Request for Project Proposal

Solicitation Number: MTEC-17-08-Multi-Topic

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

Request Issue Date: June 30, 2017

Amendment No. 02 White Papers Due Date: October 31, 2017
Noon Eastern Daylight Time

Amendment No. 02 changes the White Papers due date to October 31, 2017 at Noon Eastern Daylight Time

Table of Contents

1 Request for Project Proposal Overview

1.1 Purpose

The Medical Technology Enterprise Consortium (MTEC) is an enterprise partnership that collaborates with industry and academia to facilitate research and development activities in cooperation with the U.S. Army Medical Research and Materiel Command (USAMRMC) 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) biomedical research and prototyping;
(b) exploration of private sector technology opportunities;
(c) technology transfer; and
(d) development 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" government contractors, academic research institutions and not-for-profit organizations. For more information on the MTEC mission, see the MTEC website https://mtec-sc.org/.

This solicitation, issued by the MTEC Consortium Manager (CM), Advanced Technology International (ATI), represents a Request for Project Proposals (RPP) for MTEC support of the USAMRMC technology objectives. Strategic oversight for the award(s) supported by this RPP will be provided by USAMRMC.

MTEC operates under a prototype Other Transaction Agreement (pOTA) with USAMRMC. Proposed prototype projects should not be exploratory in nature and do require a foundation of preliminary data. As defined in the OTA Guide dated January 2017, a prototype project can generally be described as a preliminary pilot, test, evaluation, demonstration, or agile development activity used to evaluate the technical or manufacturing feasibility or military utility of a particular technology, process, concept, end item, effect, or other discrete feature. Prototype projects may include systems, subsystems, components, materials, methodology, technology, or processes. By way of illustration, a prototype project may involve: a proof of concept; a pilot; a novel application of commercial technologies for defense purposes; a creation, design, development, demonstration of technical or operational utility; or combinations of the foregoing, related to a prototype. The quantity should generally be limited to that needed to prove technical or manufacturing feasibility or evaluate military utility.

1.2 Background

The Purpose of this Multi-Topic RPP is to solicit prospective and current MTEC members for a broad range of medical technological solutions related to the seven Technology Focus Areas identified in Section 2 of this RPP.

1.3 Acquisition Approach

This RPP will be conducted using a two-staged approach. In Stage 1, prospective and current MTEC members are invited to submit White Papers using the format contained in this RPP (Attachment 1) against the seven Technology Focus Areas identified in Section 2. The Government will evaluate White Papers submitted and will select White Papers that best meet their current technology priorities using the criteria in Section 3. Offerors whose technology solution is selected for further consideration based on White Paper evaluation will be invited to submit a proposal in Stage 2. Notification letters will contain specific Stage 2 proposal submission requirements. Prospective MTEC members submitting White Papers that are selected for further consideration will not receive a Stage 2 notification letter until they become a MTEC member. Rather, prospective members will be invited to become MTEC Members should they wish to continue to Stage 2. (

1.4 Military Relevance

Relevance to the healthcare needs of military Service members, Veterans, and beneficiaries is a key feature of this RPP. Investigators are encouraged to consider the following characteristics as examples of how a project may demonstrate military relevance:

- Explanation of how the project addresses an aspect of the target disease/condition that has direct relevance to military Service members, Veterans, or other military health system beneficiaries.

- Description of how the knowledge, information, products, or technologies gained from the proposed research could be implemented in a dual-use capacity to benefit the civilian population while also addressing a military need.

- Use of military or Veteran populations or datasets in the proposed research, if appropriate to the proposed research project.

- Involvement of military consultants (Army, Air Force) or specialty leaders (Navy, Marine Corps) to the Surgeons General in a relevant specialty area.

1.5 Request for White Papers and Process Stages

MTEC recognizes that considerable effort is required to prepare a competitive proposal to MTEC. The two-stage approach for this RPP is intended to streamline the initial proposal preparation time and effort for prospective and current MTEC members. Based on the Government's

evaluation of White Papers in Stage 1, select Offerors will be invited to participate in Stage 2 and will be required to submit a full proposal for more detailed evaluation. The Stage 2 process may vary depending on the Technology Focus Area and funding available. For example, some Stage 2 processes may require oral presentations, a commercial solutions offering (solutions brief), and/or full proposal submission using either the Full Project or Small Project Proposal Preparation guides.

The due date for White Papers is found on the cover page of this RPP. White Papers will not be considered under this RPP unless the White Paper was received on or before the due date specified on the cover page. White Papers submitted under this RPP must follow the MTEC Multi-Topic White Paper Template provided in Attachment 1.

1.6 Potential Funding Availability

The funding amount for this RPP is unspecified, and the number of awards is indeterminate and contingent upon funding availability. Selection of projects is a highly competitive process and is based on the evaluation of the proposal's technical merit, programmatic considerations, and the availability of funds. Any funding that is received by the USAMRMC and is appropriate for a research area described within this RPP may be utilized to fund proposals/applications.

There are no specified funding limitations identified for a proposal submitted under this RPP. A budget should be commensurate with the nature and complexity of the proposed research. Offerors should submit budgets that include the entire period of performance of the research project. Budgets should include all direct and indirect costs, based on supportable, verifiable estimates. 1.7 Proprietary Information

The MTEC CM will oversee submission of proposals and analyze cost proposals submitted in response to this RPP. The MTEC CM shall take the necessary steps to protect all proprietary proposal information and shall not use such proprietary information for purposes other than the evaluation of an Offeror's proposal and the subsequent agreement administration if the proposal is selected for award. An Offeror's submission of a proposal under this RPP indicates concurrence with the aforementioned CM responsibilities. Also, as part of MTEC's mission to incorporate philanthropic donations, MTEC frequently makes contact with private foundations that award grants for research and operate in research areas that are aligned with those of MTEC. These private foundations may be interested in reviewing proposals within their program areas, allowing for opportunities to attract supplemental funding sources. On your White Paper Cover Page, please indicate your willingness to allow MTEC Officers access to your Technical Proposal for the purposes of engaging in outreach activities with these private foundations. MTEC Officers granted proposal access have signed Nondisclosure Agreements (NDAs) and Organizational Conflict of Interest (OCI) statements. Additionally, these MTEC Officers represent organizations that currently are not MTEC members, and therefore their parent organizations are not eligible to submit research project proposals, nor receive any research project funding through MTEC. Additionally, all Technical Evaluation Panel participants, which may include contractor support

personnel, will agree to and sign a Federal Employee Participation Agreement or a Nondisclosure/Nonuse Agreement, as applicable.

1.8 Cost Sharing Definition

Cost sharing is defined as the resources expended by the award recipients on the proposed statement of work (SOW). *The extent of cost sharing is a consideration in the evaluation of proposals.* 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; 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.).

1.9 Cost Share Requirements

Research Projects selected for funding under this RPP are required to have at least one nontraditional defense contractor participating to a significant extent. Projects that do not meet this requirement must provide at least 1/3 of the Research Project cost as cost share. Beyond that, cost sharing is encouraged if possible, as it leads to stronger leveraging of Government-contractor collaboration. More information regarding nontraditional defense contractor requirements can be found at Attachment 2. For more information regarding cost share, please see Attachment 3.

1.10 White Paper Submission

White Papers shall be submitted by the date and time specified on the cover page using the submission form located here: https://secure.ati.org/mtec/whitepaperMTEC.html. Include the MTEC-17-08-Multi-Topic Solicitation Number on each White Paper submitted.

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

1.11 Submission Format

See Attachment 1 for the White Paper template. Files should be submitted 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, or .pdf). Filenames should not contain special characters. Please follow the format and page requirements contained in Attachment 1 carefully. White Papers that do not meet these requirements are subject to disqualification at the sole discretion of the Government.

1.12 White Paper Preparation Cost

No project awards will be made based on White Paper submissions, nor will any reimbursement be provided for the information requested. Submission of a White Paper is voluntary and does not obligate the Government, the MTEC or the MTEC CM to pay or entitle the submitter to

payment. Respondents are solely responsible for all expenses associated with preparing and submitting this White Paper.

2 Technology Focus Areas

Examples of specific areas of interest include, but are not limitedto those listed below. These areas of interest are **not** listed in order of importance.

2.1 Prevention, Diagnosis and Treatment of Infectious Diseases

This technology area focuses on infectious diseases encountered by Service members during deployment and those that can significantly impact performance. Research and development efforts may include vaccines, anti-parasitic drugs, deployable field clinical diagnostics (human and vector), prophylactics and novel therapeutics to prevent and treat multi-drug resistant bacteria and fungi in combat wound infections, and control measures for arthropod vectors that transmit infectious disease – pertinent to naturally occurring endemic diseases with demonstrated or potential capability to decrease military operational effectiveness. Specific areas of interest include, but are not limited to:

- Technologies (e.g.,., biosurveillance, diagnostic tests, antibiotics, vaccines, and novel therapeutics) that combat antibiotic-resistant bacteria and fungi, especially infections that manifest as a result of injuries on the battlefield and subsequent evacuation
    - Approaches using systems biology that support the use of a single therapy for multiple clinical applications, such as those related to dysentery diseases or antibiotic resistance

2.2 Care of Combat Casualties

This technology area focuses on the development of medical interventions that can be used on the battlefield to reduce morbidity and mortality. Research and development may include efforts to develop and evaluate drugs, biologics, and/or devices for hemorrhage control, resuscitation and blood products; diagnosis and treatment of traumatic brain injury (TBI) and spinal cord injury; treatments for extremity trauma, tissue injury, lung injury and burns; in route care and intensive critical care (including advanced monitoring and pre-hospital care). Specific areas of interest include, but are not limited to:

- Drugs or devices that assist in the diagnosis of TBI, in particular those that can:
    - Assess the degree of concussive damage and be used to assist in decision-making regarding whether to order patient evacuation or return to duty
    - Be applied at the time of injury to reduce the severity and progression of TBI
    - Repair or restore function within a hospital setting
    - Act as resuscitation agents/therapeutics for treatment of shock and TBI to prevent secondary brain injury
    - Perform Evaluation of venous thrombosis chemoprophylaxis to prevent microthrombi and secondary brain injury in animal models of TBI

- Advance designs for devices intended to diagnose concussion. These advances may include efforts to miniaturize, militarize, evaluate, and/or develop or enhance output/user interfaces Technologies that can provide prolonged care to injured patients in an austere battlefield environment, including:
  - Diagnostics with new modalities or algorithms to assist in directed care for personnel
  - Treatments for extremity injury in the prolonged field care environment
    - Polymers for emergency fracture fixation in austere environments
    - Therapeutic agents for the stabilization of extremity injury to extend the window of limb salvage
  - Evaluation of hemostatic devices for junctional trauma
  - Next generation (e.g., bioresorbable) hemostatic foam for use in non-compressible hemorrhage
  - Devices and techniques to extend the time for application of resuscitative endovascular balloon occlusion of the aorta (REBOA)
  - Next generation wound dressing prototypes for prolonged field care
  - Pharmacological-based stabilization approaches
    - Tranexamic acid for trauma in the pre-hospital environment, especially where prototype evaluation can leverage existing international efforts in the assessment of this agent
    - Next generation oxygen delivery agent prototypes for use in trauma resuscitation
    - Intravenous hemostatic agents for treatment of non-compressible hemorrhage
  - Telehealth technologies and tools that transform healthcare
    - Development and optimization of prototypes for just-in-time training for bystander (non-medic) trauma resuscitation
    - Next generation decision support prototypes for triage and treatment of burn casualties
    - Monitoring tools for prolonged field care goal directed therapy
  - Devices that replace all or part of the function of the lungs for patients with acute respiratory distress syndrome or other types of pulmonary failure, and/or of the function of the kidneys for patients with acute kidney injury
- Development of a solution that will stabilize the craniomaxillofacial soft tissue envelope following acute injury from blunt force, blast, ballistic or burn injury. Solution must:
  - Be easy to apply far forward at point of injury/ point of need
  - Promote and maintain hemostasis, prevention of injury progression, provide ocular protection (preserves vision) and establish pre-regenerative milieu for scar reduction
  - Stay in place /remain secure for a moderate duration (8-72 hours) including during patient transport via ground air ambulance

- Consider the unique conditions of the facial structure
- Prevent and minimize infection
- The solution should NOT obstruct oral or nasal airway, pre-tracheal region or interfere with life saving measures

2.3 Clinical and Rehabilitative Medicine

This technology area focuses on innovation in definitive and rehabilitative care to reset wounded Service members in terms of duty, performance, and quality of life. Efforts may include developing medical technologies (drugs, biologics, and/or devices) and treatments/rehabilitation strategies (methods, guidelines, standards, and information) for acute and chronic pain management, regenerative medicine and composite tissue engineering, neuromusculoskeletal (NMS) injuries (including advanced prosthetics and orthotics), and sensory systems (vision, hearing and balance restoration). Specific areas of interest include, but are not limited to:

- Improvements to the manufacturing processes for regenerative medicine products (e.g., universal culture media, bioreactors, preservation, quality assurance, automation)
- Vision restoration, in particular:
  - Visual prosthesis (i.e., developing a brain-machine interface)
  - Regeneration/restoration/preservation of the optic nerve
  - Retinal repair or regeneration to improve or regain vision lost as a result of disease or traumatic injury
- Hearing restoration/repair technologies
- Treatments of spinal cord injury that facilitate increased movement and control of muscles within extremities (arms and legs)
- Novel implanted or external interfaces that can acquire high fidelity physiological signals to drive advanced prosthetics or provide sensory/proprioceptive input
- Technologies to objectively assess NMS rehabilitation across the spectrum of care from initial injury through return to duty/reintegration
- Decellularization/recellularization scaffolding strategies to regenerate or replace organs
- 3D bioprinting and biofabrication of tissues and organs
- Artificial organ replacement (e.g., internal support systems, external support systems and full organ replacement)
- Systemic peripherally acting analgesics for severe acute pain

2.4 Military Operational Medicine

This technology area focuses on developing effective countermeasures against stressors and to maximize health, performance, and fitness. Research and development efforts may include diagnostics, treatments, and training solutions to prevent or reduce injury and improve physiological and psychological health and resilience. This objective also 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. Specific areas of interest include, but are not limited to, the development of:

- A suite of wearable physiological and performance sensors to assess Warfighter thermal strain, energy expenditure, and cognitive and physical performance, which would provide small unit leaders with real-time, accurate, actionable information to prevent injuries and predict readiness (Health Readiness and Performance System)
- An integrated experimental and computational platform to characterize host responses to environmental health hazards in terms of pathogenic and adaptive processes to prevent or mitigate health effects of exposures to toxic chemicals and/or airborne hazards
- Methods to detect or assess risk of musculoskeletal injury, training strategies to reduce the risk of injury, and evidence-based physical fitness standards and return-to-duty criteria
- Pharmaceutical interventions to prevent hearing loss from exposure to hazardous noise
- Injury criteria and medical performance standards to protect against hearing loss, vestibular injury, and ocular facial injury from blast and directed energy threats
- Novel pharmacological and non-pharmacological interventions to promote sleep, manage sleep/work cycles, maintain cognitive performance, and improve overall Service member readiness
- Nutrition-based interventions to promote efficient and timely recovery from injury and maintain the overall health of Service members in garrison and during operations
- Evidence-based tools that address a broad range of behavioral health issues, including suicide prevention, resilience, substance abuse, Family issues and high risk behaviors
- Pharmacological- and/or behavioral-based methods to treat post-traumatic stress disorder and restore the psychological health of Warfighters

2.5 Medical Simulation and Information Sciences

This technology area focuses on exploring the implications for the use of technology for medical training and for the provision, management, and support of health services in the military. Research and development efforts may include improving military medical training through medical simulation, educational gaming, and objective training metrics, and improving the use and sharing of health related data for better strategic planning, process development, and software applications. Specific areas of interest include, but are not limited to:

- Health Information Technology/Informatics
  - Best Practices and IT systems from private industry that can be applied to Medical Logistics for shipping, inventory control and tracking and other global medical logistics capabilities
  - Medical Device Interoperability – need to have closed loop systems whereby medical devices interact with one another and provide care autonomously to support theater/operational medicine

- Business practice driven automated applications that can improve clinical outcomes and be later assimilated into the Electronic Health Record as best practice/decision assist guidelines
- Precision medicine that uses genetic profiling or proteomics to identify improved clinical approaches for hospital-based care for both military and civilian medical needs

- Medical Simulation and Modeling:
  - Open source integrated virtual models for education and training. Research, develop, and integrate multiple data-driven inputs to build open source/open architecture models to represent tissues, organs, systems, and the entire body for use within virtual/augmented/immersive reality training and education. Such data-driven inputs are (but does not exclude others): de-identified imaging sources (CT, MRI, ultrasound, etc.); de-identified tissue characterization data sources (stress/strain, stretch, cut, puncture, etc.); and accurate/appropriate physiological tissue, regional, and systemic algorithms within an open source/open architecture engine.
  - Program prototype architectures and data paths for programs within the Medical Simulation Enterprise, such as: Joint Evacuation and Transport Simulation (JETS), and Point of Injury Training System (POINTS); Theater Hospital Operations Replication (THOR); Warfighter Preparation, Resiliency and Protection (WarPReP).
  - Prototype medical simulation technologies, components, sub-systems and systems that will enable Medical Simulation Enterprise programs of records, such as: JETS, and; THOR; WarPReP.
  - Holographic technology software and hardware prototypes for medical training. Ruggedized holographic devices that are able to be utilized in the training environments of the JETS and POINTS programs replicating the operational military medical environment and situations. Operational capabilities must function in punishing training situations occurring outdoors and operate in all types of weather conditions, during day and night.
  - Medical Synthetic Training Environment prototype. Combines Live, Virtual, Constructive and Gaming training modalities into a single integrated training environment. Allows any user within the environments to be connected in a training event/sequence/scenario.

2.6 Advanced Medical Technologies

This technology area focuses on developing initiatives and products that will increase medical mobility while ensuring access to essential medical expertise and support regardless of the operating environment. Efforts may include e-health, digital warrior, hospital of the future integrative medicine, advanced orthopedic devices and treatments, advanced medical imaging technologies, robotic technologies to treat and rescue battlefield casualties, nanotechnology and

biomaterials for diagnosis and therapy, technologies for treating neurological injuries, and regenerative medicine.

2.7 Advanced Medical Regulatory and Manufacturing Technologies

This technology area focuses on developing initiatives and manufacturing-related products to support the technology areas listed above to decrease the risk and time of product development advancing through the Food and Drug Administration (FDA) regulatory process. This will impact accelerated access to medical products, reduce cost of goods manufactured, and steady the industrial base to support ongoing commercial availability of medical products most needed in surge situations.

Project Information submissions should describe projects that are based on logical reasoning and sound scientific rationale. They should not be exploratory in nature and do require a foundation of preliminary data. Please note that MTEC-sponsored projects must result in "prototype" research deliverables that transition medical solutions to industry. At a minimum, these projects must be at a stage to conduct studies required for a regulatory filing to the FDA, which suggests that the prototype design is near frozen, proof-of-concept has been demonstrated in a large animal model (if applicable), and a committed industrial partner is involved.

3 Selection/Evaluation Criteria

3.1 Stage 1: White Papers

3.1.1 Compliance Screening

The CM will conduct a preliminary screening of received White Papers to ensure compliance with the RPP requirements. As part of the preliminary screening process, White Papers that do not meet the requirements of the RPP may be eliminated from the competition or additional information may be requested (at the discretion of the CM).

3.1.2 Selection Criteria

The Government will evaluate White Papers submitted under this RPP using the following criteria:

(1) Feasibility of the proposed solution and its alignment with a Technology Focus Area;

(2) Relevancy of the proposed methodology/technology/solution to the Technology Focus Area, with special interest toward innovation, technological breakthrough, and advancement of the state-of-the-art technology;

(3) Strength of the organization/team proposed to complete the work in an effective and efficient manner, with adequate personnel, resources and facilities to deliver project objectives on schedule;

(4) Reasonableness of estimated ROM costs, to deliver value for proposed solution offered;

(5) Plan to include significant participation of non-traditional contractor or a 1/3 cost share.

Those White Papers that are favorably evaluated will be invited to participate in Stage 2 for further consideration. Only MTEC Members will be invited to participate in Stage 2. Prospective MTEC members whose White Paper is favorably evaluated will not be invited to Stage 2 until they become a member. MTEC member Offerors whose White Paper was not favorably evaluated will be provided feedback on the Government's evaluation. Non-MTEC members will not be provided feedback.

3.2 Stage 2: Full Proposal Evaluation

The Stage 2 process may vary depending upon the Technology Focus area; however, to the maximum extent practicable the evaluation criteria found at Attachment 4 are anticipated for all subsequent submissions beyond the Stage 1 process, including Full Proposals:

4 Other Factors to Consider

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

1. Warranties and Representations for Nontraditional Defense Contractors - See Attachment 5.
2. MTEC Additional Research Project Award Assessment or Royalty Payment Agreement – See Attachment 6.

5 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 Manager, Ms. Lisa Fisher, Mtec-contracts@ati.org
- Technical related questions should be directed to the MTEC Director of Research, Dr. Lauren Palestrini, Ph.D., lauren.palestrini@officer.mtec-sc.org
- Questions concerning membership should be directed to Ms. Stacey Lindbergh, MTEC Executive Director., execdirect@officer.mtec-sc.org.

- All other questions should be directed to Ms. Polly Graham, MTEC Program Manager, polly.graham@ati.org

Once an Offeror has submitted a White Paper, neither the Government nor the MTEC CM will discuss evaluation/proposal status until the source selection process is complete.

6 Acronyms/Abbreviations

ATI	Advanced Technology International
CM	Consortium Manager
CMA	Consortium Member Agreement
DHP	Defense Health Program
DoD	Department of Defense
FDA	Food and Drug Administration
FY	Fiscal Year
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
JETS	Joint Evacuation and Transport Simulation
MTEC	Medical Technology Enterprise Consortium
NDA	Nondisclosure Agreement
OCI	Organizational Conflict of Interest
OTA	Other Transaction Agreement
PMO-MD	Project Management Office, Medical Devices
POINTS	Point of Injury Training System
RDT&E	Research, Development, Test and Evaluation
REBOA	Resuscitative Endovascular Balloon Occlusion of the Aorta
RPP	Request for Project Proposals
SOW	Statement of Work
TBI	Traumatic Brain Injury
THOR	Theater Hospital Operations Replication
USAARL	U.S. Army Aeromedical Research Laboratory
USAMMA	U.S. Army Medical Materiel Agency
USAMRMC	U.S. Army Medical Research and Materiel Command
USG	U.S. Government
WarPRep	Warfighter Preparation, Resiliency and Protection

Attachment 1 - MTEC Multi-Topic White Paper Template

General Requirements: Each White Paper is limited to four pages plus a cover page (5 pages total). The White Paper must be in 11 point (or larger) type font, single-spaced, single-sided, on 8.5 inches x 11 inches paper. Smaller font may be used in figures and tables, but must be clearly legible. Margins on all sides (top, bottom, left, and right) should be at least 1 inch. The MTEC staff will share the above project ideas with various potential public and private sector sponsors. ***Please do not include confidential or proprietary information.***

Cover Page (1 page)
Title of White Paper

Principal Investigator and Institution

Statement that "This White Paper is submitted pursuant to the RPP MTEC-17-08-Multi-Topic"

- Indicate which of the following MTEC Technology Objective(s) your project fits:
- Prevention, Diagnosis and Treatment of Infectious Diseases
- Care of Combat Casualties
- Military Operational Medicine
- Clinical and Rehabilitative Medicine
- Medical Simulation and Information Sciences
- Advanced Medical Technologies
- Advanced Medical Regulatory and Manufacturing Technologies

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

Nontraditional Defense Contractor % - (See Attachment 3)

Willingness to allow MTEC Officers access to your White Paper for the purposes of engaging in outreach activities with private sector entities: Indicate YES or NO
[As part of MTEC's mission to incorporate philanthropic donations, MTEC frequently makes contact with private sector entities (e.g., foundations, organizations, individuals) that award grants or otherwise co-fund research, and/or operate in research areas that are aligned with those of MTEC. These private entities (e.g., Bill and Melinda Gates Foundation) may be interested in reviewing certain White Papers within their program areas, allowing opportunities to attract supplemental funding sources. Please indicate your willingness to allow MTEC access to your White Paper for the purposes of engaging in outreach activities with these private sector entities. MTEC staff has signed Nondisclosure Agreements (NDAs) and Organizational Conflict of Interest statements.]

MTEC Member: Indicate YES or NO
[Please indicate if your organization is a member of MTEC at the time of submission.]

White Paper (4 pages)

Specific Area(s) of Interest: [If applicable, please indicate which specific area(s) of interest outlined in the Request for White Papers your project addresses.]

Title: [Insert descriptive title of project]

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

Background: [Provide a clear description of why and how the proposed project fits into the MTEC mission. Describe how the technology addresses an unmet need in both military and civilian markets.]

Approach: [Briefly describe your approach to solving the problem. Include relevant background data about your approach. Include the current status of your approach.]

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

1. **Technical Strategy**: [Outline the proposed methodology in sufficient detail to show a clear course of action.]
2. **Anticipated Outcomes**: [Provide a description of the anticipated outcomes from the proposed work. List milestones and deliverables from the proposed work.]
3. **Technology Readiness Level (TRL)**: [Please indicate the TRL stage in which the project will start, as well as anticipated TRL at project completion. Definitions of TRLs can be found here: https://mtec-sc.org/wp-content/uploads/2016/12/TRL-definitions.pdf]

TRL at Project Start:
TRL at Project End:

Technical Maturity and Commercialization Strategy: [Provide a brief description and justification of the maturity of the proposed technology, anticipated regulatory pathway and commercialization plans. Include information about Intellectual Property/Data Rights Assertions.]

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

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

Period of Performance: [Indicate the total proposed period of performance.]

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

Rough Order of Magnitude (ROM) Pricing:
[Required: Indicate the ROM (including indirect costs), and the proposed ROM. This information will be used to provide the Sponsor with a reasonable representation of the amount of funding required to advance the project.] Sufficient cost information to substantiate the proposed cost as realistic and reasonable for the proposed effort must be provided to ensure that a complete and fair evaluation of the cost or price can be conducted. **Use the table format below as an example to provide an initial ROM.** 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.

Labor	*$ 100,000.00*
Subcontractors	*$ 50,000.00*
Consultants	*$ 10,000.00*
Material/Equipment	*$ 75,000.00*
Other Direct Costs	*$ 1,000.00*
Travel	*$ 5,000.00*
Indirect costs	*$ 48,200.00*
Total Cost	*$ 289,200.00*
Fee (*Not applicable if cost share is proposed)*	*$ 0.00*
Total Cost (plus Fee)	*$ 289,200.00*
Cost Share (if cost share is proposed then fee is un-allowable)	*$ 290,000.00*
Total Project Cost	*$ 579,200.00*

EXAMPLE

Attachment 2 – Nontraditional Defense Contractor

Nontraditional Defense Contractor Definition

A nontraditional defense contractor is a business unit that has not, for a period of **at least one year prior to the issue date of the Request for Project Proposals**, entered into or performed on any contract or subcontract that is subject to full coverage under the cost accounting standards (CAS) prescribed pursuant to section 26 of the Office of Federal Procurement Policy Act (41 U.S.C. 422) and the regulations implementing such section.

Nontraditional Defense Contractor Requirements

If the Offeror asserts either (1) it is a nontraditional defense contractor or (2) proposes a nontraditional defense contractor as a team member/subcontractor, the Offeror shall submit Warranties and Representations (Attachment 4) specifying the critical technologies being offered and/or the significant extent of participation of the nontraditional defense contractor. The nontraditional defense contractor can be an individual so long as he/she has a DUNS Number and meets the requirements in the Warranties and Representations. The significance of the nontraditional defense contractor's participation must be explained in detail in the signed Warranties and Representations. Inadequate detail can cause delay in award.
Per the DoD OT Guide, rationale to justify a *significant contribution* include:

1. Supplying a key technology or products
2. Accomplishing a significant amount of the effort
3. Use of unique skilled personnel, facilities and/or equipment
4. Causing a material reduction in cost or schedule, and/or Improvement in performance

Inclusion of Nontraditional Defense Contractors

Proposals that do not include nontraditional defense contractor participation to a significant extent, or do not propose at least one third acceptable cost sharing, will not be eligible for award. This requirement is a statutory element of the Other Transaction Authority and will be regarded as a pass/fail criterion during the Compliance Screening.

Attachment 3 – Cost Share

Cost Sharing includes any costs a reasonable person would incur to carry out (necessary to) proposed projects' statements of work (SOW) not directly paid for by the Government. There are two types of cost sharing: Cash Contribution and In-Kind Contribution. If a proposal includes cost share then it cannot include fee. Cost Share may be proposed only on cost type agreements.

Cash Contribution

Cash Contribution means the Consortium and/or the Research Project Awardee (or Awardees' lower tier subawards) financial resources expended to perform a Research Project. The cash contribution may be derived from the Consortium's or Research Project Awardee (or Awardees' subawards) funds or outside sources or from nonfederal contract or grant revenues or from profit or fee on a federal procurement contract.

An Offeror's own source of funds may include corporate retained earnings, current or prospective Independent Research and Development (IR&D) funds or any other indirect cost pool allocation. New or concurrent IR&D funds may be utilized as a cash contribution provided those funds identified by the Offeror will be spent on performance of the Statement of Work (SOW) of a Research Project or specific tasks identified within the SOW of a Research Project. Prior IR&D funds will not be considered as part of the Offeror's cash.

Cash contributions include the funds the Offeror will spend for labor (including benefits and direct overhead), materials, new equipment (prorated if appropriate), awardees' subaward efforts expended on the SOW of a Research Project, and restocking the parts and material consumed.

In-Kind Contribution

In Kind Contribution means the Offeror's non-financial resources expended by the Consortium Members to perform a Research Project such as wear-and-tear on in-place capital assets like machinery or the prorated value of space used for performance of the Research Project, and the reasonable fair market value (appropriately prorated) of equipment, materials, IP, and other property used in the performance of the SOW of the Research Project.

Prior IR&D funds will not be considered as part of the Consortium Member's cash or
In-Kind contributions, except when using the same procedures as those that authorize Pre-Award Costs, nor will fees be considered on a Consortium Member's cost sharing portion.

Attachment 4 – Stage 2 Evaluation Criteria

For Information Only - Stage 2 Requirement

6.1 Stage 2

6.1.1 Compliance Screening

The CM will conduct a preliminary screening of received proposals to ensure compliance with the RPP requirements. As part of the preliminary screening process, proposals that do not meet the requirements of the RPP may be eliminated from the competition or additional information may be requested by the CM. One of the primary reasons for non-compliance and elimination during this initial screening is that the proposal does not offer significant nontraditional defense contractor participation or cost share (see Section 1.13 above).

Evaluation Criteria

Selection Overview

The Stage 2 process may vary depending upon the Technology Focus area; however, to the maximum extent practicable the following evaluation criteria are anticipated for all subsequent submissions beyond the Stage 1 process, including Full Proposals:

Non-cost/Price Evaluation Criteria:

Technical Merit
Management Approach
Technical Impact

Cost/Price Evaluation Criteria

The Non-Cost/Price Evaluation Criteria are listed in descending order of importance. When combined the Non-Cost/Price Evaluation Criteria are significantly more important than the Cost/Price Evaluation Criteria.

Non-Cost/Price Evaluation Criteria:

The following criteria will be used to evaluate the non-cost/price aspects of the proposal.

(1) Technical Merit:: The technical approach will be evaluated for the degree to which the Offeror demonstrates:

- A written technical approach which effectively demonstrates the Offeror's understanding of the overall requirement, likelihood of successfully achieving the identified Technology Focus Area, and inclusion of complete and clear processes to execute the effort in the required time frame.
- A proposed road map and SOW that is feasible, and includes the rationale, objectives and specific aims to support the research idea.
- An innovative and novel approach to develop new technology that is currently unavailable and offers the possibility of technological breakthroughs.
- A plan to advance the technical maturity level and demonstrate projected performance improvements.
- An approach that is relevant to the specific Technology Focus Area, in support of the overarching goal of developing biomedical products and procedures to protect, project and sustain the force.

(2) Management Approach: The management approach will be evaluated for the degree to which the Offeror's Management Approach demonstrates:

- A written approach to staffing, facilities and resources that will lead to the successful accomplishment of the Technology Focus Area.
- A team of qualified, experienced and knowledgeable staff, with the unique technical and management expertise to carry out the proposed Technology Focus Area, in an efficient and effective manner.
- Clearly identified personnel, facilities and resources that are available to execute the proposed project objectives on schedule.

(3) Technical Impact: The proposal will be evaluated for the degree to which it:

- Advances the state-of-the-art of technology; through research, development and testing, which is needed to develop and transition new materials and improve medical practice for the warfighter.
- Demonstrates potential impact in the research field; the significance of this impact, and the anticipated time period for achievement.
- Demonstrates potential commercial use, and/or movement into the next phase of desired research, development or testing.
- As applicable, demonstrates an achievable approach to regulatory approval (i.e., FDA Approval).

(4) Cost Share: The proposal will be evaluated for any Cost Share proposed that is above the minimum statutory requirement of either zero percent cost share (for proposals which include significant participation of a nontraditional defense contractor) and 1/3 cost share (for proposals containing no nontraditional defense contractor participation).

- Cost Share proposed exceeding minimum requirements demonstrates strong non-federal interest in dual use medical technologies.
- Supports a primary Government objective under MTEC to leverage federal funds on proposals that attract non-federal funding sponsors.
- Increases downstream technology commercialization likelihood by securing commitment of additional stakeholders.

Cost/Price Evaluation Criteria

(1) Ratings. The Cost area will receive a narrative rating to determine whether costs are realistic, reasonable, and complete.

(2) Cost/Price Evaluation Process. The MTEC CM will evaluate the estimated cost proposed by the Offeror for performing all requirements outlined in this RPP and the appropriate MTEC PPG. Evaluation will include analysis of the proposed cost together with all supporting information. The Offeror's cost and rationale will be evaluated for realism, reasonableness, and completeness. The Government Technical Evaluators will assess cost realism as part of the source selection process. If a proposal is selected for award, the MTEC CM will review the original cost proposal and the Offeror's response to a Proposal Update Letter (PUL), if applicable. The MTEC CM will request additional information or clarification as necessary. The MTEC CM will assess the reasonableness and completeness of the cost estimates and then provide a formal assessment to the Government. The Government will review this assessment and make the final determination that the negotiated project value is fair and reasonable.

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

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

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

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

(ii) Reasonableness. The Offeror's cost proposal will be evaluated to determine if it is reasonable. For a price to be reasonable, it must represent a price to the Government that a prudent person

would pay in the conduct of competitive business. Normally, price reasonableness is established through cost and price analysis.

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

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

(iii) 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.

Best Value

The Government will conduct the source selection and MTEC CM will award the projects in Best Value sequence. If applicable, the Government will invoke a best value process to evaluate the most advantageous offer by considering and comparing factors in addition to cost or price. Based on the results of the Non-Cost/Price Evaluation, the Government reserves the right to negotiate and request changes to any or all parts of the SOW. Offeror's will have the opportunity to concur with the requested changes and revise cost proposals as necessary.

Definition of General Terms Used in Evaluations:

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 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.

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.

Attachment 5 – Warranties and Representations for Nontraditional Defense Contractors

For Information Only - Stage 2 Requirement

Authority to use Other Transaction Agreement

Section 815 of the National Defense Authorization Act (NDAA) for Fiscal Year 2016, authorizes Department of Defense organizations to carry out prototype projects that are directly relevant to enhancing the mission effectiveness of military personnel and the supporting platforms, systems, components, or materials proposed to be acquired or developed by the Department of Defense, or to improvement of platforms, systems, components, or materials in use by the armed forces. The law also requires:

(A) There is at least one nontraditional defense contractor participating to a significant extent in the prototype project, OR

(B) All significant participants in the transaction other than the Federal Government are small businesses or nontraditional defense contractors OR

(C) At least one third of the total cost of the prototype project is to be paid out of funds provided by parties to the transaction other than the Federal Government.

(INSERT ORGANIZATION NAME) hereby provides the following Warranties and Representations:

Prime Contractor

The Prime Contractor *(insert Organization Name)* for the proposed program ☐ is a traditional defense contractor ☐ is a nontraditional defense contractor. *(check one)* based on the following definition:

A nontraditional defense contractor is a business unit that has not, for a period of **at least one year prior to the issue date of the Request for Project Proposals**, entered into or performed on *any contract or subcontract that is subject to full coverage under the cost accounting standards (CAS) prescribed pursuant to section 26 of the Office of Federal Procurement Policy Act (41 U.S.C. 422) and the regulations implementing such section*

Note: Nontraditional defense contractors can be at the prime level, team members, subcontractors, lower tier vendors, or "intra-company" business units; provided the business unit makes a significant contribution to the prototype project (i.e., is a key participant).

If the prime contractor is a traditional defense contractor and proposes the use of one or more nontraditional defense contractors, the following information is required for each participating nontraditional defense contractor.

Legal Name of Nontraditional Defense Contractor:	
DUNS #:	
Address:	
Point of Contact (Name, Title, Phone #, Email):	

1 Please select at least one or more of the significant contribution(s) listed below that will be provided by the Nontraditional defense contractor cited above:	
☐	**A - The significant contribution involves developing, demonstrating or providing a key technology.** *Please describe what the key technology is; why it is key to the medical technology community, and what makes it key.*
☐	**B - The significant contribution involves developing, demonstrating or providing a new technology that is not readily available.** *Please describe what the new part or material is and why it is not readily available.*
☐	**C - The significant contribution involves use of skilled personnel (such as modeling & simulation experience, medical technology design experience, etc.), facilities and/or equipment that are within the capabilities of the designated nontraditional and required to successfully complete the program.** *Please describe the personnel, facilities and/or equipment involved in the proposed program and why they are required to successfully complete the program.*
☐	**D - The use of this designated non-traditional will cause a material reduction in the cost or schedule.** *Please describe the specific cost or schedule impact to be realized*
☐	**E - The use of this designated non-traditional will increase medical technology performance.** *Please describe what the performance increase will be attained by the use of this designated nontraditional defense contractor*
2 In addition to the above please provide the following information:	
Q1	**What additional capability beyond those described in A through E above does this Nontraditional defense contractor have that is necessary for this specific effort?**
A1	

Q2	**In which task/phase(s) of the effort will the Nontraditional defense contractor be used?**
A2	
Q3	**What is the total estimated cost associated with the Nontraditional defense contractor included in the proposal?** *Note: While cost is an indicator for the level of Nontraditional defense contractor participation, there is no particular cost threshold required.*
A3	

_____ _____

Signature of authorized representative of proposing Prime Contractor Date

Attachment 6 - MTEC Requirements

For Information Only - Stage 2 Requirement

As a tax-exempt 501(c)(3) entity, MTEC can accept contributions directly from the private sector, including industry partners who wish to co-fund a particular project, philanthropic entities who wish to co-fund a particular project, and/or philanthropic entities who wish to support the overall MTEC mission. Additional MTEC revenue streams for supporting entity operations are membership dues, research assessment fees, and royalty payments.

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 1% of the total funded value of each research project award. 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. Additionally MTEC has established two methods of payment to be made to MTEC surrounding the licensing/commercialization of Intellectual Property developed with funding received from MTEC Research Project Awards. MTEC has established two methods of payment to be made to MTEC surrounding the licensing/commercialization of Intellectual Property developed with funding received from MTEC Research Project Awards:

Royalty Payment Agreements

Government-funded research projects awarded through MTEC will be subject to a 10% royalty on all Net Revenues received by the Research Project Award recipient resulting from the licensing/commercialization of the technology, capped at 200% of the Government funding provided.

Additional Research Project Award Assessment

In lieu of providing the royalty payment agreement described above, members receiving Research Project Awards may elect to pay an additional assessment of 2% above the standard assessment percentage described in Section 3.4 of the CMA. This additional assessment applies to all research project awards, whether the award is Government funded or privately funded.

Attachment 7 – IP Rights

Intellectual Property

Intellectual Property (IP) rights for MTEC Research Project Awards will be defined in the terms of an awardee's Base Agreement and resultant Task Orders. MTEC Base Agreements are issued by the MTEC CM to MTEC members receiving Research Project Awards. Base Agreements include the applicable flow down terms and conditions from the Government's Other Transaction Agreement with MTEC, including the IP terms and conditions.

Data Rights

It is anticipated that anything delivered under a Research Project Award would be delivered to the Government with Government purpose data rights or unlimited data rights. If this is not the intent, **then the White Papers should discuss data rights associated with each item**, and possible approaches for the Government to gain Government purpose data rights or unlimited data rights as referenced in the Base Agreement. Rights in technical data in each Research Project Award shall be determined in accordance with the provisions of MTEC Base Agreement.

If applicable, complete the below table for any items to be furnished to the Government with restrictions. An example is provided.

Technical Data or Computer Software to be Furnished with Restrictions	Basis for Assertion	Asserted Rights Category	Name of Organization Asserting Restrictions	Milestone # Affected
Software XYZ	Previously developed software funded exclusively at private expense	Restricted	Organization XYZ	Milestones 1, 3, and 6
Technical Data Description	Previously developed exclusively at private expense	Limited	Organization XYZ	Milestone 2
Technical Data Description	Previously developed with mixed funding	Government Purpose Rights	Organization XYZ	Milestone 2