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

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 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).

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

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.]

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.

Addendum 2 – BIDS instructions:

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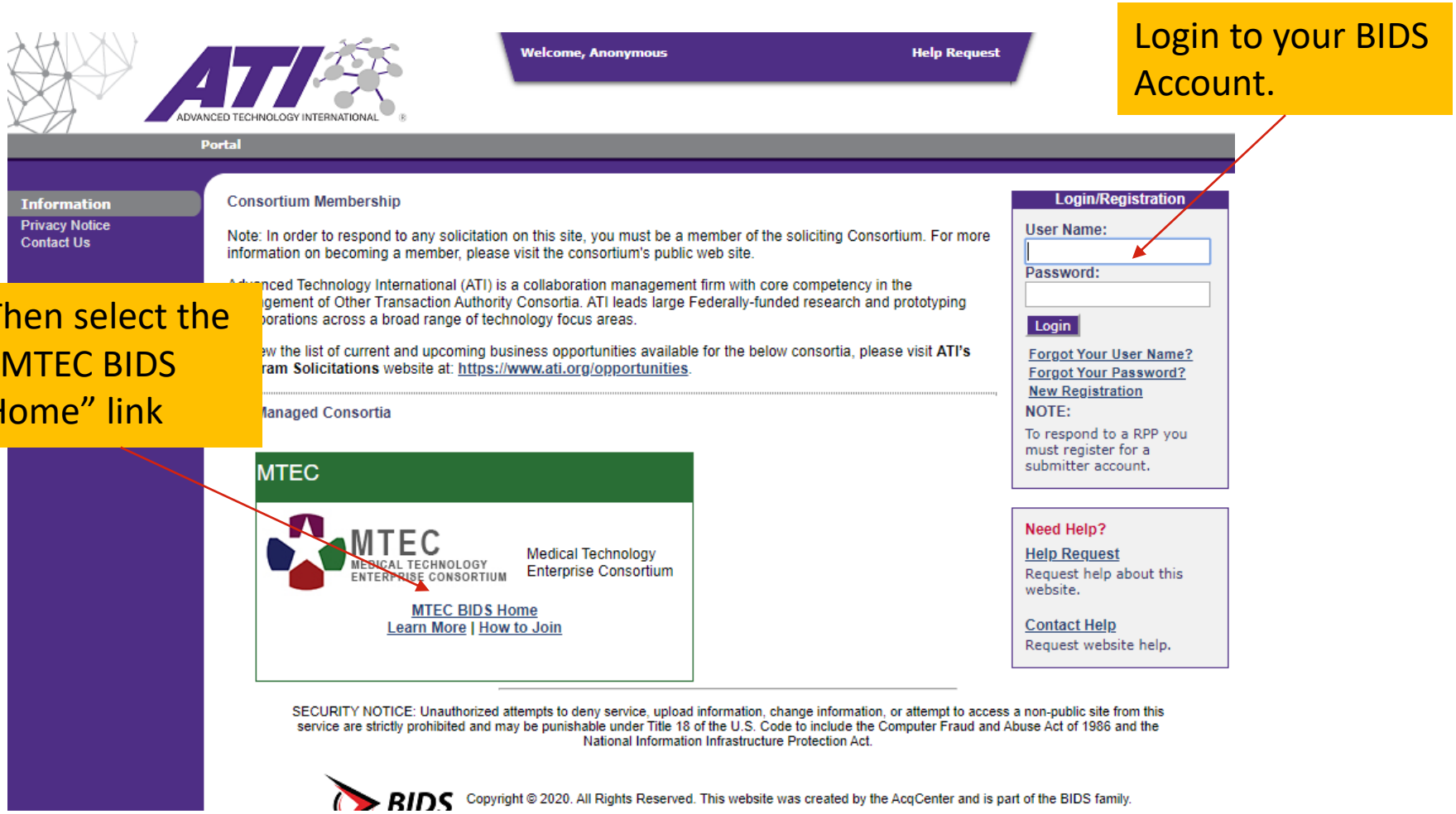
MTEC BIDS PROPOSAL SUBMISSION

MTEC BIDS URL:

HTTPS://ATI2.ACQCENTER.COM

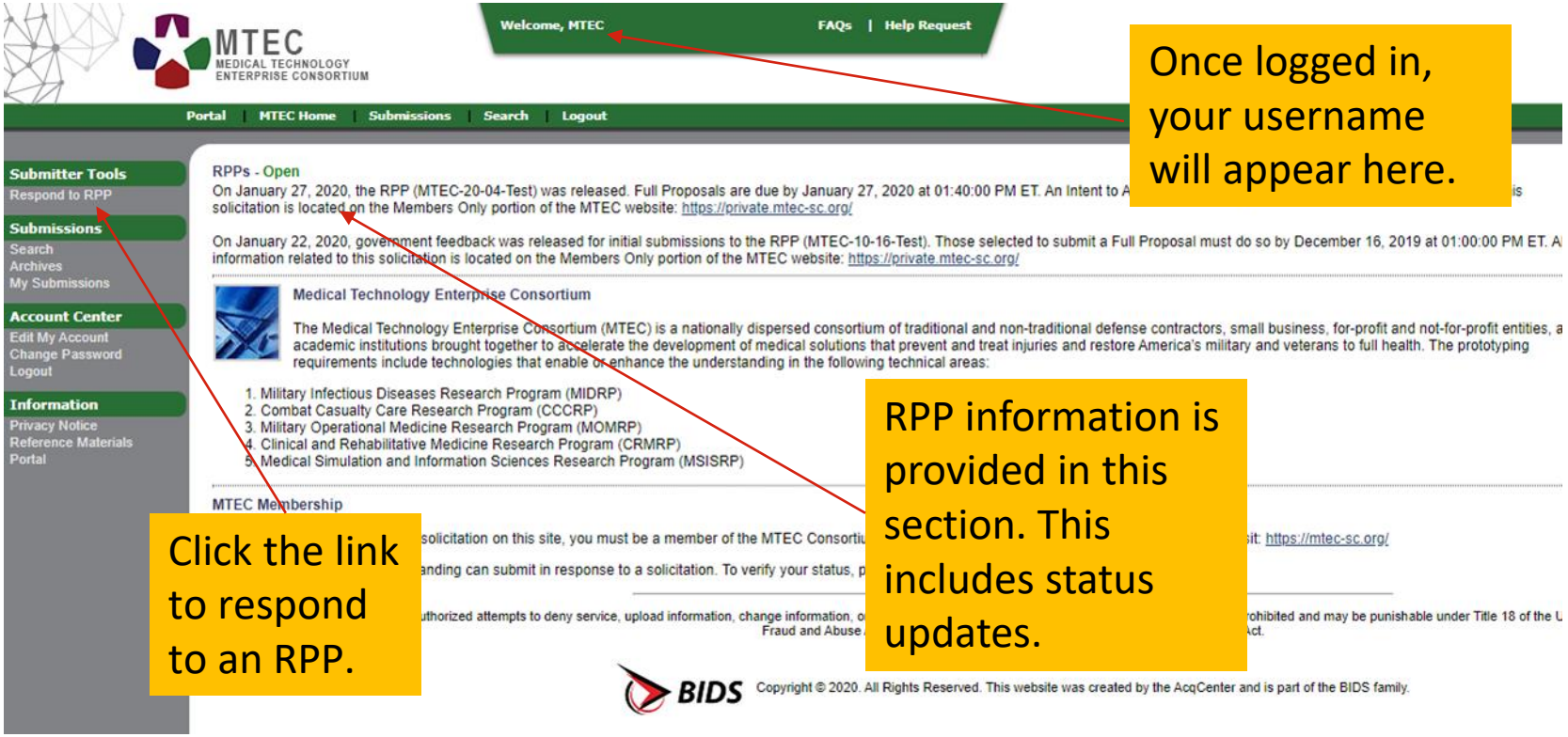
Proposal Submission BIDS

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



Proposal Submission BIDS

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



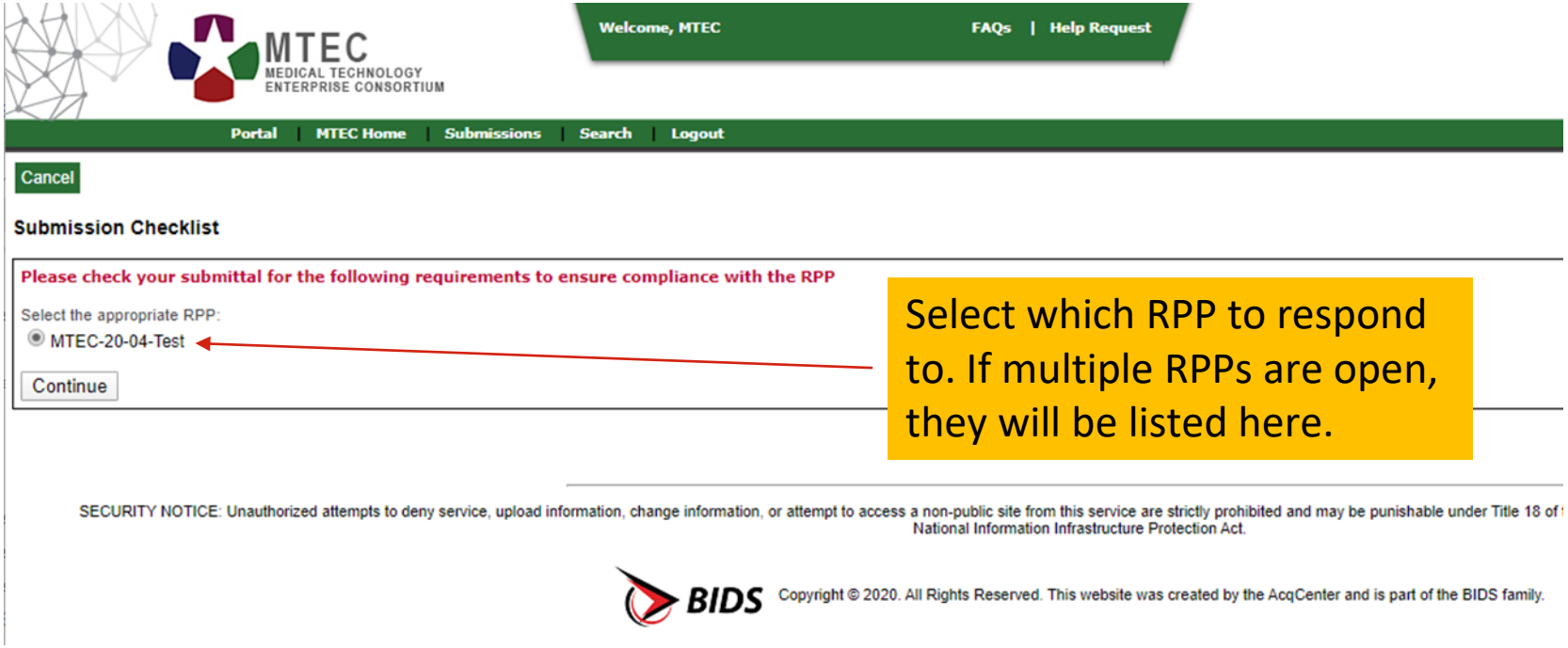
Once logged in, your username will appear here.

Click the link to respond to an RPP.

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

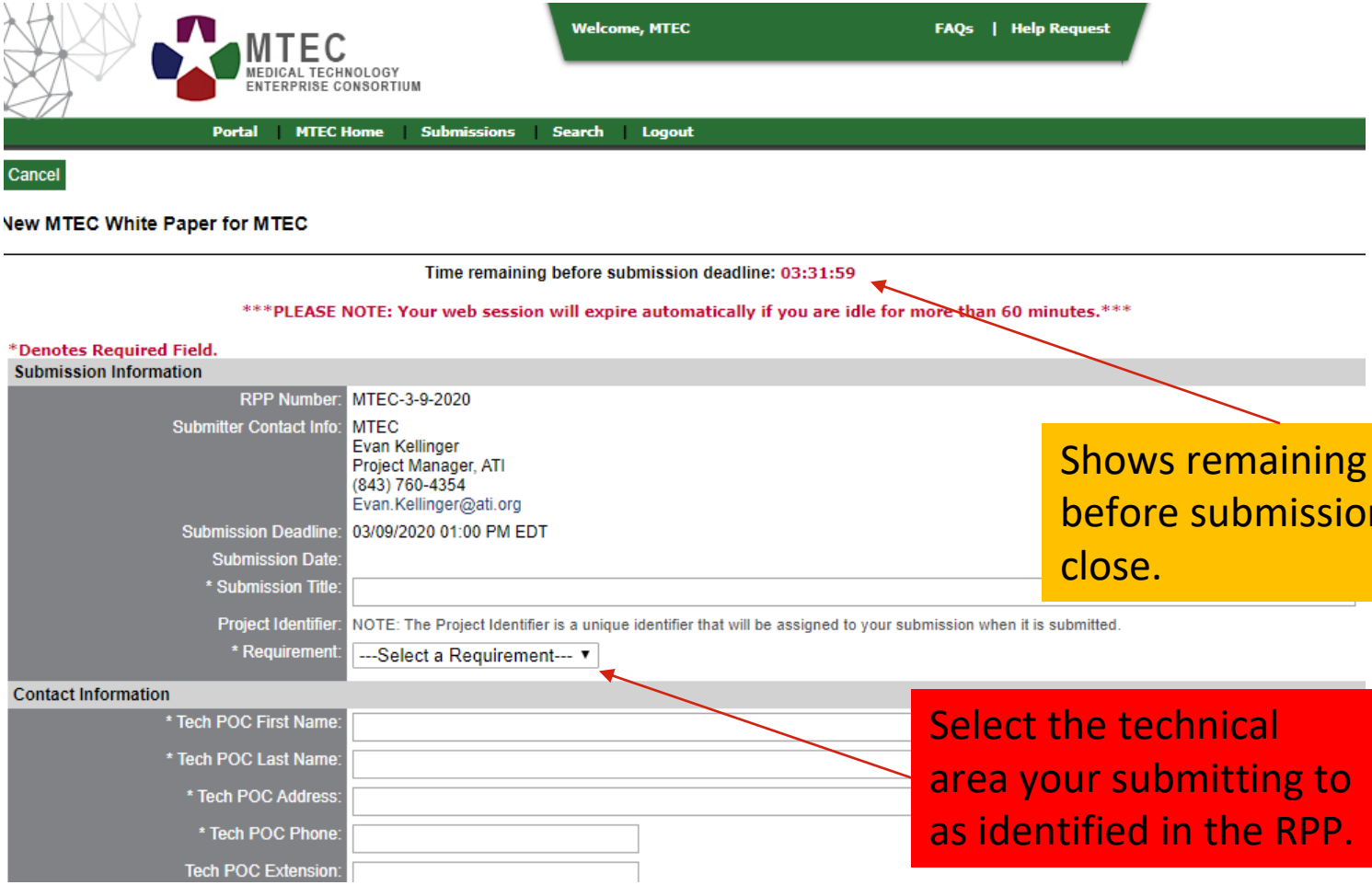
Proposal Submission BIDS

Select which RPP you will be responding to.



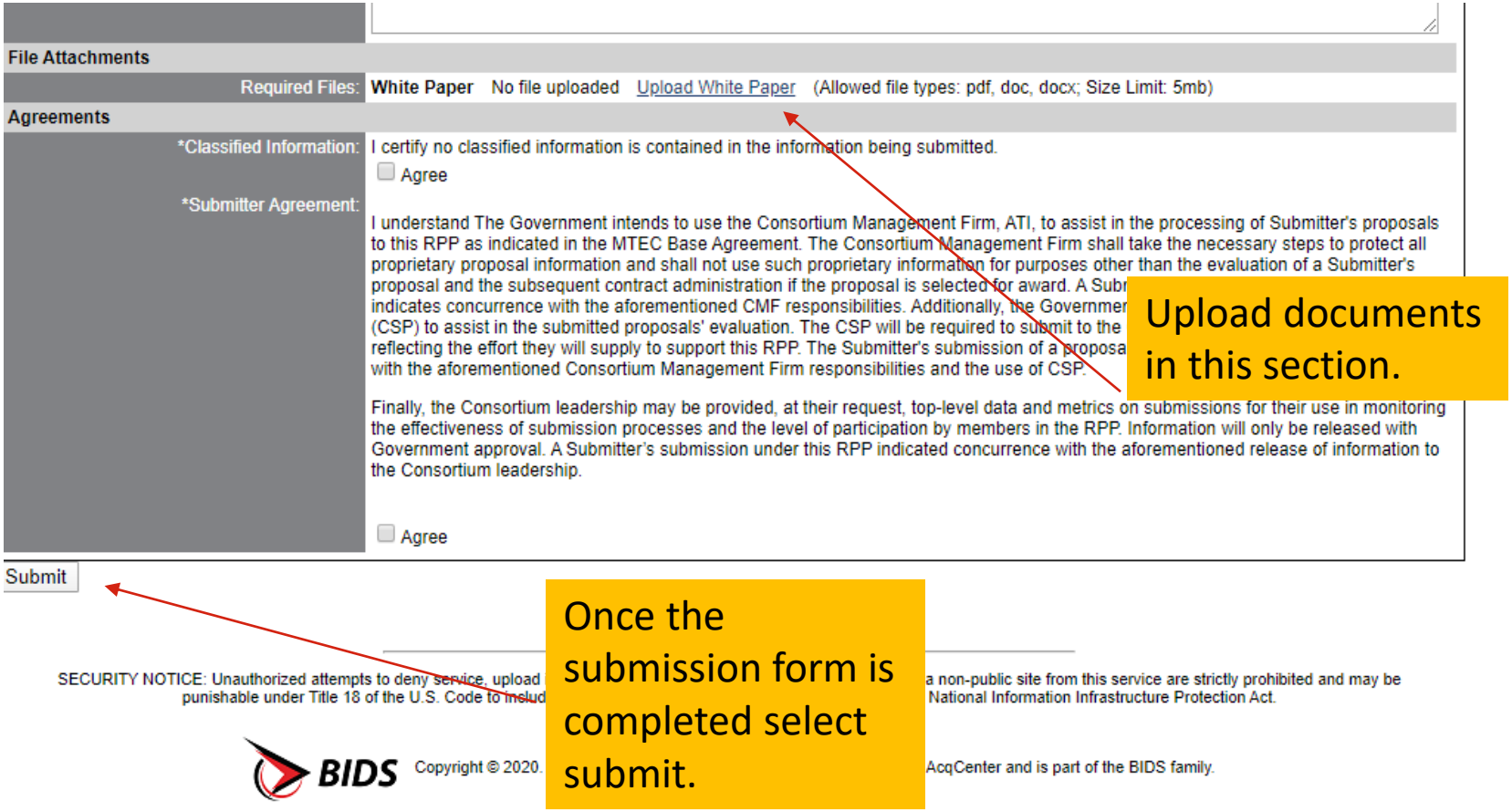
Proposal Submission BIDS

Complete the submission form.



Proposal Submission BIDS

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



Proposal Submission BIDS

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

- 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.