

## Request for Project Proposals



Solicitation Number: MTEC-20-02-NavyMultiTopic  
**Navy Multi-Topic - Advanced Biomedical Product Development for Naval Operations**

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 27, 2020**

**White Paper Due Date: March 31, 2020**  
Noon Eastern Time

**White Papers are Required**

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## 1 Request for Project Proposal Overview

### 1.1 Executive Summary

The Medical Technology Enterprise Consortium (MTEC) is an enterprise partnership that collaborates with industry and academia to facilitate research and development activities in cooperation with the U.S. Army Medical Research and Development Command (USAMRDC) and other Government agencies in the biomedical sciences (including but not limited to drugs, biologics, vaccines, medical software and medical devices) to protect, treat and optimize the health and performance of U.S. military personnel. MTEC is a nonprofit corporation with the following principal objectives:

- (a) biomedical research and prototyping;
- (b) exploration of private sector technology opportunities;
- (c) technology transfer; and
- (d) development of intellectual property (IP) and follow-on production.

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

This solicitation, issued by the MTEC Consortium Manager (CM), Advanced Technology International (ATI), represents a Request for Project Proposals (RPP) for MTEC support of Naval Advanced Medical Development. Strategic oversight for the award(s) supported by this RPP will be provided by program managers at the Naval Advanced Medical Development office.

MTEC operates under an Other Transaction Agreement (OTA) for prototype projects 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 Purpose

The Purpose of this multiple topic area (“multi-topic”) RPP is focused on the advancement of engineering and medical prototypes and knowledge products related to a broad range of medical technological needs identified below. Relevance to the enhanced readiness and resilience of Navy and Marine Corps health and performance is a key feature of this RPP.

## 1.3 Acquisition Approach

The Government will solicit a total of five Technology Focus Areas (which are: (1) Casualty Care; (2) Medical Logistics Enhancement; (3) Human Performance; (4) Prolonged and En Route Care; and (5) Operational Readiness), distributed through two RPPs. **This is the first of the two RPPs which requests the submission of White Papers for the following Technology Focus Areas** with anticipated awards to be made during FY2020:

- Technology Focus Area #1: Casualty Care;
- Technology Focus Area #2: Medical Logistics Enhancement; and
- Technology Focus Area #3: Human Performance

The second RPP is contemplated for release in FY20 with awards to be made in FY21. Each 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 the RPP. The Government will evaluate White Papers submitted and will select White Papers that best meet their current technology priorities using the criteria specified in the RPP. Offerors whose technology solution is selected for further consideration based on White Paper evaluation will be invited to submit a proposal in Stage 2.

The Stage 2 process may vary and may require different submissions compared with typical MTEC RPP’s. For example, the Government anticipates the use of two distinct Stage 2 processes under this RPP. The first will require a solution pitch (i.e., oral presentation) followed by a written detailed research strategy and full cost proposal (after evaluation of the pitch). The second will require a full proposal (to include technical and cost volumes) using the MTEC Proposal Preparation Guidelines (PPG). Note that Stage 2 Offerors will only be required to follow one of the aforementioned Stage 2 processes.

Those Offerors that are favorably evaluated during Stage 1 will receive notification letters which will serve as the formal request for a Stage 2 proposal. These letters will contain specific Stage 2 proposal submission requirements and templates.

The Government-selected Research Project Awards will be funded under the Other Transaction Agreement (OTA) Number W81XWH-15-9-0001 with MTEC administered by the CM, ATI. The CM will negotiate and execute a Base Agreement with MTEC members (if not yet executed). The same provisions will govern this Base Agreement as the OTA for prototype projects between the

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USG and MTEC. Subsequently, any proposal that is selected for award will be funded through a Research Project Award issued under the Base Agreement. A sample of the MTEC Base Agreement can be found on the MTEC website and Members-Only website at [www.mtec-sc.org](http://www.mtec-sc.org).

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

#### 1.4 Proposers Conference

MTEC will host a Proposers Conference that will be conducted via webinar approximately 1-2 weeks after the release of the RPP. Further instructions will be forthcoming via email. Offerors are advised to check the MTEC website periodically during the proposal preparation period for any clarifications found in Frequently Asked Questions (FAQ) responses.

#### 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 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 either a solution pitch (i.e., oral presentation) followed by a written detailed research strategy and full cost proposal (after evaluation of the pitch) or a full proposal (to include technical and cost volumes) in Stage 2. Notification letters will contain specific Stage 2 proposal submission requirements and templates.

*Stage 2 Offerors will only be required to follow **only one** of the aforementioned Stage 2 processes.*

#### 1.6 Potential Funding Availability

The U.S. Government (USG) currently has available a total of approximately \$17.5 million (M) of Fiscal Year (FY) 2019 and 2020 Research, Development, Test, and Evaluation (RDT&E) funds for anticipated awards to be made during FY2020. The estimated total available funding per Technology Focus Area is as follows:

- 1) TECHNOLOGY FOCUS AREA #1: CASUALTY CARE ~ \$10M
- 2) TECHNOLOGY FOCUS AREA #2: MEDICAL LOGISTICS ENHANCEMENT ~ \$2.5M
- 3) TECHNOLOGY FOCUS AREA #3: HUMAN PERFORMANCE ~ \$5M

MTEC anticipates that multiple awards may be made under each Technology Focus Area with average budgets ranging from \$500,000 to \$2,000,000 for the base period of performance (exclusive of any proposed options).

The base Periods of Performance (POP) may range from 12 to 36 months, dependent upon product type and level of maturation required. Note that projects may be phased, as appropriate, with contract options to enable the exercise of additional milestones to allow maximum flexibility in terms of the progression of work, availability of funding, and duration of the awarded project(s).

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

#### 1.7 MTEC Member Teaming

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

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

- "Collaboration Interests" - Select the type of teaming opportunities your organization would be interested in. This information is crucial when organizations need to search the membership for specific capabilities/expertise that other members are willing to offer.

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- “Solicitation Collaboration Interests” - Input specific active solicitations that you are interested in teaming on. This information will help organizations interested in a specific funding opportunities identify others that are interested to partner in regards to the same funding opportunity. Contact information for each organization is provided as part of the member profile in the collaboration database tool to foster follow-up conversations between members as needed.

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

#### 1.8 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. In accordance with the PPG, please mark all Confidential or Proprietary Information as such. 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 serving as nongovernmental advisors, 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). Offerors may choose to proposed *cost share above the statutory minimum; 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 (see Attachment 3 for definitions of each); 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 above the statutory

minimum is encouraged if possible, as it leads to stronger leveraging of Government-contractor collaboration.

#### 1.10 Cost Share Requirements

Research Projects selected for funding under this RPP are required to meet at least one of the following conditions:

- (1) There is at least one nontraditional defense contractor or nonprofit research institution participating to a significant extent in the prototype project.
- (2) 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.
- (3) 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.

Beyond that, cost sharing is encouraged if possible, as it leads to stronger leveraging of Government-contractor collaboration. More information regarding the mandatory statutory conditions with regard to the appropriate use of Other Transaction authority can be found at Attachment 2. For more information regarding cost share, please see Attachment 3.

Proposals that fail to meet the mandatory statutory conditions with regard to the appropriate use of Other Transaction authority, as listed above, will not be evaluated and will be determined ineligible for award.

#### 1.11 White Paper Submission

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

MTEC membership is required for the submission of a White Paper. Offerors must be MTEC Members in good standing. Offerors submitting White Papers as the prime contractor must be MTEC members of good standing by **Thursday, March 26, 2020**.

**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 shall 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 shall be print-capable and without a



password required. Filenames shall contain the appropriate filename extension (.docx, .doc, or .pdf). Filenames shall 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 a White Paper.

#### 1.14 Offeror Eligibility & Security Requirements

The Government anticipates that under performance of the resultant award(s), as designated in Technology Focus Areas (under Section "2 Technical Requirements" below), the performer(s) may have access to classified information. As such, the performer(s) (including any proposed subcontractors) shall comply with-

- (1) The Security Agreement (DDForm441), including the National Industrial Security Program Operating Manual (DoD 5220.22-M); and
- (2) Any revisions to that manual, notice of which has been furnished to the Contractor.

Based on the anticipated security classification specifications, all individuals performing under award(s) supporting Technology Focus Area #2 (Specific Area of Interest "a." only) and Technology Focus Area #3 (all Specific Areas of Interest) **shall be U.S. citizens and able to or already possess a SECRET clearance at the time of Stage 1 White Paper submission** (and shall maintain this SECRET clearance throughout the period of performance under the prototype project). **In addition, the performer shall already possess the required level of Facility Security Clearance (FCL) and the level of safeguarding for classified information/material required at the performer facility at the time of Stage 1 White Paper submission. Offerors shall, at minimum, include the statement found on the cover page of the White Paper Template.**

Additional and or specific requirements will be deemed by the Government on the DD Form 254 (Department of Defense Contract Security Classification Specification) associated with any resultant award.

Offerors are not required to submit a DD Form 441 or a DD Form 254 at the time of White Paper Submission. The Government anticipates providing draft copies of the DD441 and DD254 at the time Stage 2 proposals are requested. These forms shall be finalized and signed by the cognizant

security offices prior to execution of any resultant Research Project Awards for prototype projects.

#### 1.15 Intellectual Property

Offerors shall complete Attachment 7 and include this information in its Stage 1 White Paper submission. Potential offerors should be aware that the Government intends to specially negotiate the rights in intellectual property and technical data developed under this agreement and negotiate FDA sponsorship and other regulatory rights on a case-by-case basis. Accordingly, for this acquisition, the government seeks: Government Purpose Rights or Unlimited Rights. These specially negotiated rights may differ from the base MTEC terms.

## 2 Technical Requirements

All white paper submissions shall describe projects that are based on logical reasoning and sound scientific rationale. They should not be exploratory in nature and do require a foundation of preliminary data. Please note that MTEC-sponsored projects must result in “prototype” research deliverables that transition medical solutions to industry. **Proposed prototypes shall be at a minimum of a Technology Readiness Level (TRL) of 5 at the time of white paper submission.** [Note: TRL definitions can be found here: <https://mtec-sc.org/wp-content/uploads/2016/12/TRL-definitions.pdf>]

Subsequent to the completion of performance under the prototype awards resulting from this RPP, the Government reserves the right to award follow-on work. Any follow-on work for the continuation of the prototype development is contingent upon availability of future funding and the successful completion/progression of milestones. Proposed prototypes considered for further development should be at a TRL of 6 or 7 at the **conclusion** of the prototype award. A TRL of 6 or 7 means that the prototype solutions are ready, currently going through, or completed the Technology Maturation and Risk Reduction phase of the Defense Acquisition System framework or equivalent.

Proposed prototype solutions **shall** address only **ONE** of the Technology Focus Areas and only **ONE** of the associated Specific Areas of Interest outlined below in support of the Naval Advanced Medical Development (NAMD). Offerors are not limited to a single white paper submission. White Papers not aligned to **ONE** of these Focus Areas (and **ONE** of the associated Specific Areas of Interest) will not be considered for funding. These Technology Focus Areas are not listed in order of importance.

#### 1) **TECHNOLOGY FOCUS AREA #1: CASUALTY CARE:**

This area focuses on patient care at and through the continuum of care as well as products and services that sustain patient health in austere environments such as expeditionary,

littoral, and deep water. **Specific areas of interest** are as follows (*Offerors shall address only one of these in each White Paper submission*):

- a. Wound care treatments / therapies for combat injuries. Includes technologies suitable for use at point of injury and / or at medical facilities in theater.
- b. Wound care technologies for combat wound infections (e.g., bacterial and other infections of combat wounds)
- c. Innovative wound care technologies to treat and prevent biofilm formation

**2) TECHNOLOGY FOCUS AREA #2: MEDICAL LOGISTICS ENHANCEMENT**

This area focuses on patient and personnel recovery, remote health monitoring, and immersion injuries. **Specific areas of interest** are as follows (*Offerors shall address only one of these in each White Paper submission*):

- a. Long range, low power, Radio Frequency (RF) communication technologies for health and positional information (security and facility clearance required, see 1.14)
- b. Autonomous health status prediction based upon physiological and environmental data of combat casualties.

**3) TECHNOLOGY FOCUS AREA #3: HUMAN PERFORMANCE**

This area focuses on the prediction of health status and outcomes from various sources of combat related stressors and advanced biomedical electronics such as sensors and microelectronics. **Specific areas of interest** as follows (*Offerors shall address only one of these in each White Paper submission*):

- a. Quantification and validation of down-regulation techniques for physical and cognitive stress during military operations (security and facility clearance required, see 1.14)
- b. Verification and validation of individualized predication algorithms for physical and cognitive performance due to stress in operational environments (security and facility clearance required, see 1.14)
- c. Motion correction for / or motion-tolerant Photoplethysmography sensors
- d. Advanced development of miniaturized implantable devices for health monitoring
- e. Physiological monitoring system development to include wearable devices, long range communication and system infrastructures (security and facility clearance required, see 1.14)
- f. Lightweight encryption technologies for miniaturized, low-power biomedical devices (security and facility clearance required, see 1.14)

Proposed prototype solutions must be either “engineering and medical prototypes” or “knowledge products”. See below for definition of each.

- **Engineering and medical prototypes:** System, subsystem, component, or material directly or indirectly delivering or supporting a biomedical product or critical capability. These are physical, in-hand products which can be examined, tested, and demonstrated. This may also include products that require U.S. Food and Drug Administration (FDA) approval.
- **Knowledge products:** Non-material solution that includes methodology, technology, or technical process directly or indirectly supporting a biomedical product or critical capability. This may also include products such as technical reports or manuals impacting training and/or operations

**Additional points of consideration:**

- **Military Relevance:** Proposed projects must demonstrate relevance to the enhanced readiness and resilience of Navy and Marine Corps health and performance.
- **Project Maturity:** This solicitation is not meant to support development of a new prototype, but should focus on fine tuning and optimization of existing prototypes or other technologies.
- **Industry Partners:** Proposed projects are encouraged to include relevant industry partners, especially considering that the eventual goal is to transition products to industry for FDA approval and/or commercialization.

### **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:

**Factor 1: Research Strategy:**

- a. Whether the proposed work supports the objectives of only one of the three (3) Focus Areas and only one specific area of interest.

\*For Offerors responding to the relevant Specific Areas of Interest under Technology Focus Areas #2 and #3 **ONLY**, the Government will evaluate the White Paper to determine if the Offeror has demonstrated its eligibility based on the requirements detailed in Section 1.14 (Offeror Eligibility & Security Requirements). **Offerors shall, at minimum, include the statement found on the cover page of the White Paper Template to certify its eligibility.**

- 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, to include the required Technology Readiness Level (TRL). Whether the prototype is based on promising preliminary data, sound scientific rationale, and demonstrated proof-of-concept.

- d. The Government may evaluate the proposed cost, as reflected in the Rough Order of Magnitude (ROM), as it relates to research strategy. Therefore, White Papers may be evaluated based on the degree to which the proposed solution delivers value to the Government and demonstrates a feasible solution considering funding availability as well as anticipated lifecycle costs.

**Factor 2: Personnel and Team:**

- a. How the background and expertise of the personnel and organizations are appropriate to execute the proposed research.
- b. The degree to which the Offeror demonstrates a realistic, achievable performance schedule with a plan to address potential risks that could delay or otherwise impact performance.

Those White Papers that are favorably evaluated (receive an overall rating of “Acceptable” or higher) 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.

White papers will be evaluated by a panel of project managers and subject matter experts (SMEs). Evaluation of white papers will be based on an independent, comprehensive review and assessment of the work proposed against the stated evaluation factors based on the ratings table

listed below. An overall rating considering all of the aforementioned evaluation factors will be derived from the Offeror’s demonstration of its ability perform the work in accordance with all aspects of requirements outlined in this RPP. The Offeror shall clearly state how it intends to meet or exceed the RPP requirements. Mere acknowledgement or restatement of a RPP requirement is not acceptable.

| <b>TABLE: GENERAL MERIT RATING ASSESSMENTS</b> |   |
|--|---|
| <b>RATING</b>                                  | <b>DESCRIPTION</b>  |
| 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.   |

### 3.1.3 Stage 2: Full Proposal Evaluation

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

## 4 Other Factors to Consider

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

1. 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. If the Offeror already has executed an MTEC Base Agreement with the MTEC CM, then the Offeror must state on the cover page of its Proposal that, if selected for award, it anticipates the proposed effort will be funded under its executed MTEC Base Agreement.
2. Restrictions on Human Subjects, Cadavers, and Laboratory Animal Use – Please reference Section 8 of the PPG
3. Warranties and Representations for all proposals - See Attachment 5.
4. MTEC Additional Research Project Award Assessment or Royalty Payment Agreement – See Attachment 6.
5. 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."
6. Offerors are hereby notified to mark business plans and technical information that are to be protected for five years from FOIA disclosure with a legend identifying the documents as being submitted on a confidential basis. Please reference Section 3 of the PPG for additional information.

## 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, [mtec-contracts@ati.org](mailto:mtec-contracts@ati.org)
- Technical and membership and related questions should be directed to the MTEC Director of Research, Dr. Lauren Palestrini, Ph.D., [lauren.palestrini@officer.mtec-sc.org](mailto:lauren.palestrini@officer.mtec-sc.org)

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- All other questions should be directed to the MTEC Director of Program Operations, Ms. Kathy Zolman, [kathy.zolman@ati.org](mailto: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 Stage 1 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  |
| 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.) |
| M       | Million  |
| MTEC    | Medical Technology Enterprise Consortium                           |
| NDA     | Nondisclosure Agreement  |
| OCI     | Organizational Conflict of Interest                                |
| ODC     | Other Direct Costs   |
| OTA     | Other Transaction Agreement  |
| POC     | Point-of-Contact   |
| POP     | Period of Performance  |
| PPG     | Proposal Preparation Guide   |
| Q&A     | Questions and Answers  |
| RF      | Radio frequency  |
| ROM     | Rough Order of Magnitude   |
| RPP     | Request for Project Proposals                                      |
| SOW     | Statement of Work  |
| TRL     | Technology Readiness Level   |
| USAMRDC | U.S. Army Medical Research and Development 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 shall 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 shall 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-20-02-NavyMultiTopic”**

**Statement that “At the time of White Paper submission, all parties are U.S. citizens and able to or already possess a SECRET clearance. In addition, our facility possesses the required level of Facility Security Clearance (FSL) and the level of safeguarding for classified information/material required.”**

**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]

**Focus Area:** [Indicate which focus area and specific area of interest this white paper is addressing. To meet the intent of this RPP, each white paper **MUST** specifically address only **ONE** of the three Focus Areas and **ONE** Specific Area of Interest described in Section 2. Offerors are not limited to a single white paper submission. Projects not aligned with one of these Focus Areas will not be considered for funding.]

**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 the Navy's 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, small business, or 1/3 cost sharing:** [Describe the plan to include significant participation of a non-traditional defense contractor, nonprofit research institution or Small Business participants, or the ability to meet 1/3 cost sharing requirement.]

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

**Cost Share:** [While not a requirement, Offerors may 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 total project cost. 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” or “Consultants section of the table.]

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

## 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 significant *extent* include:

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

### Inclusion of Nontraditional Defense Contractors

Proposals that do not include one of the following will not be eligible for award:

(A) 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.

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(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.

This requirement is a statutory element of the Other Transaction Authority and will be regarded as a pass/fail criterion during the Compliance Screening.

### **Attachment 3 – Cost Share**

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

#### **Cash Contribution**

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

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

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

#### **In-Kind Contribution**

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

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

## **Attachment 4 – Stage 2 Evaluation Criteria**

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

### **Stage 2**

#### **Compliance Screening**

The CM will conduct a preliminary screening of received proposals to ensure compliance with the RPP requirements. As part of the preliminary screening process, proposals that do not meet the requirements of the RPP may be eliminated from the competition or additional information may be requested by the CM. The Government reserves the right to request additional information or eliminate proposals that do not meet these requirements from further consideration.

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

#### **Evaluation Process**

Qualified applications will be evaluated by a panel of subject matter experts (SMEs) who will make recommendations to a Source Selection Authority.

This process may involve the use of contractors as SME (e.g., system experts, scientists, and/or clinicians) consultants or reviewers. Where appropriate, the USG will employ non-disclosure-agreements to protect information contained in the RPP as outlined in RPP Section 2.4.

Evaluation will be based on an independent, comprehensive review and assessment of the work proposed against stated source selection criteria and evaluation factors. The Government will evaluate against the evaluation factors detailed below and assigned adjectival ratings to the non-cost/price factor(s) consistent with those defined in Table 2 (General Merit Ratings Assessments). The Offeror shall clearly state how it intends to meet and, if possible, exceed the RPP requirements. Mere acknowledgement or restatement of a RPP requirement is not acceptable.

The evaluation factors and evaluation criteria are described below.

#### **Evaluation Factors**

1. Technical Approach
2. Potential for Fielding and / or Commercialization (if applicable)
3. Cost/Price



Evaluation factors are listed in descending order of importance.

The Government technical evaluation panel reviewers will be responsible for evaluating proposals against each of the above listed non-cost/price factors. The Government anticipates assigning a rating to each factor, individually, before an overall rating is assigned collectively to these factors. Only proposals receiving an overall rating of “Acceptable” or higher will be considered for award.

The below table explains the adjectival merit ratings that will be used for the Technical Approach Factor, and Potential for Fielding and / or Commercialization factor.

| <b>TABLE - GENERAL MERIT RATING ASSESSMENTS</b> |   |
|---|---|
| <b>RATING</b>                                   | <b>DESCRIPTION</b>  |
| 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 and development efforts. The effort will be assessed for the extent to which the solution is technologically sound and innovative, strong engineering, test and evaluation principles (as applicable), and how the proposed deliverable advances the TRL Military relevance is a critical component of proposal submission. 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 Fielding and / or Commercialization**

The Potential for Fielding and / or 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, demonstration or testing.
- b) How well the project will translate promising, well-founded engineering or clinical research findings into 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, demonstration, 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 or test and evaluation 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 based on the evaluation criteria and ratings listed above. The overall award decision will be based upon all factors listed above to determine which proposal(s) represent the best value to the Government. Based on the results of the Technical Evaluation, the Government reserves the right to negotiate and request changes to any or all parts of the SOW. Offerors 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.

|   |  |                   |  |
|---|--|-------------------|--|
| <b>1. Legal Name:</b>   |  | <b>2. DUNS #:</b> |  |
| <b>3. Point of Contact:<br/>Name, Title, Phone<br/>#, Email</b>   |  |                   |  |
| <b>4. Prime Contractor is a nontraditional (Y/N)?</b>   |  |                   |  |
| <b>5. Prime Contractor is a nonprofit research institution (Y/N)?</b>   |  |                   |  |
| <b>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)?</b> |  |                   |  |
| <b>7. Prime Contractor is a small business (Y/N)?</b>   |  |                   |  |

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

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

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

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

The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding 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, the Offeror shall complete the below table for any items to be furnished to the Government with restrictions. **This table shall be provided with the Offeror’s White Paper submission.** 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]*