Request for Project Proposals



Solicitation Number: MTEC-21-11-NDMS "Military-Civilian National Disaster Medical System (NDMS) Interoperability Study (MCNIS) Pilot Program"

Issued by:
Advanced Technology International (ATI),
MTEC Consortium Manager (CM)
315 Sigma Drive
Summerville, SC 29486
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 Department of Defense (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) engage in 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 at https://mtec-sc.org/.

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 the 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. Proposed prototype projects should not be exploratory in nature and do require a foundation of preliminary data.

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 National Center for Disaster Medicine and Public Health (NCDMPH) at the Uniformed Services University (USU). Enhanced White Papers selected for award as a result of this RPP will be awarded under the authority of 10 U.S.C. § 2371b. Strategic and tactical oversight for the award(s) supported by this RPP will be provided by NCDMPH.

This RPP is focused on the development and implementation of the National Disaster Medical System (NDMS) Pilot Program ("Pilot"). The Pilot is a congressionally required prototype, which will serve as a proof of concept to inform nationwide changes to the existing NDMS. The purpose of the Pilot is to strengthen interoperable partnerships of the NDMS to care for our Nation's combat casualties by increasing medical surge capabilities and capacities at five regional sites. This will be achieved through a collaborative network of federal and civilian NDMS partners. The current Pilot Phase I activities (currently underway during Year 0) will be transitioning (as of September 30, 2021) to Phase II (Pilot Implementation). This RPP is specifically focused on the activities associated with Phase II, which include conducting further NDMS studies, systematically implementing recommended changes, measuring intervention outcomes, and iteratively making improvements to optimize Pilot performance at the five sites. The information generated in Phase II (which will include, but is not limited to, tasks awarded under this MTEC RPP) will inform system-wide changes for nationwide implementation in Phase III.

2 Administrative Overview

2.1. Request for Project Proposals (RPP)

MTEC is utilizing an accelerated approach to award for this RPP. This streamlined approach is anticipated to be a better means to highlight Offeror methodologies and skills required to address the technical requirements described herein. The Enhanced White Paper process requires 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 should submit by the date on the cover page of this RPP. Enhanced White Papers may not be considered under this RPP unless received on or before the due date specified on the cover page.

Each MTEC Enhanced White Paper submitted must be in accordance with the mandatory format provided in Section 8 of the RPP. Enhanced White Papers that fail to follow the mandatory format may be eliminated from the competition during the preliminary screening stage. The Government reserves the right to award Enhanced White Papers received from this RPP on a follow-on prototype OTA or other stand-alone OTAs as necessary to meet mission requirements.

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

2.2. Funding Availability and Period of Performance

The U.S. Government (USG) Department of Defense (DoD) Uniformed Services University of the Health Sciences (USUHS) currently has available a total of approximately **\$9.47 million (M)** to support technical requirements and sub-studies for Phase II Pilot Implementation. The Rough

Order of Magnitude (ROM) pricing required as part of Offerors' Enhanced White Paper shall follow the template in Section 8.

Award and funding from the Government is expected to be limited to the funding specified above and is contingent upon the availability of federal funds for this program. Awards resulting from this RPP are expected to be made in Fiscal Year 2021 under the authority of 10 U.S.C. § 2371b.

Cost sharing, including cash and in kind (e.g., personnel or product) contributions are strongly encouraged, have no limit, and are in addition to the Government funding to be provided under the resultant award(s).

It is expected that MTEC will make a single award to a qualified team to accomplish all tasks. The award shall be led by a centralized point of contact at the prime performer organization. If a single Enhanced White Paper is unable to sufficiently address the entire scope of this RPP's technical requirements (outlined in Section 3), 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. Therefore, it is highly recommended that only Offerors interested in the potential to collaborate with other Offerors submit proposals in response to this RPP.

Award funding will be structured incrementally and based upon completion of Milestones and Deliverables to include formal In Process Review meetings and Critical Decision points incorporated as milestones within the Milestone Payment Schedule (MPS).

The Period of Performance (PoP) is **not to exceed 12 months for the initial scope of work, which is limited to requirements 1-12 and sub-study A (see Section 3.2).** However, as the Pilot Implementation will be conducted over five years, as directed by the NDAA, any resulting award(s) may be modified to extend the PoP and add additional work to further support the overall Phase II activities.

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.

2.3. Acquisition Approach

This RPP will be conducted using the Enhanced White Paper approach. In Stage 1, Offerors are invited to submit Enhanced White Papers using the mandatory format contained in this RPP (see Section 8 of this RPP). The Government will evaluate Enhanced White Papers submitted and will select the proposal(s) that represents the best value using the evaluation criteria in Section 5 of this RPP. The Offeror(s) whose proposed solution is selected for further consideration based on the Enhanced White Paper evaluation will be invited to submit a full cost proposal in Stage 2.

Notification letters will contain specific Stage 2 proposal submission requirements as well as a detailed summary of the Enhanced White Paper technical evaluation.

If applicable, and pending successful completion of the total effort, the Government may issue a non-competitive follow-on production contract or transaction pursuant to 10 U.S.C. § 2371b section f.

The Government-selected prototype project(s) awarded as a result of this solicitation will be funded under the Other Transaction Agreement for prototype projects (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). The same provisions will govern this Base Agreement as the OTA for prototype projects between the Government and MTEC. Subsequently, any proposal that is selected for award will be funded through a Research Project Award issued under the member's Base Agreement. A sample of the MTEC Base Agreement can be found on the MTEC 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.

2.4. Proposers Conference

MTEC will host a Proposers Conference that will be conducted via webinar within two (2) weeks after the release of the RPP. The Proposers Conference is a virtual webinar format that provides potential Offerors the opportunity to interact directly with both MTEC and the Military Sponsor related to this specific funding opportunity. The flow of the Proposers Conference is as follows. First, MTEC provides an administrative overview of this solicitation. Second, the Military Sponsor provides an overview of the technical requirements outlined in Section 3. Finally, all attendees are invited to anonymously type in questions into the webinar's chat function, which are answered verbally and live by the appropriate presenter from MTEC or the Military. We highly encourage anyone interested in this funding opportunity to listen in and/or ask questions. The Proposers Conference typically lasts between 1 and 2 hours. A transcript of the questions and answers period of the Proposers Conference will be posted to the MTEC members only website. Further instructions for registration will be forthcoming via email. If you are unable to attend the Proposers Conference, please submit questions via email to Lauren.Palestrini@mtec-sc.org prior to the date of the Proposers Conference (TBD) so that MTEC can incorporate answers into the published questions and answers transcript. Offerors are advised to check the MTEC website periodically during the proposal preparation period for any clarifications found in Frequently Asked Questions (FAQ) responses.

2.5. MTEC Member Teaming

While teaming is not required for this effort, Offerors are encouraged to consider teaming during the proposal preparation period (prior to Enhanced White Paper 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. The following mechanisms are in place to help facilitate teaming in relation to this 21-11-NDMS RPP.

- 1. Collaboration Database Tool: 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, Research and Development (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.

- 2. **MTEC Public-facing Webpage:** MTEC has also launched a webpage on the MTEC public website specific to this RPP to help MTEC member organizations team with others in preparation for submission of Enhanced White Papers. Please visit for more details: https://www.mtec-sc.org/21-11-ndms-desire-to-team-partner/
- 3. MTEC Member Connect: MTEC will host a virtual "connect" session via webinar to help the membership collaborate and partner in relation to 21-11-NDMS RPP. Each organization will be allotted 1-2 mins to pitch using a standard 1-slide format. Your pitch can be focused on whatever you think would most benefit you in relation to the NDMS RPP, for example, seeking a partner or offering a capability. There will be contact info on each slide so that you can follow-up directly with whomever you would like. Both MTEC members and non-members will be invited to listen in to the presenters.

2.6. 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 who are 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.

2.7. Offeror Eligibility

Offerors must be MTEC Members in good standing. Offerors submitting Enhanced White Papers as the prime contractor must be MTEC members of good standing by May 24, 2021. To join MTEC, please visit http://mtec-sc.org/how-to-join/.

2.8. Cost Sharing Definition

Cost sharing is defined as the resources expended by the award recipients on the proposed statement of work (SOW). Cost sharing above the statutory minimum is not required in order to be eligible to receive an award under this RPP. 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 an in-kind contribution (see Attachment A for definitions); 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.).

2.9. Cost Share Requirements

In order to be compliant with 10 U.S.C. §2371b, Research Projects selected for funding under this RPP are required to meet at least <u>one</u> of the conditions specified in Attachment B ("Statutory Requirements for the Appropriate Use of Other Transaction Authority"). Beyond that, cost

sharing is encouraged if possible, as it leads to stronger leveraging of Government-contractor collaboration. For more information regarding cost share, please see Attachment A.

Proposals that fail to meet the mandatory statutory conditions with regard to the appropriate use of Other Transaction authority, as detailed in Attachment B, will not be evaluated and will be determined ineligible for award.

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 2% of the total funded value of each research project awarded. 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.

2.11. Intellectual Property and Data Rights

Baseline Intellectual Property (IP) and Data rights for MTEC Research Project Awards are defined in the terms of an awardee's Base Agreement, and specifically-negotiated terms are finalized in any resultant Research Project Award.

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 contained in their Base Agreement regarding IP and Data Rights, as modified by the specifically-negotiated IP and Data rights terms herein. It is anticipated that anything created, developed, or delivered under this proposed effort will be delivered to the Government with Government Purpose 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.

See Attachment C for more detail. **All Offerors shall complete and submit Attachment C as an appendix to the Enhanced White Paper** with the Signature of responsible party for the proposing Prime Offeror.

For more information, the CM has published a resource for Offerors entitled, "Understanding Intellectual Property and Data Rights" on the MTEC members-only website.

2.12. Expected Award Date

Offeror should plan on the period of performance beginning **September 15, 2021** (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 by 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 rejected will gain evaluation rationale for non-selection.

3 Technical Requirements

3.1. Background

The FY20 National Defense Authorization Act (NDAA) states the Pilot will be conducted over five years at no less than five locations. The FY20 NDAA was reauthorized in FY21 (Section 741), and it directs the Pilot to establish partnerships with public, private, and nonprofit healthcare organizations in these locations. It also directs the Pilot to establish requirements for staffing, specialized training, medical logistics, telemedicine, patient regulating, movement, situational status reporting, tracking, and surveillance. The Pilot will be conducted in collaboration with the Secretaries of Veteran Affairs, Health and Human Services, Homeland Security, and Transportation. These agencies selected the following five (5) sites representing regional NDMS networks at which the Pilot will be conducted: Washington, DC; San Antonio, TX; Sacramento, CA; Omaha, NE; and Denver, CO. The NDMS definitive care partners in these metropolitan regions will be comprised of military and veterans administration healthcare facilities, Federal Coordinating Centers (FCCs), NDMS partner hospitals, and local health departments within a larger metropolitan area.

The Pilot will be carried out at these sites over five (5) years in three (3) Phases. Phase I is a study called the Military-Civilian NDMS Interoperability Study (MCNIS) and is already underway. MCNIS is designed to identify the NDMS medical surge issues, gaps, and best practices for each location. MCNIS is being conducted by the Operational Research and Integration Office-National Center for Disaster Medicine and Public Health (ORION). During Phase II, study findings will be incorporated into site specific implementation plans, which will be written and operationalized at each of the Pilot sites over five (5) years, per the NDAA (*See Figure 1*). Information, procedures, activities and requirements from each of the sites will be used to develop a model prototype regional system for implementation nationally. Phase III of the Pilot will consist of reporting the results of the Pilot and planning for Pilot expansion in other NDMS locations.

Pilot implementation (Phase II), components of which are the focus of this RPP, will start on September 30, 2021 (note that this is the NDAA-mandated date for the broader Phase II activities but may not align with the actual award date for the resulting MTEC award). During Phase II, ORION will continue to strategically lead and integrate the Pilot effort and continue conducting mixed methods research to assess and guide Pilot operationalization. To complement ORION's research and strategic integration role, a Field Implementation Team (FIT) will be created through this RPP as the Phase II operational arm of the Pilot. The FIT will execute Pilot implementation through operational lines of effort and Site Operational Coordinators in full coordination with

ORION. Of note, this RPP only applies to tasks assigned to FIT during the first year of the five year Pilot implementation. It does not apply to ORION tasks. The Pilot is functionally and organizationally comprised of ORION and FIT collaboratively working together as one Pilot team to conceive, carry out, and study Pilot implementation at the five sites (*See Figure 2*).

Figure 1: Pilot Phases (This RPP focuses on Phase II, specifically Year 1)

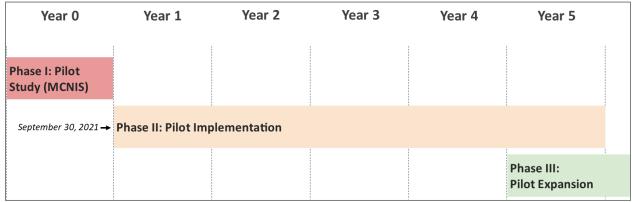
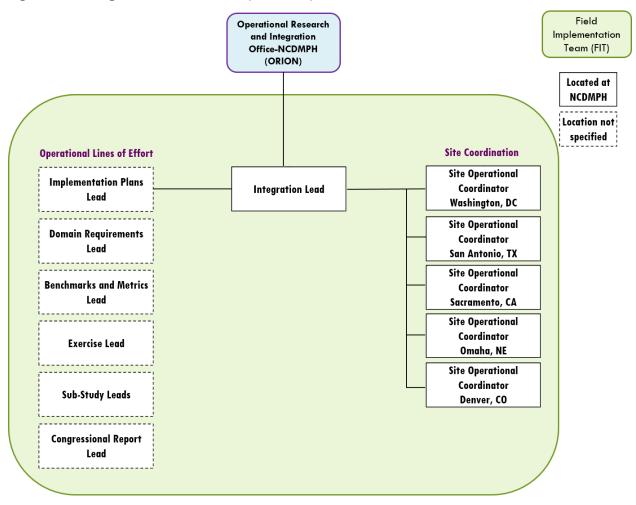


Figure 2: FIT Organization Structure (Notional)



3.2. Technical Requirements for Phase II (Year 1 of the PoP)

The intent of this RPP is to initially award requirements 1-12 in addition to sub-study (A) as described below (under 3.2.2.) with a 12-month PoP. Therefore, all Enhanced White Paper submissions **shall** propose projects that address the specific requirements listed under 3.2.2. by detailing how the Offeror will accomplish/achieve all aspects of these Year 1 requirements to include a clear approach to execute all tasks based upon the Offeror's unique methodology. Therefore, the Offeror shall also clearly identify the major milestones in the Statement of Work/Milestone Payment Schedule associated with accomplishing these Year 1 requirements.

Although Offerors are not required to detail how they will accomplish/achieve all aspects of substudies B-E (as listed under Section 3.3.), the Enhanced White Paper shall briefly outline the proposed methodology to the extent possible to demonstrate the Offeror's capability and its understanding of the resources (to include subject matter experts and subcontractors) required to address the technical requirements described in Section 3.3. Offerors are invited to provide further details to address a more specific technical approach to support these sub-studies; however, this is not mandatory to meet the minimum requirements of this RPP as the focus should be on the work that can be achieved within the funding limits detailed within Section 2.2 (Funding Availability and Period of Performance). As such, sub-studies B-E (as listed under Section 3.3.) represents the additional work contemplated by the Government that may be added in a post-award stage. Should these additional sub-studies be added to the scope of work in the post award stage, the period of performance may also be extended beyond the initial 12-month PoP. Of note, implementation at the five (5) Pilot sites will need to be sustained and studied over the following 48 months (five years total) beyond the initial 12-month PoP [funding for these additional 48 months is unknown at this time].

It is expected that MTEC will make a single award to a qualified team to accomplish all tasks. The NDMS shall be led by a centralized point of contact at the prime performer. It is possible that several subcontractors will be required to accomplish the full scope of the project throughout Phase II (remaining 48 months of Phase II). Furthermore, the Government recognizes that the composition of the team may change as the project requirements evolve over time. Therefore, the Offeror shall include the overall project management plan as part of the Enhanced White Paper submission (as required in Section 8). The Offeror shall also describe its strategy to adjust (i.e. expand) the team, as needed, throughout the period of performance (to include potential follow on tasks) to ensure the proper level of effort, access to the necessary subject matter experts, etc. Therefore, while Offerors are not required to propose against Section 3.3. in great detail, the Enhanced White Paper shall discuss how the current team would be qualified to accomplish these sub-studies and a plan to evolve the team, if applicable, to fully address the demands of those sub-study requirements.

3.2.1. <u>In Process Reviews:</u> As determined necessary by the Government, the Government may conduct periodic In Process Reviews (IPRs) with the Awardee(s) to review the work completed and recommend modifications to the project's plan and Awardee(s)'s team based on an

assessment of the progress to date and the team(s)'s capabilities to meet the program's technical requirements. These IPRs will ensure that the program maintains its maximum flexibility to adapt the direction and modify the team as new information develops and the technical requirements mature over the duration of Phase II. Offerors are required to include the following within the Milestone Payment Schedule contained within the Statement of Work (see Attachment D of the RPP):

- Awardees shall schedule an Initial Baseline Review with NCDMPH within 60 days of contract award.
- Offerors shall arrange two (2) Reviews per year to provide the NCDMPH with updates regarding the status of the contract and prototype. In Process Reviews shall occur:
 - Within 150-180 days from the contract award date, repeated annually.
 - o 30 to 60 days prior to the end of the performing year, repeated annually.

Following these Reviews, the Milestone Payment Schedule within the SOW <u>shall</u> include distinct **Critical Decision Points** (30 days following the In Process Reviews). The Critical Decision Points will serve as discrete programmatic decision points which will allow the Government to assess the progress to date, considering cost, schedule, and performance, and make a determination to proceed with subsequent milestones as awarded, renegotiate any aspect of the SOW/MPS, or end the project

- 3.2.2. Requirements 1-12 & Sub-study (A): The requirements for this prototype project against which Offerors shall propose to execute Phase II (Year one of the PoP) of the NDMS program are below. Note that Offerors are encouraged to propose the use of commercial off-the-shelf products as much as possible rather than proposing the development of new, unique systems/software to avoid extra cost to the Government related to maintenance and updates in the future.
 - Attend a Phase II Kick-off meeting in September 2021 for a debrief on the Phase I Pilot Study (MCNIS) which is currently ongoing in Year 0 (subject to change depending on the actual award date for this requirement). During this meeting, the MCNIS findings will be presented and validated by the convened Pilot stakeholders. The transition to Phase II, Pilot Implementation, will occur at that time.
 - 2. Provide comprehensive coordination between the ORION staff and each of the five sites, working by/with/through NDMS Pilot partners at each site. Provide five (5) Site Operational Coordinators (SOCs) and support teams/staff to conduct this coordination function. SOCs must have expertise in hospital emergency preparedness and experience in NDMS definitive care roles and responsibilities. Additional support staff are expected to be assigned to complete the below tasks, as directed by the FIT-Integration lead and coordinated with the SOCs at the five sites). Figure 2 illustrates the notional organizational relationships. The Offeror is expected to staff and organize against each requirement appropriately. SOCs and their support teams/staff are expected to be embedded on-site at NCDMPH with ORION staff with frequent calls, meetings, and visits

to their respective regions throughout the year. Relocation vs long-distance support/coordination to Pilot sites will be assessed for out-years (balance of Phase II time). Additionally, the FIT Integration Lead and requisite support staff are also expected to be on-site embedded with ORION for this PoP. Operational Lines of Effort staff may be on-site, but are not required; the Operational Lines of Effort structure portrayed in Figure 2 is notional and simply intended to convey functional tasks and not staffing level or organization. (Months 1-12)

- 3. In conjunction with and under the direction of ORION staff and leadership, assess MCNIS Phase I research findings; develop, refine, and translate these findings into Pilot implementation plans for the five pilot sites. (Months 1-6)
- 4. In conjunction with and under the direction of ORION staff and leadership, establish interoperable Pilot requirements for the following medical surge domains: staffing, specialized training, medical logistics, telemedicine, patient regulating, movement, situational status reporting, tracking, and surveillance. (~Months 1-3)
- 5. In conjunction with and under the direction of ORION staff and leadership, establish site-agnostic process and outcome metrics to evaluate the effectiveness of the pilot program at all five sites to include baseline medical surge capacity, capability, and interoperability of the nine medical surge domains. (~Months 1-3)
- 6. In conjunction with and under the direction of ORION staff and leadership, create medical surge interoperability benchmarks for Pilot sites with associated metrics to measure performance. (~Months 1-3)
- 7. In conjunction with and under the direction of ORION staff and leadership, work with local federal and civilian NDMS partners at each of the five sites to refine and validate site-specific implementation plans, while also synchronizing core implementation elements across all five sites to ensure consistency, where appropriate. (Months 1-6)
- 8. In conjunction with and under the direction of ORION staff and leadership, write a master implementation plan and sub-implementation plans for each of the five sites based on MCNIS Phase I findings and site-specific refinement and validation efforts. Implementation plans must establish and strengthen partnerships with "public, private, and nonprofit health care organizations, health care institutions, health care entities, academic medical centers or institutions of higher education and hospitals" to increase the local NDMS interoperability and medical surge capacity to support the definitive care requirements of a large scale overseas conflict. (Months 3-6)
- 9. In conjunction with and under the direction of ORION staff and leadership, begin to operationalize implementation plans at the five sites in collaboration with NDMS partners

(It is expected that implementation will continue beyond this PoP for the remaining four years of Phase II, pending funding) (Months 6-12)

- 10. In conjunction with and under the direction of ORION staff and leadership, conduct a federal level Pilot tabletop exercise, to include representation from the five sites, to validate MCNIS findings, refine the master implementation plan, and assess interagency and baseline public/private partnership metrics. (Months 9-12)
- 11. Provide initial draft Report to Congress to the Sponsor's Office which will be reviewed and finalized by the Government to inform Congress on the NDMS pilot program in accordance with the NDAA required elements. (Months 1-4)
- 12. Augment the implementation plans for each Pilot site, based on the direction of ORION staff and leadership and recommendations generated by the Pilot sub-studies (listed below). (Months 6-12)

Sub-Study Requirements: Enhanced White Papers shall include Sub-study A in the proposed work. However, information below related to Sub-studies B-E is for informational purposes so that Offerors can provide more complete Enhanced White Papers.

A. Conduct Sub-study (A): Assess COVID-19 lessons-learned at each Pilot site, specifically translating these lessons-learned into actionable NDMS recommendations to augment Pilot implementation plan interventions.

3.3. Technical Requirements for Phase II Not Included in the Initial PoP

The information below related to Sub-studies B-E is provided so that Offerors are able to provide more complete responses in their Enhanced White Papers. This work may be added, non-competitively, at any time after the PoP has been initiated [i.e., during the initial 12-month PoP dependent on funding availability and successful completion of milestones]. As required in Section 8, the Enhanced White Paper shall <u>briefly outline</u> the proposed methodology for each sub-study (B-E) to the extent possible to demonstrate a course of action that addresses the technical requirements described in this RPP.

- B. Conduct Sub-study (B): Perform medical surge modeling of national NDMS healthcare capacity, demonstrating the quantity, quality, and duration of available definitive care within the NDMS definitive care hospital partner network over time. Modeling must include three separate cohorts: (1) Military Treatment Facilities, (2) Veterans Affairs Medical Centers, and (3) civilian NDMS definitive care partners.
- C. Conduct Sub-study (C): Conduct a comprehensive review and analysis of the Federal NDMS legislative landscape, specifically describing: (1) the applicable Federal agency policies, plans, and procedures; and (2) the current Federal laws and regulations governing NDMS and recommending options for new or updated laws and regulations to

enable the NDMS to meet the definitive care requirements of a persistent and large scale overseas conflict. Special attention should be given to the gaps/weaknesses in authorities, responsibilities, funding (direct and indirect) and organizational structure of NDMS.

- D. Conduct Sub-study (D): Conduct a review of the State/Regional NDMS legislative landscape, specifically focused on changes needed to strengthen regional participation in NDMS to support the definitive care requirements of a large-scale overseas conflict.
- E. Conduct Sub-study (E): Conduct a study of the direct and indirect incentives which may be created, augmented, and/or aligned to ensure non-federal civilian healthcare organizations will support the NDMS definitive care mission when activated.

3.4. Deliverables of Phase II (Year 1 of the PoP)

At the end of the 1-year PoP, the following deliverables shall be provided to the Government (or successful completion of milestone(s) shall be demonstrated):

- Interoperable Pilot requirements for the following medical surge domains: staffing, specialized training, medical logistics, telemedicine, patient regulating, movement, situational status reporting, tracking, and surveillance [deliverable is due no later than January 15, 2022];
- Site-agnostic process and outcome metrics to evaluate the effectiveness of the pilot program at all five sites to include baseline medical surge capacity, capability, and interoperability of the nine medical surge domains [deliverable is due no later than January 15, 2022];
- Medical surge interoperability benchmarks for Pilot sites with associated metrics to measure performance;
- A master implementation plan and sub-implementation plans for each of the five sites based on MCNIS phase I findings and site-specific refinement and validation efforts;
- A federal level Pilot tabletop exercise, to include representation from the five sites, to validate MCNIS findings, refine the master implementation plan, and assess interagency and baseline public/private partnership metrics;
- Draft report on the NDMS pilot program in accordance with the NDAA required elements for the Sponsor to provide to Congress;
- Operationalized implementation plans at the five sites in collaboration with NDMS partners; and
- Sub-study (A) report which will assess COVID-19 lessons-learned at each Pilot site, specifically translating these lessons-learned into actionable NDMS recommendations to augment Pilot implementation plan interventions.

3.5. Potential Follow-on Tasks

There is potential for award of one or more follow-on tasks based on the success of any resultant Research Project Award(s) (subject to change depending upon Government review of work completed). Note that any potential follow on work is expected to be awarded non-competitively to resultant project awardee(s), potentially as an addition of a new subcontractor(s). Such follow-on work may include (but is not limited to) the following:

- Continuation of Phase II into Years 2 5, potentially with additional sub-studies;
- Expansion of the program into a Phase III, which will increase the number of sites participating in the Pilot and provide comprehensive recommendations for the entire NDMS.

3.6. 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.

4 Enhanced White Paper Preparation

4.1. General Instructions

Enhanced White Papers should 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-21-11-NDMS) on each Enhanced White Paper submitted. See RPP Attachment G for further information regarding BIDS registration and submission.

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

The Enhanced White Paper format, inclusive of a ROM, provided in this MTEC RPP is mandatory and shall reference this RPP number (MTEC-21-11-NDMS). Note that Cost Proposals are only required for Stage 2 and are not part of the initial Enhanced White Paper submission. Offerors are encouraged to contact the Points-of-Contact (POCs) identified herein up until the Enhanced White Paper submission date/time to clarify requirements (both administrative and technical in nature).

All eligible Offerors may 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 DoD Agreements Officer, is legally authorized to contractually bind MTEC into any resultant awards.

4.2. Instructions for the Preparation & Submission of the Stage 1 Enhanced White Paper Offerors submitting Enhanced White Papers in response to this RPP should prepare all documents in accordance with the following instructions:

Offerors should 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.

MTEC will email receipt confirmations to Offerors upon submission. Offerors may submit in advance of the 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 may not be accepted. It is the Offeror's responsibility to ensure a timely and complete submission.

Required Submission Documents (4): Submitted via BIDS

- Enhanced White Paper: One PDF document 5MB or lower.
- Appendix 1 Statement of Work: One Word document 5MB or lower.
- Appendix 2 Data Rights Assertions: One PDF document 5MB or lower.
- Appendix 3 Warranties and Representations: One Word (.docx or .doc) or PDF document 5MB or lower.

Page Limitation: The Enhanced White Paper is limited to ten (10) pages (including cover page). The following Appendices are <u>excluded</u> from the page limitation: (1) Statement of Work, (2) Data Rights Assertions, and (3) Warranties and Representations

The Enhanced White Paper and its Appendices must be in 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. Enhanced White Papers and Appendices exceeding the page and/or size limits specified above may not be accepted. Each document will be uploaded to BIDS separately (see Attachment G of RPP for BIDS instructions).

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

4.3. Stage 2: Cost Proposal (for Only Those Offerors Recommended for Funding)

This notice will be provided in the form of a notification letter from the CM 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 s specific Stage 2 proposal submission requirements, should there be any changes to those contained in this RPP. However, it is anticipated that the following will be required:

Required Submission Documents (4): Submit to mtec-contracts@ati.org

- Section I: Cost Proposal Narrative as one word or PDF document.
- Section II: Cost Proposal Formats as one excel or PDF document.
- Current and Pending Support as one Word or PDF document.

<u>Each document listed above shall be uploaded to BIDS separately (see Attachment G of RPP for BIDS instructions)</u>.

See below for additional instructions. Also refer to Section 5.2 for details on how the full Cost Proposals will be evaluated:

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 Stage 2). Separately, **Section II: Cost Proposal Formats** either in Excel (.xlsx or .xls) or PDF format is required.

Offerors are encouraged to use their own cost formats such that the necessary detail is provided. MTEC will make cost proposal formats available on the Members-Only MTEC website. The Cost Proposal formats provided in the MTEC website and within the PPG 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.

Each Offeror selected for Stage 2 will also submit a **Current and Pending Support** document **(template provided in Attachment F.** The Offeror shall provide this information for all personnel who will contribute significantly to the proposed research project. Specifically, information shall be provided for all current and pending research support (to include Government and nongovernment) including the award number and title, funding agency and requiring activity's names, period of performance (dates of funding), level of funding (total direct costs only), role, brief description of the project's goals, and list of specific aims. If applicable, identify where the proposed project overlaps with other existing and pending research projects. Clearly state if there is no overlap. If there is no current and/or pending support, enter "None."

Those Offerors invited to submit a Cost Proposal are encouraged to contact the MTEC CM and/or Government with any questions so that all aspects of the Stage 2 requirements are clearly understood by both parties.

4.4. 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.

4.5. 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. For more information, please refer to Section 6.1.1 of the MTEC PPG.

4.6. Telecommunications and Video Surveillance

Per requirements from the Acting Principal Director of Defense Pricing and Contracting dated 13 August 2020, the provision at FAR 52.204-24, "Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment" is incorporated in this solicitation. If selected for award, the Offeror(s) must complete and provide the representation as required by the provision to the CM.

5 Selection

The CM will conduct a preliminary screening of submitted Proposals to ensure compliance with the RPP requirements. As part of the preliminary screening process, Proposals that do not meet the requirements of the RPP may be eliminated from the competition or additional information may be requested by the CM. The Government reserves the right to request additional information or eliminate proposals that do not meet these requirements from further consideration. One of the primary reasons for non-compliance or elimination during the initial screening is the lack of significant nontraditional defense contractor participation, nonprofit research institution participation, or cost share (see Attachment B). Proposal Compliance with the statutory requirements regarding the appropriate use of Other Transaction Authority (as detailed within Attachment B) will be determination based upon the ratings shown in Table 1:

TABLE 1- COST SHARING/NONTRADITIONAL CONTRACTOR 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 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 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

5.1. Enhanced White Paper (Stage 1) Evaluation:

The CM will distribute all Enhanced White Papers that pass the preliminary screening (described above) to the Government for evaluation. The Government will then conduct the source selection and determine which Offerors will be invited to submit a Stage 2 cost proposal based on the following Stage 1 criteria, listed in descending order of importance. The overall award decision will be based upon a best value determination by considering factors in addition to cost/price.

- Factor 1 Technical Approach: The Offeror's proposal will be assessed for relevancy, thoroughness, and completeness of the proposed approach (e.g., the technical merit). The Government's evaluation of this factor may include the degree to which the following are addressed and demonstrated:
 - Clear and appropriate objectives;
 - Focused and detailed methodologies for Section 3.2;
 - Overarching approach briefly outlining Section 3.3; and
 - o Thorough and complete SOW and ROM Cost Estimate.
 - Factor 2 Management Approach and Relevant Experience: Strength of the organization/team, experience in enterprise level program/prototype development and execution, considering the qualifications of the personnel, services, and subcontractors, project management plan, and related administrative and information technology support proposed to complete the work. Evaluation of this factor will also be based upon the degree to which the Offeror proposes a coherent organizational structure and sufficient staffing to accomplish the technical objectives.
 - Factor 3 Potential for Transition/Expansion: Soundness and feasibility of the proposed strategy to produce outcomes that can transition to translatable processes, knowledge, capabilities, and technology for adoption across the entire NDMS.

Offerors will receive feedback on each evaluation factor in the form of strengths, weaknesses, and/or deficiencies (see below for definitions). An overall rating will be assigned to each Enhanced White Paper using the adjectival merit ratings explained in Table 2.

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.				

Upon review and evaluation of the Enhanced White Papers, Offerors who are favorably evaluated may be invited for informal discussions with the Government. Upon completion of the Stage 1, Offerors may be recommended for funding, placed into the basket, or not selected. Offerors who are recommended for funding will be invited to submit a full Cost Proposal. See RPP Section 4.3 for additional details. Offerors who are not invited to proceed into Stage 2 will be provided feedback.

The RPP review and award process may involve the use of contractor Subject Matter Experts serving as nongovernmental advisors. All members of the technical evaluation panel, to include contractor SMEs, will agree to and sign a Federal Employee Participation Agreement or a Nondisclosure/Nonuse Agreement, as appropriate, prior to accessing any proposal submission to protect information contained in the Enhanced White Paper as outlined in Section 2.6.

Definitions of General Terms Used in Evaluations:

<u>Strength</u> - 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.

<u>Significant Strength</u> - An aspect of an Offeror's proposal that has appreciable merit or appreciably exceeds specified performance or capability requirements in a way that will be appreciably advantageous to the Government during award performance.

<u>Significant Weakness</u> - A flaw that appreciably increases the risk of unsuccessful award performance.

<u>Deficiency</u> - 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.

5.2. Full Cost Proposal Cost/Price Evaluation by the Consortium Manager (for Only Those Offerors Recommended for Funding)

After completion of the technical evaluation performed by the Government sponsor, the MTEC CM will evaluate the total estimated cost proposed by the Offeror(s) recommended for funding. Evaluation will include analysis of the proposed cost together with all supporting information. The Offeror's cost and rationale will be evaluated for realism, reasonableness, and completeness. The MTEC CM will request additional information or clarification, as necessary, and then provide a formal assessment to the Government. The Government will review this assessment and make the final determination that the negotiated project value is fair and reasonable.

The Cost Proposal(s) will be evaluated using the understanding of cost realism, reasonableness and completeness as outlined below:

a) Realism. Proposals will be evaluated to determine if Costs are realistic for the work to be performed, reflect a clear understanding of the requirements, and are consistent with the various elements of the Offeror's technical approach and Statement of Work.

Estimates are "realistic" when they are neither excessive nor insufficient for the effort to be accomplished. Estimates must also be realistic for each task of the proposed project when compared to the total proposed cost. For more information on cost realism, please refer to the MTEC PPG.

The MTEC CM will make a determination by directly comparing proposed costs with comparable current and historical data, evaluator experience, available estimates, etc. Proposed estimates will be compared with the corresponding technical proposals for consistency.

b) Reasonableness. The Offeror's cost proposal will be evaluated to determine if it is reasonable. For a price to be reasonable, it must represent a price to the Government that a prudent person would pay in the conduct of competitive business. Normally, price reasonableness is established through cost and price analysis.

To be considered reasonable, the Offeror's cost estimate should be developed from applicable historic cost data. The Offeror should show that sound, rational judgment was used in deriving and applying cost methodologies. Appropriate narrative explanation and justification should be provided for critical cost elements. The overall estimate should be presented in a coherent, organized and systematic manner.

Costs provided shall be clearly attributable to activities or materials as described by the Offeror. Costs should be broken down using the Cost Proposal Formats that are located on the Members-Only MTEC website. If the MTEC template is not used, then the Offeror should submit a format providing for a similar level of detail.

c) Completeness. The MTEC CM will evaluate whether the proposal clearly and thoroughly documents the rationale supporting the proposed cost and is compliant with the requirements of the solicitation.

The proposal should clearly and thoroughly document the cost/price information supporting the proposed cost in sufficient detail and depth. The MTEC CM will evaluate whether the Offeror's cost proposal is complete with respect to the work proposed. The MTEC CM will consider substantiation of proposed cost (i.e., supporting data and estimating rationale) for all elements.

Rate and pricing information is required to properly perform the cost analysis of the proposal. If the Offeror is unwilling to provide this information in a timely manner, its proposal will be lacking information that is required to properly evaluate the proposal and the proposal cannot be selected for award.

Best Value

The Government will conduct the source selection based on the evaluation criteria and ratings contained within this RPP. The overall award decision will be based upon the Government's Best Value determination and the final award selection(s) will be made to the most advantageous offer(s) by considering and comparing factors in addition to cost or price. Based on the results of the Stage 1 Technical Evaluation, the Government reserves the right to negotiate (with the support of the MTEC CM) and request changes to any or all parts of the proposal to include the SOW. Offerors will have the opportunity to further review and/or concur with the requested changes and revise cost proposals, as necessary.

6 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@mtec-sc.org

 All other questions should be directed to the MTEC Director of Program Operations Ms. Kathy Zolman, <u>kathy.zolman@ati.org</u>

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.

7 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
FAQ Frequently Asked Questions
F&A Facilities and Administrative Costs
FCC Federal Coordinating Centers
FDA U.S. Food and Drug Administration

FIT Field Implementation Team

FOIA Freedom of Information Act (FOIA)

FY Fiscal Year

G&A General and Administrative Expenses
Government U.S. Government, specifically the DoD
HRPO Human Research Protections Office

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

MCNIS Military-Civilian NDMS Interoperability Study

MPS Milestone Payment Schedule

MTEC Medical Technology Enterprise Consortium

NCDMPH National Center for Disaster Medicine and Public Health

NDA Nondisclosure Agreement

NDAA National Defense Authorization Act
NDMS National Disaster Medical System
OCI Organizational Conflict of Interest

ODC Other Direct Charges
POC Point-of-Contact
PoP Period of performance

ORION Operational Research and Integration Office-National Center for Disaster

Medicine and Public Health

OTA Other Transaction Agreement
PPG Proposal Preparation Guide
ROM Rough Order of Magnitude
RPP Request for Project Proposals
SOCs Site Operational Coordinators

SOW Statement of Work

USAMRDC U.S. Army Medical Research and Development Command

USG U.S. Government

USU Uniformed Services University

8 Enhanced White Paper Template

See the following page for the mandatory Enhanced White Paper Template

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]

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.

Scope Statement

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

Scientific Rationale

• Describe the scientific rationale for the project, including a brief description of the previous programs/studies (use cases) that support the feasibility of proposed work.

Technical Approach

 Describe the methods, organization, and staffing plan required to accomplish the proposed approach. Describe the proposed methodology in sufficient detail to show a clear course of action.

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, if successful.

Potential Follow-On Work

- Offerors are required to price and briefly outline how (including identification of potential subcontractors) they would complete the additional work described in Section 3.3.
 Specifically, Offerors shall discuss how the current team would be qualified to accomplish these sub-studies and a plan to evolve the team, if applicable, to fully address the demands of those sub-study requirements. The additional work, if awarded, may extend the PoP.
- Briefly outline the proposed methodology **for each sub-study (B-E)** listed in Section 3.3. to the extent possible to demonstrate a course of action that addresses the technical requirements described in this RPP.
- Indicate the proposed PoP (duration) for each sub-study (B-E).
- Specify a total (including directs and indirects) cost for each sub-study (B-E).
- Offerors are also invited to propose additional "optional" tasks beyond sub-studies B-E
 that would be relevant to the overall requirement of this RPP. Specify a total (including
 directs and indirects) cost for each additional task proposed.

Team and Management Plan

- Describe the qualifications and expertise of the key personnel and organizations that will perform the proposed work (related specifically to Section 3.2. of the RPP unless the proposed work includes a broader scope).
- Indicate if the team has worked together before.
- Describe any previous enterprise-level program/prototype development and execution
- Describe the overall project management plan that clearly defines roles and responsibilities. This plan should include a communication and conflict resolution plan if the proposal involves more than one company/institution/organization.
- Availability of the team to work onsite at NCDMPH for this PoP and perform travel to Pilot sites as frequently as needed and potentially relocate in the future.
- Indicate if the team has systems/processes in place to work as a hybrid team where some team members will be on-site with ORION at the NCDMPH office and others may be offsite at the Pilot sites or in other office locations.
- Indicate which organizations or types of organizations you will need to team/partner with as your technology advances through program tasks.

Transition/Expansion Strategy

 Describe the overarching strategy to translate the processes, knowledge, capabilities, and technology to enable scalability and implementation across the entire NDMS.

Resources

• Identify any key facilities, equipment, administrative and information technology support and other resources proposed for the effort. Identified facilities, equipment and resources should be available and relevant for the technical solution being proposed.

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.

Risk Identification and Mitigation

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

Cost Sharing

The Enhanced White Paper shall describe any current and past partnerships that maximize
funding dollars from non-government entities (via agreement structure, cost sharing with
industry or other partners) for efforts similar to the NDMS requirement and how these
reduce risk for stakeholders.

- Detail past projects with cost sharing (from non-government entities) and the types and amounts of additional funding that supported previous projects.
- Describe cost share included to support the proposed scope of work.

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 example format shall be included in the Enhanced White Paper (the number of columns should reflect the proposed PoP, i.e., add or delete the yearly budget columns as needed). [NOTE: If invited to Stage 2, the total cost to the Government must not significantly increase from the estimate provided in the ROM (unless otherwise directed by the Government) as award recommendations may be based upon proposed costs within 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.
- As stated in Section 2.2, the USG DoD currently has available a total of approximately \$9.47 million (M) for the entire technical requirement described in Sections 3.2 and 3.3. The actual awarded amount is subject to change and dependent on the successful Offeror(s)'s proposed cost/price. In other words, if the total proposed work costs less than \$9.47 M, then Offerors are invited to propose additional tasks for funding that would accelerate implementation and/or benefit the effort. If the total proposed work costs more than \$9.47 M, then Offerors are invited to modify the columns of the ROM example below so that the Offeror can clearly outline what portion of the work could be accomplished for approximately \$9.47 M and how much the remaining tasks would cost.

	Tasks outlined in Section 3.2 in RPP	Task				
	Requirements 1-12 and Sub-study A	Sub-study B	Sub-study C	Sub-study D	Sub-study E	TOTAL
Labor	\$ 200,000.00	\$ 25,000.00	\$ 25,000.00	\$ 25,000.00	\$ 25,000.00	\$ 300,000.00
Labor Hours	1,500.0 hrs	400.0 hrs	500.0 hrs	500.0 hrs	100.0 hrs	3,000.0 hrs
Subcontractors	\$ 100,000.00	\$ 50,000.00	\$0.00	\$0.00	\$0.00	\$ 150,000.00
Subcontractors Hours	1,000.0 hrs	500.0 hrs	0.0 hrs	0.0 hrs	√ 0.0 hrs	1,500.0 hrs
Government/Military Partner(s)/Subcontractor(s) (subKTR)*	\$0.00	\$0.00	\$0.00		\$0.00	\$0.00
Gov't/Military Prtnrs / subKTR Hours	0.0 hrs	0.0 hre E	XAMPLE	0.0 hrs	0.0 hrs	0.0 hrs

Consultants	\$ 10,000.00	\$ 20,000.00	\$0.00	\$0.00	\$0.00	\$ 30,000.00
Consultants Hours	100.0 hrs	200.0 hrs	0.0 hrs	0.0 hrs	0.0 hrs	300.0 hrs
Material/Equipment	\$ 25,000.00	\$ 200,000.00	\$0.00	\$0.00	\$0.00	\$ 225,000.00
Other Direct Costs	\$ 1,500.00	\$ 1,500.00	\$0.00	\$0.00	\$0.00	\$ 3,000.00
Travel	\$ 10,000.00	\$ 5,000.00	\$0.00	\$0.00	\$0.00	\$ 15,000.00
Indirect costs	\$ 44,600.00	\$ 100,000.00	\$0.00	\$0.00	\$0.00	\$ 144,600.00
Total Cost	\$ 391,100.00	\$ 401,500.00				\$ 867,600.00
Fee (Not applicable if cost share is proposed)	\$ 0.00	\$ 0.00	\$0.00	\$0.00	\$0.00	\$ 0.00
Total Cost (plus Fee)	\$ 391,100.00	\$ 401,500.00	\$ 25,000.00	\$ 25,000.00	\$ 25,000.00	\$ 867,600.00
Cost Share (if cost share is proposed then fee is unallowable)	\$ 870,000.00	\$0.00	\$0.00	\$0.00	\$0.00	\$ 870,000.00
Total Project Cost	\$ 1,261,100.00	\$ 401,500.00	\$ 25,000.00	\$ 25,000.00	\$ 25,000.00	\$ 1,737,600.00

^{*}Use the rows above for "Government/Military Partner(s)/Subcontractor(s)" if the project involves one or more Government/Military Facilities (MHS facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) performing as a collaborator in performance of the project.

Estimate Rationale

• The Offeror must provide a <u>brief</u> rationale describing how the estimate was calculated and is appropriate for the proposed scope or approach.

APPENDICES (excluded from the page limit, and must be uploaded to BIDS as separate documents)

Appendix 1: Statement of Work (template provided in Attachment D)

- 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 2: Data Rights Assertions (template provided in Attachment C)

- 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 as described in Section 2.11.
- If this is not the intent, then you should discuss any restricted data rights associated with any proposed deliverables. If applicable, complete the table within the Attachment for any items to be furnished to the Government with restrictions. An example is provided.

Appendix 3: Warranties and Representations: (template provided in Attachment E)

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

Attachment A - Cost Share

Cost Sharing includes any costs a reasonable person would incur to carry out (necessary to) proposed projects' statements of work (SOW) not directly paid for by the Government. There are two types of cost sharing: Cash Contribution and In-Kind Contribution. If a proposal includes cost share then it cannot include fee. Cost Share may be proposed only on cost type agreements. Prior Independent Research and Development (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.

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 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.

Attachment B – Statutory Requirements for the Appropriate Use of Other Transaction Authority

Nontraditional Defense Contractor Definition

A nontraditional defense contractor is a business unit that has not, for a period of <u>at least one</u> <u>year prior to the issue date of the Request for Project Proposals</u>, entered into or performed on any contract or subcontract for DoD 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. 1502) and the regulations implementing such section. 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.

Significant Extent Requirements

All <u>Offerors shall submit Warranties and Representations (See Attachment E)</u> specifying the critical technologies being offered and/or the **significant extent** of participation of the nontraditional defense contractor and/or nonprofit research institution. The significance of the nontraditional defense contractor's and/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. Providing for a material increase in performance of the prototype project

Conditions for use of Prototype OT Authority

Proposals that do not include one of the following will not be eligible for award:

- (A) At least one nontraditional defense contractor or nonprofit research institution participating to a significant extent in the prototype project; or
- (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; or
- (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.

This requirement is a statutory element of the Other Transaction Authority and will be regarded as a pass/fail criterion during the Compliance Screening in order to ensure compliance with 10 U.S.C. §2371b.

Attachment C – Intellectual Property and Data Rights

Definitions

- Intellectual Property (IP) Rights for MTEC Research Project Awards will be defined in the terms of an awardee's Base Agreement, and specifically-negotiated terms will be finalized in any resultant Research Project Award. MTEC Base Agreements are issued by the MTEC CM to MTEC members receiving Research Project Awards. Base Agreements include the applicable flow down terms and conditions from the Government's Other Transaction Agreement with MTEC, including the IP terms and conditions.
- <u>Data Rights</u>: The Offeror shall comply with the terms and conditions contained in their Base Agreement regarding Data Rights, as modified by the specifically-negotiated Data rights terms herein. Refer to Section 2.11 of this RPP for expectations regarding data rights.

Directions to the Offeror

If applicable, complete the below table for any items to be furnished to the Government with restrictions. An example is provided. If the Offeror does not assert data rights on any items, a negative response is required by checking the applicable box below.

Failure to complete this attachment in its entirety (including a failure to provide the required signature) may result in removal from the competition and the proposal determined to be ineligible for award.

If the Offeror intends to provide technical data or computer software which existed prior to or was produced outside of the proposed effort, to which the Offeror wishes to maintain additional rights, these rights should be asserted through the completion of the table below.

Note that this assertion is subject to negotiation prior to award.

If Offeror WILL be asserting data rights for the proposed effort, check this box and complete the table below, adding rows as necessary.

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	Restricted	Organization XYZ	Milestones 1, 3, and 6

	exclusively at private expense			
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
If the Offeror will	NOT be asserting data	rights for the pro	posed effort, check	this box.

If the Offeror will NOT be asserting data rights for the proposed effort	rt, check this box.
Signature of responsible party for the proposing Prime Offeror	DATE

Attachment D – Statement of Work Template

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 scope 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 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. 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 multiyear 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.
- incorporate all of the milestones and deliverables detailed within Section 3 of this RPP to include the In Process Reviews followed by Critical Decision Points (scheduled 30 days after the IPRs). Note that the Critical Decision Points shall have no funding associated with them.

	N	TEC Milestone Paym	ent Sched	ule Examp	le	
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
1	IN/A	Project Nickon	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	1 st 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. Bimonthly and Final Reports should not have an assigned Government Funded or Cost Share amount.)
- 4. Bimonthly and Annual Reports include BOTH Technical and Business Reports (separate).
- 5. Final Report due date must be prior to POP end noted in Research Project Award.
- 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.
- 8. Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies [if applicable].
- 9. Allow at least 2 to 3 months for HRPO regulatory review and approval processes [if applicable].

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)

Attachment E – Warranties and Representations Template

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 r	nontraditional (Y/N)?	
5. Prime Contractor is a r	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 s	mall 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:		12. Task/Phase:	
(Name, Title, Phone #, Email)			
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 a	ddition 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.

- 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.

Attachment F – Current & Pending Support Template

Include the requested information for each person who will contribute significantly to the proposed research project

Current

Award Number:

Title:

Funding Agency/Requiring Activity:

Dates of Funding:

Total Awarded Costs:

Role: (i.e., Principal Investigator, Co-Investigator, etc.)

Brief summary of the scope of work:

Award Number:

Title:

Funding Agency/Requiring Activity:

Dates of Funding:

Total Awarded Costs:

Role: (i.e., Principal Investigator, Co-Investigator, etc.)

Brief summary of the scope of work:

[Add additional fields, if needed, to report all current support]

Pending

Title of Proposal:

Funding Agency/Requiring Activity:

Estimated Dates of Funding:

Proposed Total Direct Costs:

Role: (i.e., Principal Investigator, Co-Investigator, etc.)

Brief summary of the scope of work:

Title of Proposal:

Funding Agency/Requiring Activity:

Estimated Dates of Funding:

Proposed Total Direct Costs:

Role: (i.e., Principal Investigator, Co-Investigator, etc.)

Brief summary of the scope of work:

[Add additional fields, if needed, to report all current support]

Attachment G – BIDS Instructions
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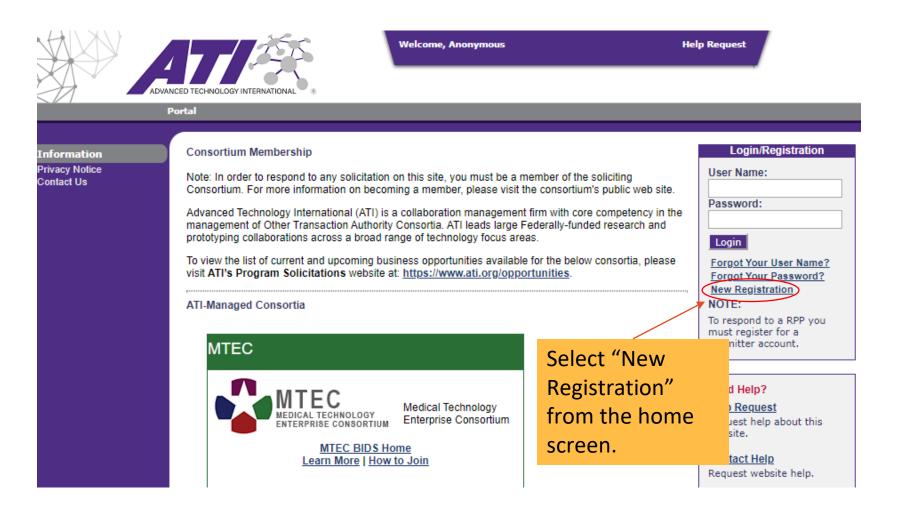
MTEC BIDS REGISTRATION

MTEC BIDS URL:

HTTPS://ATI2.ACQCENTER.COM

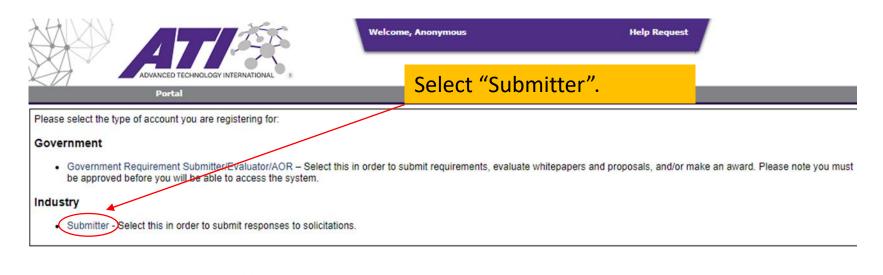


Navigate to the MTEC BIDS website and select "New Registration"





Select "Submitter"



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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:	How to receive dual factor authentication.
* 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:	selecting either when logging in. SMS (Text)
Website:	E-Mail http://
* Programs Requested:	What area do you belong to? Please select all that apply:
Submit Registration	Select "Submit Registration" to complete BIDS 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.



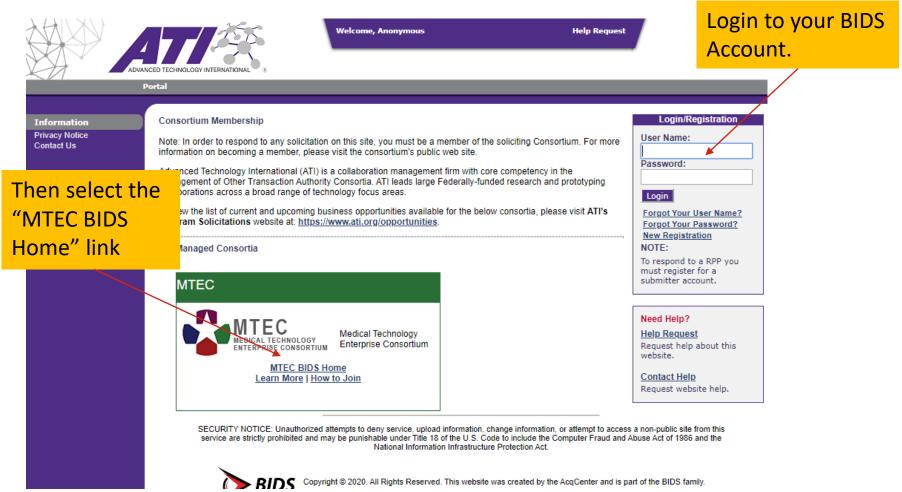
MTEC BIDS PROPOSAL SUBMISSION

MTEC BIDS URL:

HTTPS://ATI2.ACQCENTER.COM

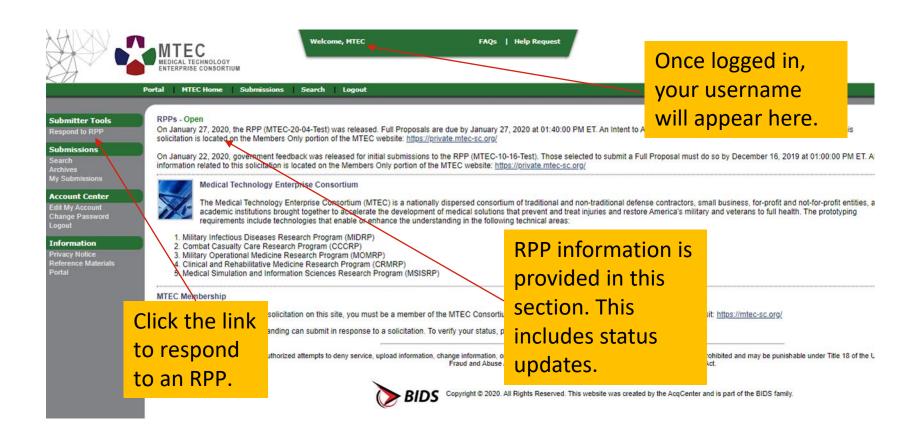


Navigate to the MTEC BIDS site and login. After login select the "MTEC BIDS Home" link.



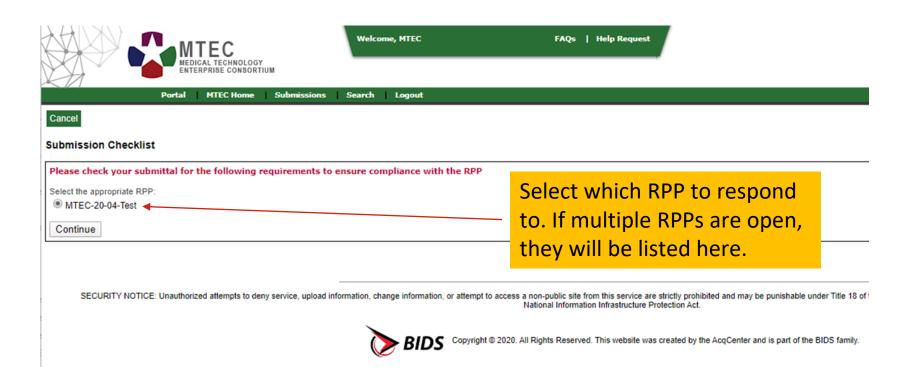


Select the "Respond to RPP" link under the submitter tools



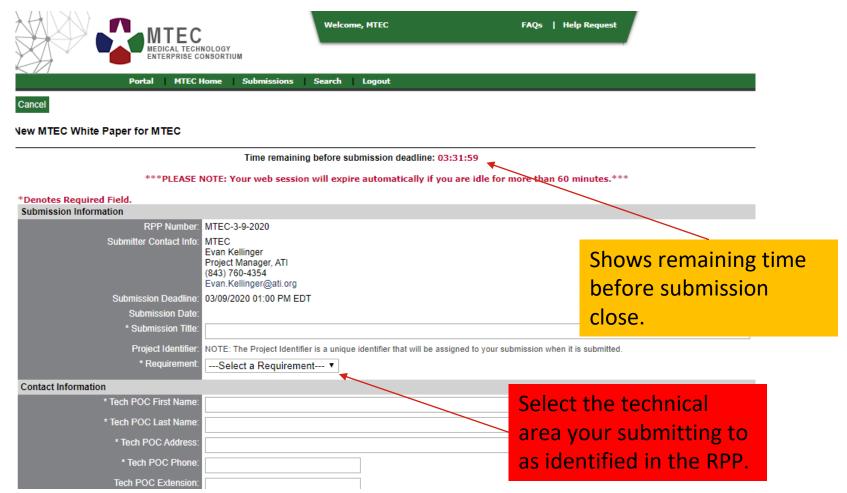


Select which RPP you will be responding to.



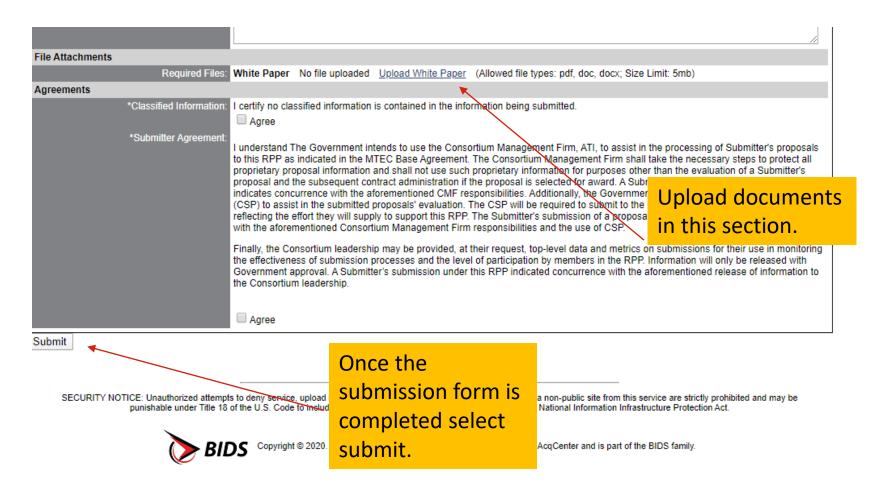


Complete the submission form.





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





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.