

Request for Project Proposal



Solicitation Number: MTEC-19-08-MuLTI
"Multi domain Life Saving Trauma Innovations (MuLTI)"

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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White Paper Due Date: March 18, 2019
Noon Eastern Time

White Papers are Required

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Number W81XWH-15-9-0001

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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” defense 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 Combat Casualty Care Research Program (CCCRP). 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 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 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.

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1.2 Background

This RPP entitled “Multi domain Life Saving Trauma Innovations (MuLTI)” will support the development of highly innovative Materiel Products and new ways, methods, or modifications to existing trauma practice (i.e., Knowledge Products) for future Multi Domain Operations (MDO) where evacuation capabilities may be significantly delayed or unavailable, including decision support, semi-autonomous, and autonomous technologies. Projects should focus on enhancing capabilities at the point of greatest need, including life-saving interventions to be rendered immediately post-injury, during periods of prolonged care in theater, and during en route care within and from theater. Encouraged characteristics of possible medical materiel solutions include, but are not limited to, concepts that address one or more of the following: mobility, low-weight and cube, low-power, modularity, interoperability, ruggedization, automation, low-complexity, decision supported, closed or semi-closed loop feedback, longer shelf life, temperature stability, low-complexity, regulatory pathway clarity, manufacturability, cost-savings, and/or life-cycle product sustainability.

1.3 Acquisition Approach

This RPP will be conducted using a two-staged approach. In Stage 1, current MTEC members are invited to submit White Papers using the format contained in this RPP (Attachment 1). 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.

*Note: Pending successful completion of this effort, the Government may issue a non-competitive follow-on production contract or transaction pursuant to 10 USC 2371b section f.

1.4 Military Relevance

Military relevance is a critical component of proposal submission. The CCCR provides integrated capabilities for current and future operations to reduce the mortality and morbidity associated with major combat-related trauma across the spectrum of combat casualty, care including point of injury and pre- or out-of-hospital care, the spectrum of en-route care, and facilities-based treatment.

1.5 Proposers Conference

MTEC will host a Proposers Conference that will be conducted via webinar approximately 1-2 weeks after the release of the RPP. Further instructions will be forthcoming via email.

1.6 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 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 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.

Stage 1: White Papers submitted under this RPP shall follow the MTEC White Paper Template provided in Attachment 1.

Stage 2: Offerors whose technology solutions are 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. An example of the proposal submission requirements is (subject to change):

- **Technical Proposal** according to the format provided in the Proposal Preparation Guidelines (PPG) available on the MTEC members-only website.
- Detailed **Statement of Work (SOW)** according to the format provided in the notification letter.
- **Cost Proposal** according to the guidance provided in the PPG.

1.7 Potential Funding Availability

The U.S. Government (USG) currently has available approximately \$10 million (M) of 2-year Fiscal Year (FY) 2018 Defense Health Program (DHP) Research, Development, Test and Engineering (RDT&E) funds.

MTEC anticipates that 4 (or more) awards of up to \$2.5M each (direct and indirect costs), totalling \$10M, will be made to qualified teams. The maximum request for Government funding for each white paper should not exceed \$2.5M. **Cost sharing, including cash and in kind (e.g., personnel or product) contributions are strongly encouraged and have no limit.**

The funding estimated for this RPP is approximate and subject to realignment. Funding of proposals received in response to this RPP is contingent upon the availability of federal funds for this program.

Award funding will be structured incrementally and based upon completion of milestones.

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The Period of Performance (POP) is project dependent and may range between 1 to 3 years.

1.8 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 and Directors 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 and Directors 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.

1.9 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 above the statutory minimum is a consideration in the evaluation of proposals; however, this 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; 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.). Cost sharing is encouraged if possible, as it leads to stronger leveraging of Government-contractor collaboration.

1.10 Cost Share Requirements

Research Projects selected for funding under this RPP are required to have at least one nontraditional defense contractor or nonprofit research institution 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

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nontraditional defense contractor requirements can be found at Attachment 2. For more information regarding cost share, please see Attachment 3.

1.11 White Paper Submission

Instructions on how to submit are included in the RPP version that is posted on MTEC Members Only Site.

MTEC membership is required for the submission of a White Paper. Offerors must be MTEC Members in good standing. Offerors submitting Proposals as the prime contractor must be MTEC members of good standing by **March 13, 2019**.

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

1.12 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.

1.13 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 Technical Requirements

The Joint Program Committee (JPC)-6/CCCRP is one of six major DHP core research program areas within the DHP medical RDT&E. JPC-6 is a committee of DoD and non-DoD medical and military technical experts in combat casualty care-related program areas. Per the program's mission statement, JPC-6/CCCRP seeks to drive medical innovation through development of knowledge and materiel solutions for the acute and early management of combat-related trauma on current and future battlefields; including point-of-injury, far-forward, prolonged, en route, and early facility based care. Innovations developed by JPC-6/CCCRP-supported research are applied in-theater across the echelons of care, and within the prehospital and critical care clinical facilities of the Military Health System. These solutions not only help to minimize the morbidity and mortality of combat-related injuries sustained by the Warfighter, they also are often translatable

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to civilian care. An excerpt from the CCCRP Vision Statement provides further illustration of the program's needs:

"In responding to mid and long term guidance which is underscored by a predicted loss of air superiority, we must adapt our perspective and tactics with regard to casualty evacuation and the "golden hour" paradigm of Operation Iraqi Freedom/Operation Enduring Freedom in order to continue to drive down case fatality and died of wound rates. There is a necessary paradigm shift away from transporting casualties to a damage control capability (Roles Of Care 2/3) to more efficiently bringing "golden hour" medical assets and intervention capabilities to the point of injury."

– Col Michael Davis, CCCRP Director
(2017)

For additional information on JPC-6/CCCRP, the program's previous and current successes, and other documents related to the program's long-term planning efforts, please visit the CCCRP official website at: <https://ccc.amedd.army.mil/Pages/default.aspx>

JPC-6/CCCRP MuLTI Focus Areas

The JPC-6/CCCRP has identified three overarching focus areas for funding under the JPC-6/CCCRP MuLTI Program. To meet the intent of this RPP, applications **MUST** specifically address at least one of the three MuLTI Focus Areas described below. Projects not aligned to at least one of these Focus Areas will not be considered for funding.

[NOTE: Projects must focus on prototype technologies that have not been submitted to MTEC under the previous 17-08 Multi-Topic RPP. The Government is already aware of prototype technologies submitted to previous MTEC solicitations, and therefore, such projects are not allowed to be resubmitted here. However, if you submitted a white paper in response to the 18-08-Open Concepts Request for Project Information (RPI), you may resubmit your concept in response to this 19-08-MuLTI RPP if you believe that your technology specifically addresses at least one of the three MuLTI Focus Areas described below.]

The MuLTI Focus Areas are:

Focus Area #1 – Prolonged Field Care and En Route Care (PFC/ERC): The PFC/ERC portfolio seeks to provide materiel and knowledge solutions to enable increased levels of care closer to the point of injury, including care provided during evacuation, to provide patient care for longer time periods when delayed evacuation exceeds available capability and/or capacity, and to extend provider capabilities in order to care for larger numbers of casualties.

Specific PFC/ERC areas of interest:

- Advanced physiological monitoring capabilities that integrate with decision support tools to enable continuous feedback loops based on physiologic status and response to various treatments, including monitoring for secondary sequelae of trauma when evacuation is delayed.
- Automated splinting/traction systems to allow combat casualties to remain independently mobile despite extremity fracture or musculoskeletal injury
- Development of automated diagnostic systems that are field portable, do not require extensive interpretation by medical providers, and reduce decision making/task saturation of providers
 - Examples include handheld ultrasound technologies with automated data processing and pathology identification
- Technologies to support the prolonged care of combat casualties including differential thermal management, mitigating effects of prolonged immobilization, providing sufficient nutrition

Focus Area #2 – Battlefield Resuscitation and Immediate Stabilization of Combat Casualties (BRISCC): Hemorrhage is the leading cause of preventable deaths among combat casualties occurring before a medical treatment facility is reached. The BRISCC portfolio seeks to provide materiel and knowledge solutions to enable the immediate stabilization at the point of injury. Current strategic objectives are to provide: (1) technologies to control bleeding in the pre-hospital environment, (2) safer, more effective, and more logistically supportable blood products, and (3) technologies and knowledge sets for improved damage control resuscitation.

Specific BRISCC areas of interest:

- New and innovative capabilities to stop non-compressible intra-cavitory hemorrhage and improved technologies to stop junctional and pelvic bleeding
- Innovative damage control resuscitation and damage control surgery technologies
- Novel capabilities to treat injury patterns in projected future MDO including high-power projectiles, cavitating projectiles, fragmentary projectiles, crush injuries, smoke and debris inhalation, and thermobaric weapons
- Capabilities that provide early detection and treatment for the coagulopathy of trauma
- Capabilities that provide early detection of hemodynamic decompensation well before decompensation occurs to enable early intervention
- Efforts to effectively model the complex pathophysiology of trauma (including immunomodulatory effects) to enable future automated and semi-automated decision support algorithms
- New and novel clinical diagnostics (light and rugged) for point of injury assessment of hemorrhage and coagulopathy (for both internal and external bleeding)

Focus Area #3 – Neurotrauma & Traumatic Brain Injury (TBI): The Neurotrauma Portfolio (NTP) is focused on closing military-relevant gaps across a broad range of research areas to improve the prevention, diagnosis, management, and treatment of TBI and related sequelae from point-of-injury through recovery. The NTP's goal is to decrease morbidity and mortality from

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neurotrauma, mitigate secondary brain injury across all TBI severities, and advance materiel and knowledge development to expand and develop new clinical practice guidelines, care algorithms, therapies, devices, and procedures that advance the decision-making capabilities of medical personnel, enabling earlier intervention and improved outcomes.

NOTE: For studies proposing animal research, provide justification for the use of non-gyrencephalic (lissencephalic) models of TBI.

Specific NTP areas of interest:

- Identify expedient interventions to reduce incidence and severity of secondary brain injury
- Develop capabilities for the rapid triage and management of life-threatening TBI
- Identify novel approaches to moderate and severe TBI intervention and stabilization (e.g. maintain glucose levels, brain oxygenation, and cerebral blood flow)
- Identify novel field expedient diagnostic capabilities (e.g., imaging, but does not require extensive interpretation by medical providers and reduces decision making/task saturation of providers)
- Identify novel approaches to resuscitate and treat hemorrhagic patients with severe TBI
- Identify novel field expedient fluid-based biomarkers
- Develop field applicable treatments for post traumatic central nervous system (CNS) tissue preservation
- Provide innovative solutions to sustain patients with TBI when evacuation is delayed (e.g., automated burr-holes devices, intracranial pressure (ICP) monitoring, etc.)

Additional points of consideration:

- **Project Maturity:** This solicitation is intended to support candidate solution development in which proof of concept has been demonstrated. The Government expects this to reflect a Technology Readiness Level (TRL) ranging from TRL 4-6. Definitions of TRLs can be found here: <https://mtec-sc.org/wp-content/uploads/2016/12/TRL-definitions.pdf>
- **Industry Partners:** It is expected that the eventual goal of projects funded by this RPP will transition to industry for FDA approval. While not a requirement, Offerors are strongly encouraged to include industry partnerships as appropriate.
- **Cost Share:** The Government funds provided for this initiative are not anticipated to be the sole funding resource for the efforts. Because the RPP is focused on prototyping activities, rather than basic science and discovery, 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 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 will 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 equally important criteria:

1. Technical Merit,
2. Military Benefit/Relevance,
3. Cost/Price

See below for additional details regarding the evaluation factors and ratings table for the Stage 1 evaluation:

Evaluation Factor 1. Technical Merit: The Offeror's proposed solution will be evaluated to determine whether the Offeror demonstrates an understanding of the overall requirement, likelihood of successfully achieving at least one of the identified three overarching focus areas, and inclusion of complete and clear processes to execute the effort in the required time frame. The Offeror's White Paper will also be evaluated to determine whether the written approach addresses resources (i.e. staffing, facilities) that will lead to the successful accomplishment of the Technology Focus Area.

The Government may determine a White Paper to be unacceptable for the Technical Merit factor if the White Paper fails to address all sections within the MTEC White Paper Template (Attachment 1).

Evaluation Factor 2. Military Benefit/Relevance: The Offeror's proposed solution will be evaluated to determine whether the Offeror demonstrates how the proposed technology meets the needs of Combat Casualty Care Research Program to include whether the proposed solution provides military-relevant benefits.

Evaluation Factor 3. Cost/Price: The Rough Order of Magnitude (ROM) Pricing will be evaluated to determine whether the estimated costs are realistic, reasonable, and complete.

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Furthermore, the ROM will be evaluated to determine if the proposed solution delivers value to the Government.

These evaluation factors, both cost/price and non-cost/price, will be evaluated on an “acceptable” or “unacceptable” basis using the following rating table:

Rating	Description
Acceptable	White Paper meets the minimum requirements of the RPP.
Unacceptable	White Paper does not meet the minimum requirements of the RPP.

Therefore, White Papers will be evaluated for acceptability but not ranked or rated using adjectival ratings. However, as all evaluation factors are considered equally important, a White Paper must receive a rating of “acceptable” for each of the three factors listed above in order to be considered favorably evaluated.

Those White Papers that are favorably evaluated will be invited to participate in Stage 2 for further consideration. Offerors whose White Papers were not favorably evaluated (do not receive a rating of “acceptable” for each of the three factors listed above) will be provided feedback on the evaluation based on the ratings table above.

3.2 Stage 2: Full Proposal Evaluation

To the maximum extent practicable the evaluation criteria found in 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. If Offerors have not yet executed a MTEC Base Agreement, then Offerors must certify on the cover page of their full proposal that, if selected for award, they will abide by the terms and conditions of the latest version of the MTEC Base Agreement.
2. Warranties and Representations for all proposals - See Attachment 5.
3. MTEC Additional Research Project Award Assessment or Royalty Payment Agreement – See Attachment 6.
4. Current and Pending Support (no page limit) – See Attachment 8
 - a. For all current and pending research support (to include government and non-government), include the award number and title, funding agency and requiring

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activity's names, period of performance (dates of funding), level of funding (total direct costs only), brief description of the project's goals, and list of specific aims. If applicable, identify where the proposed project overlaps with other existing and pending research projects. Clearly state if there is no overlap.

b. If there is no current and/or pending support, enter "None."

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 Administrator, Ms. Rebecca Harmon, 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. Kathy Zolman, MTEC Program Manager, kathy.zolman@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
BRISCC	Battlefield Resuscitation and Immediate Stabilization of Combat Casualties
CAS	Cost accounting standards
CCCRP	Combat Casualty Care Research Program
CM	Consortium Manager
CMA	Consortium Member Agreement
CNS	Central nervous system
DHA	Defense Health Agency
DHP	Defense Health Program
DoD	Department of Defense
DUNS	Data Universal Numbering System
ERC	En Route Care
F&A	Facilities and Administrative Costs
FAQ	Frequently Asked Questions
FDA	Food and Drug Administration
FY	Fiscal Year
G&A	General and Administrative Expenses
ICP	Intracranial pressure
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
JPC	Joint Program Committee
M	Million
MDO	Multi Domain Operations
MTEC	Medical Technology Enterprise Consortium
MuLTI	Multi domain Life Saving Trauma Innovations
NDA	Nondisclosure Agreement
NTP	Neurotrauma Portfolio
OCI	Organizational Conflict of Interest
ODC	Other Direct Costs
PFC	Prolonged Field Care
pOTA	Prototype Other Transaction Agreement
POC	Point-of-Contact
PPG	Proposal Preparation Guide
Q&A	Questions and Answers
RDT&E	Research, Development, Test, and Evaluation
ROM	Rough Order of Magnitude
RPP	Request for Project Proposals
SOW	Statement of Work
TBI	Traumatic brain injury
TRL	Technology Readiness Level

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USAMRMC
USG

U.S. Army Medical Research and Materiel Command
U.S. Government

Attachment 1 - MTEC White Paper Template

General Requirements: Each White Paper is limited to three pages plus a cover page (4 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 white papers 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-19-08-MuLTI"

Indicate which of the following technical focus areas the white paper addresses (select only one). Submission of the same white paper to more than one focus area is not allowed.

[NOTE: Projects must focus on prototype technologies that have not been submitted to MTEC under the previous 17-08 Multi-Topic RPP. The Government is already aware of prototype technologies submitted to previous MTEC solicitations, and therefore, such projects are not allowed to be resubmitted here. However, if you submitted a concept paper in response to the 18-08-Open Concepts Request for Project Information (RPI), you may resubmit your concept in response to this 19-08-MuLTI RPP if you believe that your technology specifically addresses at least one of the three MuLTI Focus Areas described below.]

1. Focus Area #1 – Prolonged Field Care and En Route Care (PFC/ERC)
2. Focus Area #2 – Battlefield Resuscitation and Immediate Stabilization of Combat Casualties (BRISCC)
3. Focus Area #3 – Neurotrauma & Traumatic Brain Injury (TBI)

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

Nontraditional Defense Contractor or Nonprofit Research Institution % - (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. Additional private entities may be interested in reviewing certain White Papers within their program areas, allowing opportunities to attract supplemental funding

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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.]

White Paper (3 pages)

Title: [Insert descriptive title of project]

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

Background: [Briefly state the problem that the White Paper is addressing.]

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

Specific Aims: [Specify the specific aims of the proposed effort.]

Study Design: [Outline the proposed methodology in sufficient detail to show a clear course of action.]

Anticipated Outcomes: [Provide a description of the anticipated outcomes from the proposed work. List milestones and deliverables from the proposed work.]

Military Benefit/Relevance: [Provide a description of how the proposed technology meets the needs of Combat Casualty Care Research Program.]

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

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

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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. **The maximum request for Government funding for each white paper should not exceed \$2.5M.** Cost sharing, including cash and in kind (e.g., personnel or product) contributions are **strongly encouraged and have no limit.** 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

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 or Nonprofit Research Institution 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, or (3) it is a nonprofit research institution, the Offeror shall submit Warranties and Representations (Attachment 5) specifying the critical technologies being offered and/or the significant extent of participation of the nontraditional defense contractor. The nontraditional defense contractor or nonprofit research institution 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 or nonprofit research institution'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, products, or process
2. provide a material increase in the performance, efficiency, quality or versatility of a key technology, product or process
3. Accomplishing a significant amount of the effort
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 (subject to change)

6.1 Stage 2

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. The Government reserves the right to request additional information or eliminate proposals that do not meet these requirements from further consideration.

*There is a statutory requirement for proposals to include either 1) significant participation of a Nontraditional Defense Contractor (NDC) or Nonprofit Research Institution (NRI), or 2) 1/3 cost share on projects. One of the primary reasons for elimination from further consideration is noncompliance with this statutory requirement.

To ensure both scientific excellence and programmatic relevance, the USAMRMC administers a two-tier review process. The first tier is peer review, the evaluation of applications against established criteria to determine technical merit. The second tier is programmatic review, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance.

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

Programmatic Relevance

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.

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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.
- 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.
- 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).

(2) Programmatic Relevance: The proposal will be evaluated for the degree to which it:

- Adheres to the intent of the award mechanism
- Supports overall program portfolio composition
- Supports Military relevance and dual-use purposes
- Relative impact and innovation

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(3) 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.

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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.

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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 2018, 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 or nonprofit research institution participating to a significant extent in the prototype project.
- (B) All significant participants in the transaction other than the Federal Government are small businesses (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)) or nontraditional defense contractors.
- (C) At least one third of the total cost of the prototype project is to be paid out of funds provided by sources other than the Federal Government.

A. Prime Contractor: The prime contractor must complete the following table.

1. Legal Name:	2. DUNS #:
3. Point of Contact: Name, Title, Phone #, Email	
4. Prime Contractor is a nontraditional (Y/N)?	
5. Prime Contractor is a nonprofit research institution (Y/N)?	
6. Prime Contractor will provide at least one third of the total cost of the prototype project out of funds provided by sources other than the Federal Government (Y/N)?	
7. Prime Contractor is a small business (Y/N)?	

If the prime contractor has answered “Y” to question 4, 5, or 6, skip Section B and proceed to Section C.

B. Subcontractor(s)/Vendor(s): If the prime contractor is a **traditional** defense contractor and proposes the use of one or more nontraditional defense contractors or nonprofit research institutions, the following information is required **for each** participating nontraditional defense contractor or nonprofit research institution.

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8. Legal Name:		9. DUNS #:	
10. Dollar Value to be Awarded:			
11. Point of Contact: (Name, Title, Phone #, Email)		12. Task/Phase:	
13. Subcontractor/Vendor is a nontraditional (Y/N)?			
14. Subcontractor/Vendor is a nonprofit research institution (Y/N)?			
15. Subcontractor/Vendor is a small business (Y/N)?			
16. Significant Contribution:			
<input type="checkbox"/>	A - The significant contribution involves developing, demonstrating or providing a key technology. <i>Please describe what the key technology is; why it is key to the medical technology community, and what makes it key.</i>		
<input type="checkbox"/>	B - The significant contribution involves developing, demonstrating or providing a new technology that is not readily available. <i>Please describe what the new part or material is and why it is not readily available.</i>		
<input type="checkbox"/>	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. <i>Please describe the personnel, facilities and/or equipment involved in the proposed program and why they are required to successfully complete the program.</i>		
<input type="checkbox"/>	D - The use of this designated subcontractor/vendor will cause a material reduction in the cost or schedule. <i>Please describe the specific cost or schedule impact to be realized</i>		
<input type="checkbox"/>	E - The use of this designated subcontractor/vendor will increase medical technology performance. <i>Please describe what the performance increase will be attained by the use of this designated nontraditional defense contractor</i>		
1 In addition to the above please provide the following information:			

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Q1	What additional capability beyond those described in A through E above does this subcontractor/vendor have that is necessary for this specific effort?
A1	
Q2	In which task/phase(s) of the effort will the subcontractor/vendor be used?
A2	
Q3	What is the total estimated cost associated with the subcontractor/vendor 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	

C. Signature

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. 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

Attachment 8 – Current & Pending Support Template
For Information Only - Stage 2 Requirement

Current

Award Number:

Title:

Funding Agency/Requiring Activity:

Dates of Funding:

Total Direct Costs:

Role: (*i.e. Principal Investigator, Co-Investigator, etc.*)

Brief summary of the scope of work:

Award Number:

Title:

Funding Agency/Requiring Activity:

Dates of Funding:

Total Direct Costs:

Role: (*i.e. Principal Investigator, Co-Investigator, etc.*)

Brief summary of the scope of work:

[Add additional fields, if needed, to report all current support]

Pending

Title of Proposal:

Funding Agency/Requiring Activity:

Estimated Dates of Funding:

Proposed Total Direct Costs:

Role: (*i.e. Principal Investigator, Co-Investigator, etc.*)

Brief summary of the scope of work:

Title of Proposal:

Funding Agency/Requiring Activity:

Estimated Dates of Funding:

Proposed Total Direct Costs:

Role: (*i.e. Principal Investigator, Co-Investigator, etc.*)

Brief summary of the scope of work:

[Add additional fields, if needed, to report all pending support]