

Request for Project Proposals



Solicitation Number: MTEC-22-01-BurnTraining

“Burn Provider Education Prototype Development”

Issued by:
Advanced Technology International (ATI),
MTEC Consortium Manager (CM)
315 Sigma Drive
Summerville, SC 29486
for the
Medical Technology Enterprise Consortium (MTEC)

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White Papers are NOT Required

Table of Contents

Table of Contents.....	2
1 Executive Summary.....	4
1.1. The Medical Technology Enterprise Consortium.....	4
1.2. Purpose.....	4
2 Administrative Overview	5
2.1. Request for Project Proposals (RPP)	5
2.2. Funding Availability and Period of Performance	5
2.3. Acquisition Approach	6
2.4. Proposers Conference	6
2.5. Proprietary Information	6
2.6. MTEC Member Teaming.....	7
2.7. Offeror Eligibility	8
2.8. Cost Sharing Definition.....	8
2.9. Cost Share Requirements.....	8
2.10. MTEC Assessment Fee.....	8
2.11. Intellectual Property and Data Rights	8
2.12. Expected Award Date.....	9
2.13. Proposal Selection Notification.....	9
3 Technical Requirements	9
3.1. Background.....	9
3.2. Solution Requirements.....	9
3.3. Scope of Work	10
3.4. Potential Follow-on Tasks	10
3.5. Restrictions on Animal and Human Subjects	10
3.6. Guidance Related to DoD-Affiliated Personnel for Participation	11
4 Proposal Preparation	11
4.1. General Instructions.....	11
4.2. Instructions for the Preparation & Submission of the Proposal.....	11
4.3. Full Proposal Preparation Costs	14
4.4. Freedom of Information Act (FOIA)	14
4.5. Telecommunications and Video Surveillance	14
5 Selection.....	14
5.1. Preliminary Screening	14
5.2. Proposal Evaluation.....	15
5.3. Cost/Price Evaluation by the Consortium Manager.....	18
5.4. Definitions of General Terms Used in Evaluations.....	19
6 Points-of-Contact	20
7 Acronyms/Abbreviations	20
Attachment 1 – Cost Share	22
Attachment 2 – Statutory Requirements for the Appropriate Use of Other Transaction Authority	23

Request for Project Proposal MTEC-22-01-BurnTraining
Number W81XWH-15-9-0001

Attachment 3 – Warranties and Representations Template..... 24
Attachment 4 – Statement of Work Template 29
Attachment 5 – Current & Pending Support Template 33
Attachment 6 – Intellectual Property and Data Rights..... 34
Attachment 7 – Safety Protocols 36
Attachment 8 – BIDS Instructions..... 37

1 Executive Summary

1.1. The Medical Technology Enterprise Consortium

The Medical Technology Enterprise Consortium (MTEC) is an enterprise partnership in collaboration 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 Department of Defense (DoD) 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) engage in biomedical research and prototyping;
- (b) exploration of private sector technology opportunities;
- (c) technology transfer; and
- (d) deployment 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 at <https://mtec-sc.org/>.

MTEC operates under an Other Transaction Agreement (OTA) for prototypes with USAMRDC. As defined in the DoD 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 the 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. Proposed prototype projects should not be exploratory in nature and do require a foundation of preliminary data.

1.2. Purpose

This solicitation, issued by the MTEC Consortium Manager (CM), Advanced Technology International (ATI), represents a Request for Project Proposals (RPP) for MTEC support of the DoD U.S. Army Medical Research & Development Command (USAMRDC) Combat Casualty Care Research Program (CCCRP). Proposals selected for award as a result of this RPP will be awarded

under the authority of 10 U.S.C. § 2371b. Strategic oversight for the award(s) supported by this RPP will be provided by the CCCRP.

This RPP is focused on the development and validation of an enhanced training curriculum in burn care utilizing military and civilian burn care clinician-educators to improve patient outcomes in current and future battlefields. The enhanced training curriculum will be designed for military burn care providers in the pre-deployment setting to ensure readiness in a deployed setting. This includes the development of simulation-based training tools that will improve training quality and skills retention while also reflecting operational realities for military and civilian healthcare providers delivering burn care. The curriculum should also be adapted for civilian first responders who may be called upon in the event of a domestic mass-casualty scenario.

2 Administrative Overview

2.1. Request for Project Proposals (RPP)

MTEC is utilizing a single-staged approach for this RPP. Each proposal submitted must contain both a Technical and Cost Proposal Volume as described in Section 4 of this RPP and must be in accordance with the mandatory format provided in the MTEC Proposal Preparation Guide (PPG), which is available on the Members-Only MTEC website at www.mtec-sc.org. **White papers are not required for this RPP.** The Government will evaluate Proposals submitted and will select the proposal(s) that best meets their current technology priorities using the criteria in Section 5 of this RPP.

2.2. Funding Availability and Period of Performance

The U.S. Government (USG) currently has available a total of approximately **\$4.6 million (M)** for this effort.

Award and funding from the Government is expected to be limited to the funding specified above and is contingent upon the availability of federal funds for this program. Awards resulting from this RPP are expected to be made under the authority of 10 U.S.C. § 2371b.

Cost sharing, including cash and in kind (e.g., personnel or product) contributions are strongly encouraged, have no limit, and are in addition to the Government funding to be provided under the resultant award(s).

MTEC expects to make a **single award** to a qualified Offeror in Fiscal Year 2022 to accomplish the scope of work. If a single proposal is unable to sufficiently address the entire scope of the RPP, several Offerors may be asked to work together in a collaborative manner.

Award funding will be structured incrementally and based upon completion of Milestones and Deliverables.

The Period of Performance (POP) is **not to exceed five years**.

Dependent on the results and deliverables under any resultant award(s), the USG may apply additional dollars and/or allow for additional time for non-competitive follow-on efforts with appropriate modification of the award. See Section 3.4. for additional details.

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 realignment.

2.3. Acquisition Approach

Full proposals will be required in response to this RPP thus reflecting a single stage acquisition approach. MTEC membership is required for the submission of a full proposal. The due date for Proposals is found on the cover page of this RPP. Proposals may not be considered under this RPP unless the Proposal was received on or before the due date specified on the cover page.

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

The Government-selected prototype project(s) awarded as a result of this solicitation will be funded under the Other Transaction Agreement for prototype projects (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 Government and MTEC. Subsequently, any proposal that is selected for award will be funded through a Research Project Award issued under the member's Base Agreement. The MTEC Base Agreement can be found on the MTEC website at www.mtec-sc.org.

2.4. Proposers Conference

MTEC will host a Proposers Conference that will be conducted via webinar within two (2) weeks after the release of the RPP. The intent of the Proposers Conference is to provide an administrative overview of this RPP process to award and present further insight into the Technical Requirements outlined in Section 3. 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.

2.5. 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. Therefore, on your Proposal Cover Page, please indicate your willingness to allow MTEC Officers and Directors access to your Technical Proposal for the purposes of engaging in outreach activities with these private foundations. MTEC Officers and Directors who are granted proposal access have signed Nondisclosure Agreements (NDAs) and Organizational Conflict of Interest (OCI) statements. 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.

2.6. 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 the 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, Research and Development (R&D) highlights/projects, and technical expertise. The Primary Point of Contact for each member organization is provided access to the collaboration database tool to make edits and populate their organization's profile. There are two sections as part of the profile relevant to teaming:

- "Collaboration Interests" - Select the type of teaming opportunities your organization would be interested in. This information is crucial when organizations need to search the membership for specific capabilities/expertise that other members are willing to offer.
- "Solicitation Collaboration Interests" - Input specific active solicitations that you are interested in teaming on. This information will help organizations interested in a specific funding opportunity 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.

2.7. Offeror Eligibility

Offerors must be MTEC Members in good standing to be eligible to submit a Proposal. Offerors submitting Proposals as the prime contractor must be MTEC members of good standing by January 4, 2022. Subcontractors (including all lower tier subawardees) do not need to be MTEC members. To join MTEC, please visit <http://mtec-sc.org/how-to-join/>.

2.8. Cost Sharing Definition

Cost sharing is defined as the resources expended by the award recipients on the proposed statement of work (SOW). *Cost sharing above the statutory minimum 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 1** for definitions); 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.).

2.9. Cost Share Requirements

In order to be compliant with 10 U.S.C. §2371b, Research Projects selected for funding under this RPP are required to meet at least one of the conditions specified in Attachment 2 (“Statutory Requirements for the Appropriate Use of Other Transaction Authority”). Beyond that, cost sharing is encouraged if possible, as it leads to stronger leveraging of Government-contractor collaboration. For more information regarding cost share, please see Attachment 1.

Proposals that fail to meet the mandatory statutory conditions with regard to the appropriate use of Other Transaction authority, as detailed in Attachment 2, will not be evaluated and will be determined ineligible for award.

2.10. MTEC Assessment Fee

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 2% of the total funded value of each research project awarded. 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.

2.11. Intellectual Property and Data Rights

Baseline Intellectual Property (IP) and Data Rights for MTEC Research Project Awards are defined in the terms of an awardee’s Base Agreement, and specifically-negotiated terms are finalized in any resultant Research Project Award. MTEC reserves the right to assist in the negotiation of IP, royalties, licensing, future development, etc., between the Government and the individual performers prior to final award decision and during the entire award period.

The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding IP and Data Rights. This RPP requires that the Offeror describe the format in which the training

program will be delivered to the government, and IP and data rights will be negotiated accordingly. It is anticipated that anything created, developed, or delivered under this proposed effort will be delivered to the Government with, at minimum, Government Purpose Rights; however, depending on data assertions, the government will pursue IP and increased data rights if possible.

See Attachment 6 for more detail. **All offerors shall complete and submit Attachment 6 (Intellectual Property and Data Rights) of this RPP** with the signature of the responsible party for the proposing Prime Offeror as part of the proposal submission.

For more information, the CM has published a resource for Offerors entitled, “Understanding Intellectual Property and Data Rights” on the MTEC members-only website.

2.12. Expected Award Date

Offerors should plan on the period of performance beginning May 25, 2022 (subject to change). The Government reserves the right to change the proposed period of performance start date through negotiations via the CM and prior to issuing a Research Project Award.

2.13. Proposal Selection Notification

As the basis of selections is completed, the Government will forward its selection(s) to MTEC CM to notify Offerors. Proposers will be notified by email from the MTEC CM of the results of the technical evaluation.

3 Technical Requirements

3.1. Background

Patients who suffer burn injuries face a high potential for mortality and morbidity, including restricted physical functionality, cosmetic deformity, and psychosocial disorders that may persist for the remainder of their lives. While survival from burn injuries has improved over recent decades, the incidence and long-term effects of burn injuries resulting from military conflict remains a major challenge. Furthermore, the number of healthcare providers trained in specialized burn care is insufficient to address the size of the patient population. In addition, several critical knowledge gaps have been identified in prehospital care common to both military and civilian environments, such as prolonged burn care in rural/austere settings and during extended critical care transport times. Therefore, there is an unmet need for a scalable curriculum that can be used by military personnel and civilian care providers in pre-deployment/pre-hospital settings that facilitates the development and sustainment of burn care provider skills to improve patient outcomes in current and future battlefields.

3.2. Solution Requirements

This RPP aims to develop and validate a training curriculum in burn care utilizing military and civilian burn care clinician-educators. The training curriculum will be designed for military burn

care providers in the pre-deployment setting to ensure readiness in a deployed setting. This includes the development of simulation-based training tools that will improve training quality and skills retention while also reflecting operational realities for military and civilian healthcare providers delivering burn care. The program shall also be adapted for civilian providers, such as first responders, who may be called upon in mass-casualty scenarios. Partnerships between military and civilian organizations are encouraged.

3.3. Scope of Work

The objective of this project is to develop a scalable curriculum prototype that includes the following three components:

- 1) Prehospital Burn Simulator: Biomimetic, skills-based simulator to train and assess competency at the 3D's (decontamination, debridement, & dressings)
- 2) Prehospital Burn Escharotomy Simulator: biomimetic, skills-based simulator to train and assess competency at burn eschar assessment and escharotomy
- 3) Artificial Immersive Medical Education: Asynchronous, online, scenario-based AI way-point tracking to assess, inform, & quantitatively measure clinical decisions by practitioners

The study design must include a prospective, controlled study with Role 2 and above military healthcare providers and civilian paramedics. The study design must compare the new prototype curriculum to current military and civilian burn training platforms. Study outcomes must focus on retention, standardization, & sustainment, including the assessment for skills-based points of failure and quantitative scenario-based assessments reflecting multi-dimensional battlefields. It is preferred that the Offeror has current experience with training protocols, and has access to relevant participants, such as Level 1, 2, or 3 trauma centers and burn centers.

3.4. Potential Follow-on Tasks

There is potential for award of one or more follow-on tasks based on the success of any resultant Research Project Awards (subject to change depending upon Government review of completed work and successful progression of milestones). Note that any potential follow-on work is expected to be awarded non-competitively to resultant project awardees. Potential follow-on tasks include (but are not limited to) procurement, fielding, and sustainment for this scalable burn care curriculum.

3.5. Restrictions on Animal and Human Subjects

Proposals must comply with restrictions and reporting requirements for the use of animal and human subjects, to include research involving the secondary use of human biospecimens and/or human data. The Awardee shall ensure local Institutional Animal Care and Use Committee (IACUC) and Institutional Review Board (IRB) approvals, continuing review (in the intervals specified by the local IACUC and IRB, but at a minimum, annually), and approval by the USAMRDC

Animal Care and Use and Review Office (ACURO) and the USAMRDC Human Research Protections Office (HRPO). Offerors shall include IACUC, ACURO, IRB and HRPO review and approval in the SOW/Milestones Table submitted with the Proposal, as applicable.

These restrictions include mandatory Government review and reporting processes that will impact the Offeror's schedule.

3.6. Guidance Related to DoD-Affiliated Personnel for Participation

Compensation to DoD-affiliated personnel for participation:

Please note that compensation to DoD-affiliated personnel for participation in research while on duty is prohibited with some exceptions. For more details, see Department of Defense Instruction 3216.02, Protection of Human Subjects and Adherence to Ethical Standards in DoD-Conducted and Supported Research. You may access a full version of the DoDI by accessing the following link: <https://www.esd.whs.mil/Portals/54/Documents/DD/issuances/dodi/321602p.pdf>

4 Proposal Preparation

4.1. General Instructions

Proposals should be submitted by the date and time specified on the cover page using BIDS: <https://ati2.acgcenter.com/ATI2/Portal.nsf/Start?ReadForm>. Include the MTEC Solicitation Number (**MTEC-22-01-BurnTraining**) on each proposal submitted. See Attachment 8 in this RPP for further information regarding BIDS registration and submission.

Do not submit any classified information in the proposal submission.

The MTEC PPG is specifically designed to assist Offerors in understanding the proposal preparation process. The proposal format outlined in the PPG is mandatory and shall reference this RPP number (**MTEC-22-01-BurnTraining**). Offerors are encouraged to contact the Points-of-Contact (POCs) identified herein up until the Proposal submission date/time to clarify requirements (both administrative and technical in nature).

All eligible Offerors may submit Proposals for evaluation according to the criteria set forth herein. Offerors are advised that only ATI as the MTEC's CM, with the approval of the DoD Agreements Officer, is legally authorized to contractually bind MTEC into any resultant awards.

4.2. Instructions for the Preparation & Submission of the Proposal

Offerors submitting a Proposal in response to this RPP should prepare all documents in accordance with the following instructions:

Offerors should submit files 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, searchable, and without a password required. Filenames must

contain the appropriate filename extension (.docx, .doc, .pptx, .ppt, .xlsx, .xls or .pdf). Filenames should not contain special characters. Apple users must ensure the entire filename and path are free of spaces and special characters.

An automated BIDS receipt confirmation will be provided by email. Offerors may submit in advance of the deadline. **Neither MTEC nor ATI will make allowances/exceptions for submission problems encountered by the Offeror using system-to-system interfaces. If the Offeror receives errors and fails to upload the full submission prior to the submission deadline, the submission may not be accepted. It is the Offeror's responsibility to ensure a timely and complete submission.**

Required Submission Documents (7): Submit via BIDS (5MB or lower)

- **Technical Proposal as one Word or PDF document (Refer to Section 6.2 of the PPG).**
- **Section I: Cost Proposal Narrative as one Word or PDF document (Refer to Section 7.2 of the PPG).**
- **Section II: Cost Proposal Formats as one Excel or PDF document (Refer to Section 7.3 of the PPG).**
- **Warranties and Representations for all proposals as one Word or PDF document (Attachment 3 of this RPP).**
- **Statement of Work (SOW)/Milestone Payment Schedule (MPS) as one Word document (.docx or .doc) (Attachment 4 of this RPP).**
- **Current and Pending Support as one Word or PDF document (Attachment 5 of this RPP).**
- **Intellectual Property and Data Rights Assertions as one signed Word or PDF document (Attachment 6 of this RPP).**

The following information provides additional information related to each of the required documents for the full proposal submission. The Technical Proposal and Cost Proposal must be submitted in two separate volumes, and shall remain valid for 180 days unless otherwise specified by the Offeror in the proposal. Offerors are encouraged to contact MTEC with any questions so that all aspects are clearly understood by both parties. The full proposal should include the following. **Each document will be uploaded to BIDS separately (see Attachment 8 of RPP for BIDS instructions).**

- **Technical Proposal:** The Technical Proposal (also referred to as Volume 1) format provided in the MTEC PPG is mandatory; however, it shall be limited to 30 pages. The Technical Proposal shall be single-spaced and single-sided with 12 point font (8.5 x 11 inches). Smaller type 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. Offerors are strongly encouraged to use pictures and graphics to succinctly represent proposed ideas, organization, etc. Proposals shall reference this RPP number (**MTEC-22-01-BurnTraining**). Refer to section 6.2 of the PPG for instructions regarding the format of the Technical Proposal.

- **Cost Proposal:** The Cost Proposal (also referred to as Volume 2) should clearly delineate your costs separated by focus area (if applicable), where possible. Each cost proposal should include direct costs and other necessary components as applicable, for example, fringe, General & Administrative Expense (G&A), Facilities & Administrative (F&A), Other Direct Costs (ODC), etc. Offerors shall provide a breakdown of material and ODC costs as applicable. The Cost Proposal shall be submitted in two separate sections - Section I: Cost Proposal Narrative and Section II: Cost Proposal Formats. [Refer to Section 7 of the PPG for instruction regarding the preparation of the Cost Proposal.] **Offerors are encouraged to use their own cost formats such that the necessary detail is provided.** Cost proposal formats are available on the Members-Only MTEC website. The Cost Proposal formats provided in the MTEC PPG (Attachment 1 of the PPG) are **NOT** mandatory. Refer to the MTEC PPG for additional details.
- **Warranties and Representations (template provided in Attachment 3):** One Word (.docx or .doc) or PDF file that contains all Warranties and Representations is required for each proposal. Refer to Attachment 3 for the template.
- **Statement of Work (SOW)/Milestone Payment Schedule (MPS) (template provided in Attachment 4):** The Offeror is required to provide a detailed SOW/MPS using the format provided herein (Attachment 4). The Government reserves the right to negotiate and revise any or all parts of the SOW/MPS. Offerors will have the opportunity to concur with revised SOW/MPS as necessary. [Note: Although the SOW/MPS is already included as Appendix B of the Technical Proposal (Volume 1), it must be uploaded into the BIDS system again as a separate file in either the *.docx or *.doc format.]
- **Current and Pending Support (template provided in Attachment 5):** The Offeror shall provide this information for all key personnel who will contribute significantly to the proposed research project. Specifically, information shall be provided for all current and pending research support (to include Government and non-government), including 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), role, 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. If there is no current and/or pending support, enter "None."
- **Intellectual Property and Data Rights Assertions (template provided in Attachment 6)**
 - The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding data rights. It is anticipated that anything delivered under this proposed effort would be delivered to the Government in accordance with Section 2.11 of this RPP unless otherwise asserted in the proposal and agreed to by the Government.

- If this is not the intent, then you should discuss any restricted data rights associated with any proposed deliverables. If applicable, complete the table within the Attachment 6 or any items to be furnished to the Government with restrictions. An example is provided.

Evaluation: The Government will evaluate and determine which proposal(s) to award based on criteria described in **Section 5, "Selection,"** of this RPP. The Government reserves the right to negotiate with Offerors.

4.3. Full Proposal Preparation Costs

The cost of preparing Full Proposals in response to this RPP is not considered a direct charge to any resulting award or any other contract.

4.4. Freedom of Information Act (FOIA)

To request protection from FOIA disclosure as allowed by 10 U.S.C. §2371(i), Offerors shall mark business plans and technical information with a legend identifying the documents as being submitted on a confidential basis. For more information, please refer to Section 6.1.1 of the MTEC PPG.

4.5. Telecommunications and Video Surveillance

Per requirements from the Acting Principal Director of Defense Pricing and Contracting dated 13 August 2020, the provision at FAR 52.204-24, "Representation Regarding Certain Telecommunications and Video Surveillance Services or Equipment" is incorporated in this solicitation. If selected for award, the Offeror(s) must complete and provide the representation as required by the provision to the CM.

5 Selection

5.1. Preliminary Screening

The CM will conduct a preliminary screening of submitted 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. One of the primary reasons for non-compliance or elimination during the initial screening is the lack of significant nontraditional defense contractor participation, nonprofit research institution participation, or cost share (see Attachment 2). Proposal Compliance with the statutory requirements regarding the appropriate use of Other Transaction Authority (as detailed within Attachment 2) will be determined based upon the ratings shown in Table 1:

TABLE 1- COST SHARING/NONTRADITIONAL CONTRACTOR ASSESSMENTS	
RATING	DESCRIPTION
PASS	<p>Offeror proposing an MTEC research project meets at least ONE of the following:</p> <ul style="list-style-type: none"> • Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution • Offeror's Proposal has at least one Nontraditional Defense Contractor or Nonprofit Research Institute participating to a significant extent • All significant participants in the transaction other than the Federal Government are small businesses or nontraditional defense contractors • Offeror provides at least one third of the total project cost as acceptable cost share
FAIL	<p>Offeror proposing an MTEC research project does NOT meet at least ONE of the following:</p> <ul style="list-style-type: none"> • Offeror is a Nontraditional Defense Contractor or Nonprofit Research Institution • Offeror's Proposal has at least one Nontraditional Defense Contractor or Nonprofit Research Institute participating to a significant extent • All significant participants in the transaction other than the Federal Government are small businesses or nontraditional defense contractors • Offeror provides at least one third of the total project cost as acceptable cost share

5.2. Proposal Evaluation

The CM will distribute all Proposals that pass the preliminary screening (described above and in Table 1) to the Government for full technical evaluation. Evaluation of proposals 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 each proposal against the evaluation factors detailed below and assign adjectival ratings to the non-cost/price factor(s) consistent with those defined in Table 2 (General Merit Rating 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 Transition**
- 3. Cost/Reasonableness**

Evaluation Factor 1 – Technical Approach:

This factor will evaluate the relevancy, thoroughness, completeness, and impact of the proposed approach (e.g., the technical merit) and how well the proposal defines and describes a prototype that can already meet or be modified to meet the requirements. The following will be considered:

- Soundness and clarity of the scientific rationale with supporting preliminary data and demonstrated proof-of-concept.
- Hypothesis and objectives.
- How well the proposed methodology and statement of work supports the technical objectives and development of the prototype.
- How well the approach demonstrates the Offeror’s understanding of the overall military relevance, such as the health care needs of military Service members, enhanced capabilities of their care providers, and training requirements.
- Strength of the proposed organization/team to complete the work.

Evaluation Factor 2 – Potential for Transition:

This factor will evaluate the Offeror’s proposal for its potential to transition to the Government. This factor will be based on the following:

- Soundness of the proposed strategy to produce outcomes that can transition to translatable processes, knowledge, and technology for both military and civilian use.
- How well the Offeror demonstrates the potential for the prototype to integrate into current or future burn care training programs.
- 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.
- How well the regulatory strategy is described (if applicable).

Evaluation Factor 3 – Cost/Reasonableness:

This factor will evaluate whether costs are realistic, reasonable, and complete. Proposals will be assessed to determine i) whether the project cost is within the available funding limits, and ii) the ability and/or likelihood of the offeror to successfully execute the proposed project within the financial resources proposed. The proposed cost will be based on the following ratings: Sufficient, Insufficient or Excessive. See the definitions of these ratings in Table 3 below.

With the exception of “Cost/Reasonableness”, evaluation factors will be based upon the adjectival merit ratings detailed in Table 2. See Table 3 for the definitions of the “Cost/Reasonableness” factor ratings. However, please note that the Government technical evaluation

panel may provide an additional review for the purposes of informing the CM’s detailed cost analysis, specifically with regards to the cost realism analysis.

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.

TABLE 3- “COST/REASONABLENESS” FACTOR RATINGS DEFINITIONS	
RATING	DESCRIPTION
SUFFICIENT	The estimate is within the available funding limits and considered appropriate to successfully complete the proposed project
INSUFFICIENT	The estimate is lower than what is considered appropriate to successfully complete the proposed project.
EXCESSIVE	The estimate is higher than what is considered appropriate to successfully complete the proposed project and may be outside of the available funding limits.

Please also refer to Section 5.4 for definitions of general terms used in technical evaluations.

Upon review and evaluation of the Proposals, the Government sponsor will perform proposal source selection. This will be conducted using the evaluation factors detailed above. The Government will conduct an evaluation of all qualified proposals after the preliminary screening (described in Section 5.1). The Source Selection Authority may:

- 1. Select the proposal (or some portion of the proposal) for award***
- 2. Place the proposal in the Basket if funding currently is unavailable; or***
- 3. Reject the proposal (will not be placed in the Basket)***

The RPP review and award process may involve the use of contractor subject-matter-experts (SMEs) serving as nongovernmental advisors. All members of the technical evaluation panel, including contractor SMEs, will agree to and sign a Federal Employee Participation Agreement or a Nondisclosure/Nonuse Agreement, as appropriate, to protect information contained in the RPP as outlined in Section 2.5.

5.3. Cost/Price Evaluation by the Consortium Manager

After completion of the technical evaluation performed by the Government sponsors, the MTEC CM will evaluate the total estimated cost proposed by the Offeror(s) recommended for funding. 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, realism, 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.

The Cost Proposal(s) 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 cost to be reasonable, it must represent a cost to the Government that a prudent person would pay in the conduct of competitive business. Normally, cost reasonableness is established through cost 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 contained within this RPP. The overall award decision will be based upon a Best Value determination and the final award selection(s) will be made to the most advantageous offer(s) by considering and comparing factors in addition to cost. 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 proposal to include the SOW. Offerors will have the opportunity to concur with the requested changes and revise cost proposals as necessary.

5.4. Definitions of General Terms Used in Evaluations

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.

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 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.

6 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
- Technical and membership questions should be directed to the MTEC Biomedical Research Associate, Dr. Gage Greening, Ph.D., gage.greening@mtec-sc.org
- All other questions should be directed to the MTEC Director of Program Operations, Ms. Kathy Zolman, kathy.zolman@ati.org

Once an Offeror has submitted a Proposal, the Government and the MTEC CM will not discuss evaluation/status until the source selection process is complete.

7 Acronyms/Abbreviations

ACURO	Animal Care and Use Review Office
AI	Artificial Immersive
ATI	Advanced Technology International
CAS	Cost Accounting Standards
CCCRP	Combat Casualty Care Research Program
CM	Consortium Manager
CMA	Consortium Member Agreement
DoD	Department of Defense
FAQ	Frequently Asked Questions

Request for Project Proposal MTEC-22-01-BurnTraining
Number W81XWH-15-9-0001

F&A	Facilities and Administrative Costs
FOIA	Freedom of Information Act
G&A	General and Administrative Expenses
HRPO	Human Research Protection Office
IACUC	Institutional Animal Care and Use Committee
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IRB	Institutional Review Board
IR&D	Independent Research and Development
M	Millions
MPS	Milestone Payment Schedule
MTEC	Medical Technology Enterprise Consortium
NDA	Nondisclosure Agreement
OCI	Organizational Conflict of Interest
ODC	Other Direct Costs
OTA	Other Transaction Agreement
PDF	Portable Document Format
POC	Point-of-Contact
POP	Period of Performance
PPG	Proposal Preparation Guide
R&D	Research and Development
RPP	Request for Project Proposals
SME	Subject Matter Expert
SOW	Statement of Work
USAMRDC	U.S. Army Medical Research and Development Command
USG	U.S. Government

Attachment 1 – 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. Prior Independent Research and Development (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.

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 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.

Attachment 2 – Statutory Requirements for the Appropriate Use of Other Transaction Authority

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 for DoD 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. 1502) and the regulations implementing such section. 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.

Significant Extent Requirements

All Offerors shall submit Warranties and Representations (See Attachment 3) specifying the critical technologies being offered and/or the **significant extent** of participation of the nontraditional defense contractor and/or nonprofit research institution. The significance of the nontraditional defense contractor's and/or nonprofit research institution's participation shall 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 extent* includes:

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. Providing a material increase in performance of the prototype project

Conditions for use of Prototype OT Authority

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; or
- (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; or
- (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 in order to ensure compliance with 10 U.S.C. §2371b.

Attachment 3 – Warranties and Representations Template

10 U.S.C. § 2371b 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 at least one of the following:

- (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 to Subcontractor:			
11. Point of Contact:		12. Task/Phase:	

Request for Project Proposal MTEC-22-01-BurnTraining
Number W81XWH-15-9-0001

(Name, Title, Phone #, Email)			
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 4 – Statement of Work Template

The SOW developed by the Lead MTEC member organization and included in the proposal (also submitted as a separate document) is intended to be incorporated into a binding agreement if the proposal is selected for award. If no SOW is submitted with the proposal, there may be no award. The proposed SOW shall contain a summary description of the technical methodology as well as the task description, but not in so much detail as to make the scope inflexible. DO NOT INCLUDE ANY PROPRIETARY INFORMATION OR COMPANY-SENSITIVE INFORMATION IN THE SOW TEXT. The following is the required format for the SOW.

Proposal Number:

Organization:

Title:

ACURO and/or HRPO approval needed:

Introduction/Background *(To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.)*

Scope/Project Objective *(To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.)*

This section includes a statement of what the project covers. This should include the technology area to be investigated, the objectives/goals, and major milestones for the effort.

Requirements *(To be provided initially by the Offeror at the time of proposal submission to be finalized by the Government based on negotiation of Scope/Project Objective).*

State the technology objective in the first paragraph and follow with delineated tasks required to meet the overall project goals. The work effort should be segregated into major phases, then tasks and identified in separately numbered paragraphs. Early phases in which the performance definition is known shall be detailed by subtask with defined work to be performed. Planned incrementally funded phases will require broader, more flexible tasks that are priced up front, and adjusted as required during execution and/or requested by the Government to obtain a technical solution. Tasks will need to track with established adjustable cost or fixed price milestones for payment schedule. Each major task included in the SOW should be priced separately in the cost proposal. Subtasks need not be priced separately in the cost proposal.

Deliverables *(To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.)*

Results of the technical effort are contractually binding and shall be identified herein. Offerors are advised to read the Base Agreement carefully. Any and all hardware/software to be provided to the Government as a result of this project shall be identified. Deliverables should be submitted

in PDF or MS Office format. It must be clear what information will be included in a deliverable either through a descriptive title or elaborating text.

Site Locations *(To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding.)*

Identify all site locations where project work will be conducted. Site locations should include the prime contractor, subcontractors, contract research organizations, military labs and/or units, etc. Only include information for an additional site if that site will receive funding to conduct research as outlined in the SOW. Delete the "Site 2" header if not used.

Site 1	Institution Name	Site 2	Institution Name
	Address for Primary Site		Address for Primary Site
	Principal Investigator/POC		Principal Investigator/POC

Milestone Payment Schedule *(To be provided initially by the Offeror at the time of proposal submission. Submitted information is subject to change through negotiation if the Government selects the proposal for funding. The milestone schedule included should be in editable format (i.e., not a picture))*

The Milestone Payment Schedule should include all milestone deliverables that are intended to be delivered as part of the project, a planned submission date, the monetary value for that deliverable and any cost share, if applicable. For fixed price agreements, when each milestone is submitted, the MTEC member will submit an invoice for the exact amount listed on the milestone payment schedule. For cost reimbursable agreements, the MTEC member is required to assign a monetary value to each milestone. In this case, however, invoice totals are based on cost incurred and will not have to match exactly to the amounts listed on the milestone payment schedule.

The milestones and associated deliverables proposed should, in general:

- be commensurate in number to the size and duration of the project (i.e., a \$5M multi-year project may have 20, while a \$1M shorter term project may have only 5);
- not be structured such that multiple deliverables that might be submitted separately are included under a single milestone;
- be of sufficient monetary value to warrant generation of a deliverable and any associated invoices;
- include, at a minimum, Quarterly Reports which include both Technical Reports and Business Status Reports (due the 25th of Apr, Jul, Oct, Jan), Annual Reports, as well as the Final Technical Report and Final Business Status Report. Reports shall have no funding associated with them.

Request for Project Proposal MTEC-22-01-BurnTraining
Number W81XWH-15-9-0001

MTEC-22-01-BurnTraining Milestone Payment Schedule Example						
MTEC Milestone Number	Task Num.	Significant Event/Accomplishments	Due Date	Govt Funds	Cost Share	Total Funding
1	N/A	Project Kickoff	6/15/2022	\$20,000		\$20,000
2	N/A	Quarterly Report 1 (Technical & Business)	7/25/2022	\$ -		\$ -
3	1	Protocol Synopsis	8/28/2022	\$21,075		\$21,075
4	2	Submission for HRPO approval	8/28/2022	\$21,075		\$21,075
5	3	Submission of Investigational New Drug application to the US FDA	9/14/2022	\$210,757	\$187,457	\$398,214
6	4	Toxicity Studies	10/1/2022	\$63,227		\$63,227
7	5	FDA authorization trial	10/1/2022	\$84,303		\$84,303
8	6	Research staff trained	10/15/2022	\$ -		\$ -
9	N/A	Quarterly Report 2 (Technical & Business)	10/25/2022	\$ -		\$ -
10	7	Data Management system completed	10/30/2022	\$ -		\$ -
11	8	1 st subject screened, randomized and enrolled in study	11/15/2022	\$150,000	\$187,457	\$337,457
12	9	Completion of dip molding apparatus	12/1/2022	\$157,829	\$187,457	\$345,286
13	10	Assess potential toxicology	12/1/2022	\$157,829		\$157,829
14	11	Complete 50% patient enrollment	12/15/2022	\$350,000	\$187,457	\$537,457
15	12	Electronic Report Forms developed	12/15/2022	\$315,658	\$187,457	\$503,115
16	13	Complete 75% patient enrollment	1/2/2023	\$157,829	\$93,728	\$251,557
17	N/A	Quarterly Report 3 (Technical & Business)	1/25/2023	\$ -		\$ -
18	14	Complete 100% patient enrollment	2/1/2023	\$157,829	\$93,728	\$251,557
19	15	Report results from data analysis	2/5/2023	\$157,829		\$157,829
20	N/A	Annual Report 4 (Technical & Business)	4/25/2023	\$ -		\$ -
21	N/A	Quarterly Report 5 (Technical & Business)	7/25/2023	\$ -		\$ -
22	N/A	Quarterly Report 6 (Technical & Business)	10/25/2023	\$ -		\$ -
23	N/A	Quarterly Report 7 (Technical & Business)	1/25/2024	\$ -		\$ -
24	N/A	Annual Report 8 (Technical & Business)	4/25/2024	\$ -		\$ -
25	N/A	Quarterly Report 9 (Technical & Business)	7/25/2024	\$ -		\$ -
26	N/A	Quarterly Report 10 (Technical & Business)	10/25/2024	\$ -		\$ -
27	N/A	Quarterly Report 11 (Technical & Business)	1/25/2025	\$ -		\$ -
28	N/A	Annual Report 12 (Technical & Business)	4/25/2025	\$ -		\$ -
29	N/A	Quarterly Report 13 (Technical & Business)	7/25/2025	\$ -		\$ -
30	N/A	Quarterly Report 14 (Technical & Business)	10/25/2025	\$ -		\$ -
31	N/A	Quarterly Report 15 (Technical & Business)	1/25/2026	\$ -		\$ -
32	N/A	Annual Report 16 (Technical & Business)	4/25/2026	\$ -		\$ -
33	N/A	Quarterly Report 17 (Technical & Business)	7/25/2026	\$ -		\$ -
34	N/A	Quarterly Report 18 (Technical & Business)	10/25/2026	\$ -		\$ -
35	N/A	Quarterly Report 19 (Technical & Business)	1/25/2027	\$ -		\$ -
36	N/A	Final Report (Technical & Business) <i>Must be submitted prior to PoP end</i>	5/25/2027	\$ -		\$ -
Total				\$2,025,240	\$1,124,741	\$3,149,981

Please Note:

1. Firm Fixed Price Contracts – Milestone must be complete before invoicing for fixed priced contracts.
2. Cost Reimbursable Contracts – You may invoice for costs incurred against a milestone. Invoicing should be monthly.
3. Quarterly and Annual Reports include BOTH Technical Reports and Business Status Reports (separate).
4. Final Report due date must be prior to PoP end noted in Research Project Award.
5. MTEC Milestone Numbers are used for administrative purposes and should be sequential.
6. Task Numbers are used to reference the statement of work if they are different from the MTEC Milestone Number.

Shipping Provisions (*The following information, if applicable to the negotiated SOW, will be finalized by the Government and the MTEC Consortium Manager based on negotiations*)

The shipping address is:

Classified Shipments:

Outer Packaging

Inner Packaging

Reporting

Quarterly Reports – The MTEC research project awardee shall prepare Quarterly Reports which will include a Technical Report and a Business Status Report in accordance with the terms and conditions of the Base Agreement. (Required)

Annual Reports – The MTEC research project awardee shall prepare Annual Reports which will include a Technical Report and a Business Status Report in accordance with the terms and conditions of the Base Agreement. (Required)

Final Technical Report – At the completion of the Research Project Award, the awardee will submit a Final Technical Report, which will provide a comprehensive, cumulative, and substantive summary of the progress and significant accomplishments achieved during the total period of the Project effort in accordance with the terms and conditions of the Base Agreement. (Required)

Final Business Status Report – At the completion of the Research Project Award, the awardee will submit a Final Business Status Report, which will provide summarized details of the resource status of the Research Project Award, in accordance with the terms and conditions of the Base Agreement. (Required)

Attachment 5 – Current & Pending Support Template

Include the requested information for each person who will contribute significantly to the proposed research project

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]

Attachment 6 – Intellectual Property and Data Rights

Definitions

- **Intellectual Property (IP) Rights** for MTEC Research Project Awards will be defined in the terms of an awardee’s Base Agreement, unless specifically negotiated in any resultant Research Project Award. MTEC Base Agreements are issued by the MTEC CM to MTEC members receiving a Research Project Award. 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 contained in their Base Agreement regarding Data Rights, as modified by the specifically-negotiated Data rights terms herein. Refer to Section 2.11 of this RPP.

Directions to the Offeror

If applicable, complete the below table for any items to be furnished to the Government with restrictions. An example is provided. If the Offeror does not assert data rights on any items, a negative response is required by checking the applicable box below.

Failure to complete this attachment in its entirety (including a failure to provide the required signature) may result in removal from the competition and the proposal determined to be ineligible for award.

If the Offeror intends to provide technical data or computer software which existed prior to or was produced outside of the proposed effort, to which the Offeror wishes to maintain additional rights, these rights should be asserted through the completion of the table below.

Note that this assertion is subject to negotiation prior to award.

If Offeror WILL be asserting data rights for the proposed effort, check this box and complete the table below, adding rows as necessary.

Data Item	Description of Technical Data/ Software/Other IP to be Furnished	Stage of Development & Funding	Owner of Technical Data/ Software/ Other IP	Will Government Receive Government Purpose Right?	Authority to Grant Government Purpose Rights
1	Software XYZ	To be developed under this award with Public/Private Funding	Prime Company ABC	Yes	Authorization from Prime

Request for Project Proposal MTEC-22-01-BurnTraining
Number W81XWH-15-9-0001

2	Technical Data Description	Previously developed with Public funding	Prime Company ABC	Yes	Authorization from Prime
3	Technical Data Description	Previously developed with Private funding	Third-Party DEF	Yes	License Agreement with Third Party DEF

If the Offeror will NOT be asserting data rights for the proposed effort, check this box.

Signature of Responsible Party for the Proposing Prime Offeror

DATE

Attachment 7 – Safety Protocols

Ensuring Adequate COVID-19 Safety Protocols for Federal Contractors

As prescribed in Principal Director, Defense Pricing and Contracting memorandum of October 8, 2021, Implementation of Executive Order 14042, Ensuring Adequate COVID-19 Safety Protocols for Federal Contractors, in Other Transaction Agreements, the following clause is incorporated into this solicitation. If selected for award, the Offeror(s) shall comply with the guidance provided below:

ENSURING ADEQUATE COVID-19 SAFETY PROTOCOLS FOR FEDERAL CONTRACTORS (OCT 2021)

(a) Definition. As used in this clause –

United States or its outlying areas means—

- (1) The fifty States;
- (2) The District of Columbia;
- (3) The commonwealths of Puerto Rico and the Northern Mariana Islands;
- (4) The territories of American Samoa, Guam, and the United States Virgin Islands; and
- (5) The minor outlying islands of Baker Island, Howland Island, Jarvis Island, Johnston Atoll, Kingman Reef, Midway Islands, Navassa Island, Palmyra Atoll, and Wake Atoll.

(b) Authority. This clause implements Executive Order 14042, Ensuring Adequate COVID Safety Protocols for Federal Contractors, dated September 9, 2021 (published in the Federal Register on September 14, 2021, 86 FR 50985).

(c) Compliance. The Contractor shall comply with all guidance, including guidance conveyed through Frequently Asked Questions, as amended during the performance of this contract, for contractor or subcontractor workplace locations published by the Safer Federal Workforce Task Force (Task Force Guidance) at <https://www.saferfederalworkforce.gov/contractors/>.

(d) Subcontracts. The Contractor shall include the substance of this clause, including this paragraph (d), in subcontracts at any tier that exceed \$250,000 and are for services, including construction, performed in whole or in part within the United States or its outlying areas.

(End of clause)

Attachment 8 – BIDS Instructions

THIS PAGE IS INTENTIONALLY LEFT BLANK. PLEASE SEE THE PRESENTATION BELOW.