

Request for Project Proposals



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

Issued by:
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MTEC Consortium Manager (CM)
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Summerville, SC 29486
for the
Medical Technology Enterprise Consortium (MTEC)

Amendment 1

Request Issue Date: February 27, 2020
Amendment 1 Issue Date: March 24, 2020

Proposal Due Date: April 6, 2020
Noon Eastern Time

Amendment 1 does the following:

- 1. Extends the due date from March 31, 2020 to April 6, 2020***
- 2. Provides clarification under Section 1.14 "Offeror Eligibility & Security Requirements"***
- 3. Updates Section 2 "Technology Requirements"***
- 4. Revises Attachment 1 "MTEC White Paper Template"***

No other changes have been made.

White Papers are Required

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.**

Security Requirement for Each Specific Area of Interest:

1. **Casualty Care - Clearance and FCL NOT Required**
 - a. **Clearance and FCL NOT Required**
 - b. **Clearance and FCL NOT Required**
 - c. **Clearance and FCL NOT Required**
2. **Medical Logistics Enhancement - Clearance and FCL REQUIRED**
 - a. **Clearance and FCL REQUIRED**
 - b. **Clearance and FCL NOT Required**
3. **Human Performance - Clearance and FCL REQUIRED**
 - a. **Clearance and FCL REQUIRED**
 - b. **Clearance and FCL REQUIRED**
 - c. **Clearance and FCL REQUIRED**
 - d. **Clearance and FCL REQUIRED**
 - e. **Clearance and FCL REQUIRED**

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.

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 (**security and facility clearance required, see 1.14**)
- d. Advanced development of miniaturized implantable devices for health monitoring (**security and facility clearance required, see 1.14**)
- 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

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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.

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”

The following statement is required only if submitting under Technical Focus Area 2a and all of Technical Focus Area 3. Please see RPP Section 1.14 for more information.

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.]

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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.]

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