Request for Project Proposal

Solicitation Number: MTEC-19-07-Biomfg

"Biomanufacturing for Regenerative Medicine (Biomfg)"

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: February 19, 2019

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

White Papers are Required

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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" government contractors, academic research institutions and not-for-profit organizations. For more information on the MTEC mission, see the MTEC website https://mtec-sc.org/.

This solicitation, issued by the MTEC Consortium Manager (CM), Advanced Technology International (ATI), represents a Request for Project Proposals (RPP) for MTEC support of the USAMRMC Clinical and Rehabilitative Medicine Research Program (CRMRP). Strategic oversight for the award(s) supported by this RPP will be provided by will be provided by Joint Program Committee 8 (JPC-8)/CRMRP.

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.

1.2 Background

Applications for this Request for Project Proposals (RPP) are being solicited for the Defense Health Agency, J-9 Research and Development (DHA R&D) Directorate. As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA J-9 R&D Directorate manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation.

The JPC-8/CRMRP, DHA J-9 R&D Directorate, and OASD(HA) have identified a need for regenerative medicine prototype development efforts and manufacturing technologies. Current Good manufacturing practice (cGMP) quality is a requirement by the FDA and European Medicines Agency to provide patients with clinical-grade products that are safe and have defined quality characteristics. However, standardization and robust manufacturing techniques are lacking in regenerative medicine, which will continue to impede progress in advancing regenerative medicine based technologies and treatments toward the clinic.

Based on this, **the major objective of this RPP is to develop scalable, production-ready, commercial prototypes and processes for cell, tissue, or organ bioengineering technologies that will overcome current challenges and enable successful cGMP manufacturing and clinical translation of regenerative medicine based therapies**. Technologies of interest include, but are not limited to (see Section 2 for more details):

1. Bioreactors to enable efficient and cost-effective cell and tissue expansion for regenerative medicine products
2. Cell, tissue, and product preservation for regenerative and personalized medicine
3. Large scale manufacturing and quality assurance of regenerative medicine- based products
4. Dynamic and innovative quality assurance strategy for regenerative medicine manufacturing

This RPP is a follow-on effort to MTEC's previous (2016) Regenerative Medicine Manufacturing RPP, where several technologies of interest were previously funded.

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 CRMRP focuses on innovations to reconstruct, rehabilitate, and provide definitive care for injured Service members. The ultimate goal is to return the Service members to duty and restore their quality of life. Innovations developed from CRMRP-supported research efforts are expected to improve restorative treatments and rehabilitative care to maximize function for return to duty (RTD) or civilian life. The CRMRP interest is in medical technologies (drugs, biologics, and devices) and treatment/rehabilitation strategies (methods, guidelines, standards, and information) that will significantly improve the medical care provided to our wounded Service members within the DoD health care system. Implementation of these technologies and strategies should improve: the rate of RTD of Service members, the time to RTD, clinical outcome measures, quality of life, as well as reduce the hospital stay lengths, clinical workload (patient encounters, treatments, etc.), and initial and long-term costs associated with restorative and rehabilitative or acute care. The CRMRP focuses its efforts on the following research areas: neuromusculoskeletal injury (including amputees), sensory systems (including hearing, balance, tinnitus, and vision), acute and chronic pain, and regenerative medicine.

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 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

The U.S. Government (USG) currently has available approximately $6 million (M) of Fiscal Year (FY) 2018 DHP RDT&E appropriation to support proposals received in response to this RPP. The USG expects to fund two awards at $3M (direct and indirect costs) each. Funding is dependent on the quality and number of proposals received.

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 Period of Performance (POP) is not to exceed four 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 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 Proposal. 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

Standardization and robust manufacturing techniques are lacking in regenerative medicine, which will continue to impede progress in advancing regenerative medicine based technologies and treatments toward the clinic. This is likely due to many factors which need to be developed and advanced, including:

(1) Advancing bioreactor technology for cost-effective cell and tissue expansions
(2) Improving cell, tissue, and organ preservation technology
(3) Innovating and advancing large scale manufacturing and quality assurance for regenerative medicine based products
(4) Developing dynamic and innovative quality assurance strategies for regenerative medicine manufacturing

As stated in Section 1.2, the major objective of this solicitation is to develop scalable, production-ready, commercial prototypes and processes for cell, tissue, or organ bioengineering technologies that will overcome current challenges and enable successful cGMP manufacturing and clinical translation of regenerative medicine based therapies.

This RPP is a follow-on effort to MTEC's previous (2016) Regenerative Medicine Manufacturing RPP, where several technologies of interest were funded.

Technologies of interest include, but are not limited to, the following:

1. **Bioreactors to enable efficient and cost-effective cell and tissue expansion for regenerative medicine products**

   For many regenerative medicine therapies, millions of cells are required for each patient. The cell and tissue expansion phase of the manufacturing process is by far the most expensive and time consuming step, often requiring several months to reach economically-viable numbers of cells. There is a significant need for alternatives to flat plate culture technologies for efficient and cost-effective cell and tissue expansion. Areas of interest to enhance cell expansion for regenerative medicine products include, but are not limited to:

a. Non-invasive or minimally-invasive in-process technologies that can monitor key parameters of the expansion process, including but not limited to: cell viability, cell number, endotoxin content, mycoplasma
b. Non-destructive cell harvesting technologies
c. Single-use bioreactors for the scale-up of cells
d. Infrastructure to allow cell expansion to occur in parallel
e. Cell purification processes
f. Scale up the production of organoids for industrial use

2. Cell, tissue, and product preservation for regenerative and personalized medicine

Biobanking and biopreservation offers the possibility to preserve cells and tissue sources for future use. For regenerative and personalized medicine, these cells and tissues are later developed into products that need to be preserved to maintain activity during production, through manufacturing release, and ultimately to patient application. Therefore, there is a need to develop advanced, cost-effective technologies and processes for banking cells and tissues, and preserving regenerative medicine-based products to assist with shipping and distribution. Areas of interest include, but are not limited to:

a. Novel preservation methods (e.g., non-cryogenic) that can be used on tissue engineered products during storage, shipping and distribution (including adverse environments such as austere conditions)
b. Advanced systems and processes for cell and tissue preservation, including specimen harvest, cell retrieval, and tissue-typing
c. Tests or methods to analyze or determine cell, tissue, or product viability/function following short-term and long-term storage

3. Large scale manufacturing and quality assurance of regenerative medicine- based products

Regenerative medicine products in early development are often fabricated using laboratory-based processes and lack defined product specifications. Therefore, the intent of this area of interest is to transfer these laboratory-based processes into scalable, production-ready, commercial manufacturing processes for cell, tissue, or organ bioengineering products with defined acceptance criteria. Specific areas of interest include, but are not limited to:

a. Scalable, production-ready, commercial additive manufacturing, such as 3D printing for regenerative medicine applications
b. Automated tissue digestion systems
c. High throughput cell sorting technology
d. High throughout cell separation/isolation from media
e. Automated manufacturing processes for regenerative medicine products (scaffolds and/or bioactive molecules and/or cells)

f. Develop large scale systems capable of screening and engineering adult stem cells

4. **Dynamic and innovative quality assurance strategy for regenerative medicine manufacturing**

   The identification and specification of standards and acceptance criteria are important for the regulatory approval of all implantable, manufactured products. Regenerative medicine-based products tend to have qualitative product acceptance criteria, which are difficult to standardize. Therefore, there is a need to develop and advance methods for quality assurance to assess process changes in regenerative medicine product manufacturing as well as in cell, tissue, and bioengineered organ product characteristics and function. Areas of interest to enhance the quality assurance strategy of regenerative medicine products include, but are not limited to:

   a. Systems that can provide rapid batch testing for the evaluation of a production run
   b. Automated and non-destructive imaging systems for inspection and characterization of tissue engineered products
   c. Non-destructive in-process technologies that can monitor key parameters of the manufacturing process

Additional points of consideration:

- **Military Relevance:** Although this RPP focuses on manufacturing efforts, the product that will be produced by the manufacturing processes and validation testing should be one that meets military need. Example areas of military need are: composite tissue regeneration, vascular repair/revascularization, nerve regeneration, bone regeneration, muscle protection/regeneration, treatment of burns and large skin injuries, and regeneration of the genitourinary system.

- **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. This is not meant to support pilot lot manufacturing for animal study purposes.

- **Industry Partners:** It is expected that many of the actual regenerative medicine projects may still be at the academic level, yet the manufacturing requirements demanded are most suited to industry. MTEC, therefore, considers that a teamed approach may have the greatest level of success, especially considering that the eventual goal is to transition products to industry for FDA approval.

- **Cost Share:** The Government funds provided for this biomanufacturing initiative are not anticipated to be the sole funding resource for the efforts. Because the RPP is focused on prototyping and manufacturing capabilities, 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) Research Strategy:

a. Whether the proposed work supports the objectives of at least one of the JPC-8/CRMRP Focus Areas.

b. How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.

c. How well the white paper defines a prototype that meets the requirements set forth in this RPP. Whether the prototype is based on promising preliminary data, sound scientific rationale, and demonstrated proof-of-concept.

(2) Personnel and Team:

a. How the background and expertise of the personnel and organizations are appropriate to execute the proposed research.

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.

To ensure both scientific excellence and programmatic relevance, the USAMRMC 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.

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 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
CAS	Cost accounting standards
cGMP	Current Good manufacturing practice
CM	Consortium Manager
CMA	Consortium Member Agreement
CRMRP	Clinical and Rehabilitative Medicine Research Program
DHA	Defense Health Agency
DHP	Defense Health Program
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
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
JPC	Joint Program Committee
M	Million
MTEC	Medical Technology Enterprise Consortium
NDA	Nondisclosure Agreement
OCI	Organizational Conflict of Interest
ODC	Other Direct Costs
OASD[HA]	Office of the Assistant Secretary of Defense for Health Affairs
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
RTD	Return to duty
RPP	Request for Project Proposals
SOW	Statement of Work
TRL	Technology Readiness Level
USAMRMC	U.S. Army Medical Research and Materiel Command
USG	U.S. Government

Attachment 1 - MTEC White Paper Template

General Requirements: Each White Paper is limited to four pages plus a cover page (5 pages total). The White Paper must be in 11 point (or larger) type font, single-spaced, single-sided, on 8.5 inches x 11 inches paper. Smaller font may be used in figures and tables, but must be clearly legible. Margins on all sides (top, bottom, left, and right) should be at least 1 inch. The MTEC staff will share 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-19-07-Biomfg"

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 (4 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.]

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

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

Technical Strategy: [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 Relevance: [Provide a description of how the proposed technology meets the needs of Clinical and Rehabilitative Medicine 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.]

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

Rough Order of Magnitude (ROM) Pricing:
[Required: Indicate the ROM (including indirect costs), and the proposed ROM. This information will be used to provide the Sponsor with a reasonable representation of the amount of funding required to advance the project.] Sufficient cost information to substantiate the proposed cost as realistic and reasonable for the proposed effort must be provided to ensure that a complete and fair evaluation of the cost or price can be conducted. **Use the table format below as an example to provide an initial ROM.** The labor, travel, material costs, other direct costs, and indirect costs, information should be entered for Offeror (project prime) only. Subcontractors and/or consultants should be included only in the "Subcontractor" section of the table.]

Labor	*$ 100,000.00*

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

EXAMPLE

Attachment 2 – Nontraditional Defense Contractor

Nontraditional Defense Contractor Definition

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

Nontraditional Defense Contractor Requirements

If the Offeror asserts either (1) it is a nontraditional defense contractor or (2) proposes a nontraditional defense contractor as a team member/subcontractor, the Offeror shall submit Warranties and Representations (Attachment 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 key technology or products
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)

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.

Evaluation Process

To ensure both scientific excellence and programmatic relevance, the USAMRMC 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]