Request for Project Proposals

Solicitation Number: MTEC-22-02-MPAI

"Military Prototype Advancement Initiative (MPAI)"

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

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Enhanced White Paper Due Date: April 4, 2022
Noon Eastern Time Zone

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1 Executive Summary

1.1. The Medical Technology Enterprise Consortium

The Medical Technology Enterprise Consortium (MTEC) is an enterprise partnership in collaboration with industry and academia to facilitate research and development activities, in cooperation with the Department of Defense (DoD) U.S. Army Medical Research and Development Command (USAMRDC) and other Government agencies in the biomedical sciences (including but not limited to drugs, biologics, vaccines, medical software and medical devices) to protect, treat and optimize the health and performance of U.S. military personnel. MTEC is a nonprofit corporation with the following principal objectives:

(a) engage in biomedical research and prototyping;

(b) exploration of private sector technology opportunities;

(c) technology transfer; and

(d) deployment of intellectual property (IP) and follow-on production.

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

MTEC operates under an Other Transaction Agreement (OTA) for prototypes with USAMRDC. As defined in the 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) to solicit current MTEC members for a broad range of medical prototype technological and knowledge solutions related to the Focus Areas of Interest (also called "Focus Area(s)") listed below. Proposed solutions may

include medical techniques, knowledge products, and materiel[1] (medical devices, drugs, and biologics).

- Focus Area #1: Prolonged Field Care
- Focus Area #2: Medical Readiness
- Focus Area #3: Maximizing Human Potential

2 Administrative Overview

2.1. Request for Project Proposals (RPP)

In Government Fiscal Year (FY) 2021, MTEC issued RPP MTEC-21-06-MPAI which introduced the Military Prototype Advancement Initiative (MPAI). MTEC is again utilizing a streamlined solicitation approach to award for this new version of the broad, multiple focus area RPP to solicit and fund a wide range of projects of varying scope and maturity levels under the MPAI. This solicitation mechanism has been implemented for the following reasons and has several ***unique features*** noted below.

- *Increase information exchange between the MTEC membership and the military* – This solicitation mechanism provides the MTEC membership with an official way of sending information related to their military-relevant solutions through MTEC to the military, and potentially make the military aware of new solutions that can address unmet needs.

- *Provide feedback to the MTEC membership* – This solicitation mechanism differs from the previous MTEC "Open Concepts" Request for Project Information in that MTEC membership will receive feedback from the Government, which can help Offerors realign to better meet the Government/military need downstream, or even find out whether the Government/military would be interested at all (a "not interested" is valuable feedback as well). ***Having said that, due to the anticipated high number of submissions and the need for a compressed timeline for the review cycles, feedback provided may be VERY BRIEF. Although this may be disappointing, the Government has weighed the benefits vs. costs of this more open-ended type RPP, and in order to provide a mechanism that allows members to submit Enhanced White Papers any time during the lengthy submission period, the reviewers must be allowed the opportunity to provide more succinct feedback.*** To supplement these succinct reviews, MTEC has implemented an educational webinar series and through this, hopes to offer opportunities throughout the year for MTEC members to hear from and interact with the military Sponsors. While this will not allow for direct and specific feedback on Offerors' proposals, it will allow for an open discussion regarding priorities and capability gaps within the Government's portfolios.

- *Establish an open window for the military to make awards* – The solicitation mechanism is intended to provide MTEC members with an opportunity to propose solutions

[1] Materiel is defined as equipment and supplies of a military force.

throughout the year. Offerors are advised that updates may be added via amendment at any time to reflect changes in Government requirements or other revisions, as appropriate. With an extended open submission period, awards may be made on a first-in, first-out basis. Additionally, the MTEC selection process for this solicitation includes a "basket" provision that permits holding proposed projects that have technical merit, but unfunded, for up to two years, which allows for efficient contracting as funding becomes available.

- *Solicit for key areas to support achievement of the USAMRDC strategic objectives* – The focus areas will allow MTEC members to propose innovative and relevant solutions to USAMRDC's strategic objectives.

- *Diversity in potential Sponsors* – While USAMRDC is listed throughout this RPP, sponsoring offices from outside commands may also participate in the source selection process and select projects for award depending on interest, programmatic alignment, and funding availability.

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.

*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 funding amount and PoP for this 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 this RPP may be utilized to fund Enhanced White Papers. Awards resulting from this RPP are expected to be made in FY 2022 and 2023 under the authority of 10 U.S.C. § 2371b.

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.

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).

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. § 2371b section f.

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

Award issued under the member's Base Agreement. The MTEC Base Agreement can be found on the MTEC website and Members-Only website at www.mtec-sc.org.

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

2.4. Proposers Conference

MTEC intends to host multiple Proposers Conferences that will be conducted via webinar within several weeks of the release of the RPP and may include multiple sessions as deemed appropriate. Further instructions will be forthcoming via email. The intent of the MPAI Proposers Conference series is to provide an administrative overview of this RPP process to award (anticipated as a standalone session) and to present further insight into the Focus Areas of Interest outlined in Section 3. 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 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 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 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. For this 22-02-MPAI effort, MTEC members are encouraged to utilize the dedicated Teaming/Partnering webpage. The intent of this webpage is to help MTEC member organizations team with others in preparation for submission of Enhanced White Papers in response to this effort. If you are interested in being featured on this webpage, please send the following information to Dr. Gage Greening, MTEC Biomedical Research Associate, at gage.greening@mtec-sc.org:

- Organization Name (required)
- Organization Website (optional)
- 1-2 sentences on the capability/technology that you are either looking to provide or seeking from others (required)
- 1 attachment that provides additional information to those interested in learning more (optional)
- Name and email address of the point of contact interested parties should contact. (If you are not comfortable providing your email address here, please indicate that current contact information is available in the collaboration database tool on the MTEC members only website.)

Note that this webpage is available to the public. Do not include confidential or proprietary information. Furthermore, the information listed on this webpage is not an endorsement, as you must decide for yourself if any of these teaming arrangements are in the best interest of your proposed project.

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 PGG** 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. §2371b, Research Projects selected for funding under this RPP are required to meet at least one of the conditions specified in **Section 3 of the PPG**. Beyond that, cost sharing is encouraged, if possible, as it leads to stronger leveraging of Government-contractor collaboration. For more information regarding cost share, please see **Section 7.4 of the PPG**.

Proposals that fail to meet the mandatory statutory conditions with regard to the appropriate use of Other Transaction authority, as detailed in **Section 3 of the PPG**, will not be evaluated and will be determined ineligible for award.

2.10. MTEC Assessment Fee

Per Section 3.4 of the Consortium Member Agreement (CMA), each recipient of a Research Project Award under the MTEC OTA shall pay MTEC an amount equal to 2.0% 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. Awardees are not allowed to use MTEC funding to pay for their assessment fees. Therefore, Offerors shall not include this Assessment Fee as part of their proposed direct costs. Members who have not paid the assessment fee within 90 days of the due date are not "Members in good standing".

2.11. Intellectual Property and Data Rights

Baseline Intellectual Property (IP) and Data rights for MTEC Research Project Awards (RPAs) are defined in the terms of a member's Base Agreement and, if applicable, specifically-negotiated terms are finalized in any resultant RPA. MTEC reserves the right to assist in the negotiation of IP, royalties, licensing, future development, etc., between the government and the individual performers prior to final award decision and during the entire award period.

The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding Data Rights**. It is anticipated that anything created under this proposed effort would be delivered to the Government with unlimited data rights unless otherwise asserted in the proposal and agreed to by the Government.** Rights in technical data shall be determined in accordance with the provisions of the MTEC Base Agreement.

See **Attachment 6 of the PPG** for more detail. Note that as part of Stage 1 of the RPP process (submission of an Enhanced White Paper), **Offerors shall complete and submit Attachment 6 of the PPG as an appendix to the Enhanced White Paper** with the Signature of the responsible party for the proposing Prime Offeror.

2.12. Expected Award Date

Offeror should plan on the PoP beginning no sooner than 4 months after the submission deadline (subject to change). The Government reserves the right to change the proposed PoP start date through negotiations via the CM and prior to issuing a Research Project Award.

2.13. Anticipated Enhanced White Paper Selection Notification

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

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

3 Technical Requirements

3.1. Background

In multi-domain operations, today's operating force will be overwhelmed with casualties, the ability to evacuate will be limited, first responders and medics will struggle with limited resources and ability to achieve the "Golden Day," resulting in operational units and commanders rapidly losing freedom of maneuver and combat effectiveness. Therefore, medical assets must be highly mobile and more dispersed (e.g., smaller, more modular medical units), Warfighters will require greater self-sufficiency and autonomy (e.g., may have more limited medical-related communications and re-supply), and there will be an increased cognitive and physical stress on Warfighters (they will need ways to maximize lethality and return to the fight quickly).

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. Demonstrate Military Relevance: Proposed projects shall focus on providing medical solutions to support readiness and care in future battlefield scenarios.

2. 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.

3. Meet the Minimum Knowledge/Technology Readiness Level (KRL/TRL): The minimum acceptable KRL/TRL **at the time of submission of the Enhanced White Paper** is at least KRL/TRL 3. Offerors have achieved KRL/TRL 3 if:
    - **Knowledge Products:** Offeror has validated hypotheses that suggest applications (e.g., prediction for prognosis, screening for diagnosis, or treatment for prevention)

- **Pharmaceutical (Drugs):** Offeror has demonstrated initial proof-of-concept for candidate drug constructs in a limited number of in vitro and in vivo research models
- **Pharmaceutical (Biologics, Vaccines):** Offeror has demonstrated initial proof-of-concept for biologic/vaccine constructs in a limited number of in vitro and in vivo research models.
- **Medical Devices:** Offeror has demonstrated initial proof-of-concept for device candidates in a limited number of laboratory models (may include animal studies).
- **Medical Information Management (IM)/Information Technology (IT) & Medical Informatics:** Medical Informatics data and knowledge representation schema are modeled.

*NOTE: Full definitions of TRLs can be found here. More information regarding KRLs can be found here.

4. 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. The Government is already aware of concepts submitted in response to previous MTEC solicitations including the 21-06-MPAI; therefore, such projects are not allowed to be resubmitted here. **This 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.** Enhanced White Papers reflecting substantially the same technical approach submitted multiple times under this MPAI RPP may not be evaluated by the technical evaluators and may be determined ineligible for award.

5. Align to a Specified Focus Area of Interest: Enhanced White Papers shall align to a single Focus Area of Interest specified in Section 3.3 below. Failure to align to a single Focus Area of Interest may result in an "Unacceptable" rating and render the proposal ineligible for award.

****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 of Interest 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 of Interest may not be considered for funding.

- **FOCUS AREA #1: Prolonged Field Care (PFC):** 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 focuses on developing medical techniques and materiel that can be used by combat medics and are easily transportable (i.e., small, lightweight, and durable in extreme environments and handling), easy to use and require low maintenance. Additionally, wound infection in a prolonged field care[2] (PFC) environment poses a significant threat to operational readiness and effectiveness. It is anticipated that future battlefield scenarios will necessitate the need for medical techniques, knowledge products, and materiel[3] to manage wound infections in theater. **The following focus areas of interest are (not listed in order of importance):**

- **FA1.1** Prophylactic to Prevent Infection in Battlefield Wounds from Complex Traumatic Penetrating Injuries in a Far-Forward, Austere Environment
- **FA1.2** Pathogen Agnostic Countermeasures for the Prevention and/or Treatment of Sepsis caused by wound infection
- **FA1.3** Diagnostics for invasive fungal infections resulting from battlefield wounds, for use in far forward austere environments (compatibility with platforms already in use by DoD preferred)
- **FA1.4** Advanced technologies or techniques for surgical support in far forward and austere settings. Emphasis will be placed on solutions which lead to efficiencies for damage control surgical procedures and dramatically reduce size, weight, cube, power or bandwidth.
- **FA1.5** Therapeutics that can prevent/treat Ischemia Reperfusion Injury (IRI) following vascular injury, tourniquet application, or systemic hypo-perfusion.
- **FA1.6** Technologies or therapeutics for management of lung and kidney organ injury/failure.

- **FOCUS AREA #2: Medical Readiness**: This area focuses on developing technologies that maximize medical readiness and provide mobile health solution sets for the modern Warfighter. Efforts may include diagnostics, treatments, AI-based advanced telehealth technologies, and training solutions to prevent or reduce injury and improve physiological and psychological health and resilience. This objective includes environmental health and protection including the assessment and sustainment of health and the operational effectiveness of Service members exposed to harsh operational environments including altitude, cold, heat, and exposure to environmental health hazards. This focus area also includes medical readiness in response to infectious diseases encountered by Service members during deployment and those that can significantly impact performance. **The following focus areas of interest are (not listed in order of importance):**

[2] Prolonged field care is defined as field medical care, applied beyond "doctrinal planning timelines" by a North Atlantic Treaty Organization (NATO) Special Operations Combat Medic (NSOCM) or higher, in order to decrease patient mortality and morbidity. PFC utilizes limited resources and is sustained until the patient arrives at an appropriate level of care. Rasmussen TE, Baer DG, Cap AP, et al. 2015. Ahead of the Curve. *J Trauma Acute Care Surg* 79: S61-64.

[3] Materiel is defined as equipment and supplies of a military force.

- **FA2.1** Interventions to Treat Adjustment Disorders and/or Prevent their Trajectory into Chronic Mental Health Disorders – Adjustment Disorders (AdjDs) are the most commonly diagnosed mental health disorder in the U.S. military and are associated with decreased mission readiness and a high number of evacuations from combat theatre, resulting in significant unplanned losses. By definition, AdjDs occur within 1-3 months after the start of an identifiable stressor (e.g., combat or personal stressor) and resolve within 6 months of the stressor's termination (Diagnostic and Statistical Manual of Mental Disorders, Fifth Edition [DSM-5]; International Classification of Diseases [ICD-11] update); however, the majority of individuals with an AdjD may still have a mental health diagnosis after 12 months, indicating a chronic, not resolving course. Although AdjDs are characterized by significant impairments in functioning, problematically, they remain a "sub-threshold" disorder (i.e., symptoms are "not of a sufficient specificity or severity to justify diagnosis of another mental disorder"), despite their strong association with psychiatric hospitalizations and suicidality. Applications should:
  - Develop and test an AdjD treatment intervention study with Active-Duty Service members that ultimately aims to disrupt the course of AdjDs becoming chronic mental health diagnoses. Use of a psychometrically sound, military-centric AdjD screening/diagnostic instrument is essential.
  - Access to and use of Electronic Health Records (EHR) to evaluate long term health outcomes of the intervention is of interest; however, Offeror must have a verified plan for gaining access to the EHR or a plan for de-identified data exportation if this is piece is proposed.
- **FA2.2** Solutions to Accelerate Return-to-Readiness following Musculoskeletal Injuries. This focus area includes:
  - Musculoskeletal Injury Tracking, Prevention and Management
    - Capability to enable faster recovery timelines after soft tissue injury (strain/sprain)
  - Musculoskeletal Injury Treatment and Rehabilitation
    - Capability to diagnose and restore function following peripheral nerve injuries.
    - Capability to treat and regenerate bone following fractures, breaks and non-union bone injuries.
    - Capability to treat and regenerate functional muscle following volumetric muscle loss injuries.
- **FA2.3** Repair, restore, monitor, preserve and maintain sensory system (e.g., vision, hearing, balance) function after operational threats (including but not limited to directed energy exposure). Seeking research efforts 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 sensory injury.

- **FA2.4** Solutions to Sustain Warfighter Performance in Arctic and Other Extreme Environments – Cold weather significantly impacts Warfighter effectiveness and lethality in training and on the battlefield. This focus area includes:
  - The identification and development of prophylactics, countermeasures, and training modalities that reduce the risk of injury related to extreme cold exposure.
  - New or significantly improved standard-of-care treatment assessments for cold injury development, rapid treatment paradigms for non-freezing cold injuries, and technologies that identify severity of cold-induced tissue damage.
  - Additionally, among cold-related injuries, frostbite remains a significant threat to operational readiness and performance. Given this, preventative, clinical, or materiel approaches that support the prevention, treatment, and management of frostbite are of significant interest.
  - Strategies to monitor and (or) predict likelihood of non-freezing and frostbite injuries are also sought, to include real-time core body and peripheral temperature monitoring during training and operations.
- **FA2.5** Solutions to Prevent, Treat, and Identify Susceptibility to Decompression Sickness – Decompression Sickness (DCS) is a significant risk to military divers in training and operations, and its etiology is only beginning to be understood. Some progress has been made to understand the mechanisms contributing to DCS; however, identifying an individual's susceptibility to DCS has been a persistent challenge. Given this, proposals should
  - Develop screening tools that will identify DCS susceptibility on an individual basis, to include the contribution of circulating gelsolin, are sought. Since the risk of DCS also limits mission planning and performance, solutions to prevent and treat DCS are also sought.
- **FA2.6** Sex-specific training and operational strategies to promote readiness. This focus area includes:
  - Develop sex-specific models that predict energy expenditure and physical limitations under metabolically strenuous conditions during physically fatiguing exercise
  - Utilize mechanism-based outputs to develop training strategies and/or adaptations that sustain operational readiness or optimize performance in female Warfighters in extreme training and environmental conditions.
- **FA2.7** Early, Objective Screening, and Improved Treatment of Psychological Injuries, their Comorbidities, and Subtypes. This focus area includes:
  - Validated Post Traumatic Stress Disorder (PTSD) blood-based biomarker panels that can identify PTSD status, PTSD subtypes for improved treatment-matching, or markers of response to evidence-based treatments used in military or veteran healthcare. PTSD Screening

biomarker panels should be based on data from Active-Duty Service members (or can include a subset of veteran samples), from pre- and post-deployment assessments collected within 3-4 months of redeployment. Data robust enough to obtain FDA approval will be expected, where warranted (e.g., medical device used to diagnose or treat a diagnosed disorder). Leveraging of extant datasets to support validation is encouraged.

- **FA2.8** Field Deployable Solutions to Prevent Degradation of Unit Performance and Service Member Psychological Health. This focus area includes:
  - Rapid assessment tools to aid leadership in identifying emerging mental health concerns in remote units, cutting-edge resilience training techniques that sharpen cognitive functioning.
  - Training for small-team leaders in efficient and simple techniques designed to promote sustainment of emotional resilience in small team units that may need to operate in challenging contexts.
  - Identifying novel medications/interventions (including pharmacologics, nutraceuticals, and supplements) that can be taken as a prophylaxis (or through post-exposure prophylaxis) to trauma exposure.
- **FA2.9** Medical Strategies to Sustain Service Member Alertness & Performance in complex operational conditions:
  - Tools/technologies to manage circadian disruption
  - Tools/technologies to overcome cognitive degradation due to motion sickness
- **FA2.10** Millennium Cohort Partnership Development – The Millennium Cohort Program is the DoD's established resource for longitudinal research focused on the impacts of military service on the long-term health and well-being of Service members and military families. With over a quarter of a million participants enrolled and up to 20 years of survey data collected between 2001 and 2021 and established linkages with numerous DoD and VA databases, there are untapped partnership opportunities to leverage these population-based longitudinal data to address emerging psychological, physical, and relationship health concerns and thus improve readiness. Requested proposals should:
  - Leverage Millennium Cohort data, as well as developing partnerships and collaborations with Millennium Cohort researchers.
- **FA2.11** Medical Strategies Focused on Mitochondrial Biology – Strategies to improve mitochondrial health and function aimed at enhancing Service member performance.
- **FA2.12** Omics focus area
  - Efforts to link longitudinal, individual data (e.g., multi-state biomarkers) with physiological data (from wearables) and electronic health records (EHR) to build integrated models for health status and disease prediction to inform actionable preventive strategies to maintain readiness in real-time. Efforts should emphasize/utilize large data sets to maximize the

likelihood of adequately powered initiatives to ensure recommendations and/or algorithms are mature enough for near-term use and implementation.

- **FA2.13** Antivirals for the Prevention and/or Treatment of Endemic and Emerging Infectious Diseases (non-biothreat pathogens)-Broad Spectrum and Prevention Preferred
- **FA2.14** Technologies or combat casualty care clinical practice modifications for the extreme cold weather environment.
- **FA2.15** Novel solutions for non-compressible (i.e., truncal) hemorrhage. Emphasis will be placed on 1) AI-assisted imaging technologies that can localize hemorrhage and 2) studies that seek to demonstrate clinical utility of partial aortic balloon occlusion or further develop automation of this capability.

- **FOCUS AREA #3: Maximizing Human Potential**: This area focuses on developing effective countermeasures, or a system of integrated countermeasures, against military-relevant stressors and to prevent physical and psychological injuries during training and operations in order to maximize the human potential, in support of the Army Human Performance Optimization and Enhancement, Multi-Domain Operations, and the DoD Total Force Fitness concepts. **The following focus areas of interest are (not listed in order of importance):**
  - **FA3.1** Optimizing and Enhancing Human Performance and Health – improve and sustain cognitive, physical and emotional function in multi-domain operations (MDO) by optimizing physical and psychological health & resilience and provide safe, impactful, and ethical human performance expansions.
  - **FA3.2** Solutions to Maximize Warfighter and Family Member Psychological Health and Resilience to Stressors. This focus area includes:
    - Evidence-based multi-modal assessments that build upon empirical evidence to identify the behavioral health needs of Service members and their families.
    - Preventive strategies that can be implemented early in the military lifecycle that target the behavioral health needs of Service members and their families. Specifically, evidence-based preventive solutions to decrease the occurrence of and negative impacts of self-directed and interpersonal violence and other harmful behaviors (e.g., alcohol and substance use, sexual assault & harassment, self-injurious behaviors, domestic violence, etc.) as well as increasing signature healthy behaviors, & enhancing readiness and retention.
    - Evidence-based strategies for promoting healthy family-level factors such as emotional ties, communication, support, adaptability, and health.
    - Evidence-based interventions and joint DoD guidance that promotes psychologically resilient military families and community networks over the military life cycle.

- **FA3.3** Restoration Nutrition – Nutrition-based interventions to confer clinical improvements for accelerated return-to-duty following injuries:
  - Develop tailored nutritional regimes based on injury mechanisms and/or individual susceptibilities to reduce recovery time and promote long-term sustainment of readiness to through more effective repair and regeneration. Proposals across the wide spectrum of treatment needs (musculoskeletal, neurosensory, psychological, etc.) will be considered.

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 of 3 (described in Section 3.2). 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. See Addendum 1 for a reference checklist to assist in assessing the TRL of the proposed project.

- Industry Partners: MTEC considers that an Enhanced White Paper involving an industry partner (or alternative organization(s)) to serve as the regulatory sponsor and commercialization partner (if applicable to the proposed project) may have the greatest level of success, especially considering that the eventual goal is to obtain FDA clearance/approval.

- 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 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 (FOC)
- 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

All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC Office of Research Protections (ORP), Human Research Protection Office (HRPO), prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.

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 ORP 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.

Enhanced White Papers 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. Under any resultant award(s), the Awardee(s) shall ensure local IACUC and IRB approvals, continuing review (in the intervals specified by the local IACUC and IRB, but at a minimum, annually), and approval by ACURO and HRPO. Offerors shall include IACUC, ACURO, IRB and HRPO review and approval in the SOW/Milestones Table.

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

For example, the clinical studies under this RPP shall not begin until the USAMRDC HRPO provides authorization that the research may proceed. The USAMRDC HRPO will issue written approval to begin research under separate notification. Written approval to proceed from the USAMRDC HRPO is also required for any Research Project Awardee (or lower tier subawards) that will use funds from this award to conduct research involving human subjects. Offerors must allow at least 30 days in their schedule for the ORP review and authorization process.

3.8. 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) 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 (CNACI) 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 (FAP) concerns will need to be coordinated with the Family Advocacy Research Subcommittee (FARS) per Army Regulation 608-18.

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

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

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

4.1. 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.acqcenter.com/ATI2/Portal.nsf/Start?ReadForm. **The BIDS system will open for submissions no later than January 17, 2022.** Include the MTEC Solicitation Number (**MTEC-22-02-MPAI**) 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 as this may increase the likelihood of available funding for your proposed project as awards will be made on a rolling basis.

Evaluations will be conducted individually on a submission-by-submission basis. The intent is to provide an evaluation on or about **90 days** after the receipt of an Enhanced White Paper submission. **NOTE: Some Enhanced White Papers may be sent for external peer review** (for example, but not limited to, proposed projects that involve the use of human subjects), **which will result in an extended evaluation period (expected at a minimum of 75 days longer).** Please do not worry if you do not receive notification within 90 days as we may experience slower timelines dependent on the number of Enhanced White Papers submitted.

Do not submit any classified information in the Enhanced White Paper submission.

The Enhanced White Paper format provided in this MTEC RPP (Section 8) is **mandatory** and shall reference this RPP number (**MTEC-22-02-MPAI**). Offerors are encouraged to contact the Points-of-Contact (POCs) identified herein up until the Enhanced White Paper due date/time to clarify requirements.

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

4.2. Instructions for the Preparation & Submission of the 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 (6): Submitted via BIDS (5MB or lower)

- **Enhanced White Paper:** one PDF document
- **Warranties and Representations:** one Word or PDF document (**Attachment 3 of the PPG**)
- **Statement of Work (SOW)/Milestone Payment Schedule (MPS):** one Word or PDF document (**Attachment 4 of the PPG**)
- **Intellectual Property and Data Rights Assertions:** one signed Word or PDF document (**Attachment 6 of the PPG**)
- **Technology/Knowledge Readiness Level Checklist:** one Word or PDF document (**Addendum 1 of this RPP**)
- **Extramural Research Involving Human Subjects:** one Word or PDF document (**Addendum 2 of this RPP**). *This is only required if a project involves the participation of human subjects and is conducted solely by a non-federal entity. Alternatively, if available, the Offeror is highly encouraged submit an approved clinical trial protocol instead of Addendum 2*.

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, (3) Intellectual Property and Data Rights, (4) Addendum for Technology/Knowledge Readiness Level Checklist, and (5) Addendum for Extramural Research Involving Human Subjects*

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.
- **Human Subject Recruitment and Safety Procedures** which details study population, inclusion/exclusion criteria, description of the recruitment process, description of the informed consent process, etc.
- **Letter(s) of Support**, as applicable, if the prototype project will require access to active-duty military patient populations and/or DoD resource(s) or database(s).

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

4.3. Stage 2: Cost Proposal (for Only Those Offerors Recommended for Funding)

Offerors that are recommended for funding will receive notification letters which will serve as the formal request for a full Cost Proposal (and may contain a request for Enhanced White Paper revisions and/or supplemental information, such as those examples listed in the section above, based on the results of the technical evaluation). These letters will contain specific submission requirements if there are any changes to those contained in this RPP. However, it is anticipated that the following will be required:

Required Submission Documents (2): Submit to mtec-contracts@ati.org

- **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 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.

4.4. Enhanced White Paper and Cost Proposal Preparation Costs

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

4.5. Freedom of Information Act (FOIA)

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

4.6. Telecommunications and Video Surveillance

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

5 Selection

5.1. Preliminary Screening

The CM will conduct a preliminary screening of submitted Enhanced White Papers to ensure compliance with the RPP requirements. As part of the preliminary screening process, Enhanced

White Papers that do not meet the requirements of the RPP may be eliminated from the competition or additional information may be requested by the CM. Additionally, the Government reserves the right to request additional information or eliminate 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: • Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution • Offeror's Enhanced White Paper has at least one Nontraditional Defense Contractor or Nonprofit Research Institute participating to a significant extent • All significant participants in the transaction other than the Federal Government are small businesses or nontraditional defense contractors • Offeror provides at least one third of the total project cost as acceptable cost share
FAIL	Offeror proposing an MTEC research project does **NOT** meet at least ONE of the following: • Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution • Offeror's Enhanced White Paper has at least one Nontraditional Defense Contractor or Nonprofit Research Institution participating to a significant extent • All significant participants in the transaction other than the Federal Government are small businesses or nontraditional defense contractors • Offeror provides at least one third of the total project cost as acceptable cost share

5.2. Enhanced White Paper 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.

Evaluation Factor 1 – Programmatic Relevance: The Offeror's Enhanced White Paper will be assessed for how well the proposed prototype demonstrates alignment and relevancy to the RPP's Focus Areas of Interest described in Section 3 and overall military impact. The following information will be considered as part of this factor:

- **The Clinical Problem:** The degree to which the Offeror demonstrates an innovative approach/solution and demonstrates an understanding of the research gap described in the RPP.
- **Minimum Requirements for Submission of an Enhanced White Paper:** The Offeror's ability to clearly and completely demonstrate that the following minimum requirements (as detailed in Section 3.2) have been met or exceeded:
    - **Demonstrate Military Relevance:** The degree to which the proposal demonstrates relevance by proposing medical solutions to support readiness and care in future battlefield scenarios.
    - **Fit the prototype definition:** The degree to which the proposal describes a prototype as described in Section 3.2 of this RPP.
    - **Meet the Minimum KRL/TRL:** The Offeror's ability to (i) clearly demonstrate that the proposed project meets the minimum acceptable KRL/TRL requirement at the time of submission (KRL/TRL 3) and ii) adequately support the indicated KRL/TRL of the proposed project.
    - **Represent a New Submission:** Whether the proposal represents a new proposal to MTEC and is not an identical resubmission of a previously submitted proposal.
    - **Align to RPP:** The degree to which the proposed project meets the overall intent of this RPP and aligns to a single focus area of interest specified in Section 3.3.

Evaluation Factor 2 – Technical Approach: The Offeror's proposal will be assessed for relevancy, thoroughness, and completeness of the proposed approach (e.g., the technical merit). The Government's evaluation of this factor may include the degree to which the following are addressed:

- Hypothesis and objectives;
- Scientific rationale with supporting preliminary data;
- Experimental design, feasibility, and risks;
- Ability for the technical and management team to execute the proposed SOW in an efficient and effective manner (to include addressing USAMRDC's ORP approval requirements); and
- SOW and estimated budget.

Evaluation Factor 3 – Commercialization Readiness Advancement: The Offeror's proposal will be assessed for its likelihood of achieving and advancing through the development milestones identified in its proposal, thus advancing the Offeror's commercialization readiness, analogous to Technology Readiness Levels. Examples of the information that may be assessed **(if applicable to the proposed project):**

- **Technical Maturity Advancement:** The degree to which the Offeror proposes to advance the technical maturity level during the performance of the project and advance the technology to the next level of development, from a technical and financial perspective. As such, the Government may evaluate how well the funding strategy supports that advancement.
- **Market and Business Model:** Clear articulation of 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.
- **Development Strategy (including timing and regulatory):** Feasibility of the Offeror's product development strategy, including regulatory and FDA pathway, indication of use and designation, strategy for obtaining FDA approvals or clearances. If commercialization is not relevant to the proposed project, then feasibility of the plan to transition the technology to the government may be assessed.

Table 2 explains the adjectival merit ratings that will be used for the Programmatic Relevance, Technical Approach and Commercialization Readiness Advancement factors.

TABLE 2 - GENERAL MERIT RATING ASSESSMENTS	
RATING	**DESCRIPTION**
OUTSTANDING	Proposal meets requirements and indicates an exceptional approach and understanding of the requirements. Strengths far outweigh any weaknesses. Risk of unsuccessful performance is very low.
GOOD	Proposal meets requirements and indicates a thorough approach and understanding of the requirements. Proposal contains strengths which outweigh any weaknesses. Risk of unsuccessful performance is low.
ACCEPTABLE	Proposal meets requirements and indicates an adequate approach and understanding of the requirements. Strengths and weaknesses are offsetting or will have little or no impact on contract performance. Risk of unsuccessful performance is no worse than moderate.
MARGINAL	Proposal does not clearly meet requirements and has not demonstrated an adequate approach and understanding of the requirements. The proposal has one or more weaknesses which are not offset by strengths. Risk of unsuccessful performance is high.
UNACCEPTABLE	Proposal does not meet requirements and contains one or more deficiencies. Proposal is not awardable.

Upon review of the Enhanced White Papers, Offerors who are favorably evaluated may be invited for informal discussions with the Government. Upon completion of the Stage 1 evaluations, Offerors may be selected for funding (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. Additionally, Offerors who are recommended for award will be required to submit a full Cost Proposal. See RPP Section 4.3 for additional instructions and Addendum 3 for details regarding the anticipated Stage 2 evaluation. Offerors are advised that, due to the anticipated high number of Enhanced White Paper submissions and the need for a compressed timeline for the review cycles, feedback provided may be VERY BRIEF. Although this may be disappointing, the Government has weighed the benefits vs. costs of this more open-ended type RPP, and in order to provide a mechanism that allows members to submit Enhanced White Papers any time during the lengthy submission period, the reviewers must be allowed the opportunity to provide more succinct feedback.

The RPP review and award process may involve the use of contractor subject matter experts (SMEs) serving as nongovernmental advisors. All members of the technical evaluation panel, to include contractor SMEs, will agree to and sign a Federal Employee Participation Agreement or a Nondisclosure/Nonuse Agreement, as appropriate, prior to accessing any proposal submission to protect information contained in the Enhanced White Paper as outlined in Section 2.5.

Definition of General Terms Used in Evaluations:

Significant Strength - An aspect of an Offeror's proposal that has appreciable merit or appreciably exceeds specified performance or capability requirements in a way that will be appreciably advantageous to the Government during award performance.

Strength - An aspect of an Offeror's proposal that has merit or exceeds specified performance or capability requirements in a way that will be advantageous to the Government during award performance.

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

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

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

6 Points-of-Contact

For inquiries, please direct your correspondence to the following contacts:

- Questions concerning contractual, cost or pricing related to this RPP should be directed to the MTEC Contracts Administrator, mtec-contracts@ati.org
- Technical and membership questions should be directed to the MTEC Biomedical Research Associate, Dr. Gage Greening, Ph.D., gage.greening@mtec-sc.org
- All other questions should be directed to the MTEC Director of Program Operations Ms. Kathy Zolman, kathy.zolman@ati.org

7 Acronyms/Abbreviations

ACURO	U.S. Army Animal Care and Use Review Office
AdjD	Adjustment Disorder
ATI	Advanced Technology International
CBER	Center for Biologics Evaluation and Research
CDER	Center for Drug Evaluation and Research
CDRH	Center for Devices and Radiological Health
CFR	Code of Federal Regulations
cGMP	Current Good Manufacturing Practice
CM	Consortium Manager
CMA	Consortium Member Agreement
CNACI	Child Care National Agency Check and Inquiries
DCS	Decompression Sickness
DoD	Department of Defense
DODEA	Department of Defense Education Activity
DODI	Department of Defense Instruction
EC	Ethics Committee
EHR	Electronic Health Records
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
FOIA	Freedom of Information Act
FOC	Full Operating Capability
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
HIPPA	Health Insurance Portability and Accountability Act
HRPO	U.S. Army Human Research Protections Office
HSRB	Human Subjects Research Board
HW	Hardware
IACUC	Institutional Animal Care and Use Committee
ICH	International Conference on Harmonisation
IDE	Investigational Device Exemption
IM	Information Management
IND	Investigational New Drug
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IR&D	Independent Research and Development
IRB	Institutional Review Board
IRI	Ischemia Reperfusion Injury
IT	Information Technology
KRL	Knowledge Readiness Level
M	Millions
MDO	Multi-Domain Operations
MHS	Military Health System
MPS	Milestone Payment Schedule
MTEC	Medical Technology Enterprise Consortium
NATO	North Atlantic Treaty Organization
NDA	Nondisclosure Agreement
NDAA	National Defense Authorization Act
NSCOM	NATO Special Operations Command Medic
OCI	Organizational Conflict of Interest
ODC	Other Direct Costs
ORP	USAMRDC Office of Research Protections
OTA	Other Transaction Agreement
PD	Pharmacodynamics
PDF	Portable Document Format
PFC	Prolonged Field Care
PK	Pharmacokinetics
PMA	Premarket Approval
POC	Point-of-Contact
PoP	Period of performance
PPG	Proposal Preparation Guide
PTSD	Post-Traumatic Stress Disorder
QSR	Quality System Regulation
RAC	Research Advisory Committee
ROM	Rough Order of Magnitude

RPA	Research Project Award
RPP	Request for Project Proposals
SOW	Statement of Work
SW	Software
TRL	Technology Readiness Level
USAMRDC	U.S. Army Medical Research and Development Command
USASOC	US Army Special Operations Command
USG	U.S. Government

8 Enhanced White Paper Template

Cover Page

[Name of Offeror]
[Address of Offeror]
[Phone Number and Email Address of Offeror]

DUNS #: [DUNS #]
CAGE code: [CAGE code]

[Title of Enhanced White Paper]

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

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

[A proprietary data disclosure statement if proprietary data is included. Sample:
This Enhanced White Paper includes data that shall not be disclosed outside the MTEC Consortium Management Firm and the Government 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 of interest this Enhanced White Paper is responding to [include only one area per submission], for example, **FA1.1** Prophylactic to Prevent Infection in Battlefield Wounds from Complex Traumatic Penetrating Injuries in a Far-Forward, Austere Environment.

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 but include full details in Addendum 2 – Extramural Research Involving Human Subjects.

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. 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.

	Year 1	***Year 2***	***Year 3***	***TOTAL***
Labor	*$ 100,000.00*	*$ 100,000.00*		***$ 300,000.00***
Labor Hours	*1,000.0 hrs*		*1,000.0 hrs*	***3,000.0 hrs***
Subcontractors	*$ 50,000*	*.00*	*$ 50,000.00*	***$ 150,000.00***
Subcontractors Hours	*.0 hrs*	*500.0 hrs*	*500.0 hrs*	***1,500.0 hrs***

EXAMPLE

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

*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.

Appendix 4: Technology/Knowledge Readiness Level Checklist (template provided in Addendum 1 of this RPP)

- The Offeror shall complete and submit the appropriate TRL checklist as a separate attachment depending on whether the technology qualifies as a knowledge product, pharmaceutical (drug), pharmaceutical (biologic/vaccine), medical device, or medical IM/IT or medical informatics. Note that all checkboxes must be checked up to and within a TRL in order for your technology to be considered at that TRL.

Appendix 5: Extramural Research Involving Human Subjects (template provided in Addendum 2 of this RPP) *This is only required if proposing a clinical trial*.

- If extramural research involving human subjects (clinical research, clinical trials) is proposed as part of your Enhanced White Paper, then include this addendum as a separate appendix to the submission. Human Subjects research should be described in adequate detail to address the study population and access to the population, inclusion/exclusion criteria, description of the recruitment process, description of the informed consent process, study variables/assessments/instruments, stats/data analysis etc. In addition, this addendum should address conformance with applicable regulations, guidance, and the requirements for potentially FDA regulated products. Alternatively, if available, the Offeror is highly encouraged submit draft clinical protocol documents intended for IRB review. Additional information related to the definition of human subjects research can be found here. However, if you have a specific question or need clarification, we encourage you to reach out to the Points of Contact listed in Section 6 of this RPP for further discussion.

Addendum 1 – Technology/Knowledge Readiness Level Checklist

TRLs provide a systematic way to assess and communicate the level of maturity of a particular technology or combination of technology as it relates to product development across different types of technologies. Full definitions of TRLs can be found here. More information regarding KRLs can be found here. Offerors must submit the applicable checklist below as a separate appendix (see Section 8). As various types of proposed prototypes may be submitted under the 22-02-MPAI, the Offeror shall use only the appropriate checklist that aligns with the type of prototype outlined below:

- Checklist 1: Knowledge Products
- Checklist 2: Pharmaceutical (Drugs)
- Checklist 3: Pharmaceuticals (Biologics, Vaccines)
- Checklist 4: Medical Devices
- Checklist 5: Medical IM/IT & Medical Informatics

Note that all checkboxes within a KRL/TRL (and all previous KRL/TRL rows) must be checked for your technology to be considered at that KRL/TRL (i.e., if you are at a TRL 4, all boxes for TRLs 1-4 must be checked).

Checklist 1: Knowledge Readiness Levels – Knowledge Products	
KRL	**Checklist – *The Offeror must check all boxes up to and within each section/row to be considered at that KRL.***
1	☐Generate initial or very early scientific knowledge without regard to or indication of a specific health issue.
2	☐Expand on KRL 1 finding.
3	☐Validate hypotheses that suggest applications (e.g., prediction for prognosis, screening for diagnosis, or treatment for prevention).
4	☐Generate early or very early knowledge for some health-related use.
5	☐Test *a priori* hypotheses using rigorous scientific design. ☐Directly assess whether and how a tool can work.
6	☐Replicate optimally designed KRL 5 studies. ☐Assess for whom, under what conditions, and with what frequency a tool can serve in important applications.
7	☐Conduct early studies adapting KRL 4-6 research-supported applications for use in an identified context.
8	☐End on or replicate KRL 7 studies to directly assess whether the tool works in the context of interest.
9	☐Replicate or review optimally designed KRL 7-8 studies.

Checklist 2: Technology Readiness Levels – Pharmaceuticals (Drugs)	
TRL	**Checklist** – ***The Offeror must check all boxes up to and within each section/row to be considered at that TRL.***
1	☐Maintain scientific awareness and generate scientific and bioengineering knowledge base. ☐Review and assess scientific findings as a foundation for characterizing new technologies. ☐Initiate and assess scientific literature reviews and initial market surveys.
2	☐Generate research ideas, hypothesis, and experimental designs for addressing the related scientific issues. ☐Acquire the appropriate peer-reviewed approval for research plans and/or protocols.
3	☐Perform basic research, data collection, and analysis begin to test hypothesis. ☐Explore alternative concepts and identify and evaluate technologies supporting drug development. ☐Perform initial synthesis of countermeasure candidate(s) and identify their sites and mechanisms of action. ☐Perform initial characterization of candidate(s) in preclinical studies. ☐Demonstrate initial proof-of-concept for candidate drug constructs in a limited number of *in vitro* and *in vivo* research models.
4	☐Perform non-GLP laboratory research to refine hypothesis and identify relevant parametric data required for technological assessment in a rigorous (worst case) experimental design. ☐Perform exploratory study of candidate drugs (e.g., formulation, route(s) of administration, method of synthesis, physical/chemical properties, metabolic fate and excretion or elimination, and dose ranging). ☐Evaluate candidate in defined animal model to identify/assess potential safety and toxicity problems, adverse events, and side effects. ☐Identify assays to be used during nonclinical and clinical studies in evaluating candidate drugs.
5	☐Perform both nonclinical and preclinical research studies involving parametric data collection and analysis in well-defined systems with pilot lots of candidate pharmaceuticals. ☐Results provide the basis for a manufacturing process amenable to cGMP-compliant pilot lot production. ☐Conduct GLP safety and toxicity studies in animal model systems. ☐Identify endpoints of clinical efficacy or its surrogate. ☐Conduct studies to evaluate the pharmacokinetics and pharmacodynamics of candidate drugs and initiate stability studies. ☐Results provide sufficient data on the candidate drug exist in the draft technical data package to justify proceeding with preparation of an IND application.
6	☐Hold pre-IND meeting (Type B) with CDER. ☐Prepare and submit IND. ☐Conduct Phase 1 clinical trials to demonstrate safety of candidate in a small number of humans under carefully controlled and intensely monitored clinical conditions. ☐Evaluate pharmacokinetic and pharmacodynamic data to support the design of well-controlled, scientifically valid Phase 2 studies. ☐Demonstrate production technology through production-scale cGMP plant qualification. ☐Data from Phase 1 trials meet clinical safety requirements and support proceeding to Phase 2 clinical studies.
7	☐Conduct and complete Phase 2 clinical trials to demonstrate initial efficacy and capture further safety and toxicity data. ☐Determine product activity (e.g., preliminary evidence of efficacy). ☐Determine product final dose, dose range, schedule, and route of administration established from clinical PK and PD data. ☐Present and discuss data with CDER at pre-Phase 3 meeting (Type B) to support continued drug development. ☐Determine clinical endpoints and/or surrogate efficacy markers and test plans agreed to by CDER. ☐Obtain approval for Phase 3 clinical study plan or surrogate test plan.
8	☐Implement expanded Phase 3 clinical trials or surrogate tests to gather data on the safety and effectiveness of the candidate drug. ☐Conduct trials to evaluate the overall risk-benefit of administering the candidate, and to provide an adequate basis for drug labeling. ☐Complete process validation followed by lot consistency/reproducibility studies. ☐Hold pre-NDA meeting (Type B) with CDER, prepare NDA and submit to CDER, and gain approval of the NDA for the drug by CDER. ☐Complete facility pre-approval inspection (PAI).
9	☐The pharmaceutical can be marketed and distributed.

Checklist 3: Technology Readiness Levels – Pharmaceuticals (Biologics, Vaccines)	
TRL	**Checklist –** ***The Offeror must check all boxes up to and within each section/row to be considered at that TRL.***
1	☐Maintain scientific awareness and generate scientific and bioengineering knowledge base. ☐Review and assess scientific findings as a foundation for characterizing new technologies. ☐Initiate and assess scientific literature reviews and initial market surveys.
2	☐Generate research ideas, hypothesis, and experimental designs for addressing the related scientific issues. ☐Acquire the appropriate peer-reviewed approval for research plans and/or protocols.
3	☐Perform basic research, data collection, and analysis begin to test hypothesis. ☐Explore alternative concepts and identify and evaluate critical technologies and components supporting candidate biologic/vaccine constructs research and eventual development of a candidate countermeasure. ☐Conduct agent challenge studies to support models based on presumed battlefield conditions. ☐Initiate and evaluate research-scale process. ☐Identify sites and mechanisms of action, potential correlates of protection for vaccines, and physical/chemical characterization of biologic/vaccine constructs. ☐Demonstrate initial proof-of-concept for biologic/vaccine constructs in a limited number of *in vitro* and *in vivo* research models.
4	☐Perform non-GLP laboratory research to refine hypothesis and identify relevant parametric data required for technological assessment in a rigorous (worst case) experimental design. ☐Perform exploratory study of critical technologies for effective integration into candidate biologic/vaccine constructs, for example, environmental milieu (pH, adjuvant, stabilizers and preservatives, buffers, etc.), route(s)/methods of administration, proposed production/ purification methods, further physical/chemical characterization, metabolic fate and excretion or elimination, dose ranging, and agent challenge studies for protection. ☐Evaluate candidate biologic/vaccine in defined animal model to identify/assess safety and toxicity, biological effects, adverse effects, and side effects. ☐Identify assays, surrogate markers, and endpoints to be used during nonclinical and clinical studies to evaluate and characterize candidate biologic/vaccine constructs are identified.
5	☐Perform both nonclinical and preclinical research studies involving parametric data collection and analysis in well-defined systems with pilot lots of candidate biologics/ vaccines produced and further development of selected candidates. ☐Results support proposing a potency assay, proposing a manufacturing process amenable to cGMP-compliant pilot lot production, identifying and demonstrating proof-of-concept for a surrogate efficacy marker in an animal model(s) applicable to predicting protective immunity in humans, and demonstrating preliminary safety and efficacy against an aerosol challenge in a relevant animal model. ☐Conduct GLP safety and toxicity studies in animal model systems. ☐Identify clinical efficacy endpoints or its surrogate in animal models that may be applicable to predicting protective immunity in humans. ☐Conduct studies to evaluate immunogenicity, as well as PK and PD when appropriate and initiate stability studies. ☐Results provide sufficient data on the candidate biologic/vaccine exist in the draft technical data package to justify proceeding with preparation of an IND application.
6	☐Hold pre-IND meeting (Type B) with CBER. ☐Prepare and submit IND. ☐Conduct Phase 1 clinical trials to demonstrate safety of candidate in a small number of humans under carefully controlled and intensely monitored clinical conditions. ☐Evaluate immunogenicity and/or PK and PD data to support the design of Phase 2 clinical trials. ☐Validate surrogate efficacy models. ☐Data from Phase 1 clinical trials meet clinical safety requirements and support proceeding to Phase 2 clinical trials.
7	☐Conduct and complete Phase 2 safety and immunogenicity trials. ☐Determine product immunogenicity and biological activity (e.g., preliminary evidence of efficacy). ☐Determine product final dose, dose range, schedule, and route of administration established from vaccine immunogenicity and biologic activity, and when necessary, clinical PK and PD data. ☐Present data to CBER at pre-Phase 3 (or surrogate efficacy) meeting (Type B) to support cont. development of the biologics/vaccines. ☐Determine clinical endpoints and/or surrogate efficacy markers and test plans agreed to by CBER. ☐Obtain approval for Phase 3 clinical study plan or surrogate test plan.
8	☐Implement expanded Phase 3 clinical trials or surrogate tests to gather data on the safety/effectiveness of the biologics/vaccines. ☐Conduct trials to evaluate the overall risk-benefit of administering the candidate, and to provide an adequate basis for product labeling. ☐Complete process validation followed by lot consistency/reproducibility studies. Hold pre-BLA meeting (Type B) with CBER, prepare BLA and submit to CBER, and gain approval of the BLA for biologics/vaccines by CBER. ☐Complete facility pre-approval inspection (PAI).
9	☐The pharmaceutical can be marketed and distributed.

Checklist 4: Technology Readiness Levels – Medical Devices		
TRL	**Checklist – *The Offeror must check all boxes up to and within each section/row to be considered at that TRL.***	
1	☐Maintain scientific awareness and generate scientific and bioengineering knowledge base. ☐Review and assess scientific findings as a foundation for characterizing new technologies and initiate initial market surveys.	
2	☐Generate research ideas, hypothesis, and experimental designs for addressing the related scientific issues. ☐Acquire the appropriate peer-reviewed approval for research plans and/or protocols.	
3	☐Perform basic research, data collection, and analysis to begin to test hypothesis. ☐Explore alternative concepts and identify and evaluate component technologies. ☐Conduct initial tests of the design concept and evaluate candidate(s), define study endpoints, and propose animal models (if required). ☐Perform design verification and identify critical component specifications. ☐Develop tests (if a system component, or necessary for device test and evaluation). ☐Demonstrate initial proof-of-concept for device candidates in a limited number of laboratory models (may include animal studies).	
4	☐Perform non-GLP laboratory research to refine hypothesis and identify relevant parametric data required for technological assessment in a rigorous (worst case) experimental design. ☐Perform exploratory study of candidate device(s)/systems (e.g., initial specification of device, system, and subsystems). ☐Evaluate candidate devices/systems in laboratory and/or animal models to identify and assess potential safety problems, adverse events, and side effects. ☐Identify procedures and methods to be used during nonclinical and clinical studies in evaluating candidate devices/systems. ☐Initiate the design history file, design review, and, when required, a master device record, to support either a 510(k) or PMA.	
5	510(k)	☐Determine substantially equivalent devices and their classification, validate functioning model, ensure initial testing is complete, and validate data and readiness for cGMP inspection. ☐Preliminary findings suggest the device will be substantially equivalent to a predicate device.
	PMA	☐Compare devices to existing modalities and indications for use and equivalency demonstrated in model systems (e.g., devices tested through simulation, in tissue or organ models, or animal models if required). ☐Identify and qualify all component suppliers/vendors. ☐Audit all vendors for critical components for cGMP/QSR compliance. ☐Verify component tests, component drawings, design history file, design review, and any master device record. ☐Draft Product Development Plan. ☐Hold pre-IDE meeting with CDRH and prepare and submit IDE; review by CDRH determines the investigation may begin.
6	510(k)	☐Update and verify component tests, component drawings, design history file, design review, and any master device record. ☐Finalize preparation of manufacturing facility ready for cGMP inspection. ☐Information and data demonstrate substantial equivalency to predicate device and support production of the final prototype and final testing in a military operational environment.
	PMA	☐Conduct clinical trials to demonstrate safety of candidate Class III medical device in a small number of humans under carefully controlled and intensely monitored clinical conditions. ☐Update and verify component tests, component drawings, design history file, design review, and any master device record. ☐Demonstrate production technology through production-scale cGMP plant qualification. ☐Data from the initial clinical investigation demonstrate that the Class III device meets safety requirements and supports proceeding to clinical safety and effectiveness trials.
7	510(k)	☐Produce final prototype and/or initial commercial-scale device and test in a military operational environment. ☐Information and data demonstrate substantial equivalency to predicate device and use in a military operational environment.
	PMA	☐Complete clinical safety and effectiveness trials with a fully integrated Class III prototype in an operational environment. ☐Continue study of effectiveness, and determine short-term adverse events and risks associated with the candidate product. ☐Complete functional testing of candidate devices, resulting in final down-selection of prototype device. ☐Complete final product design and produce final prototype and/or initial commercial scale device. ☐Collect, present, and discuss data with CDRH in support of continued device development. ☐Clinical endpoints and test plans agreed to by CDRH.
8	510(k)	☐Prepare and submit 510(k) application; approval of the 510(k) by CDRH has been received.
	PMA	☐Conduct trials to evaluate the overall risk-benefit of using the device and to provide an adequate basis for product labeling. ☐Complete QSR compliance, the design history file, design review, and any master device record. ☐Device production followed through lot consistency and/or reproducibility studies. ☐Hold pre-PMA meeting with CDRH and complete facility pre-approval inspection (PAI). ☐Prepare and submit PMA application; approval of the PMA by CDRH has been received.
9	☐The medical device can be marketed and distributed.	

Checklist 5: Technology Readiness Levels – Medical IM/IT and Medical Informatics	
TRL	**Checklist** – ***The Offeror must check all boxes up to and within each section/row to be considered at that TRL.***
1	☐Explore hardware (HW)/software (SW) System technology. Basic theories applied to IM/IT field suggest promise. ☐Identify the potential medical solution to mission need and define Medical Informatics data and knowledge representation issues.
2	☐Begin HW/SW Systems invention. ☐Document overall system concepts by flowcharting or other system descriptive techniques. ☐Define Medical Informatics data and knowledge representation schema.
3	☐Investigate and develop separate elements of HW/SW System components (not yet integrated or representative). ☐Model Medical Informatics data and knowledge representation schema.
4	☐Produce prototype. ☐Integrate HW/SW system components to establish that pieces will work together. ☐Instantiate Medical Informatics data and knowledge representation models with representative data or knowledge from applicable domain.
5	☐Test prototype in a laboratory environment. ☐Integrate HW/SW system components and employ realistic supporting elements so that the system can be tested in a simulated environment. ☐Specify actual interfaces to supporting systems and begin development. ☐Implement Medical Informatics data and knowledge representation models as data and/or knowledge management systems.
6	☐Perform advanced technical testing of prototype HW/SW System, to include interfaces to actual supporting systems in a relevant or simulated operational environment. ☐Outproduct is final prototype. ☐Test Medical Informatics data and knowledge management systems with target applications in a lab environment. ☐Develop configuration management.
7	☐Prototype HW/SW System is near or at planned operational system. ☐Demonstrate actual system prototype in an operational environment with end-users (first cut user test). ☐Operationally integrate and test Medical Informatics data and knowledge management systems with target applications in an operational environment.
8	☐Test and evaluate the HW/SW System in its intended environment to ensure that design specifications are met. ☐Validate fully integrated and operational Medical Informatics data and knowledge management systems in several operational environments. ☐HW/SW System has been proven to work in its final form and under expected conditions.
9	☐HW/SW System is in its final form and under mission conditions, such as those encountered in operational test and evaluation. ☐Medical Informatics knowledge maintenance and verification of data integrity are ongoing. ☐Military requirements met for transportation, handling, storage, etc. ☐Product successfully used during military mission as component of IOT&E phase. ☐Logistical demonstration successfully conducted.

Addendum 2 – Extramural Research Involving Human Subjects

If this Enhanced White Paper involves the participation of human subjects and is conducted solely by a non-federal entity, then include this addendum as a separate appendix to the submission. Human research should be described in adequate detail to assess conformance with FDA regulations, guidance, and the requirements related to development and testing of drugs, biologics, or dietary supplements. This will include compliance with applicable portions of Title 21 of the US Code of Federal Regulations (CFR) including Title 21 CFR Parts 11, 50, 54, 56, the Health Insurance Portability and Accountability Act (HIPPA) of 1996 (Pub.L. 104-191, 110 Stat. 1936, enacted August 21, 1996), and International Conference on Harmonisation (ICH) Guidelines for Good Clinical Practices (GCPs) (ICH Guidelines for Good Clinical Practice (E6), Published May 9, 1997).]. Use the template provided below. This Addendum is limited to ten (10) pages and must be in 12-point font (or larger), single-spaced, single-sided, 8.5 inches x 11 inches. Margins on all sides (top, bottom, left, and right) should be at least 0.5 inch. Additional information related to the definition of human subjects research can be found here. However, if you have a specific question or need clarification, we encourage you to reach out to the Points of Contact listed in Section 6 of this RPP for further discussion.

Continuation

- If the proposed clinical research and/or trials were initiated using other funding prior to this application, explain the history and background of the study and declare the source of prior funding. Specifically identify the portions of the study that will be supported with funds from this award.
- If the proposed clinical research and/or trials involves continuation or assumption of an ongoing effort then state the transition plan proposed (e.g., transfer of FDA Sponsorship). In the case of ongoing clinical trials, append or provide reference to previous FDA-regulated studies. Offeror must justify carefully any changes proposed to ongoing FDA-regulated protocols and provide specific rationale for alterations (e.g., FDA feedback, change in clinical resources or study sites, etc.)

FDA Interactions

- Describe plan to meet all regulatory sponsor responsibilities under International Conference on Harmonisation (ICH) parts E6, E2A, E8, and 21 Code Federal Regulation parts 312, 11, 50, 54, 56 including regulatory writing and submissions support for clinical efforts, safety reporting, pharmacovigilance, clinical monitoring, data management, regulatory writing and submissions, etc.]

Test Materials

- Describe the clinical intervention, medical drug, biologic, device or human exposure model to be tested and the projected outcomes or measures.
- Document the availability and accessibility of the drug/compound, device, or other materials needed for the proposed research.
- Describe the production/manufacturing plan for the test materials proposed.

Study Design/Clinical Protocol

- Provide a description of the purpose and objectives of the study with detailed specific aims and/or study questions/hypotheses.
- Describe the type of study to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action. Describe potential risks and challenges and alternative strategies.
- Define the study variables, outline why they were chosen, and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.
- Describe the study population, criteria for inclusion/exclusion, and the methods that will be used for recruitment/accrual of human subjects and/or samples (e.g., convenience, simple random, stratified random). This description shall include the composition of the proposed study population in terms of sex/gender, race, and ethnic group, and an accompanying rationale for the selection of subjects.
- Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers).
- Describe all study primary and secondary endpoints.

Statistical Plan and Data Analysis

- Describe the data collection plan, statistical model, and data analysis plan with respect to the study objectives. Specify the approximate number of human subjects to be enrolled or number of human samples to be studied.
- If multiple study sites are involved, state the approximate number to be enrolled or samples collected at each site.
- Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study.
- If a subpopulation of a sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study.

Technical Risks

- Identify and describe potential problem areas in the proposed approach and alternative methods and approaches that will be employed to mitigate any risks that are identified.

Ethical Issues

- Include a clear and detailed description of the potential ethical issues raised by the proposed study and provide a detailed plan for how the ethical issues will be addressed.

Training/Proficiency Requirements

- Describe your plan to ensure that personnel have appropriate training/competency.

Study Timeline/Schedule

- Describe the study timeline/schedule, including visits/follow-up. *See the example below.*

Schedule of Study Visits Example*				
	Visit 1 (Month #)	Visit 2 (Month #)	Visit 3 (Month #)	Visit 4 (Month #)
Informed Consent	X			
Medical History	X			
Complete Physical Exam	X			
Abbreviated Physical Exam		X	X	X
Height	X	X	X	X
Weight	X	X	X	X
Vital Signs	X	X	X	X
Pharmacokinetics		X		
Randomization	X			
Administration of Study Drug	X	X	X	X
Counting of Returned Study Drug		X	X	X
Concomitant Medication Review	X	X	X	X
Adverse Experiences	X	X	X	X

**This above table is meant to provide an example. Add columns and/or rows as necessary.*

Addendum 3 – Stage 2 Evaluation Criteria

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

Stage 2

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

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

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

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

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

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

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

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

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

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

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

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