Request for Project Information

Solicitation Number: MTEC-23-11-Neurotrauma

"Neurotrauma Diagnosis, Monitoring, and Assessment State of Technology Meeting"

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: July 24, 2023

Project Information Paper Due Date: September 14, 2023
Noon Eastern Time

The Medical Technology Enterprise Consortium (MTEC) is excited to post this announcement for a Request for Project Information (RPI) focused on the diagnosis, monitoring, and assessment of Traumatic Brain Injury in support of an upcoming State of the Technology Meeting**.**

CLINICAL PROBLEM:

Traumatic Brain Injury (TBI) is commonly defined as an "alteration of the brain function, or other evidence of brain pathology, caused by an external force.[1]" In military, TBI is characterized as the signature injury of the Operation Iraqi Freedom and Operation Enduring Freedom as 10 - 15% of all veterans experienced at least one TBI during their deployment. In civilians, each year at least 4.8 million people in the United States seek medical care for TBI. Among children, TBI-related injuries account for over 837,000 emergency department visits annually, which include over 16,000 TBI-related hospitalizations, and 2,774 TBI related deaths, as reported in 2020.

Medical community recognized significant gaps in the care of patients with TBI. TBI's complex pathophysiology is not fully understood, broad defined and outdated classification to mild, moderate and severe TBI significantly hamper our ability to treat TBI patients. Nevertheless, early diagnosis, treatment, monitoring, and maintenance of TBI patients in the acute setting can significantly improve long-term functional outcomes and reduce injury severity.

BACKGROUND ON THE POTENTIAL UPCOMING STATE OF THE TECHNOLOGY MEETING:

Through MTEC, the U.S. Army Medical Research and Development Command's (USAMRDC) Neurotrauma group and the Biomedical Advanced Research and Development Authority (BARDA) will host a State of Technology meeting focused on neurotrauma in early calendar year 2024. The goal of this meeting is to understand the state of the technology to**: a) better diagnose traumatic brain injury (TBI) at all levels of the continuum of care, b) understand how to monitor patients already diagnosed with TBI, and c) identify new potential products that could be developed into prototypes for the diagnosis, assessment and/monitoring of TBI.**

Examples of specific areas of interest to be addressed at the State of Technology meeting include, but are not limited to, the following items. These areas of interest are **not** listed in order of importance:

a) Molecular targets for diagnosis of TBI and minimally or non-invasive devices to monitor such markers
b) Electrophysiological markers of TBI and minimally or non-invasive devices to monitor such markers
c) Minimally or non-invasive devices to monitor progression of the disease
d) Artificial intelligence and machine learning to assess endpoints and provide diagnosis and/or treatment guidance
e) Minimally or non-invasive disruptive tools and methods to integrate novel systems into the continuum of care from front lines to fixed hospitals

Attendees of the State of Technology meeting are expected to bring an understanding of the types of minimally or non-invasive TBI diagnosis, monitoring, and assessment technologies, and a willingness to share their personal views on the current states of development including pros/cons/limitations associated with each of the various modalities. Attendees of the meeting will also gain exposure to government agencies, their respective portfolios, and potential funding opportunities relevant to TBI diagnosis, monitoring, and assessment. The intended impact of the State of the Technology meeting is to better inform possible future investments by the United States Government to advance specific technologies poised to address unmet needs in TBI care and transform the delivery of care for military and civilian populations.

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[1] Menon D.K., Schwab K., Wright D.W., Mass A.I. Position statement: Definition of traumatic brain injury. *Arch. Psyc. Med. Rehabil.* 2010;91:1637–1640. doi: 10.1016/j.apmr.2010.05.017.

The meeting organizing panel will develop a State of the Technology Report with the intent for publication following the meeting. The report will recommend next steps to inform strategic direction by USAMRDC and BARDA to continue to lead progress in this space.

PURPOSE OF THE PROJECT INFORMATION PAPER:

MTEC is seeking input from both MTEC members and the general public (non-member companies) that are developing solutions for detection, diagnosis and treatment of TBI and its short- and long-term sequelae. **We seek input to gauge interest in attendance/technology presentations and to frame the agenda on areas of concerns, unmet needs, products/technology advancements and limitations, and regulatory challenges from all interested parties, including but not limited to, healthcare providers, neuroscientists, product developers, regulatory experts, and reimbursement strategists.**

This RPI contains background material and guidance for the preparation of Project Information Papers to be submitted to MTEC. **MTEC membership is not required for submission of Project Information Paper.**

REQUIREMENTS OF THE PROJECT INFORMATION PAPER:

The intent of this RPI is to understand respondents' interest and technology capabilities in support of the State of the Technology Meeting's area of interest. MTEC is seeking input from both MTEC members and non-members via a project information paper to be considered by the panel. Project information papers will be shared with the reviewers under non-disclosure agreements. The MTEC may invite one or more of those who submit project information papers to participate in, or present to, the organizing panel during their convening.

Project Information Papers may be submitted at any time during the submission period but no later than the due date and time specified on the first page of this RPI using BIDS: https://ati2.acqcenter.com/ATI2/Portal.nsf/Start?ReadForm. See **Addendum 2 of this RPI** for further information regarding BIDS registration.

Required Submission Document (1): Submitted via BIDS (5MB or lower per document)

- **Project Information Paper: one Word document (See Addendum 1 of this RPI)**

Project Information Papers should NOT include proprietary or classified information. Information obtained through this RPI may be used to develop the State of the Technology meeting's agenda as well as be included as a component of the final State of the Technology report.

MTEC:

The MTEC mission is to assist the USAMRDC by providing cutting-edge technologies and effective materiel life cycle management to transition medical solutions to industry that protect, treat, and optimize Warfighters' health and performance across the full spectrum of military operations. MTEC is a biomedical technology consortium collaborating with multiple government agencies under a 10-year renewable Other Transaction Agreement (OTA), Agreement No. W81XWH-15-9-0001, with the U.S. Army Medical Research Acquisition Activity (USAMRAA). MTEC is currently recruiting a broad and diverse membership that includes representatives from large businesses, small businesses, "non-traditional" government contractors, academic research institutions and not-for- profit organizations.

POINTS OF CONTACT:

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

- Technical and membership questions should be directed to the MTEC Research Analyst, Dr. Seth Tomblyn, Ph.D., seth.tomblyn@ati.org
- All other questions should be directed to the MTEC Chief of Consortium Operations, Ms. Kathy Zolman, kathy.zolman@ati.org

Addendum 1
Military Technology Enterprise Consortium (MTEC)
Neurotrauma Diagnosis, Monitoring, and Assessment State of Technology Meeting
Project Information Template

[**2-page limit.** 12-point Arial font, smaller font may be used in figures and tables, but must be clearly legible. Single-spaced, single-sided, 8.5 inches x 11 inches. Margins on all sides (top, bottom, left, and right) should be at least 0.5 inch. These project information submissions will be shared with the Sponsor; therefore, all information must be **nonproprietary.** Project Information Paper should be submitted as a Word (*.doc or *.docx) document using the template provided in this RPI.]

Date: [Insert Date of Submission]

Point of Contact: [Insert name, role, organization, email address, phone number]

Answers to the following questions are required:

1) Are you interested in attending the State of Technology meeting? Yes or No
2) Describe any suggestions on specific areas of interest that align with the overall topic of this State of the Technology meeting.
3) Are there any topics for breakout sessions that you would be interested in attending or leading?
4) If you have a specific technology that you would like us to consider for presentation at the meeting, please indicate what type of presentation you wish to be considered for in the table below and include a brief narrative on the technology, its state of development, and how it aligns to the objectives.

Technology Objective Areas of Interest	**Podium Presentation (Yes/No)**	**Poster Presentation (Yes/No)**	**Technology Demonstration (Yes/No)**
Molecular targets for diagnosis of TBI and minimally or non-invasive devices to monitor such markers			
Electrophysiological markers of TBI and minimally or non-invasive devices to monitor such markers.			
Minimally or non-invasive devices to monitor progression of the disease			
Artificial intelligence and machine learning to assess endpoints and provide diagnosis and/or treatment guidance			
Minimally or non-invasive disruptive tools and methods to integrate novel systems into the continuum of care from front lines to fixed hospitals.			

Addendum 2
BIDS Instructions

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

MTEC BIDS REGISTRATION

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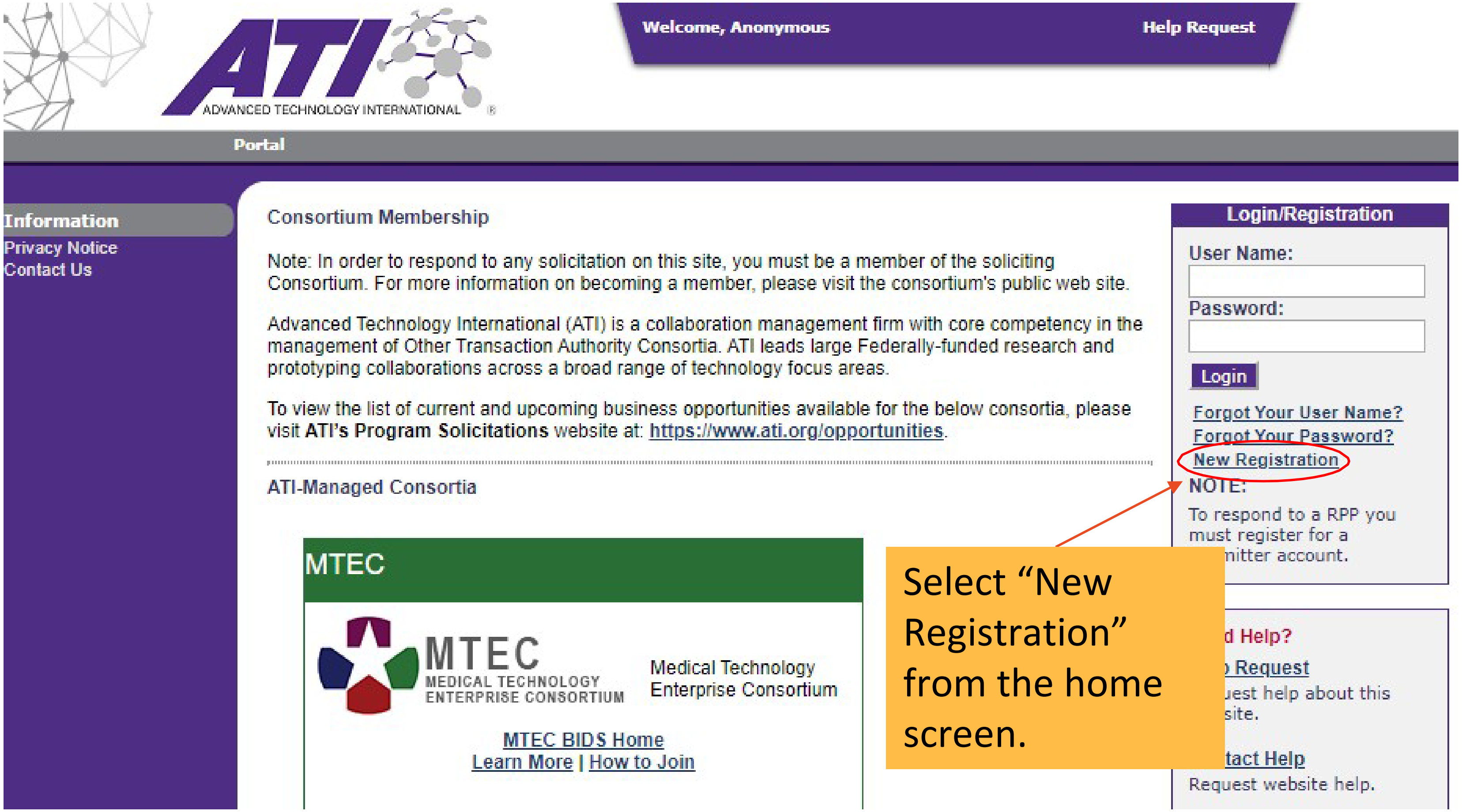

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Consortium Membership

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.

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uest help about this site.

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Request website help.

Select "New Registration" from the home screen.

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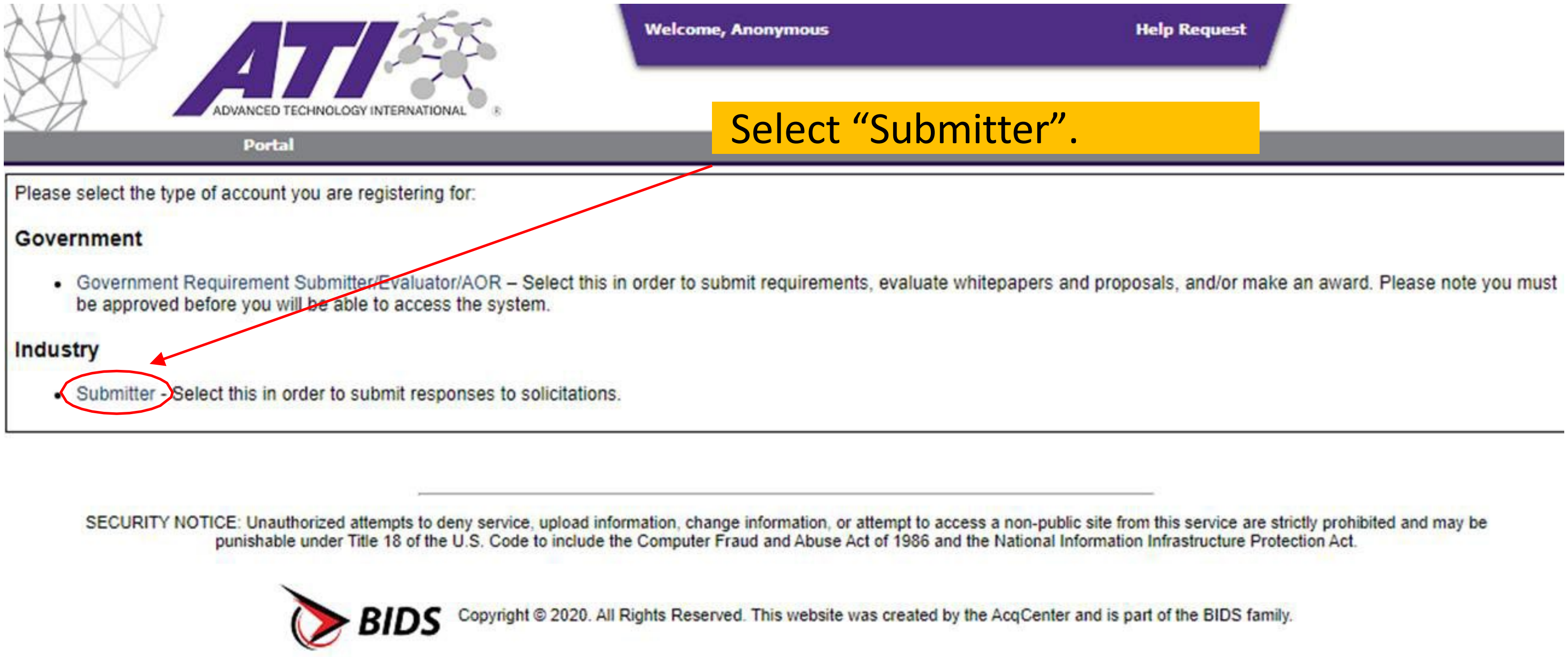

Select “Submitter”.

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.

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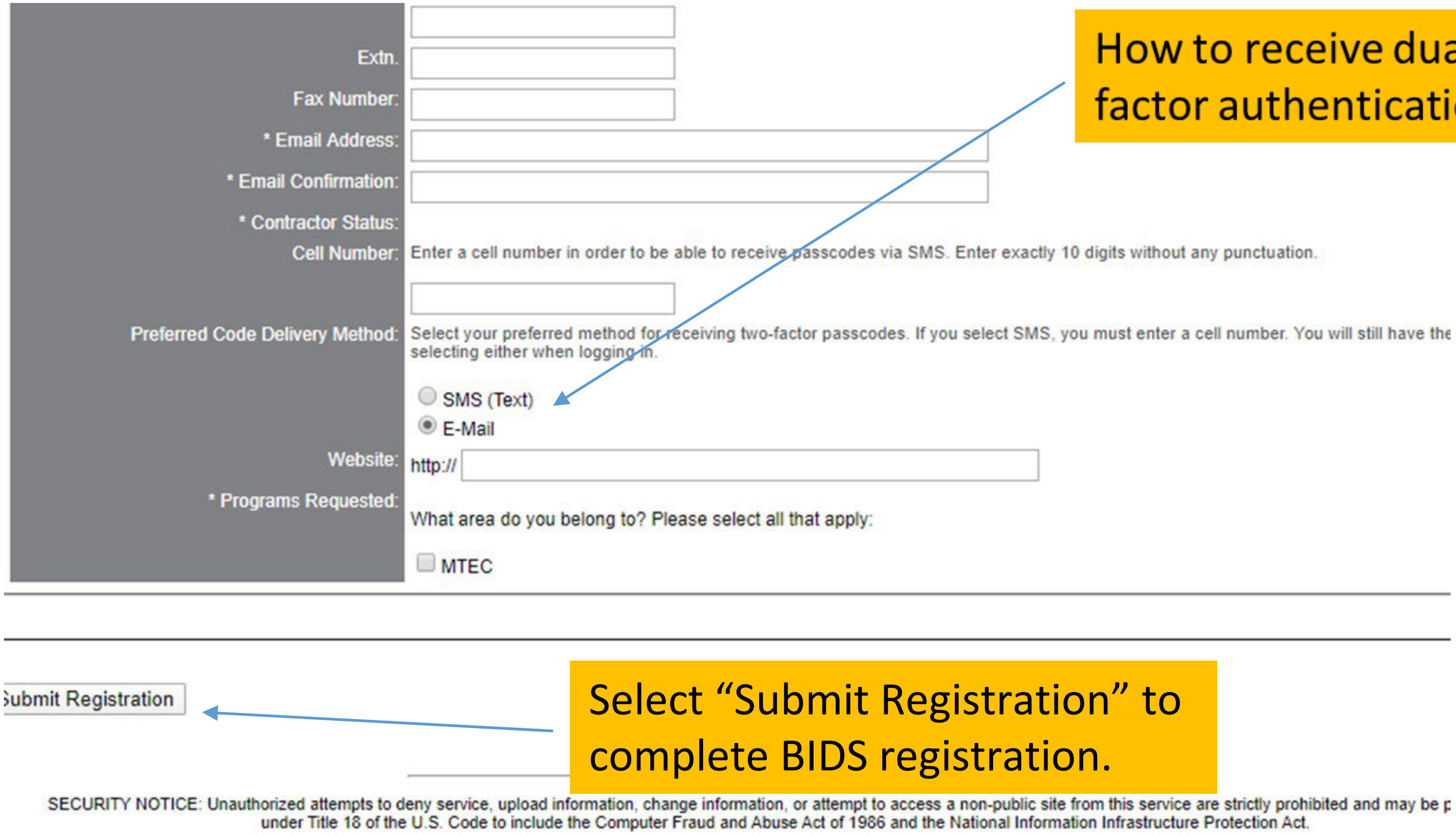
BIDS Registration: Complete the registration form. Be sure to select how you want to receive the dual factor verification code (SMS text message is recommended).



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

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How to receive dual factor authentication.

Select “Submit Registration” to complete BIDS registration.

Medical Technology Enterprise Consortium

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

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

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

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

MTEC BIDS PROPOSAL SUBMISSION

MTEC BIDS URL:

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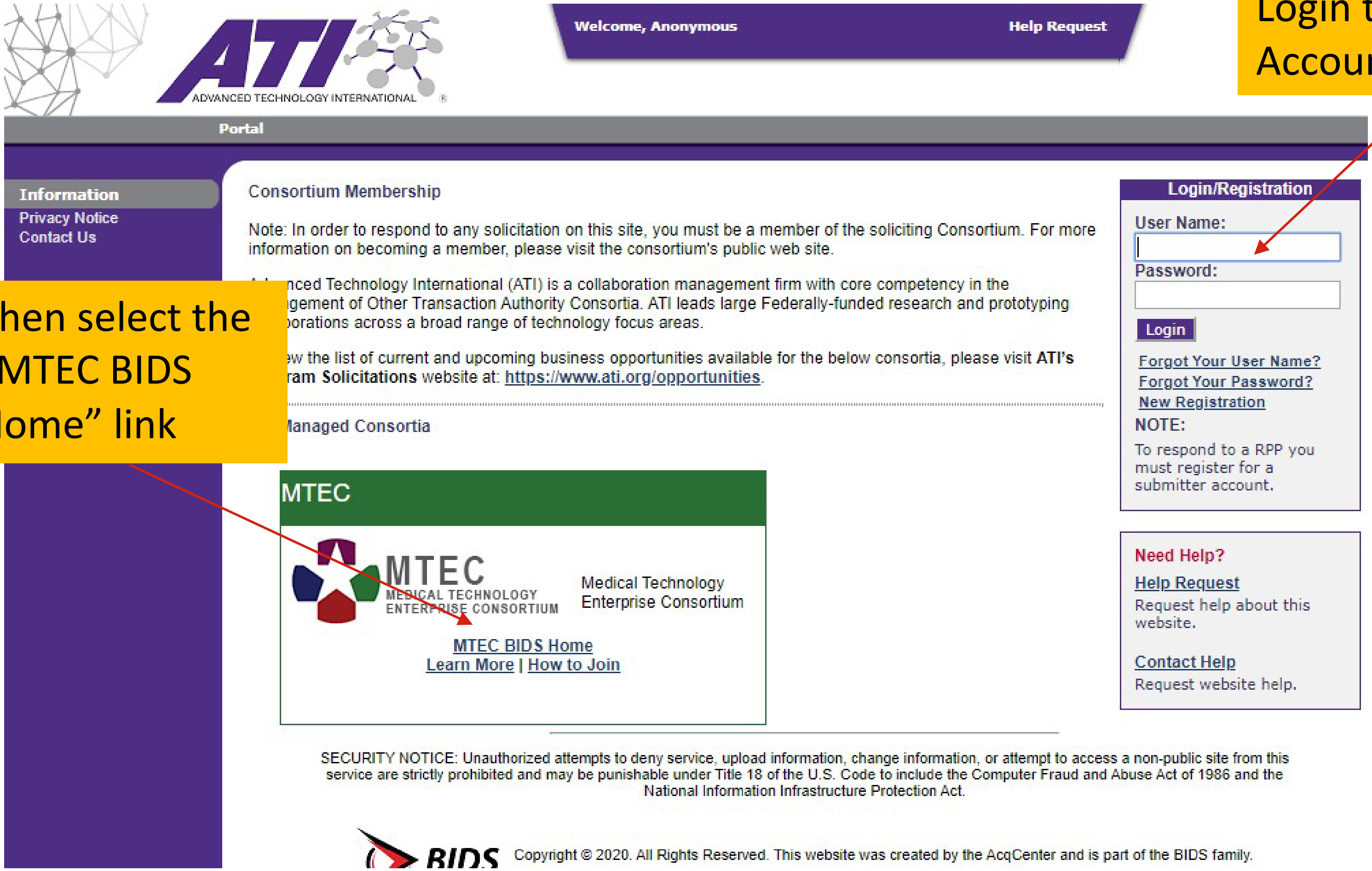
Proposal Submission BIDS

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



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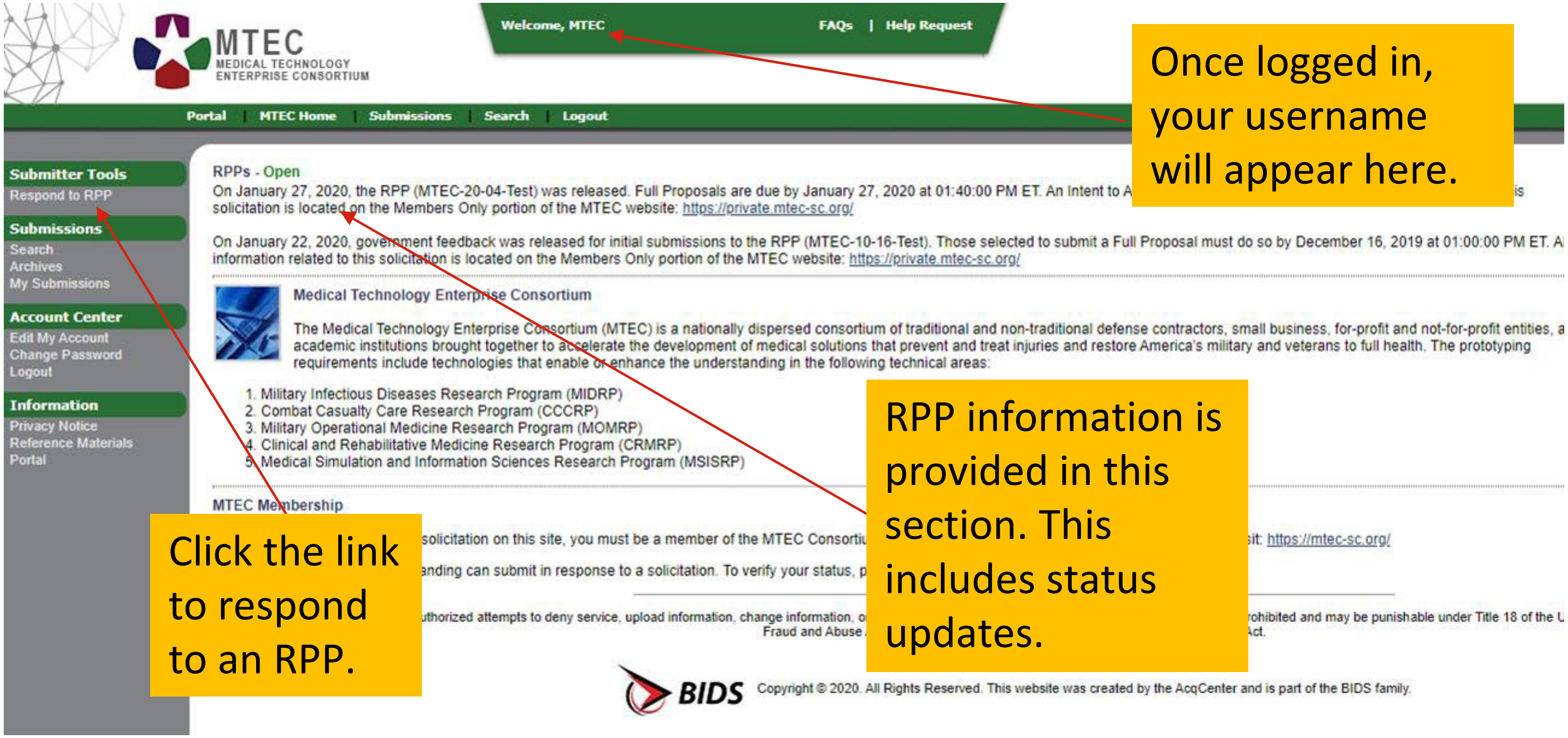
Login to your BIDS Account.

Then select the “MTEC BIDS Home” link

Proposal Submission BIDS

Select the “Respond to RPP” link under the submitter tools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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 A … is 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. A 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, a 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 (CRMRP)
5. Medical Simulation and Information Sciences Research Program (MSISRP)

MTEC Membership

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anding can submit in response to a solicitation. To verify your status, p

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Fraud and Abuse … Act.

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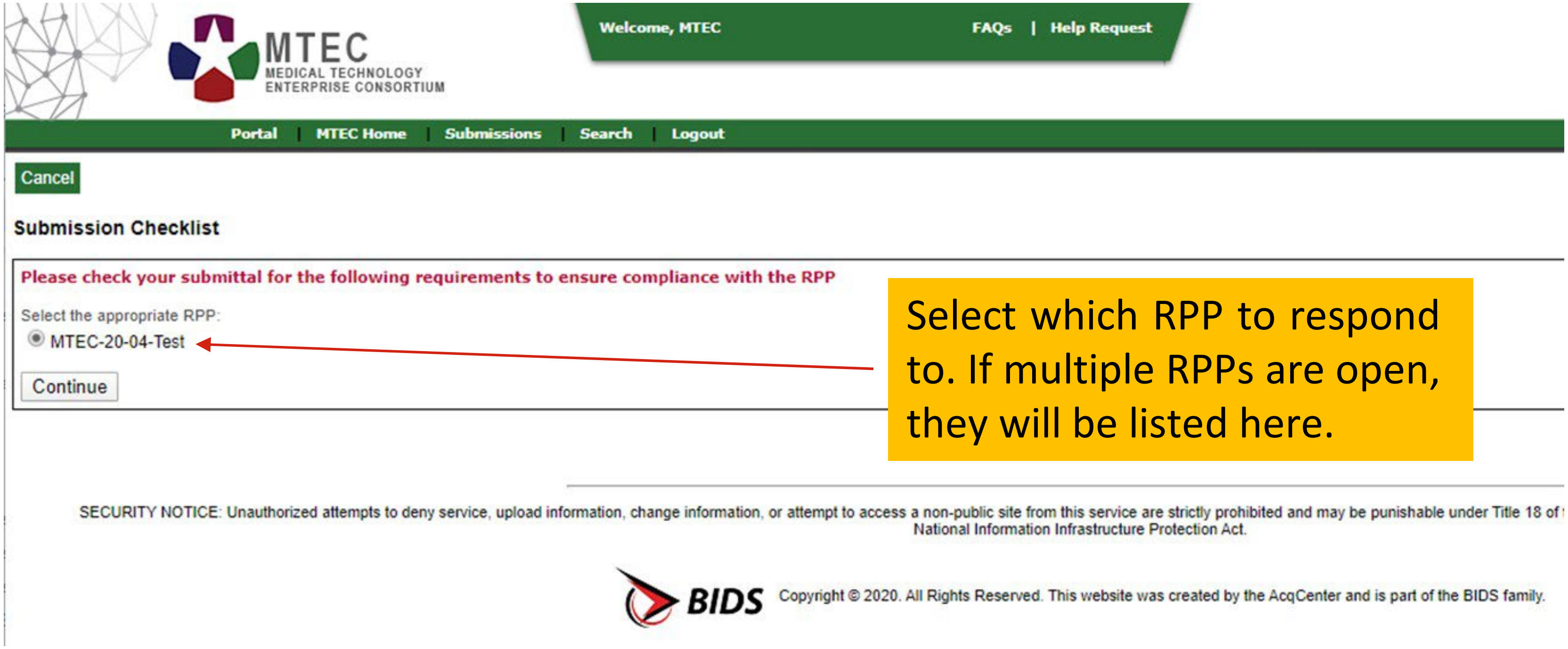
RPP information is provided in this section. This includes status updates.

Click the link to respond to an RPP.

Proposal Submission BIDS

Select which RPP you will be responding to.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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.

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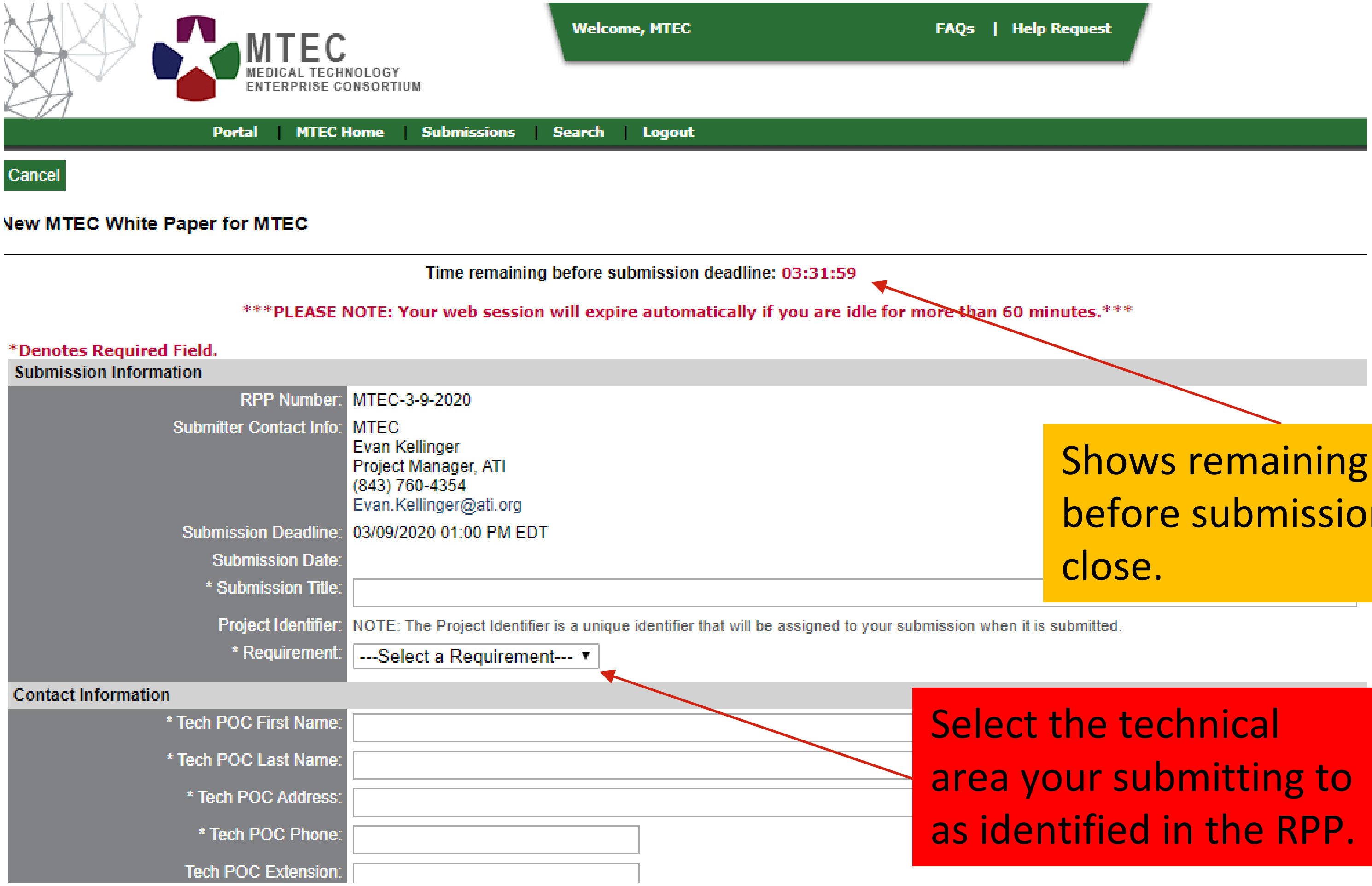
Complete the submission form.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New MTEC White Paper for MTEC

Time remaining before submission deadline: 03:31:59

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

*Denotes Required Field.

Submission Information

RPP Number: MTEC-3-9-2020

Submitter Contact Info: MTEC
Evan Kellinger
Project Manager, ATI
(843) 760-4354
Evan.Kellinger@ati.org

Submission Deadline: 03/09/2020 01:00 PM EDT

Submission Date:

* Submission Title:

Project Identifier: NOTE: The Project Identifier is a unique identifier that will be assigned to your submission when it is submitted.

* Requirement: ---Select a Requirement--- ▼

Contact Information

* Tech POC First Name:

* Tech POC Last Name:

* Tech POC Address:

* Tech POC Phone:

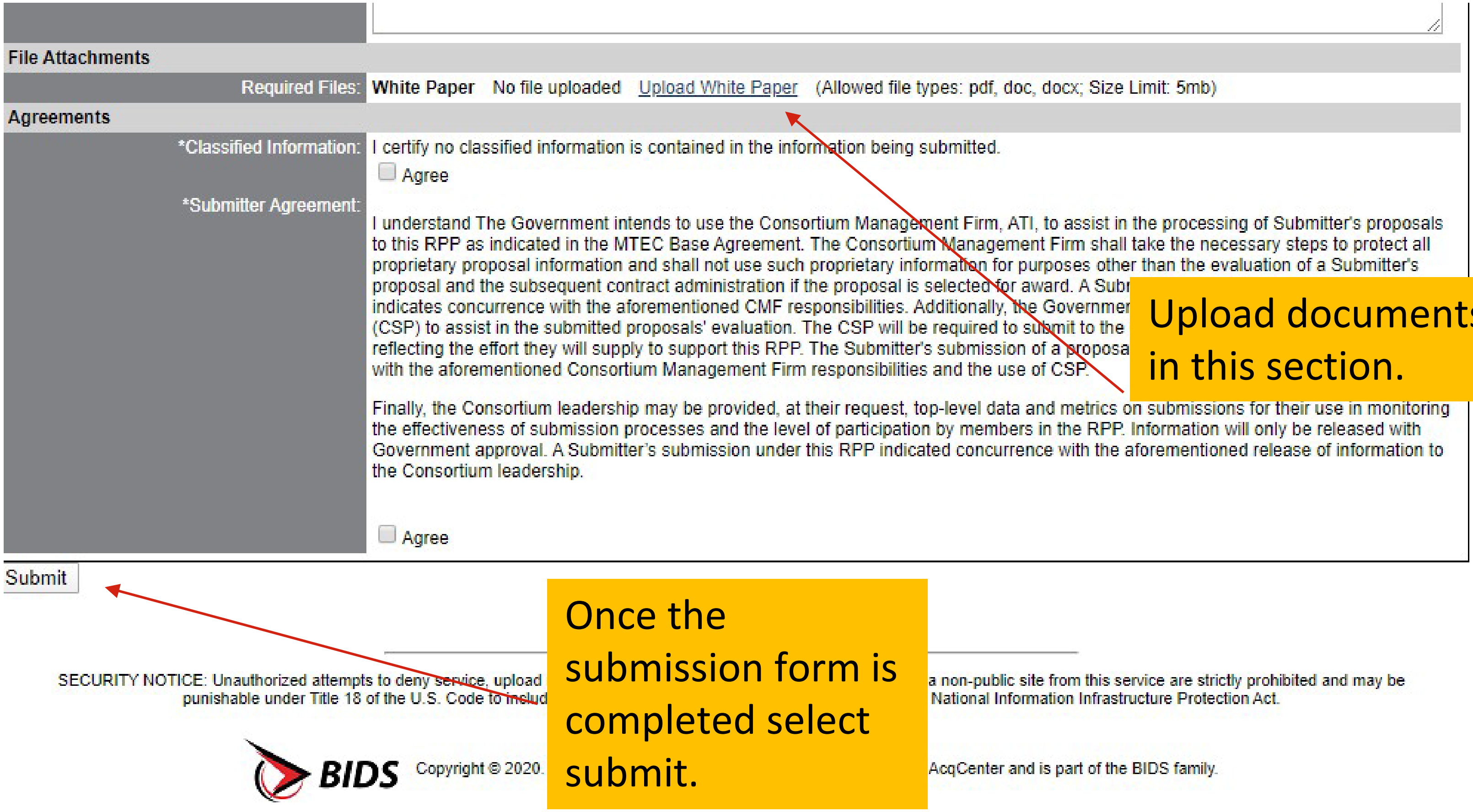
Tech POC Extension:

Shows remaining time before submission close.

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

Proposal Submission BIDS

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



File Attachments

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

Agreements

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

☐ Agree

*Submitter Agreement:

I understand The Government intends to use the Consortium Management Firm, ATI, to assist in the processing of Submitter's proposals to this RPP as indicated in the MTEC Base Agreement. The Consortium Management Firm shall take the necessary steps to protect all proprietary proposal information and shall not use such proprietary information for purposes other than the evaluation of a Submitter's proposal and the subsequent contract administration if the proposal is selected for award. A Subr indicates concurrence with the aforementioned CMF responsibilities. Additionally, the Governmer (CSP) to assist in the submitted proposals' evaluation. The CSP will be required to submit to the reflecting the effort they will supply to support this RPP. The Submitter's submission of a proposa with the aforementioned Consortium Management Firm responsibilities and the use of CSP.

Finally, the Consortium leadership may be provided, at their request, top-level data and metrics on submissions for their use in monitoring the effectiveness of submission processes and the level of participation by members in the RPP. Information will only be released with Government approval. A Submitter's submission under this RPP indicated concurrence with the aforementioned release of information to the Consortium leadership.

☐ Agree

Submit

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Upload documents in this section.

Once the submission form is completed select submit.

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

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