

Request for Project Proposals



Solicitation Number: MTEC-21-01-WBH

“Warfighter Brain Health (WBH): Late and Long-Term Consequences of Head Impact Exposure and Concussion/Mild Traumatic Brain Injury (mTBI) on Brain Health”

Issued by:

Advanced Technology International (ATI),

MTEC Consortium Manager (CM)

315 Sigma Drive

Summerville, SC 29486

for the

Medical Technology Enterprise Consortium (MTEC)

Request Issue Date: October 21, 2020

Solutions Brief Due Date: November 19, 2020

Noon Eastern Time Zone

White Papers Are NOT Required

Table of Contents

1	Executive Summary	3
1.1.	The Medical Technology Enterprise Consortium	3
1.2.	Purpose	3
2	Administrative Overview	4
2.1.	Request for Project Proposals (RPP)	4
2.2.	Proposers Conference	4
2.3.	Funding Availability and Type of Funding Instrument Issued	4
2.4.	Acquisition Approach	5
2.5.	MTEC Member Teaming	5
2.6.	Proprietary Information	6
2.7.	Offeror Eligibility	7
2.8.	Cost Sharing Definition	7
2.9.	Cost Share Requirements	7
2.10.	MTEC Assessment Fee	7
2.11.	Intellectual Property and Data Rights	8
2.12.	Expected Award Date	8
2.13.	Anticipated Solutions Brief Selection Notification	8
3	Solution Brief	8
3.1.	Solution Brief	8
3.2.	Solution Brief Submission	9
3.3.	Submission Format	9
4	Solution Brief Preparation Instructions	9
4.1.	General Instructions	9
5	Technical Requirements	10
5.1.	Introduction	10
5.2.	Scope of Work	10
5.3.	Federal Interagency Traumatic Brain Injury Research (FITBIR) Data Sharing	12
5.4.	Potential for Follow-on Work	13
5.5.	Restrictions on Animal and Human Subjects:	14
6	Solution Brief Preparation	14
6.1.	Preparation of the Solution Brief & Solution Brief Pitch	14
6.2.	Cost Proposal	19
6.3.	Solution Brief and Cost Proposal Preparation Costs	20
6.4.	Freedom of Information Act (FOIA)	20
6.5.	Telecommunications and Video Surveillance	20
7	Selection/Evaluation Criteria	20
8	Points-of-Contact (POCs)	23
9	Acronyms/Abbreviations	23
	Attachment A – Statutory Requirements for the Appropriate Use of Other Transaction Authority	26
	Attachment B – Cost Share	28
	Attachment C: – Intellectual Property and Data Rights	29
	Attachment D – Rough Order of Magnitude (ROM) Pricing	31
	Attachment E – Statement of Work (SOW)	32
	Attachment F – Current and Pending Support Template	38
	Attachment G – BIDS Instructions	39

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 Government agencies in the biomedical sciences (including but not limited to drugs, biologics, vaccines, medical software and medical devices) to protect, treat and optimize the health and performance of U.S. military personnel. MTEC is a nonprofit corporation with the following principal objectives:

- (a) biomedical research and prototyping;
- (b) exploration of private sector technology opportunities;
- (c) technology transfer; and
- (d) 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 Proposal Preparation Guide (PPG) and MTEC website.

MTEC operates under an Other Transaction Agreement (OTA) for prototypes with USAMRDC. As defined in the OTA Guide dated November 2018, a prototype project addresses a proof of concept, model, reverse engineering to address obsolescence, pilot, novel application of commercial technologies for defense purposes, agile development activity, creation, design, development, demonstration of technical or operational utility, or combinations of the foregoing. A process, including a business process, may be the subject of a prototype project. Although assistance terms are generally not appropriate in OT agreements, ancillary work efforts that are necessary for completion of the prototype project, such as test site training or limited logistics support, may be included in prototype projects. A prototype may be physical, virtual, or conceptual in nature. A prototype project may be fully funded by the Department of Defense (DoD), jointly funded by multiple federal agencies, cost-shared, funded in whole or part by third parties, or involve a mutual commitment of resources other than an exchange of funds.

1.2. Purpose

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

USAMRDC Combat Casualty Care Research Program (CCCRP). Strategic oversight for the award(s) supported by this RPP will be provided by USAMRDC. Project management will be conducted by the Congressional Directed Medical Research Program (CDMRP). Portfolio management will be conducted by CCCRP.

This program aims to focus on determining the relationship between concussion/mild traumatic brain injury (mTBI) and brain health (BH) outcomes through a longitudinal human subject study assessment.

2 Administrative Overview

2.1. Request for Project Proposals (RPP)

Each MTEC Solution Brief submitted must be in accordance with the mandatory format provided in the MTEC 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 reserves the right to award Solution Briefs received from this RPP on a follow-on prototype OTA or other stand-alone OTAs as necessary to meet mission requirements.

2.2. Proposers Conference

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

2.3. Funding Availability and Type of Funding Instrument Issued

The Government expects to have available approximately \$25 Million (M) for a period of performance (PoP) for 5 years. Award and funding from the Government of proposals received in response to this RPP is expected to be limited to approximately \$25M and is contingent upon the availability of federal funds for this program. Awards resulting from this RPP are expected to be made in Fiscal Year 2021.

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 \$25M in Government funding to be provided under the resultant award(s).

MTEC anticipates that a single award will be made to a qualified Offeror to accomplish the statement of work. However, the Government reserves the right to encourage teaming arrangements among Offerors to collaborate in a resultant award(s). Proposal(s) selected for award as a result of this RPP will be awarded under the authority of 10 U.S.C. § 2371b.

Award funding will be structured incrementally and based upon the completion of milestones.

Dependent on the results and deliverables under any resultant award(s), the Government may apply additional dollars and/or allow for additional time for follow-on efforts with appropriate modification of the award. See Section 5.4. for additional details.

2.4. Acquisition Approach

This RPP will be conducted using a multi-staged approach. In Stage 1, current MTEC members are invited to submit Solution Briefs using the mandatory format contained in this RPP (see Section 6 of this RPP). The Government will evaluate Solution Briefs submitted and will select the Solution Briefs that best meet their current technology priorities using the criteria in Section 7 of this RPP. Offerors whose proposed solution is selected for further consideration based on the Solution Brief evaluation will be invited to submit a “pitch” in Stage 2. Notification letters will contain specific Stage 2 proposal submission requirements. See Section 6 below for additional details regarding the Stage 2 solicitation process.

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

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. A sample of the MTEC Base Agreement can be found on the MTEC website and Members-Only website at www.mtec-sc.org.

At the time of the submission, if Offerors have not yet executed a Base Agreement, then Offerors must certify on the cover page of their Solution Brief that, if selected for award, they will abide by the terms and conditions of the latest version of the MTEC Base Agreement. If the Offeror already has executed an MTEC Base Agreement with the MTEC CM, then the Offeror must state on the cover page of its Solution Brief that, if selected for award, it anticipates the proposed effort will be funded under its executed MTEC Base Agreement.

2.5. MTEC Member Teaming

Solution Briefs submitted in response to this RPP are required to propose an already established and experienced clinical research network with a proven capability to recruit and maintain study individuals with TBI. Existing study data within the established network with the ability to follow this existing cohort is a requirement. If additional teaming beyond that of an already established and experienced clinical research network is needed within the context of your proposed project, Offerors are encouraged to consider teaming during the proposal preparation period (prior to Solution Brief submission) if they believe this may be beneficial to

the Government. In this case, MTEC members are encouraged to use the MTEC Database Collaboration Tool. **[Note: Please do not use the Collaboration Database Tool to build a new clinical research network as this will not meet the intent of this RPP.]** 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 opportunities identify others that are interested to partner in regards to the same funding opportunity. Contact information for each organization is provided as part of the member profile in the collaboration database tool to foster follow-up conversations between members as needed.

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

2.6. Proprietary Information

The MTEC CM will oversee submission of proposals submitted in response to this RPP. The MTEC CM shall take the necessary steps to protect all proprietary 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, including the Stage 1 Solution Brief 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 entities (e.g., foundations, investor groups, organizations, individuals) that award grants or otherwise co-fund research, and/or operates in research areas that are aligned with those of MTEC. These private entities may be interested in reviewing certain proposals within their program areas, allowing opportunities to attract supplemental funding sources. On your Solution Brief Cover Page, please indicate your willingness to allow MTEC Officers and Directors access to your proposal for the purposes of engaging in outreach activities with these private organizations. MTEC Officers and Directors who are granted Solution Brief access have

signed Non-disclosure Agreements (NDAs) and Organizational Conflict of Interest (OCI) statements. Additionally, all Technical Evaluation Panel participants will agree to, and sign a nonproprietary information and a conflict of interest document.

2.7. Offeror Eligibility

Offerors must be MTEC Members in good standing. Offerors submitting Solution Briefs as the prime contractor must be MTEC members of good standing by November 16, 2020.

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 B 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 A (“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 B.

Proposals that fail to meet the mandatory statutory conditions with regard to the appropriate use of Other Transaction authority, as detailed in Attachment A, 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 1% 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.

Additionally, MTEC has established two methods of payment to be made to MTEC surrounding the licensing/commercialization of Intellectual Property developed with funding received from MTEC Research Project Awards. Awardees must select one of the two methods:

(1) Royalty Payment Agreements

Government-funded research projects awarded through MTEC will be subject to a 10% royalty on all Net Revenues received by the Research Project Award recipient resulting from the licensing/commercialization of the technology, capped at 200% of the Government funding provided.

(2) Additional Research Project Award Assessment

In lieu of providing the royalty payment agreement described above, members receiving Research Project Awards may elect to pay an additional assessment of 2% above the standard assessment percentage described in Section 3.4 of the CMA. This additional assessment applies to all research project awards, whether the award is Government funded or privately funded.

2.11. Intellectual Property and Data Rights

Intellectual Property (IP) rights for MTEC Research Project Awards (RPAs) are defined in the terms of an awardee's Base Agreement and, if applicable, in the resultant RPA. MTEC reserves the right to assist in the negotiation of IP, royalties, licensing, future development, etc., between the government and the individual performers during the entire award period.

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 with unlimited data rights unless otherwise asserted in the proposal and agreed to by the Government.** Rights in technical data shall be determined in accordance with the provisions of MTEC Base Agreement.

See Attachment C for more detail. Note that as part of the Stage 1 of the RPP process (submission of a Solution Brief), **Offerors shall complete and submit Attachment C** with the Signature of responsible party for the proposing Prime Offeror.

2.12. Expected Award Date

Offeror should plan on the period of performance beginning July 1, 2021 (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. Anticipated Solutions Brief Selection Notification

As the basis of selections is completed, the Government will forward their selections to the MTEC CM to notify Offerors. Proposers will be notified by letter from the MTEC of the results of the evaluation. Those successful will move forward to Stage 2 of the RPP process while those rejected will gain evaluation rationale for non-selection.

3 Solution Brief

3.1. Solution Brief

The MTEC will use a streamlined, interactive approach for this RPP. Because of the nature of the requirements set forth in this RPP, this streamlined, interactive approach is anticipated to be a better means to highlight Offeror methodologies and skills that should allow the Government to gain a fuller appreciation of the work required to be completed. It provides more freedom and initiative to the Offeror to describe how the Offeror would approach and solve such an action. The following sections describe the formats and requirements of the Solution Brief.

Offerors who submit Solution Briefs in response to this RPP should submit by the date on the cover page of this RPP. Solution Briefs may not be considered under this RPP unless received on or before the due date specified on the cover page.

3.2. Solution Brief Submission

Solution Briefs should be submitted by the date and time specified on the cover page using BIDS: <https://ati2.acqcenter.com/ATI2/Portal.nsf/Start?ReadForm>. Include the **MTEC-21-01-WBH Solicitation Number** on each Solution Brief submitted. See RPP Attachment G for further information regarding BIDS registration and submission.

Do not submit any classified information in the Solution Brief submission.

3.3. Submission Format

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 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.

MTEC will email receipt confirmations to Offerors upon submission. 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.**

4 Solution Brief Preparation Instructions

4.1. General Instructions

The Solution Brief and Cost Proposal format provided in this MTEC RPP are mandatory and shall reference this RPP number (**MTEC-21-01-WBH**). Offerors are encouraged to contact the Points-of-Contact (POCs) identified herein up until the Solution Brief submission date/time to clarify requirements.

All eligible Offerors may submit Solution Briefs 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 or otherwise commit funding for selected awards as result of this RPP.

5 Technical Requirements

5.1. Introduction

The DoD Comprehensive Strategy for Warfighter Brain Health (CSWBH) addresses brain health, brain exposures, to include repetitive head impact exposures, TBI and long-term or late effects, with the goal of optimizing brain health and combating TBI. The DoD's pursuit of superior lethality, per the National Defense Strategy (2018) hinges on the Warfighter's optimal neurocognitive abilities, thus detection and management of brain injury at the time it occurs is paramount. One of the objectives of this strategy is to understand the nature and causes of long-term or late effects of single or repetitive head impact exposures and mTBI/concussion. This remains a significant gap that has stymied translatable knowledge or technology to be conveyed for the benefit of the Warfighter. Several gaps in the existing evidence remain related to the extent by which single and repetitive concussions and/or head impact exposures result in static or progressive changes in brain structure or function and performance. Additionally, the need for predictive models to assist in mitigation and prognosis efforts is critical.

5.2. Scope of Work

The overall objective of the Warfighter Brain Health (WBH) program is to advance both knowledge and technology prototypes (i.e., training, tools, and practice guidelines for assessment, metrics, and interventions) that will reduce or eliminate acute to late and long-term effects from single and repetitive concussion/mTBI. The DoD is seeking Solution Briefs for utilization of an already established and experienced Clinical Research Consortium (CRC) that will follow human subjects who have sustained a single or repeated concussion/mTBI to determine the relationship between concussion/mTBI, head impact exposures and brain health outcomes. The CRC will be expected to interact with a Government Steering Committee with involvement from the USAMRDC and other stakeholders.

Solution Briefs submitted in response to this RPP are required to propose an already established and experienced CRC with a proven capability to recruit and maintain study individuals with TBI. Existing study data within the established network with the ability to follow this existing cohort is a requirement. The CRC must include an established network of experts from research, clinical, data management, policy guidance, etc. to meet the intent of this RPP.

In addition, desirable capabilities (not listed in order of importance) of the existing CRC infrastructure are that it currently has (at the time of submission of the Solution Brief):

- The capability to recruit, enroll, and follow a large population of control and TBI patients who have sustained a single or repeated concussion/mTBI (preferably upwards of 15,000 human subjects, if feasible);
- Access to study populations and data already collected from human subjects that support the goals of this program and the ability to maintain and interpret these data;
- Ongoing relationships with both non-Government and DoD organizations that comprise the CRC network;
- Experience with sports- and military-related concussion;
- Access to military patients with brain trauma including repetitive concussion and/or head impact exposure;
- Access to human patients with concussion that are part of the National Collegiate Athletic Association (NCAA) [to compare with military patients to build the capability of predictive models and strategies for clinical interventions]; and,
- The focus to be metric-driven with requirements for prototype development toward clinical interventions, endpoints, policy and processes for mitigation and management of concussion, including the correlation of single and repetitive head impact exposure to Warfighter performance.

The end goal of the program is to deliver translatable processes, knowledge and technology (i.e., training, and practice guidelines for assessment and interventions) to better understand, optimize care for, and treat the immediate, long-term and late effects of repetitive head impact exposure (i.e. jump zones, training activities, shipboard, etc.) and single and repetitive concussions/mTBI in order to maximize WBH. It is expected that outcomes will be transitioned to inform practice guidelines, training and clinical trial endpoints.

Additional points of consideration:

- **Comprehensive and Integrated CRC with a Centralized POC:** *It is required that Solution Briefs include an already established and experienced clinical research network with a proven capability to recruit and maintain study individuals with TBI. This program is NOT intended to develop a new research network.* In other words, MTEC/DoD resources shall not be used to stand up clinical research sites; rather, the DoD expects to leverage capabilities already existing in the TBI research and development landscape. Agreements among TBI CRC members shall be handled by the CRC to the greatest extent possible. A centralized POC for the WBH CRC shall be named and will be ultimately responsible for official communication and deliverables. Offerors are expected to propose a WBH CRC comprised of the necessary qualified personnel, facilities, equipment, supplies, services, and subcontractors and related administrative and information technology support to accomplish the objectives.
- **TBI Patient Population:** It is expected that Offerors will have access to resources that can help overcome the challenges of TBI clinical research and trials. Difficulties in

conducting studies in TBI patients include the significant variability in the nature and repetitiveness of TBIs, and the overall health status of patients. TBI patient stratification, comparison to imaging, bio-samples, interim analysis, and population enrichment shall be integral parts of research protocols and trial design, and Offerors shall demonstrate expertise in these areas.

- **Federal Interagency Traumatic Brain Injury Research (FITBIR) Data Sharing:** See Section 5.3 below for details.
- **Cost Share:** The Government funds provided for this initiative are not anticipated to be the sole funding resource for the efforts. It is anticipated that the Government funds would provide incentive for non-DoD funding to join the project. While not a requirement, Offerors are strongly encouraged to include Cost Share as appropriate.
- **Military Impact:** This award must be relevant to the health care needs of the DoD. Offerors shall address the military need to better understand the impact of military-relevant single and repeated, mTBIs on brain health.
- **Award Governance Structure:** The successful Offeror(s) under this RPP will be managed by an appointed DoD program manager (PM). The successful Offeror(s) shall be prepared to communicate with the DoD PM on a routine basis for meetings in-person, or “virtually” through video conferences or teleconferences, to assure continuing synchronization and integration of Awardee efforts, and make recommendations for funding allocations based on progress of award Milestones and Deliverables. If other funding partners participate in cost sharing or co-funding, the DoD PM will make the final determination on the utilization of the DoD resources provided through this RPP.

5.3. Federal Interagency Traumatic Brain Injury Research (FITBIR) Data Sharing

The DoD requires that awardees make TBI research data generated by this award mechanism available to the research community through the FITBIR Informatics System. The FITBIR Informatics System is a free resource designed to accelerate research progress by allowing the storage, re-analysis, integration, and rigorous comparison of multiple datasets. Currently FITBIR eligible research includes all studies generating prospectively collected human TBI subject data (e.g., clinical, demographic, phenotypic, imaging, and genomic).

Data reporting to FITBIR is an opportunity for investigators to facilitate their own research and to collaborate with others engaged in similar research. While there is no direct charge to users of the FITBIR Informatics System, a project estimation tool (<https://fitbir.nih.gov/jsp/contribute/fitbir-costs.jsp>) is available to help estimate costs and manpower needs that may be associated with data submission. FITBIR guidance and policies, as well as the considerable advantages of FITBIR participation to the researcher, are detailed at <http://fitbir.nih.gov/>.

In order to share data with FITBIR, three elements must be included in the proposed research:

1. Updated informed consent language that includes FITBIR data sharing.
2. Global Unique Identifier (GUID): FITBIR encourages collaboration between laboratories, as well as interconnectivity with other informatics platforms. Such community-wide sharing requires common data definitions and standards. FITBIR allows for de-identification and storage of data (medical imaging clinical assessment, environmental and behavioral history, etc.) of various types (text, numeric, image, time series, etc.). Use of FITBIR's GUID system facilitates repeated and multi-user access to data without the need to personally identify data sources. In order to generate a GUID for a subject, the following personally identifiable information (PII) must be collected in the proposed research:
 - a. Complete legal given (first) name of subject at birth
 - b. Complete legal additional name of subject at birth (if subject has a middle name)
 - c. Complete legal family (last) name of subject at birth
 - d. Day of birth
 - e. Month of birth
 - f. Year of birth
 - g. Name of city/municipality in which subject was born
 - h. Country of birth

Note that this PII is never sent to the FITBIR system. PII cannot be extracted from the GUID. Information on GUID compliance with Health Insurance Portability and Accountability Act (HIPAA) regulations can be found at <https://fitbir.nih.gov/content/global-unique-identifier>.

3. Common Data Elements (CDEs): Research data elements must be reported using the National Institute of Neurological Disorders and Stroke (NINDS) TBI CDEs or entered into the FITBIR data dictionary as new, unique data elements (UDEs). For the most current version of the NINDS TBI CDEs, go to <http://www.commondataelements.ninds.nih.gov>. Assistance will be available to help the researchers map their study variables to specific CDEs and ensure the formats of the CDEs collected are compatible with the FITBIR Informatics System. Use of the TBI CDEs is required wherever possible in an effort to create standardized definitions and guidelines about the kinds of data to collect and the data collection methods that should be used in clinical studies of TBI. Use of UDEs is strongly discouraged and subject to program approval.

5.4. Potential for Follow-on Work

Potential follow-on work may include tasks related to clinical research with single or repeated concussion/mTBI and clinical trials for concussion/mTBI for therapeutic interventions and/or diagnostic/prognostic technology.

5.5. Restrictions on Animal and Human Subjects:

Solution Briefs 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 Use and Review Office (ACURO) and 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 Solution Brief Pitch.

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

For example, the clinical studies under this RPP shall not begin until the USAMRDC HRPO provides authorization that the research may proceed. The USAMRDC HRPO will issue written approval to begin research under separate notification. Written approval to proceed from the USAMRDC HRPO is also required for any Research Project Awardee (or lower tier sub-awards) that will use funds from this award to conduct research involving human subjects. Offerors must allow at least 60 days in their schedule for the HRPO review and authorization process.

6 Solution Brief Preparation

6.1. Preparation of the Solution Brief & Solution Brief Pitch

Offerors submitting Solution Briefs in response to this RPP will be required to submit using the following stages outlined below:

Stage 1: Solution Brief

Required Submission Documents (3): Submitted via BIDS

- **Solution Brief: One PDF document 5MB or lower.**
- **Appendix 1: One PDF document 5MB or lower.**
- **Appendix 2: One PDF document 5MB or lower.**

The Solution Brief and its Appendices must be in 12 point font (or larger), single-spaced, single-sided, 8.5 inches 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 0.5 inch.

Solution Briefs and Appendices exceeding the page limits specified below may not be

accepted. Each document will be uploaded to BIDS separately (see Attachment G of RPP for BIDS instructions).

- **Solution Brief [One PDF document 5MB or lower, Twelve-page limit including cover page].** The following sections must be included in the Solution Brief:
 - **Cover Page** (included in the page limit) must include the following information:
 - Title of Solution Brief
 - Offeror's name and contact information (such as name of the organization, point of contact's name, email address, phone number, mailing address, etc.)
 - Statement that "This Solution Brief is submitted pursuant to the RPP MTEC-21-01-WBH"
 - Dates of submission and signature of official authorized to obligate the institution contractually
 - At the time of the submission, if Offerors have not yet executed a Base Agreement, then Offerors must certify on the cover page of their Solution Brief that, if selected for award, they will abide by the terms and conditions of the latest version of the MTEC Base Agreement
 - Willingness to allow MTEC Officers access to your Solution Brief 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 Solution Briefs and Cost Proposals within their program areas, allowing opportunities to attract supplemental funding sources. Please indicate your willingness to allow MTEC access to your Solution Brief for the purposes of engaging in outreach activities with these private sector entities. MTEC staff has signed NDAs and OCI statements.]
 - **Experience:** The Solution Brief shall describe the experience of the key personnel of the WBH CRC, its management team, the lead Point of Contact, Clinical Research Organization (CRO) (if applicable), and associated subject matter experts to meet the WBH objective and requirements. Describe the experience of each key person and subject matter expert with regard to work relevant to the WBH objective. Describe and provide examples of the proven history of the CRO (if applicable) and FDA compliance capabilities.
 - **Cost Sharing:** The Solution Brief shall describe any current and past partnerships that maximize funding dollars from non-government entities (via agreement structure, cost sharing with industry or other partners) for TBI clinical research

and how these reduce risk for stakeholders. Detail past projects with cost sharing (from non-government entities) and the types and amounts of additional funding that supported previous projects.

- **Clinical Study Protocol:** The Solution Brief shall describe strategies and concepts for clinical research design to be relevant to the WBH objective. It is expected that Offerors will demonstrate expertise in and propose innovative approaches to clinical research design and conduct which address prior shortcomings in research for TBI such as: (1) accounting for the heterogeneity in the nature and repetitiveness of TBIs using patient stratification or population enrichment, and (2) use of imaging modalities for stratification or intermediate outcomes. It is expected that Offerors will have established processes and demonstrated experience in overcoming challenges in clinical research of TBI.
 - **IP and Data Rights:** Refer to Attachment C, included in the Solution Brief page limitation.
 - **Data Sharing:** The DoD will provide oversight and negotiate for the DoD interests for maximal data sharing in the spirit of sharing lessons learned across the breadth of the award. In other words, the Awardee(s) will be expected to share data for subsequent analysis and follow on questions with the DoD in a manner that helps enable a successful outcome at the end of the award's delivery schedule. The Solution Brief shall describe the necessary relationships with industry, NCAA, network and other relevant partners, including non-disclosure agreements, intellectual property agreements, and data rights and standardized informed consent for the intent of maximizing biospecimens and data use throughout the life cycle of the WBH award. Describe the data curation methods, policies and associated framework that will be used to manage data and maximize use among WBH and TBI stakeholders.
 - **Anticipated Outcomes:** Provide a description of the anticipated outcomes from the proposed work. List milestones and deliverables from the proposed work.
 - **Military Impact:** Offeror should demonstrate an appreciation of the military need.
 - **Non-traditional defense contractor, nonprofit research institution, or 1/3 cost sharing:** Describe the plan to include significant participation of a non-traditional defense contractor, nonprofit research institution, or the ability to meet 1/3 cost sharing requirement. Refer to Sections 2.8-2.11 for more information.
 - **Rough Order of Magnitude (ROM) Pricing:** Refer to Attachment D. **NOTE: The total cost to the Government of your ROM shall not substantially deviate from the total cost to the Government proposed if invited to later stages of the RPP process (unless otherwise directed by the Government).**
- **Appendix 1: Clinical Research Execution Sites [One PDF document 5MB or lower, Twenty-page limit]:** Appendix 1 shall provide a description of the existing TBI clinical

research consortium. Description should include the research sites to be used to meet the requirements, including institution, facility locations and associated required resources. Describe the proven history of TBI patient enrollment and U.S. Food and Drug Administration (FDA) compliance capabilities. Provide details on the types of TBI research conducted, how many TBI patients were enrolled overall and by site, and the time period it took to enroll those patients. Please indicate your experience with Exemption from Informed Consent (EFIC).

- **Appendix 2: Project Management Plan (PMP) [One PDF document 5MB or lower, Ten-page limit]:** Appendix 2 shall provide a PMP including, but not limited to: a proposed timeline, risk mitigation strategies for schedule and cost deviations, roles and responsibilities of the WBH CRC management team members, describe the roles and responsibilities of the CRO (if applicable), and methods to ensure proper quality oversight of subcontractors and partners to ensure reaching the Milestones and Deliverables.

Stage 2: Solution Brief Pitch:

Required Submission Documents (2): Submitted via BIDS

- **Solution Brief Pitch: One PDF document 5MB or lower.**
- **Statement of Work and Milestone Payment Schedule: One PDF or word document 5MB or lower.**
- **Current and Pending Support: One word document 5MB or lower.**

In Stage 2, the Government envisions that the Offeror(s) will provide a virtual or in-person “pitch” of the proposed project along with a SOW/Milestone Payment Schedule (MPS) and ROM Pricing (see Attachment E) during a meeting with the Government sponsors for the research. The solution brief pitch should provide more details about the technical and business viability of the proposed work outlined in Stage 1. The pitch should include the following:

- **Description:** The Offeror will provide a more robust description of its approach and emphasize why this approach is expected to result in a successful outcome. This approach should follow the SOW/MPS provided with the pitch.
- **Progress:** The Offeror will describe the milestones provided with objective, quantifiable, and measurable metrics that will be used to measure progress during the period of performance/delivery schedule and describe the oversight managerial methods that will be employed to maintain a quality and timely performance.
- **Relevant Experience:** The Offeror will convey details related to key personnel and past performance(s) that demonstrate relevance to the scope of the proposed work and build confidence in the team’s capabilities.

- **Effectiveness (Opportunity and Risk):** The Offeror shall identify, assess, evaluate, and clearly convey items (for known-knowns; known-unknowns and potential unknown-unknowns) for opportunities (e.g., reduction in cost or schedule, and/or improvement in performance) and risks within each appropriate project Cost, Schedule, Performance measure of effectiveness. The Offeror will identify objective measures and metrics used to assess each item, the triggering event(s), the expected result of Opportunities and Risk (if risk is unmitigated) item, and the mitigation plan for each identified risk item.
- **Cost:** The Solution Brief Pitch must present summarized costs at the task level. **NOTE: The total cost to the Government shall not substantially deviate from the total cost to the Government previously proposed in Stage 1 of the RPP process (unless otherwise directed by the Government).**
- **Statement of Work and Milestone Payment Schedule submission:** Separately, a Word (.docx or .doc) version of the SOW and MPS and a Word (.docx or .doc) are required. See Attachment E for additional information.
- **Current and Pending Support (no page limit):** Separately, a Word (.docx or .doc) version of which follows the template listed as Attachment F. A separate document should be provided for each person who will contribute significantly to the proposed research project. For all current and pending research support (to include government and non-government), include the award number and title, funding agency and requiring activity's names, period of performance (dates of funding), level of funding (total direct costs only), brief description of the project's goals, and list of specific aims. If applicable, identify where the proposed project overlaps with other existing and pending research projects.
If there is no current and/or pending support, enter "None" in Attachment F.

If desired, the Government can request additional information related to specific areas of interest to be included in the pitch. Specific details regarding this request for such information as well the final Stage 2 instructions and submission requirements will be provided to favorably evaluated Offerors at the end of Stage 1 and at the time of invitation to advance into Stage 2.

The information discussed during the pitch provides a means for the Government to engage in a discussion with the Offeror to gain a greater understanding of the Solution Brief and the Offeror's capabilities. The pitch should be restricted to **a maximum of One hour** with a total time of two hours to include questions from the Government and discussion. Any materials that will be presented during the pitch or included as supplementary material must be provided in advance of the meeting date. If an in-person meeting cannot be accommodated by the Offeror, then a minimum of a telephonic discussion accompanied by written support material will be

required. Briefing slides or documents or a combination thereof can be used to support this effort.

At the conclusion of the Stage 2 evaluation, Offerors who are favorably evaluated will be invited to submit a final solution brief (which may be amended from the initial brief to incorporate discussion points from the government interaction) and a cost proposal.

Stage 3: Cost Proposal

Required Submission Documents (4): Submit to mtec-contracts@ati.org

- **Section II: Cost Proposal Narrative as one word or PDF document.**
- **Section II: Cost Proposal Formats as one excel or PDF document.**
- **Warranties and Representations: One word or PDF document.**
- **Royalty or Additional Research Project Award Assessment: One signed word or PDF document.**

The Offerors invited to submit a Cost Proposal are encouraged to contact the MTEC CM and/or Government with any questions so that all aspects are clearly understood by both parties. The cost proposal should include the following and be completed in accordance with Section 3 of this RPP and the PPG.

- **Cost Proposal submission:** one Word (.docx or .doc) or PDF file for Section I: Cost Proposal Narrative (Appendix B) required. Separately, Section II: Cost Proposal Formats (by Task) either in Excel (.xlsx or .xls) or PDF format is required.
- **Warranties and Representations:** One Word (.docx or .doc) or PDF file that contains all Warranties and Representations is required.
- **Royalty or Additional Research Project Award Assessment:** Each Offeror will select either the MTEC Additional Assessment Fee or the Royalty Agreement (available on the MTEC members only website), **not both**, and submit a signed copy with the proposal.

6.2. Cost Proposal

Offerors are encouraged to use their own cost formats such that the necessary detail is provided. MTEC will make cost proposal formats available on the Members-Only MTEC website. The Cost Proposal formats provided in the MTEC PPG are **NOT** mandatory. Refer to the MTEC PPG for additional details.

Each cost 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.

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-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>

6.3. Solution Brief and Cost Proposal Preparation Costs

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

6.4. 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.

6.5. 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.

7 Selection/Evaluation Criteria

The CM will conduct a preliminary screening of submitted Solution Briefs to ensure compliance with the RPP requirements. As part of the preliminary screening process, Solution Briefs 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 RPP Section 2). Proposal Compliance with the statutory requirements regarding the appropriate use of Other Transaction Authority (as detailed within Attachment B) will be determined in accordance with the ratings listed in Table 1 below:

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 Solution Brief has at least one Nontraditional Defense Contractor or Nonprofit Research Institution 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 Solution Brief has at least one Nontraditional Defense Contractor or Nonprofit Research Institution 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

Solution Brief (Stage 1) Evaluation:

The CM will distribute all Solution Briefs that pass the preliminary screening (described above) to the Government for evaluation. The Government will evaluate and determine which Offerors will be invited to submit a Stage 2 Solution Brief Pitch based on the following Stage 1 criteria:

- **Factor 1 – Technical Feasibility:** Feasibility of the proposed solution and its alignment with the RPP’s topic area, including access to human subject population if applicable. The Government will evaluate the degree to which the Offeror demonstrates current capabilities as listed under Section 5.2 of this RPP. Technical Feasibility will also consider the Offeror’s clinical study protocol to include the strategies and concepts for clinical research design as they relate to the WBH objective. The Government may consider the estimated budget as an aspect of overall technical feasibility.
- **Factor 2 – Management Approach and Relevant Experience:** Strength of the organization/team, considering the qualifications of the personnel, facilities, equipment,

supplies, services, and subcontractors, project management plan, and related administrative and information technology support proposed to complete the work and its data sharing plan among partners of the WBH CRC and DoD that will leverage lessons learned throughout the course of the award.

- Factor 3 – Potential for Transition:** Soundness of the proposed strategy to produce outcomes that can transition to translatable processes, knowledge and technology to the DoD to better prevent the immediate, long and late-term effects of repetitive head impact exposure and concussions/mTBI in order to maximize WBH.

Table 2 explains the adjectival merit ratings that will be used for the Technical Feasibility, Management Approach and Relevant Experience, and Potential for Transition factors.

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.

Upon review of the Solution Briefs, Offerors may be invited into Stage 2 of the Solution Brief process. Offerors who are not invited to proceed into Stage 2 will be provided feedback.

Evaluation of Stage 2: The Government will evaluate the information provided in each Offeror's Solution Brief (Stage 1) and the Solution Brief Pitch (Stage 2) to determine which pitch(es) provide(s) the greatest value to the Government. Such a determination will be based on the following criteria and the ratings detailed in Table 2 above:

- **Factor 1 – Performance/Risk:** Overall technical approach and how well Offeror's solution and relevant experience enhances the DoD mission described in the RPP; including processes described to identify and manage risks/opportunities
- **Factor 2 – Schedule/Cost:** Suitability of the notional schedule, including processes described to identify and manage risks/opportunities. This fact will also include an assessment of the proposed cost of the project 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.

Upon completion of the Stage 2 evaluations and based on the results of the evaluation of the Solution Brief, the Solution Brief Pitch, and Cost Proposal, Offerors may be selected for funding, placed into the basket, or not selected.

The RPP review and award process may involve the use of contractors as subject-matter-experts or reviewers; where appropriate, the Government will employ NDAs to protect information contained in the RPP as outlined in Section 2.6.

8 Points-of-Contact (POCs)

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 Director of Research, Dr. Lauren Palestrini, Ph.D., lauren.palestrini@officer.mtec-sc.org
- All other questions should be directed to Ms. Kathy Zolman, MTEC Director of Program Operations, kathy.zolman@ati.org

Once an Offeror has submitted a Solution Brief, the DoD and the MTEC CM will not discuss evaluation/status until the evaluation results have been provided to all Offerors.

9 Acronyms/Abbreviations

ACURO U.S. Army Animal Use and Review Office

ATI	Advanced Technology International
CAS	Cost accounting standards
CRC	Clinical Research Consortium
CCCRP	Combat Casualty Care Research Program
CDE	Common Data Elements
CDMRP	Congressionally Directed Medical Research Program
CFR	Code of Federal Regulations
CM	Consortium Manager
CMA	Consortium Member Agreement
CRO	Clinical Research Organization
DoD	Department of Defense
EFIC	Exemption From Informed Consent
FAQ	Frequently Asked Questions
F&A	Facilities and Administrative Costs
FDA	U.S. Food and Drug Administration
FITBIR	Federal Interagency Traumatic Brain Injury Research (FITBIR)
FOIA	Freedom of Information Act (FOIA)
FY	Fiscal Year
G&A	General and Administrative Expenses
Government	U.S. Government, specifically the DoD
GUID	Global Unique Identifier
HRPO	Human Research Protections 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
mTBI	Mild Traumatic Brain Injury
MPS	Milestone Payment Schedule
MTEC	Medical Technology Enterprise Consortium
NDA	Nondisclosure Agreement
OCI	Organizational Conflict of Interest
ODC	Other Direct Charges
PII	Personally Identifiable Information
PM	Program Manager
POC	Point-of-Contact
POP	Period of performance
OTA	Other Transaction Agreement
PPG	Proposal Preparation Guide
ROM	Rough Order of Magnitude
RPP	Request for Project Proposals
SOW	Statement of Work

TBI	Traumatic brain injury
UDE	unique Data Elements
USAMRDC	U.S. Army Medical Research and Development Command
WBH	Warfighter Brain Health

Attachment A – 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 that is subject to full coverage under the cost accounting standards (CAS) prescribed pursuant to section 26 of the Office of Federal Procurement Policy Act (41 U.S.C. 422) and the regulations implementing such section. 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 (refer to the Proposal Preparation Guide found on the members only website) 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* include:

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

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 B – Cost Share

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

Cash Contribution

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

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

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

In-Kind Contribution

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

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

Attachment C: – Intellectual Property and Data Rights

Intellectual Property

Intellectual Property (IP) rights for MTEC Research Project Awards will be defined in the terms of an awardee’s Base Agreement and resultant RPAs. MTEC Base Agreements are issued by the MTEC CM to MTEC members receiving Research Project Awards. Base Agreements include the applicable flow down terms and conditions from the Government’s Other Transaction Agreement with MTEC, including the IP terms and conditions.

Data Rights

It is anticipated that anything delivered under a Research Project Award would be delivered to the Government with unlimited data rights. If this is not the intent, **then the Solution Brief should discuss data rights associated with each item**, and possible approaches for the Government to gain unlimited data rights as referenced in the Base Agreement. Rights in technical data in each Research Project Award shall be determined in accordance with the provisions of MTEC Base Agreement.

If applicable, complete the below table for any items to be furnished to the Government with restrictions. An example is provided. 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.

Technical Data or Computer Software to be Furnished with Restrictions	Basis for Assertion	Asserted Rights Category	Name of Organization Asserting Restrictions	Milestone # Affected
Software XYZ	Previously developed software funded	Restricted	Organization XYZ	Milestones 1, 3, and 6

Request for Project Proposals MTEC-21-01-WBH
Number W81XWH-15-9-0001

	exclusively at private expense			
Technical Data Description	Previously developed exclusively at private expense	Limited	Organization XYZ	Milestone 2
Technical Data Description	Previously developed with mixed funding	Government Purpose Rights	Organization XYZ	Milestone 2

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 D – Rough Order of Magnitude (ROM) Pricing

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 example table format and template below to provide an initial ROM.** The labor, travel, material costs, other direct costs, and indirect costs, information should be entered for Offeror (project prime) only. Subcontractors and/or consultants should be included only in the “Subcontractor” section of the table.

Labor	<i>\$ 100,000.00</i>
Labor Hours	<i>1,000.0 hrs</i>
Subcontractors	<i>\$ 50,000.00</i>
Subcontractors Hours	<i>500.0 hrs</i>
Consultants	<i>\$ 10,000.00</i>
Consultants Hours	<i>100.0 hrs</i>
Material/Equipment	<i>\$ 75,000.00</i>
Other Direct Costs	<i>\$ 1,000.00</i>
Travel	<i>\$ 5,000.00</i>
Indirect cost	<i>\$ 48,200.00</i>
Total Cost	<i>\$ 289,200.00</i>
Fee (<i>Not applicable if cost share is proposed</i>)	<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>

Attachment E – Statement of Work (SOW)

For Information Only – Stage 2 Requirement

The SOW developed by the Lead MTEC member organization and included in the Solution Brief Pitch is intended to be incorporated into a binding agreement if selected for award. If no SOW is submitted, 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 contract inflexible. DO NOT INCLUDE ANY PROPRIETARY INFORMATION OR COMPANY-SENSITIVE INFORMATION IN THE SOW TEXT. The following is the required format for the SOW.

Statement of Work

Submitted under Request for Project Proposal (*Insert current Request No.*)

(Proposed Project Title)

Introduction/Background (*To be provided initially by the Offeror at the time of Solution Brief Pitch 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 Solution Brief Pitch 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 Solution Brief Pitch 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. 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 Solution Brief Pitch 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.

Milestone Payment Schedule *(To be provided initially by the Offeror at the time of Solution Brief Pitch 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 \$700K shorter term project may have only 6);
- 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 Status and Business Status Reports (due the 25th of Apr, Jul, Oct, Jan), Annual Technical Report, Final Technical Report, and Final Business Status Report. Reports shall have no funding associated with them.

MTEC Milestone Payment Schedule Example						
MTEC Milestone Number	Task Number	Significant Event/ Accomplishments	Due Date	Government Funds	Cost Share	Total Funding
1	N/A	Project Kickoff	12/1/2019	\$20,000		\$20,000
2	N/A	Quarterly Report 1 (October - December, Technical and Business Reports)	1/25/2020	\$ -		\$ -
3	1	Protocol Synopsis	2/28/2020	\$21,075		\$21,075
4	2	Submission for HRPO Approval	2/28/2020	\$21,075		\$21,075
5	3	Submission of Investigational New Drug application to the US FDA	4/30/2020	\$210,757	\$187,457	\$398,214
6	N/A	Quarterly Reports 2 (January - March, Technical and Business Reports)	4/25/2020	\$ -		\$ -
7	N/A	Quarterly Report 3 (April - June, Technical and Business Reports)	7/25/2020	\$ -		\$ -
8	4	Toxicity Studies	10/1/2020	\$63,227		\$63,227
9	N/A	Annual Report 1	10/25/2020	\$ -		\$ -
10	5	FDA authorization trial	11/30/2020	\$84,303		\$84,303
11	6	Research staff trained	11/30/2020	\$ -		\$ -
12	7	Data Management system completed	11/30/2020	\$ -		\$ -
13	8	1 st subject screened, randomized and enrolled in study	1/1/2021	\$150,000	\$187,457	\$337,457
14	N/A	Quarterly Report 4 (October - December, Technical and Business Reports)	1/25/2021	\$ -		\$ -

Request for Project Proposals MTEC-21-01-WBH
Number W81XWH-15-9-0001

15	9	Completion of dip molding apparatus	3/1/2021	\$ 157,829	\$ 187,457	\$ 345,286
16	N/A	Quarterly Reports 5 (January - March, Technical and Business Reports)	4/25/2021	\$ -		\$ -
17	10	Assess potential toxicology	6/1/2021	\$157,829		\$157,829
18	N/A	Quarterly Report 6 (April - June, Technical and Business Reports)	7/25/2021	\$ -		\$ -
19	11	Complete 50% patient enrollment	10/1/2021	\$350,000	\$187,457	\$537,457
20	N/A	Annual Report 1	10/25/2021	\$ -		\$ -
21	N/A	Quarterly Report 7 (October - December, Technical and Business Reports)	1/25/2022	\$ -		\$ -
22	12	Electronic Report Forms Developed	3/1/2022	\$315,658	\$187,457	\$503,115
23	N/A	Quarterly Reports 8 (January - March, Technical and Business Reports)	4/25/2022	\$ -		\$ -
24	N/A	Quarterly Report 9 (April - June, Technical and Business Reports)	7/25/2022	\$ -		\$ -
25	13	Complete 100% patient enrollment	8/1/2022	\$315,658	\$187,457	\$503,115
26	N/A	Annual Report 1	10/25/2022	\$ -		\$ -
27	14	Report results from data analysis	11/1/2022	\$157,829		\$157,829
28	N/A	Final Reports (<u>Prior to the POP End</u>)	11/30/2022	\$ -		\$ -
			Total	\$2,025,240	\$1,124,742	\$3,149,982

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. Cannot receive payment for a report (i.e. Quarterly, Annual and Final Reports should not have an assigned Government Funded or Cost Share amount.)
4. Quarterly and Annual Reports include BOTH Technical and Business Reports (separate).
5. Final Report due date must be prior to POP end noted in Research Project Award.
6. MTEC Milestone Numbers are used for administrative purposes and should be sequential.
7. 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 *(The following information, if applicable to the negotiated SOW, will be provided by the Government based on negotiation)*

Report Months	Due Date
January – March	25 April
April - June	25 July
July - September	25 October
October - December	25 January

- Quarterly Reports – The MTEC research project awardee shall prepare a Quarterly Report, which will include a Technical Status Report and a Business Status Report in accordance with the terms and conditions of the Base Agreement. (Required)
- Annual Technical Report – The project awardee shall prepare an Annual Technical Report for projects whose periods of performances are greater than one year 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 F – Current and Pending Support Template

For Information Only - Stage 2 Requirement

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 Awarded 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 Awarded 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 G – BIDS Instructions

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