

Request for Project Proposals



Solicitation Number: MTEC-22-07-NavyMultiTopic

**“Navy Multi-Topic 2022 – Advanced Biomedical Product Development in Support of
Naval Operations”**

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

Request Issue Date: February 21, 2022
Amendment No. 01 Issue Date: March 17, 2022

White Paper Due Date: March 28, 2022
Noon Eastern Time

Amendment No. 01 does the following:
Extends the proposal due date from March 21, 2022 to March 28, 2022.

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 prototypes with USAMRDC. 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 support of the Naval Medical Research Center (NMRC) Naval Advanced Medical Development (NAMD) program. Proposals selected for award as a result of this RPP will be awarded under the authority of 10 U.S.C. § 2371b. The award(s) will be managed by the NAMD program office within NMRC.

The purpose of the multiple topic area (“multi-topic”) Request for Project Proposals (RPP) is focused on the advancement of engineering and medical prototypes and knowledge products related to a broad range of medical technological needs identified in the focus areas listed below. Relevance to the enhanced readiness and resilience of Navy and Marine Corps health and performance is a key feature of this RPP. This RPP includes the following focus areas:

- Focus Area #1: Combat Casualty Wound and Infection Care
- Focus Area #2: Military Dental Research
- Focus Area #3: Human Performance

2 Administrative Overview

2.1. Request for Project Proposals (RPP)

MTEC is utilizing a two-staged approach for this RPP. In Stage 1, current MTEC members are invited to submit White Papers using the mandatory format contained in this RPP (Section 8). The Government will evaluate White Papers submitted and will select White Papers 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 White Paper evaluation will be invited to submit a proposal in Stage 2. Notification letters will contain specific Stage 2 proposal submission requirements.

Each MTEC White Paper submitted must be in accordance with the mandatory format provided in Section 8 of the RPP. 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).

Note that the terms “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 **\$15 million (M)** for anticipated awards to be made during FY2022. Award and funding from the Government is expected to be limited to the funding specified above and is contingent upon the availability of federal funds for this program. Awards resulting from this RPP are expected to be made under the authority of 10 U.S.C. § 2371b. The estimated total available funding per Focus Area is as follows (subject to realignment dependent on quality of submissions):

- Focus Area #1: Combat Casualty Wound and Infection Care **~\$8M**
- Focus Area #2: Military Dental Research **~\$3-5M**
- Focus Area #3: Human Performance **~\$3-4M**

MTEC anticipates that **multiple awards** may be made under each Focus Area with average budgets ranging from \$1,750,000 to \$8,000,000 (anticipated) for the base period of performance (exclusive of any proposed options). Award funding will be structured incrementally and based upon completion of Milestones and Deliverables.

The base Periods of Performance (PoP) may range from **12 to 36 months**, dependent upon product type and level of maturation required. Note that projects may be phased, as appropriate, with contract options to enable the exercise of additional milestones to allow maximum flexibility in terms of the progression of work, availability of funding, and duration of the awarded project(s). Dependent on the results and deliverables under any resultant award(s), the USG may apply additional dollars and/or allow for additional time for follow-on efforts with appropriate modification of the award. See Section 3.5 for additional details. Award funding will be structured incrementally and based upon completion of Milestones and Deliverables.

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).

As of the release date of this RPP, future year Defense Appropriations Bills may not have been passed and there is no guarantee that any additional funds will be made available to support this program in future years. The funding estimated for this RPP is approximate and subject to realignment. Funding of proposals received in response to this RPP is contingent upon the availability of federal funds for this program.

2.3. Acquisition Approach

MTEC recognizes that considerable effort is required to prepare a competitive proposal to MTEC. The two-stage approach for this RPP is intended to streamline the initial proposal preparation time and effort for MTEC members. Based on the Government's evaluation of White Papers in Stage 1, select Offerors will be invited to participate in Stage 2 for more detailed evaluation.

The due date for White Papers is found on the cover page of this RPP. White Papers may not be considered under this RPP unless the White Paper was received on or before the due date specified on the cover page.

Stage 1: White Papers submitted under this RPP shall follow the MTEC White Paper Template provided in Section 8 of this RPP.

Stage 2: The Stage 2 process may vary and may require different submissions compared with typical MTEC RPPs. The Government is utilizing two distinct Stage 2 approaches under this RPP.

- **Stage 2 Approach A:** This Stage 2 approach will require a solution pitch (i.e., oral presentation) followed by a written detailed research strategy and full cost proposal (after evaluation of the pitch). Information on cost proposals can be found in Section 7 of the Proposal Preparation Guide (PPG).
- **Stage 2 Approach B:** This Stage 2 approach will require a full proposal (to include technical and cost volumes) using the MTEC PPG.

Note that Stage 2 Offerors will only be required to follow one of the aforementioned Stage 2 approaches. Those Offerors that are favorably evaluated during Stage 1 will receive notification

letters which will serve as the formal request for a Stage 2 proposal. These letters will contain specific Stage 2 proposal submission requirements and templates.

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

The Government-selected prototype project(s) awarded as a result of this solicitation will be funded under the Other Transaction Agreement for prototype projects (OTA) Number W81XWH-15-9-0001 with MTEC administered by the CM, ATI. The CM will negotiate and execute a Base Agreement with MTEC members (if not yet executed). The same provisions will govern this Base Agreement as the OTA for prototype projects between the Government and MTEC. Subsequently, any proposal that is selected for award will be funded through a Research Project Award (RPA) issued under the member's Base Agreement. The MTEC Base Agreement can be found on the MTEC website at www.mtec-sc.org/documents-library/.

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 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 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 focus areas of interest 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 White Papers 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 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 for opportunities to attract supplemental funding sources.

Therefore, on your White Paper 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, 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 proposal submission) if they cannot address the full scope of technical requirements of the RPP or otherwise believe a team may be beneficial to the Government.

MTEC members are encouraged to use the MTEC Database Collaboration Tool. The purpose of the tool is to help MTEC member organizations identify potential teaming partners by providing a quick and easy way to search the membership for specific technology capabilities, collaboration interest, core business areas/focus, 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 "Member 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 a White Paper. Offerors submitting White Papers as **the prime performer must be MTEC members of good standing at least 3 days prior to submission of the White Paper**. 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 10 U.S.C. §2371b, 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. Awardees are not allowed to use MTEC funding to pay for their assessment fees. 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 Intellectual Property (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 under this proposed effort would 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.

Note that as part of Stage 2 of the RPP process (submission of a pitch or full proposal), Offerors shall complete and submit **Attachment 6 of the PPG** (Intellectual Property and Data Rights) 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 September 30, 2022 (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 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 Offerors will be notified by email from the MTEC CM of the results of the evaluation. Those with favorably evaluated white papers will move forward to the next phase of the process, while those not selected will receive evaluation rationale for non-selection.

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

3 Technical Requirements

3.1. Background

All white paper submissions shall describe projects that are based on logical reasoning and sound scientific rationale. Projects should not be exploratory in nature and do require a foundation of preliminary data. Please note that MTEC-sponsored projects must result in “prototype” research deliverables that transition medical solutions to industry.

The definition of a “prototype” is as follows: Proposed prototype projects should not be exploratory in nature and do require a foundation of preliminary data. A prototype project can generally be described as a preliminary pilot, test, evaluation, demonstration, or agile development activity used to evaluate the technical or manufacturing feasibility or military utility of a particular technology, process, concept, end item, effect, or other discrete feature. Prototype projects may include systems, subsystems, components, materials, methodology, technology, or processes. By way of illustration, a prototype project may involve: a proof of concept; a pilot; a novel application of commercial technologies for defense purposes; a creation, design, development, demonstration of technical or operational utility; clinical recommendations or guidelines; or combinations of the foregoing, related to a prototype. The quantity should generally be limited to that needed to prove technical or manufacturing feasibility or evaluate military utility.

Subsequent to the completion of performance under the prototype awards resulting from this RPP, the Government reserves the right to award follow-on work. Any follow-on work for the continuation of the prototype development is contingent upon availability of future funding and the successful completion/progression of milestones.

3.2. Minimum Requirements for Submission of a White Paper

White Papers submitted in response to this RPP shall meet the following minimum requirements:

1. Meet the Minimum Knowledge/Technology Readiness Level (KRL/TRL): Proposed prototypes shall be at a KRL or TRL of 5 **at the time of submission or by the anticipated award date (at or around September 30, 2022)**. Offerors have achieved KRL/TRL 5 if:
 - **Knowledge Products:** Offeror has completed testing of *a priori* hypotheses using rigorous scientific design and directly assessed whether and how a tool can work.
 - **Pharmaceutical (Biologics, Vaccines):** Offeror has determined that sufficient data on the candidate biologic/vaccine exist in the draft technical data package to justify proceeding with preparation of an Investigational New Drug (IND) application.
 - **Medical Devices:** Investigational Device Exemption (IDE) review by the Center for Devices and Radiological Health (CDRH) results in determination that the investigation may begin. For a 510(k), preliminary findings suggest the device will be substantially equivalent to a predicate device.
 - **Medical Information Management/Information Technology & Medical Informatics:** Medical Informatics data and knowledge representation models are implemented as data and/or knowledge management systems and tested in a lab environment.

NOTE: Full definitions of TRLs can be found [here](#). More information regarding KRLs can be found [here](#).

2. Represent New or Substantially Revised Submissions to MTEC: This RPP is intended only for submission of new projects or substantially revised or modified proposals in accordance with previous Government feedback, and not identical resubmissions from previous MTEC NavyMultiTopic solicitations (including the 20-02-NavyMultiTopic and 21-10-NavyMultiTopic).
3. Align to a Specified Focus Area of Interest: White Papers shall align to a single Focus Area of Interest specified in Section 3.3 below. Failure to align to a single Focus Area of Interest may result in an “Unacceptable” rating and render the proposal ineligible for award.

3.3. Focus Areas of Interest

Proposed prototype solutions **shall** address **ONE** of the Technology Focus Areas and **ONE** of the associated Specific Areas of Interest outlined below in support of the NAMD. Offerors are not limited to a single white paper submission. White Papers not aligned to **ONE** of these Focus Areas

(and ONE of the associated Specific Areas of Interest) may not be considered for award. These Technology Focus Areas are not listed in order of importance.

1) FOCUS AREA #1: COMBAT CASUALTY WOUND AND INFECTION CARE:

This area focuses on patient care at and through the continuum of care as well as products and services that sustain patient (warfighter) health in austere environments such as expeditionary, littoral, and deep water. **Specific areas of interest** are as follows (*Offerors shall address only one of these in each White Paper submission*):

- a) Wound care treatments / therapies for combat injuries. Includes technologies suitable for use at point of injury and / or at medical facilities in theater
- b) Wound care technologies for combat wound infections (e.g., bacterial and other infections of combat wounds)
- c) Innovative wound care technologies to treat and prevent biofilm formation

2) FOCUS AREA #2: MILITARY DENTAL RESEARCH:

This area focuses on prevention and treatment of dental and maxillofacial injuries, pain, and infections to improve care for and outcomes of wounded warfighters. Research topics may encompass routine clinical dental care to maintain the resilience and readiness of the warfighter as well as methods or products to treat injuries to the oral cavity, face, and facial bones sustained during combat (e.g., combat density, fracture, burns, etc.). Also of interest are development activities focused on manufacturing readiness of technical solutions. **Specific areas of interest** are as follows (*Offerors shall address only one of these in each White Paper submission*):

- a) Clinical solutions for dental diseases and emergencies, which may include diagnostic aids, prevention or treatment modalities, restorative biomaterials, medications, therapeutic techniques, clinical guidelines, and/or knowledge products relevant to clinical practice
- b) Methods or products to treat maxillofacial injury and trauma sustained during combat for restoring the cosmetic and functional aspects of the face, including fabrication, manufacturing, and performance testing of products such as a solid dressing that contains antimicrobial silver and cerium ions and maintains antimicrobial activity for up to 3 days
- c) Military Dental Research Solutions to provide emergency dental care in austere or forward combat environments

3) FOCUS AREA #3: HUMAN PERFORMANCE:

This area focuses on the prediction and monitoring of health status using advanced biomedical and electronics solutions and well as treatments to improve human performance or mitigate negative environmental effects of Navy personnel in militarily-relevant environments (e.g., underwater, surface, and / aviation). **Specific areas of interest** as follows (*Offerors shall address only one of these in each White Paper submission*):

- a) Development of physiological monitoring systems to include wearable devices and/or tablets for verification and validation of individualized predication

algorithms for physical and cognitive performance due to stress in underwater Navy-relevant operational environments

- b) Biomedical solutions for the rapid delivery of products to improve the performance of military personnel / or mitigate negative effort of environmental condition conditions during or directly following the symptomatic onset of conditions that may otherwise comprise the efficiency of service members and their performance in militarily relevant environments (e.g., surface [motion-sickness], undersea).

3.4. Additional Points of Consideration

- **Classification of Proposed Solutions:** Proposed prototype solutions shall be either “engineering and medical prototypes” or “knowledge products”. See below for definition of each.
 - Engineering and Medical Prototypes: System, subsystem, component, or material directly or indirectly delivering or supporting a biomedical product or critical capability. These are physical, in-hand products which can be examined, tested, and demonstrated. This may also include products that require U.S. Food and Drug Administration (FDA) approval.
 - Knowledge Products: Non-material solution that includes methodology, technology, or technical process directly or indirectly supporting a biomedical product or critical capability. This may also include products such as technical reports or manuals impacting training and/or operations.
- **Military Relevance:** Proposed projects must demonstrate relevance to the enhanced readiness and resilience of Navy and Marine Corps health and performance or Joint service member applications / relevance.
- **Project Maturity:** This solicitation is not meant to support development of a new prototype but should focus on fine tuning and optimization of existing prototypes or other technologies.
- **Industry Partners:** Proposed projects are encouraged to include relevant industry partners, especially considering that the eventual goal is to transition products to industry for FDA approval and/or commercialization.
- **USG / DoD Partners:** The Offeror is encouraged to partner with DoD / Government facilities / laboratories / medical treatment centers:
 - One or more military medical treatment facilities to include the Veteran’s Affairs (VA) and/or DoD medical treatment facilities;
 - One or more military medical or scientific laboratories / centers for the conduct of the proposed efforts.

For the purposes of white paper and proposal submissions, the Offeror is expected to identify aspects of the proposed work which may be done in collaboration with USG / DoD VA and provide information of the identification and process and intent of the establishment of the future collaborations with the USG / DoD site(s). Partnership with USG / DoD is not a requirement for award.

3.5. Potential Follow-on Tasks

There is potential for award of one or more follow-on tasks based on the success of any resultant Research Project Awards (subject to change depending upon Government review of work completed and availability of funding). Note that any potential follow-on work is expected to be awarded non-competitively to resultant project awardees. Follow-on work may include tasks related to advancement of prototype maturity, and/or to expand the use or utility of the prototype. **Examples** of potential follow-on work are (**but not limited to**):

- Prototype development, refinement, maturation
- Nonclinical and preclinical studies required for the technical data package for a regulatory application
- Clinical Studies
- Establish robust quality system
- Improve efficiency and reproducibility of manufacturing process for scale up
- Work towards FDA clearance/ approval
- Military environmental and operational assessments
- Ruggedization for operation in military environments
- Advanced technical testing in relevant or simulated operational environments
- Initial Procurement

3.6. Restrictions on Animal and Human Subjects

White Papers and proposals must comply with restrictions and reporting requirements for the use of animal and human subjects, to include research involving the secondary use of human biospecimens and/or human data. The Awardee shall ensure local Institutional Animal Care and Use Committee (IACUC) and Institutional Review Board (IRB) approvals, continuing review (in the intervals specified by the local IACUC and IRB, but at a minimum, annually), and approval by the U.S. Army Medical Research and Development Command Animal Care and Use and Review Office (ACURO) and the USAMRDC Human Research Protections Office (HRPO). Offerors shall include IACUC, ACURO, IRB and HRPO review and approval in the SOW/Milestones Table submitted with the Stage 2 full proposal (if invited), as applicable.

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), HRPO, prior to research implementation. This administrative review requirement is in addition to the local IRB or Ethics Committee (EC) review. Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.

Research Involving Animals: All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRDC ORP ACURO, in addition to the local IACUC of record. Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.

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

3.7. Guidance Related 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 White Paper Preparation

4.1. General Instructions

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 White Paper format provided in this MTEC RPP is **mandatory** and shall reference this RPP number (**MTEC-22-07-NavyMultiTopic**). Note that Cost Proposals are only required for Stage 2 and are not part of the initial White Paper submission. However, Offerors are required to submit a Rough Order of Magnitude (ROM) pricing in accordance with the White Paper template (Section 8 of this RPP). Offerors are encouraged to contact the Points-of-Contact (POCs) identified herein up until the White Paper submission date/time to clarify requirements (both administrative and technical in nature).

All eligible Offerors may submit White Papers for evaluation according to the criteria set forth herein. Offerors are advised that only ATI as the MTEC's CM, with the approval of the DOD Agreements Officer, is legally authorized to contractually bind MTEC into any resultant awards.

4.2. Instructions for the Preparation & Submission of the Stage 1 White Paper

Offerors submitting White Papers 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

shall 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 (1): Submitted via BIDS

- **White Paper:** one PDF document (5MB or lower)

Page Limitation: Each White Paper is limited to four (4) pages plus a cover page (5 pages total). The White Paper must be in 11-point (or larger) type font, single-spaced, single-sided, on 8.5 inches x 11 inches paper. Smaller font 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 1 inch. The MTEC staff will share white papers with various potential public and private sector sponsors. ***Please do not include confidential or proprietary information.*** White Papers exceeding the page limits specified above may not be accepted.

4.3. Stage 2: Pitch or Full Proposal (for Only Those Offerors Recommended for Stage 2)

As outlined in Section 2.3 of this RPP, the Stage 2 process may vary and may require different submissions compared with typical MTEC RPPs. The Government is utilizing two distinct Stage 2 approaches under this RPP.

- **Stage 2 Approach A:** This Stage 2 approach will require a solution pitch (i.e., oral presentation) followed by a written detailed research strategy and full cost proposal (after evaluation of the pitch). Information on cost proposals can be found in Section 7 of the PPG.
- **Stage 2 Approach B:** This Stage 2 approach will require a full proposal (to include technical and cost volumes) using the MTEC PPG.

Note that Stage 2 Offerors will only be required to follow one of the aforementioned Stage 2 approaches. Those Offerors that are favorably evaluated during Stage 1 will receive notification letters which will serve as the formal request for a Stage 2 proposal. These letters will contain specific Stage 2 proposal submission requirements and templates.

Please note that MTEC members who are invited to participate in Stage 2 will be required to comply with the following requirements in addition to any Stage 2 proposal requirements listed above:

- **Warranties and Representations (template provided in Attachment 3 of the PPG)**
One Word (.docx or .doc) or PDF file that contains all Warranties and Representations is required for each proposal.

- **Statement of Work (template provided in Attachment 4 of the PPG)**
One Word (.docx or .doc) or PDF file. Provide a Statement of Work as a separate 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 proposal 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.
- **Current and Pending Support (template provided in Attachment 5 of the PPG)**
One Word (.docx or .doc) or PDF file. The Offeror shall provide this information for all key 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."
- **Data Rights Assertions (template provided in Attachment 6 of the PPG)**
One Word (.docx or .doc) or PDF file. The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding Data Rights. It is anticipated that anything delivered under this proposed effort would be delivered to the Government with Government Purpose Rights or Unlimited Data Rights 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.
- **Letter of Intent (Addendum 1 of this RPP)**
Provide letter(s) of intent, signed by the appropriate organizational official, confirming the work that is being done in collaboration with USG / DoD VA. Partnership with USG / DoD is not a requirement for award.
- **MTEC Base Agreement**
If Offerors have not yet executed a MTEC Base Agreement, then Offerors must certify on the cover page of their full proposal 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 Proposal that, if selected for award, it anticipates the proposed effort will be funded under its executed MTEC Base Agreement. A sample of

the MTEC Base Agreement can be found on the MTEC website at www.mtec-sc.org/documents-library/.

Evaluation: The Government will evaluate and determine which proposal(s) to award based on criteria described in **Section 5, "Selection,"** of this RPP. The Government reserves the right to negotiate with Offerors.

4.4. Proposal Preparation Costs

The cost of preparing White Papers/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 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. For more information, please refer to Section 6.1.2 of the PPG.

5 Selection

5.1. Preliminary Screening

The CM will conduct a preliminary screening of submitted White Papers to ensure compliance with the RPP requirements. As part of the preliminary screening process, 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. 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. Stage 1 (White Paper) Evaluation

The CM will distribute all White Papers that pass the preliminary screening (described above and in Table 1) to the Government for full evaluation. Evaluation of 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 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 equally important evaluation factors and evaluation criteria are described below:

Stage 1 Evaluation Factors:

- 1. Research Strategy**
- 2. Personnel and Team**

Evaluation Factor 1 – Research Strategy:

The Offeror’s White Paper will be assessed for relevancy, thoroughness, and completeness of the proposed research strategy. The following information will be considered as part of this factor:

- Whether the proposed prototype is based on promising preliminary data, sound scientific rationale, and demonstrated proof-of concept, and how well the white paper defines a prototype that meets the requirements set forth in this RPP, to include the required minimum TRL or KRL.
- How well the Offeror demonstrates the technical ability and strategy to execute the research,
- How well the specific aims and proposed methodology supports the technical objectives and the development of the prototype.
- The Government may evaluate the proposed cost, as reflected in the Rough Order of Magnitude (ROM), as it relates to research strategy. Therefore, White Papers may be evaluated based on the degree to which the proposed solution delivers value to the Government and demonstrates a feasible solution considering funding availability as well as anticipated lifecycle costs.

Evaluation Factor 2 – Personnel and Team:

The Offeror’s White Paper will be assessed for how the background and expertise of the personnel and organizations are appropriate to execute the proposed research. The following information will be considered as part of this factor:

- Strength of Team: Strength of the organization/team, considering the qualifications of the personnel, facilities, equipment, supplies, services, and subcontractors, and project management plan proposed to complete the work.
- Financial Stability: How well the funding strategy described will advance the technology to the next level of development and/or delivery to the military or civilian market.
- Schedule: The degree to which the Offeror demonstrates a realistic, achievable performance schedule with a plan to address potential risks that could delay or otherwise impact performance.

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.
GOOD	Proposal meets requirements and indicates a thorough approach and understanding of the requirements. Proposal contains strengths which outweigh any weaknesses. Risk of unsuccessful performance is low.

ACCEPTABLE	Proposal meets requirements and indicates an adequate approach and understanding of the requirements. Strengths and weaknesses are offsetting or will have little or no impact on contract performance. Risk of unsuccessful performance is no worse than moderate.
MARGINAL	Proposal does not clearly meet requirements and has not demonstrated an adequate approach and understanding of the requirements. The proposal has one or more weaknesses which are not offset by strengths. Risk of unsuccessful performance is high.
UNACCEPTABLE	Proposal does not meet requirements and contains one or more deficiencies. Proposal is not awardable.

Upon review and evaluation of the White Papers, Offerors who are favorably evaluated will be invited to participate in Stage 2 for further consideration. Offerors whose White Papers were not favorably evaluated will be provided feedback on the evaluation. Note that Offerors should receive an overall rating of at least “Acceptable” or higher in order to be considered for Stage 2; however, the Government reserves the right to make final evaluation decisions based upon programmatic relevancy and overall best value solutions determined to be in the Government’s best interest.

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 proposal as outlined in Section 2.5.

5.3. Stage 2 Evaluation (for Only Those Offerors Recommended for Stage 2)

To the maximum extent practicable, the evaluation criteria found here are anticipated for all Stage 2 submissions (subject to change).

The CM will conduct a preliminary screening of received proposals to ensure compliance with the Stage 2 RPP requirements. As part of the preliminary screening process, proposals that do not meet the requirements of the RPP may be eliminated from the competition or additional information may be requested by the CM. The Government reserves the right to request additional information or eliminate proposals that do not meet these requirements from further consideration.

Stage 2 submissions that pass the preliminary compliance screening will be evaluated by the Government technical evaluation panel who will make recommendations to a Source Selection Authority.

Evaluation 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 against the technical evaluation factors detailed below and assign adjectival ratings to

the non-cost/price factor(s) consistent with those defined in Table 2 (General Merit Ratings 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 CM will evaluate the cost proposals for those Offerors recommended for award, as detailed below, for cost reasonableness.

Stage 2 Evaluation Factors:

1. Technical Approach
2. Potential for Transition or Commercialization
3. Cost Reasonableness

Technical Approach and Potential for Transition or Commercialization will be evaluated with equal importance; however, when combined are significantly more important than cost/price.

Evaluation Factor 1 – Technical Approach:

The Offeror’s Stage 2 submission will be assessed for:

- How well the specific aims and proposed methodology support the technical objectives and the development of the prototype.
- An approach which effectively demonstrates the Offeror’s understanding of the overall requirement and inclusion of complete and clear processes to execute the effort.

Evaluation Factor 2 – Potential for Transition or Commercialization:

The Offeror’s Stage 2 submission will be assessed for:

- How well the Offeror demonstrates the potential for the prototype to integrate into current or future cross-cutting prevention initiatives.
- How well the Offeror demonstrates potential advancement into the next phase of desired research, development, testing, commercialization, and/or implementation.
- An achievable approach to regulatory approval (if applicable).

Evaluation Factor 3 – Cost Reasonableness:

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

With the exception of “Cost Reasonableness,” the Stage 2 evaluation factors will be rated based upon the adjectival merit ratings detailed in Table 2. See Table 3 for the definitions of the “Cost Reasonableness” factor ratings.

TABLE 3 - “COST REASONABLENESS” EVALUATION FACTOR RATINGS DEFINITIONS	
RATING	DESCRIPTION

SUFFICIENT	The estimate is within the available funding limits and considered appropriate to successfully complete the proposed project.
INSUFFICIENT	The estimate is lower than what is considered appropriate to successfully complete the proposed project.
EXCESSIVE	The estimate is higher than what is considered appropriate to successfully complete the proposed project and may be outside of the available funding limits.

Please also refer to Section 5.4 for definitions of general terms used in technical evaluations.

5.3.1 Cost/Price Evaluation

In addition to the evaluation of Factor 3 – Cost Reasonableness, the MTEC CM will evaluate the estimated cost proposed by the Offeror for performing all requirements outlined in this RPP and the MTEC PPG. Evaluation will include analysis of the proposed cost together with all supporting information. The Offeror’s cost and rationale will be evaluated for realism, reasonableness, and completeness. If a proposal is selected for award, the MTEC CM will review the original cost proposal and the Offeror’s response to a Proposal Update Letter, if applicable. The MTEC CM will request additional information or clarification as necessary. The MTEC CM will assess the reasonableness and completeness of the cost estimates and then provide a formal assessment to the Government. The Government will review this assessment and make the final determination that the negotiated project value is fair and reasonable.

Proposals will be evaluated using the understanding of cost realism, reasonableness and completeness as outlined below:

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

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

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

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

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

Costs provided shall be clearly attributable to activities or materials as described by the Offeror. Costs should be broken down using the Cost Proposal Formats that are located on the Members-Only MTEC website.

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.

5.3.2 Best Value

The Government will conduct the source selection based on the evaluation criteria and ratings contained within this RPP. The overall award decision will be based upon a 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/price. Based on the results of the Stage 2 Technical Evaluation, the Government reserves the right to negotiate and request changes to any or all parts of the proposal to include the SOW. Offerors will have the opportunity to concur with the requested changes and revise cost proposals as necessary.

5.4. 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 Biomedical Research Associate, Dr. Gage Greening, Ph.D., gage.greening@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

ACURO	Animal Care and Use Review Office, USAMRDC
ATI	Advanced Technology International
CDRH	Center for Devices and Radiological Health
CM	Consortium Manager
CMA	Consortium Member Agreement
DoD	Department of Defense
DODI	Department of Defense Instruction
DUNS	Data Universal Numbering System
EC	Ethics Committee
FAQ	Frequently Asked Questions
FDA	Food and Drug Administration
FOIA	Freedom of Information Act
FY	Fiscal Year
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IDE	Investigational Device Exemption
IND	Investigational New Drug
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IRB	Institutional Review Board
KRL	Knowledge Readiness Level
M	Million
MHS	Military Health System
MPS	Milestone Payment Schedule
MTEC	Medical Technology Enterprise Consortium

NAMD	Naval Advanced Medical Development
NDA	Nondisclosure Agreement
NMRC	Naval Medical Research Center
OCI	Organizational Conflict of Interest
ODC	Other Direct Costs
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
ROM	Rough Order of Magnitude
RPA	Research Project Award
RPP	Request for Project Proposals
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
VA	Veterans Affairs

8 White Paper Template

Cover Page (1 page)

[Title of White Paper]

Focus Area: [Indicate which focus area and specific area of interest this white paper is addressing. To meet the intent of this RPP, each white paper **MUST** specifically address only **ONE** of the three Focus Areas and **ONE** Specific Area of Interest described in Section 3. Offerors are not limited to a single white paper submission. Projects not aligned with one of these Focus Areas and specific areas of interest will not be considered for funding.]

[Principal Investigator]

[Institution]

Address: [Address of Offeror]

Phone Number: [Phone Number of Offeror]

Email Address: [Email Address of Offeror]

DUNS #: [DUNS #]

CAGE Code: [CAGE code]

Statement that “This White Paper is submitted pursuant to the MTEC-22-07-NavyMultiTopic” RPP.

Dates of submission and signature of official authorized to obligate the institution contractually

Nontraditional Defense Contractor or Nonprofit Research Institution %: *(see Section 3 of the PPG)*

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

Willingness to allow MTEC Officers access to your White Paper for the purposes of engaging in outreach activities with private sector entities: Indicate YES or NO

[As part of MTEC’s mission to incorporate philanthropic donations, MTEC frequently makes contact with private sector entities (e.g., foundations, organizations, individuals) that award grants or otherwise co-fund research, and/or operate in research areas that are aligned with those of MTEC. Additional private entities may be interested in reviewing certain White Papers within their program areas, allowing opportunities to attract supplemental funding sources. Please indicate your willingness to allow MTEC access to your White Paper for the purposes of engaging in outreach activities with these private sector entities. MTEC staff has signed Nondisclosure Agreements (NDAs) and Organizational Conflict of Interest statements.]

White Paper (4 pages)

(5 pages total including the cover page)

Title: [Insert descriptive title of project]

Principal Investigator: [Insert name, organization, email address, phone number]

Background: [Briefly state the problem that the White Paper is addressing.]

Approach: [Briefly describe your approach to solving the problem. Include relevant background/preliminary data about your approach. Include the current status of your approach. Indicate the technology or knowledge readiness level (TRL/KRL) at the time of submission and at end of the proposed PoP. Full definitions of TRLs can be found [here](#). More information regarding KRLs can be found [here](#). Note: References are included within the page limit. There is no required format for the inclusion of references.]

Objectives: [Specify the objectives of the proposed effort.]

Technical Strategy: [Outline the proposed methodology in sufficient detail to show a clear course of action that addresses the technical requirements described in this RPP.]

Anticipated Outcomes: [Provide a description of the anticipated outcomes from the proposed work. List milestones and deliverables from the proposed work. Also provide a high-level summary of potential follow-on tasks beyond the initial PoP, if applicable.]

Military Relevance: [Provide a description of how the proposed technology meets the needs of the Navy's Program.]

Technical Maturity and Transition or Commercialization Strategy: [Provide a brief description and justification of the maturity of the proposed solution, anticipated regulatory pathway (if applicable) and transition or commercialization plans. Include information about Intellectual Property/Data Rights Assertions.]

Schedule: [Provide an overview of the timing of initiation, duration, and completion of project activities over the course of the PoP.]

Personnel and Team: [Briefly state the qualifications of the Principal Investigator, key personnel, and organizations that will perform the SOW.]

Non-traditional defense contractor, nonprofit research institution, or 1/3 cost sharing: [Describe the plan to include significant participation of a non-traditional defense contractor, nonprofit research institution, or the ability to meet 1/3 cost sharing requirement.]

Period of Performance: [Indicate the total proposed PoP.]

Cost Share: [It is anticipated that Government funds would provide incentive for industry funding to join the project. While not a requirement, Offerors are encouraged to discuss the ability to bring leveraged funding/cost share to complete the project goals.]

Rough Order Magnitude (ROM) Pricing: [The Offeror must provide an estimate based on the technical approach proposed in the White Paper. The following ROM pricing shall be included in the White Paper. **(NOTE: If invited to Stage 2, it is preferred that the total cost to the Government proposed in the ROM not substantially deviate from the proposed cost presented in the Stage 2 pitch or full proposal (unless otherwise directed by the Government) as this may result in an unacceptable rating.) 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	\$ 100,000.00	\$ 100,000.00	\$ 100,000.00	\$ 300,000.00
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 (ODC)		\$ 1,000.00	\$ 1,000.00	\$ 3,000.00
Travel	\$ 5,000.00	\$ 5,000.00	\$ 5,000.00	\$ 15,000.00
Indirect costs	\$ 48,200.00	\$ 48,200.00	\$ 48,200.00	\$ 144,600.00
Total Cost	\$ 289,200.00	\$ 289,200.00	\$ 289,200.00	\$ 867,600.00
Fee (Not applicable if cost share is proposed)	\$ 0.00	\$ 0.00	\$ 0.00	\$ 0.00
Total Cost (plus Fee)	\$ 289,200.00	\$ 289,200.00	\$ 289,200.00	\$ 867,600.00
Cost Share	\$ 290,000.00	\$ 290,000.00	\$ 290,000.00	\$ 870,000.00

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(if cost share is proposed then fee is unallowable)				
Total Project Cost	\$ 579,200.00	\$ 579,200.00	\$ 579,200.00	\$ 1,737,600.00

* Use the row 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.

****Offerors are reminded to refer to the Selection Criteria under Section 5 of the RPP to ensure that all required information is provided.**

Addendum 1 – Letter of Intent

For Information Only – Stage 2 Requirement

Provide letter(s) of intent, signed by the appropriate organizational official, confirming the work that is being done in collaboration with USG / DoD VA. Partnership with USG / DoD is not a requirement for award.