

Request for Project Proposals



Solicitation Number: MTEC-23-03-Performance

“Technology Integration to Optimize Military Health and Performance”

Issued by:
Advanced Technology International (ATI),
MTEC Consortium Manager (CM)
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Summerville, SC 29486
for the
Medical Technology Enterprise Consortium (MTEC)

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Table of Contents

1	Executive Summary.....	3
1.1.	The Medical Technology Enterprise Consortium.....	3
1.2.	Purpose.....	4
2	Administrative Overview	4
2.1.	Request for Project Proposals (RPP)	4
2.2.	Funding Availability and Period of Performance	5
2.3.	Acquisition Approach	5
2.4.	Proposers Conference.....	6
2.5.	Proprietary Information	6
2.6.	MTEC Member Teaming.....	6
2.7.	Offeror Eligibility	7
2.8.	Cost Sharing Definition.....	8
2.9.	Cost Sharing Requirements.....	8
2.10.	MTEC Assessment Fee.....	8
2.11.	Intellectual Property and Data Rights	8
2.12.	Expected Award Date.....	9
2.13.	Anticipated Enhanced White Paper Selection Notification	9
3	Technical Requirements	9
3.1.	Background.....	9
3.2.	Solution Requirements.....	10
3.3.	Scope of Work	10
3.4.	Potential Follow-on Tasks	12
3.5.	Restrictions on Human Subjects	13
3.6.	Guidance Related to DoD-Affiliated Personnel for Participation in research	13
4	Enhanced White Paper Preparation	13
4.1.	General Instructions.....	13
4.2.	Instructions for the Preparation & Submission of the Enhanced White Paper	14
4.3.	Stage 2: Cost Proposal (for Only Those Offerors Recommended for Funding)	15
4.4.	Enhanced White Paper and Cost Proposal Preparation Costs.....	16
4.5.	Freedom of Information Act (FOIA)	16
4.6.	Telecommunications and Video Surveillance	16
5	Selection.....	17
6	Points-of-Contact	21
7	Acronyms/Abbreviations	21
8	Enhanced White Paper Template	23
	Addendum 1 – Stage 2 Evaluation Criteria.....	29

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 Military Operational Medicine Research Program (MOMRP). Proposals 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) supported by this RPP will be provided by USU.

The overall objective of this effort is to identify an organization able to serve as an “integrator” proficient at leveraging the capabilities of an existing network of performers to advance materiel and knowledge products that improve the physical, cognitive, and psychological health and performance of Service Members (SM). The goal is to create an actively coordinated “mini-consortium” program that incorporates organizations dedicated to researching, developing, testing/evaluating, and manufacturing human health and performance products. Due to the Integrator’s specialized expertise, this approach will de-risk technology development by providing capability/expertise to companies that have promising technologies but lack the ability or experience to bring their technologies to market. This structure also allows flexibility to incorporate service member feedback into the testing/evaluating process, identifying and replacing failing performance technology prototypes with more promising ones throughout the Period of Performance (PoP). Additionally, the integrator will continually synchronize and integrate awardee efforts so that performance technology prototype development might advance further and faster than if the awardee were to conduct development on their own.

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 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 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) currently has available a total of approximately \$6.7 million (M) of Fiscal Year (FY) 2022 (FY22) research, development, testing, and evaluation (RDT&E) funds for this effort. It is the Government's intent that this initial award is part of a larger and longer project, potentially providing approximately \$7M per year for follow-on work for up to 5 years (pending availability of funding and technical progress). Award and funding from the Government is expected to be limited (initially) to the funding specified above (only \$6.7M at present, but with an additional \$7M possible per year) and is contingent upon the availability of federal funds for this program.

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).

MTEC expects to make a **single award** to a qualified Offeror to accomplish the scope of work with an initial PoP not to exceed **36 months**.

2.3. Acquisition Approach

This RPP will be conducted using the Enhanced White Paper approach. In Stage 1, current MTEC members 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 represent the best value 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.

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. § 4022 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 (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 webinar within two (2) weeks after the release of the RPP. The intent of the Proposers Conference is to provide an administrative overview of this RPP process to award and present further insight into the Technical Requirements outlined in Section 3. Further instructions will be forthcoming via email. 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 (TEP) 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 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 (<https://private.mtec-sc.org/>).

2.7. 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 <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 **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.).

2.9. 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 one 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.

2.10. 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. 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”.

2.11. 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.

2.12. Expected Award Date

Offerors should plan on the period of performance beginning June of 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.

2.13. 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

Current wartime operations assume that the United States and our allies will maintain air, land, maritime, space and cyber superiority. Future conflicts against peer and near-peer adversaries are expected to be layered stand-offs, fought across multiple domains (Multi-Domain Operations, MDO) in large scale combat operations. Mission success will be determined by our ability to compete to expand the competitive space, penetrate both strategically and operationally, disintegrate enemy’s defenses, exploit enemy weaknesses and re-compete to consolidate gains. Warfighter performance plays a critical role in each aspect of MDO and enhancements to human performance will maintain Force readiness and increase soldier lethality.

In order to modernize the DOD to be a ready and resilient Force, MOMRP is seeking to build a capability through MTEC that is poised to rapidly advance performance technology prototypes related to Warfighter performance and transition these to both the Warfighter and the

commercial marketplace as appropriate. This effort requires multiple performance technology prototype solutions that address:

- Preventing or reducing physical injuries (e.g. musculoskeletal injuries (MSKI), cognitive degradation, psychological health challenges) and speeding recovery/return to duty/combat;
- Maintaining health and performance in a multi-stressor environments common in the DoD in garrison, during training, and on operations; and
- Enhancing baseline physical and mental health and performance in a safe and ethical way

3.2. Solution Requirements

Two objectives have been identified for funding under this RPP. Objective 1 is to provide prime integrator capabilities and to advance existing performance technology prototypes along their maturation pipeline. Objective 2 is to identify, review, and present (for Government approval) potential performance technology prototypes that will **undergo advancement under Objective 1 guidelines**. It is the Government's intent that this initial award is part of a larger and longer project, with the potential for significant follow-on funding (pending availability of funding and technical progress). All submissions shall detail how the Offeror will accomplish/achieve all aspects of these requirements to include a clear approach to execute all objectives based upon the Offeror's unique methodology. Therefore, the Offeror shall also clearly identify the major milestones in the SOW/Milestone Payment Schedule associated with accomplishing these requirements.

3.3. Scope of Work

OBJECTIVE 1 – Prime Integrator capabilities to translate performance technology prototypes. The project shall be led by a centralized point of contact at the prime performer to serve as the "Integrator." It is possible that several subcontractors will be required to accomplish the full scope of the project and each effort thereunder. Agreements among the established consortium members shall be handled by the Integrator to the greatest extent possible. A centralized POC for the established consortium at the Integrator shall be named and will be ultimately responsible for official communication and deliverables. Offerors are expected to propose a consortium structure that is comprised of the necessary qualified personnel, facilities (including military relevant testing environments), equipment, supplies, services, and subcontractors and related administrative and information technology support to accomplish the objectives. It is preferred that the integrator have established experience in the advancement and commercialization of technologies related to human performance. **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. **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 efforts) to ensure the proper level of effort, access to the necessary subject matter experts, etc.**

The Integrator's role may include (but is not limited to) the following activities:

1. Report directly to the SOTR at USAMRDC MOMRP.
2. Support the development activities required to advance performance technology prototypes along their maturation pipeline. The Offeror shall propose how to expand their network of vetted translational services and expertise to address specific challenges related to prototype development. The network shall also include military-relevant testing environments.
3. Oversee and manage the project portfolio to enhance the likelihood of performance technology prototype success
 - a. Conduct strategic planning to ensure successful transition of candidate performance technology prototypes to the commercial marketplace and the Warfighter
 - b. Provide resources and collaborative events for early translational activities, such as team building, strategy, project management and planning, etc.
 - c. Allocate funding based on progress of award milestones and deliverables
 - d. Provide routine technical and programmatic review of awarded projects, including multiple execution tests and evaluation events throughout the performance technology prototype advancement process
 - e. Make recommendations to MOMRP for approval regarding project status (e.g., termination, modification, continuation, etc.), implement changes to SOWs, re-partnering, terminations, reallocation of funding to current projects, adding on new projects)
4. Results dissemination
 - a. Conduct a yearly symposium that brings together key personnel from the Government, projects, and other key stakeholders [Offerors should plan for this to be tagged onto or featured as part of the MTEC Annual Membership Meeting]

OBJECTIVE 2 – Identify, review, and present performance technology prototypes to potentially be selected by the Government for Advancement under Objective 1 guidelines. The selected Integrator shall identify, review, and present a portfolio of candidate performance technology prototype projects for consideration for funding under this RPP.

- The integrator will bring forth performance technology prototypes relevant to the military priorities set forth by MOMRP. Letters of intent from a portfolio of proposed prototypes will be expected at the time of submission (see Section 8, Appendix 4 of this RPP). The proposed portfolio may range from one prototype to several, however, the total budget (Integrator's costs plus the prototype project costs) must not exceed the total available funding of \$6.7M as noted in Section 2.2.
- The Government may approve for funding all, some, or none of the projects proposed in the Enhanced White Paper's Appendix 4. If funding remains available after the evaluation of the portfolio of projects proposed in the Enhanced White Paper's Appendix 4, additional performance technology prototypes for consideration may be collected using the MTEC Request for Project Information (RPI).
- The selected Integrator, during the PoP of the award, shall be required (at the instruction of MOMRP) to work solely with MTEC to draft the necessary RPI if additional projects are needed, either after the initial project or if further projects are possible.

- MTEC will use its standard processes to post the RPI and collect the project information paper submissions. The Integrator will implement an objective review process for the evaluation of project information papers. Information papers will undergo an evaluation process that includes a highly competent evaluation panel that can provide insight into various areas of expertise including technical, regulatory, market and business model. The Offeror is required to propose an evaluation panel that is objective and represents a diverse set of organizations so that a single organization does not have the majority viewpoint. The TEP must include people with different focus areas of interest, strengths, and organizational ties. The Offeror must also present a comprehensive Conflict of Interest (COI) plan and will be expected to manage/mitigate any COIs (including the perception of COIs). The proposed projects that result from the Integrator's objective evaluation process will then be passed on for full evaluation by MOMRP. All prototype projects will require approval by MOMRP prior to addition to the Integrator's award.

The performance technology prototypes being developed in this effort must meet the following criteria:

1. **Prototype Maturity:** The performance technology prototypes may span the pipeline of maturity, but be at a minimum of a Technology Readiness Level (TRL) of 4. This program prefers technologies that are ready for user testing.
2. **Military Relevance:** Performance technology prototypes must be relevant to the following needs of the warfighter:
 - Preventing or reducing physical injuries (e.g. musculoskeletal injuries (MSKI), cognitive degradation, psychological health challenges) and speeding recovery/return to duty/combat;
 - Maintaining health and performance in a multi-stressor environments common in the DoD in garrison, during training, and on operations; and
 - Enhancing baseline physical and mental health and performance in a safe and ethical way
3. **Commercial Partners:** It is preferred that performance technology prototypes shall include partnerships with commercial entities/industry partner(s) committed to bringing the product to market.

3.4. Potential Follow-on Tasks

Under awards resulting from this RPP, there is the potential for award of one or more non-competitive follow-on tasks based on the success of the project (subject to change depending upon Government review of completed work and successful progression of milestones). Potential follow-on work may be awarded based on the advancement in prototype maturity during the PoP.

Offerors are encouraged, as appropriate, to discuss potential follow-on work in the Enhanced White Paper submission to demonstrate the ability to further advance the project maturity beyond the proposed PoP. This will also allow the Offeror to highlight the potential expansion(s)

that can be explored/achieved through short term and/or long-term advancement of the project in a way that is beneficial to the Government.

3.5. 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 Office of Research Protections (ORP) review and authorization process.

3.6. 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: <https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf>

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>. See **Attachment 7 of the PPG** for further information regarding BIDS registration and submission. The Offeror shall include MTEC Solicitation Number (**MTEC-23-03-Performance**) 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 (**Section 8 of the this RPP**)
- **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**)
- **Objective 2 Proposed Performance Technology Prototype(s):** one Word or PDF document (**See Section 8 – Appendix 4 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) Objective 2 Proposed Performance Technology Prototype(s).

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 may 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 active-duty military patient populations and/or DoD resource(s) or database(s).

The exact requirements of any such attachment/appendix is 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 (2): 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

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. §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

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	<p>Offeror proposing an MTEC research project meets at least ONE of the following:</p> <ul style="list-style-type: none"> • Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution • Offeror's Proposal 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	<p>Offeror proposing an MTEC research project does NOT meet at least ONE of the following:</p> <ul style="list-style-type: none"> • Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution • Offeror's Proposal has at least one Nontraditional Defense Contractor or Nonprofit Research Institution participating to a significant extent

	<ul style="list-style-type: none">• 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
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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.

Each proposal will be evaluated using the following evaluation factors. Separate factors will be used to evaluate Objectives 1 and 2:

OBJECTIVE 1 Evaluation Factors:

1. Evaluation Factor 1 – Technical Approach: This factor will evaluate the relevancy, thoroughness, completeness, and impact of the proposed approach (e.g., the technical merit) and how well the proposal defines and meets the requirements of the Integrator’s role and function. This includes how well the proposed methodology for advancement supports the technical objectives and development of performance technology prototypes.
2. Evaluation Factor 2 - Project Management and Experience: This factor will evaluate the project team’s expertise, key personnel, and corporate experience shall demonstrate an ability to execute the SOW. The schedule will be evaluated to determine whether the proposed work is realistic and reasonable within the proposed period of performance. This factor will also include evaluation of the Offeror’s current network in the field that includes technology providers, service providers, and collaborations that enable access to user testing in military relevant environments. Example of the information that may be assessed (if applicable to the proposed project):
 - Development Strategy (including timing and regulatory): Feasibility of the Offeror’s product development strategy, including regulatory and FDA pathway, indication of use and designation, strategy for obtaining FDA approvals or clearances. If commercialization is not relevant to the proposed project, then feasibility of the plan to transition the technology to the government may be assessed.

- Commercialization Readiness Advancement: The Offeror’s proposal will be assessed for its likelihood of achieving and advancing through the development milestones identified in its proposal, thus advancing the performance technology prototype commercialization readiness, analogous to Technology Readiness Levels.

OBJECTIVE 2 Evaluation Factors:

1. Evaluation Factor 1 – Programmatic Relevance: The Offeror’s proposal will be assessed for how well the proposed methodology to identify, review, and present performance technology prototypes ensures alignment and relevancy to the prioritization of the military needs set forth by MOMRP. The Government’s evaluation of this factor may include the proposed methodology used by the Integrator to assess the following, if applicable to the performance technology prototype:
 - Market and Business Model: Clear articulation of value proposition, competitive position, market opportunity and business model for getting to revenue through commercial use, including a description of the market (civilian and military) and sustainability.
 - Technical Maturity Advancement: The degree to which the Integrator could potentially advance the technical maturity level of performance technology prototypes during the performance of the project and advance the technology to the next level of development, from a technical and financial perspective.

2. Evaluation Factor 2 – 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 proposed methodology used to assess the of potential performance technology prototypes in terms of:
 - Hypothesis and objectives;
 - Scientific rationale with supporting preliminary data;
 - Feasibility and risks based on current performance technology prototype TRL;
 - Ability for the technical and management team to execute the proposed SOW in an efficient and effective manner; and
 - SOW and estimated budget.

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

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.

Request for Project Proposals MTEC-23-03-Performance
Number W81XWH-15-9-0001

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.

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

Significant Strength – 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.

Strength – An aspect of an Offeror’s proposal that has merit or exceeds specified performance or capability requirements in a way that will be advantageous to the Government during award performance.

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

Significant Weakness – A flaw that appreciably increases the risk of unsuccessful award performance.

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

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 Research Associate, Dr. Chuck Hutti, Ph.D., chuck.hutti@ati.org
- All other questions should be directed to the MTEC Chief of Consortium Operations, Ms. Kathy Zolman, kathy.zolman@ati.org

7 Acronyms/Abbreviations

ATI	Advanced Technology International
CM	Consortium Manager
CMA	Consortium Member Agreement
CMC	Chemistry, Manufacturing, and Controls
DCAA	Defense Contract Audit Agency
DCMA	Defense Contract Management Agency
DoD	Department of Defense
DODI	Department of Defense Instruction
EC	Ethics Committee
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.)
IRB	Institutional Review Board

Request for Project Proposals MTEC-23-03-Performance
Number W81XWH-15-9-0001

M	Millions
MDO	Multi-Domain Operations
MOMRP	Military Operational Medicine Research Program
MPS	Milestone Payment Schedule
MSKI	Musculoskeletal Injuries
MTEC	Medical Technology Enterprise Consortium
NDA	Nondisclosure Agreement
OCI	Organizational Conflict of Interest
ODC	Other Direct Costs
OHARO	Office of Human and Animal Research Oversight
OHRO	Office of Human Research Oversight
ORP	Office of Research Protections
OTA	Other Transaction Agreement
PDF	Portable Document Format
POC	Point-of-Contact
PoP	Period of Performance
PPG	Proposal Preparation Guide
R&D	Research and Development
RDT&E	Research, Development, Testing, and Evaluation
ROM	Rough Order of Magnitude
RPA	Research Project Award
RPI	Request for Project Information
RPP	Request for Project Proposals
SM	Service Member
SME	Subject Matter Expert
SOW	Statement of Work
TRL	Technology Readiness Level
USAMRDC	U.S. Army Medical Research and Development Command
USG	U.S. Government

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]

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 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 address both Objectives 1 and 2 described in Section 3 of this RPP.

Anticipated Outcomes/Impact

- Provide a description of the anticipated outcomes from the proposed work. List milestones and deliverables from the proposed work.

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. This plan should specifically outline the management of the Objective 1 Portfolio and a conflict resolution plan for Objective 1 Portfolio members.
- Describe any previous enterprise-level program/prototype development and execution

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
- Summarize any current or pending support (grants or on-going efforts) that may assist in successfully executing the requirements of this effort

Potential Follow-On Work

- Offerors are encouraged as appropriate to discuss potential follow-on work (continued development of initial prototypes and/or portfolio expansion).

Schedule

- PoP: 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 this effort’s requirements 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 ROM should include both the Integrator’s costs and all costs associated with the proposed prototypes included in Appendix 4 of the Enhanced White Paper submission. 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.

	<i>Year 1</i>	<i>Year 2</i>	<i>Year 3</i>	<i>TOTAL</i>
Labor	<i>\$ 100,000.00</i>	<i>\$ 100,000.00</i>	<i>\$ 100,000.00</i>	<i>\$ 300,000.00</i>

Request for Project Proposals MTEC-23-03-Performance
Number W81XWH-15-9-0001

Labor Hours	1,000.0 hrs	1,000.0 hrs	1,000.0 hrs	3,000.0 hrs
Subcontractors	\$ 50,000.00	\$ 50,000.00	\$ 50,000.00	\$ 150,000.00
Subcontractors Hours	500.0 hrs	500.0 hrs	500.0 hrs	1,500.0 hrs
Government/Military Partner(s)/Subcontractor(s) (subKTR)*	\$0.00	\$0.00	\$0.00	\$0.00
Gov't/Military Prtnrs / subKTR Hours*	0.0 hrs	0.0 hrs	0.0 hrs	0.0 hrs
Consultants	\$ 10,000.00	\$ 10,000.00	\$ 10,000.00	\$ 30,000.00
Consultants Hours	100.0 hrs	100.0 hrs	100.0 hrs	300.0 hrs
Material/Equipment	\$ 75,000.00	\$ 75,000.00	\$ 75,000.00	\$ 225,000.00
Other Direct Costs	\$ 1,000.00	\$ 1,000.00	\$ 1,000.00	\$ 3,000.00
Travel	\$ 5,000.00	\$ 5,000.00	\$ 5,000.00	\$ 15,000.00
Total Prototype Projects**	\$ 200,000.00	\$ 200,000.00	\$ 200,000.00	\$ 600,000.00
Indirect costs	\$ 48,200.00	\$ 48,200.00	\$ 48,200.00	\$ 144,600.00
Total Cost	\$ 489,200.00	\$ 489,200.00	\$ 489,200.00	\$ 1,467,600.00
Fee (Not applicable if cost share is proposed)	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00
Total Cost (plus Fee)	\$ 489,200.00	\$ 489,200.00	\$ 489,200.00	\$ 1,467,600.00
Cost Share (if cost share is proposed then fee is unallowable)	\$ 290,000.00	\$ 290,000.00	\$ 290,000.00	\$ 870,000.00
Total Project Cost	\$ 779,200.00	\$ 779,200.00	\$ 779,200.00	\$ 2,337,600.00

*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.

**Prototype Project Breakout – The Offeror must indicate the yearly total cost for each performance technology prototype proposed in Appendix 4 of the Enhanced White Paper using the table below (the number of rows should reflect the number of prototypes proposed in Appendix 4, i.e., add or delete rows as needed).

	Year 1	Year 2	Year 3	TOTAL COST
Prototype 1	\$ 100,000.00	\$ 100,000.00	\$ 100,000.00	\$ 300,000.00
Prototype 2	\$ 100,000.00	\$ 100,000.00	\$ 100,000.00	\$ 300,000.00

Total Prototype Projects	<i>\$200,000.00</i>	<i>\$200,000.00</i>	<i>\$200,000.00</i>	<i>\$600,000.00</i>
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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: Objective 2 Proposed Performance Technology Prototype(s)

- Provide letters of intent from a portfolio of proposed prototypes to be considered for funding under this RPP. The proposed portfolio may range from one prototype to several, however, the total budget (Integrator’s costs plus the prototype project costs) must not exceed the total available funding of \$6.7M as noted in Section 2.2.
- The intent of this appendix is for the Integrator to demonstrate prototype(s) that fit the technical scope of work requested in this RPP, of which several can be selected for award.
- Each Letter of Intent has a 2-page maximum and must include the following information:
 - Describe how the proposed prototype meets the needs specified in this RPP.

- Describe the scientific rationale for the project.
- Define the scope of the effort and clearly state the objectives of the project that would be addressed under this RPP.
- Provide a description of the anticipated outcomes or deliverables from the proposed work.
- Briefly describe the team/organizations that will perform the proposed work.
- Indicate the proposed PoP in months from award.
- Describe cost share included to support the proposed scope of work.
- Indicate the total funding required based on the technical approach proposed.
- Signature by an authorized representative of the organization with legal authority to develop the proposed prototype.

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 Reimbursable), 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.