

**Request for Project Proposals**



**Solicitation Number: MTEC-24-07-NavyDental**  
**“Military Dental Research – Seeking New Technologies and Development Partners”**

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

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## **1 Executive Summary**

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### **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 operates under an Other Transaction Agreement (OTA) for prototype projects with USAMRDC. In accordance with 10 USC 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. For more information on the MTEC, its mission, and the definition of prototype, see the MTEC website ([www.mtec-sc.org](http://www.mtec-sc.org)).

### **1.2. Purpose**

This solicitation, issued by the MTEC Consortium Manager (CM), Advanced Technology International (ATI), represents a Request for Project Proposals (RPP) for MTEC in support of the Naval Advanced Medical Development (NAMD) focused on detection, prevention, and treatment of dental diseases, oral infections, maxillofacial injuries, and orofacial pain to improve care for and outcomes of wounded warfighters.

## **2 Administrative Overview**

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### **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. Additionally, the Proposal Preparation Guide (PPG) contains several templates required for this RPP. The PPG can be found on the MTEC members only site. For information on how to join MTEC, please visit <http://mtec-sc.org/how-to-join/>. If you are already a member and would like to request access to the Members Only Website, please visit <https://mtec-sc.org/members-only-access-request/>.

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 Enhanced White Paper submitted must be in accordance with the mandatory format provided in **Section 8 of the RPP**. Enhanced White Paper 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 “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 **up to \$3 million (M)** total for this effort. 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. Dependent on the results and deliverables, additional dollars and time may be added to the period of performance for non-competitive follow-on tasks (see **Section 3.5 of this RPP** for more information).

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

MTEC expects to make **up to two awards for \$1M to \$3M per award** to a qualified Offeror(s) to accomplish the scope of work with a Period of Performance (PoP) **not to exceed 26 months**.

## **2.3. Acquisition Approach**

This RPP will be conducted using the Enhanced White Paper approach. In Stage 1, Offerors are invited to submit Enhanced White Papers using the mandatory format contained in this RPP (see **Section 8 of this RPP**). The Government will evaluate Enhanced White Papers and will select those that represent the best value using the evaluation criteria in **Section 5 of this RPP**. Offerors whose proposed solution is selected for further consideration based on the Enhanced White Paper evaluation will be invited to submit a full cost proposal in Stage 2 (and may be required to submit additional documentation or supplemental information such as those examples listed under **Section 4.2**). Notification letters will contain specific Stage 2 proposal submission requirements.

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

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

The Government-selected prototype project(s) awarded as a result of this solicitation will be funded under the Other Transaction Agreement for prototype projects (OTA) Number W81XWH-15-9-0001 with MTEC administered by the CM, ATI. The CM will negotiate and execute a Base Agreement with MTEC members (if not yet executed). The same provisions will govern this Base Agreement as the OTA for prototype projects between the Government and MTEC. Subsequently, any proposal that is selected for award will be funded through a Research Project Award 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/](http://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. Offeror Eligibility**

Offerors must be MTEC Members in good standing to be eligible to submit a proposal. 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 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/>.

**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 Proposal that, if selected for an 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 an award, it anticipates the proposed effort will be funded under its executed MTEC Base Agreement.

#### **2.5. Statutory Requirements for the Appropriate Use of Other Transaction Authority**

Enhanced White Papers that do not include one of the following will not be eligible for award (**See Section 3 of the PPG**):

- (A) At least one nontraditional defense contractor or nonprofit research institution participating to a significant extent in the prototype project; or
- (B) All significant participants in the transaction other than the Federal Government are small businesses (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)) or nontraditional defense contractors; or
- (C) At least one third of the total cost of the prototype project is to be paid out of funds provided by sources other than the Federal Government

#### **2.6. Proposers Conference**

MTEC intends to host a Proposers Conference that will be conducted via webinar within two (2) weeks of the release of the RPP. The intent of the Proposers Conference is to provide an administrative overview of this RPP and to present further insight into the technical requirements outlined in **Section 3 of this RPP**. 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.

#### **2.7. Proprietary Information**

The MTEC CM will oversee submission of Enhanced White Papers submitted in response to this RPP. The MTEC CM shall take the necessary steps to protect all proprietary information and shall not use such proprietary information for purposes other than the evaluation of an Offeror's Enhanced White Papers. **In accordance with the MTEC 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 for opportunities to attract supplemental funding sources. Therefore, on the Enhanced White Paper Cover Page, Offerors should indicate 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.

## 2.8. MTEC Member Teaming

While teaming is not required for this effort, Offerors are encouraged to consider teaming during the proposal preparation period (prior to Enhanced White Paper submission) if they cannot address the full scope of technical requirements of the RPP or otherwise believe a team may be beneficial to the Government. The following resources may help Offerors form a more complete team for this requested scope of work.

- 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. Please visit <https://www.mtec-sc.org/m-corps/> for details on current partners of the M-Corps.
- MTEC Database Collaboration Tool to help identify potential teaming partners among other MTEC members. 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.
- A dedicated Teaming Connect will be held to facilitate direct interaction amongst MTEC members in relation to this active funding opportunity. This will be a virtual "connect" session via ZOOM where MTEC members will be allowed to provide brief pitch presentations regarding to their ongoing work, organizational capabilities, and teaming preferences. More information on this event will be provided in the near future.

## 2.9. Intellectual Property

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

**Government with Government Purpose Rights or unlimited data rights unless otherwise asserted in the proposal and agreed to by the Government.** Rights in technical data in each Research Project Award shall be determined in accordance with the provisions of MTEC Base Agreement.

Note that as part of Stage 1 of the RPP process (submission of an Enhanced White Papers), 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.

#### **2.10. Expected Award Date**

Offerors should plan on the period of performance beginning September 2024 (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.

#### **2.11. Anticipated Proposal Selection Notification**

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

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

### **3 Technical Requirements**

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#### **3.1. Background**

Due to the Navy and Marine Corps' diverse warfighting capabilities, Sailors, and Marines (and Joint Service members) operate in a vast array of challenging and austere environments. Combination of physical and mental stress from extreme conditions compromise human performance capability, increasing risk and possible failure of mission objectives. In addition, operating environments cause complications and challenges in medical logistics and casualty management, both vital elements to ensuring survivability of combat casualties. To maintain warfighter lethality and operational effectiveness in challenging environments, next generation biomedical products are required.

#### **3.2. Minimum Requirements for Submission of an Enhanced White Paper**

Enhanced 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 (4QFY24).

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, 21-10-NavyMultiTopic, 22-07-NavyMultiTopic, and 23-05-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. Technical Objective**

This RPP focuses on detection, prevention, and treatment of dental diseases, oral infections, maxillofacial injuries, and orofacial pain 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 (especially in austere/extreme environments or when routine dental care is suspended) as well as methods or products to treat injuries to the oral cavity, face, and facial bones sustained during combat (e.g., blast injuries, mandibular fractures, burns, etc.). Also of interest are development activities focused on manufacturing readiness of technical solutions, including partnerships to translate biomedical prototypes and solutions out of the laboratory (military or academic) setting.

**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 detection methods (molecular or computational), preventative measures, 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, restore cosmetic and functional aspects of the face, and address chronic orofacial pain (including fabrication, manufacturing, and performance testing of products).
- c) Partnerships to manufacture dental care devices or materials (scale-up, initial production runs, etc.) developed at military or academic laboratories (prototypes may include diagnostic and detection devices or dental resins and material containing novel components, such as therapeutics, micro- or nanoparticles, micro- or nanocapsules, etc.).

NOTE: All proposals must directly relate to a military use case. Dental solutions that are specific to civilian-only use cases will not be considered.

### **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-materiel 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:** Although not required for selection of award, Offerors are encouraged to partner with DoD / Government facilities / laboratories / medical treatment centers / academic organizations:
  - 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 / academic organizations for the conduct of the proposed efforts.

### 3.5. Potential Follow-on Tasks

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

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

### 3.6. Restrictions on Animal and Human Subjects, Human Anatomical Substances, or Human Cadavers

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

If the proposed research is cooperative (i.e., involving more than one institution), a written plan for single IRB review arrangements must be provided at the time of award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

**Research Involving Animals:** All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRDC OHARO Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. Allow at least 3 to 4 months for ACURO regulatory review and approval processes for animal studies.

Proposals must comply with the above-mentioned 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 IACUC and IRB approvals, continuing review (in the intervals specified by the local IRB, but at a minimum, annually), and approval by the USAMRDC OHARO. Offerors shall include IRB and OHARO review and approval in the SOW/Milestones Table submitted with the Stage 2 full proposal (if invited), as applicable.

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

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

## **4 Proposal Preparation and Process**

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### **4.1. General Instructions**

Enhanced White Papers shall be submitted by the date and time specified on the cover page using BIDS: <https://ati2.acqcenter.com/ATI2/Portal.nsf/Start?ReadForm>. Include the **MTEC-24-07-NavyDental** on each Enhanced White Paper submitted. See **Attachment 7 of the PPG** for further information regarding BIDS registration and submission.

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.**

All eligible Offerors may submit proposals for evaluation according to the criteria set forth herein. Offerors are encouraged to contact the Points-of-Contact (POCs) identified herein until the Proposal due date/time to clarify requirements (both administrative and technical in nature).

### **4.2. Instructions for the Preparation & Submission of the Enhanced White Paper**

Offerors submitting an Enhanced White Paper in response to this RPP should prepare all documents in accordance with the following instructions:

Offerors should submit files in Microsoft Office formats or Adobe Acrobat (PDF – portable document format) as indicated below. ZIP files and other application formats are not acceptable. All files must be print-capable and without a password required. Filenames must contain the appropriate filename extension (.docx, .doc,

.pptx, .ppt, .xlsx, .xls or .pdf). Filenames should not contain special characters. Apple users must ensure the entire filename and path are free of spaces and special characters.

**Required Submission Documents (5): Submitted via BIDS**

- **Enhanced White Paper:** One Word or PDF document 5MB or lower (Required template is provided in **Section 8 of this RPP**)
- **Warranties and Representations:** one Word or PDF document (**Attachment 3 of the PPG**)
- **Statement of Work (SOW)/Milestone Payment Schedule (MPS):** one Word or PDF document (**Attachment 4 of the PPG**)
- **Current and Pending Support:** one Word or PDF document (**Attachment 5 of the PPG**)
- **Intellectual Property and Data Rights Assertions:** one signed Word or PDF document (**Attachment 6 of the PPG**)

Enhanced White Papers must be prepared **according to the mandatory format provided in Section 8** of this RPP. The Enhanced White Paper is **limited to nine pages (plus a cover page for a total of ten pages)**. References may be included in the Enhanced White Paper and are **excluded** from the page limitation. The following appendices are also **excluded** from the page limitation: (1) *Warranties and Representations*, (2) *Statement of Work*, (3) *Current and Pending Support*, and (4) *Intellectual Property and Data Rights Assertions*. Formatting requirements include 11-point font (or larger), single-spaced, single-sided, 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 exceeding the page limit may not be accepted.**

**FOR INFORMATION ONLY:** Additional attachments/appendices (henceforth referred to as supplemental information) to the White Paper submission may be requested after completion of the Stage 1 White Paper evaluation. The exact requirements of any such attachment/appendix are subject to change and will be provided at the time (or immediately following) the Stage 1 evaluation summary is provided.

**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](mailto: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.

## **5 Selection**

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### **5.1. General Information**

Evaluations at all stages of the Enhanced White Papers acquisition process shall be based on an independent, comprehensive review and assessment of the work proposed against stated evaluation factors. A rating consistent with these evaluation factors will be derived from the ability of the Offeror to perform the work in accordance with all aspects of requirements outlined in this RPP. The Offeror shall clearly state how it intends to meet the RPP requirements. Mere acknowledgement or restatement of a RPP requirement is not acceptable.

### **5.2. Enhanced White Paper Evaluation**

The CM will distribute all Proposals that pass the preliminary screening (described above) to the Government for evaluation. The Government will then conduct the source selection and determine which Offerors will be invited to submit a Stage 2 (Full Cost Proposals) based on the following Stage 1 criteria. In some cases, to ensure scientific excellence, the Government may utilize an additional evaluation process to include an external peer review for the evaluation of Proposals against established criteria to determine technical merit. Regardless of whether or not the evaluation includes a peer review, all Enhanced White Papers will be evaluated based on the following factors. The adjectival merit ratings that will be used for all evaluation factors are shown in Table 3. Feedback will be provided to the Offerors.

#### **Stage 1 - Enhanced White Paper Evaluation Factors (of equal importance):**

- 1. Programmatic and Technical Relevance**
- 2. Personnel and Team**
- 3. Cost Reasonableness**

**Evaluation Factor 1 – Programmatic and Technical Relevance:** The Offeror’s proposal will be assessed for the degree to which the Offeror demonstrates a strong solution to the defined unmet military medical need consistent with Section 3 of the RPP. The proposal will also be assessed for relevancy, thoroughness, and

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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 that describe a feasible solution;
- Focused and detailed methodologies to address the requirements outlined in Section 3.3;
- Thorough and complete SOW; and,
- Realistic, achievable performance schedule with a plan to address potential risks that could delay or otherwise impact performance.

**Evaluation Factor 2 – Personnel and Team:** This factor will evaluate the strength of the organization/team, including the Offeror’s resources, expertise, and experience of proposed personnel. As part of this evaluation factor, the Government will also consider the ability for the technical and management team to execute the proposed SOW in an efficient and effective manner.

**Evaluation Factor 3 – Cost Reasonableness:** Assessment of the cost of the project to determine i) whether the project cost is within the available funding limits, and ii) the ability and/or likelihood of the offeror to successfully execute the proposed project within the financial resources proposed.

TABLE 3- 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.

**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 during the demonstration.

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 during the demonstration.

Weakness - A flaw in the proposal that increases the risk of unsuccessful demonstration.

Significant Weakness - A flaw that appreciably increases the risk of unsuccessful demonstration.

Deficiency - A material failure of a proposal to meet the requirement or a combination of weaknesses in a proposal that increases the risk of unsuccessful demonstration to an unacceptable level.

## **6 Points-of-Contact**

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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](mailto:mtec-contracts@ati.org)
- Technical and membership questions should be directed to the MTEC Biomedical Research Associate, Dr. Chuck Hutti, Ph.D., [chuck.hutti@ati.org](mailto:chuck.hutti@ati.org)
- All other questions should be directed to the MTEC Program Manager, Mr. Evan Kellinger, [mtec-sc@ati.org](mailto:mtec-sc@ati.org)

## **7 Acronyms/Abbreviations**

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ATI	Advanced Technology International
BIDS	System for Submission of the Solution
CAGE	Commercial and Government Entity Program
CM	Consortium Manager
DoD	Department of Defense
FAQ	Frequently Asked Questions
FDA	U.S. Food and Drug Administration
Government	U.S. Government, specifically the DoD
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IT	Information Technology
MDO	Multi-Domain Operations
MHS	Military Health System
MPS	Milestone Payment Schedule
MTEC	Medical Technology Enterprise Consortium
NDA	Non-disclosure Agreement
OCI	Organizational Conflict of Interest
ODC	Other Direct Costs
OTA	Other Transaction Agreement
PDF	Portable Document Format

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POC	Point of Contact
POP	Period of Performance
PPG	Proposal Preparation Guide
ROM	Rough Order Magnitude
RPP	Request for Project Proposals
SME	Subject Matter Expert
SOW	Statement of Work
UEI	Unique Entity Identifier
USAMRDC	U.S. Army Medical Research and Development Command
USC	U.S. Code

## 8 Enhanced White Paper Template

Cover Page

**[Name of Offeror]**

[Address of Offeror]

[Phone Number and Email Address of Offeror]

Unique Entity Identifier (UEI) #: [UEI #]

CAGE code: [CAGE code]

**[Title of Enhanced White Paper]**

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

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

[A proprietary data disclosure statement if proprietary data is included. Sample: **This Enhanced White Paper includes data that shall not be disclosed outside the MTEC Consortium Management Firm and the Government and shall not be duplicated, used, or disclosed, in whole or in part, for any purpose other than to evaluate this Enhanced White Paper and negotiate any subsequent award. If, however, an award agreement is 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).**]

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, investor groups) 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.]



**[Title of Enhanced White Paper]**

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

**Background:** [Briefly state the problem that the Enhanced 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](#).]

**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.]

**Scientific Rationale / Preliminary Data:** [Describe the scientific rationale for the project, including a brief description of the previous studies or preliminary data that supports the feasibility of the proposed work. Provide relevant non-clinical data and/or clinical preliminary data.]

**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.]

**Potential Follow-On Work:** [As noted in Section 3.4 of the RPP, additional follow-on funding may become available for the continuation of prototype development. Offerors are encouraged as appropriate to discuss potential follow-on work 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. Although awards in response to this RPP may initially focus on the scope of work presented above, this section is intended to provide the Sponsor with information on the Offeror's plan for work beyond the initial proposed PoP.]

Offerors should:

- Specify the objective of each proposed follow-on task.
- Briefly outline the proposed methodology by task to the extent possible to demonstrate a course of action that addresses the technical requirements described in this RPP.
- Indicate the proposed PoP (duration) for the potential follow-on work in total.
- Specify a total cost (including direct and indirect) for each task.]

**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

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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.]

**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.]

**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 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>Year 1</i>	<i>Year 2</i>	<i>Year 3</i>	<i>TOTAL</i>
<b>Labor</b>	\$ 100,000.00	\$ 100,000.00	\$ 100,000.00	<b>\$ 300,000.00</b>
<b>Labor Hours</b>	1,000.0 hrs	1,000.0 hrs	1,000.0 hrs	<b>3,000.0 hrs</b>
<b>Subcontractors</b>	\$ 50,000.00	\$ 50,000.00	\$ 50,000.00	<b>\$ 150,000.00</b>
<b>Subcontractors Hours</b>	500.0 hrs	500.0 hrs	500.0 hrs	<b>1,500.0 hrs</b>
<b>Government/Military Partner(s)/Subcontractor(s) (subKTR)*</b>	\$0.00	\$0.00	\$0.00	<b>\$0.00</b>

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<b>Gov't/Military Prtnrs / subKTR Hours</b>	<i>0.0 hrs</i>	<i>0.0 hrs</i>	<i>0.0 hrs</i>	<b><i>0.0 hrs</i></b>
<b>Consultants</b>	\$ 10,000.00	\$ 10,000.00	\$ 10,000.00	<b>\$ 30,000.00</b>
<b>Consultants Hours</b>	<i>100.0 hrs</i>	<i>100.0 hrs</i>	<i>100.0 hrs</i>	<b><i>300.0 hrs</i></b>
<b>Material/Equipment</b>	\$ 75,000.00	\$ 75,000.00	\$ 75,000.00	<b>\$ 225,000.00</b>
<b>Other Direct Costs</b>	\$ 1,000.00	\$ 1,000.00	\$ 1,000.00	<b>\$ 3,000.00</b>
<b>Travel</b>	\$ 5,000.00	\$ 5,000.00	\$ 5,000.00	<b>\$ 15,000.00</b>
<b>Indirect costs</b>	\$ 48,200.00	\$ 48,200.00	\$ 48,200.00	<b>\$ 144,600.00</b>
<b>Total Cost</b>	\$ 289,200.00	\$ 289,200.00	\$ 289,200.00	<b>\$ 867,600.00</b>
<b>Fee (Not applicable if cost share is proposed)</b>	\$ 0.00	\$ 0.00	\$ 0.00	<b>\$ 0.00</b>
<b>Total Cost (plus Fee)</b>	\$ 289,200.00	\$ 289,200.00	\$ 289,200.00	<b>\$ 867,600.00</b>
<b>Cost Share (if cost share is proposed then fee is unallowable)</b>	\$ 290,000.00	\$ 290,000.00	\$ 290,000.00	<b>\$ 870,000.00</b>
<b>Total Project Cost</b>	\$ 579,200.00	\$ 579,200.00	\$ 579,200.00	<b>\$ 1,737,600.00</b>

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

**Estimate Rationale:** [The Offeror must provide a **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)**

The Proposal Preparation Guide (PPG) contains several templates required for this RPP. The PPG can be found on the MTEC members only site. For information on how to join MTEC, please visit <http://mtec-sc.org/how-to-join/>.

**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. Offerors will have the opportunity to concur with revised SOW/Milestone Payment Schedule as necessary.

**Appendix 3: Current and Pending Support (template provided in Attachment 5 of the PPG)**

- One Word or PDF document summarizing other sponsored research for each person who will contribute significantly to the proposed prototype project. This information for previous support should include the past five (5) years, unless otherwise specified in the request.

**Appendix 4: 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 with unlimited data rights.
- If this is not the intent, then you should discuss any restricted data rights associated with any proposed deliverables. If applicable, complete the below table for any items to be furnished to the Government with restrictions. An example is provided.

## Addendum 1 – Stage 2 Evaluation Criteria

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

### Stage 2

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

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

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

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

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

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

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