### **Request for Project Proposals**



# Solicitation Number: MTEC-18-09-APPEAR "Assessment of the Psychological and Physiological Effects of Augmented Reality (APPEAR)"

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: August 7, 2018

Solutions Brief Due Date: September 21, 2018
Noon Eastern Time Zone

White Papers Are NOT Required

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

- (a) 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.

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

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" DoD 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.

#### 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 U.S. Army Medical Research and Materiel Command (USAMRMC) Joint Program Committee-1 (JPC-1)/Medical Simulation and Information Sciences Research Program (MSISRP). Military relevance is a critical component of Solution Brief submission. Strategic and tactical oversight for the award(s) supported by this RPP will be provided by the JPC-1/MSISRP.

As an area program of the Defense Health Agency (DHA), Research, Development, and Acquisition (RDA) Directorate, the JPC-1/MSISRP Medical Simulation (MedSim) Steering Committee provides programmatic funding recommendations as directed by and for the Office of the Assistant Secretary of Defense for Health Affairs (OASDHA) Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation related to medical training and education efforts to advance the development and integration of simulation-based training systems.

### **Background:**

Augmented reality (AR) is the use of a computer-based simulation engine to add non-real sensory information to the real sensory world. Essentially, AR directs participants' attention to either existing information that they would have not been consciously aware of or to new information that changes their perceptual information. Although this co-registered information can be visually projected directly onto real objects, AR information is often presented directly to the recipient by a device attached to the recipient.

APPEAR maps to DHA's Joint Evacuation and Transport Simulation (JETS) and Point of Injury and Trauma Simulation (POINTS) programs, under the JPC-1/MSISRP Medical Simulation portfolio. It addresses the capability gaps in the Virtual Patient System (VPS) of JETS and POINTS. The VPS provides intelligent, scalable, modular medical training products, tools, and devices across globally distributed, integrated, and interconnected Live, Virtual, Constructive, and Gaming training environments. Technology using Augmented Reality (AR) is a significant piece of the VPS, at point of injury (POINTS) and point of demand across the complete chain of evacuation (JETS). This research is critical for assessing the limitations of AR that could impact learning effectiveness to ensure optimal development and utilization of AR technology to address the identified capability gaps in military medical simulation training.

Overall end goal of program: The ultimate goal of this program is to identify psychological and physiological limitations of AR prototypes currently under development or used for medical simulation training. This research will assess and inform prototype development and/or refinement of existing AR prototypes for medical simulation, reducing overall developmental risk, 1) enabling efficiency in the design of future AR scenarios, 2) identifying potential safety issues, and 3) identifying risk factors for adverse reactions to AR medical simulations. Assessing the physiological and psychological effects of AR prototypes for military medical simulations is imperative to the technological development and refinement needed to fully address the existing capability gaps identified in the JETS and POINTS programs and deliver effective solutions to the Warfighter.

<u>Objective of RPP:</u> This RPP is seeking Solution Briefs for human subjects studies that assess the psychological and/or physiological effects of medical training simulations using AR in the various military echelons of care.

### 1.3. Proposers Conference

MTEC will host a Proposers Conference tentatively scheduled for 1 week after the release of the RPP that will be conducted via webinar. Further instructions will be forthcoming via email.

#### 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 <a href="www.mtec-sc.org">www.mtec-sc.org</a>. White papers are not required for this RPP. The DoD reserves the right to award Solution Briefs received from this RPP on a follow-on prototype Other Transaction Agreement (pOTA) or other stand-alone OTAs as necessary to meet mission requirements.

### 2.2. Funding Availability and Type of Funding Instrument Issued

The U.S. Department of Defense (DoD) currently has available a minimum of \$2.5 Million (M) for this effort. A period of performance no greater than 24 months is expected, and faster timelines are acceptable.

It is expected that MTEC will make at least two awards of \$1.25M each to qualified teams to accomplish all tasks. Up to four awards may be made, contingent on the availability of additional funds. If a single Solution Brief is unable to sufficiently address the entire scope of this RPP's technical objectives, several Offerors may be asked to work together in a collaborative manner as a single project team or MTEC may make multiple, individual awards to Performers(s) to accomplish subset(s) of the key tasks.

Any potential follow-on funding would be negotiated based on outcomes, cost sharing, partner matching and estimates for additional study completion.

As of the release date of this RPP, future year Defense Appropriations Bills have not been passed and there is no guarantee that any additional funds will be made available to support this program. The funding estimated for this RPP is approximate and subject to realignment. Funding of Solution Briefs received in response to this RPP is contingent upon the availability of federal funds for this program. Award funding will be structured incrementally and based upon completion of Milestones and Deliverables.

The DoD-selected Awards will be funded under the prototype Other Transaction Agreement (pOTA) Number W81XWH-15-9-0001 (or subsequent OTAs in support of MTEC) with MTEC administered by the CM, ATI. Strategic oversight for the award(s) supported by this RPP will be provided by the JPC-1/MSISRP. The CM will negotiate and execute a Base Agreement with MTEC members. This Base Agreement will be governed by the same provisions as the pOTA between the DoD and MTEC. Subsequently, any Solution Brief that is selected for award will be funded through an Award issued under the Base Agreement. A sample of the MTEC Base Agreement can be found on the MTEC Members-Only website at <a href="https://www.mtec-sc.org">www.mtec-sc.org</a>.

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.

Offerors are advised to check the MTEC website periodically during the Solution Brief preparation period for any changes to the MTEC Base Agreement terms and conditions as well as clarifications found in Frequently Asked Questions (FAQ) responses.

#### 2.3. Proprietary Information

The MTEC CM will oversee submission of Solution Briefs and Cost Proposals and analyze Cost 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 Solution Brief and Cost Proposal and the subsequent agreement administration if the Solution Brief and Cost Proposal is selected for award. An Offeror's submission of a Solution Brief and Cost 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, 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 (e.g., Bill and Melinda Gates Foundation) may be interested in reviewing certain Solution Briefs and Cost Proposals within their program areas, allowing opportunities to attract supplemental funding sources. On your Solution Brief and Cost Proposal Cover Page, please indicate your willingness to allow MTEC Officers and Directors access to your Solution Briefs and Cost Proposals for the purposes of engaging in outreach activities with these private foundations. MTEC Officers and Directors granted access have signed Non-disclosure Agreements (NDAs) and Organizational Conflict of Interest (OCI) statements. Additionally, these MTEC Officers and Staff represent organizations that currently are not MTEC members, and therefore their parent organizations are not eligible to submit Solution Briefs or receive any research project funding through MTEC. Additionally, all DoD Evaluation Panel participants will agree to, and sign a nonproprietary information and conflict of interest document.

### 2.4. 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 September 18, 2018.

### 2.5. Inclusion of Nontraditional Defense Contractors or Nonprofit Research Institutions

Proposals that do not include Nontraditional Defense Contractor, Nonprofit Research Institution or all small business participation to a significant extent, or do not propose at least one third acceptable cost sharing, will not be eligible for award.

This requirement is a statutory element of the Other Transaction Authority and will be regarded as a pass/fail criterion during the Compliance Screening. Please see the MTEC PPG (Section 3.3.2) for additional details.

#### 2.6. Nontraditional Defense Contractor Definition

A nontraditional defense contractor is a business unit that has not, for a period of <u>at least one</u> <u>year prior to the issue date of the Request for Project Proposals</u>, entered into or performed on any contract or subcontract that is subject to <u>full coverage under the cost accounting standards</u> (<u>CAS</u>) prescribed pursuant to section 26 of the Office of Federal Procurement Policy Act (41 U.S.C. 422) and the regulations implementing such section.

### 2.7. Requirements

If the Offeror asserts either:

- (1) There is at least one nontraditional defense contractor or nonprofit research institution participating to a significant extent in the prototype project.
- (2) All significant participants in the transaction other than the Federal Government are small businesses (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)) or nontraditional defense contractors.
- (3) At least one third of the total cost of the prototype project is to be paid out of funds provided by sources other than the Federal Government.

The Offeror must submit Warranties and Representations (see Attachment 2 of the PPG) specifying the critical technologies being offered and/or the significant extent of participation of the nontraditional defense contractor or nonprofit research institution. The nontraditional defense contractor can be an individual so long as he/she has a DUNS Number and meets the requirements in the Warranties and Representations. The significance of the nontraditional defense contractor's or nonprofit research institution's participation must be explained in detail in the signed Warranties and Representations. Inadequate detail can cause delay in award.

Per the DoD OT Guide, rationale to justify a significant contribution includes:

- 1. Supplying a key technology or products
- 2. Accomplishing a significant amount of the effort
- 3. Use of unique skilled personnel, facilities and/or equipment
- 4. Causing a material reduction in cost or schedule, and/or improvement in performance

### 2.8. Cost Sharing Definition

Cost sharing is defined as the resources expended by the award recipients on the proposed statement of work (SOW). 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 in-kind contribution; provide a description of each cost share item proposed; the proposed dollar amount for each cost share item proposed; and the valuation technique used (e.g., vendor quote, historical cost,

labor hours and labor rates, number of trips, etc.). Cost sharing is encouraged if possible, as it leads to stronger leveraging of DoD-Performer collaboration.

#### **Cash Contribution**

Cash Contribution means the Consortium and/or the Awardee (or Awardees' lower tier subawards) financial resources expended to complete the SOW. The cash contribution may be derived from the Consortium's or 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 SOW or specific tasks identified within the SOW. 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, 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 the SOW 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, intellectual property (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.

See the MTEC PPG for additional details. If the Solution Brief contains multiple team members, this information shall be provided for each team member providing cost share.

### 2.9. Intellectual Property

Intellectual Property (IP) rights for MTEC Awards will be defined in the terms of an awardee's Base Agreement and resultant Task Orders. MTEC reserves the right to assist in the negotiation of IP, royalties, licensing, future development, etc., between the DoD and the individual Performers during the entire award period.

Per Section 3.4 of the Consortium Member Agreement (CMA), each recipient of an Award under the MTEC OTA shall pay MTEC an amount equal to 1% of the total funded value of each research

project award. Such deposits shall be due no later than 90 days after the 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 Awards:

### Royalty Payment Agreements

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

### Additional Research Project Award Assessment

In lieu of providing the royalty payment agreement described above, members receiving 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 awards, whether the award is DoD funded or privately funded.

### 2.10. Data Rights

The Offeror shall comply with the terms and conditions defined in the Base Agreement regarding Data Rights. It is anticipated that anything delivered under this proposed effort would be delivered to the DoD with DoD purpose data rights or 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 DoD to gain DoD purpose data rights or unlimited data rights as referenced in the Base Agreement. Rights in technical data in each Award shall be determined in accordance with the provisions of MTEC Base Agreement.

### 2.11. Expected Award Date

Offeror should plan on a period of performance (POP) that commences on April 2019. The DoD reserves the right to change the start date through negotiations via the CM and prior to issuing an Award.

#### 2.12. Anticipated Solutions Brief Selection Notification

The RPP will be conducted using a two-staged approach. As the basis of selections is completed for each stage, the DoD will forward their selections to 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 the next phase (Step 2: Solution Brief Pitch) of the solution brief 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 must submit by the date on the cover page of this RPP. Solution Briefs received after the time and date specified will not be evaluated.

#### 3.2. Solution Brief Submission

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

#### 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 with MTEC's submission form. If the Offeror receives errors and fails to upload the full submission prior to the submission deadline, the submission will not be accepted.

### 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-18-09-APPEAR). Offerors are encouraged to contact the Point-of-Contact (POC) 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

The mission of the JPC-1/MSISRP is to explore the implications of models and technology for medical education and training for the provision, management, and support of health services in the military. The JPC-1/MSISRP plans, coordinates, and oversees a responsive world-class, triservice science and technology program focused on three portfolios of research: (1) MedSim, focused on improving military medical training through medical modeling, simulation, and educational training tools; (2) Health Informatics Technology, focused on improving the use and sharing of health-related data for better strategic planning, process development, and software applications; and (3) Multi-Domain Battle, an operational environment involving greater dispersion and near isolation over great distances, which is likely to cause severe restrictions on mobility for medical missions and shortfalls in both human and materiel human resources due to area denial challenges. Combat units will need to be more self-sufficient and less dependent on logistical support. Combatant commanders with increased sick or wounded Service Members will face degradation of medical resources and encumbered combat effectiveness without new combat casualty management and Force multiplication strategies.

### **Problem Definition:**

Does augmented reality (AR) have important negative effects on cognitive (including learning), affective, and physiological states and how do they impact training?

AR is the use of a computer-based simulation engine to add non-real sensory information to the real sensory world. Essentially, AR directs participants' attention to either existing information that they would have not been consciously aware of or to new information that changes their perception. Although this co-registered information can be visually projected directly onto real objects, AR is often presented directly to the recipient by a device attached to the recipient.

There are five major types of AR that could be assessed in response to this RPP: marker-based, markerless, projection, outlining, and superimposition. Marker-based AR, i.e., image recognition, uses a camera and visual marker sensed by the camera to place virtual objects in the real-world. Conversely, as the name implies, markerless AR doesn't rely on predetermined markers and instead uses location or position based on technology embedded in other devices to place the virtual object into the real-world. Projection AR doesn't require the use of a screen, glasses, or headsets, projecting artificial light onto real-world surfaces. Outlining AR combines projection and markerless AR to project an outline onto a location or object. Finally, superimposition AR combines projection and object recognition AR to partially or fully superimpose the image on a

<sup>&</sup>lt;sup>1</sup> Marner MR, Smith RT, Walsh JA, Thomas BH. Spatial user interfaces for large-scale projector-based augmented reality. IEEE Comput Graph Appl 2014 Nov-Dec;34(6):74-82.

real-world object.<sup>2</sup> Notably, although the word simulation is used to describe what AR does, AR is capable of going beyond imitating information that exits in the real world.

AR is usually directed to the external sensory systems of sight, hearing, taste, smell, and touch, but it can affect the internal sensory systems including, but not limited to, equilibrioception (vestibular sense, body movement) and proprioception (relative motion and position). AR can also target the two sensory systems that function as both external and internal systems, namely, thermoception (heat, cold) and nociception (pain). The internal sensory systems can be inadvertently affected by AR or they can be direct or indirect targets of AR. Although AR usually delivers information to the visual system, it has been used to provide tactile<sup>3</sup> and auditory (musical, instruction, direction) information.<sup>4,5</sup>

In medicine, AR is used in training and clinical performance. It allows trainees or clinicians to "see" what cannot be seen in the real world in order to improve their clinical navigation or patient interaction<sup>6</sup> and it can provide information that guides trainees or clinicians in the proper treatment of patients. Many of the uses of AR are procedural, including surgical examples such as: total hip arthroplasty, <sup>7</sup> laparoscopic radical prostatectomy, <sup>8</sup> and maxillofacial surgery. <sup>9</sup> Unfortunately, in neurosurgery, an area very amenable to AR, no randomized, prospective studies have demonstrated that AR improves morbidity, mortality, or clinical effectiveness. <sup>10</sup>

Jan 19;4(1):eaao2623.

Linde A and Miller G. Future Advanced Educational Technologies that Incorporate Present Knowledge in Skills Decay Prediction into Medical Simulation Training Interfaces to Improve Learning. Military Medicine. In Press.
 Cañón Bermúdez GS, Karnaushenko DD, Karnaushenko D, Lebanov A, Bischoff L, Kaltenbrunner M, Fassbender J, Schmidt OG, Makarov D. Magnetosensitive e-skins with directional perception for augmented reality. Sci Adv 2018

<sup>&</sup>lt;sup>4</sup> Keebler JR, Wiltshire TJ, Smith DC, Fiore SM, Bedwell JS. Shifting the paradigm of music instruction: implications of embodiment stemming from an augmented reality guitar learning system. Front Psychol 2014 May 27;5:471.

<sup>&</sup>lt;sup>5</sup> Corrêa AGD, de Assis GA, do Nascimento M, de Deus Lopes R. Perceptions of clinical utility of an Augmented Reality musical software among health care professionals. Disabil Rehabil Assist Technol. 2017 Apr;12(3):205-216.

<sup>&</sup>lt;sup>6</sup> Kuehn BM. Virtual and augmented reality put a twist on medical education. JAMA 2018;319:756-758.

<sup>&</sup>lt;sup>7</sup> Fotouhi J, Alexander CP, Unberath M, Taylor G, Lee SC, Fuerst B, Johnson A, Osgood G, Taylor RH, Khanuja H, Armand M, Navab N. Plan in 2-D, execute in 3-D: an augmented reality solution for cup placement in total hip arthroplasty. J Med Imaging (Bellingham). 2018 Apr;5(2):021205

<sup>&</sup>lt;sup>8</sup> Lanchon C, Custillon G, Moreau-Gaudry A, Descotes JL, Long JA, Fiard G, Voros S. Augmented Reality Using Transurethral Ultrasound for Laparoscopic Radical Prostatectomy: Preclinical Evaluation. J Urol. 2016 Jul;196(1):244-50.

<sup>&</sup>lt;sup>9</sup> Suenaga H, Hoang Tran H, Liao H, Masamune K, Dohi T, Hoshi K, Mori Y, Takato T. Real-time in situ three-dimensional integral videography and surgical navigation using augmented reality: a pilot study. Int J Oral Sci. 2013 Jun;5(2):98-102.

<sup>&</sup>lt;sup>10</sup> Meola A, Chang SD. Navigation-Linked Heads-Up Display in Intracranial Surgery: Early Experience. Oper Neurosurg (Hagerstown) 2018 Mar 23.

Another use of AR is therapeutic in nature to modify abnormal cognitive/affective states to enable the patient to better adapt to societal norms. Applications of AR in this domain include the treatment of post-traumatic stress disorder,<sup>6</sup> autism,<sup>11,12,13</sup> and obesity.<sup>14</sup>

This RPP is not interested in the procedural or therapeutic use of AR, nor is it interested in the routinization of actions, i.e., the automatic performance of an integrated set of actions. It is concerned with the effects of AR on participants' cognitive, affective, and physiological states. Individuals' perceptions shape their cognitive, affective, and physiological states and AR, by modifying their perceptual reality, in turn elicits changes in cognition, affect, and behavior. The delivery of non-real perceptual information is not neutral (it is not meant to be neutral) and it may have undesirable effects on cognitive processes, including memory acquisition, storage, and retrieval; mood; and physiological states. Unfortunately, almost all AR studies are conducted by proponents of AR and its limitations and problems are rarely addressed.

There are several examples of possible limitations or negative effects of AR on cognitive, affective, and physiological states in the literature. Directing the participant's attention is called cueing and AR can function as a cueing mechanism. Maltz et al. <sup>15</sup> found that the person's reliance on cueing was related to task difficulty. AR was sometimes helpful in complex performance, but it reduced performance in simple tasks. In a randomized, prospective study of the use of AR visual cues delivered by smart glasses used by Parkinson's disease patients, Janssen et al. <sup>16</sup> found that AR cues did not improve patient performance. They suggested that the lack of effect may have been due to distraction, blockage of visual feedback, insufficient familiarization with the smart glasses, or to the display of the visual cues in the central rather than peripheral visual field. Another study found that AR was more difficult than VR, perhaps because of the higher dynamic of the scenery, due to slight changes in the point of view when moving the head, or perhaps due to distractions in the real-world environment. <sup>17</sup>

<sup>&</sup>lt;sup>11</sup> Chen CH, Lee IJ, Lin LY. Augmented reality-based self-facial modeling to promote the emotional expression and social skills of adolescents with autism spectrum disorders. Res Dev Disabil. 2014 Nov 8;36C:396-403.

<sup>&</sup>lt;sup>12</sup> Chung PJ, Vanderbilt DL, Soares NS. Social Behaviors and Active Videogame Play in Children with Autism Spectrum Disorder. Games Health J. 2015 Jun;4(3):225-34.

<sup>&</sup>lt;sup>13</sup> Liu X, Plishker W, Zaki G, Kang S, Kane TD, Shekhar R. On-demand calibration and evaluation for electromagnetically tracked laparoscope in augmented reality visualization. Int J Comput Assist Radiol Surg. 2016 Jun;11(6):1163-71.

<sup>&</sup>lt;sup>14</sup> Pallavicini F, Serino S, Cipresso P, Pedroli E, Chicchi Giglioli IA, Chirico A, Manzoni GM, Castelnuovo G, Molinari E, Riva G. Testing Augmented Reality for Cue Exposure in Obese Patients: An Exploratory Study. Cyberpsychol Behav Soc Netw. 2016 Feb;19(2):107-14.

<sup>&</sup>lt;sup>15</sup> Maltz M, Shinar D. New alternative methods of analyzing human behavior in cued target acquisition. Hum Factors. 2003 Summer;45(2):281-95.

<sup>&</sup>lt;sup>16</sup> Janssen S, Bolte B, Nonnekes J, Bittner M, Bloem BR, Heida T, Zhao Y, van Wezel RJA. Usability of Three-dimensional Augmented Visual Cues Delivered by Smart Glasses on (Freezing of) Gait in Parkinson's Disease. Front Neurol. 2017 Jun 13;8:279.

<sup>&</sup>lt;sup>17</sup> Faller J, Allison BZ, Brunner C, Scherer R, Schmalstieg D, Pfurtscheller G, Neuper C. A feasibility study on SSVEP-based interaction with motivating and immersive virtual and augmented reality. https://arxiv.org/abs/1701.03981

Does AR affect the participant's cognitive load, i.e., the amount of information that must be processed at any given moment? Hughes-Hallett et al. 18 assessed inattention blindness, i.e., the failure to perceive an unexpected object when attention is focused on another object or task. Participants watched a video with and without an AR overlay. In this object detection task, the investigators found that cognitive load, but not AR image guidance, increased inattention blindness. Kucuk et al. 19 reported that AR reduced cognitive loads when learning anatomy.

One effect of the visual presentation of non-real visual information is that there can be a mismatch between the participants' visual perception and their other sensory systems. This can disorient the participants and affect their equilibrium.<sup>20</sup> Furthermore, when they use virtual and mixed reality devices some participants report eye-strain, headache, and motion sickness, which resolves spontaneously when the non-real sensory input is removed.<sup>6</sup>

Tamir et al.<sup>21</sup> found that, when compared to subjective experience, externalizing an experience, i.e., writing the experience down, reduced the memory of the experience. Does the use of AR technology reduce the subjective aspect of experiences and, if so, does that reduce the memory of the experience?

In children, AR improves short term memory.<sup>22</sup> How well does AR information transfer from sensory to short-term to long-term memory? Furthermore, can information learned under AR be used in non-AR settings or is AR learning state-dependent, i.e., information learned in AR is best remembered in AR rather than in the real world?

Does the repeated use of AR have any effect, psychological or physiological, on the participants after they leave AR?

Are there personality characteristics that suggest that a person should not enter an augmented reality environment?

<sup>&</sup>lt;sup>18</sup> Hughes-Hallett A, Mayer EK, Marcus HJ, Pratt P, Mason S, Darzi AW, Vale JA. Inattention blindness in surgery. Surg Endosc. 2015 Nov;29(11):3184-9.

<sup>&</sup>lt;sup>19</sup> Küçük S, Kapakin S, Göktaş Y. Learning anatomy via mobile augmented reality: Effects on achievement and cognitive load. Anat Sci Educ. 2016 Oct;9(5):411-21.

<sup>&</sup>lt;sup>20</sup> Jörges B, López-Moliner J. Gravity as a Strong Prior: Implications for Perception and Action. Front Hum Neurosci. 2017 Apr 28;11:203.

<sup>&</sup>lt;sup>21</sup> Tamir DI, Templeton EM, Ward AF, Zaki J. Media usage diminishes memory for experiences. J Exp Soc Psy 2018;76:161-168.

<sup>&</sup>lt;sup>22</sup> Juan MC, Mendez-Lopez M, Perez-Hernandez E, Albiol-Perez S. Augmented reality for the assessment of children's spatial memory in real settings. PLoS One. 2014 Dec 1;9(12):e113751

Do certain central nervous system disorders, e.g. epilepsy, Meniere's disease, chronic migraines, or other physical conditions that contraindicate short-term and/or extended periods of AR exposure?

It is clear that AR can change peoples' perception of reality. Because perception has a powerful effect on cognitive, affective, and physiological states, AR must be used wisely. This means that its use for training must be safe and effective. It is not sufficient to be a proponent of AR, one must know its human effects and limitations.

#### **5.1.** Overall Objective of RPP:

The goal of this RPP is to identify psychological and physiological limitations of AR medical simulation training in the diverse high pressure and stressful context anticipated in Roles of Care 1-4, as defined below:

- Role 1 Point of injury care. First responder capabilities including immediate lifesaving measures at the point of injury in deployed/operational environments.
- Role 2 Forward resuscitative care including advanced trauma/emergency medical treatment. Some Role 2 sites are expanded to include additional medical services and Ancillary support services (e.g., Laboratory, Pharmacy, Radiology) to provide more robust care for larger Patient at Risk (PAR) populations. En route Care – Care required to maintain the phase treatment initiated prior to evacuation and the sustainment of the patient's medical condition during evacuation.
- Role 3 Theater hospitalization including robust care for resuscitation, surgery, and post-operative care.
- Role 4 Fixed Medical Treatment Facilities. CONUS- and OCONUS-based hospitals; may include VA and other long-term care facilities.

The outcomes of this work will be used to ensure that AR technology is safely and optimally utilized to enhance learning capabilities in medical simulation.

### 5.2. Technical Objectives of RPP 18-09-APPEAR

For the purposes of this RPP, research should focus on the assessment of psychological or physiological effects on the end user in training behavior. Secondary measures could assess cognitive load and/or determine conditions that would contraindicate AR exposure. The same Offeror can propose to assess both psychological and physiological effects on the end user, but must provide separate solution briefs on each focus area.

Responses to this RPP are not limited to a specific medical domain and all areas of medicine are encouraged to submit (i.e., dental, dermatology, obstetrics, ophthalmology, and surgical fields); however, medical domains that have higher alignment with (or must have at least one

demonstrated tool with traumatic/multi-casualty) treatment of traumatic and acute injuries/multi-casualty will be factored in the decision.

**Offerors are allowed to submit more than one solution brief.** Solution briefs will be expected to address the following:

- Propose a human study that focuses on <u>one</u> of the following:
  - Psychological effects of AR on the end user in training behavior (secondary assessments of cognitive load during learning using AR and/or assessment of neuropsychiatric conditions contraindicated for training with AR could be included), or
  - Physiological effects of AR on the end user in training behavior (secondary assessments of cognitive load during learning using AR and/or assessment of physical conditions contraindicated for training with AR could be included).
- Justification for targeting psychological or physiological effects of AR, including ability of team to address that focus area;
- Propose the assessment of AR prototypes currently under development or in use for military medical simulation training; and
- Provide detailed information regarding the type of AR and specific scenarios that will be involved in the clinical assessments.

The requested work is separated into two tasks. Solution Briefs should clearly respond to each task separately (i.e., technical strategy, cost, etc.). Offerors are required to submit Solution Briefs that address both tasks.

#### Task 1: Human Subjects Study Planning

Task 1 includes all planning tasks for the human subjects study, including but not limited to, IRB/HRPO approvals or exemptions (refer to the "Restrictions on Animal and Human Subjects" section below), hiring study staff, development of the clinical study protocol, and coordination with collaborators (if required). Task 1 will have a maximum period of performance of 6 months. An administrative review will be conducted after the completion of Task 1 to assess performance and approve continuation of the project into Task 2.

### Task 2: Human Study Assessment Execution

Task 2 includes execution of the human subjects study. Task 2 will have a maximum period of performance of 18 months.

This RPP is concerned with the effects of AR on participants' cognitive, affective, and physical states. It is anticipated that the outcome of Tasks 1 and 2 will achieve at least one of the following (not in rank order):

- Deliver a human subjects study that assesses the physiological or psychological effects of AR (secondary measures could assesses cognitive load and/or determine conditions that would contraindicate AR exposure) that will be analyzed and recorded in technical reports and, eventually, in the final report.
- Enable efficiency in the design of future AR scenarios/prototypes in medical simulations.
- Identify potential safety issues that should be accounted for in AR prototypes used in medical simulation training.
- Provide recommendations and/or proposed mitigation strategies regarding any safety issues identified to improve or refine development of or existing AR prototypes.
- It is anticipated that AR scenarios assessed will be relevant across the military and U.S. Department of Veterans Affairs and potential academic, clinics, rural healthcare settings, private and public hospitals, and international healthcare situations.
- If applicable, support safety data in investigational device exemption or 510K applications or provide post-mark surveillance data for Food and Drug Administration (FDA)-cleared AR technology.

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 U.S. Army Animal Use and Review Office (ACURO) and U.S. Army Human Research Protections Office (HRPO). Offerors shall include IACUC, ACURO, IRB and HRPO review and approval in the SOW/Milestone Payment Schedule (MPS) 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 USAMRMC Office of Research Protections (ORP) provides authorization that the research may proceed. The USAMRMC ORP will issue written approval to begin research under separate notification. Written approval to proceed from the USAMRMC ORP is also required for any Research Project Awardee (or lower tier subawards) 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 ORP review and authorization process.

## 5.3. Technology Objectives of Potential Follow-on Work

The intent of this RPP 18-09-APPEAR is to evaluate and initially award Tasks 1 and 2 described in section 5.2; therefore, all Solution Briefs submitted under this RPP must propose solutions to

both Tasks 1 and 2 only. This section is intended to provide context so the Offeror is aware of potential work that could follow-on after the completion of Tasks 1 and 2. The Offeror does not need to price or provide details on how they would complete this follow-on work, but they should take this information into consideration to ensure that the proposed work for Tasks 1 and 2 has the potential to meet the full description provided herein. MTEC does not intend to issue a new RPP to award Task 3.

### Potential Follow-on Task 3: AR Prototype Development

The initial 24 month period of performance should be focused on the planning and execution of the human subjects study requested in Tasks 1 and 2. Follow-on work in subsequent years may be awarded to use the knowledge product(s) generated by APPEAR in Tasks 1 and 2 to inform and/or refine AR prototypes currently in use or under development for military medical simulation training in a separately-funded, Task 3. Based on the potential impact of the proposed AR development/refinement and the availability of funds (tentatively \$2M), up to two performers may be funded at \$1M each to advance the development of the AR prototype used in Task 2 to TRL6. The anticipated period of performance of Task 3 is 18 months.

### 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 steps outlined below:

### Step 1: Solution Brief

The Offeror shall submit a Solution Brief, which describes the overall technical concept and approach along with the viability toward the Offeror's specific effort. The following sections shall be included in the Solution Brief:

- Title Page (excluded from 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-18-09-APPEAR"
  - Dates of submission and signature of official authorized to obligate the institution contractually
  - 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.]

- **Approach:** [Briefly describe your approach to solving the problem. Include relevant background data about your approach.]
- **Objectives:** [Specify the objectives of the proposed effort.]
- Technical Strategy: [Outline the proposed methodology by Task in sufficient detail to show a clear course of action that addresses the technical requirements described in this RPP. This section should identify any pilot or existing commercial methodology/technology or the development of such during the course of the work. If novel technology or methods are to be employed, then identify the path to maturation.]
- Anticipated Outcomes: [Provide a description of the anticipated outcomes from the proposed work. List milestones and deliverables from the proposed work.]
- Experience: [The Solution Brief shall describe the experience of the Principal Investigator, key personnel, partner organizations, and associated subject matters experts that are required to meet the program's objective and requirements. Identify any work of a similar nature that could be used to gauge the effectiveness and worthiness of the technical or methodological approach. This section should not highlight the contractual details of relevant experience, but should emphasize past work that is relevant and similar in nature (complexity, size, requirements) to this request and how that work's outcome relates to the expectations set forth in this RPP. Offerors should indicate how much of this relevant experience and past effort they will leverage for the proposed effort. Offeror may choose format and method of conveying this.]
- **Timeline:** [Indicate the total proposed delivery schedule. Provide an estimated Gantt Chart of the major activities proposed.]
- **Project Management Plan:** [The Solution Brief shall describe the overall project management plan.]

• **Data Rights:** [If applicable, complete the below table for any items to be furnished to the DoD with restrictions. An example is provided below.]

Technical Data or Computer Software to be Furnished with Restrictions	Basis for Assertion	Asserted Rights Category	Name of Organization Asserting Restrictions	Milestone # Affected
Software XYZ	Previously developed software funded exclusively at private expense	Restricted	Organization XYZ	Milestones 1, 3, and 6
Technical Data Description	Previously developed exclusively at private expense	Limited	Organization XYZ	Milestone 2
Technical Data Description	Previously developed with mixed funding	DoD Purpose Rights	Organization XYZ	Milestone 2

- Cost Share: [It is anticipated that Government funds would provide incentive for industry
  funding to join the project. While not a requirement, Offerors are strongly encouraged to
  discuss the ability to bring leveraged funding/cost share to complete the project goals.]
- Non-traditional defense contractor, nonprofit research institution, all small business participation, or 1/3 cost sharing: [Describe the plan to include significant participation of a non-traditional defense contractor, nonprofit research institution, all small business participation, or the ability to meet 1/3 cost sharing requirement. Refer to Sections 2.5-2.8 for more information.]
- Rough Order of Magnitude (ROM) Pricing: [Refer to Attachment B].

The Solution Brief is limited to ten (10) pages (including cover page), 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 exceeding the 10 page limit will not be accepted.

MTEC will email receipt confirmations to Offerors upon submission of Solution Briefs. Offerors may submit Solutions Briefs in advance of the deadline.

Solution Brief Evaluation:

The CM will distribute all Solution Briefs to the Government for evaluation. Solution Briefs will be evaluated based on the following criteria:

- Feasibility of the proposed solution and its alignment with the RPP's topic area. This includes such factors as (1) ability to execute the research, (2) technical ability, and (3) soundness of product development strategy.
- Relevancy, thoroughness, and completeness of the proposed methodology/plan/strategy (e.g., the technical and managerial soundness of the methodological approach to satisfy the documented needs) to meet the Government specifications listed in Table 1 and the program objective described in Section 1.2.
- Strength of the organization/team proposed to complete the work and its financial stability to potentially continue the maturation of the system beyond the scope of this RPP.
- Estimated ROM costs represent reasonable value for proposed solution offered.
- Any Cost Share proposed that is above the minimum statutory requirement of either zero
  percent cost share (for proposals which include significant participation of a
  nontraditional defense contractor) and 1/3 cost share (for proposals containing no
  nontraditional defense contractor participation).

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

### Step 2: Solution Brief Pitch:

In Step 2, 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 A) during a meeting with the Government sponsors for the research. The pitch should provide more details about the technical and business viability of the proposed work outlined in Phase 1. Specifically, the pitch should include the following:

- **Description:** The Offeror will provide a more robust description of their 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 will 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.
- Data Rights Assertions: The Solution Brief Pitch will identify any and all proprietary
  and/or intellectual property involved in the efforts and any associated restrictions that
  may possibly affect the Government's use of the property in any way whatsoever. Offeror
  must describe pathway to developing this into a product that can be used by the DoD and
  other potential customers (if applicable). Include relevant information about existing
  royalty agreements. See Section 2.10 for format.
- **Cost:** The Solution Brief Pitch must present summarized costs at the task level.
- Statement of Work and Milestone Payment Schedule submission: one Word (.docx or .doc) or PDF file. Separately, a Word (.docx or .doc) version of the SOW and MPS and a Word (.docx or .doc) are required. See Attachment A for additional information.

If desired, the Government can request additional information related to specific areas of interest to be included in the pitch. The request for such information will be provided at the end of Step 1 and at the time of invitation to advance into Step 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 1 hour** with a total time of 2 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 at least 72 hours prior to 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.

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

- Most Important (of equal importance)
  - Performance: Overall technical approach and how well Offeror's solution enhances the DoD mission described in the RPP; including processes described to

identify and manage risks/opportunities. The degree to which the Offeror proposed medical domains that have higher alignment with (or must have at least one demonstrated tool with traumatic/multi-casualty) treatment of traumatic and acute injuries/multi-casualty.

- Schedule: Suitability of the notional schedule, including processes described to identify and manage risks/opportunities.
- Cost: The parity of the relationship between the Offeror's solution and ROM costs, and whether a superior technical approach is warranted at a higher estimated cost.
- Risk-Opportunity: Identification of risks (with supportable mitigations) and opportunities with the Offeror's approach with objective measurable metrics.
- Less Important (of equal importance)
  - Relevant Experience.
  - Assessment of the potential impact of data rights assertions.

At the conclusion of the Step 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.

### Step 3: Cost Proposal

The Offerors invited to submit a Cost Proposal are encouraged to contact the MTEC and/or Government with any questions so that all aspects are clearly understood by both parties. The full 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: If Nontraditional Defense Contractor participation is proposed, Warranties and Representations are required. 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 <u>or</u> the Royalty Agreement (available on the MTEC
  members only website), not both, and submit a signed copy with the proposal.

#### 6.2. Cost Proposal

MTEC will make cost proposal formats available on the Members-Only MTEC website. **The Cost Proposal (by Task) formats provided in the MTEC PPG are 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.

### 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.

### 7. Selection

The CM will conduct a preliminary screening of submitted Solution Briefs to ensure compliance with the RPP requirements. The Government reserves the right to request additional information or eliminate Solution Briefs that do not meet these requirements from further consideration. One of the primary reasons for elimination from further consideration is the lack of significant nontraditional defense contractor participation, nonprofit research institution participation, all small business participation, or cost share (see RPP Section 2.6). The Cost Sharing/Nontraditional Contractor determination will be made as shown in Table 1:

TABLE 1- COST SHARING/NONTRADITIONAL CONTRACTOR ASSESSMENTS			
RATING	DESCRIPTION		
PASS	Offeror proposing an MTEC research project meets at least ONE of the following:  (1) There is at least one nontraditional defense contractor or nonprofit research institution participating to a significant extent in the prototype project.  (2) All significant participants in the transaction other than the Federal Government are small businesses (including small businesses participating in a program described under section 9 of the Small Business Act (15 U.S.C. 638)) or nontraditional defense contractors.  (3) At least one third of the total cost of the prototype project is to be paid out of funds provided by sources other than the Federal Government.		
FAIL	Offeror proposing an MTEC research project does <b>NOT</b> meet one of the above requirements.		

Based on the results of the evaluation of the Solution Brief, the Solution Brief Pitch and Cost Proposal, Offerors may be selected for funding or not selected. Table 2 below provides a summary of the adjectival ratings that will be used for both Step 1 and Step 2 evaluations:

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.		

The RPP review and award process may involve the use of contractors as subject-matter-experts or reviewers; where appropriate, the U.S. Government (USG) will employ NDAs to protect information contained in the RPP as outlined in Section 1.4.

#### 8. 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, Ms. Rebecca Harmon, <a href="mailto:mtec-contracts@ati.org">mtec-contracts@ati.org</a>
- Technical related questions should be directed to the MTEC Director of Research, Dr. Lauren Palestrini, Ph.D., <a href="mailto:lauren.palestrini@officer.mtec-sc.org">lauren.palestrini@officer.mtec-sc.org</a>

- Questions concerning membership should be directed to Ms. Stacey Lindbergh, MTEC Executive Director., execdirect@officer.mtec-sc.org.
- All other questions should be directed to Ms. Kathy Zolman, MTEC Program Manager, 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 source selection process is complete.

### 9. Acronyms/Abbreviations

ACURO U.S. Army Animal Use and Review Office

APPEAR Assessment of the Psychological and Physiological Effects of Augmented Reality

AR Augmented reality

ATI Advanced Technology International

CAS Cost accounting standards
CFR Code of Federal Regulations

CM Consortium Manager

CMA Consortium Member Agreement

CONUS Contiguous U.S.

DHA Defense Health Agency
DHP Defense Health Program
DoD Department of Defense
FAQ Frequently Asked Questions

F&A Facilities and Administrative Costs FDA U.S. Food and Drug Administration

FY Fiscal Year

G&A General and Administrative Expenses
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
JETS Joint Evacuation and Transport Simulation

JPC-1 Joint Program Committee-1

M Millions

MedSim Medical Simulation

MPS Milestone Payment Schedule

MSISRP Medical Simulation and Information Sciences Research Program

MTEC Medical Technology Enterprise Consortium

NDA Nondisclosure Agreement

OASDHA Office of the Assistant Secretary of Defense for Health Affairs

OCI Organizational Conflict of Interest

OCONUS Outside the contiguous U.S.

ODC Other Direct Charges

ORP Office of Research Protections, USAMRMC

POC Point-of-Contact

POINTS Point of Injury and Trauma Simulation

PAR Patient at Risk

POP Period of performance

pOTA Prototype Other Transaction Agreement

PPG Proposal Preparation Guide

RDA Research, Development, and Acquisition RDT&E Research, Development, Test, and Evaluation

ROM Rough Order of Magnitude
RPP Request for Project Proposals

SOW Statement of Work

USAMRMC U.S. Army Medical Research and Materiel Command

USG U.S. Government, specifically the DoD

VPS Virtual Patient System

### Attachment A: Statement of Work (SOW)

The SOW developed by the Lead MTEC member organization is intended to be incorporated into a binding agreement if the Solutions Brief is selected for award. If no SOW is submitted, there will 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 submission. Submitted information is subject to change through negotiation if the Government selects for funding.)

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

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

**Deliverables** (To be provided initially by the Offeror at the time of submission. Submitted information is subject to change through negotiation if the Government selects 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 submission. Submitted information is subject to change through negotiation if the Government selects 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 20th of Mar, Jun, Sep, Dec), Annual Technical Report, Final Technical Report, and Final Business Status Report. Reports shall have no funding associated with them.

Milestone No.	Significant Event/Accomplishments Description of Deliverables	Due Date	Total Program Funds	Total Share	Cost
1					
2					
3					
Total					

**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)

- Quarterly Reports The MTEC research project awardee shall submit 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 submit 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 B: 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	\$ 100,000.00
Labor Hours	1,000.0 hrs
Subcontractors	\$ 50,000.00
Subcontractors Hours	500.0 hrs
Consultants	\$ 10,000.00
Consultants Hours	100.0 hrs
Material/Equipment	\$ 75,000.00
Other Direct Costs	\$ 1,000.00
Travel	\$ 5,000.00
Indirect costs	\$ 48,200.00
Total Cost	\$ 289,200.00
Fee (Not applicable if cost share is	\$ 0.00
proposed)	
Total Cost (plus Fee)	\$ 289,200.00
Cost Share	\$ 290,000.00
(if cost share is proposed then fee is	
unallowable)	
Total Project Cost	\$ 579,200.00