Request for Project Proposals

Solicitation Number: MTEC-20-01-Hemorrhage
"Hemorrhage Detection Technology"

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: November 6, 2019

White Paper Due Date: December 6, 2019
Noon Eastern Time

White Papers are Required

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1 Request for Project Proposal Overview

1.1 Medical Technology Enterprise Consortium

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 Development Command (USAMRDC) and other Government agencies in the biomedical sciences (including but not limited to drugs, biologics, vaccines, medical software and medical devices) to protect, treat and optimize the health and performance of U.S. military personnel. MTEC is a nonprofit corporation with the following principal objectives:

(a) 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/.

MTEC operates under a prototype Other Transaction Agreement (pOTA) with USAMRDC. 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.

1.2 Purpose

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 U.S. Army Medical Materiel Development Activity (USAMMDA). The award(s) will be managed by the Warfighter Expeditionary Medicine and Treatment (W-EMT) Project Management Office (PMO). The Hemorrhage Detection Integrated Product Team (IPT) will provide consultative input into the

project as needed, and conduct annual in-progress reviews with the Milestone Decision Authority, as well as interim reviews if needed more frequently.

This Request for Project Proposals (RPP) is focused on the development of a noninvasive technology for early diagnosis and provider alert of decompensation due to hemorrhage and hemorrhagic shock in order to inform earlier lifesaving interventions and improve patient outcomes (see Section 2 for more detail).

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 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.

1.5 MTEC Member Teaming

While teaming is not required for this effort, Offerors are encouraged to consider teaming during the proposal preparation period (prior to proposal submission) if they cannot address the full scope of technical requirements of the RPP or otherwise believe a team may be beneficial to the Government.

MTEC members are encouraged to use the MTEC Database Collaboration Tool. The purpose of the tool is to help MTEC member organizations identify potential teaming partners by providing a quick and easy way to search the membership for specific technology capabilities, collaboration interest, core business areas/focus, R&D highlights/projects, and technical expertise. The Primary Point of Contact for each member organization is provided access to the collaboration database tool to make edits and populate their organization's profile. There are two sections as part of the profile relevant to teaming:

- "Collaboration Interests" - Select the type of teaming opportunities your organization would be interested in. This information is crucial when organizations need to search the membership for specific capabilities/expertise that other members are willing to offer.
- "Solicitation Collaboration Interests" - Input specific active solicitations that you are interested in teaming on. This information will help organizations interested in a specific funding opportunities identify others that are interested to partner in regards to the same funding opportunity. Contact information for each organization is provided as part of the member profile in the collaboration database tool to foster follow-up conversations between members as needed.

The Collaboration Database Tool can be accessed via the "MTEC Profiles Site" tab on the MTEC members-only website.

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 may 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 format provided in the PPG.

1.7 Potential Funding Availability and Period of Performance

The U.S. Government (USG) currently has available approximately $2 million (M) Defense Health Program (DHP) Research, Development, Test, and Engineering (RDT&E) dollars for Fiscal Year (FY)

2019. An additional $2.75M of FY20 DHP funding may be available for potential follow-on work for the continuation of prototype development.

MTEC anticipates that one or more awards will be made to qualified teams composed of teaming arrangements demonstrated to develop a hemorrhage detection technology prototype through demonstration in a relevant or operational environment.

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.

The anticipated base Period of Performance (POP) is not to exceed 1 year.

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 and Directors 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 meet at least one of the following conditions:

- Have at least one nontraditional defense contractor or nonprofit research institution participating to a significant extent
- All significant participants 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).
- 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.

1.11 White Paper Submission

Instructions on how to submit are included in the RPP version that is posted on the 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 White Papers as the prime contractor must be MTEC members of good standing by **Tuesday, December 3, 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

Hemorrhage is the leading cause of trauma-related death in both civilian and military populations. More than 33% of prehospital deaths and 50% of deaths occurring within 24 hours of traumatic injury are from hemorrhage. Approximately 50% of combat-related preventable deaths that take place before reaching a military treatment facility (MTF) are hemorrhage related. A study of 4,596 battlefield fatalities from Operation Iraqi Freedom and Operation Enduring Freedom determined that hemorrhage accounted for 91% of potentially survivable fatalities occurring prior to arrival at an MTF[1]. This supports the vital need for early detection and intervention.

This program is intended to support the development or implementation of technological solutions that can provide early diagnosis information and alert of decompensation due to hemorrhage and hemorrhagic shock in order to inform earlier lifesaving interventions and improve patient outcomes. Offerors should only propose potential devices and technology solutions that meet the following three criteria:

1. Currently be at a Technology Readiness Level (TRL) of 5 or above [definition of TRL – https://mtec-sc.org/wp-content/uploads/2016/12/TRL-definitions.pdf]
2. Currently be in development or commercially available; and
3. Must be capable of meeting the requirements specified below for use in forward deployed environments and patient transport.

Solution Requirements:
An ideal solution would meet the following requirements (not listed in order of importance):

- Have the ability to non-invasively monitor and alert the provider:
    - when a patient is decompensating and at risk of impending hemorrhagic shock earlier than indicated by traditional vital signs or clinical practice, or

[1] Eastridge, B.J., Mabry, R.L., Seguin, P., Cantrell, J., Tops, T., Uribe, P., …Backbourne, L.H. (2012). Death on the battlefield (2001-2011): Implications for the future of combat casualty care. *Joint Trauma and Acute Care Surgery,* 73(6), S431-S437.

  - that a patient is experiencing significant hemorrhage that, if untreated, will inevitably lead to hemorrhagic shock

- Be easily usable by combat medics and or physicians assistants at a Battalion Aid Station (or equivalent Service providers at Role 1) and during patient transport [Refer to the Emergency War Surgery for Role of Care definitions:

  https://www.cs.amedd.army.mil/FileDownloadpublic.aspx?docid=6f9e0685-1290-4e92-8277-c1e7b0f2fef0]

- Achieve FDA clearance/approval for use in trauma patients aged 18-65
- Provide data analysis and definitive output in real time or near real-time
- Integrated into or replace an existing patient monitoring device; or be a small portable device (4 ounces, 4 cubic inches)
- Requires no specialized personnel, maintenance requirements, or tools to operate or maintain the system
- Be compatible with military operational environments (e.g., low visibility, extreme temperature variation (hot and cold), blackout conditions)
- Be capable of passing airworthiness, safe-to-fly testing which includes electrical-magnetic interference testing, vibration testing, and crash testing [Note: Air Worthiness is a critical specification to include in the product development, but accomplishing the certification would happen much later. Explaining how you would work towards that end goal would be important, even if it isn't achievable at the end of this initial period of performance.]
- Be capable of meeting environmental testing parameters (such as drops/vibration, dust/rain/humidity and extreme temperatures) as stated in MIL STD 810H
- Be capable of meeting Risk Management Framework requirements, as applicable (NIST Special Publication 800-37, Guide for Applying the Risk Management Framework) to gain authority to operate on military networks

Although White Papers that propose to meet all of the solution requirements outlined above are preferred, we encourage you to submit even if you cannot currently meet all these specifications within this time frame. The Government may consider lesser responses based upon the parameters that could be met and the team's approach to meeting the other requirements over time. However, it is expected that an Offeror's White Paper will describe in detail what they plan to accomplish and how they plan to satisfy all of the solution requirements at some point in time.

Government Furnished Information (GFI):
Two Government laboratories have previously developed algorithms to detect decompensation due to hemorrhage using standard vital sign monitors:

- The Automated Processing of the Physiologic Registry for Assessment of Injury Severity (APPRAISE) algorithm from the Biotechnology High Performance Computing Software Applications Institute (BHSAI)
- The Compensatory Reserve Measurement (CRM) algorithm from U.S. Army Institute of Surgical Research (USAISR)

Since Government laboratories are not eligible to serve as the prime contractor of white papers in response to MTEC funding opportunities, we encourage potential Offerors to partner with these laboratories as appropriate. The Sponsor neither endorses one algorithm as preferable over the other, nor over any algorithms developed by industry or academia.

*NOTE: There is ample information publicly available regarding the APPRAISE and CRM algorithms. If you include one of these algorithms as part of your technical approach and you are invited for Full Proposal submission, then you will be provided with a point of contact at the respective Government laboratory to work with on your full proposal. Contact information for the Government laboratory partners will not be provided by MTEC at this time.

Project Scope and Potential for Follow-on Work:
The initial 12 month delivery schedule should be focused on tasks relevant to prototype development through proof of concept in a clinical study or system prototype demonstration in a relevant or operational environment for detection of decompensation due to hemorrhage and hemorrhagic shock. Allowable costs include subject matter expertise, consultation to develop a regulatory strategy, testing and evaluation, and clinical trial support. Potential follow-on work in subsequent years may be awarded to continue product development toward additional human clinical trial(s) and relevant FDA clearance/approval.

Additional points of consideration:

- **Project Maturity:** This solicitation is not meant to support development of a new prototype, but should focus on fine tuning and optimization of existing prototypes or other technologies.

- **Industry Partners:** MTEC considers that a proposal involving an industry partner (or alternative organizations) to serve as the regulatory sponsor and commercialization partner may have the greatest level of success, especially considering that the eventual goal is to obtain FDA clearance/approval.

- **Cost Share:** It is anticipated that the Government funds would provide incentive for industry funding to join the project. While not a requirement, Offerors are strongly encouraged to include Cost Share as appropriate.

3 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 Approach: Reviewers will assess for technical approach based on: i) how well the white paper defines a prototype that can already meet or be modified to meet the requirements of the ideal solution as set forth in this RPP; ii) whether the prototype is based on promising preliminary data, sound scientific rationale, and demonstrated proof-of-concept; and iii) how well the proposed methodology supports the technical objectives and the development of the prototype.

(2) Project Management: The soundness of the detailed schedule that shows the project can be completed within the proposed timeline, and whether the background and expertise of the personnel are appropriate to accomplish the proposed development, test, and evaluation.

(3) Cost: Assessment of the cost of the project and the estimated cost of the final device and consumables after modifications have been made.

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 will be provided feedback on the evaluation.

3.1.3 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 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 is 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 at mtec-contracts@ati.org
- Technical and membership related questions should be directed to the MTEC Director of Research, Dr. Lauren Palestrini, Ph.D., lauren.palestrini@officer.mtec-sc.org
- All other questions should be directed to Ms. Kathy Zolman, MTEC Director of Program Operations, 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

APPRAISE	Automated Processing of the Physiologic Registry for Assessment of Injury Severity
ATI	Advanced Technology International
BHSAI	Biotechnology High Performance Computing Software Applications Institute
CAS	Cost accounting standards
CM	Consortium Manager
CMA	Consortium Member Agreement
CRM	Compensatory Reserve Measurement
DoD	Department of Defense
DUNS	Data Universal Numbering System
F&A	Facilities and Administrative Costs
FAQ	Frequently Asked Questions
FDA	Food and Drug Administration
FY	Fiscal Year
G&A	General and Administrative Expenses
GFI	Government Furnished Information
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IPT	Integrated Product Team
IR&D	Independent Research and Development
M	Million
MTEC	Medical Technology Enterprise Consortium
MTF	Military treatment facility
NDA	Nondisclosure Agreement
NDC	Nontraditional Defense Contractor
NRI	Nonprofit Research Institution
OCI	Organizational Conflict of Interest
ODC	Other Direct Costs
PMO	Project Management Office
pOTA	Prototype Other Transaction Agreement
POC	Point-of-Contact
POP	Period of Performance
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
TRL	Technology Readiness Level
USAISR	U.S. Army Institute of Surgical Research

USAMMDA	U.S. Army Medical Materiel Development Activity
USAMRDC	U.S. Army Medical Research and Development Command
USG	U.S. Government
W-EMT	Warfighter Expeditionary Medicine and Treatment

Attachment 1 - MTEC White Paper Template

General Requirements: Each White Paper is limited to five pages plus a cover page (6 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-19-12-Hemorrhage"

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 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 (5 pages)

Title: [Insert descriptive title of project]

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

Technical Approach: [Focus this section by responding to the specific information requested below]

a) Describe the existing technology, including the TRL, and its ability to detect hemorrhage leading to shock or early signs of shock from the far forward point of injury to a medical treatment facility, including during patient transport

b) Describe the existing technology's detection method and corresponding output for assisting clinical decision

c) Describe any Personally Identifiable Information data that is captured or stored on the device

d) Describe how the existing technology meets the requirements of the ideal solution as stated in Section 2 of this RPP; or how the technology could be modified to meet the requirements

e) What is the estimated or actual cost per device as it stands today and at the point of commercialization; include any parts, supply, and consumable items, as well as training, software maintenance, and manuals

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.]

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 (by Task):
[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.

****The ROM must be broken by task (in other words, provide a separate ROM for each of the two tasks):**

a) **For initial prototype development through proof of concept in human**
b) **For any additional proposed work toward relevant FDA clearance/approval**

	Task 1	*Task 2*	*Total*
Labor	*$ 100,000.00*	*$ 100,000.00*	*$200,000.00*
Subcontractors	*$ 50,000.00*	*$ 50,000.00*	*$100,000.00*
Consultants	*$ 10,000.00*	*$ 10,000.00*	*$20,000.00*
Material/Equipment	*$ 75,000.00*	*$ 75,000.00*	*$150,000.00*
Other Direct Costs	*$ 1,000.00*	*$ 1,000.00*	*$2,000.00*
Travel	*$ 5,000.00*	*$ 5,000.00*	*$10,000.00*
Indirect costs	*$ 48,200.00*	*$ 48,200.00*	*$96,400.00*
Total Cost	*$ 289,200.00*	*$ 289,200.00*	*$578,400.00*
Fee *(Not applicable if cost share is proposed)*	*$ 0.00*	*$ 0.00*	*$0.00*
Total Cost (plus Fee)	*$ 289,200.00*	*$ 289,200.00*	*$578,400.00*
Cost Share (if cost share is proposed then fee is un-allowable)	*$ 290,000.00*	*$ 290,000.00*	*$580,000.00*
Total Project Cost	*$ 579,200.00*	*$ 579,200.00*	*$1,158,400.00*

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 5) 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 new key technology, product or process
2. Supplying a novel application or approach to an existing technology, product or process
3. Providing a material increase in the performance, efficiency, quality or versatility of a key technology, product or process
4. Accomplishing a significant amount of the prototype Project
5. Causing a material reduction in the cost or schedule of the prototype project

Inclusion of Nontraditional Defense Contractors

Proposals that do not include small business or 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)

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), 2) all significant participants other than the Federal Government being Small Businesses or 3) 1/3 cost share on projects. One of the primary reasons for elimination from further consideration is noncompliance with this statutory requirement.

Evaluation Process

To ensure both scientific excellence and programmatic relevance, the USAMRDC administers a two-tier review process where all proposals/applications are evaluated by scientists and clinicians. The first tier is peer review, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. 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. The highest-scoring proposals/applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors and programmatic relevance.

Evaluation Factors

1. Technical Approach
2. Potential for Transition and Commercialization
3. Cost/Price

Evaluation factors are listed in descending order of importance.

Military evaluation panel reviewers will be responsible for making notations in each evaluation factor and providing a consolidated response to proposers upon completion of the evaluation and selection process.

Table 2 explains the adjectival merit ratings that will be used for the Technical Approach Factor, and Potential for Transition and Commercialization factor.

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

Evaluation Factor 1. Technical Approach
The Technical Approach factor will be evaluated using the merit rating as shown in Table 2.

The Offeror's proposed solution will be assessed for the likelihood of successfully achieving the requirements of the technology of interest as defined in Section 2 above. The likelihood of success will be determined by considering the soundness and clarity of the technical approach. Additional consideration will be given to the degree to which any preliminary existing data supports the proposed project plan and the suitability of the proposed statistical plan. The SOW should provide a succinct approach for achieving the project's objectives. The SOW will be evaluated for how well the rationale, objectives, and specific aims support the proposed research. The effort will be assessed for the extent to which the solution is technologically innovative and how the proposed deliverable advances the TRL Military relevance is a critical

component of proposal submission. This relevance includes the health care needs of military Service members, Veterans, and/or other Military Health System beneficiaries and the extent to which the proposal offers a joint Service solution. A description of the project team's expertise, key personnel, and corporate experience should demonstrate an ability to execute the SOW.

Evaluation factor 2: Potential for Transition and Commercialization
The Potential for Transition and Commercialization factor will be evaluated using the merit rating as shown in Table 2.

The Offeror's proposal will be assessed for:

a) How well the Offeror provides sufficient evidence that the effort is ready to move into the proposed stage of research, development, or clinical testing.
b) How well the project will translate promising, well-founded basic or clinical research findings into clinical applications for military Service members and or their beneficiaries.
c) How well the funding strategy described will advance the technology to the next level of development and/or delivery to the military or civilian market.
d) How well the proposal identifies intellectual property ownership, describes any appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development.
e) How well the regulatory strategy is described, if applicable.

Evaluation Factor 3. Cost/Price
The Cost/Price area will receive a narrative rating to determine whether costs are realistic, reasonable, and complete.

The MTEC CM will evaluate the estimated cost proposed by the Offeror for performing all requirements outlined in this RPP and the 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. 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, 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:

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

b) 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.

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

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

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

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 Technical Approach 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 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.

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:			

☐	**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 subcontractor/vendor 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 subcontractor/vendor will increase medical technology performance.** *Please describe what the performance increase will be attained by the use of this designated nontraditional defense contractor*
1	**In addition to the above please provide the following information:**

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 current support]