



Request for Project Proposals

Solicitation Number: MTEC 20-16-mTBI

“Advancement of Drugs for the Treatment of Repeated Mild Traumatic Brain Injury (mTBI)”

Issued by:
Advanced Technology International (ATI),
MTEC Consortium Manager (CM)
315 Sigma Drive
Summerville, SC 29486
for the
Medical Technology Enterprise Consortium (MTEC)

Request Issue Date: September 15, 2020

***Proposal Due Date: November 10, 2020
Noon Eastern Time***

White Papers Are NOT Required

Table of Contents

- 1 Executive Summary** 3
 - 1.1 The Medical Technology Enterprise Consortium (MTEC) 3
 - 1.2 BrightFocus Foundation (BF) 3
 - 1.3 Purpose..... 3
- 2 Administrative Overview** 3
 - 2.1 Funding Availability 3
 - 2.2 Period of Performance 4
 - 2.3 Type of Funding Instrument Issued..... 4
 - 2.4 MTEC Member Teaming..... 4
 - 2.5 Proprietary Information 4
 - 2.6 Offeror Eligibility 5
 - 2.7 MTEC Assessment Fee..... 5
 - 2.8 Intellectual Property..... 5
 - 2.9 Expected Award Date..... 6
 - 2.10 Anticipated Proposal Selection Notification 6
- 3 Technical Requirements**..... 6
 - 3.1 Clinical Need..... 6
 - 3.2 Technical Objective 7
 - 3.3 Scope of Work 8
 - 3.4 Restrictions on Animal and Human Subjects: 9
- 4 Proposal Preparation** 9
 - 4.1 General Instructions..... 9
 - 4.2 Proposal Submission 9
 - 4.3 Submission Format..... 9
 - 4.4 Preparation of the Proposal..... 10
- 5 Selection** 11
 - 5.1 Selection Process..... 11
 - 5.2 Evaluation Factors 11
 - 5.3 Best Value..... 14
 - 5.4 Definition of General Terms Used in Evaluations: 14
- 6 Points-of-Contact** 15
- 7 Acronyms/Abbreviations**..... 15
- 8 BIDS Instructions** 17

1 Executive Summary

1.1 The Medical Technology Enterprise Consortium (MTEC)

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

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

MTEC is a nonprofit corporation that 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 (<https://www.mtec-sc.org/>).

1.2 BrightFocus Foundation (BF)

BrightFocus funds exceptional scientific research worldwide to defeat Alzheimer’s disease, macular degeneration, and glaucoma and provides expert information on these heartbreaking diseases. We seek to find the cures for the devastating conditions we all fear most: loss of sight and loss of mind.

We fund cutting-edge ideas from scientists all over the world who are dedicated to making groundbreaking discoveries. Since our beginning, we have invested nearly \$225 million in bold, innovative scientific research. For more information, visit BrightFocus.org.

1.3 Purpose

The intent of this jointly funded Request for Project Proposals (RPP) by MTEC and BF, issued by the MTEC Consortium Manager (CM), Advanced Technology International (ATI), is to **enable the advancement of candidate drugs into human clinical trials for the treatment of repeated mild traumatic brain injury (mTBI)**.

2 Administrative Overview

2.1 Funding Availability

MTEC and BF anticipate the total project funding to be up to \$500,000 to make one or more awards. 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 funds for this

program. Award funding will be structured incrementally and based upon completion of milestones.

2.2 Period of Performance

The initial Period of Performance (POP) is not to exceed 24 months; however, faster timelines are highly encouraged.

2.3 Type of Funding Instrument Issued

Awards will be in the form of firm fixed price type agreements invoiced in accordance with the Statement of Work/Milestone Payment Schedule (MPS) (See MTEC-20-16-mTBI Proposal Preparation Manual). The amount invoiced should correlate with the amount associated with that particular milestone in the MPS and each milestone must be 100% complete before invoicing.

2.4 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.

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.

2.5 Proprietary Information

The MTEC CM will oversee submission of Proposals submitted in response to this RPP. The MTEC CM shall take the necessary steps to protect all proprietary information and shall not use such proprietary information for purposes other than the evaluation of an Offeror's Proposal and the subsequent agreement administration if the Proposal is selected for award. Please be sure to

mark all Confidential or Proprietary Information as such. An Offeror's submission of a Proposal under this RPP indicates concurrence with the aforementioned CM responsibilities.

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

2.6 Offeror Eligibility

MTEC membership is required for submission of a Proposal. Offerors submitting Proposals as the prime contractor must be MTEC members in good standing by **November 1, 2020**. Refer to the MTEC website for more information on how to join: <https://www.mtec-sc.org/how-to-join-2/>

2.7 MTEC Assessment Fee

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

2.8 Intellectual Property

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:

1) Royalty Payment Agreements

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 MTEC-BF 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.

2.9 Expected Award Date

Offeror should plan on the period of performance beginning **April 1, 2021** (subject to change). MTEC 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.

2.10 Anticipated Proposal Selection Notification

As the basis of selections is completed, the MTEC CM will notify Offerors.

3 Technical Requirements

3.1 Clinical Need

Treating traumatic brain injury (TBI) remains one of the top priorities for the Department of Defense (DoD). In the last two decades, there have been approximately 420,000 documented incidents of Service members sustaining at least one TBI. Future combat operations are expected to result in an increase in time to evacuation, delaying TBI diagnosis and treatment during the most critical period after injury. The DoD and the military services require solutions to fill the capability gap to treat TBI as close to point of injury as possible, to reduce primary and secondary brain damage.

TBI has been shown to increase long-term mortality and reduce life expectancy. Furthermore, studies have shown that suffering from repeated mTBIs,¹² or a single moderate or severe TBI³ increases the risk of developing pathological changes to the brain that are characteristics of Alzheimer's disease (AD), an irreversible, progressive disease that negatively impacts memory, cognitive ability, and behavior.⁴ Some studies have shown that those who have experienced a TBI have had a significantly earlier onset of AD.^{5,6} The onset of dementia can even occur in patients who seemingly fully recover from their initial TBI.

For this RPP, repeated mTBIs are the focus. Military mTBI is typically caused from either concussive events or exposure to explosive blast injury, and results in physical changes to the brain. Since these changes associated with a single mTBI seem to be reversible, Warfighters often return to duty and risk exposure to repeated mTBIs. However, repeated mTBIs have been

¹ Washington P.M., Villapol S., Burns M.P. Polypathology and dementia after brain trauma: does brain injury trigger distinct neurodegenerative diseases, or should they be classified together as traumatic encephalopathy? *Exp. Neurol.* 2016;275(Pt 3):381–388.

² Blennow K., Brody D.L., Kochanek P.M., Levin H., Mckee A., Ribbers G.M., Yaffe K., Zetterberg H. Traumatic brain injuries. *Nat. Rev. Dis. Primers.* 2016;2:16084.

³ Plassman BL, Havlik RJ, Steffens DC, Helms MJ, Newman TN, Drosdick D, et al. Documented head injury in early adulthood and risk of Alzheimer's disease and other dementias. *Neurology.* 2000;55:1158–66.

⁴ Fleminger S, Oliver DL, Lovestone S, Rabe-Hesketh S, Giora A. Head injury as a risk factor for Alzheimer's disease: The evidence 10 years on; a partial replication. *J Neurol Neurosurg Psychiatry.* 2003;74:857–62.

⁵ Schofield PW, Logroscino G, Andrews HF, Albert S, Stern Y. An association between head circumference and Alzheimer's disease in a population-based study of aging and dementia. *Neurology.* 1997;49:30–7

⁶ Ramos-Cejudo J, Wisniewski T, Marmar C, et al. Traumatic Brain Injury and Alzheimer's Disease: The Cerebrovascular Link. *EBioMedicine.* 2018;28:21-30. doi:10.1016/j.ebiom.2018.01.021

suggested to cause chronic traumatic encephalopathy (CTE) and the later onset of dementia or AD.⁷

The estimated economic costs of care for TBI are >\$75 Billion per year according to the Centers for Disease Control (CDC), which is on top of the \$290 Billion in costs required to care for the 5.8 million Americans with dementia. The current standard of care for both TBI and AD remains supportive in nature, based on management of symptoms, with no drug therapies that address the brain damage. Despite numerous clinical trials on potential therapies, there is no U.S. Food and Drug Administration (FDA) approved drug therapy for the treatment of TBI. **Therefore, it is important to develop a drug therapy for the treatment of repeated mTBI that will decrease lost military duty time of those in active service and support the long-term healthy aging of veterans (i.e., prevent the potential later onset of dementia).**

3.2 Technical Objective

The intent of this jointly funded program by MTEC and BF is to enable the advancement of candidate drugs into human clinical trials for the treatment of repeated mTBI. Many drugs have shown promising results in animal models. Despite this, the average rate of successful translation from animal models to human clinical trials is very low. This is largely due to the limited ability that animal models have in mimicking the complex processes of injury and disease that occurs in humans. To this end, human clinical studies are often required by the U.S. Food and Drug Administration (FDA) to determine the true benefit of the technology. **Therefore, the goal of this RPP is to catapult drugs for the treatment of repeated mTBI with dual-use (military and civilian applications) toward human clinical trials to ensure that a pipeline of drug candidates is ready for safety and efficacy evaluation. Relevance to both the military and Alzheimer's disease (AD) is an important aspect of this RPP.**

Eligibility Requirements

This RPP aims to significantly advance the readiness of drug candidates into the next major stage of development/to the next major milestone within a 2 year period of performance. Offerors should only propose drug candidates that meet the following criteria (not listed in order of importance):

1) **Prototype Maturity:**

- a. Drug candidates must be at a Technology Readiness Level (TRL) of 4 at the time of proposal submission. Offerors must have a candidate therapeutic with pre-clinical data in TBI and AD models suggesting safety and/or efficacy at the time of submission.
- b. It is preferred that Offerors have had a pre-submission meeting with the U.S FDA. If available, it would be helpful if proposals included a description of the FDA's feedback related to relevant issues such as classification and associated regulatory requirements, the clinical plan or clinical endpoints, and indication.

⁷ McKee AC, Robinson ME. Military-related traumatic brain injury and neurodegeneration. *Alzheimers Dement.* 2014;10(3 Suppl):S242-S253. doi:10.1016/j.jalz.2014.04.003

- c. Drug candidates are expected to advance to a TRL 5 by the end of the period of performance
 - d. Definition of TRLs – <https://mtec-sc.org/wp-content/uploads/2016/12/TRL-definitions.pdf>
- 2) **Intellectual Property (IP)/Data Rights:** The Offeror must be the exclusive owner or exclusive licensee of rights relevant to developing/commercializing the proposed drug.
 - 3) **Industry Partners:** Projects must eventually result in deliverables that transition medical solutions to industry partners. Offerors are strongly encouraged to include industry partnerships as appropriate.
 - 4) **Impact:** Priority will be given to technologies that demonstrate an appreciation of both the military and commercial markets for TBI interventions. Offerors should demonstrate an understanding of the military need for therapeutic interventions for repeated, mild TBI in a far-forward operational environment. It is preferable that Offerors also provide logical reasoning with data (your own data or published literature) that suggests the linkage between treatment with the proposed drug candidate and the prevention of the later onset of dementia or AD.

3.3 Scope of Work

Proposed projects should focus on tasks that support the submission of an Investigational New Drug (IND) application to the U.S. FDA in support of a Phase 1 Clinical Trial. Examples of acceptable proposed project tasks include, but are not limited to:

- Development of a regulatory strategy for a new product
- Development of a clinical trial protocol to be included in a regulatory submission
- Manufacturing under Good Manufacturing Practice (GMP) and documentation required to support a regulatory submission
- Manufacturing of the investigational product to be used in the clinical trial
- Conduct of final animal tests required to complete the regulatory package
- Compilation and completion of the regulatory package to be submitted to the FDA for the approval of a Phase 1 Clinical Trial
- Onboarding and training of clinical site(s) in preparation for the execution of the clinical trial.

The **deliverable at the end of the period of performance** is the submission of an IND application by the Awardee for a Phase 1 clinical trial to the U.S. FDA.

[NOTE: Through MTEC, the DoD U.S. Army Medical Material Development Activity (USAMMDA) has recently made an award and established a contractual relationship with a competent and experienced TBI Clinical Trial Network to enable the rapid clinical testing of several TBI drug candidates. The intent of this prior award was to establish an experienced and funded infrastructure that could be made available to drug sponsors/industry partners for the evaluation of candidate TBI drugs in Phase 2 clinical trials. The awarded Network brings 18 potential clinical sites and staff that are very familiar with TBI diagnosis, studies and treatment. The already awarded TBI Clinical Trial Network is now poised and ready to collaborate with several drug

sponsors/industry partners to design and execute focused Phase 2 clinical trials on TBI drug candidates, with the goal to reduce the overall risk of future investment in a Phase 3 clinical trial for TBI. If the work from this MTEC-BF award is successful, Awardees may have the potential to transition into funded Phase 2 clinical trials by this TBI Clinical Trial Network downstream when appropriate.]

3.4 Restrictions on Animal and Human Subjects:

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). Offerors shall include IACUC and IRB review and approval in the SOW submitted with the proposal.

4 Proposal Preparation

4.1 General Instructions

Each MTEC research project proposal submitted shall contain both a Technical and Cost Proposal Volume as described below. The Technical and Cost Proposal format shall reference this RPP number (MTEC-20-16-mTBI). Offerors are encouraged to contact the Points-of-Contact (POCs) identified herein up until the proposal submission date/time to clarify requirements.

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

4.2 Proposal Submission

Proposals shall be submitted by the date and time specified on the cover page using BIDS: <https://ati2.acqcenter.com/ATI2/Portal.nsf/Start?ReadForm>. Include the MTEC-20-16-mTBI Solicitation Number on each proposal submitted. See Section 8 of the RPP for further information regarding BIDS registration and submission.

Do not submit any classified information in the Proposal submission.

Any export controlled technical data must be clearly identified.

4.3 Submission Format

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

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

4.4 Preparation of the Proposal

Required Submission Documents (5): Submitted via BIDS

- **Technical Proposal: One PDF document (5MB or lower).**
- **Statement of Work: One Word document (5MB or lower).**
- **Section I: Cost Proposal Narrative as one word or PDF document (5MB or lower).**
- **Section II: Cost Proposal Formats as one excel or PDF document (5MB or lower).**
- **Royalty or Additional Research Project Award Assessment: One signed word or PDF document.**

The Proposal format provided in the MTEC-20-16-mTBI Proposal Preparation Manual is mandatory. Proposals shall reference this RPP number (MTEC-20-16-mTBI). Proposals shall remain valid for 180 days unless otherwise specified by the Offeror in the proposal. Offerors are encouraged to contact MTEC with any questions so that all aspects are clearly understood by both parties. The full proposal should include the following. Each document will be uploaded to BIDS separately. See Section 8 of the RPP for further information regarding BIDS submission.

- **Technical Proposal:** one signed Technical Proposal (.pdf). The Technical Proposal is limited to 15 pages. Refer to the MTEC-20-16-mTBI Proposal Preparation Manual for more information.
- **Statement of Work:** one Word (.docx or .doc). The Offeror is required to provide a SOW using the format provided in the 20-16-mTBI Proposal Preparation Manual.
- **Cost Proposal submission:** one Word (.docx or .doc) or PDF file for Section I: Cost Proposal Narrative (see below from guidance) required. Separately, one Excel (.xlsx or .xls) file for Section II: Cost Proposal Formats using Enclosure 1 (available on the MTEC members only website). Refer to the MTEC-20-16-mTBI Proposal Preparation Manual for more information.
- **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.

5 Selection

5.1 Selection Process

Qualified applications will be evaluated by a technical evaluation panel (TEP) that will make recommendations to MTEC and BF leadership teams. The TEP may:

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

This process may involve the use of contractors as subject matter experts (SME) consultants or reviewers. Where appropriate, the MTEC and BF will employ non-disclosure agreements (NDAs) to protect information contained in submissions. The TEP may be comprised of:

- SMEs appointed by the MTEC CM
- SMEs appointed by BF
- At least one representative from the U.S. Army MRDC with neurotrauma expertise

MTEC and BF will have equal weight in the scoring and ranking of proposals. The MRDC representative will provide input on technical merit and alignment with U.S. military needs, but will not have a vote on proposal ranking.

Evaluation of proposals shall be based on an independent, comprehensive review and assessment of the work proposed against stated evaluation factors. A rating consistent with these evaluation factors will be derived from the ability of the Offeror to perform the work in accordance with all aspects of requirements outlined in this RPP. The Offeror shall clearly state how it intends to meet the RPP requirements. Mere acknowledgement or restatement of a RPP requirement is not acceptable.

MTEC reserves the right to negotiate with Offerors.

5.2 Evaluation Factors

The evaluation factors and evaluation criteria are described below.

Evaluation Factors

1. Technical Approach
2. Programmatic Relevance
3. Potential for Transition and Commercialization
4. Cost Reasonableness

Evaluation factors are listed in descending order of importance. Evaluation Factors 1-3, when combined, are significantly more important than the Cost/Price factor; however, Cost/Price will contribute substantially to the selection decision. As the collective non-cost factors begin to

reach equality in the technical evaluation ratings, cost becomes a more important factor in the trade off analysis.

Table 1 explains the adjectival merit ratings that will be used for the Technical Approach Factor, Programmatic Relevance Factor, and the Potential for Transition and Commercialization Factor.

TABLE 1- 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.

Evaluation Factor 1. Technical Approach

The Technical Approach factor will be evaluated using the merit rating as shown in Table 1.

The Offeror’s proposed solution will be assessed for the likelihood of successfully achieving the requirements of the technology defined in the Technical Requirements section of this RPP. The likelihood of success will be determined by considering the soundness and clarity of the technical approach. Significant consideration will be given to the degree to which the relevant preliminary/supportive data (results of prior studies) regarding the proposed drug candidate justifies its technical feasibility, current TRL, and its readiness to advance into human clinical trials in the near term. The Offeror’s proposal will be assessed for how well feedback from a pre-submission meeting with the FDA supports an identifiable pathway forward. The SOW should provide a succinct approach for achieving the project’s objectives. The SOW will be evaluated for how well the rationale, objectives, and specific aims support the proposed research. The effort will be assessed for the extent to which the solution is technologically innovative and how the

proposed deliverable advances the TRL. A description of the project team's expertise, key personnel, and corporate experience should demonstrate an ability to execute the SOW.

Evaluation Factor 2. Programmatic Relevance

The Programmatic Relevance factor will be evaluated using the merit rating as shown in Table 1.

The Offeror's proposed solution and follow-on clinical trial plan will be assessed for relevance to both the military and AD. It will be evaluated for how well the prototype maturity and proposed scope of work aligns with the overall intent of the announcement.

Evaluation Factor 3. Potential for Transition and Commercialization.

The Potential for Transition and Commercialization factor will be evaluated using the merit rating as shown in Table 1.

The Offeror's proposal may be assessed for:

- a) How well the Offeror provides sufficient evidence that the effort is ready to move into the proposed stage of development.
- b) How well the project will translate promising, well-founded basic or clinical research findings into clinical applications for military Service members and the AD community.
- c) How well the proposal identifies intellectual property ownership, describes any appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development.
- d) How well the regulatory strategy is described and how well FDA feedback from a pre-submission meeting has been incorporated into the strategy.
- e) How well the commercialization strategy is described for both military and civilian markets.

Evaluation Factor 4. Cost Reasonableness

The Evaluation Panel shall assess the cost of the project to determine (1) whether the project cost is within the available funding limits, and (2) the ability and/or likelihood of the Offeror to successfully execute the proposed project within the financial resources proposed. The proposed cost will be evaluated with the following ratings: Sufficient, Insufficient or Excessive. The definitions of the ratings are as follows:

- Sufficient – The estimate is within the available funding limits and is 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.

This is not a formal evaluation but rather helps to inform the detailed cost analysis performed by the MTEC Consortium Manager.

5.3 Best Value

Projects will be awarded in Best Value sequence. If applicable, a best value process will be invoked to evaluate the most advantageous offer by considering and comparing factors in addition to cost or price. MTEC and BF reserve the right to negotiate and request changes to any or all parts of the SOW. Offeror's will have the opportunity to concur with the requested changes and revise cost proposals as necessary.

5.4 Definition of General Terms Used in Evaluations:

Strength - An aspect of an Offeror's proposal that has merit or exceeds specified performance or capability requirements in a way that will be advantageous to MTEC and BF 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 MTEC and BF 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 the requirement or a combination of weaknesses in a proposal that increases the risk of unsuccessful award performance to an unacceptable level.

6 Points-of-Contact

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

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

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

7 Acronyms/Abbreviations

AD	Alzheimer's disease
ATI	Advanced Technology International
BF	BrightFocus Foundation
CDC	Centers for Disease Control
CM	Consortium Manager
CMA	Consortium Member Agreement
CTE	Chronic Traumatic Encephalopathy
DoD	Department of Defense
FAQ	Frequently Asked Questions
F&A	Facilities and Administrative Costs
FDA	U.S. Food and Drug Administration
G&A	General and Administrative Expenses
GMP	Good Manufacturing Practice
IACUC	Institutional Animal Care and Use Committee
IND	Investigational New Drug
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IRB	Institutional Review Board
IR&D	Independent Research and Development
mTBI	Mild Traumatic Brain Injury
MTEC	Medical Technology Enterprise Consortium
NDA	Nondisclosure Agreement
OCI	Organizational Conflict of Interest
ODC	Other Direct Costs
POC	Point-of-Contact
POP	Period of Performance

PPG	Proposal Preparation Guide
RPP	Request for Project Proposals
SME	Subject Matter Expert
SOW	Statement of Work
TBI	Traumatic Brain Injury
TEP	Technical Evaluation Panel
TRL	Technology Readiness Level
USAMRDC	U.S. Army Medical Research and Development Command

8 BIDS Instructions

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

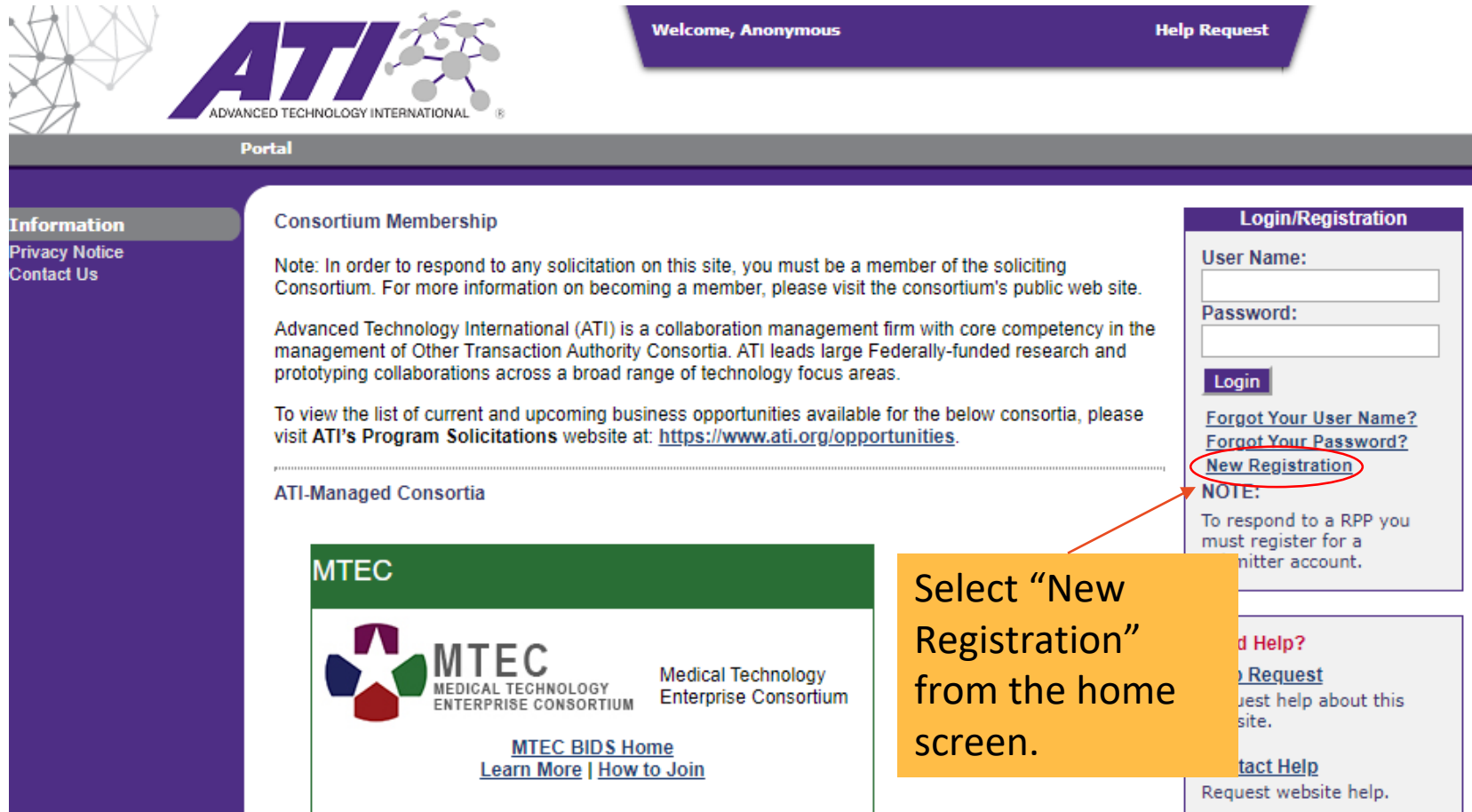
MTEC BIDS REGISTRATION

MTEC BIDS URL:

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

BIDS New Registration

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



ATI
ADVANCED TECHNOLOGY INTERNATIONAL

Welcome, Anonymous [Help Request](#)

Portal

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

Consortium Membership


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

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

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

ATI-Managed Consortia

MTEC

 **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](#)

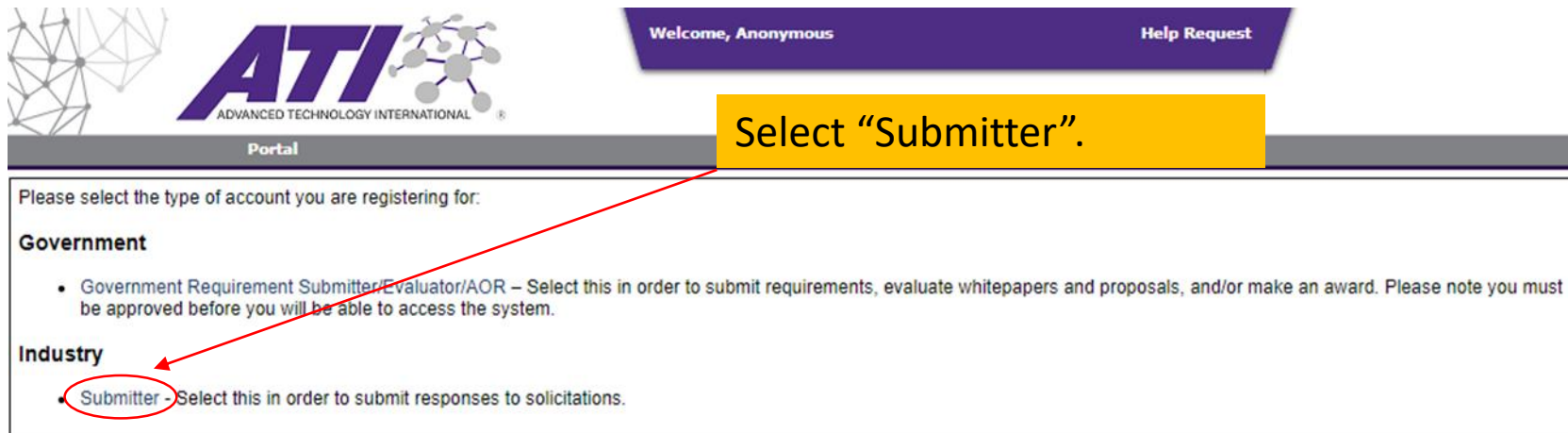
NOTE:
To respond to a RPP you must register for a twitter account.

[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.

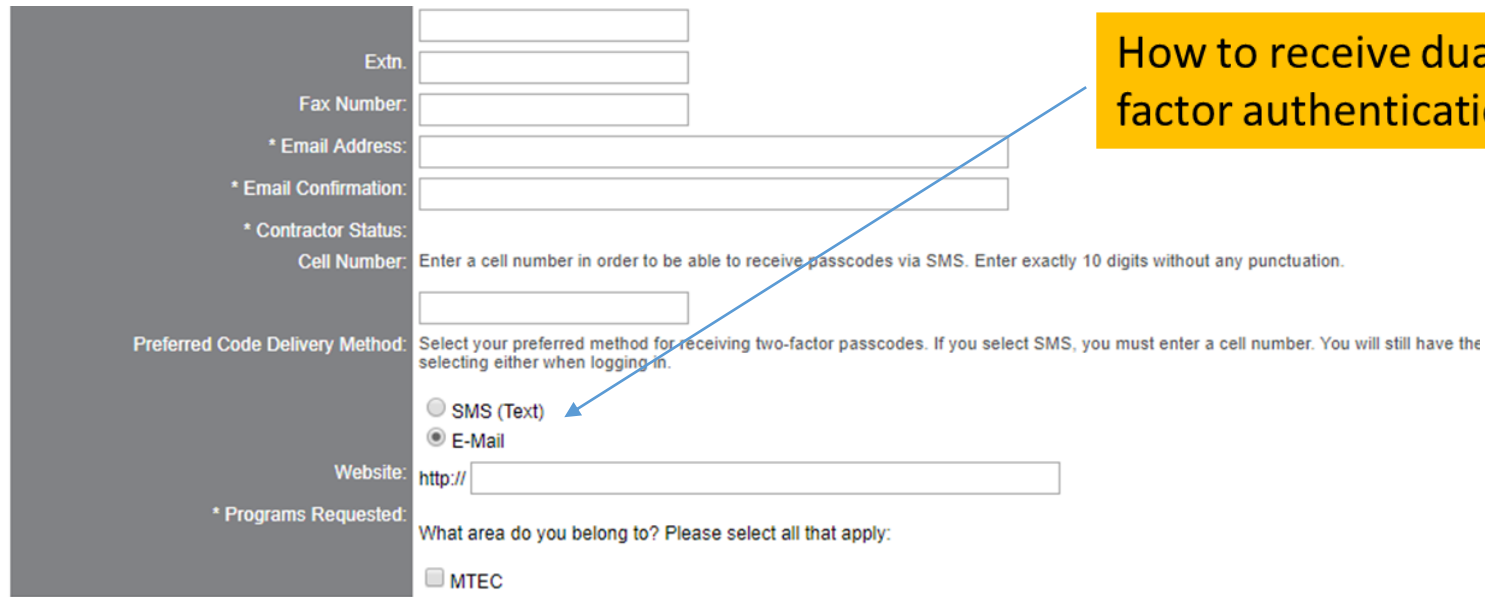
SECURITY NOTICE: Unauthorized attempts to deny service, upload information, change information, or attempt to access a non-public site from this service are strictly prohibited and may be punishable under Title 18 of the U.S. Code to include the Computer Fraud and Abuse Act of 1986 and the National Information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



Copyright © 2020. All Rights Reserved. This website was created by the AcqCenter and is part of the BIDS family.

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).



The screenshot shows a registration form with the following fields and instructions:

- Extn. [input field]
- Fax Number: [input field]
- * Email Address: [input field]
- * Email Confirmation: [input field]
- * Contractor Status: [input field]
- Cell Number: [input field] Enter a cell number in order to be able to receive passcodes via SMS. Enter exactly 10 digits without any punctuation.
- Preferred Code Delivery Method: Select your preferred method for receiving two-factor passcodes. If you select SMS, you must enter a cell number. You will still have the selecting either when logging in.
 - SMS (Text) ← **How to receive dual factor authentication .**
 - E-Mail
- Website: http:// [input field]
- * Programs Requested: What area do you belong to? Please select all that apply:
 - MTEC

Select "Submit Registration" to complete BIDS registration.

BIDS New Registration

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

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

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

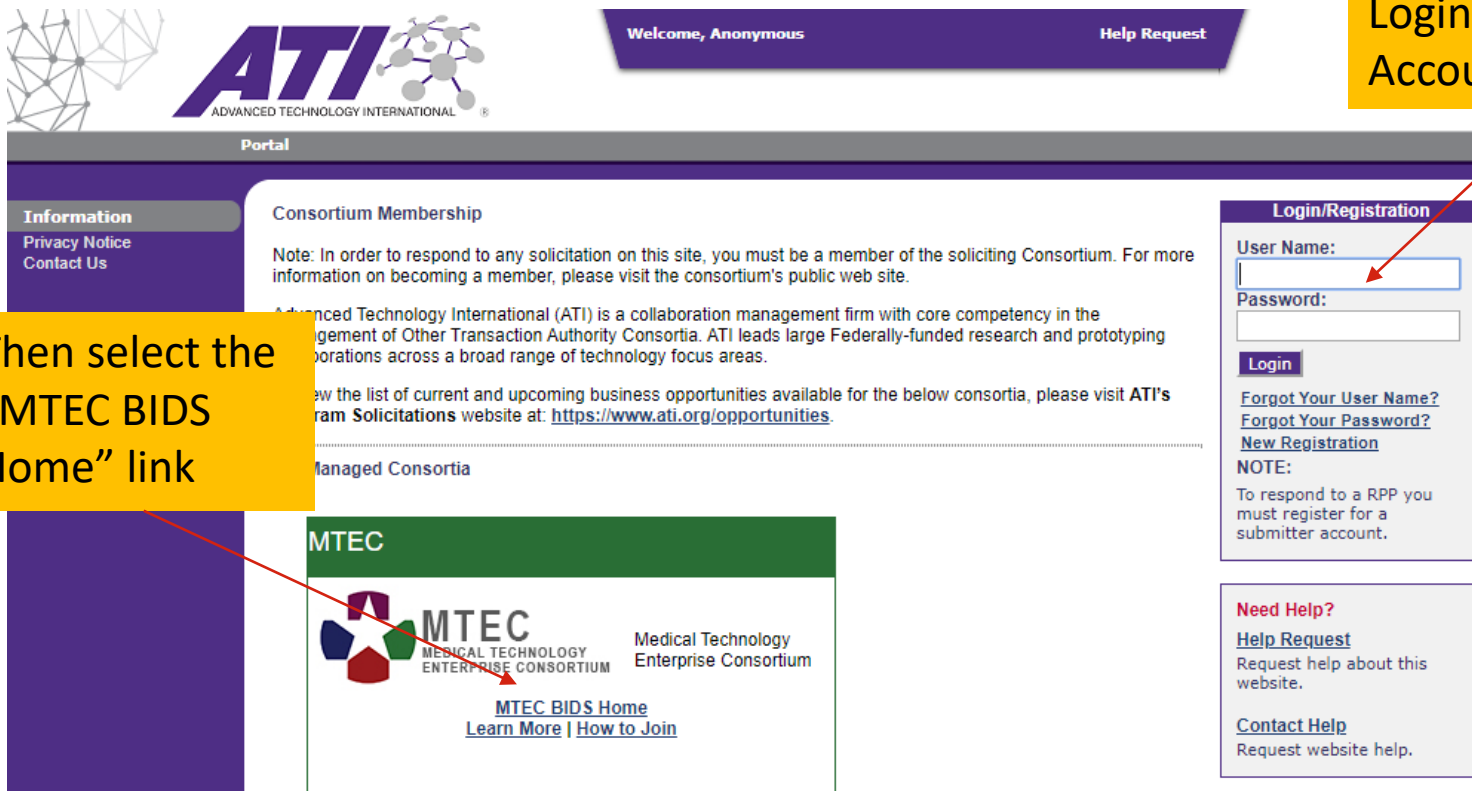
ALL PROPOSALS MUST BE SUBMITTED BEFORE THE SUBMISSION DUE DATE AND TIME. LATE PROPOSALS CAN NOT BE ACCEPTED.

MTEC BIDS PROPOSAL SUBMISSION

MTEC BIDS URL:

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

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



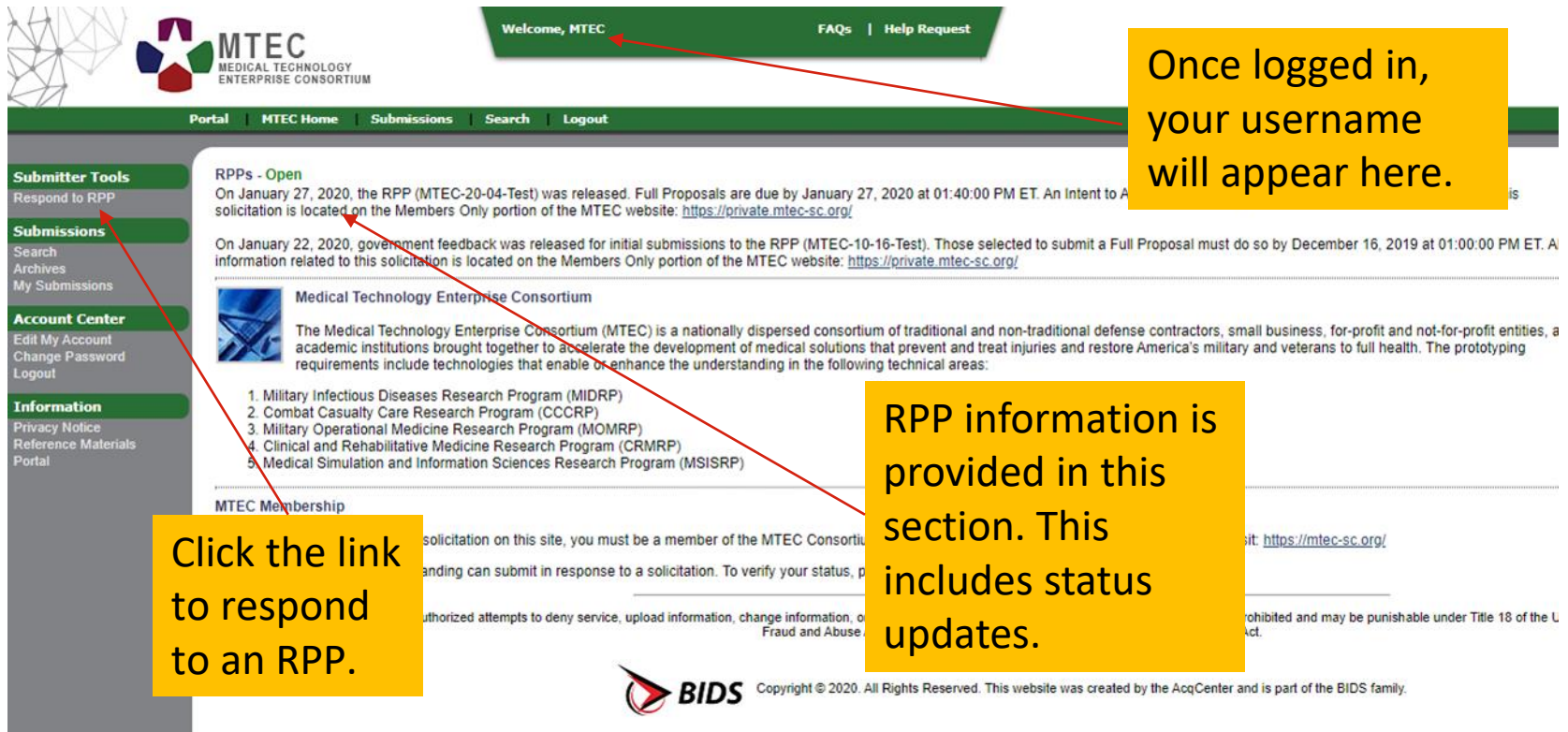
The screenshot shows the MTEC BIDS website interface. At the top, there is a navigation bar with "Welcome, Anonymous" and a "Help Request" link. Below this is a "Portal" header. The main content area is divided into several sections: "Information" (Privacy Notice, Contact Us), "Consortium Membership" (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 feature is the "MTEC" section, which includes the MTEC logo and the text "Medical Technology Enterprise Consortium". Below this, there is a link for "MTEC BIDS Home" with sub-links for "Learn More" and "How to Join". On the right side, there is a "Login/Registration" section with input fields for "User Name:" and "Password:", a "Login" button, and links for "Forgot Your User Name?", "Forgot Your Password?", and "New Registration". Below this is a "NOTE:" section stating "To respond to a RPP you must register for a submitter account." and a "Need Help?" section with links for "Help Request" (Request help about this website.) and "Contact Help" (Request website help.).

Login to your BIDS Account.

Then select the “MTEC BIDS Home” link

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

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



Once logged in, your username will appear here.

Click the link to respond to an RPP.

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

Welcome, MTEC FAQs | Help Request

Portal | MTEC Home | Submissions | Search | Logout

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

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

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


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

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

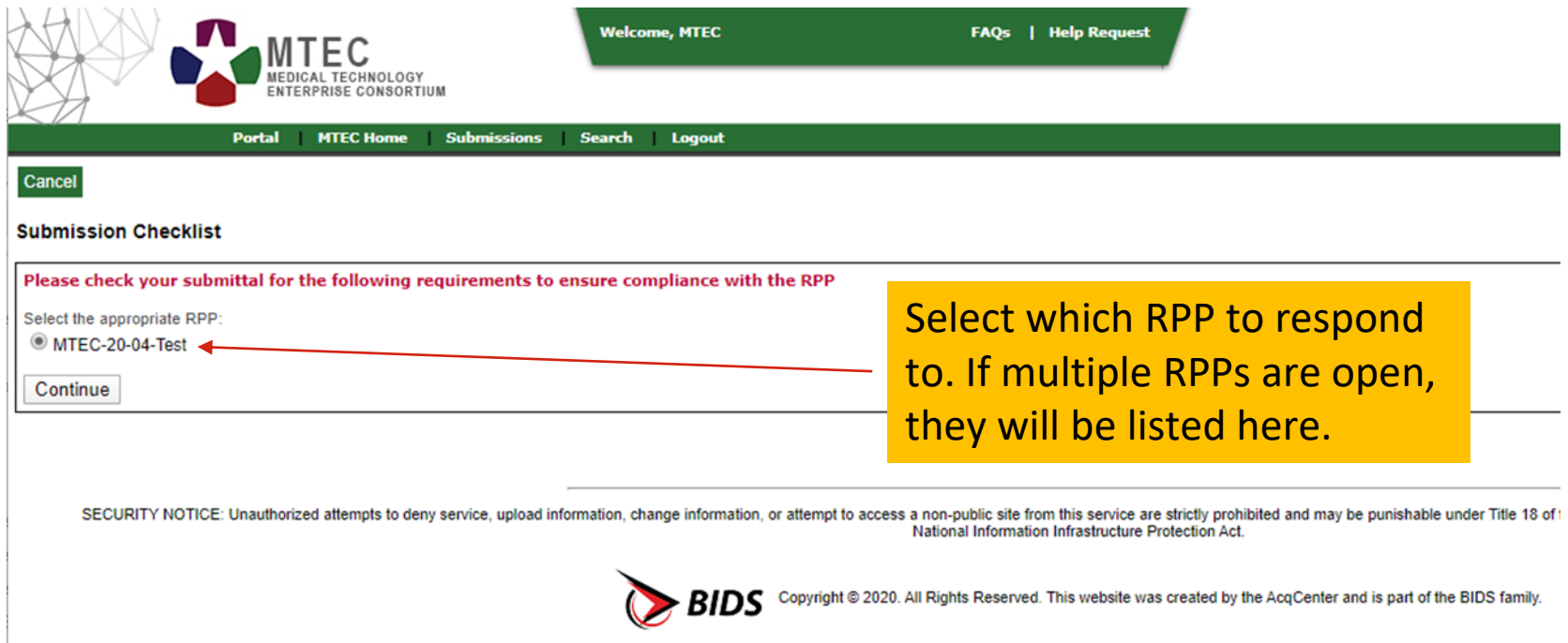
MTEC Membership
solicitation on this site, you must be a member of the MTEC Consortium. To verify your status, please visit: <https://mtec-sc.org/>

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

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

 **BIDS** Copyright © 2020. All Rights Reserved. This website was created by the AcqCenter and is part of the BIDS family.

Select which RPP you will be responding to.



The screenshot shows the MTEC submission checklist interface. At the top, there is a navigation bar with the MTEC logo and the text "MTEC MEDICAL TECHNOLOGY ENTERPRISE CONSORTIUM". Below the navigation bar, there is a "Cancel" button and a "Submission Checklist" section. The checklist contains the following text: "Please check your submittal for the following requirements to ensure compliance with the RPP". Below this, it says "Select the appropriate RPP:" and lists "MTEC-20-04-Test" with a radio button selected. A red arrow points from a yellow callout box to the selected radio button. Below the list is a "Continue" button. At the bottom of the page, there is a "SECURITY NOTICE" and the BIDS logo with the text "Copyright © 2020. All Rights Reserved. This website was created by the AcqCenter and is part of the BIDS family."

Cancel

Submission Checklist

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


Select the appropriate RPP:

MTEC-20-04-Test

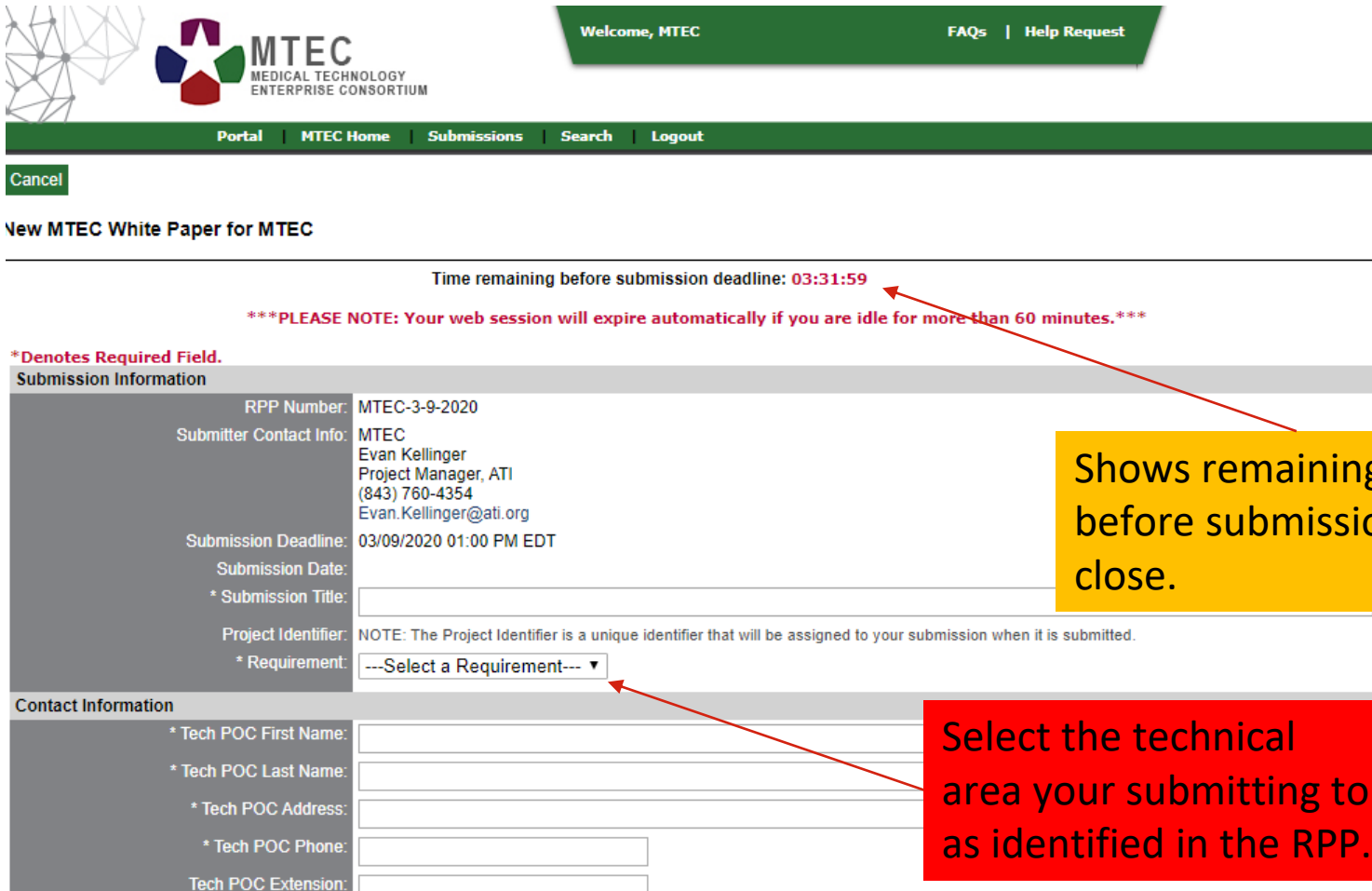
Continue

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

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

 **BIDS** Copyright © 2020. All Rights Reserved. This website was created by the AcqCenter and is part of the BIDS family.

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" (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 with "--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.

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

Upload documents in this section.

Submit

Once the submission form is completed select submit.

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

Proposal Submission BIDS

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

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

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

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