

Request for Project Proposals



Solicitation Number: MTEC-22-09-BrainHealth

“Warfighter Brain Health Technology Integration”

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

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**Amendment No. 01 does the following:
To increase the page limit for the Enhanced White Paper from 15 to 21 pages.**

All other terms and conditions remain unchanged.

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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 2371b (now 4022), 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. Prototype Project

This solicitation, issued by the MTEC Consortium Manager (CM), Advanced Technology International (ATI), represents a Request for Project Proposals (RPP) for MTEC support of the U.S. Army Medical Materiel Development Activity (USAMMDA). Strategic oversight for the award(s) supported by this RPP will be provided by the Warfighter Brain Health Project Management Office (WBH PMO).

This “Warfighter Brain Health Technology Integration” prototype project aims to create a systems integratory approach to developing an array of brain health medical solutions related to traumatic brain injury and behavioral health to meet the needs of the Warfighter. This prototype project is an innovative business arrangement for a system integrator to identify and rapidly test brain health medical solutions across the continuum of care that aid in the prevention, detection, and treatment of neurotrauma and behavioral health of our U.S. Service Members. Therefore, this RPP aims to establish an agreement with an organization able to provide the integration of technology, resources and expertise required to translate technologies related to Warfighter brain health from early-stage development to transition to the Warfighter and the commercial marketplace. This RPP also includes the development of a non-invasive neuro assessment device (NINAD) as the first prototype to be translated, but includes the innovative business component of identifying, rapidly prototyping and testing additional medical solutions along the continuum of care for Warfighter brain health. This prototype project includes prototyping projects that spans the breadth of medical solutions intended to meet joint capability requirements for materiel prototypes that will protect, identify, assess, monitor, treat, and promote the recovery and restoration of Warfighters at risk/subject to TBI, behavioral health stressors and disorders (ex: post-traumatic stress disorder), cognitive impairment, neurological injuries, and other means that impact the brain health and performance of our warfighters.

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 **\$1.7 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 \$5-10 M per year for follow-on work for up to 10 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 \$1.7M at present, but with an additional \$5-10M 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).

It is expected that MTEC will make **a single award** to qualified Offerors in FY22 to accomplish the scope of work. Note, however, that the Government reserves the right to make final evaluation and award decisions based upon, among other factors, programmatic relevancy and overall best value solutions determined to be in the Government’s best interest. Therefore, if a single Enhanced White Paper is unable to sufficiently address the entire scope of this RPP’s technical and regulatory requirements (outlined in Section 3), several Offerors may be asked to work together in a collaborative manner. However, if an optimal team is not identified, then MTEC may make multiple, individual awards to Offeror(s) to accomplish subset(s) of the key tasks.

Award funding will be structured incrementally and based upon completion of Milestones and Deliverables.

The Period of Performance (PoP) **for the initial scope of work is not to exceed 12 months** , as outlined in Section 3.3. **However, the intent of the Government is that this prototype project will span 10 years, in order to continue the development of the NINAD and additional medical solutions along the warfighter brain health continuum. Medical solutions will be down-selected for translation as appropriate and as related to Warfighter brain health capabilities (see Section 3.4). Any resulting award(s) may be modified to extend the PoP and add additional work to further support the longer-term vision of this “Warfighter Brain Health Technology Integration” project.**

Dependent on the results and deliverables under any resultant award(s), the USG may apply additional dollars and/or allow for additional time for non-competitive follow-on efforts with appropriate modification of the award. See Section 3.4 for additional details.

As of the release date of this RPP, future year Defense Appropriations Bills have not been passed and there is no guarantee that any additional funds will be made available to support this program. The funding estimated for this RPP is approximate and subject to realignment.

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 submitted and will select those that best meet their current technology priorities using the 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(s) or transaction pursuant to 10 U.S.C. § 2371b section f.

The Government-selected prototype project(s) awarded as a result of this solicitation will be funded under the Other Transaction Agreement for prototype projects (OTA) Number W81XWH-15-9-0001 with MTEC administered by the CM, ATI. The CM will negotiate and execute a Base Agreement with MTEC members (if not yet executed). The same provisions will govern this Base Agreement as the OTA for prototype projects between the Government and MTEC. Subsequently, any proposal that is selected for award will be funded through a Research Project Award (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 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. **Since this RPP is specifically seeking a prime contractor to provide the integration of technology, resources and expertise required to translate technologies related to Warfighter brain health from early-stage development to transition to the Warfighter and the commercial marketplace, it is encouraged that Offerors bring forth a proposal that includes a dynamic network of potential partners to assist as needed as the prototypes advance through their pipelines to maturation. 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.

2.7. 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, 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, 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 considered 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 defined in the Base Agreement regarding IP and Data Rights. **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 shall be determined in accordance with the provisions of the 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 on or before September 30, 2022** (subject to change). The Government reserves the right to change the proposed PoP start date through negotiations via the CM and prior to issuing a Research Project Award.

2.13. Anticipated Enhanced White Paper Selection Notification

As the basis of selections is completed, the Government will forward their selections to 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 strategic and operationally, disintegrate enemy's defenses, exploit enemy weaknesses and re-compete to consolidate gains. Medical plays a critical role in each aspect of MDO and must modernize rapidly to maintain Force readiness and increase soldier lethality.

In order to modernize the Army to be a ready and resilient Force, USAMMDA is seeking to build a capability through MTEC that is poised to rapidly advance medical prototypes related to Warfighter brain health and transition these to both the Warfighter and the commercial marketplace as appropriate. The WBH PMO requires multiple prototype medical solutions that address traumatic brain injury (TBI), behavioral health, and other related brain health topics.

Although this MTEC project is intended to advance multiple prototypes for a variety of brain health indications over the project's lifetime, the initial prototype that will be developed in the base PoP will focus on the development of a NINAD, which is a capability for far-forward (Role of Care (ROC) 1 and 2) assessment of TBI. Development of such a capability will not only serve to indicate the severity of TBI, but will also serve to enable far-forward triage evacuation decisions and inform (for those TBI casualties who are able to remain in theater) return to duty. Accordingly, the early assessment, far-forward in the acute setting will significantly improve the long-term outcomes by enabling early intervention, reducing injury severity.

3.2. Solution Objective

This project aims to establish a partnership with an organization able to serve as the “integrator” to translate technologies related to Warfighter brain health from early-stage development to transition to the Warfighter and the commercial marketplace. The intent is to maintain this partnership for up to 10 years, and to translate several brain health medical products throughout the years. 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 and experience to bring their technologies to market. This structure also allows flexibility to replace failing prototypes with more promising ones throughout the PoP. Additionally, the integrator will provide acquisition strategy and DoD 5000 series deliverables to support acquisition aspects of the program as per the needs in each effort.

3.3. Scope of Work

The DoD has identified two tasks for funding under this RPP. The intent of this RPP is to initially award Tasks 1 and 2 with a 12 month PoP, with the potential for significant follow-on work. It is the Government’s intent that this initial award is part of a larger and longer project, potentially providing approximately \$5-10 M per year for follow-on work for up to 10 years (pending availability of funding and technical progress) as described in Section 3.4. All Enhanced White Paper submissions **shall** detail how the Offeror will accomplish/achieve all aspects of these Year 1 requirements to include a clear approach to execute all tasks based upon the Offeror’s unique methodology. Therefore, the Offeror shall also clearly identify the major milestones in the SOW/Milestone Payment Schedule associated with accomplishing these Year 1 requirements.

In Process Reviews (IPRs): As determined necessary by the Government, the Government may conduct periodic IPRs with the Awardee(s) to review the work completed and recommend modifications to the project’s plan and Awardee(s)’s team based on an assessment of the progress to date and the team(s)’s capabilities to meet the program’s technical requirements. These IPRs will ensure that the program maintains its maximum flexibility to adapt the direction and modify the team as new information develops and the technical requirements mature over the duration of the effort. Offerors are required to include the following within the Milestone Payment Schedule contained within the SOW (see Attachment 4 of the PPG):

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

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

To meet the intent of this RPP, each proposal MUST ADDRESS BOTH TASKS 1 AND 2 described below.

Task 1 – Prime Integrator capabilities to translate brain health prototypes: It is expected that MTEC will make a single award to a qualified team to accomplish all tasks. 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.

The Integrator’s main role will be to support the development activities required to advance prototypes related to Warfighter brain health along their maturation pipeline. The integrator’s role may include (but not limited to) the following activities (as necessary for each effort):

1. Scout (on-going market research) and propose promising prototypes for development related to Warfighter Brain Health for approval by the USAMMDA WBH PMO and its associated DoD Integrated Product Team, with the goal for add on to this award for the execution of activities required for prototype translation.
2. Conduct strategic planning with the WBH PMO to ensure successful transition of market candidates and/or transitions from USAMRDC’s science and technology programs to USAMMDA for advanced product development.
3. Provide resources for early translational activities, such as team building, strategy, project management and planning, etc.
4. Provide access to vetted translational services and expertise related to the prototype development, including but not limited to:
 - Non-clinical testing (to include pre-clinical, bench, and animal testing)
 - Biocompatibility studies
 - Prototype refinement/maturation progressing toward a clinical product
 - Stability and shelf-life studies
 - Establishment of Good Manufacturing Practice capabilities for clinical trials and for market release [Contract Manufacturing Organization capabilities (CMO)]
 - Clinical feasibility and pivotal studies (as needed) to support regulatory approval/clearance
 - Regulatory and reimbursement strategy
 - Clinical Research Organization (CRO) capabilities
 - Regulatory affairs and compliance capabilities
 - Investigational New Drug/ Investigational Device Exemption Holder /Sponsor responsibilities as per 21CFR312 subpart D
 - Prototype delivery for military-relevant testing
 - Draft product support documentation (e.g., training guides, product inserts, etc.)
 - Development of a business and/or commercialization plan for market release
 - Development of DoD 5000 documentation and activities to support acquisition maturation
5. Work closely with the USAMMDA Brain Health PMO to ensure alignment with the military requirement and to conduct military user testing as appropriate.

It is preferred that the integrator have established experience in the advancement and commercialization of technologies related to brain health. It is also preferred that the integrator already have an established network of translational service providers at the time of enhanced white paper submission.

In the enhanced white paper, Offerors are expected to outline how they will conduct Activities #1-5 listed above. However, since Activities #3, 4, and 5 will ultimately be tailored to the specific prototype to be translated, Offerors will be evaluated on their general approach to conducting these activities for any prototype translation effort.

Furthermore, the Government recognizes that the composition of the team may change as the project requirements evolve over time. Therefore, the Offeror shall include the overall project management plan as part of the Enhanced White Paper submission (as required in Section 8). **The Offeror shall also describe its strategy to adjust (i.e. expand) the team, as needed, throughout the period of performance (to include potential follow on tasks) to ensure the proper level of effort, access to the necessary subject matter experts, etc.**

Task 2 – Refinement of the Concept of Operations (CONOPS) and Analysis of Alternatives (AoA) for a far-forward assessment of TBI called the Non-Invasive Neuro Assessment Device (NINAD).

The goal for a NINAD solution is currently defined as translation of a prototype technology to detect and assess the severity of Warfighter casualties suspected to have TBI in MDO which include austere environment(s), prolonged field care with focus on use in ROC 1 and ROC 2. The NINAD solution is intended to be used by the combat Medic to inform triage, evacuation, and treatment decisions far-forward in the field with low logistical footprint and (preferably) low unit cost. NINAD solutions should also be able to assess the status of confirmed TBI casualties that remain in theater and enable return to duty decisions. This latter part may contain cognitive assessment aspects.

The ideal NINAD solution shall meet the following requirements:

- Prototypes that are currently at a Technology Readiness Level of 3 or above and currently in development and commercially available (in at least prototype status) to enable use in an Early User Evaluation; specifically to inform CONOPS which will provide criteria for use in an AoA.
- Prototype solutions must be capable of use at ROC 1 and ROC 2 in austere environments. As such, logistics footprint should be minimal. The need for cold chain is discouraged. Any potency and dated related consumables (if required) should not require cold chain and should have a shelf life of at least 12 months. [Refer to the Emergency War Surgery for ROCs definitions: <https://www.cs.amedd.army.mil/FileDownloadpublic.aspx?docid=6f9e0685-1290-4e92-8277-c1e7b0f2fef0>]
- Solutions, ultimately, must have the ability to achieve high sensitivity and specificity (>85%).

- It is desired that the candidates will be of low unit cost. (Upon award, a market research report will be provided to the Performer for further information.)

The WBH PMO realizes achievement of all the above requirements of the ideal NINAD solution may not be contemporaneously possible; necessitating the assessment of available candidates to inform CONOPS. Subsequently, the Government will use the assessment data to develop the CONOPS which will provide specifications to assist in the AoA (or equivalent) and a subsequent down-selection process.

The objective of Task 2 is for the Integrator to assist the WBH PMO through the Materiel Solutions Analysis Phase of the Defense Acquisition Process (as outlined in the DoD Instruction (DODI) 5000 series) as it relates to the NINAD, including an analysis of alternatives and implementation of a sound, evidence-based down-selection process. The results of this assessment and the technology platform down-selection will be subject to review by the Milestone Decision Authority (MDA) at a forthcoming Milestone A decision. [NOTE: The MDA determines the point at which an activity enters the acquisition process and approves the program into subsequent phases of the acquisition process. For more information about the MDA, Milestone A, and the DoDI 5000 series can be found here: www.acq.osd.mil]

The end deliverables of Task 2 are to:

- Plan and conduct the activities required to enable a successful Milestone A (obtain approval by the Milestone Decision Authority (MDA)) to enter the Technology Maturation and Risk Reduction (TMRR) Phase, including activities to enable refinement/maturation of the existing CONOPS, New Concepts of Employment (CONEMPs), and the Capability Development Document (CDD) related to the NINAD,
- Plan and conduct an Early User Evaluation,
- Plan and conduct an AoA (or equivalent) using input/data from the aforementioned activities, and
- Propose a strategy for and produce other Milestone A related DOD 500 series documentation using an approach to “tailor in” necessary documentation.

Offerors are expected to describe the strategy and plan that will be employed to enable the assessment of available candidates and how the assessment data will be used to refine the CONOPS/CONEMPS and establish specifications/attributes that will be used in a subsequent AoA (or equivalent), enabling the down-select a candidate technology platform. The Government will provide, as Government Furnished Information, upon award: the Market Research Report, Draft CONOPS, and a draft CDD.

In order to achieve the above, the Offerors shall describe in their enhanced white papers (as applicable) the strategy and plan they will use to conduct preliminary user assessment(s) of up to five different NINAD candidate solutions that will enable refinement of the existing CONOPS, CONEMPs, and the CDD; ensuring that the Government can substantiate the AoA and resulting technology platform down-selection, and provide other milestone A requirements (per DoD 5000

series) for presentation to the MDA. These activities, and the subsequent Milestone A decision (if successful) will ensure that the Government is developing the correct technology platform in (potential) follow-on NINAD translation effort(s). Offerors should describe how they will interact with the WBH PMO to develop a plan to enable a successful Milestone A; including refinement/maturation of CONOPS, CONEMPS, CDD, and the subsequent planning and facilitation of the AoA to include development of the AoA report to support the Milestone A. The completed AoA report will enable a recommendation (to the MDA) for down-selection to a technology platform that will best meet the needs of the end user. The Offeror will also propose an acquisition strategy and produce other milestone documentation as appropriate to fulfill the requirements for a successful Milestone A decision.

At the time of submission, the Offeror is not required to have contractual relationships with the NINAD candidates that are proposed, but should describe how they will gain access to the proposed prototypes for evaluation.

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. For example, follow-on work may be awarded to continue the translation of the NINAD and/or inclusion of additional prototypes related to Warfighter brain health. Additional prototyping that is within scope of this agreement is work that spans the breadth of medical solutions intended to meet joint capability requirements for materiel prototypes that will protect, identify, assess, monitor, treat, and promote the recovery and restoration of Warfighters at risk/subject to TBI, behavioral health stressors and disorders (ex: post-traumatic stress disorder), cognitive impairment, neurological injuries, and other means that impact the brain health and performance of our warfighters. Some examples of prototypes include, but are not limited to, TBI field monitoring solutions, TBI treatment solutions, mobile brain health applications, battlefield behavioral health solutions, etc.

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

3.6. Guidance Related to DoD-Affiliated Personnel for Participation

Compensation to DoD-affiliated personnel for participation:

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.acgcenter.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-22-09-BrainHealth**) 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 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 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 (4): Submitted via BIDS (5MB or lower per document)

- **Enhanced White Paper:** one PDF document
- **Warranties and Representations:** one Word or PDF document (**Attachment 3 of the PPG**)
- **Statement of Work (SOW)/Milestone Payment Schedule:** 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**)

Page Limitation: The Enhanced White Paper is limited to twenty-one (21) pages (including cover page). The following Appendices are **excluded** from the page limitation: (1) *Warranties and Representations*, (2) *Statement of Work*, and (3) *Data Rights*

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 selected 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.

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

4.4. Enhanced White Paper and Cost Proposal Preparation Costs

The cost of preparing Enhanced White Papers and Cost Proposals in response to this RPP is not considered a direct charge to any resulting award or any other contract. Additionally, the MTEC Assessment Fee (see Section 2.10 of this RPP) is not considered a direct charge to any resulting award or any other contract.

4.5. Freedom of Information Act (FOIA)

To request protection from FOIA disclosure as allowed by 10 U.S.C. §2371(i), Offerors shall mark business plans and technical information with a legend identifying the documents as being submitted on a confidential basis. For more information, please refer to Section 6.1.1 of the MTEC PPG.

4.6. Telecommunications and Video Surveillance

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

5 Selection

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 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

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 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 (of equal importance).

Evaluation Factors

- 1. Management Approach, Teaming, and Expertise**
- 2. Technical Feasibility**

- **Factor 1 – Management Approach, Teaming, and Expertise:** The Offeror’s proposal will be evaluated for the strength of the organization/team, experience in enterprise level program/prototype development and execution, considering the qualifications of the personnel, services, and subcontractors, project management plan, integrator oversight/management of subcontractors and management of efforts hereunder in collaboration with the government to complete the work. Evaluation of this factor will also be based upon the degree to which the Offeror proposes a coherent organizational structure and sufficient staffing to accomplish the technical objectives.

- **Factor 2 – Technical Feasibility:** The Offeror’s proposal will be assessed for relevancy, thoroughness, and completeness of the proposed approach (e.g., the technical merit). The Government’s evaluation of this factor may include the degree to which the following are addressed and demonstrated:
 - Clear and appropriate objectives;
 - Focused and detailed methodologies for Section 3.3;
 - Overarching approach briefly outlining Section 3.4; and
 - Thorough and complete SOW and Rough Order of Magnitude (ROM) Cost Estimate.

Table 2 explains the adjectival merit ratings that will be used for the Management Approach, Teaming, and Expertise as well as the Technical Feasibility 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.
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.
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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)***

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 Director of Research Programs, Lauren Palestrini, Ph.D., lauren.palestrini@mtec-sc.org
- All other questions should be directed to the MTEC Director of Program Operations, Ms. Kathy Zolman, kathy.zolman@ati.org

7 Acronyms/Abbreviations

ATI	Advanced Technology International
BIDS	Proposal submission platform
CM	Consortium Manager
CMC	Chemistry, Manufacturing and Controls
CMO	Contract Manufacturing Organization
CRO	Contract Research Organization
CONOPS	Concept of Operations
CONEMPS	Concepts of Employment
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
HRPO	Human Research Protection Office
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IPR	In Process Review
IRB	Institutional Review Board
M	Millions
MDO	Multi-Domain Operations
MTEC	Medical Technology Enterprise Consortium
NDA	Nondisclosure Agreement
NINAD	Non-invasive neuro assessment device
OCI	Organizational Conflict of Interest
ODC	Other Direct Costs
ORP	Office of Research Protections
OTA	Other Transaction Agreement
PDF	Portable Document Format
PMO	Project Management Office
PoP	Period of Performance
PPG	Proposal Preparation Guide

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R&D	Research and Development
RDT&E	Research, Development, Testing, and Evaluation
ROC	Role of Care
ROM	Rough Order of Magnitude
RPA	Research Project Award
RPP	Request for Project Proposals
SME	Subject Matter Expert
SOW	Statement of Work
TBI	Traumatic brain injury
USAMMDA	U.S. Army Medical Materiel Development Activity
USAMRDC	U.S. Army Medical Research and Development Command
USG	U.S. Government
WBH	Warfighter Brain Health

8 Enhanced White Paper Template

Cover Page

[Name of Offeror]

[Address of Offeror]

[Phone Number and Email Address of Offeror]

DUNS #: [DUNS #]

CAGE code: [CAGE code]

[Title of Enhanced White Paper]

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

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

[A proprietary data disclosure statement if proprietary data is included. Sample:

This Enhanced White Paper includes data that shall not be disclosed outside the MTEC Consortium Management Firm and the Government. 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]
[Prime Integrator Organization]

Section I: Executive Summary

- Provide a high-level overview of your Enhanced White Paper, clearly delineating Tasks 1 and 2. Limit the executive summary to 1 page.

Section II: Proposal for Task 1

Programmatic Relevance

- Provide the background and the Offeror's understanding of the problem and/or technology gap/process deficiency.

Scope Statement

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

Rationale

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

Technical Approach

- Describe the methods, organization, and staffing plan required to accomplish the proposed approach. Describe the proposed methodology in sufficient detail to show a clear course of action. Describe approach to risk mitigation/management. Describe approach and processes for Governance of each task awarded under the effort.

Technical and Management Team

- 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. If not, indicate which components of your team that have not 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 the ability of the management team to advance the technology.
- Indicate which organizations or types of organizations you will need to team/partner with as your technology advances through program tasks.
- Describe how you will on and off-board support providers (ex: regulatory affairs, milestone documentation development, risk management, CMO, CRO, etc.)
- Describe the process you will use to on and off-board technology candidate/prototype providers
- Explain how you intend to manage competitive prototyping as well as how you will interact with the government to facilitate go/no-go decision making.

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.
- Identify resources that are not yet part of your network and your approach to adding these in.

Expansion Strategy

- Describe the overarching strategy to translate the processes, knowledge, capabilities, and technology to enable scalability as more prototypes are added to the project for translation.

Anticipated Impact

- Describe the impact that the proposed integrator would have on this project.

Risk Identification and Mitigation

- Identify key technical, schedule, and cost risks related to Task 1. Discuss the potential impact of the risks, as well as potential mitigations.

Section III: Proposal for Task 2

Programmatic Relevance

- Describe how the proposed technology(ies) meets the needs specified in this RPP (Offerors are able to propose up to 5 candidate prototypes for NINAD devices for consideration by the Government) within user evaluations

Objectives

- Clearly state the objectives for each proposed NINAD prototype.

Scientific Rationale / Preliminary Data

- Describe the scientific rationale for the project, including a brief description of previous related work data that supports the feasibility of proposed work.

Technical Approach

- Outline the proposed methodology for each prototype in sufficient detail to show a clear course of action that addresses the technical requirements described in this RPP.
- Describe the work to be conducted during the first 12 month PoP. Describe the work to be conducted in follow-on years to bring the solution to the Warfighter and commercial marketplace.

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.

Market and Business Model

- Clearly articulate the 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.

Product Development Strategy

- Describe the final vision of what the NINAD would look like and how that product would be delivered for military and civilian use.
- Describe previous/existing partnerships with industry or the USG/DoD (including any resultant contracts/grants/awards and/or IP).

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. Schedules should have an endpoint for each prototype that reaches the commercial marketplace.

Risk Identification and Mitigation

- Identify key technical, schedule, and cost risks related to Task 2. Discuss the potential impact of the risks, as well as potential mitigations.

Section IV: Cost

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 Warfighter Brain Health 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 related to both Tasks 1 and 2.

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.

	<i>Task 1</i>	<i>Task 2</i>	<i>TOTAL</i>
Labor	<i>\$ 100,000.00</i>	<i>\$ 100,000.00</i>	<i>\$ 200,000.00</i>
Labor Hours	<i>1,000.0 hrs</i>	<i>1,000.0 hrs</i>	<i>2,000.0 hrs</i>
Subcontractors	<i>\$ 50,000.00</i>	<i>\$ 50,000.00</i>	<i>\$ 100,000.00</i>
Subcontractors Hours	<i>500.0 hrs</i>	<i>500.0 hrs</i>	<i>1,000.0 hrs</i>
Government/Military Partner(s)/Subcontractor(s) (subKTR)*	<i>\$0.00</i>	<i>\$0.00</i>	<i>\$0.00</i>
Gov't/Military Prtnrs / subKTR Hours*	<i>0.0 hrs</i>	<i>0.0 hrs</i>	<i>0.0 hrs</i>
Consultants	<i>\$ 10,000.00</i>	<i>\$ 10,000.00</i>	<i>\$ 20,000.00</i>
Consultants Hours	<i>100.0 hrs</i>	<i>100.0 hrs</i>	<i>200.0 hrs</i>
Material/Equipment	<i>\$ 75,000.00</i>	<i>\$ 75,000.00</i>	<i>\$ 150,000.00</i>
Other Direct Costs	<i>\$ 1,000.00</i>	<i>\$ 1,000.00</i>	<i>\$ 2,000.00</i>
Travel	<i>\$ 5,000.00</i>	<i>\$ 5,000.00</i>	<i>\$ 10,000.00</i>
Indirect costs	<i>\$ 48,200.00</i>	<i>\$ 48,200.00</i>	<i>\$ 96,600.00</i>
Total Cost	<i>\$ 289,200.00</i>	<i>\$ 289,200.00</i>	<i>\$ 578,400.00</i>
Fee (Not applicable if cost share is proposed)	<i>\$ 0.00</i>	<i>\$ 0.00</i>	<i>\$ 0.00</i>
Total Cost (plus Fee)	<i>\$ 289,200.00</i>	<i>\$ 289,200.00</i>	<i>\$ 578,400.00</i>
Cost Share (if cost share is proposed then fee is unallowable)	<i>\$ 290,000.00</i>	<i>\$ 290,000.00</i>	<i>\$ 580,000.00</i>
Total Project Cost	<i>\$ 579,200.00</i>	<i>\$ 579,200.00</i>	<i>\$ 1,158,400.00</i>

*Use the rows above for “Government/Military Partner(s)/Subcontractor(s)” if the project involves one or more Government/Military Facilities (Military Health System (MHS) facility,

research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) performing as a collaborator in performance of the project.

Estimate Rationale

- The Offeror must provide a **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.

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

Costs provided shall be clearly attributable to activities or materials as described by the Offeror. Costs should be broken down using the Cost Proposal Formats that are located on the Members-Only MTEC website. If the MTEC template is not used, 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.