

Request for Project Information: MTEC-24-08-Plasma

Request for Project Information



Solicitation Number: MTEC-24-08-Plasma

“Dried Plasma Product System – Seeking New Technologies and Development Partners”

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

Request Issue Date: March 26, 2024

Project Information Paper Due Date: April 25, 2024
Noon Eastern Time

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The Medical Technology Enterprise Consortium (MTEC), in support of the Naval Medical Research Command (NMRC) and Naval Advanced Medical Development (NAMD), is excited to post this Request for Project Information (RPI) focused on surveying the current state of engineering and medical prototypes, knowledge products, and manufacturing capacity related to the dried plasma products for use by warfighters.

PURPOSE OF THE PROJECT INFORMATION PAPER:

This Request for Project Information (RPI) contains background material and guidance for the preparation of project information papers to MTEC. Project information papers will be reviewed by the Sponsor and used in a manner that shapes NAMD efforts in this technology space. The results of the project information paper submission will serve to assess the development landscape and potentially focus efforts that will follow.

As a note: This RPI is issued solely for information and planning purposes and does not constitute a solicitation. Neither unsolicited proposals nor any other kind of offers will be considered in response to this RPI. Responses to this notice are not offers and will not be accepted by the government to form a binding contract. Responders are solely responsible for all expenses associated with responding to this RPI. All information received in response to this RPI that is marked "Proprietary" will be handled accordingly.

BACKGROUND:

Due to the Navy and Marine Corps' diverse warfighting capabilities, Sailors, Marines and Joint Service members operate in a vast array of challenging, remote, and austere environments. Hemorrhage is the leading cause of death in combat zone trauma. The gold standard for immediate treatment of hemorrhage is transfusion of whole blood however, the availability of whole blood and conventional blood products on forward missions is challenging. The quantities needed to resuscitate and transport injured warfighters back to medical facilities away from the field may not be available in addition to the demands of thermoregulation controls and energy requirements and the availability for accessory equipment required for conventional whole blood and frozen plasma stores. Dried plasma products present a potential solution to these logistical issues for meeting the needs of warfighters in the field. It is lightweight, and thermostable across a spectrum of temperatures without requiring refrigeration or freezing. Dried plasma products have been repeatedly called for from role of care (ROC) level 1 up through ROC 4 personnel and further up the chain of command to the Secretary of Defense's office. This vital blood product is needed to meet the goals of aiding wounded warriors within the golden hour or sooner out in the field at the point of injury. Dried plasma offers the opportunity to have a lightweight, room temperature thermostable product in a ruggedized kit so that it can be stored in a medic's pack, submarine or in field/ship hospitals without requiring refrigeration or special handling.

FOCUS AREA OF INTEREST – ADVANCEMENT OF DRIED PLASMA PRODUCTION SYSTEM:

The government is interested in mature technologies, devices, and methods for the production of a dried plasma product suitable for universal blood types. This plasma product is to be used where fresh or frozen plasma is unavailable for the treatment of traumatic or mass casualty

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events occurring in military populations, often operating for extended periods of time in austere/extreme environments. Alternative technologies capable of filling the role of dried plasma during traumatic or mass casualty events may also be of interest.

The government invites Offerors with the following production capabilities to submit informational papers using the template included in **Addendum 1 of this RPI**. Should an Offeror be unable to meet all the desired capabilities, they should detail a plan to establish the remaining functions.

Offerors should have:

- Established Good Manufacturing Practice (GMP) ready methods with fully designed hardware and functional disposables.
- Input plasma that meets all requirements of the U.S. Food and Drug Administration (FDA) (21 CFR 630.10 and 630.15; Part 640, Subpart G) with clear standard operating procedures and documentation as described in relevant transfusion-transmitted infections (RTTI; 21 CFR 610.40).
- Pathogen reduction capability using FDA approved methods. This would ideally be at the forefront of manufacturing whether on the preparation of the plasma pre- or post-drying.
- Clearly defined chemistry, manufacturing, and controls processes.
- Full characterization of analytes not limited to those described within the FDA guidance entitled, "Considerations for the Development of Dried Plasma Intended for Transfusion" (2019).
- A notional estimate of any cost share and other funding sources that the offeror has secured.

Interested Offerors should include information on their expertise in any or all the following technology areas as it relates to the dried plasma development and combat injuries involving the need for transfusion:

- Development of mature products at technology readiness level (TRL) 6 or higher that require funds and guidance to navigate the US regulatory landscape at the FDA as it relates to blood products. Full definitions of TRLs can be found [here](#).
- Ruggedization of the dried plasma kit to meet the needs of the military in austere environments.
- Manufacturing of dried plasma kits and or equipment (scale-up, initial production runs, etc.) that may include proprietary processes, programming, and materials.
- Conduct of non-inferiority clinical studies in support of the demonstration of human safety and effectiveness of the dried plasma product when compared to current standard of care.
- Activities related to securing regulatory approval by the FDA for a biologics license applications (BLA) and/or De Novo class 3 medical device clearance (at the discretion of the FDA) with indications for transfusion and trauma.
- Developing cybersecurity compliance with section 524B of the FD&C Act (if using networked devices to manufacture the dried plasma product).

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REQUIREMENTS OF THE PROJECT INFORMATION PAPER:

The intent of this RPI is to understand respondents' interest and technology capabilities within the abovementioned focus area. MTEC is seeking input from both MTEC members and non-members via a project information paper to be considered by the government. Project information papers will be shared with the reviewers under non-disclosure agreements.

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 **cover 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. **MTEC membership is NOT required for submission of Project Information Paper.**

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 Dr. Chuck Hutti, MTEC Biomedical Research Associate, chuck.hutti@ati.org
- All other questions should be directed to the MTEC Program Manager, Mr. Evan Kellinger, mtec-sc@ati.org

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Addendum 1 – Project Information Template

[3-page limit. Times New Roman 11 point (or larger), Single-spaced, single-sided, 8.5 inches x 11 inches). Smaller type may be used in figures and tables but must be clearly legible. Margins on all sides (top, bottom, left, and right) should be at least 0.5 inch. 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 (*.docx) document using the template provided in this RPI.]

Date: [Insert Date of Submission]

Title: [Insert descriptive title of project]

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

Technology: [Provide a clear description of the proposed technologies, devices, and methods for the production of a dried plasma product that fit into the focus area of this RPI.]

Technology/Knowledge Readiness Level (TRL/KRL): [Please indicate the TRL/KRL stage in which the project will start as well as anticipated TRL/KRL level at project completion.]

Readiness Level at Project Start:

Readiness Level at Project End:

Preliminary Data: [Summarize the preliminary data that supports the current TRL designation.]

Capabilities and Expertise: [Indicate which of the desired production capabilities listed in this RPI are currently established. Additionally, describe any expertise in the abovementioned technology areas as it relates to the dried plasma development and combat injuries involving the need for transfusion.]

Next Steps: [Outline development goals and objectives for the proposed technology in sufficient detail to show a clear course of action. Provide a proposed period of performance. List milestones and deliverables from the proposed work. These next steps should include a plan for how any production capabilities not currently established may be met during the proposed period of performance.]

Anticipated Regulatory and Commercialization Strategy: [Provide a brief description of the anticipated regulatory pathway and commercialization plans, as applicable. Include information on any previous interactions with the FDA.]

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

Personnel: [Briefly state the qualifications of the key personnel to perform the work.]

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Estimated Funding Required to Advance Project: [Please estimate the required funding needed for each major task that advances the project into its next stage of development/milestone dependent upon its current maturity. Examples of tasks include, but are not limited to:

- late animal testing and regulatory filing.
- the next clinical trial.
- device manufacturing; etc.

Do not provide budget detail – only provide a total estimated budget for each major milestone.

***Additionally, please include a notional estimate of any cost share and other funding sources that the offeror has secured for the advancement of this project.** This information will be used to provide the Sponsor with a reasonable representation of the amount of funding required to advance the project.

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Addendum 2 – BIDS instructions:

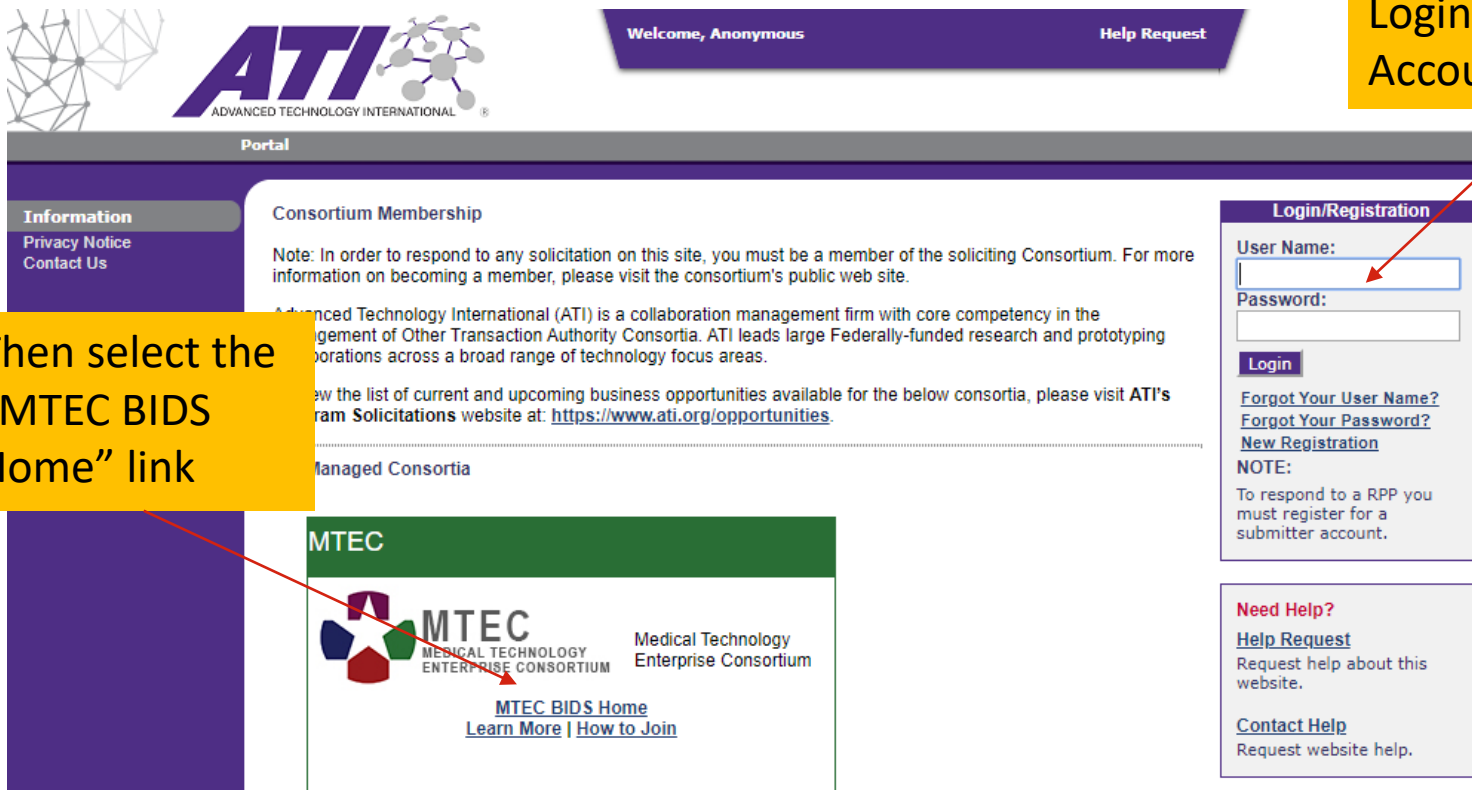
THIS PAGE IS INTENTIONALLY LEFT BLANK. PLEASE SEE THE PRESENTATION BELOW.

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.



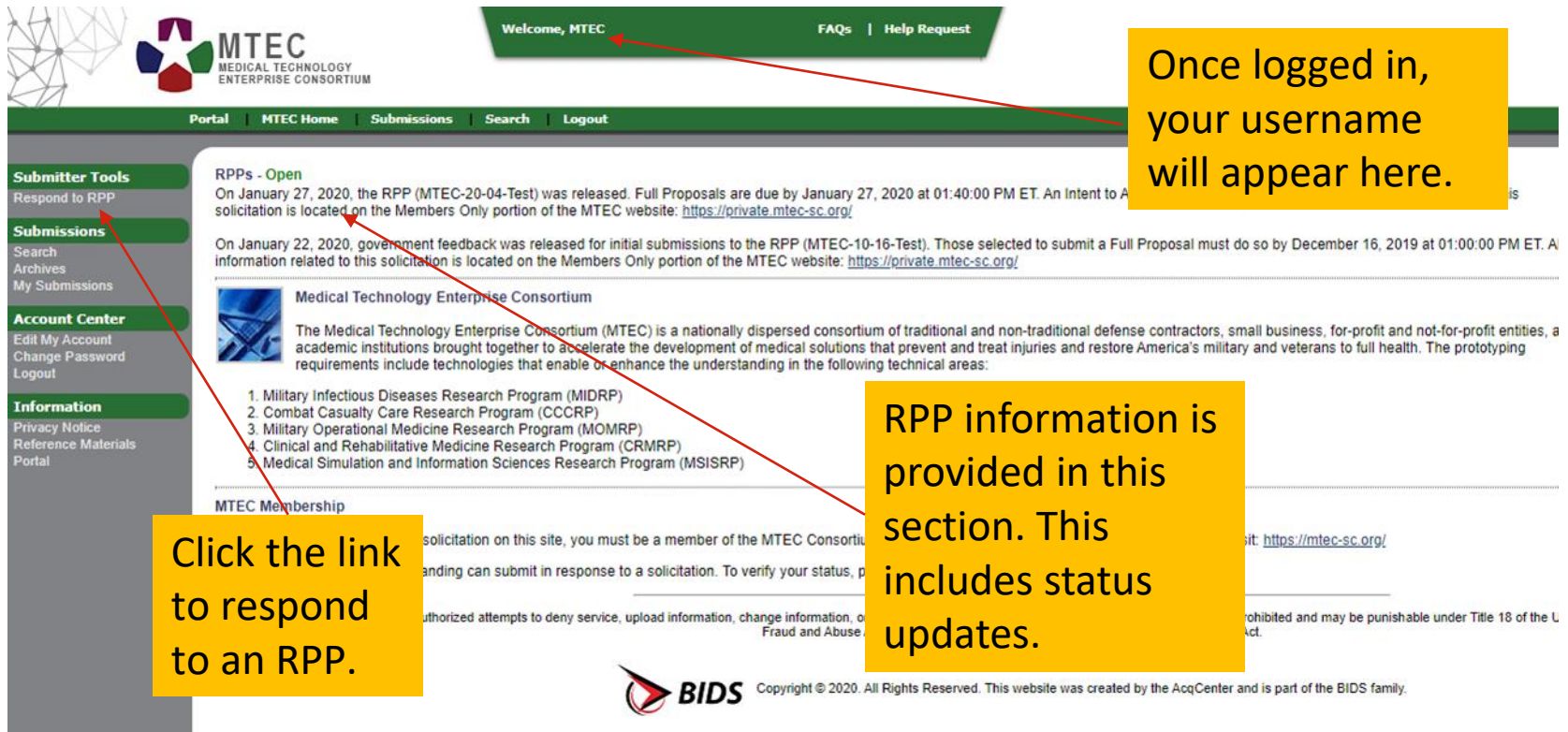
The screenshot shows the MTEC BIDS website interface. At the top, there is a navigation bar with "Welcome, Anonymous" and a "Help Request" link. Below this is a "Portal" header. The main content area is divided into several sections: "Information" (Privacy Notice, Contact Us), "Consortium Membership" (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. 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>), 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". A "NOTE:" section states: "To respond to a RPP you must register for a submitter account." Below this is 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

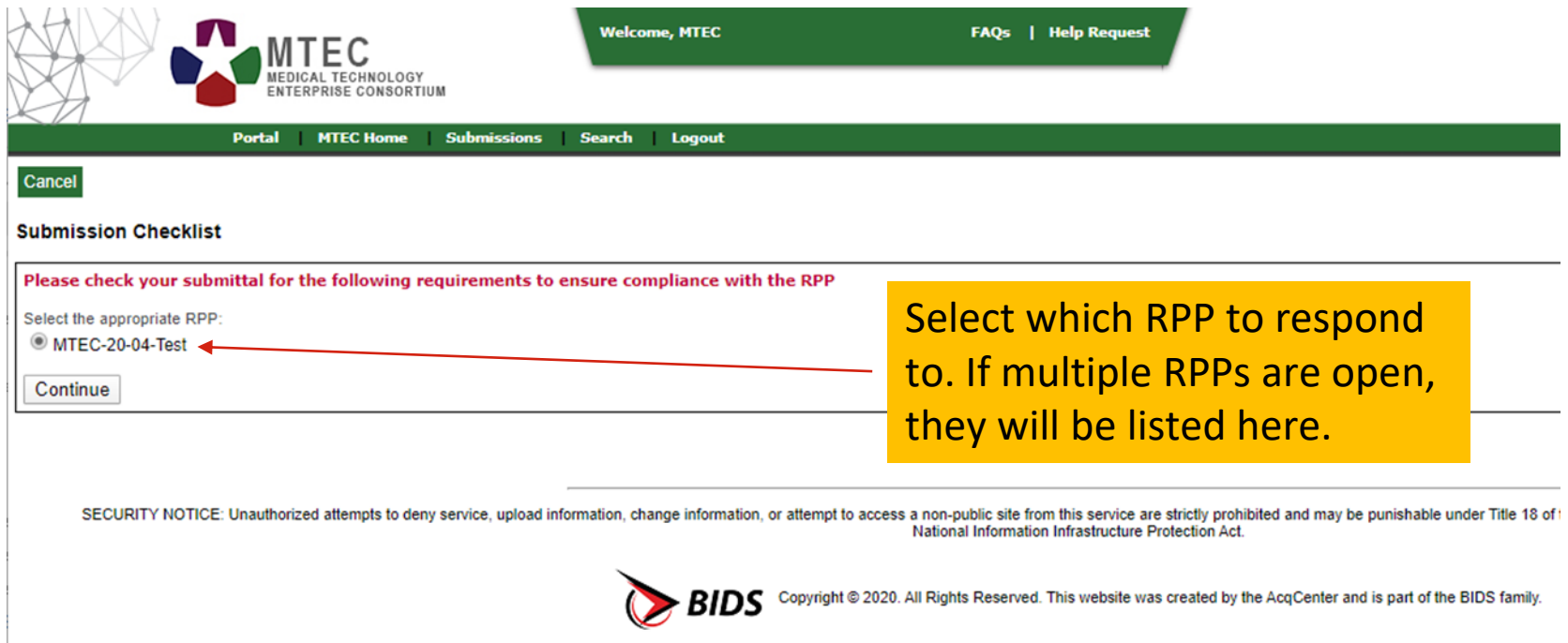
solicitation on this site, you must be a member of the MTEC Consortium. To verify your status, please visit: <https://mtec-sc.org/>

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.



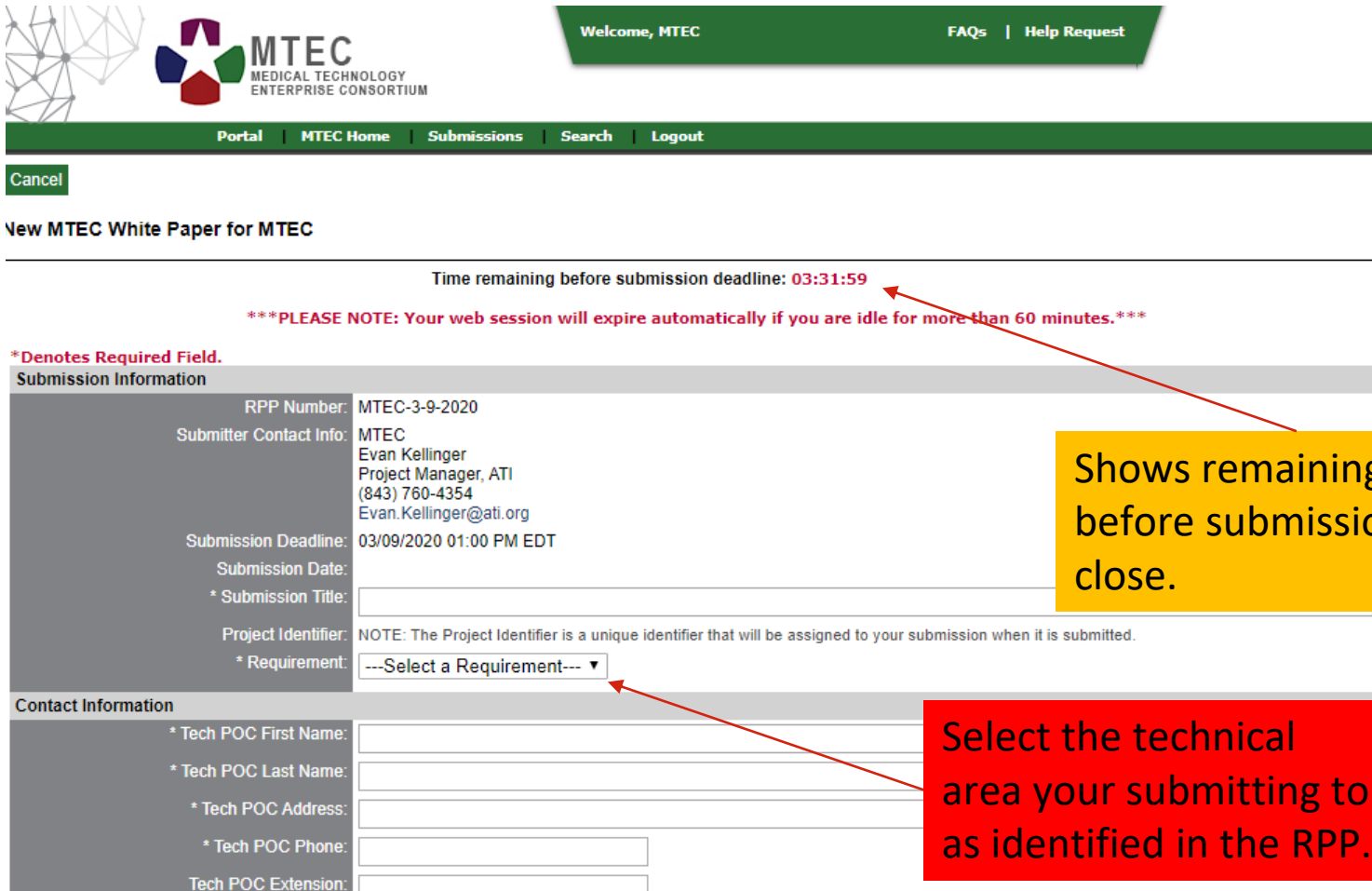
The screenshot shows the MTEC submission checklist interface. At the top, there is a navigation bar with the MTEC logo and the text "MTEC MEDICAL TECHNOLOGY ENTERPRISE CONSORTIUM". Below this is a green header with "Welcome, MTEC" and links for "FAQs" and "Help Request". A secondary green bar contains navigation links: "Portal", "MTEC Home", "Submissions", "Search", and "Logout".

The main content area is titled "Submission Checklist" and includes a "Cancel" button. A red heading reads: "Please check your submittal for the following requirements to ensure compliance with the RPP". Below this, the instruction "Select the appropriate RPP:" is followed by a radio button selection 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 selection.

A yellow callout box on the right side of the interface contains the text: "Select which RPP to respond to. If multiple RPPs are open, they will be listed here."

At the bottom of the page, a "SECURITY NOTICE" states: "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." The BIDS logo and copyright information "Copyright © 2020. All Rights Reserved. This website was created by the AcqCenter and is part of the BIDS family." are also present.

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 box), "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.

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.