Request for Project Proposals

Solicitation Number: MTEC-20-12-COVID-19_Diagnostics
"Wearable Diagnostic for Detection of COVID-19 Infection"

Issued by:
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for the
Medical Technology Enterprise Consortium (MTEC)

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1 Executive Summary

1.1. The Medical Technology Enterprise Consortium

The Medical Technology Enterprise Consortium (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 DoD 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 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.

MTEC operates under an Other Transaction Agreement (OTA) for prototypes with USAMRDC. As defined in the OTA Guide dated November 2018, a prototype project addresses a proof of concept, model, reverse engineering to address obsolescence, pilot, novel application of commercial technologies for defense purposes, agile development activity, creation, design, development, demonstration of technical or operational utility, or combinations of the foregoing. A process, including a business process, may be the subject of a prototype project. Although assistance terms are generally not appropriate in OT agreements, ancillary work efforts that are necessary for completion of the prototype project, such as test site training or limited logistics support, may be included in prototype projects. A prototype may be physical, virtual, or conceptual in nature. A prototype project may be fully funded by DoD, jointly funded by multiple federal agencies, cost-shared, funded in whole or part by third parties, or involve a mutual commitment of resources other than an exchange of funds.

1.2. Purpose

This solicitation, issued by the MTEC Consortium Manager (CM), Advanced Technology International (ATI), represents a Request for Project Proposals (RPP) for MTEC support of the USAMRDC's Military Infectious Diseases Research Program (MIDRP) and Military Operational Medicine Research Program (MOMRP). Military relevance is a critical component of Enhanced White Paper submission. Strategic and tactical oversight for the award(s) supported by this RPP will be provided by the MIDRP and MOMRP.

The goal of this RPP is to develop a wearable diagnostic capability for the pre-/very early-symptomatic detection of COVID-19 infection.

*Note: Pending successful completion of this effort, the Government may issue a non-competitive follow-on production contract or transaction pursuant to 10 USC 2371b section f.

2 Administrative Overview

2.1. Request for Project Proposals (RPP)

Each MTEC Enhanced White Paper submitted must be in accordance with the mandatory format provided in Section 10 of the RPP.

Note that the terms Enhanced White Paper and Proposal are used interchangeably throughout this RPP.

2.2. Funding Availability and Type of Funding Instrument Issued

The U.S. Government (USG) Department of Defense (DoD) currently has available approximately $25 Million (M) of FY20 funds. Any potential follow-on funding is expected to be awarded non-competitively and negotiated based on outcomes, cost sharing, partner matching and estimates for additional study completion.

The anticipated Period of Performance (PoP) is up to 9 months. Dependent on the results and deliverables, additional time may be added to the period of performance for follow-on tasks.

As of the release date of this RPP, future year Defense Appropriations Bills have not been passed and there is no guarantee that any additional funds will be made available to support this program. The funding estimated for this RPP is approximate and subject to realignment. Funding of Enhanced White Papers received in response to this RPP is contingent upon the availability of federal funds for this program. Award funding will be structured incrementally and based upon completion of Milestones and Deliverables.

2.3. Acquisition Approach

It is expected that MTEC will make up to 10 awards to qualified teams to accomplish the statement of work. If a single Enhanced White Paper is unable to sufficiently address the entire scope of this RPP's technical requirements (outlined in Section 5), several Offerors may be asked to work together in a collaborative manner. However, if an optimal team is not identified, then MTEC may make multiple, individual awards to Offeror(s) to accomplish subset(s) of the key tasks.

The Government-selected Awards will be funded under the Other Transaction Agreement (OTA) Number W81XWH-15-9-0001 with MTEC administered by the CM, ATI. The CM will negotiate and

execute a Base Agreement with MTEC members (if not yet executed). This Base Agreement will be governed by the same provisions as the OTA between the USG and MTEC. Subsequently, any Enhanced White Paper that is selected for award is expected to be funded through a Research Project Award issued under the Base Agreement. A sample of the MTEC Base Agreement can be found on the MTEC Members-Only website at www.mtec-sc.org.

At the time of the submission, if Offerors have not yet executed a Base Agreement, then Offerors must certify on the cover page of their Enhanced White Paper that, if selected for award, they will abide by the terms and conditions of the latest version of the MTEC Base Agreement. If the Offeror already has executed an MTEC Base Agreement with the MTEC CM, then the Offeror must state on the cover page of its Enhanced White Paper that, if selected for award, it anticipates the proposed effort will be funded under its executed MTEC Base Agreement.

Offerors are advised to check the MTEC website periodically during the Enhanced White Paper preparation period for any changes to the MTEC Base Agreement terms and conditions as well as clarifications found in Frequently Asked Questions (FAQ) responses.

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 to the Government. 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 can be accessed via the "MTEC Profiles Site" tab on the MTEC members-only website.

Collaboration with DoD investigators is also encouraged.

2.5. Proprietary Information

The MTEC CM will oversee submission of Enhanced White Papers 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 Enhanced White Paper and the subsequent agreement administration if the Proposal is selected for award. Please 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, these MTEC Officers and Staff represent organizations that currently are not MTEC members, and therefore their parent organizations are not eligible to submit Proposals or receive any research project funding through MTEC. Additionally, all Technical Evaluation Panel participants will agree to, and sign a nonproprietary information and conflict of interest document.

2.6. Offeror Eligibility

MTEC membership is <u>not required</u> for the submission of an Enhanced White Paper in response to this upcoming MTEC RPP. However, membership will be required for Offerors recommended for award. To join MTEC, please visit http://mtec-sc.org/how-to-join/.

2.7. Inclusion of Nontraditional Defense Contractors or Nonprofit Research Institutions

Enhanced White Papers that fail to meet the mandatory statutory conditions with regard to the appropriate use of Other Transaction authority, as listed below, will not be evaluated and will determined ineligible for award. Please see Appendix 4.3 of the Enhanced White Paper template in Section 10 of the RPP for additional details.

Mandatory statutory conditions (the Offeror shall assert that at least one of the one of the following conditions is met):

(1) There is at least one nontraditional defense contractor or nonprofit research institution participating to a significant extent in the prototype project.

(2) All significant participants in the transaction other than the Federal Government are small businesses (including small businesses participating in a program described under section 9 of

the Small Business Act (15 U.S.C. 638)) or nontraditional defense contractors.

(3) At least one third of the total cost of the prototype project is to be paid out of funds provided by sources other than the Federal Government.

The Offeror shall submit Warranties and Representations (see Section 10, Appendix 4.3) specifying the critical technologies being offered and/or the significant extent of participation of the nontraditional defense contractor, small business or nonprofit research institution. The nontraditional defense contractor can be an individual so long as he/she has a DUNS Number and meets the requirements in the Warranties and Representations. The significance of the nontraditional defense contractor's, small business' or nonprofit research institution's participation shall be explained in detail in the signed Warranties and Representations. Inadequate detail can cause delay in award.

Per the DoD OT Guide, rationale to justify a *significant extent* includes:

1. Supplying a new key technology, product or process
2. Supplying a novel application or approach to an existing technology, product or process
3. Providing a material increase in the performance, efficiency, quality or versatility of a key technology, product or process
4. Accomplishing a significant amount of the prototype project
5. Causing a material reduction in the cost or schedule of the prototype project
6. Provide for a material increase in performance of the prototype project

2.8. Nontraditional Defense Contractor Definition

A nontraditional defense contractor is a business unit that has not, for a period of **at least one year prior to the issue date of the Request for Project Proposals**, entered into or performed on any contract or subcontract that is subject to full coverage under the cost accounting standards (CAS) prescribed pursuant to section 26 of the Office of Federal Procurement Policy Act (41 U.S.C. 422) and the regulations implementing such section.

2.9. Cost Sharing Definition

Cost sharing is defined as the resources expended by the award recipients on the proposed statement of work (SOW). If cost sharing is proposed, then the Offeror shall state the amount that is being proposed and whether the cost sharing is a cash contribution or in-kind contribution (see below for a definition of each); provide a description of each cost share item proposed; the proposed dollar amount for each cost share item proposed; and the valuation technique used (e.g., vendor quote, historical cost, labor hours and labor rates, number of trips, etc.). Cost sharing above the statutory minimum is encouraged if possible, as it leads to stronger leveraging of Government-contractor collaboration.

Cash Contribution

Cash Contribution means the Consortium and/or the Research Project Awardee (or Awardees' lower tier subawards) financial resources expended to perform a Research Project. The cash contribution may be derived from the Consortium's or Research Project Awardee (or Awardees' subawards) funds or outside sources or from nonfederal contract or grant revenues or from profit or fee on a federal procurement contract.

An Offeror's own source of funds may include corporate retained earnings, current or prospective Independent Research and Development (IR&D) funds or any other indirect cost pool allocation. New or concurrent IR&D funds may be utilized as a cash contribution provided those funds identified by the Offeror will be spent on performance of the Statement of Work (SOW) of a Research Project or specific tasks identified within the SOW of a Research Project. Prior IR&D funds will not be considered as part of the Offeror's cash.

Cash contributions include the funds the Offeror will spend for labor (including benefits and direct overhead), materials, new equipment (prorated if appropriate), awardees' subaward efforts expended on the SOW of a Research Project, and restocking the parts and material consumed.

In-Kind Contribution

In Kind Contribution means the Offeror's non-financial resources expended by the Consortium Members to perform a Research Project such as wear-and-tear on in-place capital assets like machinery or the prorated value of space used for performance of the Research Project, and the reasonable fair market value (appropriately prorated) of equipment, materials, IP, and other property used in the performance of the SOW of the Research Project.

Prior IR&D funds will not be considered as part of the Consortium Member's cash or In-Kind contributions, except when using the same procedures as those that authorize Pre-Award Costs, nor will fees be considered on a Consortium Member's cost sharing portion.

If the offer contains multiple team members, this information shall be provided for each team member providing cost share.

2.10. MTEC Assessment Fee

Per Section 3.4 of the Consortium Member Agreement (CMA), each recipient of a Research Project Award under the MTEC OTA 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.

Additionally, 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:

Royalty Payment Agreements
Government-funded 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 Government funding provided.

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. This additional assessment applies to all research project awards, whether the award is Government funded or privately funded.

2.11. Intellectual Property and Data Rights

Intellectual Property (IP) rights for MTEC Research Project Awards will be defined in the terms of an awardee's Base Agreement and resultant Task Orders. MTEC reserves the right to assist in the negotiation of IP, royalties, licensing, future development, etc., between the government and the individual performers during the entire award period.

The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding Data Rights. **It is anticipated that anything delivered under this proposed effort will be delivered to the Government with Government purpose data rights or unlimited data rights unless otherwise asserted in the proposal and agreed to by the Government.** Rights in technical data in each Research Project Award shall be determined in accordance with the provisions of MTEC Base Agreement.

The Offeror is required to complete Appendix 4.2 in Section 10 of the RPP, Data Rights of the Enhanced White Paper template, in order to identify any items to be furnished to the Government with restrictions.

2.12. Expected Award Date

Offeror should plan on the period of performance beginning June 1, 2020 (subject to change). The Government 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.

2.13. Anticipated Enhanced White Paper Selection Notification

As the basis of selections is completed, the Government will forward their selections to MTEC CM to notify Offerors. Proposers will be notified via email from the MTEC CM of the results of

the evaluation. Those successful will move forward to the next phase of the process while those not selected will gain evaluation rationale for non-selection.

3 Enhanced White Paper

3.1. Enhanced White Paper Rationale

The MTEC will use an accelerated approach to award for this RPP. Because of the nature and urgency of the requirements set forth in this RPP, this streamlined approach is anticipated to be a better means to highlight company methodologies and skills required to address the technical requirements described herein. The Enhanced White Paper process requires extremely quick turnaround times by Offerors. The following sections describe the formats and requirements of the Enhanced White Paper.

Offerors who submit Enhanced White Papers in response to this RPP must submit by the date on the cover page of this RPP. Enhanced White Papers received after the time and date specified will not be evaluated.

3.2. Enhanced White Paper Submission

Enhanced White Papers 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 Solicitation Number (MTEC-20-12-COVID-19_Diagnostics) on each Enhanced White Paper submitted.

Do not submit any classified information in the Enhanced White Paper submission.

3.3. Submission Format

Offerors shall 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 full submission prior to the submission deadline, the submission will not be accepted. It is the Offeror's responsibility to ensure a timely and complete submission.**

4 Enhanced White Paper Preparation Instructions

4.1. General Instructions

The Enhanced White Paper and Cost Proposal format provided in this MTEC RPP are mandatory and shall reference this RPP number (MTEC-20-12-COVID-19_Diagnostics). Offerors are encouraged to contact the Point-of-Contact (POC) identified herein up until the Enhanced White Paper submission date/time to clarify requirements.

Offerors shall submit Enhanced White Papers for evaluation according to the criteria set forth herein. Offerors are advised that only ATI as the MTEC's CM, with the approval of the Government Agreements Officer, is legally authorized to contractually bind or otherwise commit funding for selected Awards as result of this RPP.

5 Technical Requirements

5.1. Introduction

The pandemic COVID-19, a disease caused by a novel coronavirus, continues to spread worldwide. There is a dire and urgent need for development of rapid, accurate wearable diagnostics to identify and isolate pre-symptomatic COVID-19 cases and track/prevent the spread of the virus.

5.2. Solution Requirements

The goal of this RPP is to develop a wearable diagnostic capability for the pre-/very early-symptomatic detection of COVID-19 infection.

Offerors should only propose technology solutions that meet the following two criteria as the following specifications define the minimum prototype requirements that all proposals must demonstrate:

1. Currently be at a Technology Readiness Level (TRL) of 3/4 or above [definition of TRL – https://mtec-sc.org/wp-content/uploads/2016/12/TRL-definitions.pdf], and
2. Currently be in development or commercially available.

An ideal solution would meet the following capabilities or specifications (not listed in order of importance). [Although Enhanced White Papers that propose to meet all of the solution requirements outlined below are preferred, we encourage you to submit even if you cannot currently meet all these specifications within this time frame. The Government may consider lesser responses based upon the parameters that could be met and the team's approach to meeting the other requirements over time. **However, it is expected that an Offeror's Enhanced White Paper will describe in detail what they plan to accomplish and how they plan to satisfy all of the solution requirements throughout the period of performance.]**

- Platform must be designed for pre-detection (e.g., physiological monitoring of readiness) and early detection of infection and pathogenic response that can be utilized pre-clinically leading to use at Point-of-Need role of care (ROC) 1/2, local doctor's office, emergency departments, urgent care centers and immediate care clinics.

- The capability should be "wearable", non- or minimally-invasive and be able to assess physiological markers to monitor the health state of the user. A single device is preferred, but a combination of technologies is acceptable.

- Device(s) should be designed to be worn for continuous physiological monitoring in a non-obtrusive manner and should not affect the daily activity of the wearer. Physiological markers indicative of health state that are of interest to this RPP include, but are not limited to, physiological markers of early COVID symptomology (elevated temperature / fever, respiratory difficulty / cough, etc.), antibodies against COVID 19, and molecular biomarkers indicative of COVID 19 exposure (not all markers are necessary but sufficient markers to provide evidence of COVID exposure are required). Sampling of physiological markers/antibodies/biomarkers can occur "on demand" to conserve power. Device should be worn until exposure has been verified or until a medical professional has deemed the device is no longer needed.

- Results should be easy to interpret by non-laboratory personnel and results should be collected and able to be saved and shared in a standard and secure (maintain HIPPA) format.

- The device must be able to be stored and operated between 4°C to 45°C.

- Physiologic surveillance for COVID-19 positive individuals that do not yet show clear medical symptoms is an ultimate goal. Physiological signatures therefore must produce predictive algorithms that can be tied into validated and relevant antibody/molecular measurements.

- Offeror must have an established manufacturing capability for the platform and assay kits on a large-scale.

<u>Scope of Work:</u>

- During the PoP, the Awardee(s) will be expected to develop a working prototype and perform testing on clinically relevant human samples (known positive and negative) and compared to current gold standard. Specificity to detect COVID-19 infection or markers of current infection from asymptomatic or symptomatic patients should be demonstrated.

- Current Institutional Review Board (IRB) approval is preferred at the time of enhanced white paper submission. Awardee(s) will be required to obtain protocol approval from USAMRDC's Human Research Protections Office (HRPO) at the start of the PoP. Offerors are required to bring forth access to data sets of utility to prediction of infection.

- Offerors shall have a plan to obtain an Emergency Use Authorization (EUA) status from the U.S. Food and Drug Administration (FDA) within the first 45 days of the PoP if the product will be an FDA-regulated COVID diagnostic.

- During the PoP, the Offeror is expected to file for clearance/approval by the U.S. FDA along the appropriate regulatory pathway (i.e., 510(k), de novo, etc.).

The deliverable at the end of the POP is to have an EUA for the new wearable capability and be ready to distribute the device and test kits within 15 days of receiving the EUA.

5.4. Restrictions on Animal and Human Subjects

Enhanced White Papers 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), and approval by the U.S. Army Animal Use and Review Office (ACURO) and U.S. Army Human Research Protections Office (HRPO). Offerors shall include IACUC, ACURO, IRB and HRPO review and approval in the SOW/Milestones Table.

These restrictions include mandatory government review and reporting processes that will impact the Offeror's schedule.

For example, the clinical studies under this RPP shall not begin until the USAMRDC HRPO provides authorization that the research may proceed. The USAMRDC HRPO will issue written approval to begin research under separate notification. Written approval to proceed from the USAMRDC HRPO is also required for any Research Project Awardee (or lower tier subawards) that will use funds from this award to conduct research involving human subjects. Offerors must allow at least 30 days in their schedule for the ORP review and authorization process.

6 Enhanced White Paper Preparation

6.1. Preparation of the Enhanced White Paper

Offerors submitting Enhanced White Paper in response to this RPP will be required to submit using the following steps outlined below:

Step 1: Enhanced White Paper

The Offeror shall submit an Enhanced White Paper using the template provided in Section 10, which describes the overall technical concept and approach along with the viability toward the Offeror's specific effort. Enhanced White Papers shall be submitted by the date and time specified on the cover page using BIDS:
https://ati2.acqcenter.com/ATI2/Portal.nsf/Start?ReadForm.

Enhanced White Papers **exceeding the page limit specified in Section 10 of the RPP may not be accepted.**

6.2. Enhanced White Paper Evaluation:

(1) The CM will distribute all Enhanced White Papers to the Government for scientific and programmatic relevance evaluation.

(2) Initial Screening: The Government will perform an initial screening of the submissions. This initial screening will be based on the content of **Section 1 of the Enhanced White Paper** (see Section 10 of the RPP for the Enhanced White Paper Template). The remaining sections of the Enhanced White Paper will not be reviewed at this stage of the screening process – ONLY SECTION 1 of the Enhanced White Paper will be reviewed by the Government at this stage. Any Enhanced White Papers found **not** to meet the minimum acceptable qualifications as detailed below may be removed from consideration, no further evaluation will be performed, and feedback will not be provided to these Offerors. Section 1 of each Enhanced White Paper submission will be reviewed by the Government using the following criteria in order to determine if the submitted Enhanced White Paper meets the qualifications to receive a full evaluation:

- **TRL at time of submission** – Is the proposed technology at a minimum of a TRL 3 at the time of submission?
- **Programmatic relevance** – Does the proposed project align with the scope of the RPP? Is the proposal relevant to addressing a military need?
- **Timeliness –** Does the proposed project support the end goal of the RPP which is to have an EUA for the new wearable capability and be ready to distribute the device and test kits within 9 months of award date?
- **Preliminary data –** Has the Offeror provided evidence of non-clinical and/or clinical data to support the technical approach and demonstrated manufacturing feasibility of the proposed technology?
- **Feasibility –** Does the technical abstract demonstrate a feasible approach to the solution accounting for technical, administrative, and/or programmatic considerations?

(3) Full Evaluation: Any Enhanced White Papers found to meet the minimum acceptable qualifications outlined in the initial screening will receive a full evaluation. Offerors will receive feedback on the full evaluation. The full technical evaluation of the complete Enhanced White Paper submissions will be conducted based on the following criteria (evaluation factors are of equal importance):

- **Factor 1 – Technical Approach**: Relevancy, thoroughness, and completeness of the proposed approach (e.g., the technical merit). This includes such factors as 1) objectives; 2) scientific rationale with supporting preliminary data; 3) scientific study design feasibility. The Government may consider SOW and estimated budget as an aspect of overall scientific feasibility.
- **Factor 2 – Programmatic Relevance:** Relevance of the proposed solution and its alignment with the RPP's topic area and the program objective described in Section 5. The Government may consider the project management plan and experience as an aspect of overall programmatic relevance.
- **Factor 3 – Regulatory and Commercialization Plan:** Feasibility of regulatory and commercialization strategy.
- **Factor 4 - Impact –** Evaluation of the significance of the impact of the proposed project on the current COVID-19 outbreak.

The Government will conduct the source selection based on the evaluation criteria listed above. The overall award decision will be based upon a Best Value determination by considering and comparing factors in addition to cost or price. See the table entitled "Table 2 - General Merit Rating Assessments" under Section 7 of this RPP for details regarding the adjectival merit ratings that will be used for the non-cost/price evaluation factors detailed above. The Offeror shall clearly state how it intends to meet and, if possible, exceed the RPP requirements. Mere acknowledgement or restatement of an RPP requirement is not acceptable

Upon review of the Enhanced White Papers, Offerors who are favorably evaluated may be invited for informal discussions with the Government. Offerors who are recommended for award will be required to submit a full Cost Proposal. See RPP Section 6.3 for additional details.

6.3. Step 2: Cost Proposal (for Only Those Offerors Recommended for Funding)

Offerors that are recommended for funding will receive notification letters which will serve as the formal request for a full Cost Proposal (and may contain a request for Enhanced White Papers revisions based on the results of the technical evaluation). These letters will contain specific submission requirements if there are any changes to those contained in this RPP.

The Cost Proposal shall be submitted in two separate sections. One Word (.docx or .doc) or PDF file for **Section I: Cost Proposal Narrative** (the MTEC Proposal Preparation Guide will be provided by MTEC to Offerors invited to Step 2). Separately, **Section II: Cost Proposal Formats** either in Excel (.xlsx or .xls) or PDF format is required.

Each offeror selected for Step 2 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 full proposal. Please see RPP Section 2.10 for additional information.

Offerors are encouraged to use their own cost formats. MTEC will make cost proposal formats available to Offerors invited to Step 2. These Cost Proposal formats provided by MTEC are **NOT** mandatory**.**

Each cost should include direct costs and other necessary components as applicable, for example, fringe, General & Administrative Expense (G&A), Facilities & Administrative (F&A), Other Direct Costs (ODC), etc. Offerors shall provide a breakdown of material and ODC costs as applicable.

Please note that compensation to Federal personnel (civil servants or Service members) participating as human subjects (when "On-Duty"), whether or not the research is Federally funded, is **unallowable** (with the exception of some blood draws) in accordance with Department of Defense Instruction number 3216.02 (SUBJECT: Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research). You may access a full version of the DODI by accessing the following link:
https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf

6.4. Freedom of Information Act (FOIA)

To request protection from FOIA disclosure as allowed by 10 U.S.C. §2371(i), Offerors shall mark business plans and technical information with a legend identifying the documents as being submitted on a confidential basis.

6.5. Enhanced White Paper and Cost Proposal Preparation Costs

The cost of preparing Enhanced White Papers and Cost Proposals in response to this RPP is not considered a direct charge to any resulting award or any other contract.

7 Selection

Immediately at the time that the RPP closes, the CM will conduct a preliminary screening of submitted Enhanced White Papers to ensure compliance with the RPP requirements (prior to the initial screening described above under Section 6.2). Enhanced White Papers that do not meet these requirements may be eliminated from the competition without further review or evaluation. One of the primary reasons for non-compliance or elimination during the initial administrative compliance screening is the lack of significant nontraditional defense contractor participation, nonprofit research institution participation, small business participation or cost share (see RPP Section 2.7). The appropriate use of Other Transaction authority with regards to the mandatory statutory Cost Sharing or inclusion of a Nontraditional Defense Contractor, small business or nonprofit research institution participating to a significant extent determination will be made as shown in the Table below:

TABLE 1 - APPROPRIATE USE OF OTHER TRANSACTION AUTHORITY ASSESSMENTS	
RATING	**DESCRIPTION**
PASS	Offeror proposing an MTEC research project meets at least ONE of the following: • Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution • Offeror's Enhanced White Paper has at least one Nontraditional Defense Contractor or Nonprofit Research Institute participating to a significant extent • All significant participants in the transaction other than the Federal Government are small businesses or Nontraditional Defense Contractors • Offeror provides at least one third of the total project cost as acceptable cost share
FAIL	Offeror proposing an MTEC research project does **NOT** meet any of the following: • Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution • Offeror's Enhanced White Paper has at least one Nontraditional Defense Contractor or Nonprofit Research Institution participating to a significant extent • All significant participants in the transaction other than the Federal Government are small businesses or Nontraditional Defense Contractors • Offeror provides at least one third of the total project cost as acceptable cost share

Based on the results of the evaluation of the Enhanced White Papers, Offerors may be selected for funding or not selected.

7.1 Best Value

The Government will conduct the source selection based on the evaluation criteria detailed in Section 6 of the RPP and ratings listed in Table 2. The overall award decision will be based upon a Best Value determination by considering and comparing factors in addition to cost or price. Based on the results of the evaluation, the Government reserves the right to negotiate and request changes to any or all parts of the Offeror's proposal. Offerors will have the opportunity to concur with the requested changes, proposed further changes and revise cost proposals, as necessary.

The RPP review and award process may involve the use of contractors as subject-matter-experts or reviewers; where appropriate, the U.S. Government (USG) will employ NDAs to protect information contained in the RPP as outlined in Section 2.5.

TABLE 2 – 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.

7.2 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 the Government during award performance.

- Weakness - A flaw in the proposal that increases the risk of unsuccessful award performance.

- Deficiency - A material failure of a proposal to meet a Government requirement or a combination of weaknesses in a proposal that increases the risk of unsuccessful award performance to an unacceptable level.

8 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@tunnellgov.com
- 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 an Enhanced White Paper, the Government and the MTEC CM will not discuss evaluation/status until the source selection process is complete.

9 Acronyms/Abbreviations

ACURO	U.S. Army Animal Use and Review Office
ATI	Advanced Technology International
CAS	Cost accounting standards
CFR	Code of Federal Regulations
CM	Consortium Manager
CMA	Consortium Member Agreement
DoD	Department of Defense
EUA	Emergency Use Authorization
FAQ	Frequently Asked Questions
F&A	Facilities and Administrative Costs
FDA	U.S. Food and Drug Administration
FY	Fiscal Year
G&A	General and Administrative Expenses
HIPPA	Health Insurance Portability and Accountability Act
HRPO	Human Research Protections Office, USAMDRC
IACUC	Institutional Animal Care and Use Committee
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IRB	Institutional Review Board
IR&D	Independent Research and Development
M	Millions
MPS	Milestone Payment Schedule
MTEC	Medical Technology Enterprise Consortium
NDA	Nondisclosure Agreement
OCI	Organizational Conflict of Interest
ODC	Other Direct Charges
OTA	Other Transaction Agreement
POC	Point-of-Contact
POP	Period of Performance
ROC	Role of Care
ROM	Rough Order of Magnitude

RPP	Request for Project Proposals
SOW	Statement of Work
USAMRDC	U.S. Army Medical Research and Development Command
USG	U.S. Government, specifically the DoD

10 Enhanced White Paper Template

Page Limitation: The Enhanced White Paper is limited to thirteen (13) pages (including cover page). The following Appendices are excluded from the page limitation: *(4.1) Statement of Work, (4.2) Data Rights, and (4.3) Warranties and Representations*

Required Format: 12 point font (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.

Please note a full Cost Proposal will be requested if the Enhanced White Paper is selected for funding.

Cover Page

[Name of Offeror]
[Address of Offeror]
[Phone Number and Email Address of Offeror]

DUNS #: [DUNS #]
CAGE code: [CAGE code]

[Title of Enhanced White Paper]

[Offeror] certifies that, if selected for award, the Offeror will abide by the terms and conditions of the MTEC Base Agreement.

[Offeror] certifies that this Enhanced White Paper is valid for 3 years from the close of the applicable RPP, unless otherwise stated.

[A proprietary data disclosure statement if proprietary data is included. Sample:
This Enhanced White Paper includes data that shall not be disclosed outside the MTEC Consortium Management Firm and the Government and shall not be duplicated, used, or disclosed, in whole or in part, for any purpose other than to evaluate this Enhanced White Paper and negotiate any subsequent award. If, however, an agreement is awarded as a result of, or in connection with, the submission of this data, the MTEC Consortium Management Firm and the Government shall have the right to duplicate, use, or disclose these data to the extent provided in the resulting agreement. This restriction does not limit the MTEC Consortium Management Firm and the Government's right to use the information contained in these data if they are obtained from another source without restriction. The data subject to this restriction is (clearly identify) and contained on pages (insert page numbers).]

[Title of Enhanced White Paper]

SECTION 1: INITIAL SCREENING SUMMARY (2 page limit)

- **Programmatic Relevance:** [Provide a description of how the proposed technology needs described in this RPP. Include a description to address how the proposed technology addresses a military need]
- **TRL at time of submission:** [Insert]
- **Preliminary Data:** [Briefly describe relevant non-clinical data and/or clinical data.]
- **Technical Abstract and Feasibility:** [Describe the project goals, study design, and deliverables. This description shall also demonstrate a feasible approach to the solution accounting for technical, administrative, and/or programmatic considerations.]
- **Timeliness:** [Indicate estimated timeline for the proposed effort. Briefly describe how the proposed project will provide the end deliverable of the RPP (to have an EUA for the new wearable capability and be ready to distribute the device and test kits within 15 days of receiving the EUA) by the end of the PoP.]
- **Team Capabilities and Expertise**: [Briefly describe the Offeror's capabilities and expertise in relation to the effort proposed.]

SECTION 2: TECHNICAL

Section 2.1: Programmatic Relevance

- Provide the background and the Offeror's understanding of the problem and/or technology gap/process deficiency.
- Provide a description of how the proposed technology meets the needs specified in this RPP.

Section 2.2: Scope Statement

- Define the scope of the effort and clearly state the objectives of the project.

Section 2.3: Scientific Rationale / Preliminary Data

- Describe the scientific rationale for the project, including a brief description of the previous studies or preliminary data that support the feasibility of proposed work.
- Describe relevant non-clinical data and/or clinical preliminary data.
- Describe your demonstration of the manufacturing feasibility of the prototype diagnostic.

Section 2.4: Technical Approach

- Describe the experimental design, methods, and materials required to accomplish the proposed approach. Describe the proposed methodology in sufficient detail to show a clear course of action

- Clinical Trials (if applicable): Clinical trials should be described in adequate detail to assess conformance with FDA regulations, guidance, and the requirements related to its appropriate pathway for development and testing.
    - Provide a description of the purpose and objectives of the study.
    - Describe the clinical intervention, medical drug, biologic, device or human exposure model to be tested. Document the availability and accessibility of the drug/compound, device, or other materials needed for the proposed research.
    - Include a description of study variables, appropriate controls and the endpoints to be tested.
    - Outline the proposed methodology (e.g., study design, data analysis, etc.) in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate.
    - Describe current status of interactions with the U.S. Food and Drug Administration and your plan to meet all regulatory sponsor responsibilities.

Section 2.5: Anticipated Outcomes/Impact

- Provide a description of the anticipated outcomes from the proposed work. List milestones and deliverables from the proposed work.
- Describe the impact that the proposed project would have on the current COVID-19 outbreak, if successful.

Section 2.6: Team

- Describe the qualifications and expertise of the key personnel and organizations that will perform the proposed work.

Section 2.7: Project Management Plan

- Describe the overall project management plan.

Section 2.8: Regulatory and Commercialization Plan

- Briefly describe the regulatory plan, including FDA pathway and designation, strategy for obtaining FDA approvals or clearances.
- Briefly describe the transition and commercialization plan, including a description of the market (civilian and military) and sustainability.

Section 2.9: Resources

- Identify any key facilities, equipment and other resources proposed for the effort. Identified facilities, equipment and resources should be available and relevant for the technical solution being proposed.

Section 2.10: Schedule

- Period of Performance: Indicate the proposed period of performance in months from award.

- Proposed Schedule: Provide a schedule (e.g. Gantt chart) that clearly shows the plans to perform the program tasks in an orderly, timely manner. Provide each major task as a separate line.

Section 2.11: Risk Identification and Mitigation

- Identify key technical, schedule, and cost risks. Discuss the potential impact of the risks, as well as potential mitigations.

SECTION 3: COST ESTIMATE

Section 3.1: Rough Order Magnitude (ROM) Pricing

- The Offeror must provide an estimate based on the technical approach proposed in the Enhanced White Paper. The following ROM pricing shall be included in the Enhanced White Paper. **Use the example table format and template below to provide the ROM pricing.** The labor, travel, material costs, other direct costs, and indirect costs, information should be entered for Offeror (project prime) only. Subcontractors and/or consultants should be included only in the "Subcontractor" section of the table. If selected for award, a full cost proposal will be requested.

Labor	*$ 100,000.00*
Labor Hours	*1,000.0 hrs*
Subcontractors	*$ 50,000.00*
Subcontractors Hours	*500.0 hrs*
Consultants	*[illegible],000.00*
Consultants Hours	*[illegible]00.0 hrs*
Material/Equipment	*$ 75,000.00*
Other Direct Costs	*$ 1,000.00*
Travel	*$ 5,000.00*
Indirect costs	*$ 48,200.00*
Total Cost	*$ 289,200.00*
Fee (*Not applicable if cost share is proposed)*	*$ 0.00*
Total Cost (plus Fee)	*$ 289,200.00*
Cost Share (if cost share is proposed then fee is unallowable)	*$ 290,000.00*
Total Project Cost	*$ 579,200.00*

EXAMPLE

Section 3.2: Estimate Rationale

- The Offeror must provide a **brief** rationale describing how the estimate was calculated and is appropriate for the proposed scope or approach.

SECTION 4: APPENDICES (Please provide as separate attachments)

Appendix 4.1: Statement of Work (template provided below)

- Provide a draft Statement of Work as a separate Word document to outline the proposed technical solution and demonstrate how the contractor proposes to meet the Government objectives. Submitted information is subject to change through negotiation if the Government selects the Enhanced White Paper for award. The format of the proposed Statement of Work shall be completed in accordance with the template provided below.
- The Government reserves the right to negotiate and revise any or all parts of SOW/Milestone Payment Schedule. Offerors will have the opportunity to concur with revised SOW/Milestone Payment Schedule as necessary.

Appendix 4.2: Data Rights Assertions (template provided below)

- The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding Data Rights. It is anticipated that anything delivered under this proposed effort would be delivered to the Government with Government Purpose Data Rights or Unlimited Data Rights.
- If this is not the intent, then you should discuss any restricted data rights associated with any proposed deliverables. If applicable, complete the below table for any items to be furnished to the Government with restrictions. An example is provided.

Appendix 4.3: Warranties and Representations: (template provided below)

- Warranties and Representations are required. One Word (.docx or .doc) or PDF file that contains all Warranties and Representations is required.

APPENDIX TEMPLATES

Appendix 4.1: Statement of Work

The SOW developed by the Lead MTEC member organization and included in the proposal (also submitted as a separate document) is intended to be incorporated into a binding agreement if the proposal is selected for award. If no SOW is submitted with the proposal, there may be no award. The proposed SOW shall contain a summary description of the technical methodology as well as the task description, but not in so much detail as to make the contract inflexible. DO NOT INCLUDE ANY PROPRIETARY INFORMATION OR COMPANY-SENSITIVE INFORMATION IN THE SOW TEXT. The following is the required format for the SOW.

Proposal Number:
Organization:
Title:
ACURO and/or HRPO approval needed:
Introduction/Background (*To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.)*
Scope/Project Objective (*To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.)*
This section includes a statement of what the project covers. This should include the technology area to be investigated, the objectives/goals, and major milestones for the effort.
Requirements (*To be provided initially by the Offeror at the time of proposal submission to be finalized by the Government based on negotiation of Scope/Project Objective).*
State the technology objective in the first paragraph and follow with delineated tasks required to meet the overall project goals. The work effort should be segregated into major phases, then tasks and identified in separately numbered paragraphs (similar to the numbered breakdown of these paragraphs). Early phases in which the performance definition is known shall be detailed by subtask with defined work to be performed. Planned incrementally funded phases will require broader, more flexible tasks that are priced up front, and adjusted as required during execution and/or requested by the Government to obtain a technical solution. Tasks will need to track with established adjustable cost or fixed price milestones for payment schedule. Each major task included in the SOW should be priced separately in the cost proposal. Subtasks need not be priced separately in the cost proposal.

Deliverables (*To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.)*

Results of the technical effort are contractually binding and shall be identified herein. Offerors are advised to read the Base Agreement carefully. Any and all hardware/software to be provided to the Government as a result of this project shall be identified. Deliverables should be submitted in PDF or MS Office format. It must be clear what information will be included in a deliverable either through a descriptive title or elaborating text.

Milestone Payment Schedule (*To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding. The milestone schedule included should be in editable format (i.e., not a picture)***)**

The Milestone Payment Schedule should include all milestone deliverables that are intended to be delivered as part of the project, a planned submission date, the monetary value for that deliverable and any cost share, if applicable. For fixed price agreements, when each milestone is submitted, the MTEC member will submit an invoice for the exact amount listed on the milestone payment schedule. For cost reimbursable agreements, the MTEC member is required to assign a monetary value to each milestone. In this case, however, invoice totals are based on cost incurred and will not have to match exactly to the amounts listed on the milestone payment schedule.

The milestones and associated deliverables proposed should, in general:

- be commensurate in number to the size and duration of the project (i.e., a $5M multi-year project may have 20, while a $700K shorter term project may have only 6);
- not be structured such that multiple deliverables that might be submitted separately are included under a single milestone;
- be of sufficient monetary value to warrant generation of a deliverable and any associated invoices;
- include at a minimum Bimonthly Reports (submitted every other month) which include both Technical Status and Business Status Reports (due the 25th of the respective month), Final Technical Report, and Final Business Status Report. Reports shall have no funding associated with them.

MTEC Milestone Payment Schedule Example						
MTEC Milestone Number	**Task Number**	**Significant Event/ Accomplishments**	**Due Date**	**Government Funds**	**Cost Share**	**Total Funding**
1	N/A	Project Kickoff	12/1/2019	$20,000		$20,000
2	N/A	Bimonthly Report 1 (November - December, Technical and Business Reports)	1/25/2020	$ -		$ -

3	1	Protocol Synopsis	2/28/2020	$21,075		$21,075
4	2	Submission for HRPO Approval	2/28/2020	$21,075		$21,075
5	3	Submission of Investigational New Drug application to the US FDA	3/14/2020	$210,757	$187,457	$398,214
6	N/A	Bimonthly Reports 2 (January - February, Technical and Business Reports)	3/25/2020	$ -		$ -
7	4	Toxicity Studies	4/1/2020	$63,227		$63,227
8	5	FDA authorization trial	4/1/2020	$84,303		$84,303
9	6	Research staff trained	4/15/2020	$ -		$ -
10	7	Data Management system completed	4/30/2020	$ -		$ -
11	8	1st subject screened, randomized and enrolled in study	5/15/2020	$150,000	$187,457	$337,457
12	N/A	Bimonthly Report 3 (March - April, Technical and Business Reports)	5/25/2020	$ -		$ -
13	9	Completion of dip molding apparatus	6/1/2020	$157,829	$187,457	$ 345,286
14	10	Assess potential toxicology	6/1/2020	$157,829		$157,829
15	11	Complete 50% patient enrollment	6/15/2020	$350,000	$187,457	$537,457
16	12	Electronic Report Forms Developed	6/15/2020	$315,658	$187,457	$503,115
17	13	Complete 75% patient enrollment	7/1/2020	$157,829	$93,728	$251,55
18	N/A	Bimonthly Report 4 (May - June, Technical and Business Reports)	7/25/2020	$ -		$ -
19	14	Complete 100% patient enrollment	8/1/2020	$157,829	$93,728	$251,557

20	15	Report results from data analysis	8/5/2020	$157,829		$157,829
21	N/A	Final Reports **(Prior to the POP End**)	8/31/2020	$ -		$ -
			Total	**$2,025,240**	**$1,124,741**	**$3,149,981**

Please Note:

1. Firm Fixed Price Contracts – Milestone must be complete before invoicing for fixed priced contracts.
2. Cost Reimbursable Contracts – You may invoice for costs incurred against a milestone. Invoicing should be monthly.
3. Cannot receive payment for a report (i.e. Quarterly, Annual and Final Reports should not have an assigned Government Funded or Cost Share amount.)
4. Quarterly and Annual Reports include BOTH Technical and Business Reports (separate).
5. Final Report due date must be prior to POP end noted in subcontract.
6. MTEC Milestone Numbers are used for administrative purposes and should be sequential.
7. Task Numbers are used to reference the statement of work if they are different from the MTEC Milestone Number.

Shipping Provisions (*The following information, if applicable to the negotiated SOW, will be finalized by the Government and the MTEC Consortium Manager based on negotiations)*

The shipping address is:
Classified Shipments:
Outer Packaging
Inner Packaging

Reporting

Bimonthly Reports – The MTEC research project awardee shall prepare a Bimonthly Report which will include a Technical Status Report and a Business Status Report in accordance with the terms and conditions of the Base Agreement. (Required)
Final Technical Report – At the completion of the Research Project Award, the awardee will submit a Final Technical Report, which will provide a comprehensive, cumulative, and substantive summary of the progress and significant accomplishments achieved during the total period of the Project effort in accordance with the terms and conditions of the Base Agreement. (Required)

Final Business Status Report – At the completion of the Research Project Award, the awardee will submit a Final Business Status Report, which will provide summarized details of the resource status of the Research Project Award, in accordance with the terms and conditions of the Base Agreement. (Required)

Appendix 4.2: Data Rights Assertions

Data Rights

The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding Data Rights.

It is anticipated that anything delivered under this proposed effort would be delivered to the Government with **Government purpose data rights** or **unlimited data rights**. If this is not the intent, then the proposal should discuss data rights associated with each item, and possible approaches for the Government to gain Government purpose data rights or unlimited data rights as referenced in the Base Agreement. Rights in technical data in each Research Project Award shall be determined in accordance with the provisions of MTEC Base Agreement.

If applicable, complete the below table for any items to be furnished to the Government with restrictions. An example is provided.

Please indicate your assertion:

☐ Unlimited Data Rights.

☐ Government Purpose Data Rights.

☐ Restricted Government Rights as described below.

Technical Data or Computer Software to be Furnished with Restrictions	Basis for Assertion	Asserted Rights Category	Name of Organization Asserting Restrictions	Milestone # Affected
Software XYZ	Previously developed software funded exclusively at private expense	Restricted	Organization XYZ	Milestones 1, 3, and 6
Technical Data Description	Previously developed exclusively at private expense	Limited	Organization XYZ	Milestone 2
Technical Data Description	Previously developed with mixed funding	Government Purpose Rights	Organization XYZ	Milestone 2

Appendix 4.3: Warranties and Representations:
Authority to use Other Transaction Agreement

Section 815 of the National Defense Authorization Act (NDAA) for Fiscal Year 2018, authorizes Department of Defense organizations to carry out prototype projects that are directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or to improvement of platforms, systems, components, or materials in use by the armed forces. The law also requires at least one of the following:

(A) There is at least one nontraditional defense contractor or nonprofit research institution participating to a significant extent in the prototype project.

(B) All significant participants in the transaction other than the Federal Government are small businesses (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)) or nontraditional defense contractors.

(C) At least one third of the total cost of the prototype project is to be paid out of funds provided by sources other than the Federal Government.

A. Prime Contractor: The prime contractor must complete the following table.

1. Legal Name:		**2. DUNS #:**	
3. Point of Contact: Name, Title, Phone #, Email			
4. Prime Contractor is a nontraditional (Y/N)?			
5. Prime Contractor is a nonprofit research institution (Y/N)?			
6. Prime Contractor will provide at least one third of the total cost of the prototype project out of funds provided by sources other than the Federal Government (Y/N)?			
7. Prime Contractor is a small business (Y/N)?			

If the prime contractor has answered "Y" to question 4, 5, or 6, skip Section B and proceed to Section C.

B. Subcontractor(s)/Vendor(s): If the prime contractor is a **traditional** defense contractor and proposes the use of one or more nontraditional defense contractors or nonprofit research institutions, the following information is required **for each** participating nontraditional defense contractor or nonprofit research institution.

8. Legal Name:		**9. DUNS #:**	
10. Dollar Value to be Awarded to Subcontractor:			
11. Point of Contact: (Name, Title, Phone #, Email)		**12. Task/Phase:**	
13. Subcontractor/Vendor is a nontraditional (Y/N)?			
14. Subcontractor/Vendor is a nonprofit research institution (Y/N)?			
15. Subcontractor/Vendor is a small business (Y/N)?			
16. Significant Contribution:			

☐	**A - The significant contribution involves developing, demonstrating or providing a key technology.** *Please describe what the key technology is; why it is key to the medical technology community, and what makes it key.*
☐	**B - The significant contribution involves developing, demonstrating or providing a new technology that is not readily available.** *Please describe what the new part or material is and why it is not readily available.*
☐	**C - The significant contribution involves use of skilled personnel (such as modeling & simulation experience, medical technology design experience, etc.), facilities and/or equipment that are within the capabilities of the designated nontraditional and required to successfully complete the program.** *Please describe the personnel, facilities and/or equipment involved in the proposed program and why they are required to successfully complete the program.*
☐	**D - The use of this designated subcontractor/vendor will cause a material reduction in the cost or schedule.** *Please describe the specific cost or schedule impact to be realized*
☐	**E - The use of this designated subcontractor/vendor will increase medical technology performance.** *Please describe what the performance increase will be attained by the use of this designated nontraditional defense contractor*
1	**In addition to the above please provide the following information:**
Q1	**What additional capability beyond those described in A through E above does this subcontractor/vendor have that is necessary for this specific effort?**
A1	
Q2	**In which task/phase(s) of the effort will the subcontractor/vendor be used?**
A2	
Q3	**What is the total estimated cost associated with the subcontractor/vendor included in the proposal?** *Note: While cost is an indicator for the level of nontraditional defense contractor participation, there is no particular cost threshold required.*
A3	

C. Signature

_____ _____

Signature of authorized representative of proposing Prime Contractor Date

Warranties and Representations Instructions

Section A must be completed for the Prime Contractor.

1. Insert prime contractor's legal name.
2. Insert prime contractor's DUNS #.
3. Insert the Point of Contact (Name, Title, Phone #, Email) for the prime contractor.
4. Indicate Yes (Y) or No (N) if the prime contractor is a nontraditional defense contractor (Note: A nontraditional defense contractor means an entity that is not currently performing and has not performed, for at least the one-year period preceding the issue date of the solicitation, any contract or subcontract for the Department of Defense that is subject to full coverage under the cost accounting standards prescribed pursuant to Section 1502 of Title 41 and the regulations implementing such section.).
5. Indicate Yes (Y) or No (N) if the prime contractor is a nonprofit research institution.
6. Indicate Yes (Y) or No (N) if the prime contractor will provide at least one third of the total cost of the prototype project out of funds provided by sources other than the Federal Government (i.e. will the project contain at least 1/3 cost share).
7. Indicate Yes (Y) or No (N) if the prime contractor is a small business (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)).

Section B must be completed if the Prime Contractor is **traditional** and has proposed nontraditional defense contractors, nonprofit research institutions, or small businesses. Copy, paste, and complete the table found in Section B **for each** participating nontraditional defense contractor, nonprofit research institutions, or small business.

8. Insert subcontractor/vendor's legal name.
9. Insert subcontractor/vendor's DUNS #.
10. Insert the dollar value (cost and fee) to be awarded to the subcontractor/vendor.
11. Insert the Point of Contact (Name, Title, Phone #, Email) for the subcontractor/vendor.
12. Indicate in which specific task/phase(s) of the effort will the subcontractor/vendor be used.
13. Indicate Yes (Y) or No (N) if the subcontractor/vendor is a nontraditional defense contractor (Note: A nontraditional defense contractor means an entity that is not currently performing and has not performed, for at least the one-year period preceding the issue date of the solicitation, any contract or subcontract for the Department of Defense that is subject to full coverage under the cost accounting standards prescribed pursuant to Section 1502 of Title 41 and the regulations implementing such section.).
14. Indicate Yes (Y) or No (N) if the subcontractor/vendor is a nonprofit research institution.
15. Indicate Yes (Y) or No (N) if the subcontractor/vendor is a small business (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)).
16. Explain the subcontractor/vendor's Significant Contribution to the project by answering the questions below.

A - The significant contribution involves developing, demonstrating or providing a key technology. ***Please describe what the key technology is; why it is key to the medical technology community, and what makes it key***.

B - The significant contribution involves developing, demonstrating or providing a new technology that is not readily available. ***Please describe what the new part or material is and why it is not readily available.***

C - The significant contribution involves use of skilled personnel (such as modeling & simulation experience, medical technology design experience, etc.), facilities and/or equipment that are within the capabilities of the designated nontraditional and required to successfully complete the program. ***Please describe the personnel, facilities and/or equipment involved in the proposed program and why they are required to successfully complete the program.***

D - The use of this designated subcontractor/vendor will cause a material reduction in the cost or schedule. ***Please describe the specific cost or schedule impact to be realized.***

E - The use of this designated subcontractor/vendor will increase medical technology performance. ***Please describe what the performance increase will be attained by the use of this designated nontraditional defense contractor***.

Q1 - What additional capability beyond those described in A through E above does this subcontractor/vendor have that is necessary for this specific effort?

Q2 - In which task/phase(s) of the effort will the subcontractor/vendor be used?

Q3 - What is the total estimated cost associated with the subcontractor/vendor included in the proposal? Note: While cost is an indicator for the level of nontraditional defense contractor participation, there is no particular cost threshold required.

Section C must be signed by an authorized representative of the prime contractor.

General Guidance

- Nontraditional defense contractors can be at the prime level, team members, subcontractors, lower tier vendors, or "intra-company" business units, provided that the business unit makes a significant contribution to the prototype project.
- All nontraditional defense contractors must have a DUNS number.
- A foreign business can be considered a nontraditional if it has a DUNS number and can comply with the terms and conditions of the MTEC Base Agreement.

11 BIDS Instructions

This Page Is Intentionally Left Blank. Please See the Presentations Below.

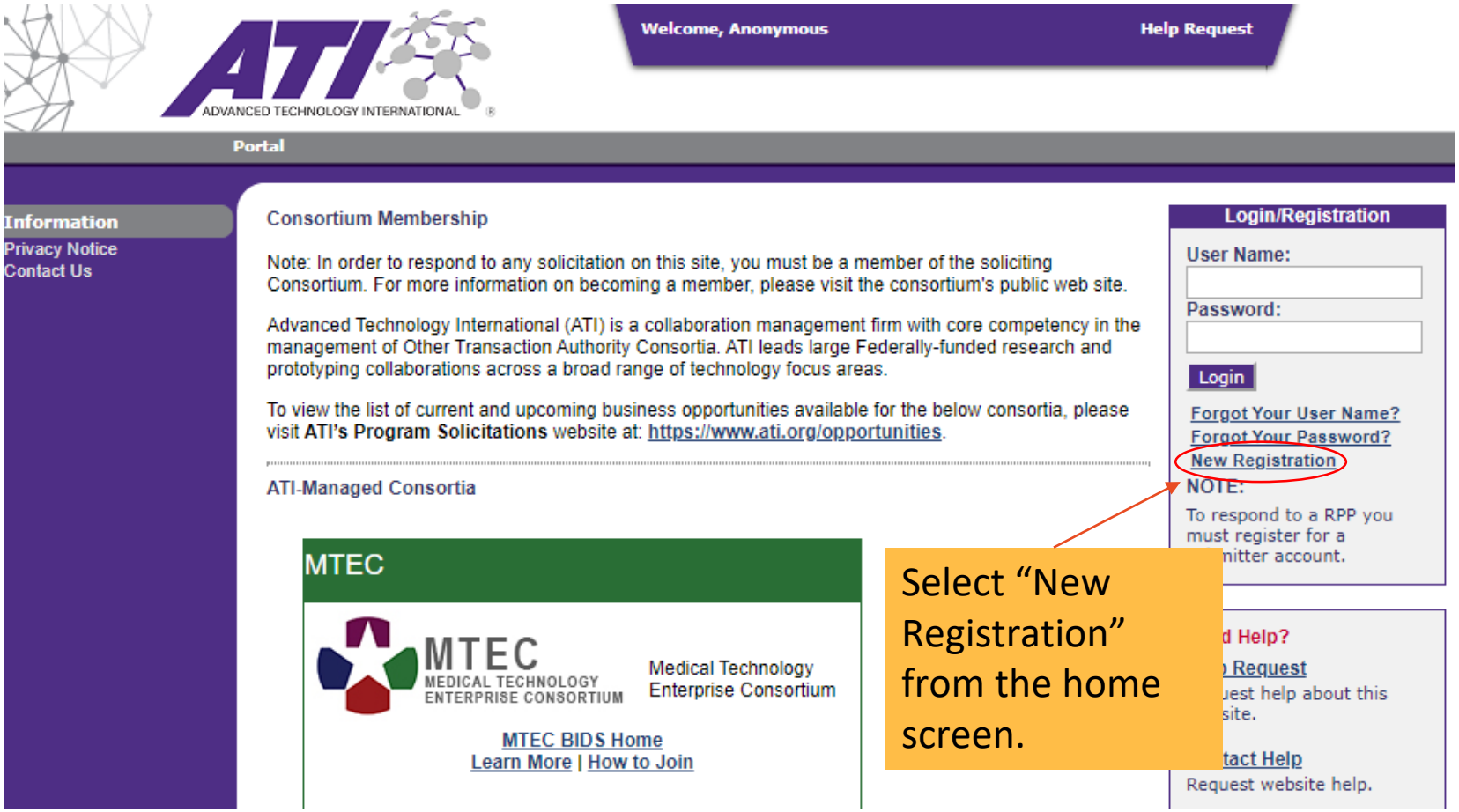
MTEC BIDS REGISTRATION

MTEC BIDS URL:

HTTPS://ATI2.ACQCENTER.COM

BIDS New Registration

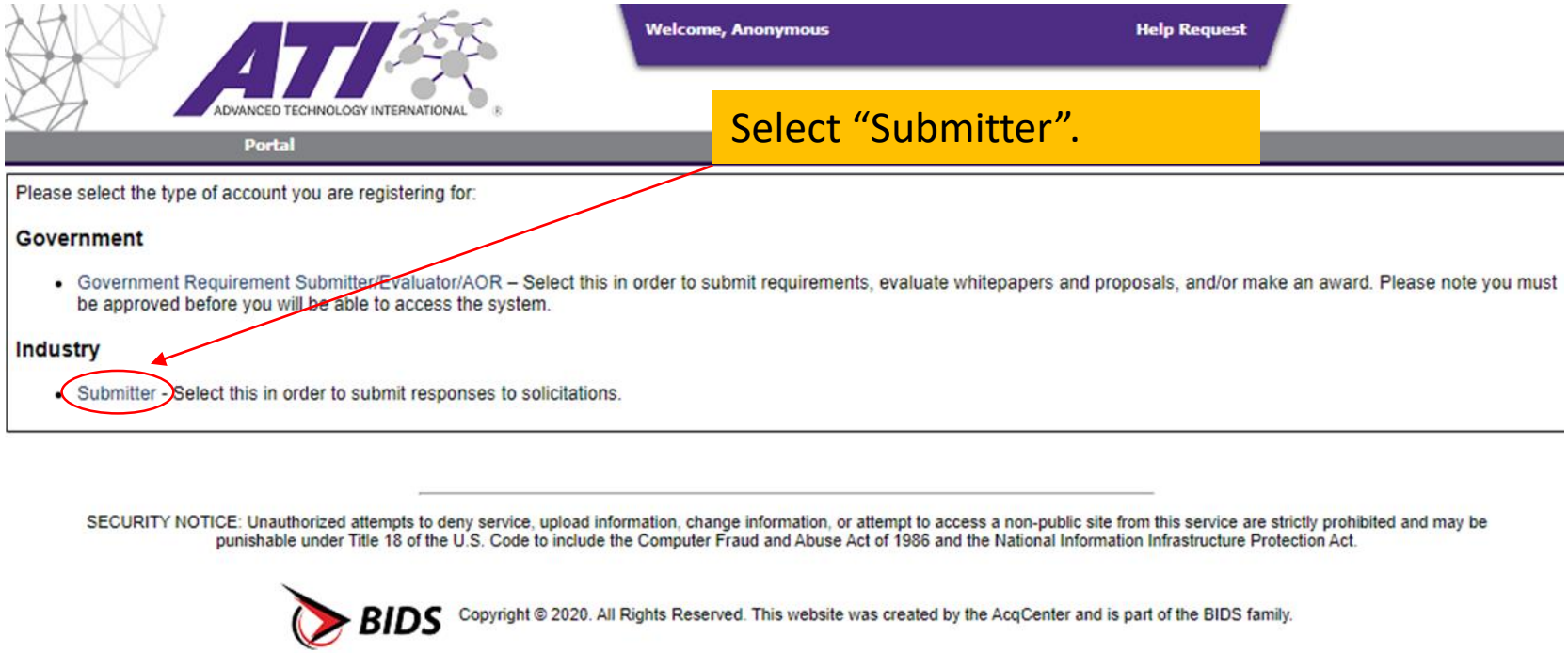
Navigate to the MTEC BIDS website and select “New Registration”



Select “New Registration” from the home screen.

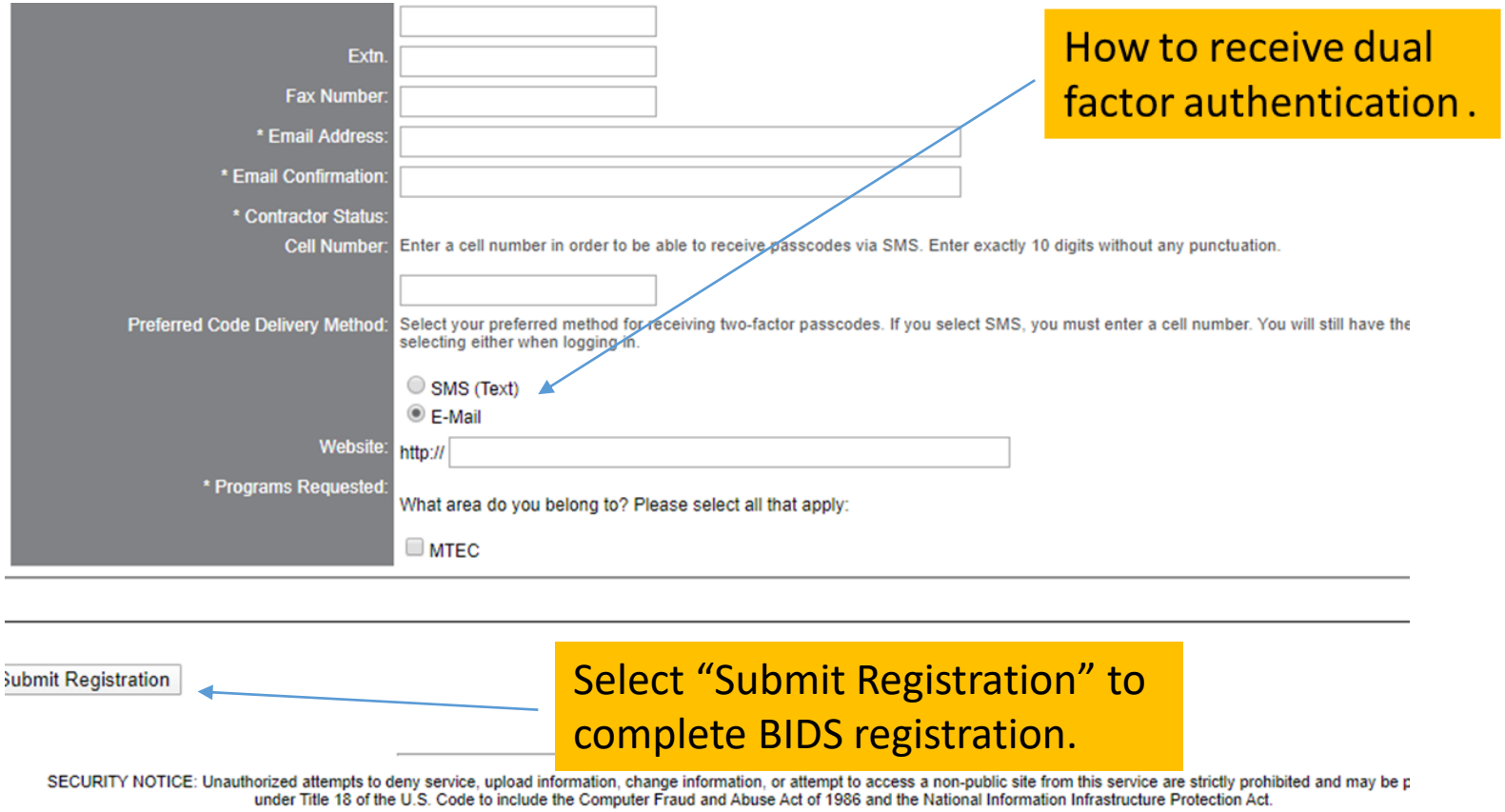
BIDS New Registration

Select “Submitter”



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).



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:

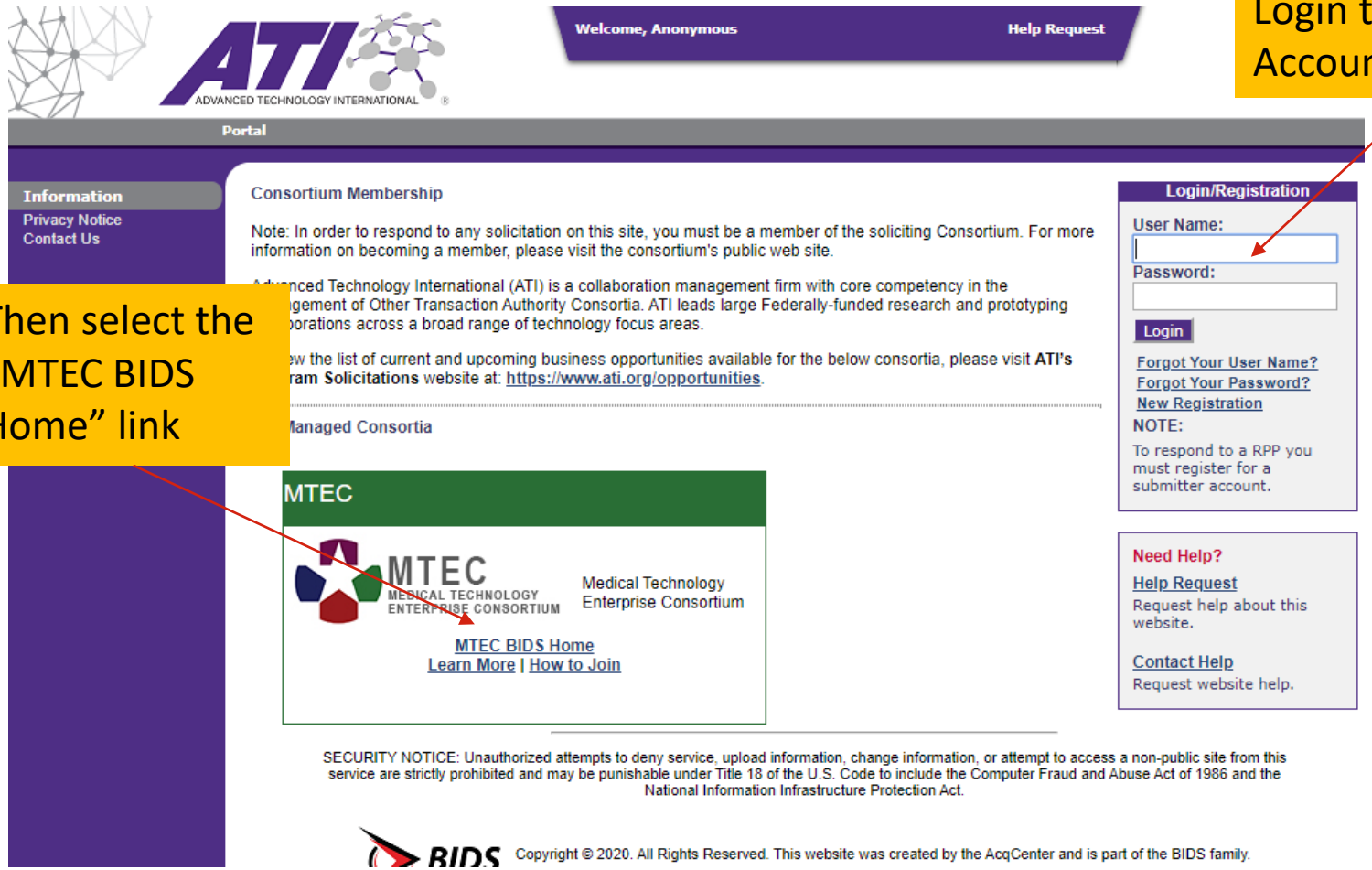
HTTPS://ATI2.ACQCENTER.COM

Proposal Submission BIDS

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

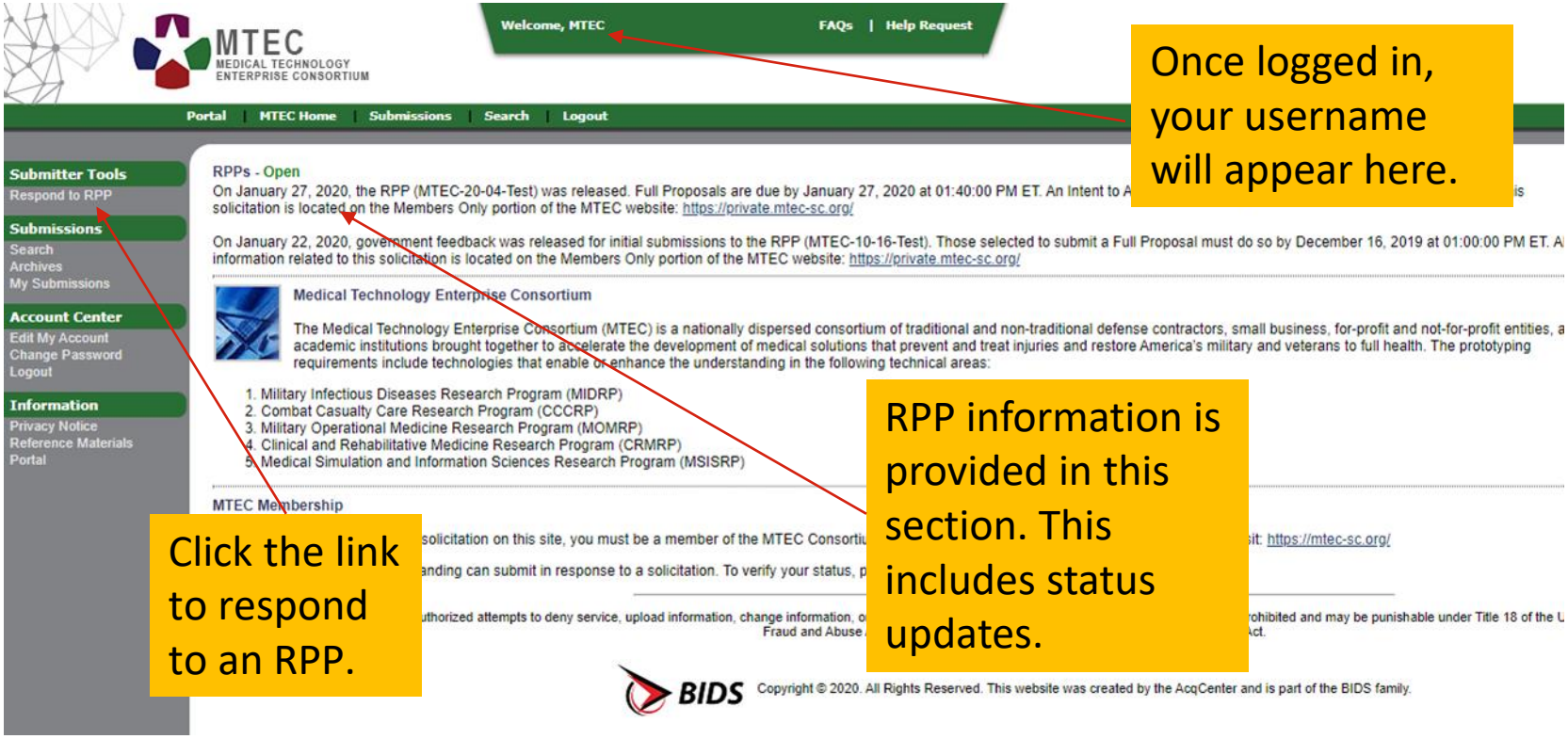
Login to your BIDS Account.

Then select the “MTEC BIDS Home” link



Proposal Submission BIDS

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



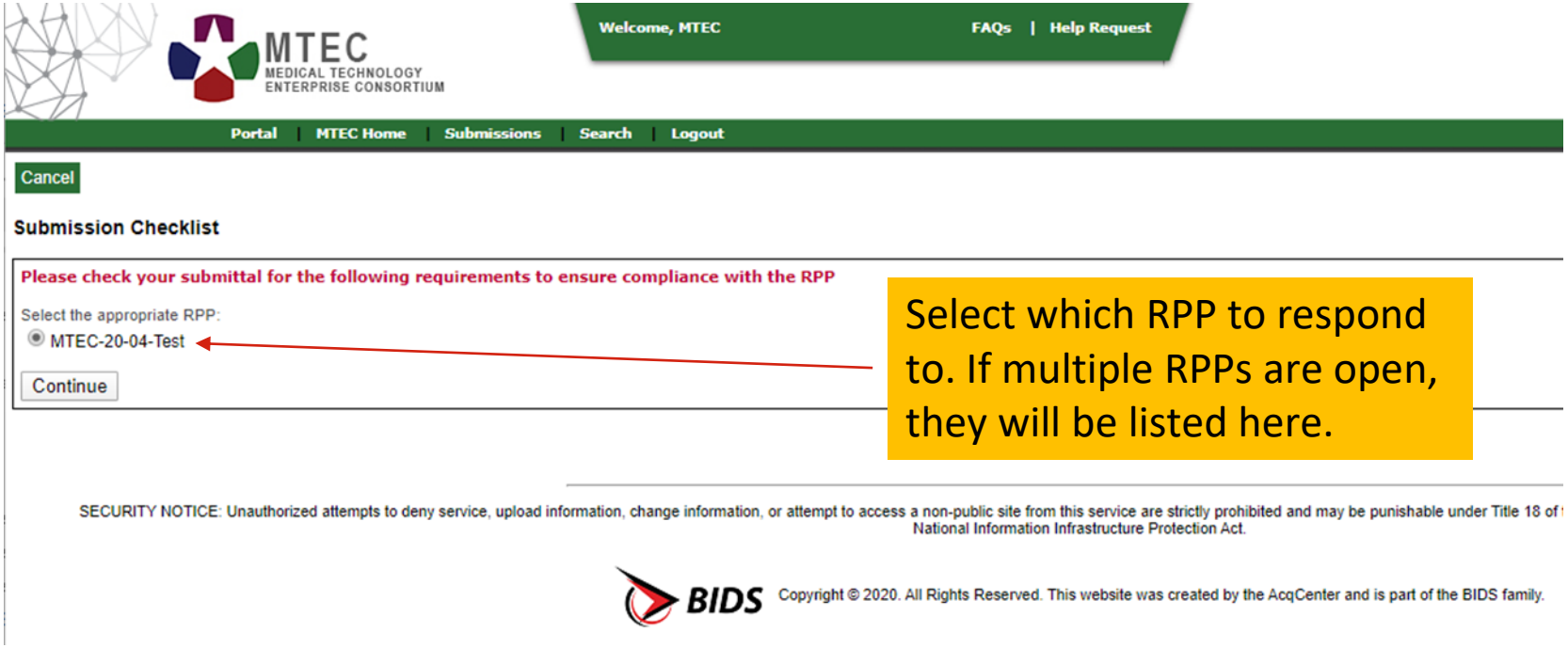
Once logged in, your username will appear here.

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.



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

Proposal Submission BIDS

Complete the submission form.

MTEC
MEDICAL TECHNOLOGY ENTERPRISE CONSORTIUM

Welcome, MTEC FAQs | Help Request

Portal | MTEC Home | Submissions | Search | Logout

Cancel

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

Upload documents in this section.

Once the submission form is completed select submit.

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

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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 <u>two stages</u> (i.e. White Paper to Full Proposal) <u>only the account that submitted the stage 1 proposal</u> (the White Paper) <u>will be allowed to submit for stage 2</u> (the Full Proposal), if selected.

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