

Pre-Announcement, August 2023



PRE-ANNOUNCEMENT

“Fiscal Year 2023 Military Prototype Advancement Initiative (MPAI)”

The Medical Technology Enterprise Consortium (MTEC) is excited to post this pre-announcement for the upcoming Military Prototype Advancement Initiative (MPAI) Request for Project Proposals (RPP) focused on the advancement of engineering and medical prototypes and knowledge products related to a broad range of medical technological needs identified in the Focus Areas listed below. Relevance to the U.S. Army Medical Research and Development Command’s (USAMRDC’s) priorities related to their Combat Casualty Care Research Program, Military Infectious Diseases Research Program, and Military Operational Medicine Research Program, as well as relevance to the priorities of the US Air Force School of Aerospace Medicine are key features of the RPP.

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.

FOCUS AREAS:

To meet the intent of the RPP, each proposal ***SHALL*** specifically address ***ONLY ONE*** Focus Area described below. Offerors are not limited to a single proposal submission. Projects that fail to align with only one of these Focus Areas may not be considered for funding. Additional information on listed Focus Areas or new Focus Areas may be added and will be included in the posted Request for Project Proposals (RPP) for this effort.

COMBAT CASUALTY CARE – Because battlefield conditions impose severe constraints on available manpower, equipment, and medical supplies available for casualty care, there is a need for medical interventions that can be used within the battle area or as close to it as possible, before or during medical evacuation. This area prioritizes technologies that are easily transportable (i.e., small, lightweight, and durable in extreme environments and handling), easy to use and require low maintenance. Focus areas of interest include battlefield resuscitation, hemorrhage and resuscitation, battlefield pain control, organ support, forward surgical capabilities, wound management, enroute care and autonomous care and evacuation. All proposed solutions should be supported with preliminary/published data with a minimum of TRL 4 and have an identified pathway to FDA approval (where required). **The following are focus areas of interest (not listed in order of importance):**

Pre-Announcement, August 2023

- **Blood Product Development:** Next generation resuscitation technologies and strategies to extend the shelf-life and/or minimize the cold chain for whole blood and other blood products. This may include optimization of storage techniques or development of novel technologies that function similarly to blood products in terms of volume expansion, hemostasis, and oxygen carrying capabilities. Potential technologies may include infusible hemostatics (i.e., nanoparticle solutions), oxygen carriers, and combination blood products. Technologies should effectively manage hemorrhage with attributes that include ease of delivery/use, extended shelf-life, and storage in extreme conditions.
- **Anti-shock Pharmacology:** Evaluation of drugs to mitigate the pathophysiology associated with hemorrhagic shock. Therapeutics should address metabolic acidosis, mitochondrial dysfunction, and/or trauma-induced coagulopathy. Priority will be given to evaluation of existing pharmaceutical technologies that can be repurposed for this indication.
- **Battlefield Pain Control:** Therapeutics (analgesics, anesthetics) to manage acute battlefield pain that are devoid of performance-limiting side effects. Therapeutics should address the management of pain following traumatic injury (i.e., hemorrhage) and impacts to cardiovascular and respiratory responses. This may include systemic therapeutics, as well as next generation regional analgesia techniques.
- **Organ Support Devices and Therapeutics:** Novel technologies and optimization of current technologies are required to provide renal support in the austere setting and treat ischemia reperfusion injury in severely injured casualties. Solutions may include pharmaceuticals or medical devices. All solutions should prioritize ease of delivery and the need for reduced size, weight and power.
- **Surgical Support Technologies:** Solutions to extend surgical capability and enable surgical procedures to be safely performed at Role 2-3. Current surgical capabilities are relatively cumbersome and more mobile surgical capabilities typically have significantly reduced patient capacity. Novel solutions should increase surgical capacity and decrease size, weight, and power (SWAP) requirements, contributing to improved mobility. This focus area includes both surgical technologies, as well as technologies that enable forward surgical capability such as advanced imaging, surgical sterilization, and intelligent anesthesia capabilities.
- **Complex Wound Management:** Advanced wound management therapies and solutions for operationally relevant trauma injuries such as complex soft tissue, open fracture, penetrating torso, and blast injuries. Additionally, development of solutions for delays in care of penetrating abdominal injuries and prevention/ management of deep space infections are of particular interest. Proposed solutions should be optimized for far forward use with low size, weight, and power (SWAP) requirements. Priority will be given to technologies that can be applied early in the treatment course following injury or initial debridement in order to impact the trajectory of wound recovery.
- **Burn Wound Recovery:** Safe, effective, field deployable, topical and/or systemic treatment capabilities (i.e., best practices/CPGs) to promote rapid recovery of skin functions following deep partial thickness and/or full thickness burn injury, agnostic of mechanism. This may include novel and/or repurposed therapeutics capable of initiating/accelerating burn wound healing and closure (including temporary or permanent coverage). Prioritized candidate solutions will reduce follow-on medical care required for full functional recovery, improve burn-injured Warfighter function far forward in austere or prolonged care scenarios, avoid post-burn complications, as well as improve

Pre-Announcement, August 2023

long-term clinical and functional outcomes. Clinical trials and translational studies are of high interest. This topic prioritizes capability development other than antimicrobial treatments. Studies focused primarily on developing a delivery platform are of significantly less interest compared to studies of the efficacy of the novel or repurposed therapeutics themselves.

- **En Route Care:** Advanced methods and/or materiel solutions to enable high volume or prolonged patient movement. Technologies should be supported by preliminary, published data with a focus on mitigating the potential negative effects of patient movement in an operational environment while also optimizing care to multiple patients simultaneously. Additional considerations include functionality and effectiveness under conditions of vibration, acceleration, altitude and extreme environments.
- **Autonomous Care and Evacuation:** Advanced data-driven solutions for the optimization of provider(s) treatment based on dynamic monitoring of available resources and casualty status. Solutions should present an analysis of critical factors (e.g., casualty status, casualty location, number of providers, medical supplies, environmental constraints, etc.) and an AI/ML algorithm which optimizes casualty priority and provider alignment/assignment to increase clinical capacity at the point of injury. Solutions should focus on the clinical aspects of optimizing triage, patient management, and medical regulating, rather than logistics or re-supply. It is encouraged that the algorithmic solution be compatible/capable to be deployed with existing field medic platforms (such as BATDOK, MEDCOP, etc.).
- **Semi-autonomous Procedural Support:** Technologies that enable semi-autonomous assistance for resuscitative procedures using artificial intelligence and robotic technologies. These technologies should optimize the technical completion of the necessary task through speed, efficiency and accuracy in order to improve the safe completion of the procedure and mitigate training decay and differences in provider expertise. Example technologies include facilitating venous and arterial access, as well as regional analgesia.
- **Ukraine** - The current conflict in Ukraine provides an unprecedented opportunity to understand medical care and challenges associated with modern large scale combat operations. Section 736 of the Fiscal Year 2023 National Defense Authorization Act has directed the US Department of Defense to seek partnerships with Ukraine in the area of trauma education and research. This funding opportunity prioritizes both capability development and study of medical care challenges within the current conflict. Proposals submitted in this area must provide a clear benefit to the Ukraine system of care, as well as providing lessons learned for the US military medical system in anticipation of potential future large-scale conflicts. ***NOTE: Offerors submitting proposals in this focus area must provide documentation of: 1) Ability to conduct work within Ukraine without US personnel entering the country; 2) Evidence of a capable Ukrainian partner and any necessary support from the Ukraine Ministry of Health or Ministry of Defense; 3) Where appropriate, a clear plan for necessary regulatory, ethics, and human protections approvals within the US and Ukraine.***
 - **Clinical Trial Capabilities:** Development of observational or interventional trial capabilities and subsequent conduct of studies related to care of the war wounded in Ukraine. Areas of interest include, but are not limited to wound infection/management, tourniquet use, hemorrhage and resuscitation, evacuation, traumatic brain injury, rehabilitation and traumatic stress. Of particular interest is the impact of time delays

Pre-Announcement, August 2023

between wounding and initial care as well as throughout the care continuum. Trauma registry development and data analysis is an additional priority.

- Casualty Care Technologies: Studies related to the implementation of existing casualty care technologies, including utility, ease of use, compatibility with the forward operating environment, and clinical outcomes. Priority will be given to understanding technologies that already have received regulatory approval in the US or Europe and to technologies that have previously or are currently in development by the US Department of Defense.

MILITARY INFECTIOUS DISEASES – This technology area focuses on vaccines, drugs, vector detection assays, and novel therapeutics to treat multidrug-resistant organisms in combat wound infections, as well as vector control measures for insect vectors that transmit naturally occurring endemic diseases with demonstrated or potential capability to decrease military operational effectiveness. This effort specifically focuses on solutions for prolonged care scenarios, where wound infection poses a significant threat to operational readiness and effectiveness, as well as solutions enhancing medical readiness in response to infectious diseases encountered by Service members during deployment that can significantly impact performance. **The following are focus areas of interest (not listed in order of importance):**

- **Prophylactic to Prevent Infection in Battlefield Wounds from Complex Traumatic Penetrating Injuries in a Far-Forward, Austere Environment:** Development of materiel solutions with the following specificities:
 - Must be able to conform to 3-dimensional wound shape (i.e., not a bandage)
 - Must be self-absorbing or removable through wound irrigation
 - Single solution with ability to provide antibiotics, pain analgesics, and/or hemostasis compounds strongly preferred
 - Must be effective against at least one, but preferably multiple, high priority pathogens: *Pseudomonas aeruginosa*, *Klebsiella pneumoniae*, *Acinetobacter baumannii*, *Staphylococcus aureus*
 - Integration of novel antibiotic drug classes against Gram-negative pathogens strongly preferred
 - Must have preclinical efficacy data; toxicity data preferred if required by FDA
 - Regulatory strategy with documented FDA engagement (including minutes from pre-submission meetings) strongly preferred
- **Pathogen Agnostic Countermeasures for the Treatment of Sepsis caused by wound infection:** Development of drug / biological treatments for sepsis, including host-based therapeutics. Offerors must have preclinical efficacy data; toxicity data is preferred if required by the FDA.
- **Antivirals for the Prevention and/or Treatment of Endemic and Emerging Infectious Diseases (non-biothreat pathogens):** Development of broadly acting antivirals (small molecules, innovative antibody approaches, repurposed antivirals) that can be administered via oral (PO), intramuscular (IM), transdermal (TD) or subcutaneous (SC) routes (Intravenous (IV) not preferred) that are effective against pathogens relevant to the military:
 - Two or more pathogens from the Bunyavirales order (e.g., Lassa virus, Crimean Congo Hemorrhagic Fever virus, Severe Fever with Thrombocytopenia Syndrome virus)
 - The Flaviviridae family with Dengue virus as the primary target (against all four serotypes) and all other flaviviruses as secondary targets

Pre-Announcement, August 2023

Offerors must have preclinical efficacy data; toxicity data is preferred if required by the FDA. Regulatory strategy with documented FDA engagement (including minutes from pre-submission meetings) strongly preferred

- **Prevention of Endemic Diarrheal Diseases:** Development of immunoprophylactics for endemic viral diarrheal diseases, with a focus on norovirus. Offerors must have preclinical efficacy data; toxicity data is preferred if required by the FDA.
- **Knowledge Product Solutions for the Prevention of Infection in Traumatic Penetrating Wounds:** Solutions are expected to optimize Clinical Practice Guidelines for at least one of the following (**not listed in order of importance**)
 - Decipher the intricate relationship between combat polytrauma, infections and sepsis for data-driven clinical practice guideline revisions and field medicine
 - Assess the effects of Acute Traumatic Wound Management guidelines¹
 - Leverage polytrauma of infection preclinical models to evaluate emerging solutions and therapeutics

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).

The following are focus areas of interest (not listed in order of importance):

- **Individual Occupational and Environmental Exposure Monitoring:** The development and refinement of a health assurance platform integration with environmental and physiological sensor technologies for individual occupational and environmental exposure monitoring. Required capabilities include the integration and testing of specialized volatile organic compound (VOC) and fine particulate matter sensing capabilities; algorithms for environmental hazard monitoring and physiological effects; development of a suite of modules enabling remote monitoring of bio-fluids for examination of biomarkers and exposure levels; and operational validation of the above capabilities in at least one or more military-relevant environments.
- **Applied and advanced research using multi-enclave AI analytics of biomedical readiness for formation-centric military performance:** Required capabilities include the ability to perform AI analytics on biomedical readiness data, to include the synthesis of medical readiness and training readiness collected at point of need and transferred as required, across multiple network enclaves with differential security / firewall permissions. Demonstration of analytic and/or data movement

¹ https://jts.health.mil/assets/docs/cpgs/Wound_Management_PFC_24_Jul_2017_ID62.pdf

Pre-Announcement, August 2023

capability required in military-relevant environments with military formation-centric focus, either garrison / training or deployed or both.

- **Understanding Tinnitus:** The importance of mitigation of tinnitus is to sustain Soldier lethality in multi-domain operations (MDO). Tinnitus can have severe effects on battlefield situational awareness and diminish the effectiveness on Soldier readiness. Depending on severity, tinnitus can impact effective communication within military maneuver units and/or airborne air support craft. Tinnitus and hearing loss are the top two disabilities for all Veterans awarded compensation for service-connected disabilities. The underlying cause of tinnitus is not known, and there is no objective test for tinnitus. We are looking for research efforts that would address the following research activities:
 - to understand the basic mechanism of tinnitus so we can advance effective strategies to prevent, test, manage and treat for this condition,
 - to address the impact of tinnitus on the warfighter to optimize restoration and rehabilitation of hearing following service-related neurosensory traumatic injury.
- **Leverage medical health data for neurosensory injury prevention and treatment strategies:** Leverage medical health data has become a DoD wide focus. Neurosensory injuries such as optical trauma, hearing loss and vestibular dysfunction, are prevalent among military personnel due to the nature of their duties. By leveraging medical health information, the comprehensive information could be gathered about the occurrence, patterns, and outcomes of these injuries. This data enables researchers and healthcare providers to identify risk factors, develop preventive measures, and design targeted treatment strategies for military exposure induced neurosensory injuries. It also facilitates the monitoring and evaluation of interventions, leading to evidence-based practices and can improve both the short-term and long-term outcomes for the neurosensory injury in the military context. This effort would address the following research activities, the advancement of these activities may potentially lead to the follow-on work related to improved prevention, management and treatments of neurosensory injuries:
 - Collect and analyze medical health data from service members to identify patterns, associations, and governing forces related to neurosensory injuries.
 - Incorporate military hazardous exposure data, such as noise exposure levels, duration, and specific environments, in conjunction with medical health data to discover hidden correlations and risk factors.
 - Utilize advanced data analytics and machine learning techniques to identify predictive indicators, potential intervention strategies, and personalized risk assessments for neurosensory injuries.
 - Establish data-driven insights and recommendations to enhance prevention strategies and inform treatment protocols.
- **Brain Computer Interface (BCI) Translations:** These advancements in BCI for vision restoration have the potential to benefit military service members who may have acquired vision loss due to military traumatic injuries, improving their quality of life and the ability to return to duties. BCI prototypes that are within scope must stimulate part of the visual pathway, such as the retina, optic nerve, and visual cortices, to generate visual perceptions. This focus area aims to fund This effort would be a prototyping effort addressing the following researching activities:
 - a human study or clinical trial focusing on using brain computer interfaces, specifically visual neural prostheses, to offer a more direct approach to restore vision. Approved IDE is desired for the selected research.

Pre-Announcement, August 2023

- These prostheses stimulate different parts of the visual pathway, such as the retina, optic nerve, and visual cortices, to generate visual perceptions.
- **Temporary Cornea Repair (TCR):** Ocular injuries are a major cause of battlefield casualty and permanent disability and represent a threat to operational readiness and a socioeconomic burden. Closure of these injuries requires surgical intervention by an ophthalmologic surgeon and most often must occur within 24 hours to preserve any amount of residual vision, with the time to primary surgical repair strongly correlated with final visual acuity. Delays in initiation of pre-operative treatment in animal models of eye injury have been shown to have a negative impact on physiological values associated with injury severity, and case studies indicate that delays in pharmacological treatment for endophthalmitis correlate with worse outcomes, suggesting that acute care in the emergency setting has the potential to improve outcomes. Currently DoD is lacking solutions to address this military requirement for ocular injuries in the battlefield. This effort would be a prototyping effort addressing the following requirement.
 - To address a near-term solution potential that could repurpose an FDA-approved surgical aid-indicated solution already shown to improve wound healing efficacy in clinical trials. This should be an expanded indication without the need for a full New Drug Application to the FDA and the full scope of clinical trials, suggesting the potential for a near-term solution meeting all research requirements.
 - To develop a medium -term solution that would likely to require funding of advancement in cGMP-capable manufacturing of the prototype and FDA device approval. Such a solution is likely a medium-term solution requiring an estimated minimum of 3 years of effort with consistent funding and real property investment in manufacturing capability.
 - To develop a far-term solution with FDA approval eye stabilization device for role 1 care as a result of the improved safety profile in animal studies and apparent therapeutic effects. It would be expected that no aspect of this potential solution has reached any stage of clinical testing in humans, and this approach also requires the development of a new FDA-approved eye shield device.
- **Psychological Health, including Psychological Disorders Treatment:** Mature and integrate a scalable, digital health suite of tools that extends options for monitoring and care management of adjustment disorders to behavioral health officers (BHOs), offers self-care for Service members with adjustment disorders in garrison settings who may have limited access to clinical providers, and offers providers and leaders a more upstream evaluation and monitoring of risk-related events/problems and symptoms in members within their units. Of interest is a military-centric digital e-health platform, provider dashboard, and individual app all with military-specific content to mitigate adjustment disorders, and also capabilities for monitoring high frequency events and person-level risk factors for adjustment-related difficulties and offering evidence-based treatment/interventions for one or more of the conditions/issues commonly co-occurring with adjustment disorders (e.g., insomnia, distress) which could be self-administered where appropriate. Requirements for submissions are as follows:
 - The proposed digital platform must have proven (tested) capabilities for secure and asynchronous connectivity, for use in remote and/or austere environments with ADSMs
 - Offeror must provide established supporting data on their platform's feasibility and acceptability in Active-Duty Service Member (ADSM) and military provider populations
 - Must use psychometrically-sound measures
 - Must align to be compatible with existing DoD Behavioral Health tools used by BHOs (e.g., the BH Pulse).

Pre-Announcement, August 2023

- Offeror must have a verifiable plan for access to an ADSM population to conduct the research to further test this platform and content for effectiveness of the interventions and BH monitoring capabilities.
- Teaming is strongly encouraged, especially with DoD research laboratories who have expertise in these content areas. Datasets regarding existing DoD Behavioral Health tools in use (e.g., BH Pulse) may be available for sharing/leveraging upon award.
- **Objective Behavioral Health Assessment and Monitoring:** Non-invasive assessment and monitoring of behavioral health-related conditions and symptoms (e.g., depression, PTSD, acute stress reactions, acute stress disorder, pain, somatic symptoms) using analysis of paralinguistic features from audio recordings acquired immediately after a potentially traumatic event (e.g, car accident, assault), and the following weeks of recovery. The desired use case for this prototype would be identifying if BH symptoms are improving or declining, and/or using predicting changes in symptoms from one timepoint to the next.
 - Proposals utilizing Artificial Intelligence/Machine Learning approaches should be substantiated by demonstrating expertise in this field.
 - Refer to Technical Requirements - Offeror must provide a description of the supporting preliminary data demonstrating a TRL 3 which will be used to refine analyses of paralinguistic markers.
 - Use of publicly available paralinguistic analysis packages are acceptable and encouraged
- **Effective, Scalable Treatments for Full Remission:** Evaluate and refine scalable treatments or treatment regimens that maximize full remission of PTSD symptoms in ADSM populations, to maintain medical readiness.
 - Must provide preliminary treatment/intervention data from clinical RCTs that can inform refinement strategies and hypotheses. Minimum of KRL 4 is required, such as a pilot intervention trial. Proposals for new (initial pilot) treatment RCTs will not be considered.
 - Therapies for co-occurring PTSD and Alcohol Use Disorder will not be considered for this RFP, as this topic area is resourced by a separate Program.
 - Given the shortage of Behavioral Health clinicians in the U.S., the preferred treatments are those which are more scalable, such as portable neuromodulation, stellate ganglion block, or other non-psychotherapy treatments. Scalability includes considerations for the required personnel resources (i.e., avoid treatments that solely rely on psychologists and other highly experienced behavioral health personnel to administer in a 1:1 regimen), individuals' logistical barriers to care, highly specialized or lengthy provider training, unit cost per person, etc.
- **Postventions for Suicide:** Development of theory-based military-specific postventions for suicide, particularly after discharge from in-patient treatment for suicide ideations or attempt (e.g., reintegrating Service Members back into their unit/installation), after a suicide exposure, or during the transition phase from active duty to Veteran status. Postvention solutions may include but are not limited to crisis response plan components, military peer/buddy resources, lethal means safety interventions, or other evidence-based interventions for postvention support. Proposed solutions should be intended for use by non-clinical personnel (e.g., military leaders, peers, family, unit prevention staff, or chaplains) and should be developed with the intention to transition into military installations.

Pre-Announcement, August 2023

- **Cross-Cutting Prevention:** This Focus Area seeks theory-based research to support program, training, or intervention development, program, training, or intervention efficacy/effectiveness testing, and implementation of military primary prevention approaches that have cross-cutting impacts on multiple harmful behaviors, including suicide, sexual assault/violence and harassment, ostracism, domestic abuse, and alcohol and substance misuse. Solutions for this Focus Area are intended to be comprehensive prevention approaches that address multiple ecological levels (e.g., individual, unit, installation, leadership), to promote healthy behaviors and reduce risk factors for harmful behaviors. Solutions should be designed with intention to transition into military installations.
- **Precision Treatment Approaches for PTSD:** Evaluate and refine AI/ML approaches to reliably identifying those who have responded or will respond to a PTSD treatment (or those who are likely to not respond) (i.e., inform optimal treatment-matching).
 - Must provide preliminary data from initial treatment datasets that can inform refinement strategies.
 - Given the shortage of PH clinicians in the U.S., the preferred treatments to be investigated for this Precision Treatment line of effort are those which are more scalable in nature, such as portable neuromodulation, stellate ganglion block, or other non-psychotherapy treatments
 - Must include at least 40% ADSM participants
 - Offeror must have a verifiable plan for access to an ADSM population, where necessary
- **Warfighter Fitness to include Musculoskeletal Injury Prevention and Treatment** (minimum TRL4).
 - Validated musculoskeletal injury risk screening and assessment tools to identify individual and unit-level musculoskeletal injury risk and performance decrements.
 - Advancement of imaging devices or objective assessment tools that can accurately distinguish bone, muscle, tendon and/or ligament injury and recovery.
 - Biologic or drug therapy that can speed recovery of minor tendon/ligament injuries in an operational environment for rapid return to duty. Animal studies are not permitted.
 - Solutions to design AND develop AND implement training programs for Warfighter health and fitness.
- **Performance Decrement and Injury Risk in Ground Soldiers due to Head Supported Mass (HSM):** Operationally-relevant helmet and helmet-borne system (or head-supported mass [HSM]) guidance to minimize performance decrement is needed for dismounted Soldier populations. Using biomechanical/physiologic, operational performance, and user feedback data obtained human subject volunteers, HSM guidance will be generated to provide thresholds on HSM properties (mass and longitudinal CM offset) to material developers and health hazard assessors specifically for dismounted Soldier populations. The awardee will be expected to:
 - Leverage computational models to assess the biomechanical response of the human spine during dismounted operations.
 - Use physiologic, biomechanical, and kinematic data collected during DoD human subject field- and lab-based testing as inputs into newly developed or existing musculoskeletal models to assess spinal response to HSM.
 - Perform static and dynamic optimizations of cervical spine movements associated with dismounted maneuvers and techniques with vary HSM conditions.
 - Conduct analyses to estimate metrics such as ligament strain, intervertebral stresses, joint angles, joint forces and moments, and muscle forces under different HSM conditions.

Pre-Announcement, August 2023

The metrics will assist in the extrapolation of both operational performance decrement and potentially injurious effects resulting from HSM exposures. The ability to associate these model-predicted outputs with the reported spinal pain symptomology and other applicable medical outcomes or health effects that have been associated with HSM exposures such as neck pain/discomfort, neck muscle activation, and neck fatigue will support the development of guidance and thresholds to minimize HSM-related operational and biomechanical performance decrement.

- **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. The Awardee will be expected to:
 - 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.

US AIR FORCE SCHOOL OF AEROSPACE MEDICINE – The Air Force Aerospace and Operational Medicine Enterprise (AOME) seeks to maximize Airman performance and readiness, as well as the development of mitigation measures for physical and psychological stressors, illness and injuries during Airman training and operations by executing studies and analyses. The Studies and Analysis Portfolio general focus areas can be broadly categorized into the following areas of interest: Aerospace Medicine and Physiology, Public Health and Preventative Medicine, Occupational Medicine and Bioenvironmental Engineering, and En Route Care and Expeditionary Medicine. The following focus areas are based on urgent and near-term needs and issues identified within the Air Force (AF) population. **Proposals must be appropriate for one-year, short term investigations to address specific areas of interest listed below (not listed in order of importance):**

- **Musculoskeletal Injury Prevention and Treatment for Aircrew and Maintainers** – Neck and back pain is a known occupational hazard for the high-performance aircraft community. The government seeks solutions, including tools to prevent, reduce, screen and diagnose musculoskeletal condition

Pre-Announcement, August 2023

as well as alternative/integrative medicine approaches, for prevention or treatment of musculoskeletal injuries.

- **Aerospace Physiology:** Development of knowledge products relating to the physiologic assessment in high altitude Fighters/Trainers, including the effects of fluctuating pressure, high O₂, air quality, breathing resistance, thermal burden, dehydration, rest/sleep (physical fatigue), cognitive fatigue, AFE integration, and combined stressors on performance and decision making in ground-based testing and operational environments, including the analysis of potential countermeasures to optimize pilot performance and eliminate sources of risk.
- **Carcinogens (source NDAA 2021 Sec 750)** – Development of technologies relating to one of the following areas (not listed in order of importance):
 - Identification of the carcinogenic toxins or hazardous materials associated with military flight operations from shipboard or land bases or facilities.
 - Identification of exposures to ionizing radiation and nonionizing radiation in which airmen could have received increased radiation amounts.
 - Identification of demographics for each airman to include duty stations, duties and aircraft flow.
 - Identification of duties and potential exposures of airmen that are associated with higher incidence of cancer.
 - Identification of potential exposures not related to aviation.
 - Determination of appropriate screening tools/methods.
- **Precision Medicine and Medical Standards** – Development of technologies relating to one of the following areas (not listed in order of importance):
 - Surveillance of conditions, indications, clinical practice guidelines adherence, and outcomes to support cost benefit analyses for AF population.
 - Genomics for mishap investigations (gene expression, subtracting human and molecular autopsy).
 - Mental health and psychological disorders amongst airmen and potential influence on readiness and retention.
 - Neurocognitive diversity; cognitive testing and correlates with mental health and other outcomes.
 - Assessment of the feasibility of integrating the use of personality data and wearable technology to facilitate adjustment and success during career specific training. Personality assessments and wearables as tools to facilitate positive change, well-being, and performance by increasing self-awareness.

MINIMUM REQUIREMENTS FOR SUBMISSION OF AN ENHANCED WHITE PAPER:

Enhanced White Papers submitted in response to the 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

Pre-Announcement, August 2023

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 proposal submission, with the following exceptions: Combat Casualty Care topics

*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 22-02-MPAI and 23-06-USAMRDC-MultiTopic. The Government is already aware of concepts submitted in response to previous MTEC solicitations including the 22-02-MPAI and 23-06-USAMRDC-MultiTopic; therefore, such projects are not allowed to be resubmitted here. **The RPP is intended only for submission of new projects to MTEC or i.e., 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. Failure to align to a single Focus Area may result in an “Unacceptable” rating and render the proposal ineligible for award.

POTENTIAL FOLLOW-ON TASKS:

There is potential for award of one or more follow-on tasks based on the success of any resultant Research Project Award(s) (subject to change depending on Government review of work completed and successful progression of milestones). Note that any potential follow-on work is expected to be awarded non-competitively to the resultant project awardee(s).

POTENTIAL FUNDING AVAILABILITY AND PERIOD OF PERFORMANCE:

The funding amount and Period of Performance (PoP) for the RPP is unspecified, and the number of awards is indeterminate and contingent upon funding availability. Selection of prototype projects is a highly competitive process and is based on the evaluation of the proposal’s technical merit, programmatic considerations (to include program portfolio composition), and the availability of funds. The quantity of meaningful submissions received normally exceeds the number of awards that the available funding can support. Any funding that is received by the USAMRDC and is appropriate for a Focus Area of Interest described within the RPP may be utilized to fund Enhanced White Papers. Awards resulting from the RPP are expected to be made in FY 2024 and 2025.

A proposed budget and PoP should be commensurate with the nature, scope and complexity of the proposed research. Offerors should submit budgets that include the entire PoP of the research project. Yearly budgets should include all direct and indirect costs, based on supportable, verifiable estimates. Offerors are encouraged to scope out their budgets in alignment with major deliverables of their proposed work so that large budgets are easier to evaluate, and Sponsors can more easily allocate available funding.

For informational purposes, the average size of MTEC awards for the initial PoP is approximately \$2.0 – 3.5M over a 2-3-year PoP.

Pre-Announcement, August 2023

ACQUISITION APPROACH:

MTEC is once again utilizing a streamlined solicitation approach for the Military Prototype Advancement Initiative (MPAI). This approach has been shown to be a better means to highlight Offeror methodologies and skills required to address the technical requirements described in the upcoming RPP. The Enhanced White Paper process used for this effort requires quick turnaround times by Offerors. The following sections describe the formats and requirements of the Enhanced White Paper.

MTEC MEMBER TEAMING:

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

- The MTEC M-Corps is a network of subject matter experts and service providers to help MTEC members address the business, technical, and regulatory challenges associated with medical product development. M-Corps offers members a wide variety of support services, including but not limited to: Business Expertise [i.e., business development, business and investment planning, cybersecurity, finance, intellectual asset management, legal, logistics/procurement, pitch deck coaching, transaction Advisory], and Technical Expertise [i.e., chemistry, manufacturing and controls, 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.
- 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/>).
- 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/>.

MTEC:

The MTEC mission is to assist the U.S. Army Medical Research and Development Command (USAMRDC) by providing cutting-edge technologies and supporting life cycle management to transition medical solutions to industry that protect, treat, and optimize Warfighters’ health and performance across the full spectrum of military operations. MTEC is a biomedical technology consortium collaborating with multiple government agencies under a 10-year renewable Other Transaction Agreement (OTA), Agreement No. W81XWH-15-9-0001, with the U.S. Army Medical Research Acquisition Activity (USAMRAA). MTEC is currently recruiting a broad and diverse membership that includes representatives from large businesses,

Pre-Announcement, August 2023

small businesses, “nontraditional” defense contractors, academic research institutions and not-for-profit organizations.

POINT OF CONTACT:

For inquiries regarding this pre-announcement, please direct your correspondence to Dr. Chuck Hutti, MTEC Biomedical Research Associate, chuck.hutti@ati.org.

Sincerely,

MTEC Team

