

Request for Project Proposals



Solicitation Number: MTEC-21-10-NavyMultiTopic  
**“Navy Multi-Topic 2021 - Advanced Biomedical Product Development in Support of  
Naval Operations”**

Issued by:  
Advanced Technology International (ATI),  
MTEC Consortium Manager (CM)  
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for the  
Medical Technology Enterprise Consortium (MTEC)

**Request Issue Date: February 22, 2021**  
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**White Paper Due Date: March 22, 2021**  
Noon Eastern Time

**Amendment No. 01 revises that page limit in the White Paper template.**

**White Papers are Required**

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## **1 Executive Summary**

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

The Medical Technology Enterprise Consortium (MTEC) is an enterprise partnership in collaboration with industry and academia to facilitate research and development activities, in cooperation with the U.S. Army Medical Research and Development Command (USAMRDC) and other Department of Defense (DoD) 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) commercialization of intellectual property (IP) and follow-on production.

MTEC is openly recruiting members to join a broad and diverse biomedical consortium that includes representatives from large businesses, small businesses, contract research organizations, “nontraditional” defense contractors, academic research institutions and not-for-profit organizations; for more information on the MTEC mission, see the MTEC website at <https://mtec-sc.org/>.

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

### **1.2. Purpose**

This solicitation, issued by the MTEC Consortium Manager (CM), Advanced Technology International (ATI), represents a Request for Project Proposals (RPP) for MTEC support of the Naval Medical Research Center (NMRC) Naval Advanced Medical Development (NAMD)

program. Proposals selected for award as a result of this RPP will be awarded under the authority of 10 U.S.C. § 2371b. The award(s) will be managed by the NAMD program office within Naval Medical Research Center.

The purpose of the multiple topic area (“multi-topic”) Request for Project Proposals (RPP) is focused on the advancement of engineering and medical prototypes and knowledge products related to a broad range of medical technological needs identified in the focus areas listed below. Relevance to the enhanced readiness and resilience of Navy and Marine Corps health and performance is a key feature of this RPP.

- Focus Area #1: Combat Casualty Wound and Infection Care
- Focus Area #2: Enterotoxigenic Escherichia Coli (ETEC) Disease Research
- Focus Area #3: Human Performance / Physiological Episodes

## **2 Administrative Overview**

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

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

### **2.2. Funding Availability and Period of Performance**

The U.S. Government (USG) currently has available a total of approximately \$25 million (M) for anticipated awards to be made during FY2021. The estimated total available funding per Focus Area is as follows (subject to realignment dependent on quality of submissions):

- Focus Area #1: Combat Casualty Wound and Infection Care ~\$12M
- Focus Area #2: Enterotoxigenic Escherichia Coli (ETEC) Disease Research ~ \$10M
- Focus Area #3: Human Performance / Physiological Episodes ~\$3M

MTEC anticipates that multiple awards may be made under each Focus Area with average budgets ranging from \$1,750,000 to \$10,000,000 for the base period of performance (exclusive of any proposed options). Award funding will be structured incrementally and based upon completion of Milestones and Deliverables.

The base Periods of Performance (POP) may range from 12 to 36 months, dependent upon product type and level of maturation required. Note that projects may be phased, as appropriate, with contract options to enable the exercise of additional milestones to allow

maximum flexibility in terms of the progression of work, availability of funding, and duration of the awarded project(s). Dependent on the results and deliverables under any resultant award(s), the USG may apply additional dollars and/or allow for additional time for follow-on efforts with appropriate modification of the award. See Section 3.4 for additional details.

**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).**

As of the release date of this RPP, future year Defense Appropriations Bills may not have been passed and there is no guarantee that any additional funds will be made available to support this program in future years. The funding estimated for this RPP is approximate and subject to realignment. Funding of proposals received in response to this RPP is contingent upon the availability of federal funds for this program.

### **2.3. Acquisition Approach**

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

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

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

Stage 2: The Stage 2 process may vary, and may require different submissions compared with typical MTEC RPPs. The Government is utilizing two distinct Stage 2 approaches under this RPP.

Stage 2 Approach A: This Stage 2 approach will require a solution pitch (i.e., oral presentation) followed by a written detailed research strategy and full cost proposal (after evaluation of the pitch).

Stage 2 Approach B: This Stage 2 approach will require a full proposal (to include technical and cost volumes) using the MTEC Proposal Preparation Guidelines (PPG).

Note that Stage 2 Offerors will only be required to follow one of the aforementioned Stage 2 approaches. Those Offerors that are favorably evaluated during Stage 1 will receive notification letters which will serve as the formal request for a Stage 2 proposal. These letters will contain specific Stage 2 proposal submission requirements and templates.

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

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

#### **2.4. Proposers Conference**

MTEC will host a Proposers Conference that will be conducted via webinar within two (2) weeks after the release of the RPP. The intent of the Proposers Conference is to provide an administrative overview of this RPP process to award and present further insight into the focus areas of interest outlined in Section 3. Further instructions will be forthcoming via email. Offerors are advised to check the MTEC website periodically during the proposal preparation period for any clarifications found in Frequently Asked Questions (FAQ) responses.

#### **2.5. Proprietary Information**

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

## **2.6. MTEC Member Teaming**

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

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

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

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

## **2.7. Offeror Eligibility**

Offerors must be MTEC Members in good standing. Offerors submitting White Papers as the prime contractor must be MTEC members of good standing by March 17, 2021. To join MTEC, please visit <http://mtec-sc.org/how-to-join/>.

## **2.8. Cost Sharing Definition**

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



valuation technique used (e.g., vendor quote, historical cost, labor hours and labor rates, number of trips, etc.).

### **2.9. Cost Share Requirements**

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

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

### **2.10. MTEC Assessment Fee**

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

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

#### **(1) Royalty Payment Agreements**

Government-funded research projects awarded through MTEC will be subject to a 10% royalty on all Net Revenues received by the Research Project Award recipient resulting from the licensing/commercialization of the technology, capped at 200% of the Government funding provided.

#### **(2) Additional Research Project Award Assessment**

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

### **2.11. Intellectual Property and Data Rights**

Intellectual Property (IP) rights for MTEC Research Project Awards are defined in the terms of an awardee’s Base Agreement and resultant Task Orders. MTEC reserves the right to assist in

the negotiation of IP, royalties, licensing, future development, etc., between the government and the individual performers during the entire award period.

The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding Data Rights. **It is anticipated that anything created under this proposed effort would 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 shall be determined in accordance with the provisions of MTEC Base Agreement.

Note that as part of the Stage 2 of the RPP proposal (submission of a pitch or full proposal), Offerors shall complete and submit Attachment C with the signature of responsible party for the proposing Prime Offeror.

#### **2.12. Expected Award Date**

Offerors should plan on the period of performance beginning September 30, 2021 (subject to change). The Government reserves the right to change the proposed period of performance start date through negotiations via the CM and prior to issuing a Research Project Award.

#### **2.13. White Paper Selection Notification**

As the basis of selections is completed, the Government will forward their selections to MTEC CM to notify Offerors. All Offerors will be notified by email from the MTEC CM of the results of the evaluation. Those with favorably evaluated white papers will move forward to the next phase of the process, while those not selected will receive evaluation rationale for non-selection.

### **3 Technical Requirements**

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#### **3.1. Background**

All white paper submissions shall describe projects that are based on logical reasoning and sound scientific rationale. They should not be exploratory in nature and do require a foundation of preliminary data. Please note that MTEC-sponsored projects must result in “prototype” research deliverables that transition medical solutions to industry.

The definition of a “prototype” is as follows: Proposed prototype projects should not be exploratory in nature and do require a foundation of preliminary data. A prototype project can generally be described as a preliminary pilot, test, evaluation, demonstration, or agile development activity used to evaluate the technical or manufacturing feasibility or military utility of a particular technology, process, concept, end item, effect, or other discrete feature. Prototype projects may include systems, subsystems, components, materials, methodology, technology, or processes. By way of illustration, a prototype project may involve: a proof of concept; a pilot; a novel application of commercial technologies for defense purposes; a

creation, design, development, demonstration of technical or operational utility; clinical recommendations or guidelines; or combinations of the foregoing, related to a prototype. The quantity should generally be limited to that needed to prove technical or manufacturing feasibility or evaluate military utility.

Proposed prototypes shall be at a Knowledge Readiness Level (KRL) or Technology Readiness Level (TRL) of 5 **at the time of submission or by the anticipated award date (at or around September 30, 2021)**. Offerors have achieved KRL/TRL 5 if:

- **Knowledge Products:** Offeror has completed testing of *a priori* hypotheses using rigorous scientific design and directly assessed whether and how a tool can work.
- **Pharmaceutical (Biologics, Vaccines):** Offeror has determined that sufficient data on the candidate biologic/vaccine exist in the draft technical data package to justify proceeding with preparation of an IND application.
- **Medical Devices:** Investigational Device Exemption (IDE) review by the Center for Devices and Radiological Health (CDRH) results in determination that the investigation may begin. For a 510(k), preliminary findings suggest the device will be substantially equivalent to a predicate device.
- **Medical Information Management/Information Technology & Medical Informatics:** Medical Informatics data and knowledge representation models are implemented as data and/or knowledge management systems and tested in a lab environment.

NOTE: Full definitions of TRLs can be found [here](#). More information regarding KRLs can be found [here](#).

Subsequent to the completion of performance under the prototype awards resulting from this RPP, the Government reserves the right to award follow-on work. Any follow-on work for the continuation of the prototype development is contingent upon availability of future funding and the successful completion/progression of milestones.

### 3.2. Focus Areas of Interest

Proposed prototype solutions **shall** address **ONE** of the Technology Focus Areas and **ONE** of the associated Specific Areas of Interest outlined below in support of the Naval Advanced Medical Development (NAMD). Offerors are not limited to a single white paper submission. White Papers not aligned to **ONE** of these Focus Areas (and **ONE** of the associated Specific Areas of Interest) may not be considered for award. These Technology Focus Areas are not listed in order of importance.

#### 1) **FOCUS AREA #1: COMBAT CASUALTY WOUND AND INFECTION CARE:**

This area focuses on patient care at and through the continuum of care as well as products and services that sustain patient health in austere environments such as expeditionary, littoral, and deep water. **Specific areas of interest** are as follows (*Offerors shall address only one of these in each White Paper submission*):

- a. Wound care treatments / therapies for combat injuries. Includes technologies suitable for use at point of injury and / or at medical facilities in theater.
- b. Wound care technologies for combat wound infections (e.g., bacterial and other infections of combat wounds)
- c. Innovative wound care technologies to treat and prevent biofilm formation

**2) FOCUS AREA #2: ENTEROTOXIGENIC ESCHERICHIA COLI (ETEC) DISEASE RESEARCH**

This area focuses on medical technology and solutions that support the prevention and solutions that treat and/or cure ETEC. ETEC may cause diarrhea, vomiting, dehydration, and other debilitating symptoms for several days or more that often result in an incapacitating symptoms. ETEC and ETEC-related illnesses may negatively impact duties and operations by reducing team manning, delaying movement, and increasing costs related to seeking medical treatment and potentially evacuation. **Specific areas of interest are as follows** (*Offerors shall address only one of these in each White Paper submission*):

- a. ETEC pre-exposure prophylaxis strategies that can be used prior to exposure and / or at the point of infection that may reduce risk, shorten the duration of acute illness and/or mitigate of ETEC and ETEC-related illnesses.
- b. ETEC therapeutic treatments that can be issued to symptomatic patients to treat the effects of ETEC that may be suitable for usage in in a forward environment.

**3) FOCUS AREA #3: HUMAN PERFORMANCE / PHYSIOLOGICAL EPISODES**

This area focuses on the prediction / improvement of health status and outcomes from various sources of combat related stressors that may include advanced biomedical electronics such as sensors and microelectronics and other medical technology solutions that mitigate the risk of physiological episodes (PEs). PEs may be a result of hypoxia, toxic exposure, decompression illness, hyperventilation, spatial disorientation, or other physiological conditions that occur in operational environments. Occurrence of PEs may result in physiological discomfort, loss of consciousness, loss of life, and/or failed mission. **Specific areas of interest are as follows** (*Offerors shall address only one of these in each White Paper submission*):

- a. Body-worn devices that detect changes in physiological conditions associated with the onset of PE including a risk alert to the user during tactical performance in time to implement corrective actions.
- b. Enabling capabilities that increase the effectiveness and fieldability of PE detection and alert systems including, but not limited to, physiological risk profiles, specialized device hardware components, improved wearability.
- c. Pre- and post-exposure treatments or biotechnology solutions that enhance / restore operator performance or reduce operator impacts /susceptibility from / to PE conditions, thus maximizing operator resilience / recovery.

### 3.3. Additional Points of Consideration

- **Classification of Proposed Solutions:** Proposed prototype solutions shall be either “engineering and medical prototypes” or “knowledge products”. See below for definition of each.
  - Engineering and medical prototypes: System, subsystem, component, or material directly or indirectly delivering or supporting a biomedical product or critical capability. These are physical, in-hand products which can be examined, tested, and demonstrated. This may also include products that require U.S. Food and Drug Administration (FDA) approval.
  - Knowledge products: Non-material solution that includes methodology, technology, or technical process directly or indirectly supporting a biomedical product or critical capability. This may also include products such as technical reports or manuals impacting training and/or operations
- **Military Relevance:** Proposed projects must demonstrate relevance to the enhanced readiness and resilience of Navy and Marine Corps health and performance.
- **Project Maturity:** This solicitation is not meant to support development of a new prototype, but should focus on fine tuning and optimization of existing prototypes or other technologies.
- **Industry Partners:** Proposed projects are encouraged to include relevant industry partners, especially considering that the eventual goal is to transition products to industry for FDA approval and/or commercialization.
- **USG / DoD Partners:** The Offeror is encouraged to partner with DoD / Government facilities / laboratories / medical treatment centers:
  - One or more military medical treatment facilities to include the Veteran’s Administration (VA) and/or DoD medical treatment facilities;
  - One or more military medical or scientific laboratories / centers for the conduct of the proposed efforts.

For the purposes of white paper and proposal submissions, the Offeror is expected to identify aspects of the proposed work which may be done in collaboration with USG / DoD VA, and provide information of the identification and process, and letter of intent (Attachment G) of the establishment of the future collaborations with the USG / DoD site(s). Partnership with USG / DoD is not a requirement for award.

### 3.4. Potential Follow-on Tasks

There is potential for award of one or more follow-on tasks based on the success of any resultant Research Project Awards (subject to change depending upon Government review of

work completed and availability of funding). Note that any potential follow on work is expected to be awarded non-competitively to resultant project awardees. Follow-on work may include tasks related to advancement of prototype maturity, and/or to expand the use or utility of the prototype. **Examples** of potential follow-on work are **(but not limited to)**:

- Prototype development, refinement, maturation
- Nonclinical and preclinical studies required for the technical data package for a regulatory application
- Clinical Studies
- Establish robust quality system
- Improve efficiency and reproducibility of manufacturing process for scale up
- Work towards FDA clearance/ approval
- Military environmental and operational assessments
- Ruggedization for operation in military environments
- Advanced technical testing in relevant or simulated operational environments
- Initial Procurement

### **3.5. Restrictions on Animal and Human Subjects**

White Papers and proposals must comply with restrictions and reporting requirements for the use of animal and human subjects, to include research involving the secondary use of human biospecimens and/or human data. The Awardee shall ensure local Institutional Animal Care and Use Committee (IACUC) and Institutional Review Board (IRB) approvals, continuing review (in the intervals specified by the local IACUC and IRB, but at a minimum, annually), and approval by the U.S. Army Medical Research and Development Command Animal Care and Use and Review Office (ACURO) and the USAMRDC Human Research Protections Office (HRPO). Offerors shall include IACUC, ACURO, IRB and HRPO review and approval in the SOW/Milestones Table submitted with the Stage 2 full proposal (if invited), as applicable.

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

### **3.6. Guidance related to DOD-affiliated personnel for participation**

Please note that compensation to DOD-affiliated personnel for participation in research while on duty is prohibited with some exceptions. For more details, see Department of Defense Instruction 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DOD-Conducted and Supported Research. You may access a full version of the DODI by accessing the following link:

<https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf>

## **4 White Paper Preparation**

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#### **4.1. General Instructions**

White Papers should be submitted by the date and time specified on the cover page using BIDS: <https://ati2.acgcenter.com/ATI2/Portal.nsf/Start?ReadForm>. Include the MTEC Solicitation Number (**MTEC-21-10-NavyMultiTopic**) on each white paper submitted. See RPP Attachment H for further information regarding BIDS registration and submission.

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

The White Paper format provided in this MTEC RPP is mandatory and shall reference this RPP number (**MTEC-21-10-NavyMultiTopic**). Note that Cost Proposals are only required for Stage 2 and are not part of the initial White Paper submission. However, Offerors are required to submit a Rough Order of Magnitude (ROM) pricing in accordance with the White Paper Template. Offerors are encouraged to contact the Points-of-Contact identified herein up until the White Paper submission date/time to clarify requirements (both administrative and technical in nature).

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

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

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

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

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

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

- **White Paper: One PDF document 5MB or lower.**

**Each White Paper is limited to four pages plus a cover page (5 pages total).** The White Paper must be in 11 point (or larger) type font, single-spaced, single-sided, on 8.5 inches x 11 inches paper. Smaller font may be used in figures and tables, but must be clearly legible. Margins on all sides (top, bottom, left, and right) should be at least 1 inch. The MTEC staff will share white papers with various potential public and private sector sponsors. ***Please do not include confidential or proprietary information.*** White Papers exceeding the page limits specified above may not be accepted.

#### **4.3. Stage 2 Pitch or Full Proposal (for Only Those Offerors Recommended for Stage 2)**

As already outlined in Section 2.3 of this RPP, the Stage 2 process may vary and may require different submissions compared with typical MTEC RPPs. The Government is utilizing two distinct Stage 2 approaches under this RPP.

- Stage 2 Approach A: This Stage 2 approach will require a solution pitch (i.e., oral presentation) followed by a written detailed research strategy and full cost proposal (after evaluation of the pitch).
- Stage 2 Approach B: This Stage 2 approach will require a full proposal (to include technical and cost volumes) using the MTEC Proposal Preparation Guidelines (PPG).

Note that Stage 2 Offerors will only be required to follow one of the aforementioned Stage 2 approaches. Those Offerors that are favorably evaluated during Stage 1 will receive notification letters which will serve as the formal request for a Stage 2 proposal. These letters will contain specific Stage 2 proposal submission requirements and templates.

Please note that MTEC members who are invited to participate in Stage 2 will be required to comply with the following requirements in addition to any Stage 2 proposal requirements listed above:

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

**Current and Pending Support (template provided in Attachment F):** For all current and pending research support (to include government and non-government), include the



award number and title, funding agency and requiring activity's names, period of performance (dates of funding), level of funding (total direct costs only), 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."

- **Letter of Intent (Attachment G):** Provide letter(s) of intent, signed by the appropriate organizational official, confirming the work that is being done in collaboration with USG / DoD VA. Partnership with USG / DoD is not a requirement for award.
- **Data Rights Assertions (template provided in Attachment C)**
  - The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding Data Rights. It is anticipated that anything delivered under this proposed effort would be delivered to the Government with Government purpose data rights or unlimited data rights unless otherwise asserted in the proposal and agreed to by the Government.
  - If this is not the intent, then you should discuss any restricted data rights associated with any proposed deliverables. If applicable, complete the table within the Attachment for any items to be furnished to the Government with restrictions. An example is provided.
  - Note: This document is no longer required as part of the Technical Proposal (Volume 1) and will be uploaded as a separate attachment into the BIDS system.
- **MTEC Base Agreement:** If Offerors have not yet executed a MTEC Base Agreement, then Offerors must certify on the cover page of their full proposal that, if selected for award, they will abide by the terms and conditions of the latest version of the MTEC Base Agreement. If the Offeror already has executed an MTEC Base Agreement with the MTEC CM, then the Offeror must state on the cover page of its Proposal that, if selected for award, it anticipates the proposed effort will be funded under its executed MTEC Base Agreement. A sample of the MTEC Base Agreement can be found on the MTEC website at [www.mtec-sc.org](http://www.mtec-sc.org).

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

#### **4.4. White Paper and Full Proposal Preparation Costs**

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

#### **4.5. Freedom of Information Act (FOIA)**

To request protection from FOIA disclosure as allowed by 10 U.S.C. §2371(i), Offerors shall mark business plans and technical information with a legend identifying the documents as being submitted on a confidential basis.

**4.6. Telecommunications and Video Surveillance**

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

**5 Selection**

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**5.1. Preliminary Screening**

The CM will conduct a preliminary screening of submitted White Papers to ensure compliance with the RPP requirements. As part of the preliminary screening process, White Papers that do not meet the requirements of the RPP may be eliminated from the competition or additional information may be requested by the CM. The Government reserves the right to request additional information or eliminate proposals that do not meet these requirements from further consideration. One of the primary reasons for non-compliance or elimination during the initial screening is the lack of significant nontraditional defense contractor participation, nonprofit research institution participation, or cost share (see Attachment B). Proposal Compliance with the statutory requirements regarding the appropriate use of Other Transaction Authority (as detailed within Attachment B) will be determination based upon the ratings shown in Table 1:

TABLE 1- COST SHARING/NONTRADITIONAL CONTRACTOR ASSESSMENTS	
RATING	DESCRIPTION
PASS	<p>Offeror proposing an MTEC research project meets at least ONE of the following:</p> <ul style="list-style-type: none"> <li>• Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution</li> <li>• Offeror's White Paper has at least one Nontraditional Defense Contractor or Nonprofit Research Institute participating to a significant extent</li> <li>• All significant participants in the transaction other than the Federal Government are small businesses or nontraditional defense contractors</li> <li>• Offeror provides at least one third of the total project cost as acceptable cost share</li> </ul>

FAIL	Offeror proposing an MTEC research project does <b>NOT</b> meet at least ONE of the following: <ul style="list-style-type: none"><li>• Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution</li><li>• Offeror's White Paper has at least one Nontraditional Defense Contractor or Nonprofit Research Institution participating to a significant extent</li><li>• All significant participants in the transaction other than the Federal Government are small businesses or nontraditional defense contractors</li><li>• Offeror provides at least one third of the total project cost as acceptable cost share</li></ul>
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### 5.2. White Paper (Stage 1) Evaluation

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

1. Research Strategy
2. Personnel and Team

**Factor 1 – Research Strategy:** The Offeror’s white paper will be assessed for relevancy, thoroughness, and completeness of the proposed research strategy. The following information will be considered as part of this factor:

- Whether the proposed prototype is based on promising preliminary data, sound scientific rationale, and demonstrated proof-of concept.
- How well the white paper defines a prototype that meets the requirements set forth in this RPP, to include the required minimum TRL or KRL.
- How well the Offeror demonstrates the technical ability and strategy to execute the research.
- How well the specific aims and proposed methodology supports the technical objectives and the development of the prototype.
- The Government may evaluate the proposed cost, as reflected in the ROM, as it relates to research strategy. Therefore, White Papers may be evaluated based on the degree to which the proposed solution delivers value to the Government and demonstrates a feasible solution considering funding availability as well as anticipated lifecycle costs.

**Factor 2 – Personnel and Team:** The Offeror’s white paper will be assessed for how the background and expertise of the personnel and organizations are appropriate to execute the proposed research. The following information will be considered as part of this factor:

- a) Strength of Team: Strength of the organization/team, considering the qualifications of the personnel, facilities, equipment, supplies, services, and subcontractors, and project management plan proposed to complete the work.
- b) Financial Stability: How well the funding strategy described will advance the technology to the next level of development and/or delivery to the military or civilian market.
- c) Schedule: The degree to which the Offeror demonstrates a realistic, achievable performance schedule with a plan to address potential risks that could delay or otherwise impact performance.

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

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

***Upon review and evaluation of the White Papers, Offerors who are favorably evaluated will be invited to participate in Stage 2 for further consideration. Offerors whose White Papers were not favorably evaluated will be provided feedback on the evaluation. Note that Offerors should receive an overall rating of at least “Acceptable” or higher in order to be considered for Stage 2; however, the Government reserves the right to make final evaluation decisions based upon programmatic relevancy and overall best value solutions determined to be in the Government’s best interest.***

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

### **5.3. Stage 2 Evaluation (for Only Those Offerors Recommended for Stage 2)**

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

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

Stage 2 submissions that pass the preliminary compliance screening will be evaluated by the Government technical evaluation panel who will make recommendations to a Source Selection Authority.

Evaluation will be based on an independent, comprehensive review and assessment of the work

proposed against stated source selection criteria and evaluation factors. The Government will evaluate against the technical evaluation factors detailed below and assign adjectival ratings to the non-cost/price factor(s) consistent with those defined in Table 1 (General Merit Ratings Assessments). The Offeror shall clearly state how it intends to meet and, if possible, exceed the RPP requirements. Mere acknowledgement or restatement of a RPP requirement is not acceptable. The CM will evaluate the cost proposals for those Offerors recommended for award, as detailed below, for cost reasonableness.

#### **Stage 2 Evaluation Factors**

1. Technical Approach
2. Potential for Transition or Commercialization
3. Cost Reasonableness

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

**Factor 1 – Technical Approach:** The Offeror’s Stage 2 submission will be assessed for:

- a) How well the specific aims and proposed methodology support the technical objectives and the development of the prototype.
- b) How well the approach effectively demonstrates the Offeror’s understanding of the overall requirement and inclusion of complete and clear processes to execute the effort.

**Factor 2 - Potential for Transition or Commercialization:** The Offeror’s Stage 2 submission will be assessed for:

- a) How well the Offeror demonstrates the potential for the prototype to integrate into current or future cross-cutting prevention initiatives.
- b) How well the Offeror demonstrates potential advancement into the next phase of desired research, development, testing, commercialization, and/or implementation.
- c) How well an Offeror demonstrates an achievable approach to regulatory approval (if applicable).

**Factor 3 – Cost Reasonableness:** Assessment of the cost of the project to determine: i) whether the project cost is within the available funding limits, and ii) the ability and/or likelihood of the offeror to successfully execute the proposed project within the financial resources proposed. The proposed cost will be based on the following ratings: Sufficient, Insufficient or Excessive. See the definitions of these ratings in Table 2 below.

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

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

Please also refer to Section 5.4 for definitions of general terms used in technical evaluations.

**5.3.1 Cost/Price Evaluation**

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In addition to the evaluation of Factor 3 – Cost Reasonableness, the MTEC CM will evaluate the estimated cost proposed by the Offeror for performing all requirements outlined in this RPP and the MTEC PPG. Evaluation will include analysis of the proposed cost together with all supporting information. The Offeror's cost and rationale will be evaluated for realism, reasonableness, and completeness. If a proposal is selected for award, the MTEC CM will review the original cost proposal and the Offeror's response to a Proposal Update Letter, if applicable. The MTEC CM will request additional information or clarification as necessary. The MTEC CM will assess the reasonableness and completeness of the cost estimates and then provide a formal assessment to the Government. The Government will review this assessment and make the final determination that the negotiated project value is fair and reasonable.

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

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

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

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

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

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

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

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

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

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

### **5.3.2 Best Value**

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

### **5.4. Definitions of General Terms Used in Evaluations:**

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

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

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

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



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

## 6 Points-of-Contact

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

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

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

## 7 Acronyms/Abbreviations

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ACURO	Animal Care and Use Review Office, USAMRDC
ATI	Advanced Technology International
CAS	Cost accounting standards
CM	Consortium Manager
CMA	Consortium Member Agreement
DoD	Department of Defense
DUNS	Data Universal Numbering System
ETEC	Enterotoxigenic Escherichia Coli
F&A	Facilities and Administrative Costs
FAQ	Frequently Asked Questions
FDA	Food and Drug Administration
FOC	Full Operating Capability
FOIA	Freedom of Information Act
FY	Fiscal Year
G&A	General and Administrative Expenses
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IRB	Institutional Review Board
IR&D	Independent Research and Development
KRL	Knowledge readiness level
M	Million
MPS	Milestone Payment Schedule

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MTEC	Medical Technology Enterprise Consortium
NAMD	Naval Advanced Medical Development
NDA	Nondisclosure Agreement
NDC	Nontraditional Defense Contractor
NMRC	Naval Medical Research Center
NRI	Nonprofit Research Institution
OCI	Organizational Conflict of Interest
ODC	Other Direct Costs
OTA	Other Transaction Agreement
PE	Physiologic episodes
POP	Period of Performance
PPG	Proposal Preparation Guide
Q&A	Questions and Answers
ROM	Rough Order of Magnitude
RPP	Request for Project Proposals
SOW	Statement of Work
TRL	Technology readiness level
USAMRDC	U.S. Army Medical Research and Development Command
USG	U.S. Government
VA	Veterans Administration

## 8 White Paper Template

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See the following page for the mandatory White Paper Template.

### **Cover Page (1 page)**

#### **Title of White Paper**

**Focus Area:** [Indicate which focus area and specific area of interest this white paper is addressing. To meet the intent of this RPP, each white paper **MUST** specifically address only **ONE** of the three Focus Areas and **ONE** Specific Area of Interest described in Section 3. Offerors are not limited to a single white paper submission. Projects not aligned with one of these Focus Areas and specific areas of interest will not be considered for funding.]

#### **Principal Investigator and Institution**

**Statement that “This White Paper is submitted pursuant to the RPP MTEC-21-10-NavyMultiTopic”**

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

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

**Willingness to allow MTEC Officers access to your White Paper for the purposes of engaging in outreach activities with private sector entities:** Indicate YES or NO

[As part of MTEC’s mission to incorporate philanthropic donations, MTEC frequently makes contact with private sector entities (e.g., foundations, organizations, individuals) that award grants or otherwise co-fund research, and/or operate in research areas that are aligned with those of MTEC. Additional private entities may be interested in reviewing certain White Papers within their program areas, allowing opportunities to attract supplemental funding sources. Please indicate your willingness to allow MTEC access to your White Paper for the purposes of engaging in outreach activities with these private sector entities. MTEC staff has signed Nondisclosure Agreements (NDAs) and Organizational Conflict of Interest statements.]

### **White Paper (4 pages)**

**Title:** [Insert descriptive title of project]

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

**Background:** [Briefly state the problem that the White Paper is addressing.]

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

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

**Technical Strategy:** [Outline the proposed methodology in sufficient detail to show a clear course of action that addresses the technical requirements described in this RPP.]

**Anticipated Outcomes:** [Provide a description of the anticipated outcomes from the proposed work. List milestones and deliverables from the proposed work. Also provide a high-level summary of potential follow-on tasks beyond the initial PoP, if applicable.]

**Military Relevance:** [Provide a description of how the proposed technology meets the needs of the Navy's Program.]

**Technical Maturity and Transition or Commercialization Strategy:** [Provide a brief description and justification of the maturity of the proposed solution, anticipated regulatory pathway (if applicable) and transition or commercialization plans. Include information about Intellectual Property/Data Rights Assertions.]

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

**Personnel and Team:** [Briefly state the qualifications of the Principal Investigator, key personnel, and organizations that will perform the SOW.]

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

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

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

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

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

\*Use the row above for “Government/Military Partner(s)/Subcontractor(s)” if the project involves one or more Government/Military Facilities (MHS 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.

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

## **Attachment A – Cost Share**

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

### **Cash Contribution**

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

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

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

### **In-Kind Contribution**

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

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

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### **Nontraditional Defense Contractor Definition**

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

### **Significant Extent Requirements**

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

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

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

### **Conditions for use of Prototype OT Authority**

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

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



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

## **Attachment C – Intellectual Property and Data Rights**

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### **For Information Only - Stage 2 Requirement**

#### **Definitions**

- **Intellectual Property (IP) Rights** for MTEC Research Project Awards will be defined in the terms of an awardee’s Base Agreement, unless specifically negotiated at the RPA level. MTEC Base Agreements are issued by the MTEC CM to MTEC members receiving Research Project Awards. Base Agreements include the applicable flow down terms and conditions from the Government’s Other Transaction Agreement with MTEC, including the IP terms and conditions.
- **Data Rights:** It is anticipated that anything delivered under a Research Project Award would be delivered to the Government with **Government with Government purpose data rights or unlimited data rights unless otherwise asserted in the proposal and agreed to by the Government**. If this is not the intent, **then the White Paper should discuss data rights associated with each item**, and possible approaches for the Government to gain unlimited data rights as referenced in the Base Agreement. Rights in technical data in each Research Project Award shall be determined in accordance with the provisions of MTEC Base Agreement.

#### **Directions to the Offeror**

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

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

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

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

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

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

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

\_\_\_\_\_  
Signature of responsible party for the proposing Prime Offeror

\_\_\_\_\_  
DATE

## Attachment D – Statement of Work Template

---

### For Information Only - Stage 2 Requirement

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

**Proposal Number:**

**Organization:**

**Title:**

**ACURO and/or HRPO approval needed:**

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

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

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

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

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

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

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

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

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

The milestones and associated deliverables proposed should, in general:

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

### MTEC Milestone Payment Schedule Example

MTEC Milestone Number	Task Number	Significant Event/ Accomplishments	Due Date	Government Funds	Cost Share	Total Funding
-----------------------	-------------	---------------------------------------	----------	------------------	------------	---------------

Request for Project Proposal MTEC-21-10-NavyMultiTopic  
Number W81XWH-15-9-0001

1	N/A	Project Kickoff	12/1/2019	\$20,000		\$20,000
2	N/A	Bimonthly Report 1 (November - December, Technical and Business Reports)	1/25/2020	\$ -		\$ -
3	1	Protocol Synopsis	2/28/2020	\$21,075		\$21,075
4	2	Submission for HRPO Approval	2/28/2020	\$21,075		\$21,075
5	3	Submission of Investigational New Drug application to the US FDA	3/14/2020	\$210,757	\$187,457	\$398,214
6	N/A	Bimonthly Reports 2 (January - February, Technical and Business Reports)	3/25/2020	\$ -		\$ -
7	4	Toxicity Studies	4/1/2020	\$63,227		\$63,227
8	5	FDA authorization trial	4/1/2020	\$84,303		\$84,303
9	6	Research staff trained	4/15/2020	\$ -		\$ -
10	7	Data Management system completed	4/30/2020	\$ -		\$ -
11	8	1 <sup>st</sup> subject screened, randomized and enrolled in study	5/15/2020	\$150,000	\$187,457	\$337,457
12	N/A	Bimonthly Report 3 (March - April, Technical and Business Reports)	5/25/2020	\$ -		\$ -
13	9	Completion of dip molding apparatus	6/1/2020	\$157,829	\$187,457	\$ 345,286
14	10	Assess potential toxicology	6/1/2020	\$157,829		\$157,829
15	11	Complete 50% patient enrollment	6/15/2020	\$350,000	\$187,457	\$537,457
16	12	Electronic Report Forms Developed	6/15/2020	\$315,658	\$187,457	\$503,115
17	13	Complete 75% patient enrollment	7/1/2020	\$157,829	\$93,728	\$251,55

Request for Project Proposal MTEC-21-10-NavyMultiTopic  
Number W81XWH-15-9-0001

18	N/A	Bimonthly Report 4 (May - June, Technical and Business Reports)	7/25/2020	\$ -		\$ -
19	14	Complete 100% patient enrollment	8/1/2020	\$157,829	\$93,728	\$251,557
20	15	Report results from data analysis	8/5/2020	\$157,829		\$157,829
21	N/A	Final Reports ( <u>Prior to the POP End</u> )	8/31/2020	\$ -		\$ -
			<b>Total</b>	<b>\$2,025,240</b>	<b>\$1,124,741</b>	<b>\$3,149,981</b>

**Please Note:**

1. Firm Fixed Price Contracts – Milestone must be complete before invoicing for fixed priced contracts.
2. Cost Reimbursable Contracts – You may invoice for costs incurred against a milestone. Invoicing should be monthly.
3. Cannot receive payment for a report (i.e. Quarterly, Annual and Final Reports should not have an assigned Government Funded or Cost Share amount.)
4. Quarterly and Annual Reports include BOTH Technical and Business Reports (separate).
5. Final Report due date must be prior to POP end noted in Research Project Award.
6. MTEC Milestone Numbers are used for administrative purposes and should be sequential.
7. Task Numbers are used to reference the statement of work if they are different from the MTEC Milestone Number.
8. Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.
9. Allow at least 2 to 3 months for HRPO regulatory review and approval processes.

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

*The shipping address is:*

*Classified Shipments:*

*Outer Packaging*

*Inner Packaging*

**Reporting**

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

Request for Project Proposal MTEC-21-10-NavyMultiTopic  
Number W81XWH-15-9-0001

Final Technical Report – At the completion of the Research Project Award, the awardee will submit a Final Technical Report, which will provide a comprehensive, cumulative, and substantive summary of the progress and significant accomplishments achieved during the total period of the Project effort in accordance with the terms and conditions of the Base Agreement. (Required)

Final Business Status Report – At the completion of the Research Project Award, the awardee will submit a Final Business Status Report, which will provide summarized details of the resource status of the Research Project Award, in accordance with the terms and conditions of the Base Agreement. (Required)

## Attachment E – Warranties and Representations Template

---

**For Information Only - Stage 2 Requirement**

Section 864 of the National Defense Authorization Act (NDAA) for Fiscal Year 2018, authorizes Department of Defense organizations to carry out prototype projects that are directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or to improvement of platforms, systems, components, or materials in use by the armed forces. The law also requires at least one of the following:

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

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

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

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

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

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

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

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



Request for Project Proposal MTEC-21-10-NavyMultiTopic  
Number W81XWH-15-9-0001

<b>15. Subcontractor/Vendor is a small business (Y/N)?</b>		
<b>16. Significant Contribution:</b>		
<input type="checkbox"/>	<b>A - The significant contribution involves developing, demonstrating or providing a key technology.</b> <i>Please describe what the key technology is; why it is key to the medical technology community, and what makes it key.</i>	
<input type="checkbox"/>	<b>B - The significant contribution involves developing, demonstrating or providing a new technology that is not readily available.</b> <i>Please describe what the new part or material is and why it is not readily available.</i>	
<input type="checkbox"/>	<b>C - The significant contribution involves use of skilled personnel (such as modeling &amp; 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.</b> <i>Please describe the personnel, facilities and/or equipment involved in the proposed program and why they are required to successfully complete the program.</i>	
<input type="checkbox"/>	<b>D - The use of this designated subcontractor/vendor will cause a material reduction in the cost or schedule.</b> <i>Please describe the specific cost or schedule impact to be realized</i>	
<input type="checkbox"/>	<b>E - The use of this designated subcontractor/vendor will increase medical technology performance.</b> <i>Please describe what the performance increase will be attained by the use of this designated nontraditional defense contractor</i>	
<b>1 In addition to the above please provide the following information:</b>		
<b>Q1</b>	<b>What additional capability beyond those described in A through E above does this subcontractor/vendor have that is necessary for this specific effort?</b>	
A1		
<b>Q2</b>	<b>In which task/phase(s) of the effort will the subcontractor/vendor be used?</b>	
A2		
<b>Q3</b>	<b>What is the total estimated cost associated with the subcontractor/vendor included in the proposal?</b> <i>Note: While cost is an indicator for the level of nontraditional defense contractor participation, there is no particular cost threshold required.</i>	
A3		

**C. Signature**

---

Signature of authorized representative of proposing Prime Contractor

---

Date

**Warranties and Representations Instructions**

Section A must be completed for the Prime Contractor.

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

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

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

the questions below.

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

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

### **General Guidance**

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

## Attachment F – Current & Pending Support Template

---

### For Information Only - Stage 2 Requirement

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

#### **Current**

Award Number:

Title:

Funding Agency/Requiring Activity:

Dates of Funding:

Total Awarded Costs:

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

Brief summary of the scope of work:

Award Number:

Title:

Funding Agency/Requiring Activity:

Dates of Funding:

Total Awarded Costs:

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

Brief summary of the scope of work:

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

#### **Pending**

Title of Proposal:

Funding Agency/Requiring Activity:

Estimated Dates of Funding:

Proposed Total Direct Costs:

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

Brief summary of the scope of work:

Title of Proposal:

Funding Agency/Requiring Activity:

Estimated Dates of Funding:

Proposed Total Direct Costs:

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

Brief summary of the scope of work:

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

## **Attachment G – Letter of Intent**

---

*For Information Only - Stage 2 Requirement*

Provide letter(s) of intent, signed by the appropriate organizational official, confirming the work that is being done in collaboration with USG / DoD VA. Partnership with USG / DoD is not a requirement for award.

**Attachment H – BIDS Instructions**

---

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# MTEC BIDS REGISTRATION

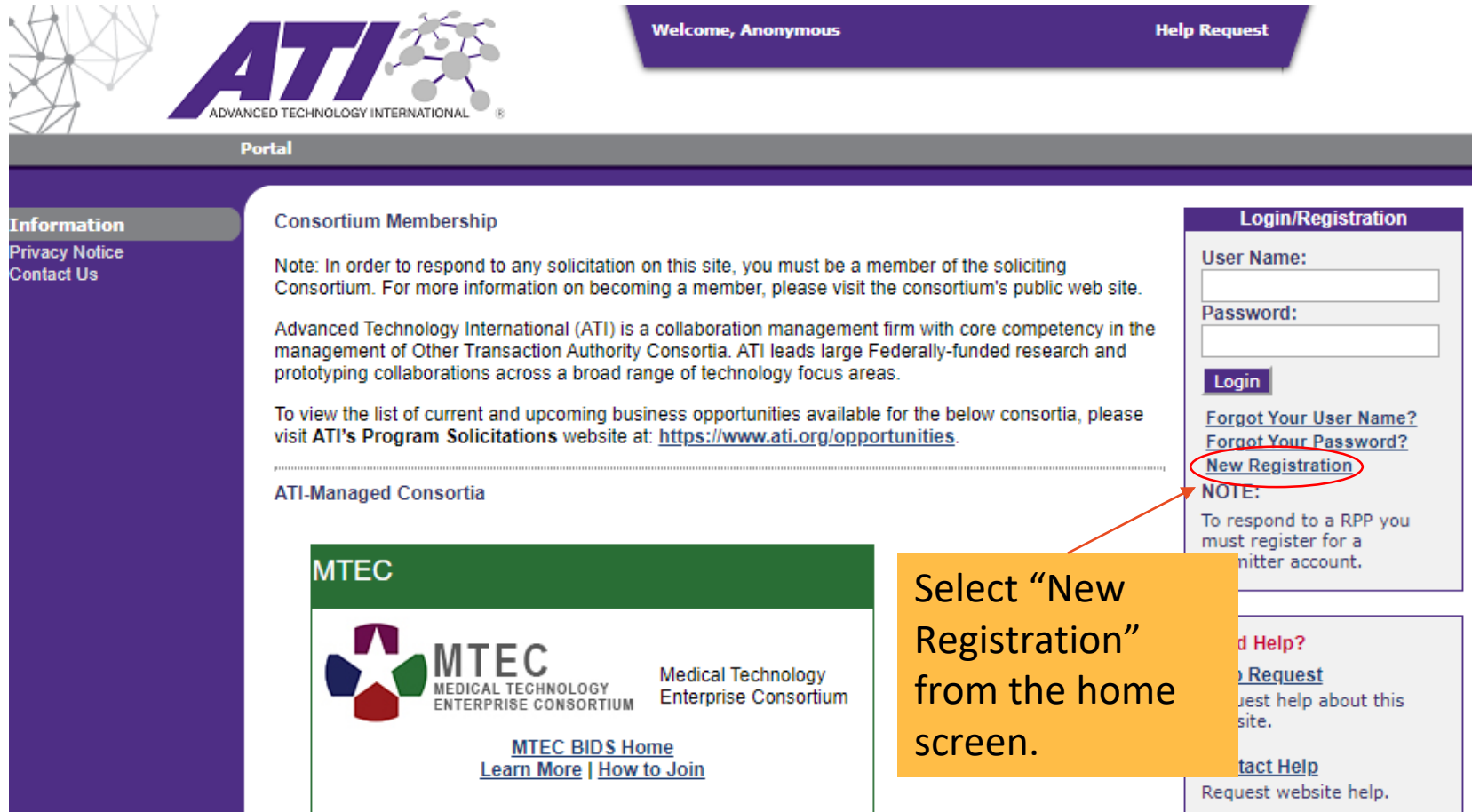
*MTEC BIDS URL:*

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



# BIDS New Registration

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



**ATI**  
ADVANCED TECHNOLOGY INTERNATIONAL

Welcome, Anonymous [Help Request](#)

Portal

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

**Consortium Membership**

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

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

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

ATI-Managed Consortia

**MTEC**  
MEDICAL TECHNOLOGY  
ENTERPRISE CONSORTIUM

Medical Technology  
Enterprise Consortium

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

**Login/Registration**

User Name:

Password:

[Login](#)

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

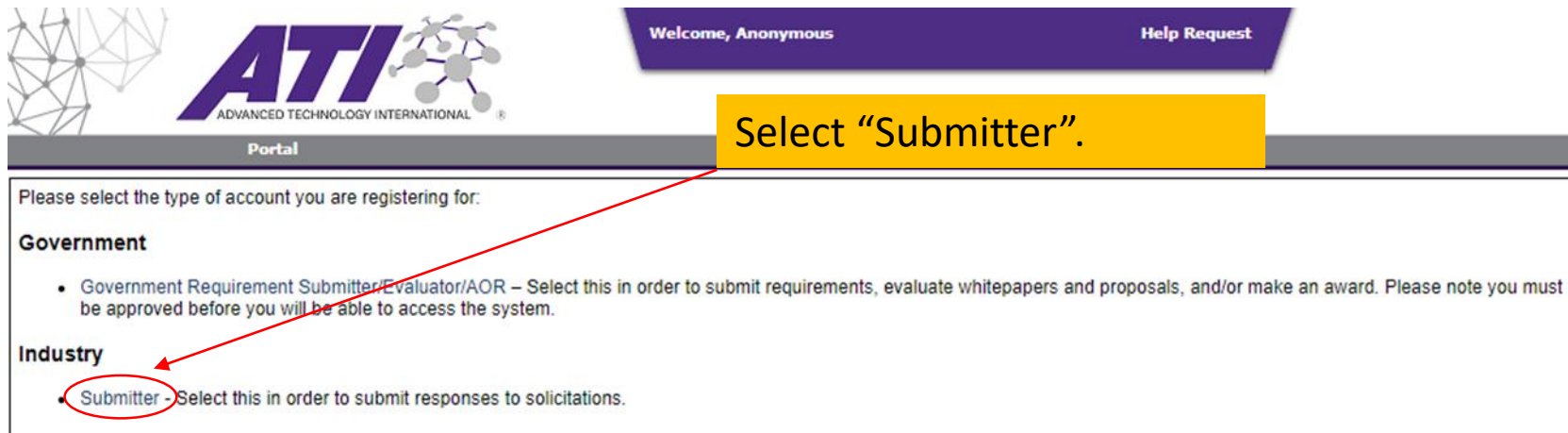
NOTE:  
To respond to a RPP you must register for a twitter account.

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

[Contact Help](#)  
Request website help.

Select “New Registration” from the home screen.

## Select “Submitter”



Portal

Welcome, Anonymous Help Request

Select “Submitter”.

Please select the type of account you are registering for:

**Government**

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

**Industry**

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

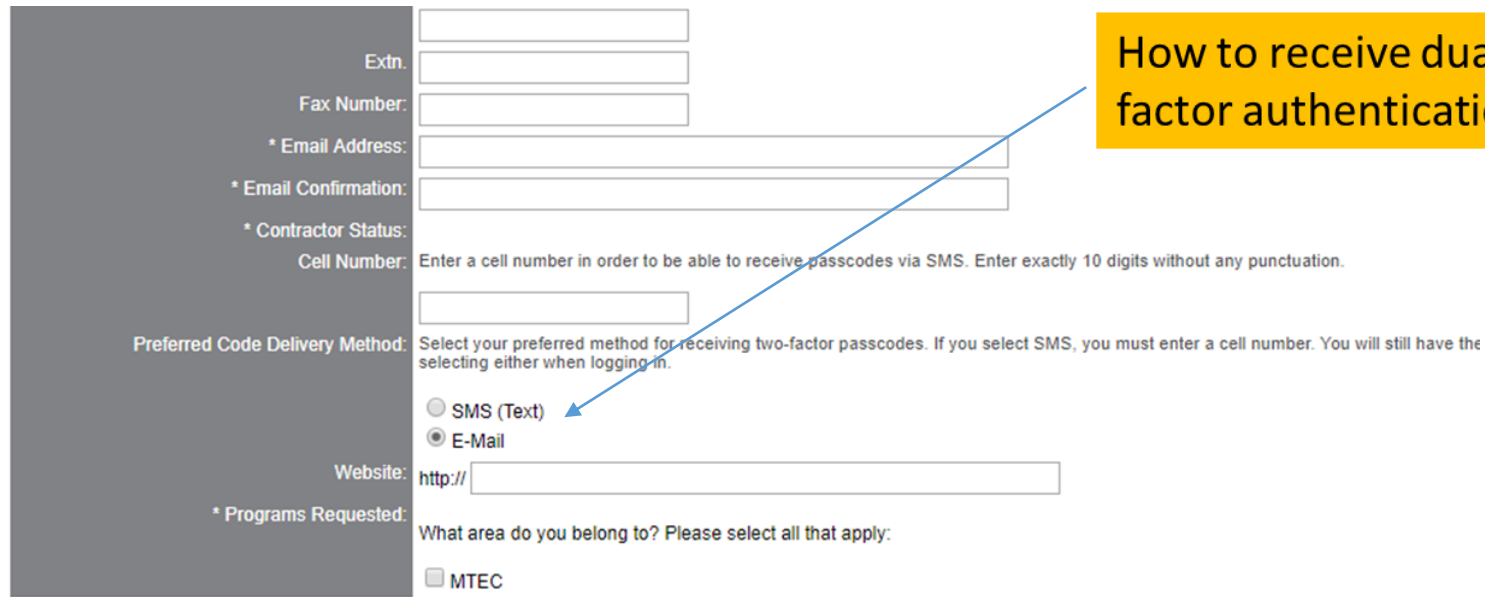
SECURITY NOTICE: Unauthorized attempts to deny service, upload information, change information, or attempt to access a non-public site from this service are strictly prohibited and may be punishable under Title 18 of the U.S. Code to include the Computer Fraud and Abuse Act of 1986 and the National Information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



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# BIDS New Registration

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



Extn.

Fax Number:

\* Email Address:

\* Email Confirmation:

\* Contractor Status:

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

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

SMS (Text) ←

E-Mail

Website: http://

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

MTEC

How to receive dual factor authentication .

Select "Submit Registration" to complete BIDS registration.

# BIDS New Registration

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

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

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

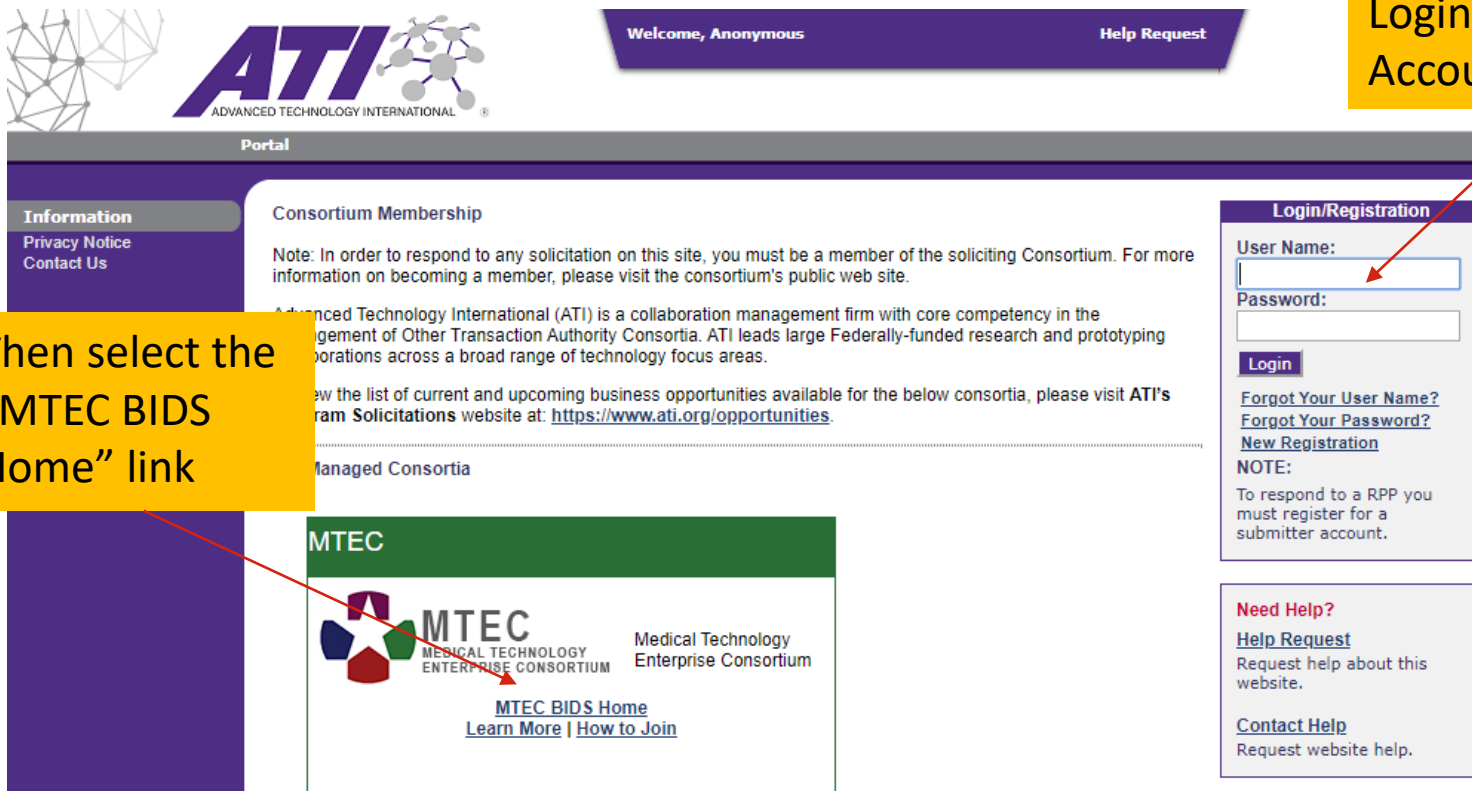
**ALL PROPOSALS MUST BE SUBMITTED BEFORE THE SUBMISSION DUE DATE AND TIME. LATE PROPOSALS CAN NOT BE ACCEPTED.**

# MTEC BIDS PROPOSAL SUBMISSION

*MTEC BIDS URL:*

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

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



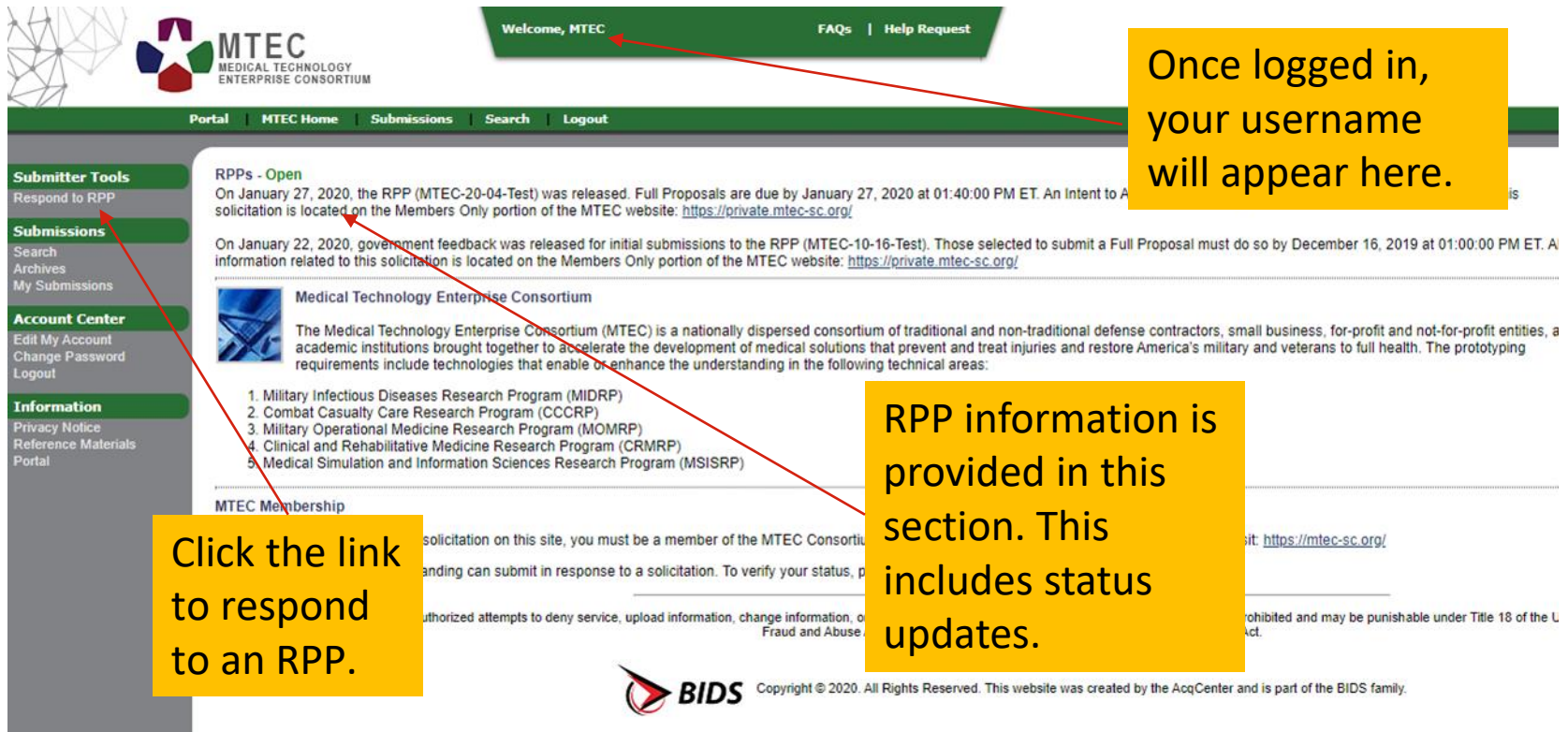
The screenshot shows the MTEC BIDS website interface. At the top, there is a navigation bar with "Welcome, Anonymous" and "Help Request" links. Below this is a "Portal" header. The main content area is divided into several sections: "Information" (Privacy Notice, Contact Us), "Consortium Membership"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

Login to your BIDS Account.

Then select the “MTEC BIDS Home” link

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

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



Once logged in, your username will appear here.

Click the link to respond to an RPP.

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

Welcome, MTEC    FAQs | Help Request

Portal | MTEC Home | Submissions | Search | Logout

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

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

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

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


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

MTEC Membership

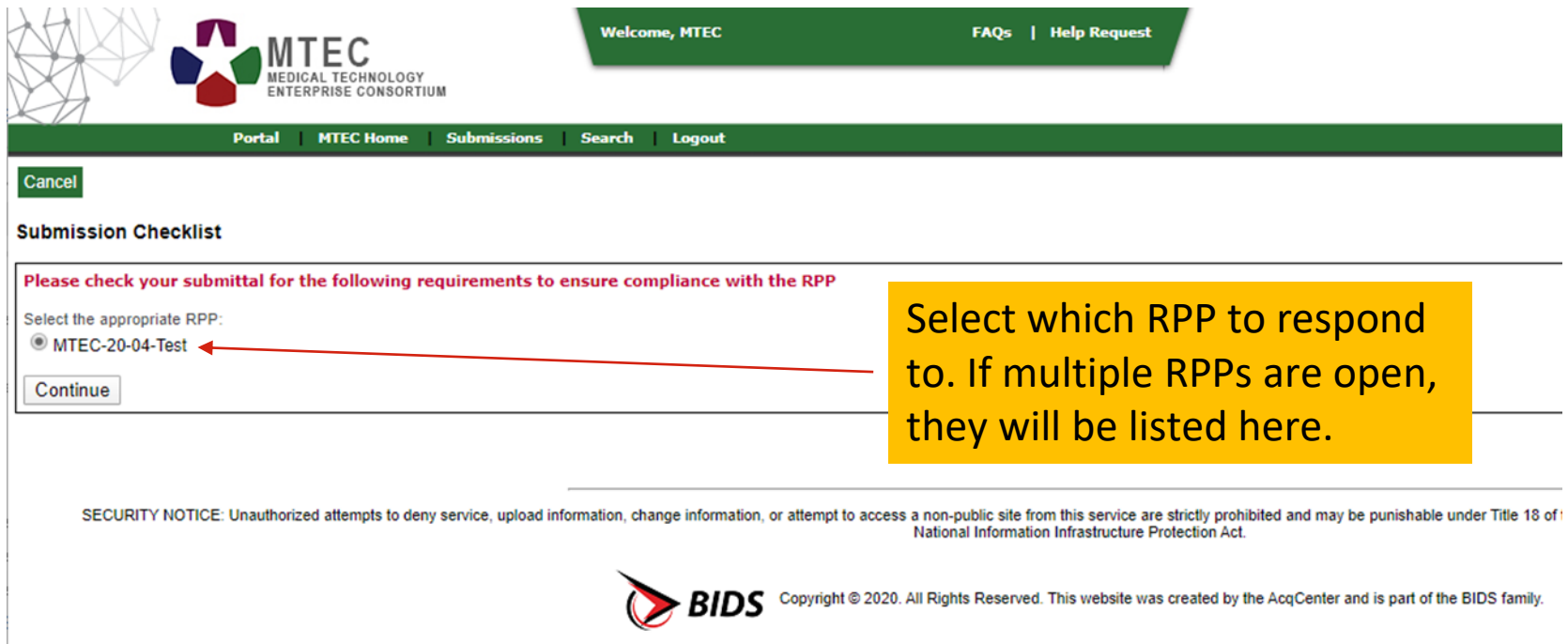
solicitation on this site, you must be a member of the MTEC Consortium. To verify your status, please visit: <https://mtec-sc.org/>

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

authorized attempts to deny service, upload information, change information, or engage in Fraud and Abuse. Prohibited and may be punishable under Title 18 of the U.S. Code, Section 1030.

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Select which RPP you will be responding to.



The screenshot shows the MTEC submission checklist interface. At the top, there is a green navigation bar with the MTEC logo and the text "Welcome, MTEC" and "FAQs | Help Request". Below this is a dark green bar with navigation links: "Portal", "MTEC Home", "Submissions", "Search", and "Logout". The main content area has a "Cancel" button and a "Submission Checklist" section. The checklist contains the text "Please check your submittal for the following requirements to ensure compliance with the RPP" and "Select the appropriate RPP:". Below this, there is a radio button selected for "MTEC-20-04-Test". A red arrow points from a yellow callout box to this radio button. A "Continue" button is located below the radio button. At the bottom of the page, there is a "SECURITY NOTICE" and the BIDS logo with the text "Copyright © 2020. All Rights Reserved. This website was created by the AcqCenter and is part of the BIDS family."

Cancel

**Submission Checklist**


Please check your submittal for the following requirements to ensure compliance with the RPP

Select the appropriate RPP:

MTEC-20-04-Test

Continue

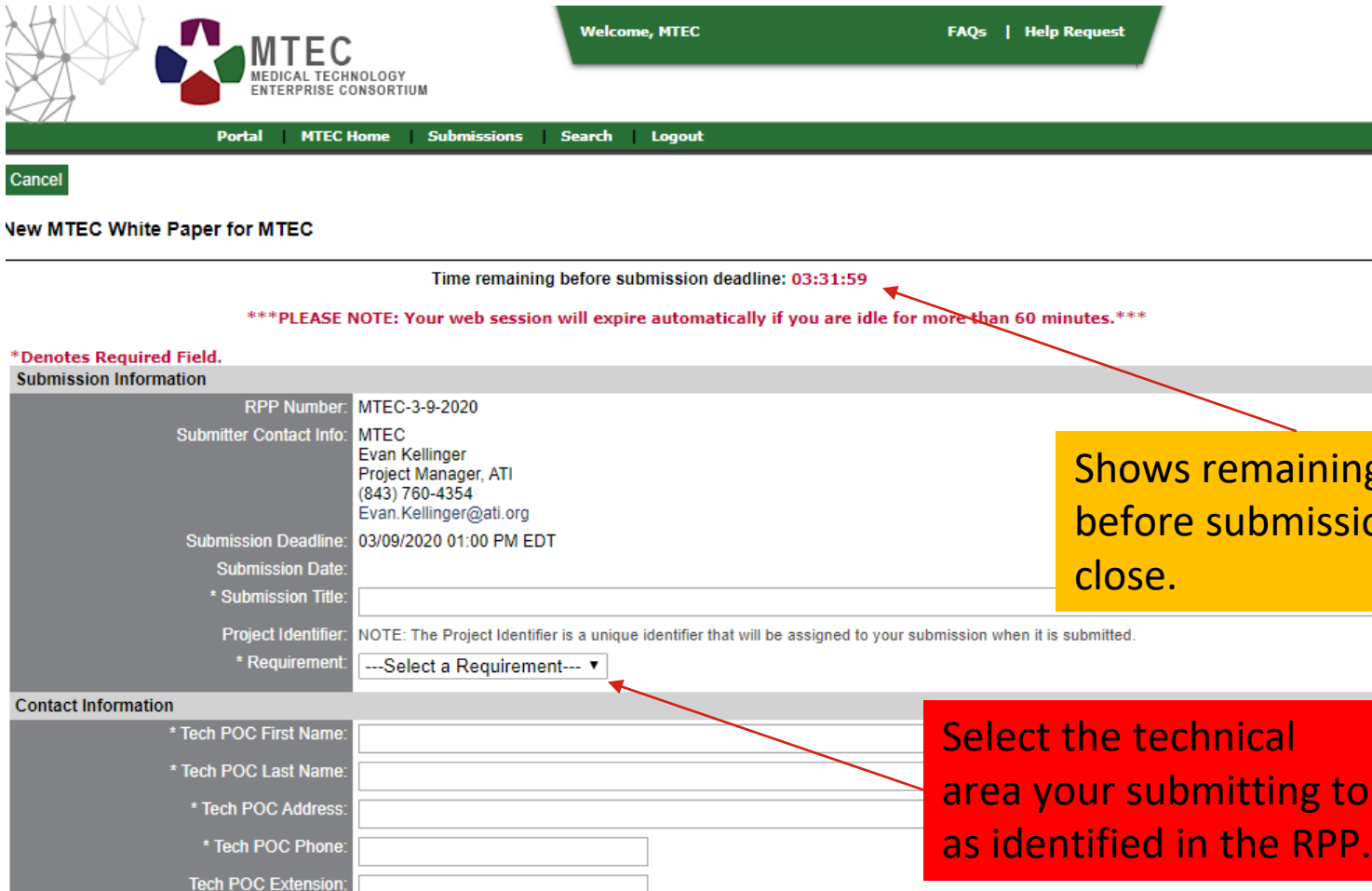
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Select which RPP to respond to. If multiple RPPs are open, they will be listed here.



Complete the submission form.



The screenshot shows the MTEC submission form interface. At the top, there is a green navigation bar with the MTEC logo and text: "Welcome, MTEC" and "FAQs | Help Request". Below this is a secondary green bar with navigation links: "Portal | MTEC Home | Submissions | Search | Logout". A "Cancel" button is visible on the left. The main content area displays "New MTEC White Paper for MTEC" and a countdown timer: "Time remaining before submission deadline: 03:31:59". A red note states: "\*\*\*PLEASE NOTE: Your web session will expire automatically if you are idle for more than 60 minutes.\*\*\*". A section titled "\*Denotes Required Field." contains the "Submission Information" form. This form includes fields for "RPP Number" (MTEC-3-9-2020), "Submitter Contact Info" (MTEC, Evan Kellinger, Project Manager, ATI, (843) 760-4354, Evan.Kellinger@ati.org), "Submission Deadline" (03/09/2020 01:00 PM EDT), "Submission Date", "\* Submission Title" (empty text input), "Project Identifier" (NOTE: The Project Identifier is a unique identifier that will be assigned to your submission when it is submitted.), and "\* Requirement" (dropdown menu showing "---Select a Requirement---"). Below this is the "Contact Information" section with fields for "\* Tech POC First Name", "\* Tech POC Last Name", "\* Tech POC Address", "\* Tech POC Phone", and "Tech POC Extension". Two callout boxes provide instructions: a yellow box points to the timer with the text "Shows remaining time before submission close.", and a red box points to the requirement dropdown with the text "Select the technical area your submitting to as identified in the RPP."

# Proposal Submission BIDS

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

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

Upload documents in this section.

Submit

Once the submission form is completed select submit.

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

# Proposal Submission BIDS

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

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

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

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