Request for Project Proposals



Solicitation Number: MTEC-24-05-AutoDocSensor "Passive Data Collection using Autonomous Documentation (AutoDoc) Project – Development of Passive Sensor Suite"

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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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 Department of Defense (DoD) 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 operates under an Other Transaction Agreement (OTA) for prototype projects with USAMRDC. In accordance with 10 USC 4022, the MTEC OTA enables the Government 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. For more information on the MTEC, its mission, and the definition of prototype, see the MTEC website (<u>www.mtecsc.org</u>).

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 in support of the Telemedicine and Advanced Technology Research Center (TATRC). Proposals selected for award as a result of this RPP will be awarded under the authority of 10 U.S.C. § 4022. Strategic oversight for the award(s) supported by this RPP will be provided by TATRC.

The purpose of this RPP is focused on developing a system of sensor suites that can reliably and passively collect the core data needed to identify casualty status, key tasks performed by medics, and real-time resource use in casualty care scenarios under realistic battlefield conditions.

2 Administrative Overview

2.1. Request for Project Proposals (RPP)

MTEC is utilizing a multi-staged acquisition approach for this RPP. This is intended to provide the government with a robust form of evaluating the best solution. The following sections describe the formats and requirements of solution proposals. Additionally, the Proposal Preparation Guide (PPG) contains several templates required for this RPP. The PPG can be found on the MTEC members only site, <u>https://private.mtec-sc.org/</u>. For information on how to join MTEC, please visit <u>http://mtec-sc.org/how-to-join/</u>.

In Stage 1 of this effort, Offerors are invited to submit Solution Briefs to describe their proposed solutions. 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.

Each Solution Brief submitted must be in accordance with the mandatory format provided in **Section 8 of the RPP**. Solution Briefs that fail to follow the mandatory format may be eliminated from the competition during the CM's preliminary screening stage (see **Section 5** for more details on the Selection process).

Note that the terms "Solution Brief" and "Proposal" are used interchangeably throughout this RPP.

2.2. Funding Availability and Period of Performance

The U.S. Government (USG) currently has available a total of approximately **\$1.5 million (M)** for anticipated

awards to be made through this effort during FY2024. 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.

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 **up to two awards** to a qualified Offeror(s) to accomplish the scope of work with a Period of Performance (PoP) **not to exceed 24 months.**

2.3. Acquisition Approach

As noted above, MTEC is utilizing a multi-stage approach for this effort:

- <u>Stage 1 [Solution Brief]</u>: MTEC Members are invited to submit a Solution Brief using the format contained in **Section 8 of this RPP**. The government will evaluate proposed solutions using the criteria listed in **Section 5.2 of this RPP**.
- <u>Stage 2 [Solution Brief Pitch]</u>: Offerors who are favorably evaluated during Stage 1- Solution Brief will be invited to present and discuss their proposed solution with the Government sponsors via a virtual "pitch" of the proposed project along with a SOW/Milestone Payment Schedule and cost information. The Government will evaluate these pitches using the criteria listed in **Section 5.3 of this RPP**.
- <u>Stage 3 [Virtual Demonstration]</u>: Offerors selected to advance to Stage 3 will arrange for 4 complete fully functional passive technology solution set(s) to be shipped to TATRC headquarters (Fort Detrick, MD). After an initial live virtual demonstration by the Offeror, the Government will conduct a technical evaluation of the product over the course of four (4) weeks using the Assessments listed in **Section 5.4 of this RPP**. During this time, the Government expects a technical representative from the offeror to be available for phone or video conferencing to answer questions from the Government.
- <u>Stage 4 [Selection for Award]</u>: Upon completion of the Government's evaluation, Offeror(s) will be notified of the final award decision. Those Offeror(s) selected for award will be invited to submit a detailed Cost Proposal in accordance with the MTEC PPG.

The due date for Solution Briefs is found on the **cover page of this RPP**. Solution Briefs may not be considered under this RPP unless the Solution Brief 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. § 4022 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/documents-library/.

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 <u>conditions of the latest version of the MTEC Base Agreement</u>. 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.

2.4. Offeror Eligibility

Offerors must be MTEC Members in good standing to be eligible to submit a proposal. Offerors submitting Solution Briefs as **the prime performer must be MTEC members of good standing at least 3 days prior to submission of the Solution Brief**. Subcontractors (including all lower tier subawardees) do not need to be MTEC members. To join MTEC, please visit <u>http://mtec-sc.org/how-to-join/</u>.

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

2.5. Proposers Conference

MTEC intends to host a Proposers Conference that will be conducted via webinar within one week of the release of the RPP. The intent of the Proposers Conference is to provide an administrative overview of this RPP and to present further insight into the technical requirements outlined in **Section 3 of this RPP**. Further instructions will be forthcoming via email. Offerors are advised to check the MTEC website periodically during the proposal preparation period for any clarifications found in Frequently Asked Questions (FAQ) responses. The presentation slides and a transcript of the questions and answers session of the proposers conference will be posted to the MTEC members-only website.

2.6. Proprietary Information

The MTEC CM will oversee submission of Solution Briefs 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 Solution Brief, Solution Brief Pitch, and the Demonstration of a proposed technology. In accordance with the MTEC Proposal Preparation Guide (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 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 for opportunities to attract supplemental funding sources. Therefore, 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 entities. 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.

2.7. MTEC Member Teaming

While teaming is not required for this effort, Offerors are encouraged to consider teaming during the proposal preparation period (prior to Enhanced Solution Brief submission) if they cannot address the full scope of

technical requirements of the RPP or otherwise believe a team may be beneficial to the Government. The following resources may help Offerors form a more complete team for this requested scope of work.

- The MTEC M-Corps is a network of subject matter experts and service providers to help MTEC members address the business, technical, and regulatory challenges associated with medical product development. Please visit <u>https://www.mtec-sc.org/m-corps/</u> for details on current partners of the M-Corps.
- MTEC Database Collaboration Tool to help identify potential teaming partners among other MTEC members. 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 <u>MTEC members-only website</u>.
- A dedicated Teaming Connect will be held to facilitate direct interaction amongst MTEC members in relation to this active funding opportunity. This will be a virtual "connect" session via ZOOM where MTEC members will be allowed to provide brief pitch presentations regarding to their ongoing work, organizational capabilities, and teaming preferences. More information on this event will be provided after the release of this RPP.

2.8. Intellectual Property

Baseline Intellectual Property (IP) and Data Rights for MTEC Research Project Awards are defined in the terms of an awardee's Base Agreement and, if applicable, 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 contained in their Base Agreement regarding IP and Data Rights, as modified by the specifically negotiated IP and Data rights terms herein. It is anticipated that anything created, developed, or delivered under this proposed effort will be delivered to the Government with Government Purpose Rights or unlimited data rights unless otherwise asserted in the proposal and agreed to by the Government. Rights in technical data in each Research Project Award shall be determined in accordance with the provisions of MTEC Base Agreement.

Note that as part of Stage 1 of the RPP process (submission of a Solution Brief), Offerors shall complete and submit **Attachment 6 of the PPG** (Intellectual Property and Data Rights) with the Signature of the responsible party for the proposing Prime Offeror. For more information, the CM has published a resource for Offerors entitled, "Understanding Intellectual Property and Data Rights" on the MTEC members-only website.

2.9. Expected Award Date

Offerors should plan on the period of performance beginning July 2024 (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.

2.10. Anticipated Solutions Brief Selection Notification

As the basis of selections is completed, the Government will forward its selections to the MTEC CM to notify Offerors. All Proposers will be notified by email from the MTEC CM of the results of the evaluation. Those successful will move forward to the next stage of the process.

Offerors are hereby notified that once a Solution Brief has been submitted, neither the Government nor the MTEC CM will discuss evaluation/status until after the Offeror receives the formal notification with the results of this evaluation.

3 <u>Technical Requirements</u>

3.1. Background

The Military Health System (MHS) lacks a robust, accurate, and reliable methodology to collect, store, and track tactical combat casualty care (TCCC) data. Establishing a prehospital environment medical data set is an essential, foundational step to modernizing Military TCCC medical care. Without a means to collect and seamlessly transmit data reliably and passively from the point of need/care (e.g. point of injury [POI] through higher echelons of care), the MHS will continue to lack the essential data to develop a trustworthy artificial intelligence (AI) stack^{1,2} to support future concepts that will sustain Military medical operations in the various environments of Multi-Domain Operations (MDO), including, but not limited to Large Scale Combat Operations (LSCO). By leveraging trustworthy AI in future conflicts, the MHS can reduce the caregiver cognitive load and mitigate impacts of a LSCO medical asset overburden, enabling greater efficiencies and capabilities.

Military prehospital care often occurs in austere, chaotic environments. Military medics and combat lifesavers in the battlespace are focused on prioritizing casualty severity and managing a large patient load with limited supplies and assistance. During times of intense activity, they must prioritize their patients over documenting delivering care to save the lives of their fellow warfighters. Medical documentation for these providers is challenging, if not impossible in many instances. Being able to capture the medical care being delivered in these venues may be secondary to saving lives in that moment; however, the need for timely, accurate medical documentation remains. In the near term, this data generates valuable information to higher echelons of care, medical resupply/logistics systems, and Command situational awareness (SA). The additional, long-term benefit is the ability to leverage machine learning (ML) and AI to enhance care delivery in the tactical environment in the future based on lessons learned from current care requirements (see Figure 1).



To enhance TCCC and improve medical documentation in the MHS, a passive, (e.g., with minimal human effort) autonomous documentation solution of medical care in operational environments is an essential requirement to establishing these critical TCCC data sets. Furthermore, it is vital that the processes in collecting this data does <u>not</u> distract the medic/caregiver's capability and capacity to deliver care.

Current medical IT capabilities rely on combat medics diverting their attention away from care delivery to document their efforts. This either detracts from the medics' capability and capacity for performing essential care tasks or necessitates documentation in a delayed manner, often under significant time constraints, that reduce the quality and accuracy of the documentation. In future LSCO engagements, medical assets will be significantly stressed, increasing the likelihood of a complete absence, or incomplete, poor-quality documentation.

¹ Cindy Crump, Loretta M. Schlachta-Fairchild, "Achieving a trusted, reliable, Al-ready infrastructure for military medicine and civilian care," Proc. SPIE 11413, Artificial Intelligence and Machine Learning for Multi-Domain Operations Applications II, 114130C (21 April 2020); doi: 10.1117/12.2557514

² Carnegie Mellon University School of Computer Science, "AI Stack," (2019).

At present, the MHS has two programs of record (POR)/program instructions that focus on providing resources to document combat casualty care:

- (1) The Joint Operational Medicine Information Systems (JOMIS) under the Program Executive Office, Defense Healthcare Management Systems (PEO DHMS) provides interoperable medical information technology (IT) capabilities across the full spectrum of military operations using tactical communication networks. The JOMIS portfolio includes capabilities for Medical Mission Command, MHS Genesis Theater electronic health record (EHR), Operational Medical Data cloud, and a virtual health capability. A recent addition to the JOMIS portfolio is a medical IT software solution to document combat causality care called Battlefield Assisted Trauma Distributed Observation Kit (BATDOK). BATDOK's software tools were developed by the Air Force Research Laboratory (AFRL) and are leveraged at the POI and lower echelons of care (e.g., Roles 1-2).
- (2) The Medical Communications for Combat Casualty Care (MC4) under the Program Executive Office, Enterprise Information Systems (PEO EIS), which will transition to Operational Medical Information System – Army (OMIS-A) in fiscal year (FY) 24. The OMIS-A Role 1 and 2 centered portfolios include the MC4 semi-ruggedized system of systems containing fielded medical software systems, for initial EHR documentation, medical logistic ordering, and medic screening.

Thus, both the JOMIS and MC4 programs could benefit from the research, development and use of passive, autonomous documentation in tactical military medical care, largely independent of caregiver interactions, will lead to opportunities to inform and potentially achieve the following modernizations (see **Figures 2 & 3**):

- Semi-autonomous casualty care delivery
- Autonomous resource triage/assessments
- Autonomous resupply

- Autonomous resupply / medical regulating
- Just in Time (JIT) decision making across echelons of care
- JIT situational awareness for military leaders / decision makers



Figure 2. Operational Viewpoint (OV-1): High Level Operational Concept Graphic for the AC2 Portfolio

3.2. Technical Objective

To augment and supplement the current processes of medical documentation for TCCC, it is necessary to develop passive data inputs into the medical IT systems of record to reduce and or eliminate the need for

manual entry of care delivery into these systems. This will allow the medic/combat lifesaver to remain focused on their primary task, saving lives. The Autonomous Casualty Care (AC2) Research Portfolio and the Passive Data Collection using AutoDoc project seeks to develop systems of sensor suites that passively collect accurate and reliable data about casualty status, caregiver (e.g., medic and/or combat lifesaver) actions, and real time resource usage. This passive data collection will be leveraged in a follow-on project phase (see Section 3.4 of this RPP) to create algorithms that will autonomously document a TCCC card (e.g., DD Form 1380) (See **Addendum 1**).

The aim of this AutoDocSensor project is to establish a system of sensor suites that can reliably collect the core data needed to identify casualty status, key tasks performed by medics, and real-time resource use in casualty care scenarios under realistic battlefield conditions. This system is expected to be a multi-modal suite of sensors (medic and/or casualty-worn, environmental, robotic or drone based; see **Figure 3**) that can provide a reliable source of passive data to algorithms that can describe casualty care activities including:

- Medic performance of casualty care (e.g., medic registration, actions, tasks, decisions, etc.);
- Patient status (e.g., registration, physiologic, injury patterns, mental status, etc.); and
- Resource utilization (e.g., IVs, blood, tubing, bandages, dressings, medications, etc.).

Figure 3. Pre-Decisional/Conceptual Diagram of Data Agregation from AutoDoc Sensor Suites



The Government is seeking Solution Briefs describing a passive technology solution set(s) that supports the above-mentioned aim of the Passive Data Collection using the AutoDoc project. Offerors should describe the current capabilities of their passive technology solution set(s) and explore the art of the possible (e.g., using <u>mature</u> sensor technologies in <u>novel</u> ways to support passive data collection for autonomous TCCC). Candidate passive technology solution sets described in proposals will <u>NOT</u> be constrained to tactical communications in this initial phase, but those constraints should be considered for future phases (for example, follow-on work and other separate RPPs).

The overall plan for the execution of Task 1 of this AutoDocSensor project is outlined in Figure 4. Offerors are expected to propose work in alignment with the breakdown of tasks and time increments outlined in Figure 4. Offerors shall include a proposed plan for all sub-Tasks (i.e., Task 1A, 1B, 1C, and 1D). During Task 1A, Offerors are expected to provide 4 complete, fully functional passive sensor suites for assessment by the Government. Upon completion of the assessment, the sensor suites will be returned to the Awardee, from which further development can occur as outlined in Tasks 1B, 1C & 1D. During Tasks 1B, 1C and 1D, the Government may require additional sensor suites with a maximum of 20 complete, fully functional passive technology solution set(s) over the course of the POP.

*Note: <u>Task 2 is included in Figure 4 for informational purposes only</u> to indicate that algorithm development

will occur concurrent with the Task 1 POP. Task 2 is outside of the scope of this RPP. Proposals should not include workplans related to Task 2.





As noted in Figure 4, a "Government Peer Review and Down Selection" process will be conducted as part of each sub-task, which will include three specific government lead, independent assessments:

- Assessment 1: Face Validity Assessment (e.g., Technical Specifications Documentation [TSD] and Heuristic Usability Evaluation (HUE)
- Assessment 2: Simulated Use Testing (e.g., assessment of usability of the technology solution sets under simulated conditions leveraging medic participants and TCCC scenarios)
- Assessment 3: Data Quality Assessments (DQA)

At the end of each "Government Peer Review and Down Selection" process, feedback will be given to the Awardee so that refinement of the sensor suite solutions can occur as part of the next sub-task.

Sensor Categories	Sensor Technology Examples*	Patient Status	Caregiver Actions	Resource Consumption	Potential DD1380 Section/Form Fields
Audio Inputs	Wireless, wearable microphones		Ø	Ø	Identification Injury Signs/Symptoms Treatments Notes
Video Inputs	Body Cameras Action Cameras Eye Tracking Systems	Ø	Ø	Ø	Identification Injury Signs/Symptoms Treatments Notes
Physiological Monitors / Vital Sign Monitors (VSMs)	Wireless Vital Sign Monitors (WVSMs) - Pulse Oximeter (finger clip) - Blood Pressure (BP) Cuff - Electrocardiogram (ECG), etc.	V	Ø		Signs/Symptoms Notes

Table 1. Description of Sensor Types/Classifications

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	1				
Wearables	Smart Devices (watches, glasses,	$\overline{\mathbf{A}}$	\square		Injury
	bracelets, rings, finger clip				Signs/Symptoms
	applications)				Notes
	Skin Patches/dermal sensors				
	Smart Clothing (shirts, pants, belts,				
	socks, shoes etc.)				
	Smart Helmets				
	Ingestible Sensors				
	Simultaneous Global Positioning				
	System (S-GPS) body controls				
	General Packet Radio Service (GPRS)				
	body controls				
	Bluetooth key trackers				
Radio Frequency	Bar Codes/Quick Response (QR)	V	Ø	\square	Identification
Identification	codes				Treatments
(RFID)	Smart Dog Tags				Notes
technologies					

*Note: Table above is NOT an exhaustive list of sensor technologies or DD1380 documentation opportunities, it is intended for illustrative purposes only

3.3. Desired Solution Characteristics

Proposed solution sets should expect to conform to the following desired solution characteristics to satisfy a Minimum Viable Product (MVP), characterized by Technology Requirements, Data Output Requirements, and Documentation Requirements outlined below. Offerors are encouraged to propose solutions that meet as many of the desired solution characteristics (listed below) as possible at the time of proposal submission with clear strategies for incorporating <u>all</u> other desired characteristics during the period of performance.

All solution sets will conform to the Technology Requirements, Data Output Requirements, and Documentation Requirements outlined below:

Technology Requirements:

- 1. The passive technology solution set(s) will be inclusive of multiple sensors (e.g., 2 or more) combined into a single technology suite for data collection. The resulting sensor technology suite must NOT distract from care delivery, and will be inclusive of the passive monitoring of the following:
 - Individual patient status(es)
 - Caregiver actions
 - Resource consumption (use of medical supplies/logistics)
- 2. Individual sensor technology components of the passive technology solution set(s) can be inclusive of, **but not limited to**:
 - Audio inputs/devices
 - Video inputs/devices
 - Physiological monitors / VSMs (heart rate, blood pressure, respiratory rate, SpO₂, other telemetry, et al)
 - Wearables
 - RFID technologies
- 3. Wearable sensors components of the passive sensor technology solution set(s) can be worn by the patient AND caregiver, and data outputs generated from these wearable devices should be able to distinguish the user origin/user roles, when relevant/applicable.
- 4. The passive technology solution set(s) will be:

- Comprised of existing, proven sensor technologies (e.g., Offerors should NOT focus on notional/pilot sensor concepts/technologies, but rather the aggregation of mature technologies sensors into a set/suite deliverable).
- Reliable and valid (e.g., generates consistent/repeatable, and accurate data outputs).
- Effective and intuitive with respect to form factor and end user interfaces (e.g., does not interfere with care delivery, does not require extensive training to use, etc.).
- Effective regarding size, weight, and power (SWaP), and provide a minimum of 2 hours of run time.
- Relevant/applicable to data collection for combat casualty care at POI; (e.g., care under fire, tactical field care, prolonged casualty care, etc.).
- Effective and efficient with respect to data processing.
- To the largest extent possible, suitable for future use in austere, tactical environments (e.g., extreme temperatures [heat/cold], variable lighting venues, noisy/loud [gunfire, explosives, rockets et al] environments, urban warfare conditions, disrupted, disconnected, intermittent and low-bandwidth [DDIL] communication venues, etc.).

Data Output Requirements:

- 1. All data gathered from the sensor suites must be accessible and available for download.
 - During the initial government assessment, in the absence of any development efforts to achieve a physical data aggregation point, individual sensor data outputs will be manual exports.
 - For Offerors selected to advance to Task 1A, the passive technology solution set(s) will generate standardized data outputs that will be collected into a physical data aggregation point (to be developed). Data from these physical data aggregation points will be designed to be exported and stored into a centralized data repository/data collection system maintained by the government (for research assessments).
- 2. Data outputs must use recognized industry standard formats (e.g., not propriety or inaccessible), as applicable and appropriate.
- 3. Data outputs will be organized and timestamped using a common clock and will be inclusive of information (e.g., meta tagging et al) for future phases of development and analytics (e.g., algorithm development and ML/AI).
- 4. To the greatest extent possible, raw sensor data should be provided in the standardized data outputs. This will allow the government to leverage the raw data outputs for algorithm development in future project phases.

Documentation Requirements. Documentation of the passive technology solution set(s) will include the following electronic files [Please refer to Sections 4.2 and 4.3 to determine which of the below documents are required for Stage 1 – Solution Brief vs Stage 2 – Solution Brief Pitch]:

- Summary of the specific data elements on the DD Form 1380 (TCCC Card) which can currently be captured and a proposed conceptual plan of how the prototype passive technology solution set could inform future algorithms. [Requirement as part of Stage 1 – Solution Brief submission]
- Passive technology solution set data format(s) (e.g., data dictionary et al.) is required. When applicable, the specific data formats (JSON, XML, MP4 [resolution/frames per second, .mp4/.m4a/.m4b/.m4r/.m4v etc.], SSML, WAV, MOV, CSV [with column header descriptions]) and industry standards (e.g., Integrated Clinical Environment (ICE), Institute of Electrical and Electronics Engineers [IEEE] 11073, Health Level Seven [HL7], Audio/Video CODECs, Observation Medical Outcomes Partnership [OMOP] Common Data Model [CDM], Lab Streaming Layer [LSL] et al.) must be identified as part of this data output format documentation packet. [Requirement if invited to Stage 2 Solution Brief Pitch]

- 3. When raw data outputs are not possible, if the passive technology solution set includes sensors that capture waveform data and feature internal algorithms to locally process data elements, general descriptions of algorithm function(s) and waveform data are required. [Requirement if invited to Stage 2 Solution Brief Pitch]
- 4. Description of the estimated output data size (per hour of use) and projected bandwidth requirements and formats for communications for the prototype equipment set. [Requirement if invited to Stage 2 Solution Brief Pitch]
- 5. Power requirements and/or battery life of the prototype equipment set. [Requirement if invited to Stage 2 Solution Brief Pitch]
- 6. Complete, comprehensible, and concise user manuals and training documentation of the passive technology solution set will be provided (to include, but not limited to a quick start guide). [Requirement if invited to Stage 2 Solution Brief Pitch]
- 7. Training curriculum/plan (includes both end user and system technical operations information). [Requirement if invited to Stage 2 Solution Brief Pitch]

Participation/Collaboration Requirements of Awardees:

For awareness, the following requirements outline the expected actions required of Awardees that will occur during the PoP, if selected for award:

- For Offeror teams who advance to additional development of their solution set, they will be expected to participate in interoperability working group meetings (approximately 2 times per month) to ensure that the data outputs from the future passive sensor suite development efforts result in data outputs that are formatting in a standardized way.
- For Offeror teams who advance to additional development of their solution set, they will be expected to collaborate with other extramural and/or government performers to combine the highest performing/assessed features and components into a mature solution.

3.4. Potential Follow-on Tasks

Under awards resulting from this RPP, there is the potential for award of one or more non-competitive followon tasks based on the success of the project (subject to change depending upon Government review of completed work and successful progression of milestones). Potential follow-on work may be awarded based on the advancement in prototype maturity during the PoP.

Offerors are encouraged, as appropriate, to discuss potential follow-on work in Solution Brief submission to demonstrate the ability to further advance the project maturity beyond the proposed PoP. This will also allow the Offeror to highlight the potential capabilities that can be explored/achieved through short term and/or long-term advancement of the project in a way that is beneficial to the Government.

<u>For awareness only</u>: The government anticipates the release of a separate solicitation in the near future seeking to satisfy the following aims of the AutoDoc Project:

- Develop task identification algorithms that reliably document elements of a DD Form 1380 TCCC card (see **Addendum 1**).
- Build an infrastructure database of data passively collected from combat medics performing casualty care tasks in lab, training, and hyper-realistic battlefield settings.

4 Solution Brief Preparation and Process

4.1. Solution Brief Submission

Solution Briefs shall be submitted by the date and time specified on the cover page using BIDS: <u>https://ati2.acqcenter.com/ATI2/Portal.nsf/Start?ReadForm</u>. **The BIDS system will open for submissions no later than February 27, 2024.** Include the **MTEC-24-05-AutoDocSensor** on each Solution Brief submitted. See **Attachment 7 of the PPG** for further information regarding BIDS registration and submission.

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.

All eligible Offerors may submit proposals for evaluation according to the criteria set forth herein. Offerors are encouraged to contact the Points-of-Contact (POCs) identified herein until the Proposal due date/time to clarify requirements (both administrative and technical in nature).

4.2. Instructions for the Preparation of the Stage 1 Solution Brief

Offerors submitting Solution Briefs 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 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.

Required Submission Documents (5): Submitted via BIDS. Individual submission documents must be 5MB or lower.

- Solution Brief: One Word or PDF document (Required template is provided in Section 8 of this RPP)
- Warranties and Representations: one Word or PDF document (See Attachment 3 of the PPG)
- **Current and Pending Support**: one Word or PDF document (**Attachment 5 of the PPG**) summarizing other sponsored research for each person who will contribute significantly to the proposed prototype project. The information for previous support should include the past five (5) years, unless otherwise specified in the request. Additionally, information pertaining to this proposal submission in regard to foreign involvement should be addressed.
- Intellectual Property and Data Rights Assertions: one signed Word or PDF document (See Attachment 6 of the PPG)
- **Documentation:** one word of PDF document including the following information:
 - a. Summary of the specific data elements on the Tactical Combat Casualty Care Card (e.g., DD Form 1380) which can currently be captured.

Solution Briefs must be prepared **according to the mandatory format provided in Section 8** of this RPP. The Solution Brief is **limited to five pages (plus a cover page for a total of six pages)**. References may be included in the Solution Brief and are **excluded** from the page limitation. Appendices are also **excluded** from the page limitation. Formatting requirements include 11-point font (or larger), single-spaced, single-sided, 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 exceeding the page limit may not be accepted.

FOR INFORMATION ONLY: Additional attachments/appendices (henceforth referred to as supplemental information) to the Solution Brief submission <u>may</u> be requested after completion of the Stage 1 Solution Brief evaluation. The exact requirements of any such attachment/appendix are subject to change and will be provided at the time (or immediately following) the Stage 1 evaluation summary is provided.

4.3. Instructions for the Preparation of the Stage 2 Solution Brief Pitch

Upon review of the Solution Briefs, Offerors may be invited into Stage 2 of this effort. Offerors that are recommended for Stage 2 will receive notification letters which serve as formal requests for Stage 2 (Solution Brief Pitches) and may contain requested revisions or supplemental information. These letters will contain specific submission requirements if there are any changes to those contained in this RPP. However, it is anticipated that the following will be required:

Required Submission Documents (3): Submitted via BIDS. Individual submission documents must be 5MB or lower.

- 1) Solution Brief Pitch: One PDF document.
- 2) **Documentation:** One word or PDF document including the following information:
 - a. Passive technology solution set data format(s) (e.g., data dictionary et al.) is required.
 - b. Description of the estimated output data size (per hour of use) and projected bandwidth requirements and formats for communications for the prototype equipment set.
 - c. Identify power requirements and/or battery life of the prototype equipment set.
 - d. User manuals and training documentation of the passive technology solution set (to include, but not limited to a quick start guide)
 - e. Training curriculum/plan

In Stage 2, the Offeror(s) will provide a virtual "pitch" of the proposed project during a meeting with the Government. The solution brief pitch should provide more details about the proposed technology outlined in Stage 1 (Solution Brief). The information discussed during the solution brief pitch provides a means for the Government to engage in a discussion with the Offeror to gain a greater understanding of the proposal and the Offeror's capabilities. The solution brief pitch should be restricted to a maximum of 20 minutes for the presentation by the Offeror with a total time of 45 minutes to include questions from the Government. Any materials that will be presented during the solution brief pitch or included as supplementary material must be provided in advance of the meeting date. Briefing slides or documents or a combination thereof can be used to support this effort.

The Solution Brief Pitch is expected to include the following:

- <u>Technology Description and Approach</u>: A more robust description of the technology, approach and emphasize why this approach is expected to result in a successful outcome. This discussion should include relevance to the military use cases.
- **Development Strategy (including timing and regulatory):** Feasibility of the Offeror's product development strategy, including regulatory pathway, indication of use and designation, strategy for obtaining regulatory approvals or clearances. Offerors are also encouraged to include costs associated with their development strategy.
- <u>Interoperability</u>: The Offeror will convey details related to product interoperability with compatible systems and plans for future algorithm inclusion.
- <u>**Relevant Experience:**</u> The Offeror will convey details related to key personnel and past performance(s) that demonstrate relevance to the program objective and solution requirements

described in Section 3 of this RPP and build confidence in the team's capabilities.

- <u>Effectiveness (Opportunity and Risk)</u>: The Offeror will identify, assess, evaluate, and clearly convey items for opportunities (e.g., reduction in cost or schedule, and/or improvement in performance) and risks within each appropriate project measure, and the mitigation plan for each identified risk item.
- <u>Partnerships/Collaborations</u>: The Offeror will describe any current or potential partnerships or collaborations that may be of use when developing this product, especially in regards to algorithm development. Partnering with Government laboratories may be required downstream.
- <u>**Competitive Advantage:**</u> A clearly defined competitive advantage of the proposed technology over already existing solutions and other solutions in development by others in the field.
- <u>Market and Business Model</u>: Clear articulation of value proposition, competitive position, market opportunity and business model for getting to revenue through commercial use, including a description of the market (civilian and military) and sustainability.
- <u>Military Transition</u>: Offeror will describe the pathway to developing this into a product that can be used by the military.

4.4. Instructions for the Preparation of the Stage 3 Demonstration

During this stage, offerors will be invited to demonstrate their technology for TATRC personnel at Fort Detrick, MD. During this stage:

- Offerors selected for Stage 3 Demonstrations will provide the government with 4 complete, fully functional passive technology solution set(s) that meet the desired solution characteristics outlined in Section 3.3 for independent assessment. Offeror team will deliver the passive sensor suite candidate equipment to the government one week from receipt of the invitation letter to participate in Stage 3. The invitation letter will also specify the exact date the equipment will need to be shipped by at the time of notification.
- Offeror teams will participate in an initial meeting to introduce the capability to the government assessment team. During this meeting the Offeror team members will be expected to provide a detailed briefing on all the features and capabilities of the passive technology solution set(s) (e.g., research prototype).
- Offeror team will provide either an in-person or virtual guided demonstration (which will be recorded) to the government (at Fort Detrick, Maryland and/or other locations as required) of the passive technology solution set(s) on day 1 & 2 of any scheduled government assessment event, as required.
- Offeror team will allow an independent, government independent assessment team to use their candidate passive technology solution set during a multi-day clinical scenario driven assessment (e.g., as a standalone solution without Offeror guidance/mentorship).
- Offeror team will provide a technical point of contact (POC) to support the government in the preparation, execution, and post execution independent assessment process. This on call, remote availability for the prototype is estimated to be no more than 30 days via and would be limited to weekdays.

4.5. Instructions for the Preparation of the Stage 4 Selection for Award

Offerors that are recommended for award will receive notification letters which will serve as the formal request for a full Cost Proposal (and may contain a request for revisions and/or supplemental information based on the results of the technical evaluation). These letters will contain specific submission requirements if there are any changes to those contained in this RPP. However, it is anticipated that the following will be required:

Required Submission Documents (2): Submit to mtec-contracts@ati.org

- Section I: Cost Proposal Narrative as one Word or PDF document.
- Section II: Cost Proposal Formats as one Excel or PDF document.

See the PPG for additional instructions for submission requirements. Also refer to Addendum 5 of this RPP for details on how the full Cost Proposals will be evaluated.

5 <u>Selection</u>

5.1. General Information

Evaluations at all stages of the Solution Brief acquisition process shall be based on an independent, comprehensive review and assessment of the work proposed against stated evaluation factors. A rating consistent with these evaluation factors will be derived from the ability of the Offeror to perform the work in accordance with all aspects of requirements outlined in this RPP. The Offeror shall clearly state how it intends to meet the RPP requirements. Mere acknowledgement or restatement of a RPP requirement is not acceptable.

The Solution Brief and/or the Solution Brief Pitch process may involve the use of contractors as subject matter experts (SME) serving as nongovernmental advisors. Where appropriate, MTEC will employ NDAs to protect information contained in submissions. All members of the technical evaluation panel, to include contractor SMEs, will agree to and sign a Federal Employee Participation Agreement or a Nondisclosure/Nonuse Agreement, as appropriate, prior to accessing any proposal submission to protect information as outlined in Section 2.6. The adjectival merit ratings that will be used for all evaluation factors are shown in Table 3.

TABLE 3- 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.	

In support of this multi-stage acquisition approach, the Government sponsor will perform proposal source selection at each stage of the process. This will be conducted using the evaluation factors detailed below. The Government will conduct an evaluation of all qualified proposals. Upon completion of Stage 3, 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)

In rare cases, the following recommendation may be provided: "Recommendation Undetermined." This is reserved for situations in which additional information/documentation is needed by the Government evaluators before finalizing a recommendation to one of those listed above and is intended to facilitate the release of all evaluator comments within the BIDS System.

5.2. Solution Brief (Stage 1) - Selection and Evaluation Process

The CM will distribute all Proposals that pass the preliminary screening (described above) to the Government for evaluation. The Government will then conduct the source selection and determine which Offerors will be invited to submit a Stage 2 (Solution Brief Pitch) based on the following Stage 1 criteria. In some cases, to ensure scientific excellence, the Government may utilize an additional evaluation process to include an external peer review for the evaluation of Proposals against established criteria to determine technical merit. Regardless of whether or not the evaluation includes a peer review, all Solution Briefs will be evaluated based on the following factors. Feedback will be provided to the Offerors.

Stage 1 - Solution Brief Evaluation Factors (of equal importance):

- 1. Programmatic and Technical Relevance
- 2. Personnel and Team

Evaluation Factor 1 – Programmatic and Technical Relevance: The Offeror's proposal will be assessed for the extent at which the following are satisfied:

- Military Relevance: The degree to which the Offeror demonstrates a strong solution to the defined unmet military medical need consistent with Section 3 of the RPP.
- Technical Merit: The degree to which the Offeror presents a medical technology with strong supporting preliminary data that meets the Desired Solution Characteristics outlined in Section 3.3.

Evaluation Factor 2 – Personnel and Team: This factor will evaluate the strength of the organization/team that has proposed a solution to the military requirement. The Offeror's resources, expertise, and experience of personnel may be considered as part of this factor.

5.3. Solution Brief Pitch (Stage 2) - Selection and Evaluation Process

Offerors invited to Stage 2 (Solution Brief Pitch) will then be evaluated by a judging panel assembled by the Government Sponsor. The judging panel will make recommendations for invitation to Stage 3 (Demonstration).

Stage 2 - Solution Brief Pitch Evaluation Factors (of equal importance):

- 1. Technical Feasibility
- 2. Scalability and Sustainment

Evaluation Factor 1 – Technical Feasibility: Feasibility of the proposed solution and its alignment with the RPP's topic area. This factor will also include evaluation of the Offeror's approach to the solution set and product development strategy.

Evaluation Factor 2 – Scalability and Sustainment: This factor will evaluate the Offeror's:

- Plan for interoperability
- Plan for future algorithms
- Partnership/collaboration potential

5.4. Demonstration (Stage 3) Evaluation

Technology submitted by invited Offerors will be evaluated by the Government. Evaluation will include three specific government lead, independent assessments:

Stage 3 – Demonstration Evaluation (of equal importance):

- 1. Face Validity Assessment
- 2. Assessment of Simulated Use Testing
- 3. Data Quality Assessments

Evaluation Factor 1 - Face Validity Assessment (e.g., Technical Specifications Documentation and Heuristic Usability Evaluation

Evaluation Factor 2 - Assessment of Simulated Use Testing (e.g., assessment of usability of the technology solution sets under simulated conditions leveraging medic participants and TCCC scenarios)

Evaluation Factor 3 - Data Quality Assessments

The Government and MTEC CM will request additional information or clarification as necessary.

5.5. Definition of General Terms Used in Evaluations

<u>Significant Strength</u> - 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 during the demonstration.

<u>Strength</u> - An aspect of an Offeror's proposal that has merit or exceeds specified performance or capability requirements in a way that will be advantageous during the demonstration.

Weakness - A flaw in the proposal that increases the risk of unsuccessful demonstration.

Significant Weakness - A flaw that appreciably increases the risk of unsuccessful demonstration.

<u>Deficiency</u> - A material failure of a proposal to meet the requirement or a combination of weaknesses in a proposal that increases the risk of unsuccessful demonstration to an unacceptable level.

The following terms may be used to evaluate the Rough Order of Magnitude (ROM) cost/price estimate:

<u>Sufficient</u> - The ROM estimate is within the available funding limits and considered appropriate to successfully complete the proposed project.

<u>Insufficient</u> - The ROM estimate is lower than what is considered appropriate to successfully complete the proposed project.

<u>Excessive</u> - The ROM estimate is higher than what is considered appropriate to successfully complete the proposed project.

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, <u>mtec-contracts@ati.org</u>
- Technical and membership questions should be directed to the MTEC Biomedical Research Associate, Dr. Chuck Hutti, Ph.D., <u>chuck.hutti@ati.org</u>
- All other questions should be directed to the MTEC Program Manager, Mr. Evan Kellinger, <u>mtec-sc@ati.org</u>

7 Acronyms/Abbreviations

AC2	Autonomous Casualty Care
AI	Artificial Intelligence
AFRL	Air Force Research Laboratory
API	Application Programing Interface
ATI	Advanced Technology International
AutoDoc	Autonomous Documentation
BATDOK	Battlefield Assisted Trauma Distributed Observation Kit
BIDS	System for Submission of the Solution
BP	Blood Pressure
CDM	Common Data Model
CODEC	Coder and Decoder
СМ	Consortium Manager
CSV	Comma Separated Values
DDIL	Disrupted, Disconnected, Intermittent and Low-Bandwidth
DHA-PI	Defense Health Agency Procedural Instruction
DoD	Department of Defense
DQA	Data Quality Assessments
ECG	Electrocardiogram
FAQ	Frequently Asked Questions
FDA	U.S. Food and Drug Administration
GPRS	General Packet Radio Services
HITL	Human-In-the-Loop
HL7	Health Level Seven
HOTL	Human-On-the-Loop
HUE	Heuristic Usability Evaluation
ICE	Integrated Clinical Environment
IEEE	Institute of Electrical and Electronics Engineers
IP	Intellectual Property (e.g., patents, copyrights, licensing, etc.)
IT	Information Technology
JIT	Just In Time
JOMIS	Joint Operational Medicine Information Systems
JSON	Javascript Object Notation
LSCO	Large Scale Combat Operations
LSL	Lab Streaming Layer
MC4	Medical Communications for Combat Casualty Care
MD	Maryland
MDO	Multi-Domain Operations
MHS	Military Health System

ML	Machine Learning
MOV	Quicktime Multimedia File Format
MTEC	Medical Technology Enterprise Consortium
MVP	Minimum Viable Product
NDA	Non-disclosure Agreement
OCI	Organizational Conflict of Interest
OMIS-A	Operational Medical System - Army
OMOP	Observational Medical Outcomes Partnership
ОТ	Other Transaction
ΟΤΑ	Other Transaction Agreement
OV	Operational Viewpoint
PEO DHMS	Program Executive Office, Defense Healthcare Management Systems
PEO EIS	Program Executive Office, Enterprise Information Systems
POC	Point of Contact
POI	Point of Injury
POP	Period of Performance
POR	Programs of Record
PPG	Proposal Preparation Guide
QR	Quick Response
RFID	Radio Frequency Identification
RPP	Request for Project Proposals
SA	Situational Awareness
SDK	Software Development Kit
S-GPS	Simultaneous Global Positioning System
SME	Subject Matter Expert
SSML	Speech Synthesis Markup Language
SWaP	Size, Weight, and Power
TATRC	Telemedicine and Advanced Technology Research Center
ТССС	Tactical Combat Casualty Care
TSD	Technical Specifications Documentation
UEI	Unique Entity Identifier
USAMRDC	U.S. Army Medical Research and Development Command
USC	U.S. Code
Government	U.S. Government, specifically the DoD
VSM	Vital Sign Monitor
WAV	Waveform Audio File Format
WVSM	Wireless Vital Sign Monitors
XML	Extensible Markup Language

8 Solution Brief Template

Cover Page

[Name of Offeror] [Address of Offeror] [Phone Number and Email Address of Offeror]

Unique Entity Identifier (UEI) #: [UEI #] CAGE code: [CAGE code]

[Title of Solution Brief]

[Offeror] certifies that, if selected for selected for an Award, the Offeror will abide by the terms and conditions of the MTEC Base Agreement.

[A proprietary data disclosure statement if proprietary data is included. Sample: This Solution Brief includes data that shall not be disclosed outside the MTEC Consortium Management Firm and the Government and shall not be duplicated, used, or disclosed, in whole or in part, for any purpose other than to evaluate this Solution Brief and negotiate any subsequent award. If, however, an award agreement is a result of, or in connection with, the submission of this data, the MTEC Consortium Management Firm and the Government shall have the right to duplicate, use, or disclose these data to the extent provided in the resulting agreement. This restriction does not limit the MTEC Consortium Management Firm and the Government's right to use the information contained in these data if they are obtained from another source without restriction. The data subject to this restriction is (clearly identify) and contained on pages (insert page numbers).]

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 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 Nondisclosure Agreements (NDAs) and Organizational Conflict of Interest statements.]

[Title of Solution Brief]

Programmatic Relevance

- Provide the background and the Offeror's understanding of the problem and/or technology gap/process deficiency.
- Provide a robust description of the technology.
- Emphasize how the proposed technology meets the overall objective specified in this RPP.

Scientific Rationale / Preliminary Data

- Demonstrate how your proposed solution currently meets the Desired Solution Characteristics described in **Section 3.3**.
- Should your proposed solution not meet all the Desired Solution Characteristics described in **Section 3.3**, detail how those characteristics will be met during the period of performance.
- Include previous studies or preliminary data [non-clinical and/or clinical] that support the feasibility of the proposed passive technology solution set.
- Describe your demonstration of the manufacturing feasibility of the prototype.

Proposed Project Plan and Follow-on Work

- Describe your proposed project plan for Task 1.
- Follow-on Work: Describe how the initial prototype can be enhanced/expanded over time, to include options to integrate with external algorithms and enterprise systems (e.g., BATDOK, Operational Medical Information System-Army (OMIS-A) et al.) beyond the 24-month project PoP of Task 1.

Team

- Describe the qualifications and expertise of the key personnel and organizations associated with the proposed passive technology solution.
- Detail any past performance(s) that demonstrate relevance to the program objective and solution requirements.

Resources

- Identify any key facilities, equipment, and other resources relevant for the technical solution being proposed.
- Describe any current or potential partnerships or collaborations that may be of use when developing this product, especially in regard to algorithm development.

Market and Business Model

• Clearly articulate the value proposition, competitive position, market opportunity and business model for getting to revenue through commercial use, including a description of the market (civilian and military) and sustainability.

Product Development Strategy

- Describe the final vision of what the product would look like and how that product would be administered or delivered for military use (required) and civilian use (if applicable).
- Include any information or plans for product interoperability with established military health systems.
- Detail any plans for future algorithm development / inclusion.
- Briefly describe the regulatory plan, including FDA pathway and designation, strategy for obtaining FDA approvals or clearances (as applicable).

- Briefly describe the commercialization plan, including a description of the market (civilian and military) and sustainability. If commercialization is not relevant to the proposed project, then describe the plan to transition the technology to the military market for government use/implementation.
- Briefly describe your funding strategy to advance the technology to the next level of development and/or delivery to the military or civilian market.
- Offerors are encouraged to include costs associated with their development strategy.

Risk Identification and Mitigation

• Identify key technical, schedule, and cost risks. Discuss the potential impact of the risks, as well as potential mitigations.

APPENDICES excluded from the page limit, and must be uploaded to BIDS as separate documents)

Appendix 1: Warranties and Representations: (template provided in Attachment 3 of the PPG)

• Warranties and Representations are required. One Word (.docx or .doc) or PDF file that contains all Warranties and Representations is required.

Appendix 2: Current and Pending Support (template provided in Attachment 5 of the PPG)

• Current and Pending Support document is required. Identify other sponsored research for each person who will contribute significantly to the proposed prototype project. The information for previous support should include the past five (5) years, unless otherwise specified in the request. Include information pertaining to this proposal submission in regards to foreign involvement.

Appendix 3: Intellectual Property and Data Rights Assertions (template provided in Attachment 6 of the PPG)

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

Appendix 4: Documentation (no template provided)

• Summary of the specific data elements on the TCCC (e.g., DD Form 1380) which can currently be captured and a proposed conceptual plan of how the prototype passive technology solution set could inform future algorithms. Note that Offerors invited for Stage 2 (Solution Brief Pitch) may be asked questions regarding this information.



C:		Name Volum		Route	Time
	Fluid				
	Blood Product				
AED	S:	Name	Dose	Route	Time
	Analgesic (e.g., Ketamine, Fentanyl, Morphine)				
(Antibiotic e.g., Moxifloxacin, Ertapenem)				
	Other (e.g., TXA)				
)ТН]]]]]]]]]]]]]]]]]]]]]]]]]]]]]]]]]	ER:	ill-Pack Eye revention Type:	-Shield (🗌 R	□L) □S	plint

Addendum 1 – Front and Back of the DD Form 1380, TCCC Card