

Request for Project Proposals



Solicitation Number: MTEC 19-04-WRAIR-CARB
“Small molecule antibiotic drug development for Combating Antibiotic Resistant Bacteria (CARB)”

Advanced Technology International (ATI),
MTEC Consortium Manager (CM)
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Summerville, SC 29486
for the
Medical Technology Enterprise Consortium (MTEC)

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Proposal Due Date: January 24, 2019
Noon Eastern Time

White Papers are Required

Table of Contents

1	Request for Project Proposal Overview	3
1.1	Purpose.....	3
1.2	Background.....	4
1.3	Acquisition Approach	4
1.4	Proposers Conference	4
1.5	Request for White Papers and Process Stages	5
1.6	Potential Funding Availability.....	5
1.7	Proprietary Information	6
1.8	Cost Sharing Definition.....	6
1.9	Cost Share Requirements.....	6
1.10	White Paper Submission	7
1.11	Submission Format.....	7
1.12	White Paper Preparation Cost	7
2	Technical Requirements	7
3	Selection/Evaluation Criteria	9
3.1	Stage 1: White Papers	9
3.1.1	Compliance Screening.....	9
3.1.2	Selection Criteria.....	10
3.2	Stage 2: Full Proposal Evaluation	10
4	Other Factors to Consider.....	10
5	Points-of-Contact	11
6	Acronyms/Abbreviations	12
	Attachment 1 - MTEC White Paper Template	14
	Attachment 2 – Nontraditional Defense Contractor or Nonprofit Research Institutions	17
	Attachment 3 – Cost Share	18
	Attachment 4 – Stage 2 Evaluation Criteria.....	19
	Evaluation Factor 1. Technical Approach	20
	Evaluation factor 2: Potential for Transition and Commercialization	19
	Evaluation Factor 3. Cost/Price.....	20
	Best Value	22
	Definition of General Terms Used in Evaluations:.....	23
	Attachment 5 – Warranties and Representations.....	24
	Attachment 6 - MTEC Requirements	29
	Attachment 7 – IP Rights	29

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.

*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.

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

This solicitation, issued by the MTEC Consortium Manager (CM), Advanced Technology International (ATI), represents a Request for Project Proposals (RPP) for MTEC support of the Walter Reed Army Institute of Research (WRAIR) technology objectives. Military relevance is a critical component of the White Paper submission. Strategic oversight for the award(s) supported by this RPP will be provided by the Division of Experimental Therapeutics (ET) and Bacterial Diseases Branches (BDB) at Walter Reed Army Institute of Research (WRAIR).

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

related to a prototype. The quantity should generally be limited to that needed to prove technical or manufacturing feasibility or evaluate military utility.

1.2 Background

Problem Definition:

The goal of this RPP is to develop an effective antibacterial small molecule or compound class that overcomes drug resistance mechanisms in a narrow (genus) or broad (gram-negative) spectrum of multidrug-resistant (MDR) clinical isolates.

Limitations of current technology:

Skin and soft tissue infections caused by the ESKAPE pathogens (*Enterococcus faecium*, *Staphylococcus aureus*, *Klebsiella pneumoniae*, *Acinetobacter baumannii*, *Pseudomonas aeruginosa*, and *Enterobacter species*) are of serious concern for hospitalized Wounded Warriors. These infections are often MDR can lead to amputations, amputation revision, sepsis, and death. Current antibiotics are becoming less efficacious as resistance is being built into the military population. A new therapeutic with extensive coverage and acceptance is required.

Overall end goal of program:

The prototype compound (pre-clinical candidate) must be efficacious against clinically-relevant gram negative bacteria in animal infection models, have clinically acceptable pharmacokinetics and dynamics for oral or parenteral administration, and a low-to-acceptable toxicity profile.

RPP Objective:

The focus of this RPP is to recruit a partner(s) (i.e., antibiotic (AB)-focused pharmaceutical companies and/or product-focused academic/non-profit research institutions) to move an AB hit or early lead molecule from lead optimization or early preclinical development to a preclinical decision. The Offeror can utilize this funding independently, or propose to partner with WRAIR ET and BDB AB test systems to complete the workplan. See Section 2 for more information.

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 Sponsor (i.e., WRAIR) 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.

1.4 Proposers Conference

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

1.5 Request for White Papers and Process Stages

MTEC recognizes that considerable effort is required to prepare a competitive proposal to MTEC. The two-stage approach for this RPP is intended to streamline the initial proposal preparation time and effort for MTEC members. Based on the Government's evaluation of White Papers in Stage 1, select Offerors will be invited to participate in Stage 2 and will be required to submit a full proposal for more detailed evaluation.

The due date for White Papers is found on the cover page of this RPP. White Papers will not be considered under this RPP unless the White Paper was received on or before the due date specified on the cover page.

Stage 1: White Papers submitted under this RPP must 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)/Milestone Payment Schedule** according to the format provided in the notification letter.
- **Cost Proposal** according to the format provided in the PPG.

1.6 Potential Funding Availability

The U.S. Government (USG) potentially has available \$1 Million (M) Defense Health Program (DHP) Research, Development, and Engineering (RD&E) dollars.

As of the release date of this RPP, future year Defense Appropriations Bills have not been passed and there is no guarantee that any additional funds will be made available to support this program. The funding estimated for this RPP is approximate and subject to adjustments or realignment. Funding of white papers and 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 and Deliverables.

MTEC anticipates that one award at \$ 1M (direct and indirect costs) will be made to a qualified team who demonstrates the ability to achieve the technical objectives of this RPP.

The Period of Performance (POP)/delivery schedule is not to exceed 24 months.

1.7 Proprietary Information

The MTEC CM will oversee submission of proposals and analyze cost proposals submitted in response to this RPP. The MTEC CM shall take the necessary steps to protect all proprietary proposal information and shall not use such proprietary information for purposes other than the evaluation of an Offeror's proposal and the subsequent agreement administration if the proposal is selected for award. An Offeror's submission of a proposal under this RPP indicates concurrence with the aforementioned CM responsibilities. Also, as part of MTEC's mission to incorporate philanthropic donations, MTEC frequently makes contact with private foundations that award grants for research and operate in research areas that are aligned with those of MTEC. These private foundations may be interested in reviewing proposals within their program areas, allowing for opportunities to attract supplemental funding sources. On your White Paper Cover Page, please indicate your willingness to allow MTEC Officers, MTEC Staff, and Directors access to your Technical Proposal for the purposes of engaging in outreach activities with these private foundations. MTEC Officers and Staff who are granted proposal access have signed Nondisclosure Agreements (NDAs) and Organizational Conflict of Interest (OCI) statements. Additionally, these MTEC Officers, MTEC Staff, 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.

1.8 Cost Sharing Definition

Cost sharing is defined as the resources expended by the award recipients on the proposed statement of work (SOW). *The extent of cost sharing is a consideration in the evaluation of proposals.* If cost sharing is proposed, then the Offeror shall state the amount that is being proposed and whether the cost sharing is a cash contribution or an in-kind contribution; provide a description of each cost share item proposed; the proposed dollar amount for each cost share item proposed; and the valuation technique used (e.g., vendor quote, historical cost, labor hours and labor rates, number of trips, etc.). Cost sharing is encouraged if possible, as it leads to stronger leveraging of Government-contractor collaboration.

1.9 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 and nonprofit research institution requirements can be found at Attachment 2. For more information regarding cost share, please see Attachment 3.

1.10 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 **January 21, 2019**.

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

1.11 Submission Format

See Attachment 1 for the White Paper template. Files should be submitted in Microsoft Office formats or Adobe Acrobat (PDF – portable document format) as indicated below. ZIP files and other application formats are not acceptable. All files must be print-capable and without a password required. Filenames must contain the appropriate filename extension (.docx, .doc, or .pdf). Filenames should not contain special characters. Please follow the format and page requirements contained in Attachment 1 carefully. White Papers that do not meet these requirements are subject to disqualification at the sole discretion of the Government.

1.12 White Paper Preparation Cost

No project awards will be made based on White Paper submissions, nor will any reimbursement be provided for the information requested. Submission of a White Paper is voluntary and does not obligate the Government, the MTEC or the MTEC CM to pay or entitle the submitter to payment. Respondents are solely responsible for all expenses associated with preparing and submitting this White Paper.

2 Technical Requirements

Technical Objective: The WRAIR CARB effort is a sub-set of the 2015 CARB Presidential initiative wherein WRAIR was tasked to develop a preclinical AB candidate within five years.

The goal of this MTEC award will be to develop a small molecule AB candidate or chemical series with the following characteristics:

- Efficacious against clinically-relevant, MDR, Gram-negative bacteria in mean inhibitory concentration (MIC) 90 panels of relevant, MDR, clinical isolates. This efficacy can be either genus specific (narrow spectrum) for *Klebsiella*, *Acinetobacter*, or *Pseudomonas* species, or broadly effective against clinical Gram-negative pathogens.
- Efficacious against clinically-relevant MDR Gram-negative bacteria in standard animal soft tissue infection models (e.g., thigh and lung).

- *In vitro* and *in vivo* data supporting clinically acceptable pharmacokinetics and dynamics for oral or parenteral administration, an acceptable toxicity profile.

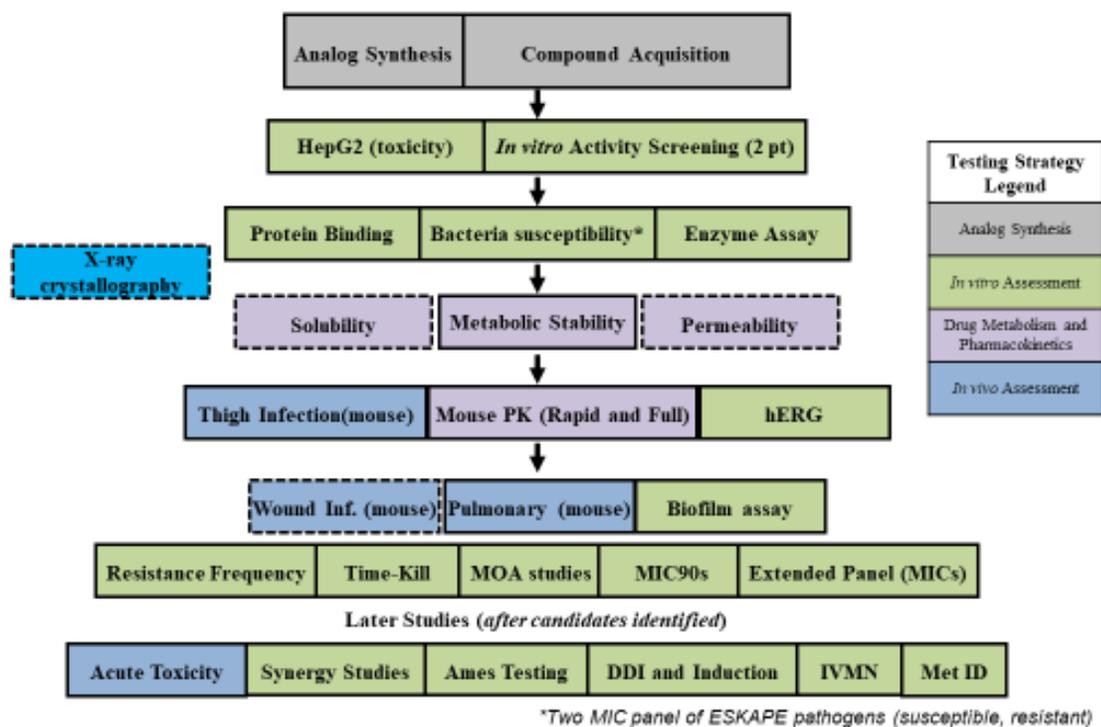
Offerors must propose studies that are IND-application-enabling, but Good Laboratory Practice (GLP)-compliant studies, at this stage of development, are not a requirement.

*Please note that awards are not to be exploratory in nature and require a foundation of preliminary data. Research involving animals is allowed and expected.

WRAIR's Capabilities: In 2016, WRAIR's Division of ET created an MDR Gram-negative AB target product profile (TPP), gated-tier testing paradigm (see below), and a portfolio of internal and external projects (using cooperative and inter-agency agreements [CA and IAA]) that cover the early, middle, and late stages of preclinical development. ET's and the BDB AB test systems include *in vitro* efficacy, metabolism, permeability, and solubility, as well as *in vivo* efficacy and pharmacokinetics (PK). The tiered testing strategy (displayed below) allows the WRAIR to conduct consistent and comparative testing that can allow for a down selection of candidate technologies for further development.

Offerors may propose a workplan that includes a partnership with WRAIR to execute the tests specified in this tiered testing strategy. This partnership is encouraged where appropriate. Offerors whose Stage 1 white papers are invited to Stage 2 of the RPP process for the submission of full proposals will have an opportunity to interface directly with WRAIR so that they can provide the appropriate level of detail into their development plans. MTEC will make an introduction to the appropriate WRAIR contact to those Offerors that are invited to submit full proposals at Stage 2 of the RPP process.

WRAIR ET/BDB Antibacterial Testing Strategy



Potential for Follow-on Work: The initial 24 month delivery schedule should be focused on the execution of animal testing and manufacturing required for an IND application for the desired indications. Follow-on work in subsequent years may be awarded to support:

- Conduct of clinical trials pursuant to an FDA marketing approval (New Drug Approval).
- Development of validated assays used to determine efficacy and potency of the product.
- Development of a GMP manufacturing capability.
- Conduct of collaborative animal testing to support FDA filings, such as toxicity studies.

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 criteria:

(1) Research Strategy:

- a. Whether the proposed work supports the objectives of the WRAIR. How well the research will address a healthcare issue relevant to military Service members.
- b. How well the specific aims and proposed methodology support the technical objectives and the development of the prototype.
- 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 accomplish the proposed research.
- b. Ability to execute the 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.

3.2 Stage 2: Full Proposal Evaluation

To the maximum extent practicable, the evaluation criteria found in Attachment 4 are anticipated for 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.

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 or MTEC Chief Operating Officer, Mr. Bill Howell, William.Howell@tunnellgov.com.
- 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

AB	Antibacterial
ATI	Advanced Technology International
BDB	Bacterial Diseases Branches
CARB	Combating antibiotic resistant bacteria
CAS	Cost accounting standards
CM	Consortium Manager
CMA	Consortium Member Agreement
CA	Cooperative agreement
DHP	Defense Health Program
DoD	Department of Defense
DUNS	Data Universal Numbering System
ESKAPE	<i>Enterococcus faecium, Staphylococcus aureus, Klebsiella pneumoniae, Acinetobacter baumannii, Pseudomonas aeruginosa, and Enterobacter species</i>
ET	Experimental Therapeutics
FDA	Food and Drug Administration
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practices
IAA	Inter-agency agreement
IND	Investigational new drug
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
M	Million
MDR	multidrug-resistant
MIC	Mean inhibitory concentration
MTEC	Medical Technology Enterprise Consortium
NDA	Nondisclosure Agreement
OCI	Organizational Conflict of Interest
OTA	Other Transaction Agreement
PDF	Portable Document format
PK	Pharmacokinetics
pOTA	Prototype Other Transaction Agreement
POP	Period of Performance/Delivery Schedule
PPG	Proposal Preparation Guide
RD&E	Research, Development, and Evaluation
ROM	Rough Order of Magnitude
RPP	Request for Project Proposals
PUL	Proposal Update Letter
SOW	Statement of Work
TPP	Target Product Profile

USAMRMC
USG
WRAIR

U.S. Army Medical Research and Materiel Command
U.S. Government
Walter Reed Army Institute of Research

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 Organization

Statement that “This White Paper is submitted pursuant to the RPP MTEC-19-04-WRAIR-CARB”

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 (OCI) statements.]

White Paper (4 pages)

Title: [Insert descriptive title of project]

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

Approach: [Briefly describe your approach to solving the problem. Include relevant background data about your approach. Include the current capabilities of the device to be modified, accuracy testing data summary results, source of accuracy testing, and summary results of other testing data. 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 that addresses the technical requirements described in this RPP. This section should identify any pilot or existing commercial methodology/technology or the development of such during the course of the work. If novel technology or methods are to be employed, then identify the path to maturation.]

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

Product Development Strategy: [Provide a description and justification of the maturity of the proposed technology, manufacturing, regulatory, and commercialization plans. Include information about Intellectual Property/Data Rights Assertions.]

Experience: [The White Paper shall describe the experience of the Principal Investigator, key personnel, partner organizations, and associated subject matters experts that are required to meet the program's objective and requirements. Identify any work of a similar nature that could be used to gauge the effectiveness and worthiness of the technical or methodological approach. This section should not highlight the contractual details of relevant experience, but should emphasize past work that is relevant and similar in nature (complexity, size, requirements) to this request and how that work's outcome relates to the expectations set forth in this RPP. Offerors should indicate how much of this relevant experience and past effort they will leverage for the proposed effort. Offeror may choose format and method of conveying this. If a novel approach is proposed, describe how this approach differs and why it may be more feasible than current commercial standards.]

Timeline: [Indicate the total proposed period of performance. Provide an estimated Gantt Chart of the major activities proposed.]

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

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). 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 unallowable)	\$ 290,000.00
Total Project Cost	\$ 579,200.00

Attachment 2 – Nontraditional Defense Contractor or Nonprofit Research Institutions

Nontraditional Defense Contractor Definition

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

Nontraditional Defense Contractor or Nonprofit Research Institution Requirements

If the Offeror asserts either (1) it is a nontraditional defense contractor or (2) proposes a nontraditional defense contractor as a team member/subcontractor, or (3) it is a nonprofit research institution, the Offeror shall submit Warranties and Representations (Attachment 4) specifying the critical technologies being offered and/or the significant extent of participation of the nontraditional defense contractor. The nontraditional defense contractor or nonprofit research institution can be an individual so long as he/she has a DUNS Number and meets the requirements in the Warranties and Representations. The significance of the nontraditional defense contractor's or nonprofit research institution's participation must be explained in detail in the signed Warranties and Representations. Inadequate detail can cause delay in award.

Per the DoD OT Guide, rationale to justify a *significant contribution* include:

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

Inclusion of Nontraditional Defense Contractors

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

Attachment 3 – Cost Share

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

Cash Contribution

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

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

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

In-Kind Contribution

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

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

Attachment 4 – Stage 2 Evaluation Criteria

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

Stage 2

Compliance Screening

The CM will conduct a preliminary screening of submitted proposals to ensure compliance with the RPP requirements. The Government reserves the right to request additional information or eliminate proposals that do not meet these requirements from further consideration. One of the primary reasons for elimination from further consideration is the lack of significant nontraditional defense contractor participation, nonprofit research institution participation, all small business participation, or cost share (see Section 1.8 above).

Evaluation Process

Stage 2 proposals will be evaluated by WRAIR ET/BDB to ensure both scientific excellence and programmatic relevance. Senior leadership at WRAIR ET/BDB will review and finalize the recommendations for funding.

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 5.2 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 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:			
<input type="checkbox"/>	A - The significant contribution involves developing, demonstrating or providing a key technology. <i>Please describe what the key technology is; why it is key to the medical technology community, and what makes it key.</i>		
<input type="checkbox"/>	B - The significant contribution involves developing, demonstrating or providing a new technology that is not readily available. <i>Please describe what the new part or material is and why it is not readily available.</i>		
<input type="checkbox"/>	C - The significant contribution involves use of skilled personnel (such as modeling & simulation experience, medical technology design experience, etc.), facilities and/or equipment that are within the capabilities of the designated nontraditional and required to successfully complete the program. <i>Please describe the personnel, facilities and/or equipment involved in the proposed program and why they are required to successfully complete the program.</i>		
<input type="checkbox"/>	D - The use of this designated subcontractor/vendor will cause a material reduction in the cost or schedule. <i>Please describe the specific cost or schedule impact to be realized</i>		
<input type="checkbox"/>	E - The use of this designated subcontractor/vendor will increase medical technology performance. <i>Please describe what the performance increase will be attained by the use of this designated nontraditional defense contractor</i>		
1 In addition to the above please provide the following information:			

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? <i>Note: While cost is an indicator for the level of nontraditional defense contractor participation, there is no particular cost threshold required.</i>
A3	

C. Signature

Signature of authorized representative of proposing Prime Contractor

Date

Warranties and Representations Instructions

Section A must be completed for the Prime Contractor.

1. Insert prime contractor's legal name.
2. Insert prime contractor's DUNS #.
3. Insert the Point of Contact (Name, Title, Phone #, Email) for the prime contractor.
4. Indicate Yes (Y) or No (N) if the prime contractor is a nontraditional defense contractor (Note: A nontraditional defense contractor means an entity that is not currently performing and has not performed, for at least the one-year period preceding the issue date of the solicitation, any contract or subcontract for the Department of Defense that is subject to full coverage under the cost accounting standards prescribed pursuant to Section 1502 of Title 41 and the regulations implementing such section.).
5. Indicate Yes (Y) or No (N) if the prime contractor is a nonprofit research institution.
6. Indicate Yes (Y) or No (N) if the 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 (i.e. will the project contain at least 1/3 cost share).
7. Indicate Yes (Y) or No (N) if the prime contractor is a small business (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)).

Section B must be completed if the Prime Contractor is **traditional** and has proposed nontraditional defense contractors, nonprofit research institutions, or small businesses. Copy, paste, and complete the table found in Section B **for each** participating nontraditional defense contractor, nonprofit research institutions, or small business.

8. Insert subcontractor/vendor's legal name.
9. Insert subcontractor/vendor's DUNS #.
10. Insert the dollar value (cost and fee) to be awarded to the subcontractor/vendor.
11. Insert the Point of Contact (Name, Title, Phone #, Email) for the subcontractor/vendor.
12. Indicate in which specific task/phase(s) of the effort will the subcontractor/vendor be used.
13. Indicate Yes (Y) or No (N) if the subcontractor/vendor is a nontraditional defense contractor (Note: A nontraditional defense contractor means an entity that is not currently performing and has not performed, for at least the one-year period preceding the issue date of the solicitation, any contract or subcontract for the Department of Defense that is subject to full coverage under the cost accounting standards prescribed pursuant to Section 1502 of Title 41 and the regulations implementing such section.).
14. Indicate Yes (Y) or No (N) if the subcontractor/vendor is a nonprofit research institution.
15. Indicate Yes (Y) or No (N) if the subcontractor/vendor is a small business (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)).
16. Explain the subcontractor/vendor's Significant Contribution to the project by answering the questions below.

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.***

Q1 - What additional capability beyond those described in A through E above does this subcontractor/vendor have that is necessary for this specific effort?

Q2 - In which task/phase(s) of the effort will the subcontractor/vendor be used?

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.

Section C must be signed by an authorized representative of the prime contractor.

General Guidance

- Nontraditional defense contractors can be at the prime level, team members, subcontractors, lower tier vendors, or "intra-company" business units, provided that the business unit makes a significant contribution to the prototype project.
- All nontraditional defense contractors must have a DUNS number.

A foreign business can be considered a nontraditional if it has a DUNS number and can comply with the terms and conditions of the MTEC Base Agreement.

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