government reserves the right to negotiate and request changes to any or all parts of the proposal, to include the SOW.

Addendum 7 – BIDS Instructions

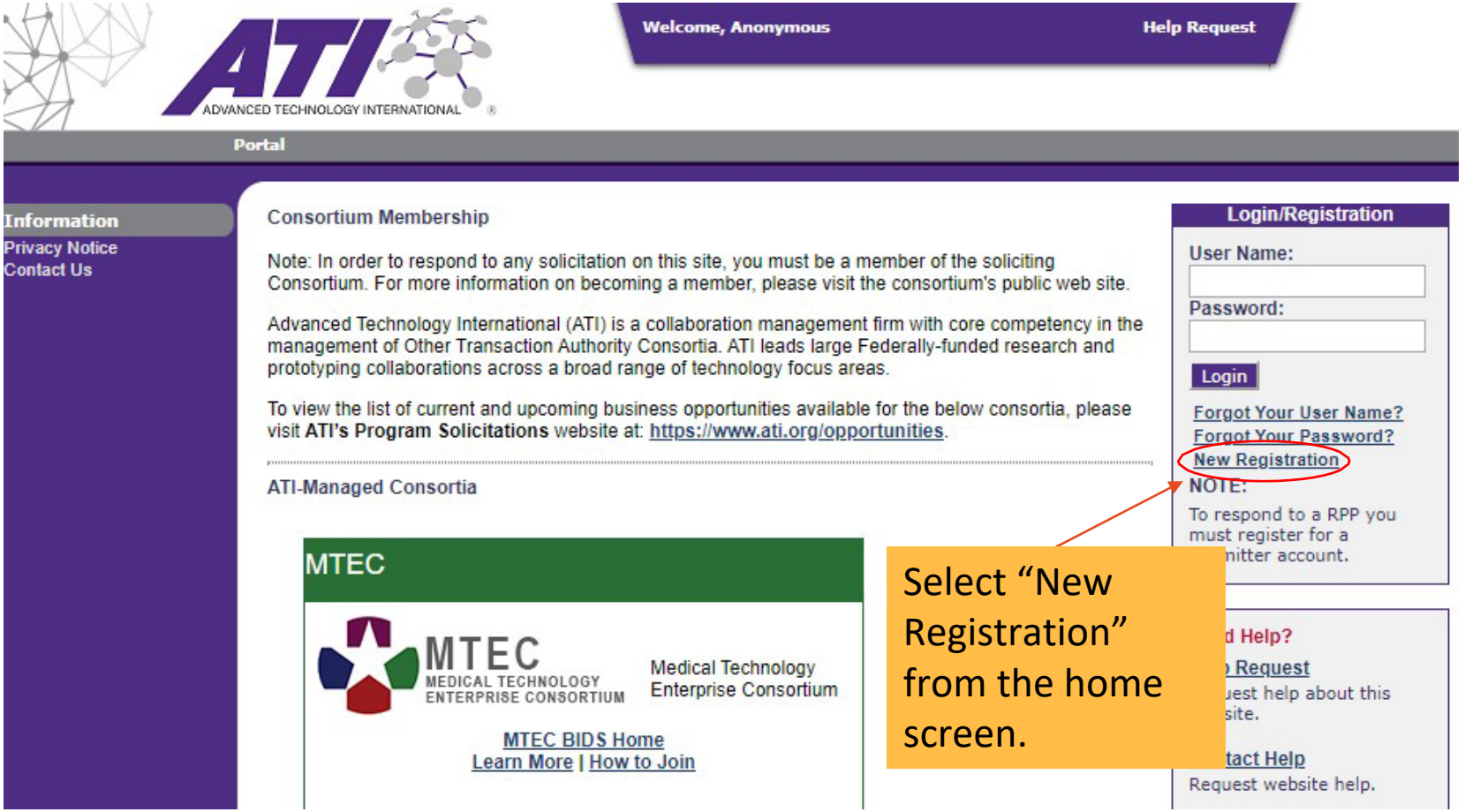
THIS PAGE IS INTENTIONALLY LEFT BLANK. PLEASE SEE THE PRESENTATION BELOW.

MTEC BIDS REGISTRATION

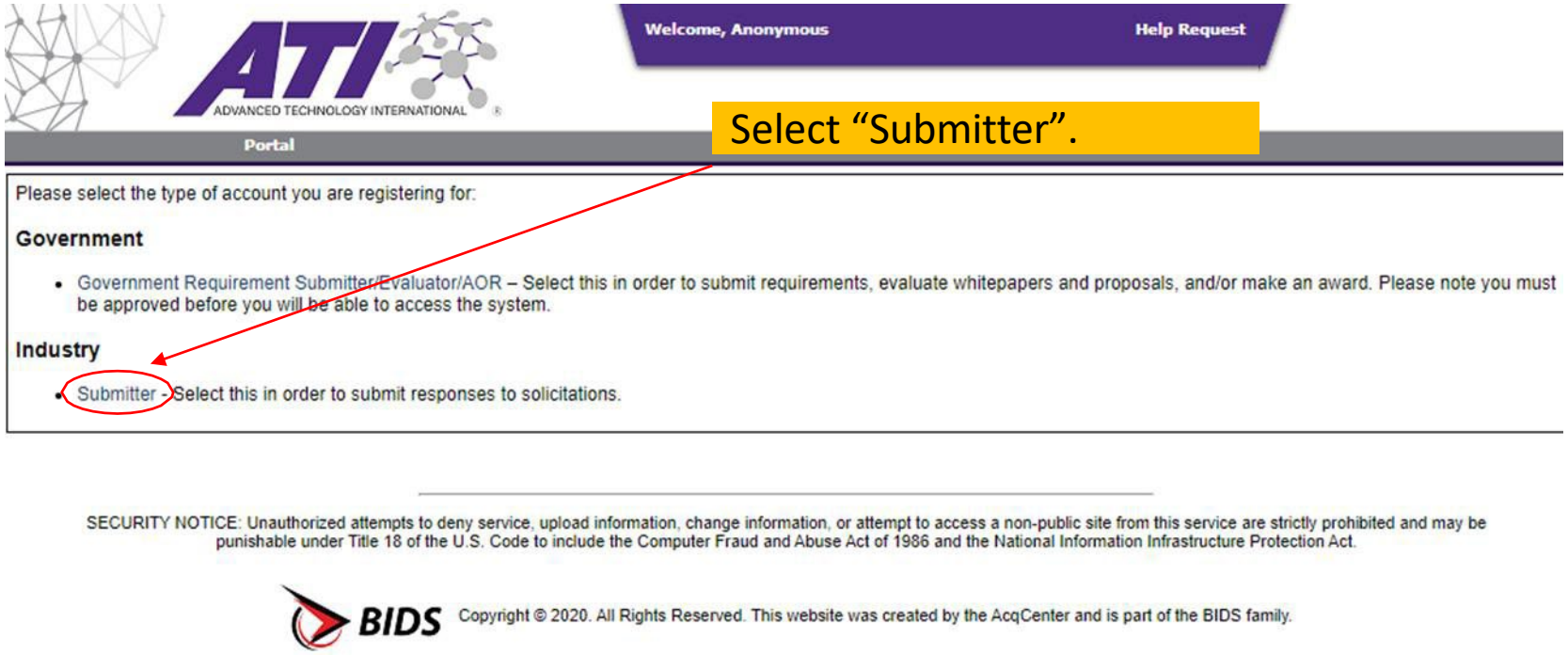
MTEC BIDS URL:

HTTPS://ATI2.ACQCENTER.COM/ATI2/PORTAL.NSF/START?READFORM

BIDS New Registration

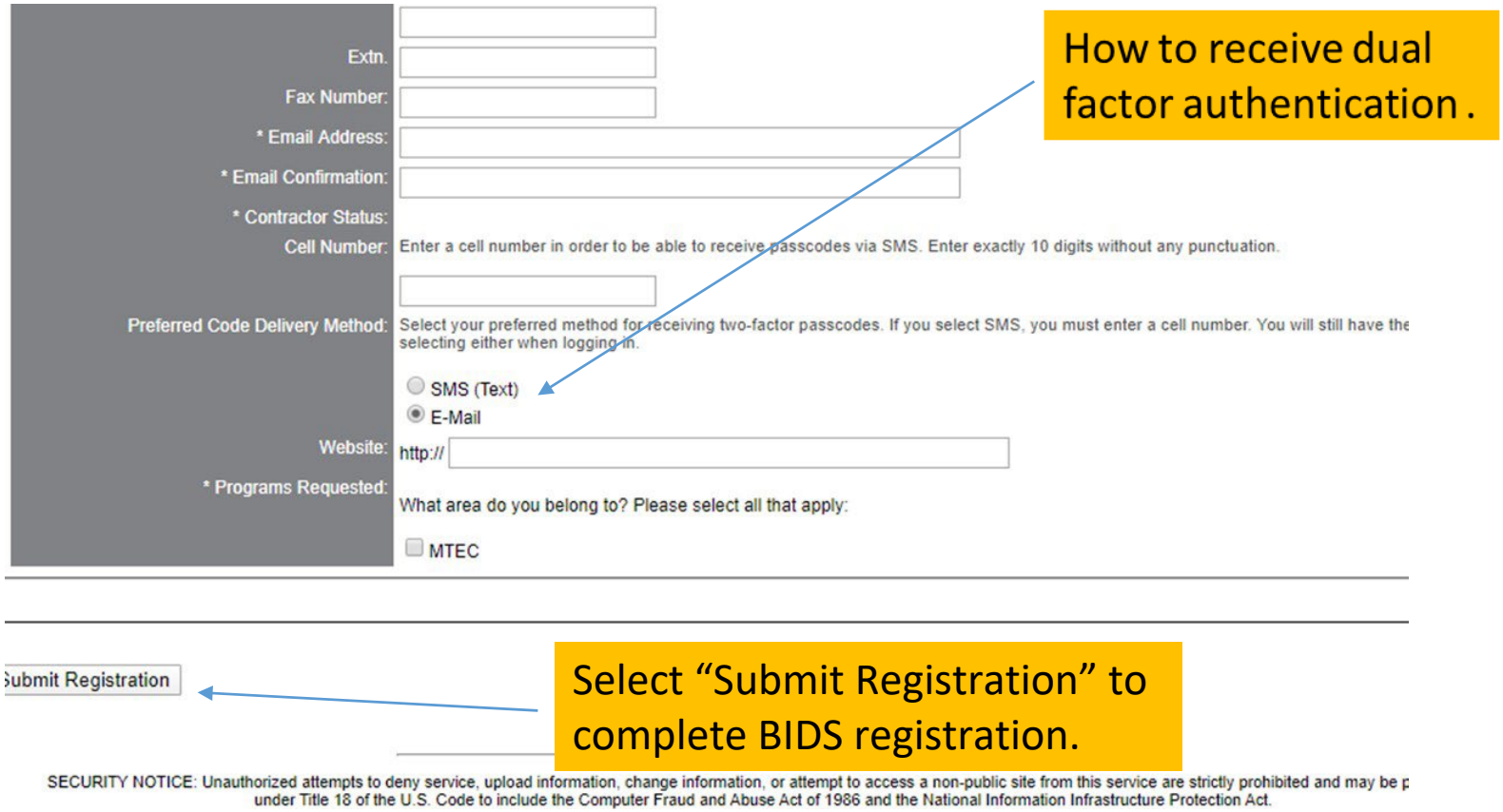


BIDS New Registration



BIDS New Registration

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



Medical Technology Enterprise Consortium

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.

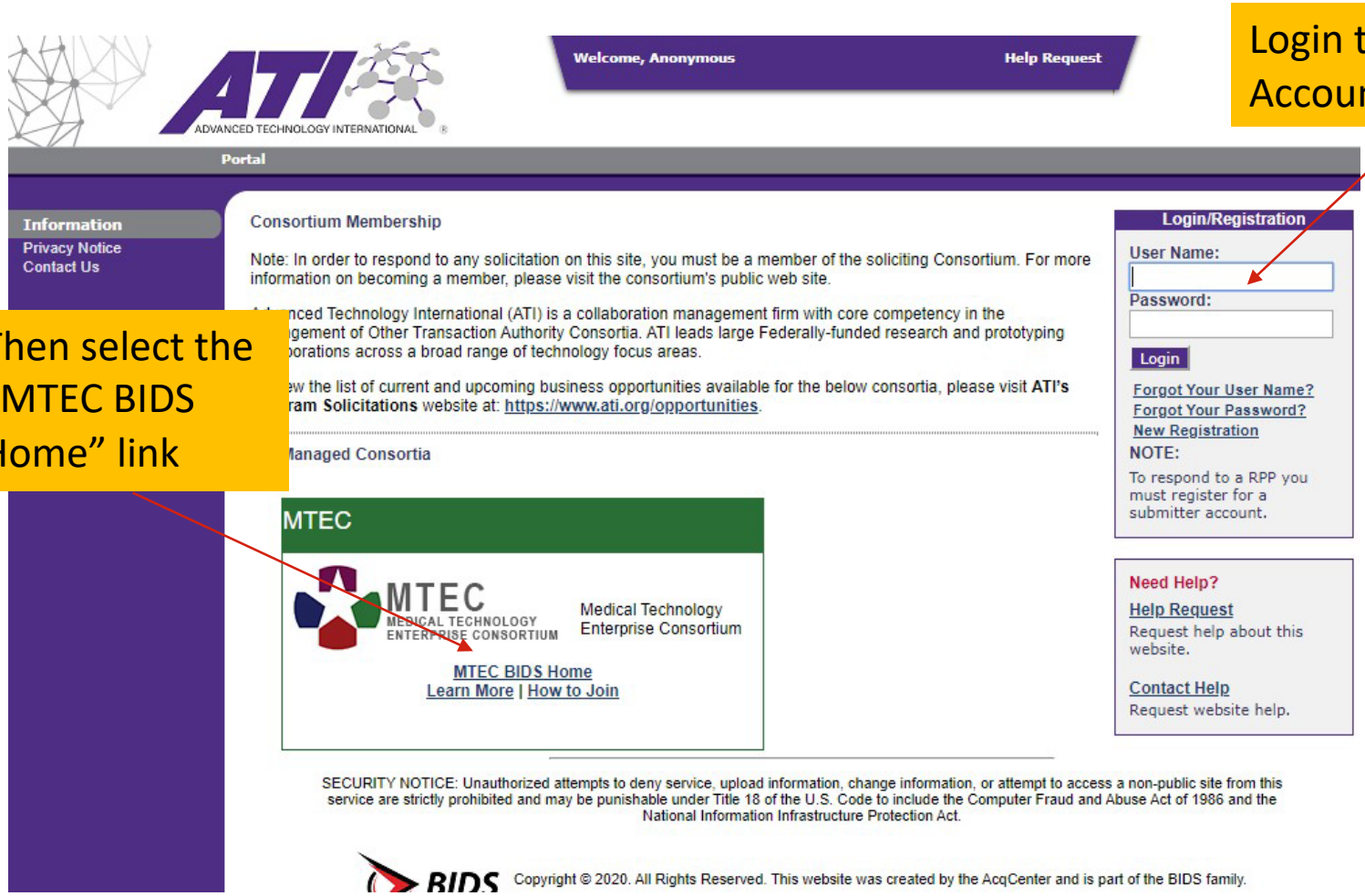
MTEC BIDS Proposal Submission

MTEC BIDS URL:

HTTPS://ATI2.ACQCENTER.COM/ATI2/PORTAL.NSF/START?READFORM

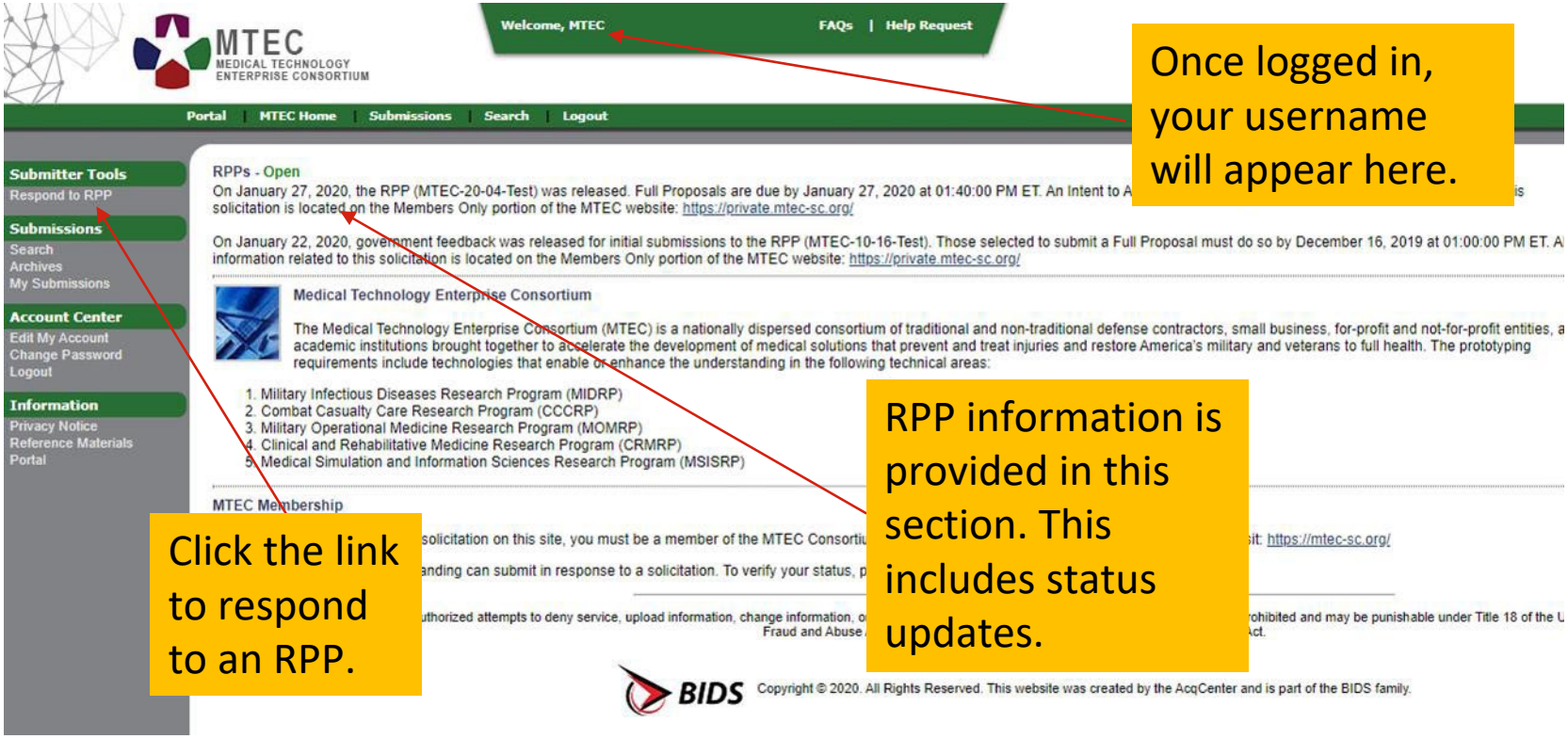
Proposal Submission BIDS

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



Proposal Submission BIDS

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



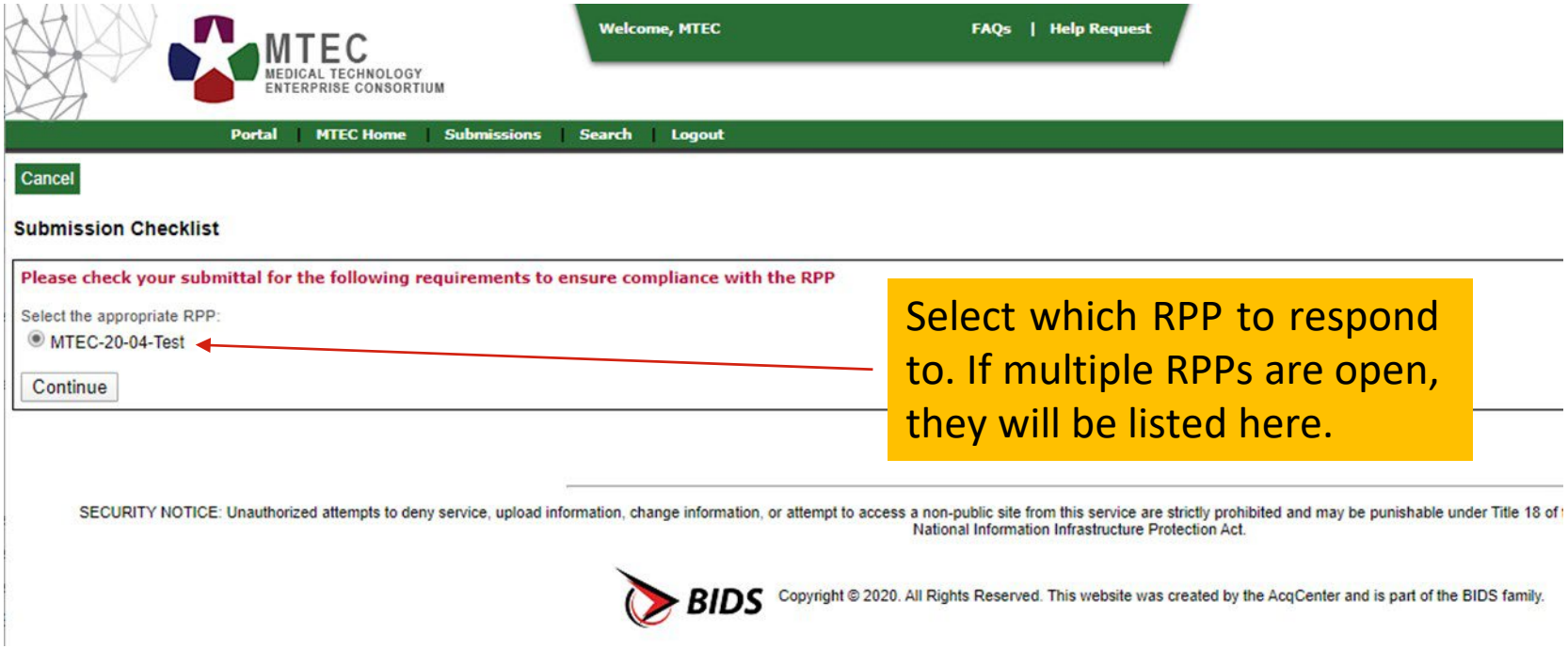
Once logged in, your username will appear here.

Click the link to respond to an RPP.

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

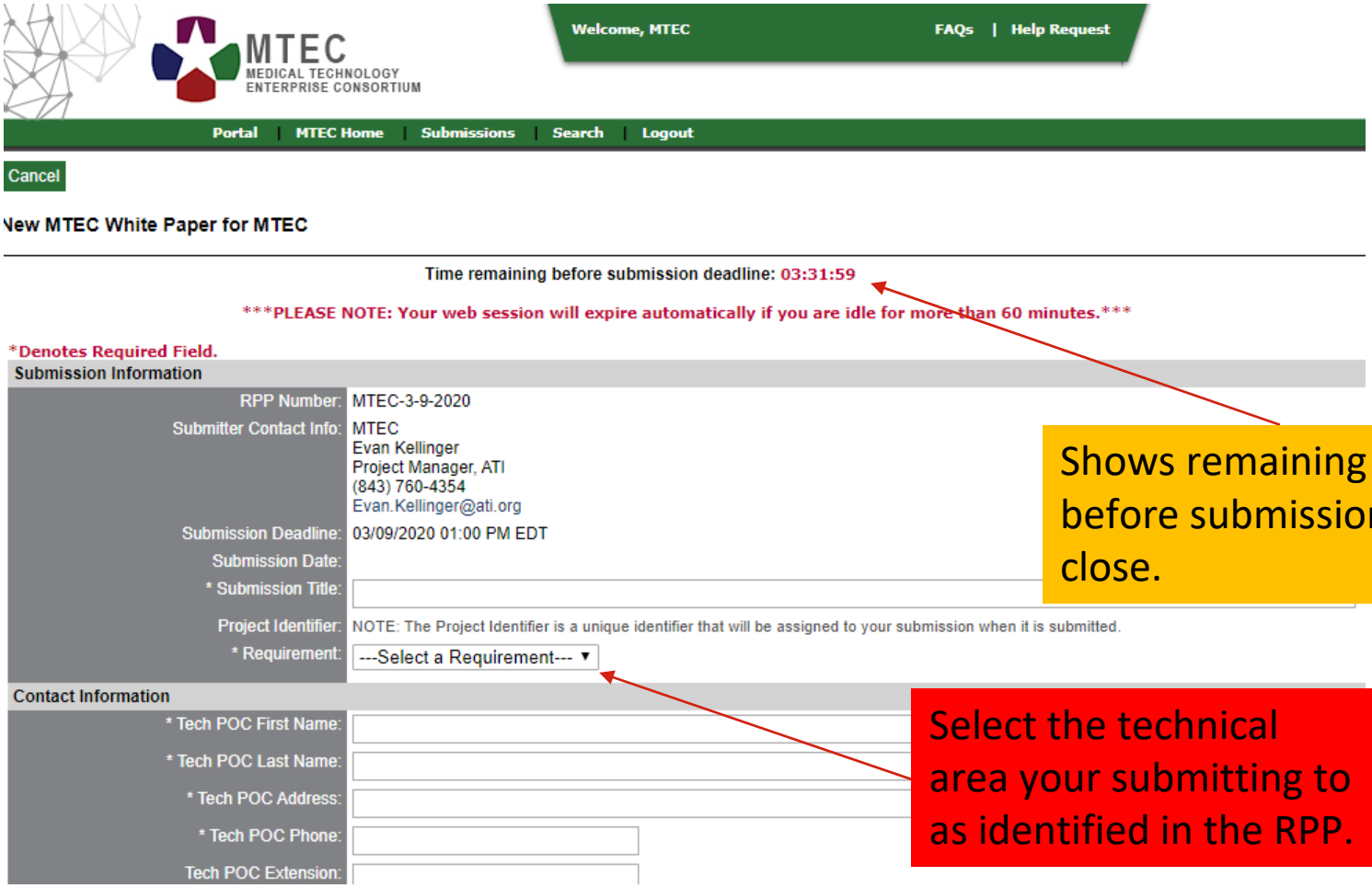
Proposal Submission BIDS

Select which RPP you will be responding to.



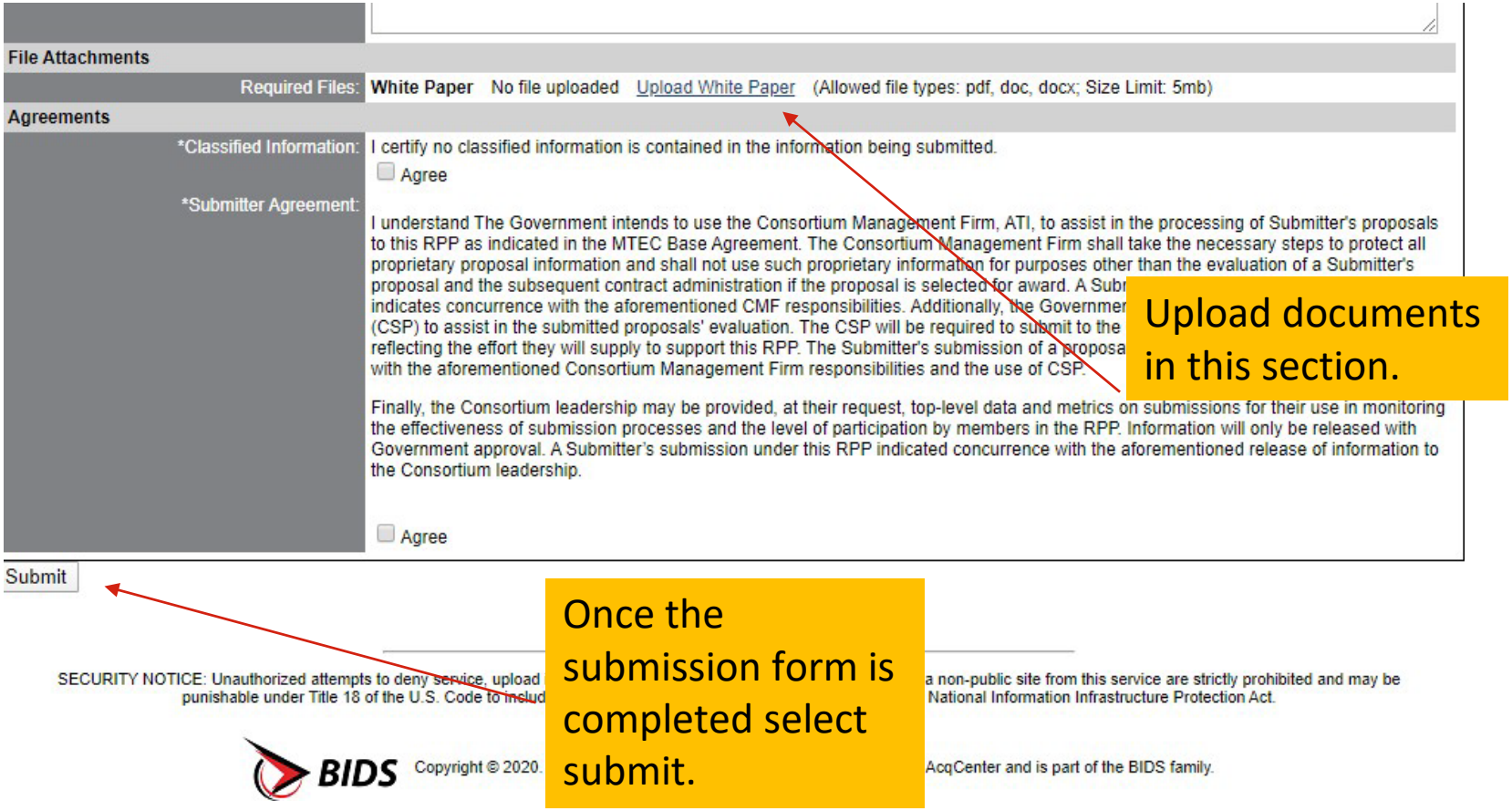
Proposal Submission BIDS

Complete the submission form.



Proposal Submission BIDS

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



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).

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.