

## Request for Project Proposals



**Solicitation Number: MTEC-23-06-USAMRDC Multi-Topic**

**“Fiscal Year 2023 USAMRDC Multi-Topic”**

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

**Request Issue Date: March 16, 2023**  
**Amendment No. 01 Issue Date: March 22, 2023**

**Enhanced White Paper Due Date: April 17, 2023**  
Noon Eastern Time Zone

**Amendment No. 01 does the following:**  
**Revises language in Section 3.3 for Focus Areas 3, 5, and 8.**

**All other terms and conditions remain unchanged.**

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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 is a nonprofit corporation with the following principal objectives:

- (a) engage in biomedical research and prototyping;
- (b) exploration of private sector technology opportunities;
- (c) technology transfer; and
- (d) deployment of intellectual property (IP) and follow-on production.

MTEC is a broad and diverse biomedical consortium that includes representatives from large businesses, small businesses, contract research organizations, “nontraditional” defense contractors, academic research institutions and not-for-profit organizations; for more information on the MTEC mission, see the MTEC website at <https://mtec-sc.org/>.

MTEC operates under an Other Transaction Agreement (OTA) for prototype projects with USAMRDC. In accordance with 10 USC 4022, the MTEC OTA enables the Government to carry out prototype projects that are directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or to improvement of platforms, systems, components, or materials in use by the armed forces. As defined in the DoD OTA Guide dated November 2018, a prototype project addresses a proof of concept, model, reverse engineering to address obsolescence, pilot, novel application of commercial technologies for defense purposes, agile development activity, creation, design, development, demonstration of technical or operational utility, or combinations of the foregoing. A process, including a business process, may be the subject of a prototype project. Although assistance terms are generally not appropriate in OT agreements, ancillary work efforts that are necessary for completion of the prototype project, such as test site training or limited logistics support, may be included in prototype projects. A prototype may be physical, virtual, or conceptual in nature. A prototype project may be fully funded by the DoD, jointly funded by multiple federal agencies, cost-shared, funded in whole or part by third parties, or involve a mutual commitment of resources other than an exchange of funds. Proposed prototype projects should not be exploratory in nature and do require a foundation of preliminary data.

### **1.2. Purpose**

This solicitation, issued by the MTEC Consortium Manager (CM), Advanced Technology International (ATI), represents a Request for Project Proposals (RPP) focused on the advancement of medical prototypes and knowledge products related to a broad range of medical technological needs identified in the Focus Areas listed below. Relevance to USAMRDC's priorities related to their Combat Casualty Care Research Program and Military Operational Medicine Research Program and is a key feature of this RPP.

## 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.

Offerors who submit Enhanced White Papers in response to this RPP should submit by the date on the cover page of this RPP (see **Section 4.1** for details on the submission period). *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 Papers that fail to follow the mandatory format may be eliminated from the competition during the CM's preliminary screening stage (see Section 5 for more details on the Selection process). The Government reserves the right to award Enhanced White Papers received from this RPP on a follow-on prototype OTA or other stand-alone OTAs as necessary to meet mission requirements.

Awards may be made on a first-in, first-out basis. Additionally, the MTEC selection process for this solicitation includes a "basket" provision which allows for a means to identify those proposals with technical merit and warrant further consideration, however funding is currently unavailable. The proposals placed in the basket are eligible for funding for two years after date of submission.

\*Note that the terms "Enhanced White Paper" and "Proposal" are used interchangeably throughout this RPP.

### 2.2. Funding Availability and Period of Performance (PoP)

The U.S. Government (USG) currently has available a total of approximately \$51 million (M) for anticipated awards to be made beginning in FY2023. The funding amounts and the number of expected awards will be limited and is contingent upon the availability of federal funds for each program. Awards resulting from this RPP are expected to be made under the authority of 10 U.S.C. § 4022. The estimated total available funding per Focus Area is as follows:

- **Focus Area 1 - Sterilization:** ~\$4.18 M total with award(s) ranging from \$1-2.5 M with a PoP not to exceed 36 months.
- **Focus Area 2 – Hemostasis:** ~\$4.5 M total for a single award with a PoP not to exceed 36 months.
- **Focus Area 3 – Neurotrauma** ~\$1.2 M total for a single award with an initial PoP not to exceed 24 months.
- **Focus Area 4 – Sustainment of Expeditionary Medical Skills:** ~\$1 M total for a single award with a PoP not to exceed 36 months.
- **Focus Area 5 – En-route Care:** ~965 K total for a single award with a PoP not to exceed 36 months.
- **Focus Area 6 – Autonomous Care and Evacuation Trauma Research:** A total of \$4.15 M for awards ranging from \$1-3 M with a PoP not to exceed 36 months.
- **Focus Area 7 – Autonomous Care and Evacuation Critical Care Technologies:** A total of \$3.22 M for award(s) ranging from \$1-3.22 M with a PoP not to exceed 36 months.
- **Focus Area 8 – Pharmacological/Technological Approaches to Measure & Manipulate the Glymphatic/Lymphatic (G/L) System in Humans during Sleep:** ~\$2.5 M total with award(s) ranging from \$1-2.5 M with a PoP not to exceed 36 months.
- **Focus Area 9 – Musculoskeletal Injury Prevention and Reduction:** ~\$1.965 M total with award(s) ranging from \$1-2 M with a PoP not to exceed 48 months.
- **Focus Area 10 – Musculoskeletal Injury Treatment and Rehabilitation:** ~\$8.845 M total for multiple awards ranging from \$1-5 M and a PoP not to exceed 48 months.
- **Focus Area 11 – Psychological Health and Resilience:** ~\$4.914 M total with award(s) ranging from \$2-3 M with a PoP not to exceed 60 months.
- **Focus Area 12 –Performance Decrement and Injury Risk in Ground Soldiers due to Head Supported Mass:** ~\$400 K total with award(s) (up to 2) ranging from \$200K to 400K with a PoP not to exceed 18 months.
- **Focus Area 13 – Metabolic Sensor:** ~\$600 K total for a single award with a PoP not to exceed 18 months.
- **Focus Area 14 – Wearable Blast Exposure Sensor and Its Clinical Decision Support:** ~\$1.77 M total for a single award with a PoP not to exceed 24 months.

- **Focus Area 15 – Neurosensory Injury Prevention and Treatment:** ~\$9.8 M total for multiple awards with a PoP not to exceed 18 months.
- **Focus Area 16 – Biomedical Tolerance of the Human Head to High-Rate Localized Blunt Impacts:** ~\$393 K total for a single award with a PoP not to exceed 18 months.

**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). See Section 2.9 for additional cost share information/requirements.**

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

Dependent on the results and deliverables under any resultant award(s), the U.S. Government (USG) may, non-competitively, award additional dollars and/or allow for additional time for scope increases and/or follow-on efforts with appropriate modification of the award. See Section 3.6. for additional details.

### **2.3. Acquisition Approach**

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

Pending successful completion of the total effort, the Government may issue a non-competitive follow-on production contract 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 and Members-Only website at [www.mtec-sc.org](http://www.mtec-sc.org).

***At the time of the submission, if Offerors have not yet executed a Base Agreement, then Offerors must certify on the cover page of their Enhanced White Paper that, if selected for award, they will abide by the terms and conditions of the latest version of the MTEC Base Agreement.*** If the Offeror already has executed an MTEC Base Agreement with the MTEC CM, then the Offeror must state on the cover page of its Enhanced White Paper that, if selected for award, it anticipates the proposed effort will be funded under its executed MTEC Base Agreement.

#### **2.4. Proposers Conference**

MTEC 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 process to award and to present further insight into the Focus Areas 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 Enhanced White Papers and analyze cost proposals 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 Paper, cost proposal, and the subsequent agreement administration if the Proposal is selected for award. **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 contacts private entities (e.g., foundations, investor groups, organizations, individuals) that award grants or otherwise co-fund research, and/or operates in research areas that are aligned with those of MTEC. These private entities may be interested in reviewing certain Proposals within their program areas, allowing opportunities to attract supplemental funding sources. On your Proposal Cover Page, please indicate your willingness to allow MTEC Officers and Directors access to your Proposal for the purposes of engaging in outreach activities with these private organizations. MTEC Officers and Directors who are granted Proposal access have signed Non-disclosure Agreements (NDAs) and Organizational Conflict of Interest (OCI) statements. Additionally, these MTEC Officers and Staff represent organizations that currently are not MTEC members, and therefore their parent organizations are not eligible to submit Proposals or receive any research project funding through MTEC. Additionally, all Technical Evaluation Panel participants will agree to, and sign a nonproprietary information and conflict of interest document.

#### **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. The following resources may help prime contractors provide a more complete team for this requested scope of work.

#### *2.6.1. MTEC M-Corps*

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

#### *2.6.2. MTEC Database Collaboration Tool*

MTEC Database Collaboration Tool to help identify potential teaming partners among other MTEC members. The Database Collaboration Tool provides a quick and easy way to search the membership for specific technology capabilities, collaboration interest, core business areas/focus, R&D highlights/projects, and technical expertise. Contact information for each organization is provided as part of the member profile in the collaboration database tool to foster follow-up conversations between members as needed. The Collaboration Database Tool can be accessed via the “MTEC Profiles Site” tab on the MTEC members-only website (<https://private.mtec-sc.org/>).

#### *2.6.3. Chat Forum*

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

### **2.7. Offeror Eligibility**

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

### **2.8. Cost Sharing Definition**

Cost sharing is defined as the resources expended by the award recipients on the proposed statement of work (SOW). *Cost sharing above the statutory minimum is not required in order to be eligible to receive an award under this RPP*. If cost sharing is proposed, then the Offeror shall

state the amount that is being proposed and whether the cost sharing is a cash contribution or an in-kind contribution (see **Section 7.4 of the PPG** for definitions); provide a description of each cost share item proposed; the proposed dollar amount for each cost share item proposed; and the valuation technique used (e.g., vendor quote, historical cost, labor hours and labor rates, number of trips, etc.).

## **2.9. Cost Share Requirements**

In order to be compliant with 10 U.S.C. § 4022, 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 2.0% of the total funded value of each research project awarded. Such deposits shall be due no later than 90 days after the research project award is executed. The MTEC Assessment Fee is not allowable as a direct charge to any resulting award or any other contract. Therefore, Offerors shall not include this Assessment Fee as part of their proposed direct costs. Members who have not paid the assessment fee within 90 days of the due date are not “Members in good standing”.

## **2.11. Intellectual Property and Data Rights**

Baseline IP and Data Rights for MTEC Research Project Awards are defined in the terms of an awardee’s Base Agreement and, if applicable, specifically-negotiated terms are finalized in any resultant Research Project Award. MTEC reserves the right to assist in the negotiation of IP, royalties, licensing, future development, etc., between the Government and the individual performers prior to final award decision and during the entire award period.

The Offeror shall comply with the terms and conditions contained in their Base Agreement regarding IP and Data Rights, as modified by the specifically-negotiated IP and Data rights terms herein. **It is anticipated that anything created, developed, or delivered under this proposed effort will be delivered to the Government with Government Purpose Rights or unlimited data rights unless otherwise asserted in the proposal and agreed to by the Government.** Rights in technical data in each Research Project Award shall be determined in accordance with the provisions of MTEC Base Agreement.

Note that as part of Stage 1 of the RPP process (submission of an Enhanced White Paper), Offerors shall complete and submit **Attachment 6 of the PPG** (Intellectual Property and Data

Rights) 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**

The Offeror should plan on the PoP beginning September 2023 (subject to change). The Government reserves the right to change the proposed PoP start date through negotiations via the CM and prior to issuing a Research Project Award.

### **2.13. Anticipated Enhanced White Paper Selection Notification**

As the basis of selections is completed, the Government will forward 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**

Current wartime operations assume that the United States and our allies will maintain air, land, maritime, space and cyber superiority. Future conflicts against peer and near-peer adversaries are expected to be layered stand-offs and fought across multiple domains. Mission success will be determined by our ability to compete to expand the competitive space, penetrate both strategically and operationally, disintegrate enemy’s defenses, exploit enemy weaknesses, and re-compete to consolidate gains. Medical capabilities play a critical role in each aspect of the future battlespace and must modernize rapidly to maintain Force readiness and increase soldier lethality.

### **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. Fit the Prototype Definition: Proposed prototype projects should not be exploratory in nature and do require a foundation of preliminary data. The definition of a “prototype” is as follows: 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.

2. Meet the Minimum Knowledge/Technology Readiness Level (KRL/TRL): The minimum acceptable KRL/TRL is 3 at the time of submission of the Enhanced White Paper, with the following exceptions: Focus Area # 3, 5, and 7 are a minimum TRL/KRL of 4 (see Section 3.3 for more detail).

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

3. Represent New Submissions to MTEC: Focus on proposed solutions that have not been submitted to MTEC under previous RPPs within the past 2 years, including the 21-06-MPAI and 22-02-MPAI. The Government is already aware of concepts submitted in response to previous MTEC solicitations including the 21-06-MPAI and 22-02-MPAI; therefore, such projects are not allowed to be resubmitted here. **This RPP is intended only for submission of new projects to MTEC or substantially revised or modified proposals in accordance with previous Government feedback, not identical resubmissions.**
4. Align to a Specified Focus Area: Enhanced White Papers shall align to a single Focus Area 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.

**\*\*NOTE:** Failure to meet any or all of these minimum requirements may result in an overall “Unacceptable” rating of the Enhanced White Paper with minimum or no additional feedback provided.

### 3.3. Focus Areas of Interest

To meet the intent of this RPP, each Enhanced White Paper **SHALL** specifically address **ONLY ONE** Focus Area described below. Offerors are not limited to a single Enhanced White Paper submission. Projects that fail to align with only one of these Focus Areas may not be considered for funding.

- **COMBAT CASUALTY CARE** – This technology area provides integrated capabilities for current and future operations to reduce the mortality and morbidity associated with major combat-related trauma across the spectrum of combat casualty care, including point of injury and pre- or out-of-hospital care, the spectrum of en-route care, and facilities-based treatment. **Focus areas are as follows (NOT listed in order of importance):**
  - **Focus Area 1 – Sterilization:** Solutions for rapid sterilization of metal surgical instruments with low size, weight, and power requirements for use in low resource environments. Rapid sterilization with low resources will be required in future large scale combat operations to support continued surgical procedures in prolonged care and/or mass casualty scenarios.

- **Focus Area 2 – Hemostasis:** Freeze-dried platelet hemostatic agent regulatory enabling studies and manufacturing scale-up
- **Focus Area 3 – Neurotrauma:** Traumatic brain injury (TBI) is a major health burden in both military and civilian populations. In the last two decades, there have been approximately 420,000 documented incidents of Service members sustaining at least one TBI. Future operations are expected to result in higher casualty volumes, greater injury severities, and reduced capability in the forward-operating environment. Technologies to reduce the severity of life-threatening TBI casualties during times of evacuation are unavailable and will help bridge casualties until they reach more definitive care.

**Solutions should focus on** minimally invasive intracranial access with automatic disengagement of drill to enable hematoma drainage and monitoring of intracranial pressure. The proposed technology must have completed TRL-4 and have manufacturing and sterile packaging in place, and regulatory pathway for initial U.S. Food and Drug Administration (FDA) clearance within 3 years.

**As a note:** The DoD requires that awardees make Traumatic Brain Injury (TBI) research data generated by this award mechanism available to the research community through the Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System. More information on FITBIR and this requirement can be found in **Addendum 1 of this RPP**.

- **Focus Area 4 – Sustainment of Expeditionary Medical Skills:** Solutions for non-invasive, non-disruptive, AI-guided surgical skills assessment using marker less motion capture systems that enable longitudinal measurement and recording of detailed three-dimensional position and motion for hand, tool/instrument, and body to assess degradation and the influences of supplementary training within subject and between subject and exemplar.
- **Focus Area 5 – En-route Care: *Specific areas are as follows:***  
***Note that Offerors shall propose solutions aligned with only one Focus Area (either Focus Area 5.1 or Focus Area 5.2)***
  - **Focus Area 5.1 –** Solutions focused on methods and materiel to mitigate negative effects of En-route Care during long hold, long haul evacuation. Further consideration of vibration, acceleration, and altitude as well as extreme weather during long hold, long haul evacuation is encouraged.
  - **Focus Area 5.2 – Solutions focused on methods and materiel to enable high volume movement to mitigate transport effects on patient outcomes. Additional consideration of solutions to enhance ERC provider**

**skill transfer, sustainment, and replication of best practices in a mass casualty and/or prolonged care environment.**

- **Focus Area 6 – Autonomous Care and Evacuation Trauma Research:** Trauma Research to enhance triage to optimize advanced medical regulating capability within the medical common operating picture towards intelligent forward deployed systems. Proposals should lead to enabling intelligent systems that assist with casualty identification and triage. Work may leverage available/ existing sensors.
- **Focus Area 7 – Autonomous Care and Evacuation Critical Care Technologies:** Studies to develop advanced autonomous critical care technologies and semi-autonomous medical devices to enable triage and medical regulating. Solutions focused to provide capabilities to conduct closed loop/lifesaving interventions (resuscitative care, airway management, hemorrhage control) during evacuation and prolonged care environments while increasing capacity to assess, treat, and maintain severe trauma cases in forward environment using robotic and autonomous technologies.
- **MILITARY OPERATIONAL MEDICINE** - This technology area aims to maximize health, readiness, and performance by countering stressors and preventing physical and psychological injuries during training and operations. Research and development Focus Areas are categorized into the following general areas: (1) Environmental Health and Protection (performance optimization and biomarker validation during heat/cold/altitude exposures); (2) Injury Prevention and Reduction (countermeasures against aviation stressors; blast, blunt trauma, and accelerative injury prevention strategies; neurosensory injury protection; injury return-to-duty standards and strategies; and physiological mechanisms of musculoskeletal injury); (3) Physiological Health and Performance (performance and recovery nutrition, weight balance optimization, cognitive health and performance sustainment in the face of operational challenges, restorative sleep, and establishment of a physiological basis for resilience to operational and environmental stressors); and (4) Psychological Health and Resilience (post-traumatic stress disorder, suicide prevention, resilience, substance abuse prevention, and violence prevention within the military). **Focus areas are as follows (NOT listed in order of importance):**
  - **Focus Area 8 – Pharmacological/Technological Approaches to Measure & Manipulate the Glymphatic/Lymphatic (G/L) System during Sleep:** Solutions must be within a TRL 4-6 range that demonstrate that the G/L system can be reliably measured in humans or nonhuman primates during sleep and directly manipulated through pharmacological/technological approaches; demonstrate efficacy of their approach to positively impact cognitive performance and psychological health outcomes; develop or adapt approaches to improve or enhance brain fluid movement in humans or nonhuman primates; **or** develop models that quantify the impacts of G/L clearance in the brain on short term impacts on the restorative effects of sleep.

- **Focus Area 9 – Musculoskeletal Injury Prevention and Reduction:** Offerors may respond to any combination of these specific areas that follow. However, a proposal shall address a minimum of one of these bullets:
  - Solutions to prevent and/or reduce common overuse tendon and ligament injuries
  - Solutions to prevent, reduce, or mitigate joint instability
  - Novel solutions or therapeutics to prevent muscle atrophy
  
- **Focus Area 10 – Musculoskeletal Injury Treatment and Rehabilitation:** Offerors may respond to any combination of these specific areas that follow. However, a proposal shall address a minimum of one of these bullets (*Clinical Studies are encouraged*):
  - Solutions to optimize short-term and/or long-term outcomes following soft tissue injury (e.g., sprains/strains)
  - Biologic or drug therapy that can accelerate recovery of musculoskeletal injuries
  - Therapeutic interventions to accelerate recovery timelines and/or optimize outcomes following battle-related and/or training-related musculoskeletal injury
  - Validated assessments to optimize and inform return-to-duty guidelines following musculoskeletal injury
  
- **Focus Area 11 – Psychological Health and Resilience:** Specific areas are as follows *Note that Offerors shall propose solutions aligned with only one Focus Area (either Focus Area 11.1 or Focus Area 11.2)*
  - **Focus Area 11.1 - Suicide Prevention** (*Offerors may address either or both bullets*):
    - Mature, non-clinical, upstream interventions/approaches for suicide prevention that include components of crisis response planning and lethal means safety and that can be delivered by peers or other non-behavioral health provider personnel and that can be evaluated for dual efficacy and implementation trials within military installations.
    - Develop Military-specific postventions for suicide, particularly after discharge from in-patient treatment, after suicide exposure, and during critical military transition periods such as during the first year of service, after deployment, and during the separation phase from active duty.
  - **Focus Area 11.2 - Cross-cutting Prevention:**
    - Validate mature primary integrated prevention interventions or trainings aimed to reduce harmful behaviors (including but not limited to sexual assault and harassment, violence, alcohol/substance misuse, ostracism, and non-suicidal self-injury, and suicide) within the Military Health System (MHS) or within non-medical military installations.

○ **Focus Area 12 – Performance Decrement and Injury Risk in Ground Soldiers due to Head Supported Mass:**

**An ideal solution would meet the following requirements (not listed in order of importance).** Proposed prototypes do not have to meet all the following Requirements / Specifications at the time of Enhanced White Paper submission, but Offerors must describe what they do plan to accomplish during the proposed PoP. The Government may consider responses proposing how to achieve only a portion of these Ideal Solution Requirements if the Offeror's approach sufficiently demonstrates how the remaining requirements/specifications can be met over time (Offerors should specify the projected timeline). Therefore, an Offeror's Enhanced White Paper will describe in detail how they plan to satisfy **all** the following Requirements (either during the proposed PoP of the resultant award or beyond that period):

- Develop assessments to characterize the exposures to the head/neck complex during simulated ground maneuvers, and to measure the physiological and biomechanical response during these maneuvers.
- Develop assessments to determine the impact of overall or full-body versus localized or isolated neck muscle fatigue on physiologic and biomechanical, performance, kinematic, and subjective metrics under varied Head Supported Mass conditions.
- Develop solutions (computational modeling) to assess the biomechanical response of the human spine during ground Soldier operations.
- Develop validated guidelines to address tolerance limits for mass/center mass offset and wear duration of Head Supported Mass in ground Soldier populations.
- Develop and deliver preliminary cervical spine injury Head Supported Mass guidance for ground Soldier populations associated with extended career and environmental exposure (dismounted and/or during transport).

○ **Focus Area 13 – Metabolic Sensor:** Solutions for a hand-held personal metabolic sensor that accurately measures the volume, and oxygen (O<sub>2</sub>) and carbon dioxide (CO<sub>2</sub>) concentrations, of expired breath, and calculates the rates of oxygen consumption (VO<sub>2</sub>) and carbon dioxide production (VCO<sub>2</sub>) on demand, using this information to estimate metabolic energy expenditure and the percent of energy derived from oxidation of carbohydrates versus fats. Please see **Addendum 2 of this RPP** for further information on this Focus Area.

○ **Focus Area 14 – Wearable Blast Exposure Sensor and Its Clinical Decision Support:** The Offeror's proposal will be expected to address **all** of the following:



- Develop direction-independent wearable blast sensor for deployed environments, that is able to capture blast exposure from all directions and report critical blast parameters.
    - Blast parameters should include but are not limited to full waveform of blast overpressure, peak incident and reflective pressures, peak impulse and equivalent blast overpressure.
  - Develop an accompanying software package for PCs and/or handheld devices to wirelessly pull raw data, analyze blast events from the sensors and produce a summary of each blast event using previously described blast parameters.
- **Focus Area 15 – Neurosensory injury prevention and treatment:** Repair, restore, monitor, preserve and maintain neurosensory system (e.g., vision, hearing, balance) function after military exposures. Research efforts should seek to develop innovative strategies and technologies that may include medical devices, pharmaceuticals, rehabilitation strategies, and regenerative medicine-based approaches, to assess, diagnose, treat, restore, and preserve spared tissue and function, and/or rehabilitate patients due to neurosensory injury.
- **Focus Area 16 – Biomechanical Tolerance of the Human Head to High-Rate Localized Blunt Impacts.** Injury criteria for high-rate blunt impacts to the head, such as those resulting from ballistic-induced behind helmet blunt trauma, are required to develop injury -based performance criteria for DoD personal protective equipment (PPE). The purpose is to have medically based criteria for future development and evaluation of next generation PPE. There is also a need to develop medically-based performance requirements for helmets in order to protect against the whole spectrum of head/brain injuries occurring in military operational environments.

**An ideal solution would meet the following requirements (not listed in order of importance).** Proposed prototypes do not have to meet all the following Requirements / Specifications at the time of Enhanced White Paper submission, but Offerors must describe what they do plan to accomplish during the proposed PoP. The Government may consider responses proposing how to achieve only a portion of these Ideal Solution Requirements if the Offeror's approach sufficiently demonstrates how the remaining requirements/specifications can be met over time (Offerors should specify the projected timeline). Therefore, an Offeror's Enhanced White Paper will describe in detail how they plan to satisfy all the following Requirements (either during the proposed PoP of the resultant award or beyond that period):

- Leverage existing published literature, and previous DoD-funded projects investigating head injuries caused by blunt impacts at loading rates ranging from sports-related impacts and motor vehicle accidents to behind-armor blunt impacts resulting from defeated ballistic projectiles.

- Leverage existing and emerging clinical data and emerging field data on head injuries being collected by the DoD, law enforcement community, industry, and academia.
- Develop and conduct, in cooperation with DoD laboratories, innovative medical research to characterize physiological response (e.g., head injury, traumatic brain injury), and head impact parameters under military-relevant exposures, using mechanical, cadaveric, or animal surrogates.
- Collaborate with DoD laboratories, industry, and academia to leverage existing computational models of the head, brain, and torso to support, and potentially expand, the experimental studies mentioned above.
- Correlate physiological response to impact parameters to develop and deliver injury risk thresholds or probability risk curves for head injuries related to high rate localized blunt impacts.
- Collaborate with DoD laboratories with complementary capabilities to leverage DoD research expertise and to ensure operational relevance of the proposed research.

#### **3.4. Additional Points of Consideration**

- **Project Maturity:** This solicitation is not meant to support development of a new prototype and shall meet the minimum TRL or KRL requirement described in Section 3.2 (unless otherwise stated in Section 3.3.). Offerors shall adequately describe how their proposed technology meets the definition of a prototype and should clearly address how the prototype meets the indicated TRL at the time of submission.
- **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
- **Cost Share:** It is anticipated that the Government funds would provide incentive for industry funding to join the project. While not a requirement, Offerors are strongly encouraged to include Cost Share as appropriate.

#### **3.5. Examples of Proposed Tasks**

The PoP should be focused on tasks relevant to advance the prototype to the next TRL or KRL. Project scope should be proposed based on the prototype's maturity at the time of submission.

**Examples** of the work that could be included in the PoP are **(but not limited to):**

- Non-GLP (Good Laboratory Practice) laboratory research to refine hypothesis and identify relevant parametric data required for technological assessment in a rigorous (worst case) experimental design
- Exploratory study of candidate devices/systems/drugs

- Candidate devices/drugs/vaccines are evaluated in laboratory or animal model(s) to identify and assess potential safety problems, adverse events, and side effects
- Prototype development, refinement, maturation
- Nonclinical and preclinical studies required for the technical data package for a regulatory application
- Preparation of regulatory packages (e.g., Investigational New Drug application, Investigational Device Exemption application), including regulatory consultant costs.
- Prototype refinement/maturation progressing towards clinical product
- Clinical feasibility studies (as needed) to support regulatory approval/clearance
- Clinical pivotal studies (as needed) to support regulatory approval/clearance
- Stability and shelf-life studies
- Prototype delivery for military-relevant testing
  - Testing of prototypes
  - System prototype demonstration in a relevant or operational environment
- Establishment of Good Manufacturing Practice (GMP) manufacturing for clinical trials and for market release
- Initial production runs; first article testing, etc.
- Low-rate initial product runs to reach Full Operating Capability
- Draft product support documentation (e.g., training guides, product inserts, etc.)
- Development of a business and/or commercialization plan for market release
- Integration of medical informatics system components and system is evaluated in a simulated environment/ Develop interfaces to supporting systems
- Advanced technical testing in a laboratory environment and ultimately in a relevant or simulated operational environment of an informatics system including actual interfaces to realistic supporting elements

### **3.6. Potential Follow-on Tasks**

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

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.

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

**3.8. Inclusion of Women and Minorities in Study**

Consistent with the Belmont Report, “Ethical Principles and Guidelines for the Protection of Human Subjects,” and Congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRDC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Under any resultant awards, Offerors may be required to describe the strategy for the inclusion of women and minorities in the clinical trial appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, race, and ethnicity, and an accompanying rationale for the selection of subjects. Such strategy should provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The suggested Inclusion Enrollment Report format is a one-page fillable PDF form, which can be downloaded from the Documents Library on the MTEC Public Site ([mtec-sc.org](http://mtec-sc.org)) and the Members Only Site.

**3.9. Guidance for research studies targeting DoD personnel for survey research**

Protocols that target DoD personnel for research in which the primary data collection tool is a survey require additional administrative review per Department of Defense Instruction (DODI) 1100.13. Investigators will need to coordinate with HRPO to identify current submission requirements.

**3.10. Guidance for research studies targeting military families and children**

In accordance with DODI 1402.5 and Army Directive 2014-23, Child Care National Agency Check and Inquiries background investigations are required for all individuals who have regular contact with military dependents under 18 years of age. All individuals who regularly interact with children under 18 years of age in Army sponsored and sanctioned programs are required to undergo specific initial background checks and periodic re-verifications. Investigators who propose work involving contact with military dependents under 18 years of age should plan for the additional time and funds required for such investigations.

Per Department of Defense Education Activity (DODEA) Administrative Instruction 2071.3, DODEA approval is required for research studies involving DODEA school personnel, school facilities, students, sponsors, and/or data. Investigators proposing to conduct any research activities involving DODEA schools should plan for the additional time (~3-6 months) and effort required to obtain approval from DODEA to conduct such activities. Procedures and requirements for the review and approval of a research study request can be found at <http://www.dodea.edu/datacenter/research/requests.cfm>

Research studies that address Army Family Advocacy Program concerns will need to be coordinated with the Family Advocacy Research Subcommittee per Army Regulation 608-18.

### **3.11. Guidance for research studies involving US Army Special Operations Command**

Per US Army Special Operations Command policy 24-18, studies involving US Army Special Operations Command Soldiers as human subjects require additional review by the US Army Special Operations Command Research Advisory Committee and Human Subjects Research Board.

### **3.12. Compensation to DoD-affiliated personnel for participation**

Please note that compensation to DoD-affiliated personnel for participation in research while on duty is prohibited with some exceptions. For more details, see Department of Defense Instruction 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 the following link: <https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf>

## **4 Enhanced White Paper Preparation**

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### **General Instructions**

Enhanced White Papers may be submitted at any time during the submission period but no later than the due date and time specified on the cover page using BIDS: <https://ati2.acgcenter.com/ATI2/Portal.nsf/Start?ReadForm>. Include the MTEC Solicitation Number (**MTEC-23-06-USAMRDC MultiTopic**) on each Enhanced White Paper submitted. See **Attachment 7 of the PPG** for further information regarding BIDS registration. Instructions regarding BIDS submissions will be forthcoming.

**Evaluations and recommendations for award are expected to be conducted on a first-in, first-out basis. Therefore, we highly encourage Offerors to submit as soon as possible during the open submission period. Project awards will be made on a rolling basis.**

The Enhanced White Paper format provided in this MTEC RPP (Section 8) is **mandatory** and shall reference this RPP number (**MTEC-23-06-USAMRDC MultiTopic**). Note that Cost Proposals are only required for Stage 2 and are not part of the initial Enhanced White Paper submission. Offerors are encouraged to contact the Points-of-Contact (POCs) identified herein up until the Enhanced White Paper due date/time to clarify requirements (both administrative and technical in nature).

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

### **Instructions for the Preparation & Submission of the Stage 1 Enhanced White Paper**

Offerors submitting Enhanced White Papers 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.

An automated BIDS receipt confirmation will be provided by email. Offerors are encouraged to submit in advance of the deadline. **Neither MTEC nor ATI will make allowances/exceptions for submission problems encountered by the Offeror using system-to-system interfaces. If the Offeror receives errors and fails to upload the full submission prior to the submission deadline, the submission may not be accepted. It is the Offeror’s responsibility to ensure a timely and complete submission.**

#### **Required Submission Documents (4): Submitted via BIDS (5MB or lower)**

- **Enhanced White Paper:** one PDF document
- **Warranties and Representations:** one Word or PDF document (**See Attachment 3 of the PPG**)
- **Statement of Work (SOW)/Milestone Payment Schedule (MPS):** one Word or PDF document (**See Attachment 4 of the PPG**)
- **Intellectual Property and Data Rights Assertions:** one signed Word or PDF document (**See Attachment 6 of the PPG**)

Page Limitation: The Enhanced White Paper is limited to ten (10) pages (including cover page). The following appendices are **excluded** from the page limitation: (1) *Warranties and Representations*, (2) *Statement of Work*, and (3) *Intellectual Property and Data Rights Assertions*.

The Enhanced White Paper and its Appendices must be in 12-point font (or larger), single-spaced, single-sided, 8.5 inches x 11 inches. Smaller type may be used in figures and tables but must be clearly legible. Margins on all sides (top, bottom, left, and right) should be at least 0.5 inch. Enhanced White Papers and Appendices exceeding the page limits and/or the specified file size above may not be accepted. **Each document shall be uploaded to BIDS separately (see Attachment 7 of PPG for BIDS instructions).**

Enhanced White Papers **exceeding the page limit specified in this section of the RPP may not be accepted.**

*FOR INFORMATION ONLY:* Please note a full Cost Proposal will only be requested if the Enhanced White Paper is selected for funding (see Section 4.3 for additional details). Furthermore,

additional attachments/appendices (henceforth referred to as supplemental information) to this proposal submission may be requested after completion of the technical evaluation to include the following:

- **Previous, Current and Pending Support** summarizing other sponsored research for each person who will contribute significantly to the proposed prototype project. The information for previous support should include the past five (5) years, unless otherwise specified in the request.
- **Letter(s) of Support**, as applicable, if the prototype project will require access to active-duty military patient populations and/or DoD resource(s) or database(s).

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

### **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 as one Word or PDF document.**
- **Section II: Cost Proposal Formats as one Excel or PDF document.**

See below for additional instructions. Also refer to **Addendum 3 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** (the MTEC PPG will be provided by MTEC to Offerors invited to Stage 2). Separately, **Section II: Cost Proposal Formats** in either Excel (.xlsx or .xls) or PDF format 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.

**Enhanced White Paper and Cost Proposal Preparation Costs**

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

**Freedom of Information Act (FOIA)**

To request protection from FOIA disclosure as allowed by 5 U.S.C. § 552, Offerors shall mark business plans and technical information with a legend identifying the documents as being submitted on a confidential basis. For more information, please refer to Section 6.1.1 of the MTEC PPG.

**Telecommunications and Video Surveillance**

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

**5 Selection**

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**Preliminary Screening**

The CM will conduct a preliminary screening of submitted Enhanced White Papers to ensure compliance with the RPP requirements. As part of the preliminary screening process, Enhanced White Papers that do not meet the requirements of the RPP may be eliminated from the competition or additional information may be requested by the CM. Additionally, the Government reserves the right to request additional information or eliminate Enhanced White Papers 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 determination based upon the ratings shown in Table 1:

| TABLE 1 - COST SHARING/NONTRADITIONAL CONTRACTOR ASSESSMENTS |   |
|--|---|
| RATING   | DESCRIPTION   |
| PASS   | Offeror proposing an MTEC research project meets at least ONE of the following: |

|   |   |
|---|---|
|   | <ul style="list-style-type: none"> <li>• Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution</li> <li>• Offeror's Enhanced White Paper has at least one Nontraditional Defense Contractor or Nonprofit Research Institute participating to a significant extent</li> <li>• All significant participants in the transaction other than the Federal Government are small businesses or nontraditional defense contractors</li> <li>• Offeror provides at least one third of the total project cost as acceptable cost share</li> </ul>   |
| <p style="text-align: center;">FAIL</p> | <p>Offeror proposing an MTEC research project does <b>NOT</b> meet at least ONE of the following:</p> <ul style="list-style-type: none"> <li>• Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution</li> <li>• Offeror's Enhanced White Paper has at least one Nontraditional Defense Contractor or Nonprofit Research Institute participating to a significant extent</li> <li>• All significant participants in the transaction other than the Federal Government are small businesses or nontraditional defense contractors</li> <li>• Offeror provides at least one third of the total project cost as acceptable cost share</li> </ul> |

**Stage 1 (Enhanced White Paper) Evaluation**

The CM will distribute all Enhanced White Papers 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 cost proposal 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 Enhanced White Papers 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 overall award decision will be based upon a best value determination by considering factors in addition to cost/price.

**Stage 1 Evaluation Factors:**

- 1. Research Strategy**
- 2. Personnel and Team**
- 3. Potential for Transition**

**Evaluation Factor 1 – Research Strategy:**

The Offeror’s Proposal 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 how well the proposal defines a prototype that meets the requirements set forth in this RPP.
- How well the Offeror demonstrates the technical ability and strategy to execute the research,
- How well the specific aims and proposed methodology supports the Focus Area and the development of the prototype.
- The Government may evaluate the proposed cost, as reflected in the Rough Order of Magnitude (ROM) pricing, as it relates to research strategy. Therefore, Enhanced 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:**

This factor will evaluate the strength of the organization/team proposed to complete the work. The Offeror’s resources (key facilities, equipment, etc.), project management plan, expertise, and experience of personnel may be considered as part of this factor.

**Evaluation Factor 3 – Potential for Transition:**

Soundness of the proposed strategy to produce outcomes that can transition to translatable processes, knowledge and technology for both civilian and military use. Examples of the information that may be assessed (if applicable to the proposed project):

- Regulatory and Commercialization Plan: Feasibility of the Offeror’s regulatory strategy, including FDA pathway, indication of use and designation, strategy for obtaining FDA approvals or clearances. Feasibility of the commercialization strategy including the degree to which the Offeror demonstrates potential commercial use, including a description of the market (civilian and military) and sustainability.
- Transition: If the above is not applicable to the proposed project, then feasibility of the plan to transition the knowledge and technology to the government may be assessed.

Table 2 explains the adjectival merit ratings that will be used for the abovementioned 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. |

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|              |   |
|--------------|---|
| 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 completion of the Stage 1 evaluations, Offerors may be selected for funding and invited to participate in Stage 2 for further evaluation (receive an overall recommendation of "Award"), placed into the basket, or not selected. Selection of prototype projects is a highly competitive process and is based on the evaluation of the Enhanced White Paper's technical merit, programmatic considerations, and the availability of funds. Therefore, Enhanced White Papers that receive the highest merit ratings and thus demonstrating technical merit are not automatically recommended for funding as such decisions consider funding priorities and how to best achieve program objectives. All Offerors will receive feedback to include a summary of the technical evaluation for their proposal submission.***

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**.

#### **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

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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 Chief of Consortium Operations, Ms. Kathy Zolman, [kathy.zolman@ati.org](mailto:kathy.zolman@ati.org)

## 7 Acronyms/Abbreviations

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|            |   |
|------------|---|
| ACURO      | U.S. Army Animal Care and Use Review Office         |
| ATI        | Advanced Technology International                   |
| BLE        | Bluetooth Low Energy                                |
| CDE        | Common Data Element                                 |
| CFR        | Code of Federal Regulations                         |
| CM         | Consortium Manager                                  |
| CMA        | Consortium Member Agreement                         |
| CNACI      | Child Care National Agency Check and Inquiries      |
| DoD        | Department of Defense                               |
| DODEA      | Department of Defense Education Activity            |
| DODI       | Department of Defense Instruction                   |
| EE         | metabolic Energy Expenditure                        |
| ERC        | En-route Care                                       |
| F&A        | Facilities and Administrative Costs                 |
| FAP        | Family Advocacy Program                             |
| FAQ        | Frequently Asked Questions                          |
| FARS       | Family Advocacy Research Subcommittee               |
| FDA        | U.S. Food and Drug Administration                   |
| FITBIR     | Federal Interagency Traumatic Brain Injury Research |
| FOIA       | Freedom of Information Act                          |
| FY         | Fiscal Year   |
| G&A        | General and Administrative Expenses                 |
| GCP        | Good Clinical Practice                              |
| GLP        | Good Laboratory Practice                            |
| GMP        | Good Manufacturing Practice                         |
| Government | U.S. Government, specifically the DoD               |
| GUI        | Graphical User Interface                            |

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|         |  |
|---------|--|
| GUID    | Global Unique Identifier   |
| HIPPA   | Health Insurance Portability and Accountability Act                |
| IACUC   | Institutional Animal Care and Use Committee                        |
| ICH     | International Conference on Harmonisation                          |
| IDE     | Investigational Device Exemption                                   |
| IP      | Intellectual Property (e.g., patents, copyrights, licensing, etc.) |
| IRB     | Institutional Review Board   |
| IT      | Information Technology   |
| KRL     | Knowledge Readiness Level  |
| M       | Millions   |
| MHS     | Military Health System   |
| MPS     | Milestone Payment Schedule   |
| MTEC    | Medical Technology Enterprise Consortium                           |
| NDA     | Nondisclosure Agreement  |
| NHP     | Nonhuman Primates  |
| NINDS   | National Institute of Neurological Disorders and Stroke            |
| OCI     | Organizational Conflict of Interest                                |
| ODC     | Other Direct Costs   |
| OHARO   | Office of Human and Animal Research Oversight                      |
| OHRO    | Office of Human Research Oversight                                 |
| ORP     | USAMRDC Office of Research Protections                             |
| OTA     | Other Transaction Agreement  |
| PAI     | Pre-approval Inspection  |
| PDF     | Portable Document Format   |
| PI      | Principal Investigator   |
| POC     | Point-of-Contact   |
| PoP     | Period of performance  |
| PPE     | Personal Protective Equipment                                      |
| PPG     | Proposal Preparation Guide   |
| R&D     | Research and Development   |
| RER     | Respiratory Exchange Rate  |
| RH      | Relative Humidity  |
| ROM     | Rough Order of Magnitude   |
| RPP     | Request for Project Proposals                                      |
| SME     | Subject Matter Experts   |
| SOW     | Statement of Work  |
| T       | Temperature  |
| TBI     | Traumatic Brain Injury   |
| TRL     | Technology Readiness Level   |
| UDE     | Unique Data Element  |
| USAMRDC | U.S. Army Medical Research and Development Command                 |
| USASOC  | US Army Special Operations Command                                 |
| USG     | U.S. Government  |

## 8 Enhanced White Paper Template

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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 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 agreement is awarded as a result of, or in connection with, the submission of this data, the MTEC Consortium Management Firm and the Government shall have the right to duplicate, use, or disclose these data to the extent provided in the resulting agreement. This restriction does not limit the MTEC Consortium Management Firm and the Government's right to use the information contained in these data if they are obtained from another source without restriction. The data subject to this restriction is (clearly identify) and contained on pages (insert page numbers).]*

## [Title of Enhanced White Paper]

### Focus Area

- Indicate which focus area this Enhanced White Paper is responding to [include only one area per submission], for example, “**Focus Area 1 – Sterilization:** Solutions for rapid sterilization of metal surgical instruments with low size, weight, and power requirements for use in low resource environments”

### Programmatic Relevance

- Provide the background and the Offeror’s understanding of the problem and/or technology gap/process deficiency.
- Provide a description of how the proposed technology meets the needs specified in this RPP.
- Describe the relevance of your proposed technology to the healthcare needs of military.
- Describe how the proposed technology meets the definition of a prototype as defined in **Section 3.2.**
- Please indicate the KRL/TRL stage of the proposed solution at the time of submission of the Enhanced White Paper, as well as anticipated KRL/TRL at project completion. Full definitions of TRLs can be found [here](#). More information regarding KRLs can be found [here](#).

KRL/TRL at Time of Submission:

KRL/TRL at Project End:

### Scope Statement

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

### Scientific Rationale / Preliminary Data

- Describe the scientific rationale for the project, including a brief description of the previous studies or preliminary data that support both the feasibility of proposed work and the indicated TRL/KRL. Please reference the [TRL definitions](#) for further information regarding expected scope of work for advancement toward the next TRL.
- Describe relevant non-clinical data and/or clinical preliminary data.
- Describe your demonstration of the manufacturing feasibility of the prototype.

### Technical Approach

- Describe the experimental design, methods, and materials required to accomplish the proposed approach. Describe the proposed methodology in sufficient detail to show a clear course of action.
- If you are proposing clinical research and/or trials, then please briefly describe your technical approach here in the Enhanced White Paper

### Anticipated Outcomes/Impact



- Provide a description of the anticipated outcomes from the proposed work. List milestones and deliverables from the proposed work.
- Describe the impact that the proposed project would have, if successful.

#### **Potential Follow-On Work**

- [As noted in **Section 3.6 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.]
- 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 directs and indirects) for each task.

#### **Technical and Management Team**

- Describe the qualifications and expertise of the key personnel and organizations that will perform the proposed work.
- Describe the overall project management plan that clearly defines roles and responsibilities. If applicable, this plan should include a communication and conflict resolution plan if the proposal involves more than one company/institution/organization.
- Describe the ability of the management team to advance the technology toward later TRLs beyond the scope of the proposed work described in the Enhanced White Paper.

#### **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.

#### **Market and Business Model**

- Clearly articulate the value proposition, competitive position, market opportunity and business model for getting to revenue through commercial use, including a description of the market (civilian and military) and sustainability.

#### **Product Development Strategy**

- Describe the final vision of what the product would look like and how that product would be administered or delivered for military use (required) and civilian use (if applicable).

- Describe previous interactions with the FDA related to this proposed prototype solution (e.g., pre-submission meeting).
- Briefly describe the regulatory plan, including FDA pathway and designation, strategy for obtaining FDA approvals or clearances.
- Briefly describe the transition and commercialization plan, including a description of the market (civilian and military) and sustainability.
- Briefly describe your funding strategy to advance the technology to the next level of development and/or delivery to the military or civilian market.
- If commercialization is not relevant to the proposed project, then describe the plan to transition the technology to the military market for government use/implementation.

**Schedule**

- PoP: Indicate the proposed PoP in months from award.
- Proposed Schedule: Provide a schedule (e.g., Gantt chart) that clearly shows the plans to perform the program tasks in an orderly, timely manner. Provide each major task (to include regulatory-specific tasks) as a separate line. Do not duplicate the level of detail presented in the Statement of Work.

**Risk Identification and Mitigation**

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

**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>   |

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|   |               |               |               |                        |
|---|---------------|---------------|---------------|------------------------|
| <b>Government/Military Partner(s)/Subcontractor(s) (subKTR)*</b>      | \$0.00        | \$0.00        | \$0.00        | <b>\$0.00</b>          |
| <b>Gov't/Military Prtnrs / subKTR Hours</b>                           | 0.0 hrs       | 0.0 hrs       | 0.0 hrs       | <b>0.0 hrs</b>         |
| <b>Consultants</b>  | \$ 10,000.00  | \$ 10,000.00  | \$ 10,000.00  | <b>\$ 30,000.00</b>    |
| <b>Consultants Hours</b>  | 100.0 hrs     | 100.0 hrs     | 100.0 hrs     | <b>300.0 hrs</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)**

**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: 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 – Federal Interagency Traumatic Brain Injury Research Requirement**

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### **FITBIR Data Sharing**

The DoD requires that awardees make TBI research data generated by this award mechanism available to the research community through the FITBIR Informatics System. The FITBIR Informatics System is a free resource designed to accelerate research progress by allowing the storage, re-analysis, integration, and rigorous comparison of multiple datasets. Currently FITBIR eligible research include all studies generating prospectively collected human TBI subject data (e.g., clinical, demographic, phenotypic, imaging, and genomic).

Data reporting to FITBIR is an opportunity for investigators to facilitate their own research and to collaborate with others engaged in similar research. While there is no direct charge to users of the FITBIR Informatics System, a project estimation tool (<https://fitbir.nih.gov/jsp/contribute/fitbir-costs.jsp>) is available to help estimate costs and manpower needs that may be associated with data submission. FITBIR guidance and policies, as well as the considerable advantages of FITBIR participation to the researcher, are detailed at <http://fitbir.nih.gov/>.

In order to share data with FITBIR, three elements must be included in the proposed research:

1. Updated informed consent language that includes FITBIR data sharing. Sample consent language is included in Appendix III.
2. Global Unique Identifier (GUID): FITBIR encourages collaboration between laboratories, as well as interconnectivity with other informatics platforms. Such community-wide sharing requires common data definitions and standards. FITBIR allows for de-identification and storage of data (medical imaging clinical assessment, environmental and behavioral history, etc.) of various types (text, numeric, image, time series, etc.). Use of FITBIR's GUID system facilitates repeated and multi-user access to data without the need to personally identify data sources. In order to generate a GUID for a subject, the following personally identifiable information (PII) must be collected in the proposed research:
  - a. Complete legal given (first) name of subject at birth
  - b. Complete legal additional name of subject at birth (if subject has a middle name)
  - c. Complete legal family (last) name of subject at birth
  - d. Day of birth
  - e. Month of birth
  - f. Year of birth
  - g. Name of city/municipality in which subject was born
  - h. Country of birth

Note that this PII is never sent to the FITBIR system. PII cannot be extracted from the GUID. Information on GUID compliance with Health Insurance Portability and

Accountability Act (HIPAA) regulations can be found at <https://fitbir.nih.gov/content/global-unique-identifier>.

3. Common Data Elements (CDEs): Research data elements must be reported using the National Institute of Neurological Disorders and Stroke (NINDS) TBI CDEs or entered into the FITBIR data dictionary as new, unique data elements (UDEs). For the most current version of the NINDS TBI CDEs, go to <http://www.commondataelements.ninds.nih.gov>. Assistance will be available to help the researchers map their study variables to specific CDEs and ensure the formats of the CDEs collected are compatible with the FITBIR Informatics System. Use of the TBI CDEs is required wherever possible to create standardized definitions and guidelines about the kinds of data to collect and the data collection methods that should be used in clinical studies of TBI. Use of UDEs is strongly discouraged and subject to program approval.

## **Addendum 2 – Supplemental Information for Focus Area 13**

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### **Background**

Metabolic dysfunction represents a national security issue across all service branches and phases of a military career, including recruitment, training, deployment, and retirement from the service. According to a 2015 report [1], one in three young adults of recruitment age is unqualified for military service because of excessive body weight or weight-related disorders [2]. During training and deployment, metabolic fitness levels impact mission readiness, and optimizing soldier performance requires matching nutrition to individual metabolic needs [3]. During the later stages of a military career and retirement, avoiding obesity and type 2 diabetes is a concern for the service organizations as well as aging soldiers. A 2003 study [4] indicated that 15 percent of the patients in Veterans' Health Administration hospital care were diabetic, and the Department of Defense was spending over \$4 billion per year treating weight-related diseases. The national crises of diabetes and obesity have only grown worse since then [5]. The military numbers reflect the overall decline in metabolic health in the general population. According to the Centers for Disease Control and Prevention, in 2016, nearly half of the adults in the United States were either prediabetic (86 million) or diabetic (29 million) [6]. In addition, more than 35 percent of American adults and close to 17 percent of children were obese.

Given this background, the U.S. military has an interest in noninvasive, comprehensive metabolic measurement and tracking systems for maintaining soldiers' metabolic health and wellness, as well as optimizing the performance of soldiers under demanding physical conditions. The measurement technique, known as indirect calorimetry, has been practiced for over 100 years, and requires measuring the volumetric rate of oxygen consumption and carbon dioxide production in exhaled breath, from which energy expenditure and fuel substrate (percent of energy derived from fats versus carbohydrates) can be determined. However, to date, the systems available for making such measurements in the field are too large, costly, and awkward for use by a cohort of dozens of soldiers involved in a variety of load-bearing activities over the course of many hours or days. To make concurrent metabolic field measurements for dozens of soldiers affordable, the individual sensors must be low cost and easy to use without extensive training. The sensor must also be sufficiently small and lightweight to minimize impact on the normal load carriage and not interfere with activities performed by active duty soldiers.

The ability to track metabolic performance of individual soldiers will provide previously unavailable information and statistics to inform mission planning and doctrine. For example, as described in the Department of the Army 2022 Foot Marches manual ATP 3-21.18, *commanders must determine how the amount and type of equipment carried and rate of march—length and number of rests equates with Soldiers' physical endurance. Detailed planning and leadership must move Soldiers and equipment to the right place at the right time ready for combat. Commanders ensure Soldiers arrive in good condition to accomplish their mission.* Metabolic tracking of individual soldier energy expenditure and macronutrient utilization will improve knowledge of soldier nutritional needs and endurance capacity, as well as providing more accurate models for planning mission operations, including the rate and duration of troop movements by foot.

In terms of maintaining metabolic health of military personnel in retirement, personal metabolic tracking of energy expenditure and macronutrient utilization will enable individuals to develop personalized meal plans and exercise regimens to avoid progression into obesity and type-2 diabetes. Numerous studies have shown that glycemic response to foods, as well as weight loss in response to calorie restriction, vary greatly across individuals, limiting the value of one-size-fits-all dietary and exercise recommendations and regimens. Personal daily measurements of metabolic energy expenditure and respiratory exchange ratio (which provides an indication of the fat-to-carbohydrate fuel mix utilized to meet metabolic energy demands) will enable individuals to tailor exercise and nutrition programs to ensure their metabolic health plans are succeeding.

#### Background References

1. B. Christeson, K. Clifford, A.D. Taggart, and B. Goodman, "Too Fat, Frail, and Out-of-Breath to Fight," *Mission Readiness*, 23 Apr. 2015, available at <http://missionreadiness.s3.amazonaws.com/wp-content/uploads/TX-Physical-Activity-Report.pdf>.
2. J. Levy, L.M. Segal, K. Thomas, R. St. Laurent, A. Lang, and J. Rayburn, "F as in Fat: How Obesity Threatens America's Future," Trust for America's Health/Robert Wood Johnson Foundation, 16 Aug. 2013, available at <https://www.rwjf.org/en/library/research/2013/08/f-as-in-fat-how-obesity-threatens-america-s-future-2013.html>.
3. K.S. Mudambo, C.M. Scrimgeour, and M.J. Rennie, "Adequacy of Food Rations in Soldiers During Exercise in Hot, Day-Time Conditions Assessed by Doubly Labelled Water and Energy Balance Methods," *European Journal of Applied Physiology and Occupational Physiology*, vol. 76, no. 4, 1997, pp. 346–351.
4. Y. Wei, A. Ravelo, T.H. Wagner, C.S. Phibbs, A. Bhandari, S. Chen, and P.G. Barnett, "Prevalence and Costs of Chronic Conditions in the VA Health Care System," *Medical Care Research and Review*, vol. 60, supp. 3, 2003, pp. 146S–167S.
5. W. Youfa and M.A. Beydoun, "The Obesity Epidemic in the United States—Gender, Age, Socioeconomic, Racial/Ethnic, and Geographic Characteristics: A Systematic Review and Meta-Regression Analysis," *Epidemiologic Reviews*, vol. 29, no. 1, 2007, pp. 6–28.
6. Centers for Disease Control and Prevention, "National Center for Health Statistics Obesity Data," 29 Mar. 2017, available at <https://www.cdc.gov/chronicdisease/resources/publications/aag/pdf/2016/diabetes-aag.pdf>

#### Solution Requirements

The overall goal of this program is to develop a hand-held personal metabolic sensor that accurately measures the volume, and oxygen (O<sub>2</sub>) and carbon dioxide (CO<sub>2</sub>) concentrations, of expired breath, and calculates the rates of oxygen consumption (VO<sub>2</sub>) and carbon dioxide production (VCO<sub>2</sub>) on demand, using this information to estimate metabolic energy expenditure and the percent of energy derived from oxidation of carbohydrates versus fats. This will entail the development and integration of hardware, algorithms, and firmware for real-time measurement and data storage as well as support for control and streaming of measurements from a smart phone via Bluetooth low energy (BLE) wireless interface. In addition to development and demonstration of a small number of prototypes, a comprehensive production package suitable for mass manufacture of the hardware and supporting firmware is required.

The intent is that the metabolic sensor will be suitable for use in a variety of contexts and will be sufficiently small and low cost to enable proliferation and personal ownership. Uses envisioned include metabolic tracking during training, mission rehearsal and planning, selection of individuals for missions requiring endurance with minimal nutritional resources, and optimization of personal nutritional regimens. Statistical means and variances of energy



expenditure and macronutrient utilization associated with various mission related activities such as foot marches, load bearing equipment carriage, will better inform doctrine and, for example, provide a means to quantify the impact of terrain and altitude on energy expenditure and macronutrient reserves.

While a personal use sensor is envisioned, it must also support field studies in which a Principal Investigator or team leader can pair with a sensor and stream data from the sensor, as well as record meta data such as specific events, on the sensor via BLE wireless interface.

**Offerors should only propose technology solutions that are currently at a TRL of 4 or above.**

**An ideal solution would meet the following requirements (not listed in order of importance).** Proposed prototypes do not have to meet all the following Ideal Solution Requirements / Specifications at the time of Enhanced White Paper submission, but Offerors must describe what they do plan to accomplish during the proposed PoP. The Government may consider responses proposing to achieve only a portion of these Ideal Solution Requirements if the Offeror's approach sufficiently demonstrates how the remaining requirements/specifications can be met over time (Offerors should specify the projected timeline). Therefore, an Offeror's Enhanced White Paper will describe in detail how they plan to satisfy **all** the Ideal Solution Requirements (either during the proposed PoP of the resultant award or beyond that period):

- Hand-held, self-contained sensor system to satisfy the following size, weight, power, environmental and sanitization constraints:
  - The sensor system, exclusive of the passive breath sampling unit (e.g. mask or mouthpiece with no active valves or pumps required), shall be no larger than 100cc.
  - The breath sampling unit shall not require individual customization to the user, but be swappable among users after proper sanitation by immersion in a disinfectant such as Madacide.
  - The sensor system, including the breath sampling component, shall weigh less than 200g.
  - The sensor system power shall be supplied from a single rechargeable battery capable of holding the system in a quiescent state ready for on-demand breath measurement for at least 14 hours without recharge or battery replacement.
  - Sensor System shall be capable of functioning in temperature, humidity, and altitude extremes above freezing experienced by military personnel during training and theater operations, and withstand exposure to rain without damage to the system.
  - The sensor system shall incorporate a USB-C interface to enable data downloads, calibration and firmware updates, time synchronization and battery recharging.
- Sensor System Training, Ease of Use and Mission Impact
  - The sensor system shall be wearable with options for attachment to standard MOLLE webbing found on body armor, duty belts and elsewhere, by means of a quick disconnect to support on-demand measurements.
  - Positioning of the breath sampling unit by the user to begin a measurement should require at most one hand to acquire and position the unit followed by hands-free collection of data during the measurement period, followed by one hand stowage of

- the breath sample unit at the conclusion of the measurement.
- The breath sampling unit should not require removal of helmet, goggles, or headsets in order to make a measurement.
  - The sensor system should require no more than 2 minutes to collect a sufficient number of breath samples to ensure a valid gas and flow measurement. Longer measurements can be made at the discretion of the user or the Principal Investigator (PI) or team leader in charge of field tests
  - The sensor system should require minimal training, basically how to turn it on and off and how to use the breath sample unit, and should automatically detect breathing and record data without requiring a smart phone or other means of control. The sensor system shall also provide minimum status to the user of “ready to record”, “recording” and “fault condition” using visual means such as colored and/or flashing LEDs. More detailed status shall be available on demand via a BLE link to a smart phone by means of a sensor system graphical user interface (GUI).
  - Sensor system measurement functions, calibration, and accuracy
    - The sensor system shall maintain a real-time clock to enable time tagging of gas, volumetric flow, temperature and humidity conditions at rates of at least 20Hz. Date and time tagging of metadata entered via BLE interface shall also be required.
    - The sensor system shall provide the capability to measure ambient temperature, humidity, and barometric pressure with sufficient accuracy to determine the ambient oxygen concentration to an absolute accuracy of 0.3%, or better by correcting the nominal 20.95% dry air oxygen concentration. Alternatively, the system shall have the capability of measuring the ambient O<sub>2</sub> concentration to an absolute accuracy of 0.3% or better.
    - The sensor system shall provide a mechanism for equilibration of the nominal 37°C, saturated water vapor exhaled breath with ambient air prior to contact with the gas and flow sensors to avoid condensation on the gas and flow sensors and electronics. Alternatively, the sensor system gas sensors will perform non-contact gas and flow measurement of exhaled air.
    - The sensor system shall be capable of supporting a range of physical activity levels, from resting (peak flow rates of < 15 L/min) to high-intensity exercise (peak flow rates of > 300 L/min) while maintaining the respiratory burden at less than 2” H<sub>2</sub>O.
    - The sensor system shall be capable of performing a simple gas calibration check and recalibration, if needed, in the field. Ideally, an adequate gas calibration check can be performed using ambient air to confirm the correct oxygen sensor span and the correct carbon-dioxide sensor offset. Alternatively, a certified gas calibration mixture such as 21% O<sub>2</sub>, 5% CO<sub>2</sub>, balance N<sub>2</sub> can be used to check the calibration and perform a simple recalibration by adjusting the span of the O<sub>2</sub> and CO<sub>2</sub> gas sensors.
    - Bench-top calibration of the system in the laboratory shall include the use of a temperature-controlled oven to enable a temperature-dependent correction to be developed and validated for the O<sub>2</sub> and CO<sub>2</sub> gas sensors.
  - Sensor System Data Recording, Processing, Streaming and Accuracy
    - The sensor system shall detect the onset of breathing and record all raw data measurements as they are made, including O<sub>2</sub> concentration, CO<sub>2</sub> concentration,

ambient relative humidity (RH) & Temperature (T), gas sample RH & T, and barometric pressure so that subsequent to data collection, updated gas and flow calibration coefficients can be applied to the raw data to improve accuracy. All raw data measurements will be made at a sample rate of 20Hz or more and include a time tag. No external equipment or devices will be required to measure and record the relevant breath data.

- The sensor system firmware will implement raw data scaling and calculation of metabolic performance metrics in near real-time to support streaming to a device such as a smart phone or tablet hosting an Android GUI.
- In addition to recording raw data, at a minimum, the following scaled data and data products shall be recorded and available for live streaming
  - Ambient relative humidity (RH) & Temperature (T)
  - Sample RH & T
  - VE LPM (expiratory flow rate in liters per minute)
  - Raw O<sub>2</sub> concentration
  - Raw CO<sub>2</sub> concentration
  - FEO (%) oxygen gas fraction in expired breath
  - FECO<sub>2</sub> (%) carbon dioxide gas fraction in expired breath
  - VO<sub>2</sub> STPD (rate of oxygen consumption in LPM) (standard temperature and pressure, dry)
  - VCO<sub>2</sub> (rate of carbon dioxide production in LPM) STPD
  - RER (respiratory exchange ratio) (VCO<sub>2</sub> / VO<sub>2</sub>)
  - Breath-by-breath tidal volume
  - Metabolic Energy expenditure (EE) (kJ/min, kcal/min)
- Measurement accuracy of gas concentrations and minute volumes shall be sufficient to result in average errors in energy expenditure of 10% or less and average errors in RER of 15% or less, where the normal range of RER is 0.7 to 1.2. Consequently a 15% error in RER range corresponds to an absolute error in RER of .075 or less.
- Sensor System Settings and Control
  - The Android GUI developed for streaming and review of data collection using a hand-held device such as a smart phone or tablet, should enable the PI or team leader to pair with a user's sensor, and select specific raw and processed data for streaming including:
    - Raw gas measurements
    - Calibration gas measurements
    - RH & T measurements
    - VO<sub>2</sub> and VCO<sub>2</sub> in ATPS (ambient temperature, pressure, saturated) or STPD units
    - Respiration rate in BPM (breaths per minute)
  - The Android GUI shall also enable the PI or team leader to select the display format including:
    - Scrolling plots of parameters versus time
    - Scrolling tabular display of selected parameters with specified update rate
    - Moving averages of selected parameters with specified window length and indication of minimum and maximum values observed

- The Android GUI shall enable the PI or team leader to view system health including
  - Available memory
  - Estimated battery life
  - Out of bound metrics such as RER below 0.7 or above 1.2
  - Unrealistic flow rates (combinations of respiration rate and tidal volume)
  - Indication of condensation
- Prototype Sensor System Laboratory Validation
  - Laboratory demonstration of the accuracy of measured and derived parameters such as RER and EE shall be demonstrated by means of a mechanical lung simulator and injection of certified dry gas mixtures to enable simulation of a range of tidal volumes from 0.5L to 2.0L, a range of respiration rates from 6 BPM to 40 BPM and a range of RERs from 0.7 to 1.2 with each RER comprised of both low and high values of simulated O<sub>2</sub> consumption and CO<sub>2</sub> production
  - Validation will be performed for several sensor systems to ensure consistency across systems and several barometric pressures to ensure gas calibration integrity.

#### **Additional Preferred Characteristics**

Beyond the Ideal Solution Requirements outlined above, Offerors may consider addressing the following characteristics which are **preferred, but not required**. Proposed solutions that address any or all of these characteristics may warrant a higher technical rating (see Table 2 – General Merit Rating Assessments) as achieving or demonstrating these characteristics would exceed the stated solution requirements, as described above under Ideal Solution Requirements. Therefore, Offerors are encouraged to describe how their proposed prototype may meet none, some, or all of the following additional preferred characteristics:

- A mode in which the sensor system can be used with a nasal cannula to make continuous measurements of exhaled O<sub>2</sub> and CO<sub>2</sub> gas concentrations (but not volume flow rates) during sleep in order to compute RER and respiration rate during sleep.
- Implementation of an open system architecture where the data formats, and interface and communication standards, are readily interpretable, to enable the sensor system data to be integrated into database and reported over the squad-level short range wireless network.
- Field swappable battery or battery charging during use via USB port.

## Addendum 3 – Stage 2 Evaluation Criteria

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

### Stage 2

The MTEC 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 represent what the cost of the project should be for the effort to be accomplished assuming reasonable economy and efficiency. 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, in its nature and amount, 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 based upon verifiable techniques such as estimates developed from applicable and relevant historic cost data. The Offeror should show that sound, rational judgment was used in deriving and applying cost methodologies. Appropriate narrative explanation and justification should be provided for critical cost elements. The overall estimate should be presented in a coherent, organized and systematic manner.

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

c) **Completeness.** The MTEC CM will evaluate whether the proposal clearly and thoroughly documents the rationale supporting the proposed cost and is compliant with the requirements of the solicitation.

The proposal should clearly and thoroughly document the cost/price information supporting the proposed cost in sufficient detail and depth. The MTEC CM will evaluate whether the Offeror's cost proposal is complete with respect to the work proposed. The MTEC CM will consider substantiation of proposed cost (i.e., supporting data and estimating rationale) for all elements.

Rate and pricing information is required to properly perform the cost analysis of the proposal. If the Offeror is unwilling to provide this information in a timely manner, its proposal will be lacking information that is required to properly evaluate the proposal and the proposal cannot be selected for award.

#### **Government Access to Information**

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

#### **Best Value**

The overall award decision will be based upon the Government's Best Value determination and the final award selection(s) will be made to the most advantageous offer(s) by considering and comparing factors in addition to cost or price. The Government anticipates entering into negotiations with all Offerors recommended for funding with the MTEC CM acting on the Government's behalf and/or serving as a liaison. The Government reserves the right to negotiate and request changes to any or all parts of the proposal, to include the SOW.