

**Request for Project Information**



**Solicitation Number: MTEC-20-18-Burns  
“PLANAR DELIVERY PLATFORM FOR CERIUM AND SILVER INTO BURN WOUNDS”**

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: August 4, 2020***

***Amendment No. 01 Issue Date: August 28, 2020***

***Project Information Due Date: September 2, 2020  
Noon Eastern Time***

**Amendment No. 01 extends the due date from September 1, 2020 at 11:59pm ET to September 2, 2020 at 12:00pm ET.**

**All other terms and conditions remain unchanged.**

**ANNOUNCEMENT**  
**REQUEST FOR PROJECT INFORMATION**

**MTEC-20-18-Burns**

**“PLANAR DELIVERY PLATFORM FOR CERIUM AND SILVER INTO BURN WOUNDS”**

The Medical Technology Enterprise Consortium (MTEC) is excited to post this announcement for a Request for Project Information (RPI) focused on the development and fabrication of a medical-grade planar delivery system for effective delivery of cerium and silver into burn wounds for improved burn outcome. This Request for Project Information (RPI) contains background information and guidance for MTEC members and non-members to prepare Project Information Papers for submission to MTEC. Project Information Papers will be used by the Sponsor (the U.S. Army Institute of Surgical Research, USAISR) to shape a potential future MTEC Request for Project Proposals (RPP) for the development of the product.

**BACKGROUND**

Without timely treatment, burn wounds deteriorate, become infected, causing unwanted short- and long-term outcomes, and at worst, increased mortality. Under large scale multi-domain operations, delayed evacuation of the combat wounded is anticipated. Therefore, under prolonged field care environments, the treatment of burn injuries to stabilize the wounds, lessen progression, and limit complications is paramount to improve wound outcomes and decrease mortality.

Severely burn-injured skin forms an eschar (dead skin) that includes denatured macromolecules and other metabolites that contribute to local and systemic inflammation, immunosuppression, hypermetabolism, and ultimately multi-organ dysfunction. Early excision of the eschar and autologous skin grafting within a few days of injury reduces these detrimental effects and lowers infection risk, reducing morbidity and mortality. But eschar excision and grafting under prolonged field care during combat is not possible. Therefore, to mitigate the detrimental effects of the burn eschar when it cannot be excised, treatments are needed to temporize burn wounds. One such treatment with demonstrated effectiveness is cerium nitrate (CN).

Topical treatment of burn wounds with CN has been established to stabilize the eschar to: 1) reduce burn-injured patient care burden, 2) decrease inflammatory mediators in burn tissue and circulation, and 3) provide a leathery covering resistant to eschar detachment and infection that permits delayed excision and grafting.

Flammacerium, a cream formulation that contains both silver sulfadiazine and CN, is a topical antimicrobial that has been in widespread use in European burn units, particularly in Belgium, Netherlands, Switzerland, France, and the UK since the mid-1980s. It has also been compounded in hospital pharmacies and used in the U.S., including in New York after the 9/11 terrorist attacks

under an emergency Investigational New Drug (IND) filing with the U.S. Food and Drug Administration (FDA).

At the USAISR (Sponsor), researchers have demonstrated that CN solution (40 mM) treatment of rat full-thickness scald burns (Walker-Mason model) can reduce pro-inflammatory damage-associated molecular patterns (DAMPs), including high-mobility group box protein 1 (HMGB1), hyaluronan, and xanthine oxidase (XDH) in circulation on post-burn day 1. On post-burn day 7, both the DAMPs in circulation and the pro-inflammatory mediators, IL-1 $\beta$ , IL-10, GRO-KC, and MIP-1 $\alpha$  in wound tissue were on average halved by CN treatment (Qian L. et al. J Burn Care & Res. 2020. 41(3):576-584. PMID: 31808807).

Moreover, researchers at the USAISR have investigated the use of fabric-based silver dressings to deliver CN to burn wounds. Compared to the silver dressings alone, the combination of silver dressings and CN reduced burn wound inflammation and restricted microbial growth in the burned tissue (rat model; manuscript in revision).

### **TECHNOLOGY FOCUS AREA**

The USAISR is seeking technology input(s) for the development and fabrication of a planar system for the delivery of cerium and silver to burn wounds. The delivery system must be stable, light weight, small footprint, and easy to deploy by medical and non-medical personnel for treating burn wounds at or near the point of injury under prolonged field care.

### **KEY FEATURES OF THE PLANAR DELIVERY PLATFORM**

- Planar delivery platform (e.g., textile). SEMI-SOLID FORMULATIONS WILL NOT BE CONSIDERED.
- Conformable to various body and wound surface contours and anatomical structures and suited for the treatment of severe burn wounds.
- Controlled and continuous release of CN and silver to burned human or animal skin for a minimum of 72 hours.
- Scalable and cost-effective manufacturing process.
- Stable during storage and operation (based on ICH Guidelines).

### **REQUIREMENTS OF THE PROJECT INFORMATION PAPER**

- Format
  - 4-page limit, inclusive of contact information
  - 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
  - Project Information Paper should be in \*.pdf format
  - These project information submissions will be shared with the Sponsor; therefore, all information must be **nonproprietary**.

- The Project Information Paper must include the following information:
  - Date: [Insert Date of Submission]
  - PI Organization: [Insert submitter’s name, organization, email address, phone number]
  - Approach: [Describe your approach to solving the problem. Include relevant background/preliminary data about your approach. Describe the existing technology. Include strategies for incorporating silver and cerium into the Planar Delivery Platform with details of risks and mitigations. Note: References are included within the page limit. There is no required format for the inclusion of references.]
  - Manufacturing: [Describe your ability to produce under good manufacturing practices (GMP) conditions and distribution capabilities and partnerships.]
  - Intellectual Property: [Describe relevant intellectual property and patent right assertions in U.S. and abroad.]
  - Experience: [Have submitters and/or their partners obtained FDA approval and marketed other solutions?]
  - 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. Do not provide budget detail – only provide a total estimated budget for each major milestone. This information will be used to provide the Sponsor with a reasonable representation of the amount of funding required to advance the project. Examples of tasks include, but are not limited to:
    - late animal testing and regulatory filing;
    - conduct Phase 1 clinical trials

## **MTEC**

The MTEC mission is to assist the USAMRDC by providing cutting-edge technologies and supporting 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, “nontraditional” government contractors, academic research institutions, and not-for-profit organizations.

## **ADMINISTRATIVE INFORMATION**

Project Information Papers must be submitted by **12:00 pm ET on September 2, 2020** via [BIDS: https://ati2.acqcenter.com/ATI2/Portal.nsf/Start?ReadForm](https://ati2.acqcenter.com/ATI2/Portal.nsf/Start?ReadForm). Include the MTEC Solicitation Number (MTEC-20-18-Burns) on each Project Information Paper submitted. Project Information

Papers may be submitted by both MTEC members and non-members. Please note that MTEC membership is required for the submission of a proposal in response to a future MTEC Request for Project Proposals for Planar Delivery Platform for Cerium and Silver. To join MTEC, please visit <http://mtec-sc.org/how-to-join/>

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

- Technical questions - Dr. Lauren Palestrini, PhD, MTEC Director of Research, [Lauren.Palestrini@officer.mtec-sc.org](mailto:Lauren.Palestrini@officer.mtec-sc.org)
- Other questions – Ms. Kathy Zolman, MTEC Director of Program Operations, [Kathy.Zolman@ati.org](mailto:Kathy.Zolman@ati.org)

Sincerely,  
**MTEC Project Team**



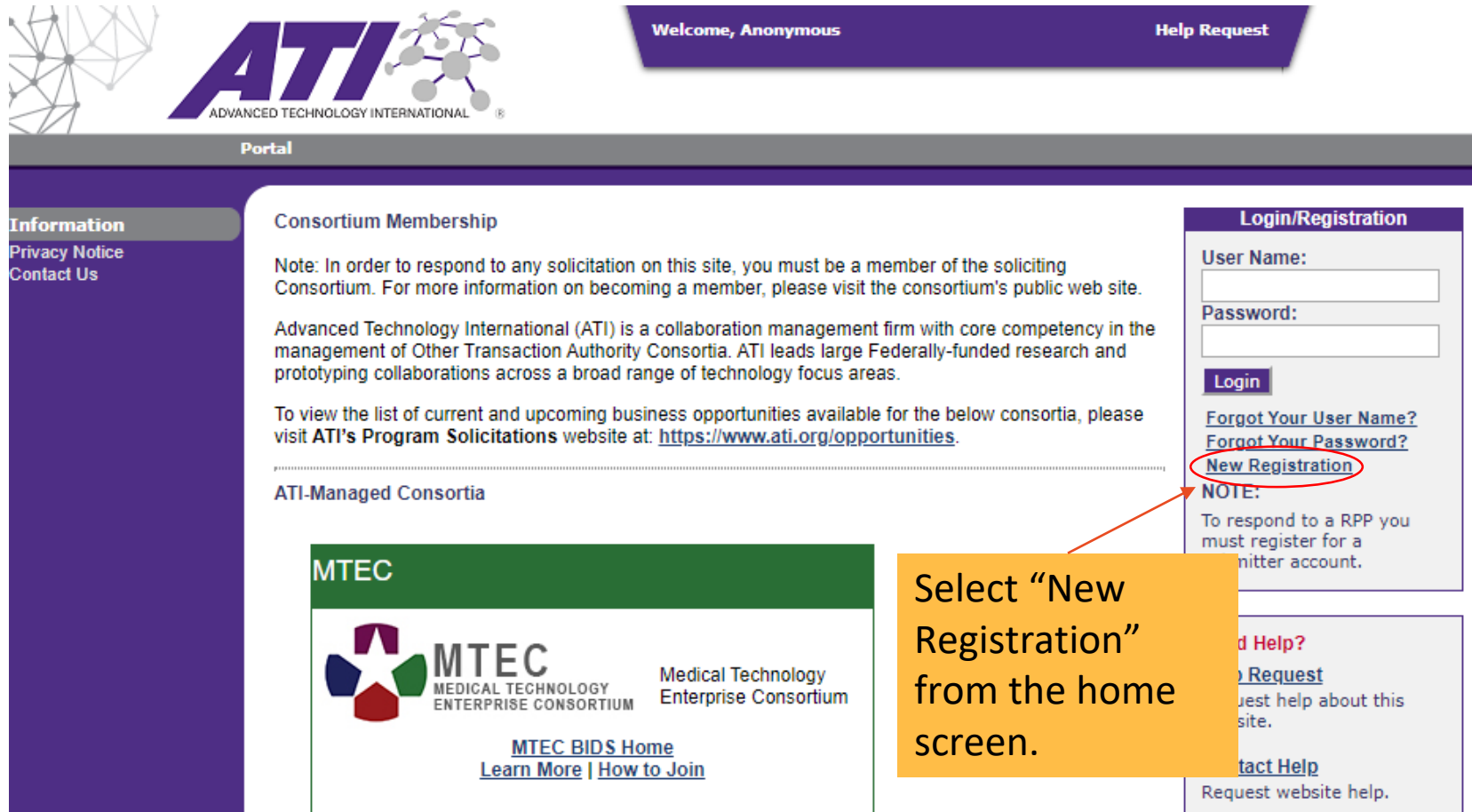
# MTEC BIDS REGISTRATION

*MTEC BIDS URL:*

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

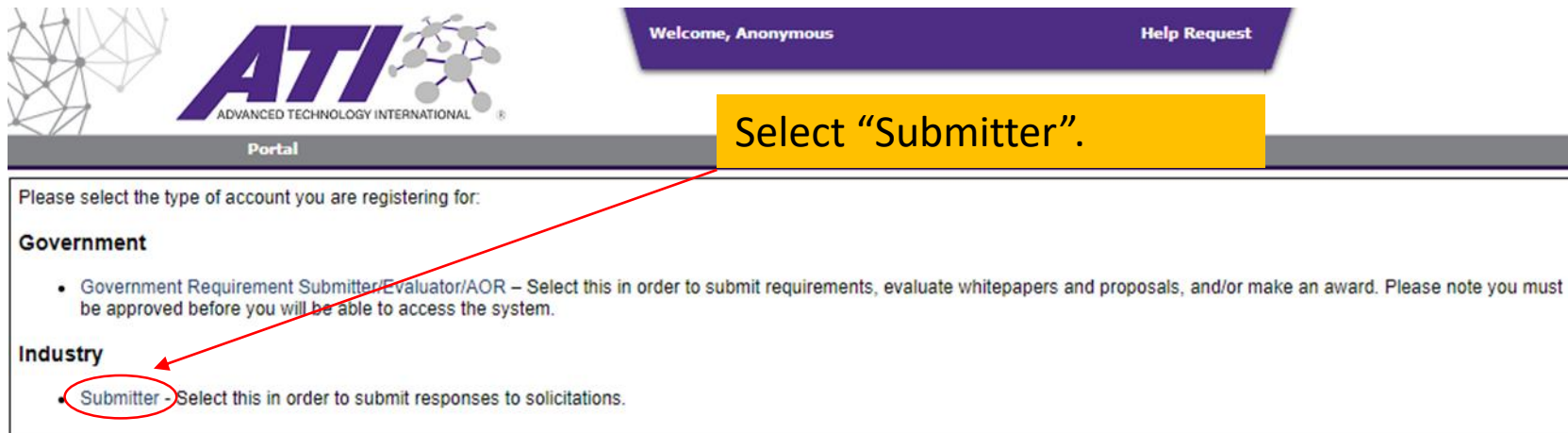
# BIDS New Registration

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



The screenshot shows the MTEC BIDS website home page. At the top, there is a purple navigation bar with "Welcome, Anonymous" and "Help Request" links. Below this is the ATI logo (Advanced Technology International) and a "Portal" header. The main content area is divided into 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 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>.), and "ATI-Managed Consortia". The "ATI-Managed Consortia" section features a green header for "MTEC" and a logo for "MTEC MEDICAL TECHNOLOGY ENTERPRISE CONSORTIUM". Below the logo are links for "MTEC BIDS Home" and "Learn More | How to Join". On the right side, there is a "Login/Registration" box with fields for "User Name:" and "Password:", a "Login" button, and links for "Forgot Your User Name?", "Forgot Your Password?", and "New Registration". The "New Registration" link is circled in red, and a red arrow points from a yellow callout box to it. The callout box contains the text: "Select 'New Registration' from the home screen." Below the "New Registration" link is a "NOTE:" section with the text: "To respond to a RPP you must register for a twitter account." At the bottom right, there is a "Request Help?" section with a "Request" link and the text: "Request help about this site." and "Contact Help" link with the text: "Request website help."

## Select “Submitter”



Portal

Welcome, Anonymous Help Request

Select “Submitter”.

Please select the type of account you are registering for:

**Government**

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

**Industry**

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

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

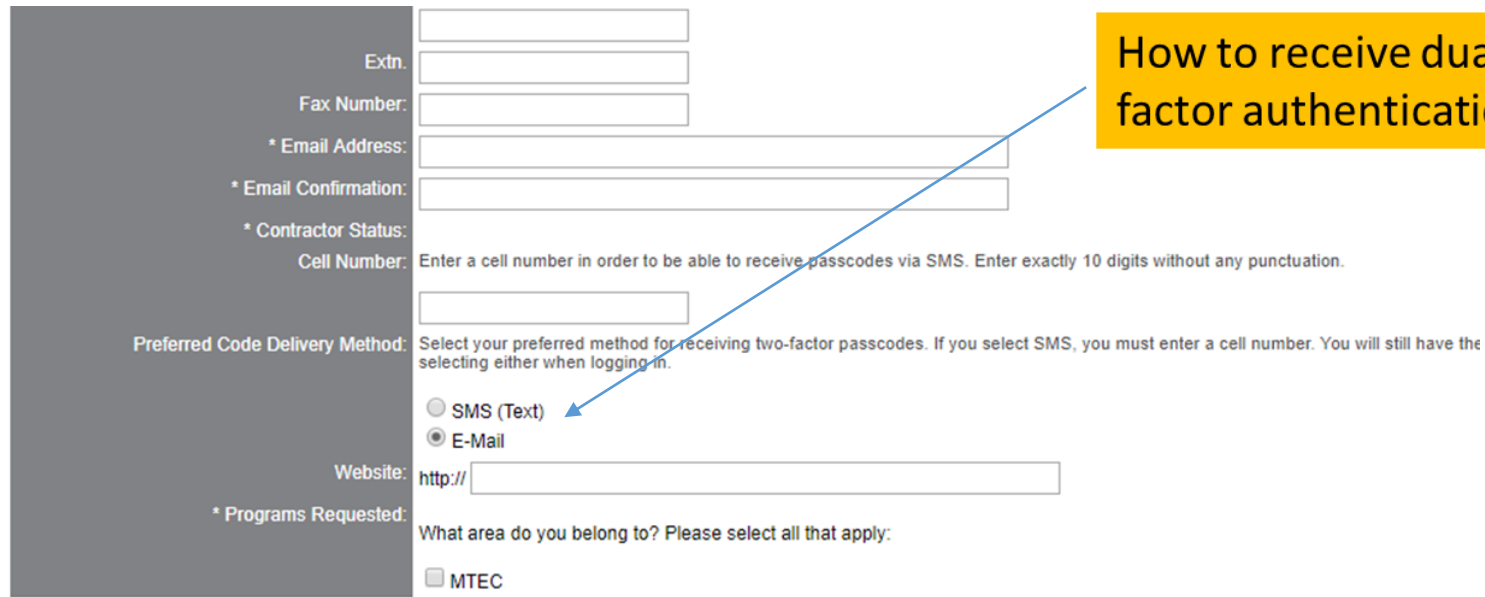


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# BIDS New Registration

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



Extn.

Fax Number:

\* Email Address:

\* Email Confirmation:

\* Contractor Status:

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

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

SMS (Text) ←

E-Mail

Website: http://

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

MTEC

How to receive dual factor authentication .

Select "Submit Registration" to complete BIDS registration.

# BIDS New Registration

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

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

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

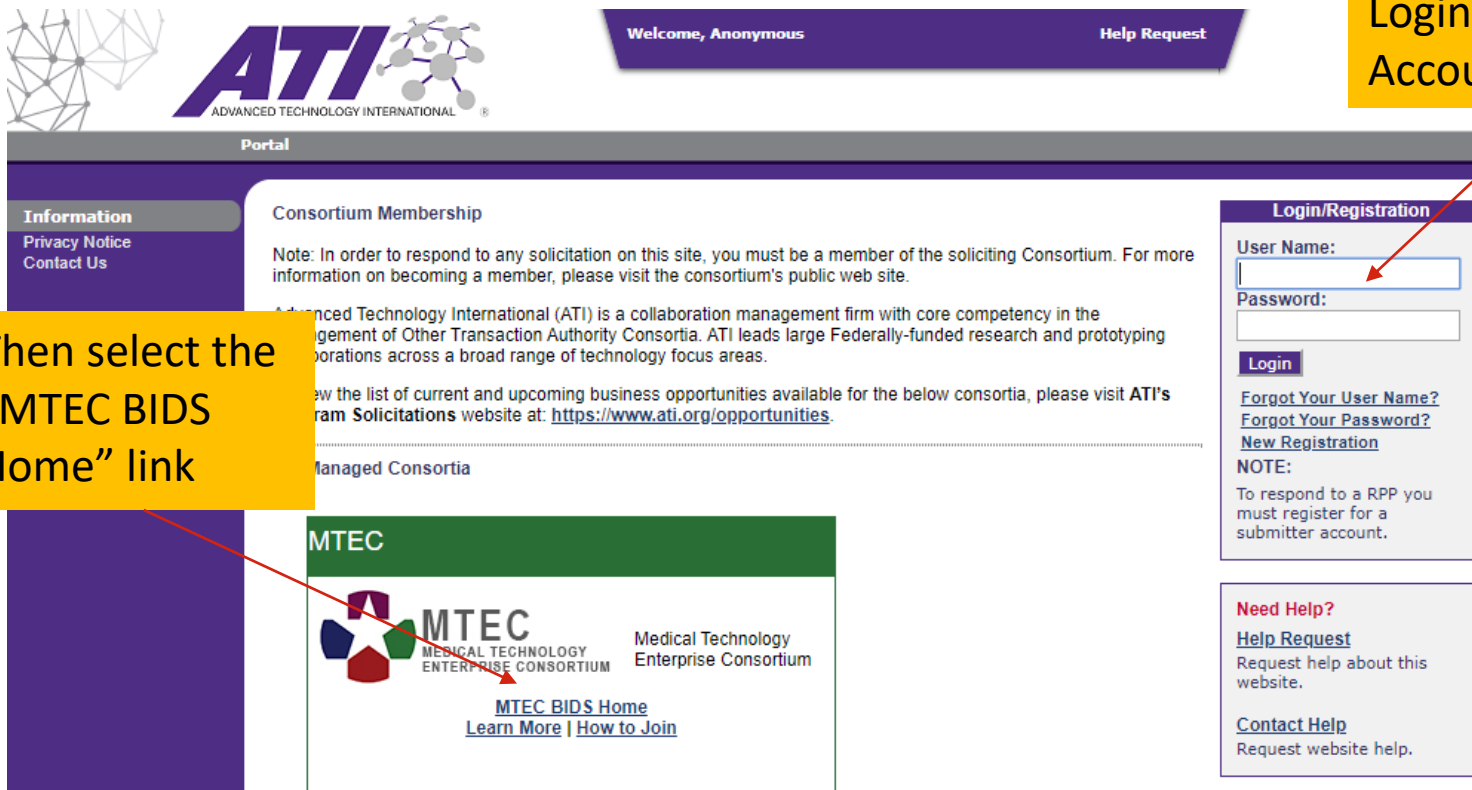
**ALL PROPOSALS MUST BE SUBMITTED BEFORE THE SUBMISSION DUE DATE AND TIME. LATE PROPOSALS CAN NOT BE ACCEPTED.**

# MTEC BIDS REQUEST FOR PROJECT INFORMATION (RPI) 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.



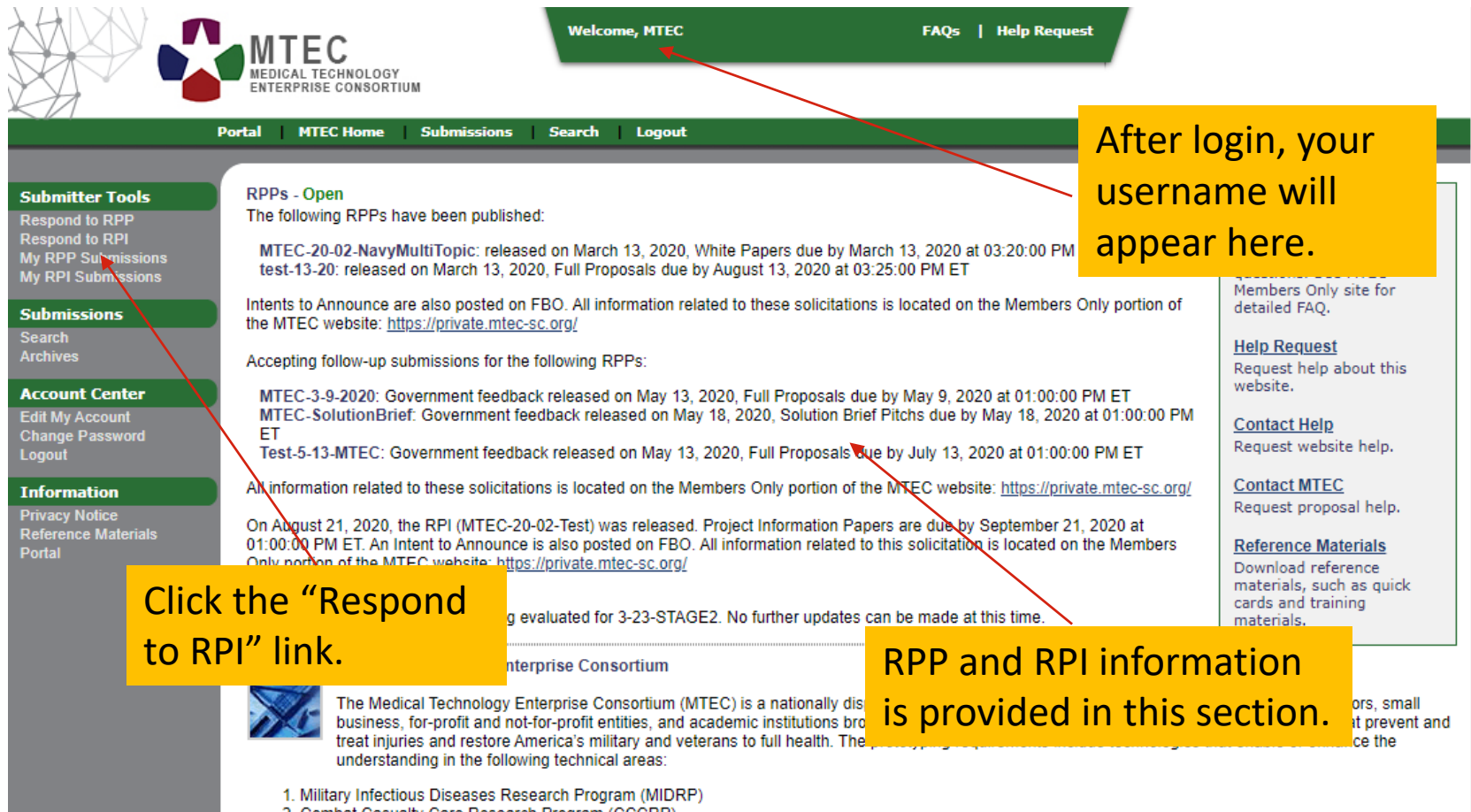
The screenshot shows the MTEC BIDS website interface. At the top, there is a navigation bar with "Welcome, Anonymous" and a "Help Request" link. Below this, the "Portal" section is visible, featuring a "Consortium Membership" notice and a "Login/Registration" form. The "Login/Registration" form includes 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 below the form states: "To respond to a RPP you must register for a submitter account." To the right of the login form, there is a "Need Help?" section with links for "Help Request" and "Contact Help". At the bottom of the page, there is a "MTEC" banner with the MTEC logo and the text "Medical Technology Enterprise Consortium". Below the banner, there are links for "MTEC BIDS Home", "Learn More", and "How to Join".

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 RPI” link under the submitter tools.



**Submitter Tools**

- Respond to RPP
- Respond to RPI
- My RPP Submissions
- My RPI Submissions

**Submissions**

- Search
- Archives

**Account Center**

- Edit My Account
- Change Password
- Logout

**Information**

- Privacy Notice
- Reference Materials
- Portal

Welcome, MTEC      FAQs | Help Request

Portal | MTEC Home | Submissions | Search | Logout

**RPPs - Open**  
The following RPPs have been published:

- MTEC-20-02-NavyMultiTopic: released on March 13, 2020, White Papers due by March 13, 2020 at 03:20:00 PM ET
- test-13-20: released on March 13, 2020, Full Proposals due by August 13, 2020 at 03:25:00 PM ET

Intents to Announce are also posted on FBO. All information related to these solicitations is located on the Members Only portion of the MTEC website: <https://private.mtec-sc.org/>

Accepting follow-up submissions for the following RPPs:

- MTEC-3-9-2020: Government feedback released on May 13, 2020, Full Proposals due by May 9, 2020 at 01:00:00 PM ET
- MTEC-SolutionBrief: Government feedback released on May 18, 2020, Solution Brief Pitches due by May 18, 2020 at 01:00:00 PM ET
- Test-5-13-MTEC: Government feedback released on May 13, 2020, Full Proposals due by July 13, 2020 at 01:00:00 PM ET

All information related to these solicitations is located on the Members Only portion of the MTEC website: <https://private.mtec-sc.org/>

On August 21, 2020, the RPI (MTEC-20-02-Test) was released. Project Information Papers are due by September 21, 2020 at 01:00:00 PM ET. An Intent to Announce is also posted on FBO. All information related to this solicitation is located on the Members Only portion of the MTEC website: <https://private.mtec-sc.org/>

...g evaluated for 3-23-STAGE2. No further updates can be made at this time.

...nterprise Consortium

The Medical Technology Enterprise Consortium (MTEC) is a nationally dis... business, for-profit and not-for-profit entities, and academic institutions bro... treat injuries and restore America's military and veterans to full health. The... understanding in the following technical areas:

1. Military Infectious Diseases Research Program (MIDRP)
2. Combat Casualty Care Research Program (C3RP)

Members Only site for detailed FAQ.

[Help Request](#)  
Request help about this website.

[Contact Help](#)  
Request website help.

[Contact MTEC](#)  
Request proposal help.

[Reference Materials](#)  
Download reference materials, such as quick cards and training materials.

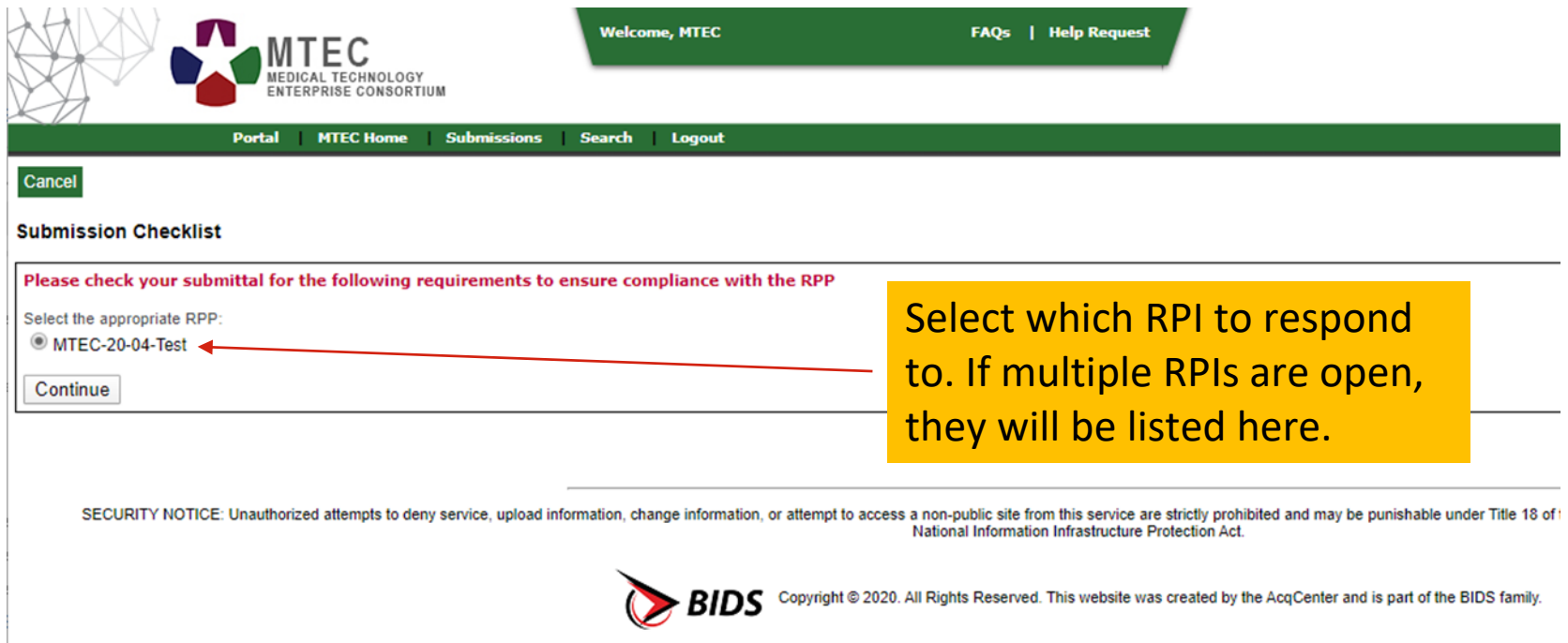
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After login, your username will appear here.

Click the “Respond to RPI” link.

RPP and RPI information is provided in this section.

Select which RPI you will be responding to.



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

Cancel

**Submission Checklist**


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

Select the appropriate RPP:

MTEC-20-04-Test

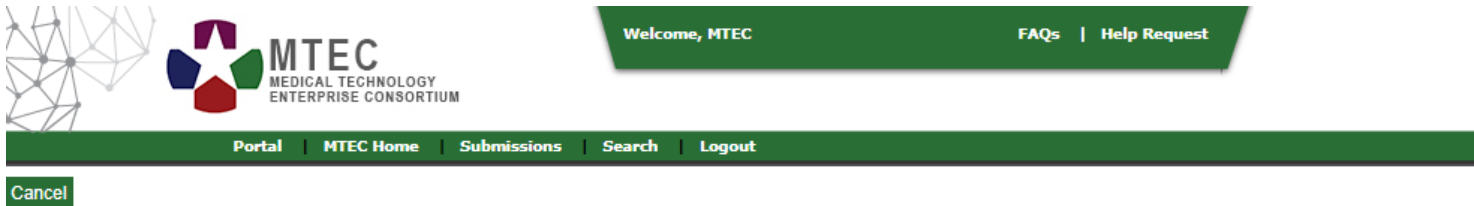
Continue

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Select which RPI to respond to. If multiple RPIs are open, they will be listed here.

Complete the submission form.



The screenshot shows the MTEC website header. On the left is the MTEC logo. In the center, a green banner contains the text "Welcome, MTEC" and "FAQs | Help Request". Below this is a dark green navigation bar with links for "Portal", "MTEC Home", "Submissions", "Search", and "Logout". A "Cancel" button is visible on the left side of the page.

**\*\*\*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:	<input type="text"/>
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:	<input type="text"/>
* Tech POC Last Name:	<input type="text"/>
* Tech POC Address:	<input type="text"/>
* Tech POC Phone:	<input type="text"/>
Tech POC Extension:	<input type="text"/>

Select the Focus Area or Technical Area your submitting to as identified in the RPI.

# Proposal Submission BIDS

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

<b>File Attachments</b>	
Required Files:	<b>White Paper</b> No file uploaded <a href="#">Upload White Paper</a> (Allowed file types: pdf, doc, docx; Size Limit: 5mb)
<b>Agreements</b>	
*Classified Information:	I certify no classified information is contained in the information being submitted. <input type="checkbox"/> Agree
*Submitter Agreement:	<p>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 will use a Consortium Management Firm (CSP) to assist in the submitted proposals' evaluation. The CSP will be required to submit to the Submitter a report reflecting the effort they will supply to support this RPP. The Submitter's submission of a proposal indicates concurrence with the aforementioned Consortium Management Firm responsibilities and the use of CSP.</p> <p>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.</p> <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).

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