# **Request for Project Proposals**



#### Solicitation Number: MTEC-23-09-NDMS-Modular

#### "National Disaster Medical System (NDMS) – Modular/Convertible Capability Pilot"

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 Department of Defense (DoD) U.S. Army Medical Research and Development Command (USAMRDC) and other Government 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 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 prototype projects with USAMRDC. In accordance with 10 USC 4022 (formerly 10 USC 2371b), the MTEC OTA enables the Government 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. As defined in the DoD 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 in support of the Deputy Assistant Director, Acquisition & Sustainment at the Defense Health Agency (DHA). Enhanced White Papers selected for award as a result of this RPP will be awarded under the authority of 10 U.S.C. § 4022. Strategic oversight for the award(s) resulting from this RPP will be provided by DHA.

The National Disaster Medical System (NDMS) modular/convertible capability Pilot Program is a congressionally required prototype, which will serve as a proof of concept to inform nationwide changes to the existing NDMS program. The Pilot's intent is to increase medical surge capabilities and capacities to care for our Nation's combat casualties by strengthening interoperable NDMS partnerships at five Pilot medical facility sites (referred to as "Pilot sites"). As directed by the FY21 NDAA, the Pilot is a collaboration between the Secretary of Defense and the Secretaries of Veteran Affairs, Health and Human Services, Homeland Security, and Transportation. These agencies are supporting the five Pilot sites: Washington, DC / National Capital Region; San Antonio, TX; Sacramento, CA; Omaha, NE; and Denver, CO. The Government is requesting proposals from healthcare facilities, academic institutions, and professional entities with experience in agile development and testing of modular and/or convertible medical facilities. The Pilot will leverage a collaborative network of federal and civilian NDMS partners who currently support the ongoing interoperability pilot being facilitated by the Uniformed Services University (USU). This RPP is specifically focused on the activities associated with prototype development and testing of a modular/convertible medical surge capability with iterative improvements to optimize the capability, as well as development of a training curriculum required to activate the surge capability.

\*Note: Pending successful completion of this effort, the Government may issue a non-competitive follow-on production contract or transaction pursuant to 10 U.S.C. § 4022 section f.

# 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 this RPP. Enhanced White Papers that fail to follow the mandatory format

may be eliminated from the competition during the CM's preliminary screening stage (see Section 5 for more details on the Selection process). The Government reserves the right to award Enhanced White Papers received from this RPP on a follow-on prototype OTA or other standalone 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 USG currently has available \$12,815,730 for Fiscal Year (FY) 2022 for an initial base period of performance (PoP1) of up to 12 months (see the Acquisition Approach and Rolling Downselection details under Section 2.3. below). The proposed budget should be commensurate with the nature, scope and complexity of the proposed research and development; however, it is highly encouraged that the maximum budget requested by each Offeror is \$6,000,000. Offerors are encouraged to scope out their budgets in alignment with major deliverables of the proposed work so that large budgets are easier to evaluate, and the USG can more easily allocate available funding. The USG reserves the right to request adjustments to proposed budgets as a condition of award. Additional FY23 funding of approximately \$17,193,750 is anticipated for the performer(s) that is selected for the continuation of prototype development under the subsequent PoP (PoP2) of the resultant award(s), after the Go/No-go Decision Point. Additionally, there is the potential for funding in the outyears. Note, however, that as of the release date of this RPP, future year Defense Appropriation Bills have not been approved and there is no guarantee that any additional funds will be made available to support this program past FY23 funding.

The funding estimated for this RPP is approximate and subject to realignment. Award and funding from the Government is contingent upon the availability of federal funds for this program.

MTEC anticipates that multiple awards to qualified Offerors will be made in FY23 to accomplish the scope of work, but more than one award is not guaranteed as final award decisions will be based upon, among other factors, programmatic relevancy and overall best value solutions determined to be in the Government's best interest.

The initial PoP (PoP1) is not to exceed **12 months**, and is expected to begin in September 2023. This solicitation is focused on proposals that offer near-term solutions to immediately improve the NDMS, which can be completed within the specified PoP.

# 2.3. Acquisition Approach and Rolling Downselection

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 and will select those that best meet its current priorities using the evaluation criteria in Section 5 of this RPP. Offerors 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 and may be required to submit additional documentation or supplemental information such as those examples listed under Section 4.2. Notification letters will contain specific Stage 2 proposal submission requirements as well as a detailed summary of the Enhanced White Paper technical evaluation.

Offerors are hereby notified that the Government intends to utilize a **rolling downselect** approach <u>during the performance</u> of prototype projects awarded as a result of this RPP. Using this approach, the Government intends to award projects, structured into two PoPs with an initial base period (PoP1) reflecting *the first of the two PoPs*. After an In-Process Review (IPR), an evaluation of project deliverables and other considerations to include progress towards completion of the base PoP1 tasks, the Government intends to award a second PoP, referred to as the subsequent PoP (PoP2), to the performer(s) that demonstrates a best value approach for follow-on tasks. Award decisions for the subsequent PoP (PoP2) work will be completed during the Go/No-go Decision Point which is expected to occur at approximately 9 months into PoP1. See the information related to the "Go/No-Go Decision Point for Downselects" provided under Section 3.3. of this RPP for additional details.

The Government reserves the right to end all awarded projects after the initial base period and award no subsequent PoP2 tasks depending on project outcomes, availability of funding, and changing Government requirements. Additionally, the Government reserves the right to negotiate with performers (selected for award under this RPP), on a noncompetitive basis, to award additional scope to successful projects. While this is anticipated to occur after the subsequent PoP2, this may occur at any time following award of OTA for prototype projects.

The Government reserves the right to reduce the scope/funding of the subsequent PoP2 for the continuation of prototype development as part of the rolling downselect, if the Offeror's technology after the initial base period (PoP1) excels only in a limited number of the solutions requirements detailed in Section 3 of this RPP. Furthermore, the Government reserves the right to encourage teaming arrangements between any or all of the base PoP1 awardees / performers to collaborate in the subsequent PoP award phase (PoP2) to maximize performance across the greatest number of the solutions requirements, and may allocate the subsequent PoP2 funds in accordance with participation in such a collaboration.

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 (RPA) issued under the member's Base Agreement. The MTEC Base Agreement can be found on the MTEC website and Members-Only website at www.mtec-sc.org. At the time of the submission, if Offerors have not yet executed a Base Agreement, then Offerors must certify on the cover page of their Enhanced White Paper that, if selected for award, they will abide by the terms and conditions of the latest version of the MTEC Base Agreement. If the Offeror already has executed an MTEC Base Agreement with the MTEC CM, then the Offeror must state on the cover page of its Enhanced White Paper that, if selected for award, it anticipates the proposed effort will be funded under its executed MTEC Base Agreement.

# **2.4.** Proposers Conference

MTEC will host a Proposers Conference that will be conducted via virtual webinar within two weeks after the release of the RPP. The Proposers Conference will provide an administrative overview of this RPP process to award and present further insight into the Technical Requirements outlined in Section 3 of this RPP. It is highly encouraged to attend the Proposers Conference if you are interested in submitting a proposal in response to this RPP. 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. Proprietary Information

The MTEC CM will oversee submission of proposals and analyze cost proposals submitted in response to this RPP. The MTEC CM shall take the necessary steps to protect all proprietary proposal information and shall not use such proprietary information for purposes other than the evaluation of an Offeror's proposal and the subsequent agreement administration if the proposal is selected for award. In accordance with the Proposal Preparation Guide (PPG), 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. Therefore, 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 entities. MTEC Officers and Directors who are granted proposal access have signed Nondisclosure 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, which may include contractor support personnel serving as nongovernmental advisors, will agree to and sign a Federal Employee Participation Agreement or a Nondisclosure/Nonuse Agreement, as applicable.

# 2.6. 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 two resources may help prime contractors provide a more complete team for this requested scope of work.

# 2.6.1. MTEC M-Corps

The MTEC M-Corps is a network of subject matter experts and service providers to help MTEC members address the business, technical, and regulatory challenges associated with medical product development. M-Corps offers members a wide variety of support services, including but not limited to: Business Expertise [i.e., business development, business and investment planning, cybersecurity, finance, intellectual asset management, legal, logistics/procurement, pitch deck coaching, transaction Advisory], and Technical Expertise [i.e., chemistry, manufacturing and controls (CMC), clinical trials, concepts and requirements development, design development and verification, manufacturing, process validation, manufacturing transfer quality management, regulatory affairs]. Please visit https://www.mtec-sc.org/m-corps/ for details on current partners of the M-Corps.

# 2.6.2. MTEC Database Collaboration 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 regard 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 Tool can be accessed via the "MTEC Profiles Site" tab on the MTEC members-only website.

# 2.6.3. Chat Forum

A dedicated chat forum has been established to facilitate direct interaction amongst MTEC members in relation to this active funding opportunity. The chat forum can be accessed via the "Team Portal" on the MTEC members-only website - <u>https://private.mtec-sc.org/</u>.

# 2.6.4. MTEC Member Connect

MTEC will host a virtual "connect" session via webinar to help the membership collaborate and partner in relation to 23-09-NDMS-Modular 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 be most beneficial to 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. A separate email will be sent to the MTEC membership with details on the date/time and registration link.

## 2.6. Offeror Eligibility

Offerors must be MTEC Members in good standing to be eligible to submit an Enhanced White Paper. Offerors submitting Enhanced White Papers as **the prime performer must be MTEC members of good standing at least 3 days prior to submission of the Enhanced White Papers**. Subcontractors (including all lower tier subawardees) do not need to be MTEC members. To join MTEC, please visit <u>http://mtec-sc.org/how-to-join/</u>.

### 2.7. 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 **Section 7.4 of the PPG** 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.).

#### 2.8. Cost Sharing Requirements

In order to be compliant with the statute for awarding prototype projects, Research Projects selected for funding under this RPP are required to meet at least <u>one</u> of the conditions specified in **Section 3 of the PPG**. 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 **Section 7.4 of the PPG**. Proposals that fail to meet the mandatory statutory conditions with regard to the appropriate use of Other Transaction authority, as detailed in **Section 3 of the PPG**, will not be evaluated and will be determined ineligible for award.

#### 2.9. 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. The MTEC Assessment Fee is not allowable as a direct charge to any resulting award or any other contract. Therefore, Offerors shall not include this Assessment Fee as part of their proposed direct costs. Members who have not paid the assessment fee within 90 days of the due date are not "Members in good standing".

# 2.10. Intellectual Property and Data Rights

Baseline IP and Data Rights for MTEC Research Project Awards are defined in the terms of an awardee's Base Agreement and, if applicable, 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 prior to final award decision and 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 6 of the PPG** for more detail. Note that as part of the Stage 1 of the RPP process (submission of an Enhanced White Paper), **Offerors shall complete and submit Attachment 6 of the PPG (Intellectual Property and Data Rights) as an appendix to the Enhanced White Paper** with the Signature of the 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.

# 2.11. Expected Award Date

Offerors should plan on the period of performance beginning September 30, 2023 (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.

# 2.12. Anticipated Enhanced White Paper Selection Notification

As the basis of selections is completed, the Government will forward its selections to the MTEC CM to notify Offerors. All Proposers will be notified by email from the MTEC CM of the results of the evaluation. Those successful will move forward to the next stage of the process.

Offerors are hereby notified that once an Enhanced White Paper has been submitted, neither the Government nor the MTEC CM will discuss evaluation/status until after the Offeror receives the formal notification with the results of this evaluation.

# **3** Technical Requirements

# 3.1. Background

National Defense Authorization Act (NDAA) of FY20 authorized the Department of Defense (DoD) Pilot on civilian and military partnerships to enhance interoperability and medical surge capability and capacity of the NDMS. The FY22 DoD Appropriations Act included funding to initiate a Pilot to develop a joint civilian-military modular surge facility. The DoD assigned responsibility for the Pilot to the DHA. DHA has engaged the Uniformed Services University (USU) to leverage their ongoing NDMS and to align initiatives to best support the NDMS and meet congressional intent. This RPP extends the Pilot by focusing on activities associated with prototype development and testing of a modular/convertible medical surge capability with iterative improvements to optimize the capability, as well as development of a training curriculum (to be further defined during PoP2) required to activate the surge capability.

#### **3.2. Solution Requirements**

The specific objective of this RPP is to resolve the issue of limited medical surge capabilities during a national disaster to support the Nation's homeland security defense mission through the development of modular and/or convertible medical facilities. This part of the NDMS Pilot will be led by the DHA where an integrated product team has already been established to lead the pilot modular program plan and that will be responsible for identifying the appropriate materiel solution(s) to meet congressional intent for this Pilot.

The modular and/or convertible surge capability prototype is required to be physically adjacent to one of the existing five Pilot sites (Washington, DC/National Capital Region; San Antonio, TX; Sacramento, CA; Omaha, NE; and Denver, CO). The modular and/or convertible medical surge facility should include laboratories, intensive care units, x-rays, and be able to use the staffing and services available in the medical facility that it is adjacent to.

It is expected that Offerors will propose an initial program schedule, plan of actions and milestones, estimated funding needed for planning, design, testing, transition to implementation, and sustainment of a full-scale prototype medical surge capability. A program plan will be developed during the PoP1 and should include draft design(s) and drawings, inventory of equipment/devices/supplies required to support prototyping, and an initial testing plan. As the requirement is further defined by Congressional reports periods of performance, the program plan will be updated, a training plan for activation of the surge facility will be developed, and development of recommendations for how the modular surge materiel solution could potentially be integrated into a Joint Center for Emergency Medical Training, Readiness, and Coordination in partnership with the Department of Health and Human Services. Additional requirements of the award will include finalizing the design, development of the initial protype(s), development initial training to support the modular surge facility, and testing the initial prototype(s) of the modular and/or convertible surge facility.

# **NOTE: Physical Location Preference**

In this Phase of the Pilot, project awards resulting from this RPP will take place at the five Pilot sites utilized by the ongoing USU pilot: Washington, DC/National Capital Region; San Antonio, TX; Sacramento, CA; Omaha, NE; and Denver, CO. In order to meet the intent of this RPP, the Government prefers that Offerors <u>currently have</u> an office or project partner located within close proximity (e.g., within 75-mile radius) of one of the Pilot sites. Therefore, preference will be given to proposals that include a local or regional healthcare partner where appropriate. If the Offeror is not within close proximity to the Pilot Site at the time of proposal submission, then the Offeror should demonstrate a plan to secure a physical location in close proximity and disclose the associated timeline (preferably prior to the start of the PoP) within the Enhanced White Paper. This reflects both the importance of the Offeror's understanding of the local NDMS network and reinforces the congressional intent for this Pilot.

# **3.3. Go/No-Go Decision Point for Downselect**

Prior to the end of the base PoP1 (tentatively projected to occur 9 months into PoP1), the Government will conduct an in-process review (IPR), in which the Awardees will attend and participate in, to assess the work completed for each PoP1 Awardee. The IPR will be either a virtual or an in-person meeting at DHA at Falls Church, VA. Following the IPR, the Government intends to down-select Awardees to a smaller number for continuation of funding for the conduct of follow-on work representing PoP2 or the subsequent PoP of the prototype project. This down-select represents the Go/No-Go Decision point between PoP1 (base) and PoP2 (subsequent).

In preparation for the IPR, all awardees may be required to submit a deliverable to the Government outlining the initial details of the tasks proposed for the subsequent PoP2 phase, in separate technical and cost volumes. The exact due date for this deliverable is TBD (anticipated on or about two weeks prior to the date of the IPR). This deliverable will be reviewed and evaluated as part of the Go/No-Go decision point during which time the Government will make award recommendations for the subsequent PoP2 selections.

All Offerors responding to this RPP should be prepared for the potential IPR deliverable requirement by identifying these as a milestone(s) in the Stage 1 (White Paper) proposal submission (under the "Anticipated Outcomes" section of the white Paper and elsewhere, as appropriate).

# Potential Follow-On Tasks:

Potential follow-on work to include PoP2 (but may also include additional, non-competitive tasks negotiated after OTA award) may be awarded based on the advancement in prototype maturity during the base PoP1. Potential follow-on work may include tasks related to advancement of prototype maturity, and/or to expand the use or utility of the prototype. Such follow-on work may include (but is not limited to):

- Update the plan for transition to implementation and sustainment of the full-scale capability
- Development of the full-scale prototype

• Sustainment of the full-scale prototype

## **3.4.** Restrictions on Human Subjects

Research Involving Humans: All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC Office of Human and Animal Research Oversight (OHARO) Office of Human Research Oversight (OHRO) prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Allow a minimum of 2 to 3 months for OHRO regulatory review and approval processes.

Enhanced White Papers must comply with the above-mentioned restrictions and reporting requirements for the use of human subjects, to include research involving the secondary use of human biospecimens and/or human data. The Awardee shall ensure local IRB approvals, continuing review (in the intervals specified by the local IRB, but at a minimum, annually), and approval by the USAMRDC OHRO. Offerors shall include IRB and OHRO review and approval in the SOW/Milestones Table submitted with the Proposal, as applicable.

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

The USAMRDC OHRO will issue written approval to begin research under separate notification. Written approval to proceed from the USAMRDC OHRO is also required for any Research Project Awardee (or lower tier subawards) that will use funds from this award to conduct research involving human subjects. Offerors must allow at least 30 days in their schedule for the OHRO review and authorization process.

#### **3.5. Guidance Related to DoD-Affiliated Personnel for Participation in Research**

Please note that compensation to DoD-affiliated personnel for participation in research while on duty is prohibited with some exceptions. For more details, see Department of Defense Instruction (DODI) 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and -Supported Research. You may access a full version of the DODI by accessing this link: <u>https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf</u>

# 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: <u>https://ati2.acqcenter.com/ATI2/Portal.nsf/Start?ReadForm</u>. See **Attachment 7 of the PPG** for further information regarding BIDS registration and submission. The Offeror shall include MTEC Solicitation Number (**MTEC-23-09-NDMS-Modular**) in the Enhanced White Paper.

The Enhanced White Paper format provided in this MTEC RPP (Section 8) is **mandatory**. 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 due 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 Enhanced White Paper

Offerors submitting an Enhanced White Paper, inclusive of a Rough Order of Magnitude cost/price estimate, in response to this RPP shall 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, searchable, and without a password required. Filenames must contain the appropriate filename extension (.docx, .doc, .pptx, .ppt .xlsx, .xls or .pdf). Filenames should not contain special characters. Apple users must ensure the entire filename and path are free of spaces and special characters.

An automated BIDS receipt confirmation will be provided by email. Offerors may submit in advance of the deadline. 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 (5): Submitted via BIDS (5MB or lower per document)** 

- Enhanced White Paper: one PDF document (See Section 8)
- Warranties and Representations: one Word or PDF document (Attachment 3 of the PPG)
- Statement of Work (SOW)/Milestone Payment Schedule (MPS): one Word or PDF document (Attachment 4 of the PPG)
- Intellectual Property and Data Rights Assertions: one Word or PDF document (Attachment 6 of the PPG)
- Technical Addendum for Potential Follow-On Work in PoP2: one Word or PDF document (Addendum 2 of this RPP)

Page Limitation: The Enhanced White Paper is limited to ten (10) pages (including cover page). The following Appendices are **excluded** from the page limitation: (1) Warranties and Representations, (2) Statement of Work, (3) Intellectual Property and Data Rights Assertions, and (4) Technical Addendum for Potential Follow-On Work in PoP2.

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 limitations and/or the file size specified above may not be accepted. Each document shall be uploaded to BIDS separately (see Attachment 7 of the PPG for BIDS instructions).

FOR INFORMATION ONLY: Please note a full Cost Proposal will be requested if the Enhanced White Paper is recommended for funding (see Section 4.3 for additional details). Furthermore, additional attachments/appendices (henceforth referred to as supplemental information) to this proposal submission <u>may</u> be requested after completion of the technical evaluation to include the following:

- Human Subject Recruitment and Safety Procedures which details study population, inclusion/exclusion criteria, description of the recruitment process, description of the informed consent process, etc.
- Letter(s) of Support, as applicable, if the prototype project will require access to activeduty military patient populations and/or DoD resource(s) or database(s).

The exact requirements of any such attachment/appendix are subject to change and will be provided at the time (or immediately following) the technical evaluation summary is provided (as part of the Selection Notification described in 2.13).

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

Offerors that are recommended for funding will receive notification letters which will serve as the formal request for a full Cost Proposal (and may contain a request for Enhanced White Paper revisions and/or supplemental information, such as those examples listed in the section above, based on the results of the technical evaluation). These letters will contain specific submission requirements if there are any changes to those contained in this RPP. However, it is anticipated that the following will be required:

# Required Submission Documents (3): Submit to mtec-contracts@ati.org

- Section I: Cost Proposal Narrative: one Word or PDF document
- Section II: Cost Proposal Formats: one Excel or PDF document
- **Current and Pending Support:** one Word of PDF document

See below for additional instructions. Also refer to **Addendum 1 of this RPP** 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** and one Excel (.xlsx or .xls) or PDF file for **Section II: Cost Proposal Formats** 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 proposal 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. Refer to the MTEC PPG for additional details.

Each Offeror selected for Stage 2 will also submit a **Current and Pending Support** document **(template provided in Attachment 5 of the PPG)**. 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 non- government) 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 allowable as a direct charge to any resulting award or any other contract. Additionally, the MTEC Assessment Fee (see Section 2.10 of this RPP) is not allowable as 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. §4021(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

As stated in Section 6.1.2 of the MTEC PPG, 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

# 5.1 Preliminary Screening

The CM will conduct a preliminary screening of submitted Enhanced White Papers to ensure compliance with the RPP requirements. As part of the preliminary screening process, Enhanced White Papers that do not meet the requirements of the RPP may be eliminated from the competition or additional information may be requested by the CM. Additionally, 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 Section 3 of the PPG). Proposal Compliance with the statutory requirements regarding the appropriate use of Other Transaction Authority (as detailed within Section 3 of the PPG) will be determined based upon the ratings shown in Table 1:

TABLE 1 - COST SHARING/NONTRADITIONAL CONTRACTOR ASSESSMENTS					
RATING DESCRIPTION					
PASS	<ul> <li>Offeror proposing an MTEC research project meets at least ONE of the following: <ul> <li>Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution</li> <li>Offeror's Proposal has at least one Nontraditional Defense Contractor or Nonprofit Research Institute participating to a significant extent</li> <li>All significant participants in the transaction other than the Federal Government are small businesses or nontraditional defense contractors</li> <li>Offeror provides at least one third of the total project cost as acceptable cost share</li> </ul> </li> </ul>				
FAIL	<ul> <li>Offeror proposing an MTEC research project does NOT meet at least ONE of the following: <ul> <li>Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution</li> <li>Offeror's Proposal has at least one Nontraditional Defense Contractor or Nonprofit Research Institution participating to a significant extent</li> <li>All significant participants in the transaction other than the Federal Government are small businesses or nontraditional defense contractors</li> </ul> </li> </ul>				

•	Offeror provides at least one third of the total project cost as acceptable cost share
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## 5.2 Enhanced White Paper (Stage 1) Evaluation

The CM will distribute all Enhanced White Papers that pass the preliminary screening (described above and in Table 1) to the Government for full evaluation. Evaluation of Enhanced White Papers will be based on an independent, comprehensive review and assessment of the work proposed against the stated source selection criteria and evaluation factors. The Government will evaluate each Enhanced White Paper against the evaluation factors detailed below and assign adjectival ratings to the non-cost/price factor(s) consistent with those defined in Table 2 (General Merit Rating Assessments). The Offeror shall clearly state how it intends to meet and, if possible, exceed the RPP requirements. Mere acknowledgement or restatement of a RPP requirement is not acceptable. The overall award decision will be based upon a best value determination by considering factors in addition to cost/price.

The evaluation factors and evaluation criteria are described below.

## **Evaluation Factors (of equal importance)**

- 1. Technical Approach and Merit
- 2. Cost Reasonableness
- 3. Management Approach and Relevant Experience
- 4. Potential for Transition/Expansion

#### **Evaluation Factor 1 – Technical Approach and Merit:**

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:

- A technical approach which effectively demonstrates the Offeror's understanding of the overall NDMS and more specifically the joint civilian-military modular surge facility requirement and demonstrates the likelihood of successfully achieving the requirements outlined in this RPP
- SOW that provides a clear approach for meeting the project's objectives

The Risk Identification and Mitigation section of the Enhanced White Paper will be evaluated by the Government to ensure there is a realistic understanding and plan proposed by the Offeror.

#### **Evaluation Factor 2 – Cost Reasonableness:**

Assessment of the cost of the project to determine i) whether the project cost is within the available funding limits, and ii) the ability and/or likelihood of the offeror to successfully execute the proposed project within the financial resources proposed. The proposed cost will be based on the following ratings: Sufficient, Insufficient or Excessive. See the definitions of these ratings in Table 2 below.

## **Evaluation Factor 3 – Management Approach and Relevant Experience:**

Strength of the organization/team, their NDMS and/or healthcare emergency preparedness/response knowledge and experience in the Pilot site region, as well as the strength of personnel qualifications, services, subcontractors, project management plan, and related administrative and information technology support proposed to complete the work.

<u>Of note</u>: As noted in Section 3.3 above, the Government prefers that Offerors and/or their teammate(s) currently have an office physically located (e.g., within 75-mile radius) in the geographic area of the proposed pilot project(s) or propose a plan to secure a physical location in close proximity prior to the start of the initial PoP1.

## **Evaluation Factor 4 – Potential for Transition/Expansion:**

Soundness and feasibility of the proposed project or solution to improve, enhance or increase capabilities, capacities and/or interoperability amongst the partners across the entire NDMS network. Furthermore, this evaluation factor may consider proposed potential follow-on tasks to further advance the project maturity beyond the proposed initial PoP1 to include the Offeror's high-level description of subsequent Period of Performance tasks (PoP2) for the continuation of prototype development or expansion of use, as provided in the Technical Addendum for the Subsequent PoP Work (PoP2).

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.		

Table 2 explains the adjectival merit ratings that will be used for the Evaluation Factors.

The following table provides the ratings specific to Evaluation Factor 2 – Cost Reasonableness:

TABLE 3 - "COST REASONABLENESS" FACTOR RATINGS DEFINITIONS			
RATING	DESCRIPTION		
SUFFICIENT	The estimate is within the available funding limits and considered		
	appropriate to successfully complete the proposed project		
INSUFFICIENT	The estimate is lower than what is considered appropriate to successfully		
	complete the proposed project.		
EXCESSIVE	The estimate is higher than what is considered appropriate to successfully complete the proposed project and may be outside of the available funding limits.		

Please also refer to Section 5.3 for definitions of general terms used in technical evaluations.

Upon review and evaluation of the Proposals, the Government sponsor will perform proposal source selection. This will be conducted using the evaluation factors detailed above. The Government will conduct an evaluation of all qualified proposals. The Source Selection Authority may:

- 1. Select the proposal (or some portion of the proposal) for award
- 2. Place the proposal in the Basket if funding currently is unavailable; or
- 3. Reject the proposal (will not be placed in the Basket)

In rare cases, the following recommendation may be provided: "Recommendation Undetermined." This is reserved for situations in which additional information/documentation is needed by the Government evaluators before finalizing a recommendation to one of those listed above and is intended to facilitate the release of all evaluator comments within the BIDS System.

The RPP review and award process may involve the use of contractor subject matter experts (SMEs) 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 2.5.

# 5.3 Definition of General Terms Used in Evaluations

<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>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.

<u>Weakness</u> – A flaw in the proposal that increases the risk of unsuccessful 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.

# 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, <u>mtec-contracts@ati.org</u>
- Technical and membership questions should be directed to the MTEC Biomedical Research Associate, Dr. Chuck Hutti, Ph.D., <u>chuck.hutti@ati.org</u>
- All other questions should be directed to the MTEC Chief of Consortium Operations, Ms. Kathy Zolman, <u>kathy.zolman@ati.org</u>

# 7 Acronyms/Abbreviations

ACS/ACF	Alternate Care Sites/Facilities
ATI	Advanced Technology International
СМ	Consortium Manager
CMA	Consortium Member Agreement
СМС	Chemistry, Manufacturing, and Controls
DHA	Defense Health Agency
DoD	Department of Defense
DODI	Department of Defense Instruction
F&A	Facilities and Administrative Costs
FAQ	Frequently Asked Questions
FOIA	Freedom of Information Act
FY	Fiscal Year
G&A	General and Administrative Expenses
Government	U.S. Government, specifically the DoD
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IPR	In Process Review
IRB	Institutional Review Board

М	Millions
MPS	Milestone Payment Schedule
MTEC	Medical Technology Enterprise Consortium
NDA	Nondisclosure Agreement
NDAA	National Defense Authorization Acts
NDMS	National Disaster Medical System
OCI	Organizational Conflict of Interest
ODC	Other Direct Costs
OHARO	Office of Human and Animal Research Oversight
OHRO	Office of Human Research Oversight
ΟΤΑ	Other Transaction Agreement
PDF	Portable Document Format
POC	Point-of-Contact
РоР	Period of Performance
PPG	Proposal Preparation Guide
R&D	Research and Development
ROM	Rough Order of Magnitude
RPA	Research Project Award
RPP	Request for Project Proposals
SME	Subject Matter Expert
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

Cover Page

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

> Unique Entity ID: [UEI] 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. 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]

# Pilot Site(s) Addressed by this Proposal [Check all that apply]

Washington, DC/National Capital Region
 San Antonio, TX
 Sacramento, CA
 Omaha, NE
 Denver, CO

#### Programmatic Relevance

- Provide the background and the Offeror's understanding of the problem and/or technology gap/process deficiency.
- Describe how the proposed approach 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 / Preliminary Data

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

#### **Technical Approach**

- Describe your approach specific to PoP1 activities that focus on the development of the program plan, including an integrated master schedule and plan of actions and milestones, transition to implementation, and sustainment of a full-scale prototype medical surge capability. 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 to develop and test the proposed solution.
- Specify how you satisfy the Physical Location Preference described in Section 3.3. If the Offeror is not within close proximity to the Pilot Site at the time of proposal submission, then the Offeror should demonstrate a plan to secure a physical location in close proximity and disclose the associated timeline (preferably prior to the start of the PoP1).

#### 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, on strengthening the capabilities and interoperability of the NDMS not only at the pilot site(s) identified but also if scaled at the national level.

#### Team and Management Plan

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

- Indicate if the team has worked together before.
- 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.
- Describe any previous enterprise-level program/prototype development and execution
- Availability of the team to work onsite at the Pilot sites as needed.

## 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 and other resources proposed for the effort. Identified facilities, equipment and resources should be available and relevant for the technical solution being proposed.
- Summarize the administrative and information technology support proposed to complete the work

#### Potential Follow-On Work

• Offerors are encouraged as appropriate to discuss potential follow-on work.

#### Schedule

- PoP1: Indicate the proposed PoP 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. Do not duplicate the level of detail presented in the Statement of Work.

#### **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.

	Year 1 <mark>(PoP1)</mark>		
Labor	\$ 100,000.00		
Labor Hours	1,000.0 hrs		
Subcontractors	\$ 50,000.00		
Subcontractors Hours	500.0 hrs		
Government/Military			
Partner(s)/Subcontractor(s)	\$0.00		
(subKTR)*			
Gov't/Military Prtnrs / subKTR Hours* Consultants EXAMPLE	0.0 hrs		
Consultants EXAM	\$ 10,000.00		
Cor	100.0 hrs		
Mai	\$ 75,000.00		
Other Direct Costs	\$ 1,000.00		
Travel	\$ 5,000.00		
Indirect costs	\$ 48,200.00		
Total Cost	\$ 289,200.00		
<b>Fee</b> (Not applicable if cost share is proposed)	\$ 0.00		
Total Cost (plus Fee)	\$ 289,200.00		
Cost Share			
(if cost share is proposed then fee	\$ 290,000.00		
is unallowable)			
Total Project Cost	\$ 579,200.00		

\*Use the rows above for "Government/Military Partner(s)/Subcontractor(s)" if the project involves one or more Government/Military Facilities (Military Health System 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 **brief** 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: Warranties and Representations: (template provided in Attachment 3 of the PPG)

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

## Appendix 2: Statement of Work (template provided in Attachment 4 of the PPG)

- 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 (MPS). Offerors will have the opportunity to concur with revised SOW/Milestone Payment Schedule as necessary.

#### Appendix 3: Data Rights Assertions (template provided in Attachment 6 of the PPG)

- 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 in accordance with Section 2.11 of the RPP unless otherwise asserted in the proposal and agreed to by the Government.
- If this is not the intent, then you should discuss any restricted data rights associated with any proposed deliverables/milestones. If applicable, complete the table within the referenced attachment for any items to be furnished to the Government with restrictions.

# Appendix 4: Technical Addendum for the Subsequent PoP Work (PoP2) (template provided in Addendum 2 of this RPP)

This document is a required part of the submission. One Word (.docx or .doc) or PDF file that contains the information in the template is required.

# Addendum 1 – Stage 2 Evaluation Criteria

# For Information Only - Stage 2 Requirement (subject to change)

#### Stage 2

The MTEC Consortium Manager (CM) will evaluate the cost proposed together with all supporting information for realism (as applicable, dependent upon contract type, i.e., Firm Fixed Price, Cost Reimbursement), reasonableness, and completeness as outlined below. The MTEC CM will then provide a formal assessment to the Government at which time the Government will make the final determination that the negotiated project cost is fair and reasonable.

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 (Enhanced White Papers) 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, in its nature and amount, 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 based upon verifiable techniques such as estimates developed from applicable and relevant 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, 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.

## **Government Access to Information**

After receipt of the cost proposal and after the CM's completion of the cost analysis summarized above, the government may perform a supplemental cost and/or price analysis of the submitted cost proposal. For purposes of this analysis, the Agreement Officer and/or a representative of the Agreement Officer (e.g., DCAA, DCMA, etc.) shall have the right to examine the supporting records and/or request additional information, as needed.

#### **Best Value**

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. The Government anticipates entering into negotiations with all Offerors recommended for funding with the MTEC CM acting on the Government's behalf and/or serving as a liaison. The Government reserves the right to negotiate and request changes to any or all parts of the proposal, to include the SOW.

# Addendum 2 – Technical Addendum for the Subsequent PoP Work (PoP2) Template

**General Instruction:** As noted in Section 2.2 of the RPP, an additional \$17.2M of funding may be available for the performer(s) that is selected for the continuation of prototype development under the subsequent PoP2 after the Go/No-go Decision Point. The PoP2 work will be dependent on the advancement in prototype maturity of the prototype during PoP1 of up to 12 months, as it applies to each resultant award(s). Although awards in response to this RPP will initially focus on the scope of work for the first 12 months, this addendum is intended to provide the Sponsor with information on the Offeror's plan for work beyond the base PoP1. The following template is a required document to be uploaded with your enhanced white paper submission via BIDS.

**Technical Tasks:** [Specify the objective of each proposed follow-on task. Outline the proposed methodology **by task** to the extent possible to demonstrate a course of action that addresses the technical requirements described in this RPP. Describe your approach specific to PoP2 tasks that supports the continuation of activities from PoP1 such as the advancement of the program plan, including an integrated master schedule and plan of actions and milestones, transition to implementation, and sustainment of a full-scale prototype medical surge capability.]

## PoP: [Indicate the proposed PoP (duration) for the potential follow-on work in total.]

# Gantt Chart: [Include a Gantt chart that demonstrates the timeline for each proposed potential follow-on task.]

**Anticipated Outcomes**: [Provide a description of the anticipated outcomes from the proposed PoP2 work. List milestones and deliverables for the proposed PoP2 work.]

**Participants:** [Briefly state the qualifications of the Principal Investigator, key personnel, and organizations that will perform the proposed follow-on tasks. If there are no anticipated changes to the team from PoP1 then the offeror does not need to restate information already provided in the EWP. If additional qualifications are required for PoP2 to continue prototype development offerors should specifically address those new qualifications.]

# Rough Order of Magnitude (ROM) Pricing:

[Indicate the ROM pricing (including indirect costs) **using the table format below**. The ROM table should include a column for each potential PoP2 task. This information will be used to provide the Sponsor with a reasonable representation of the amount of funding required <u>for each potential PoP2 task</u> required to advance the project toward military fielding and/or production tasks. 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.]

	Potential	Potential	Potential	Potential
	PoP2 Task 1	PoP2 Task 2	PoP2 Task 3	PoP2 Task 4
Labor	\$200,000.00	\$200,000.00	\$200,000.00	\$200,000.00
Subcontractors	\$100,000.00	\$100,000.00	\$100,000.00	\$100,000.00
Consultants	\$20,000.00	\$20,000.00	52	\$20,000.00
Material/Equipment	\$150,000.00	\$150	1000.00	\$150,000.00
Other Direct Costs	\$2,000.00	XAMPLE	\$2,000.00	\$2,000.00
Travel	San D	<i>,10,000.00</i>	\$10,000.00	\$10,000.00
<u> </u>				
Indirect costs	ə96,400.00	\$96,400.00	\$96,400.00	\$96,400.00
Total Cost	\$578,400.00	\$578,400.00	\$578,400.00	\$578,400.00
Fee (Not applicable if cost share	\$0.00	\$0.00	\$0.00	\$0.00
is proposed)				
Total Cost (plus Fee)	\$578,400.00	\$578,400.00	\$578,400.00	\$578,400.00
Cost Share	\$580,000.00	\$580,000.00	\$580,000.00	\$580,000.00
(if cost share is proposed then				
fee is un-allowable)				
Total Project Cost	\$1,158,400.00	\$1,158,400.00	\$1,158,400.00	\$1,158,400.00