“Assessment of the Psychological and Physiological Effects of Augmented Reality (APPEAR)”

The Medical Technology Enterprise Consortium (MTEC) is excited to post this pre-announcement for a Request for Project Proposals (RPP) focused on conducting assessments to understand the psychological or physiological effects of augmented reality (AR) medical simulations that may impact learning effectiveness in humans. The ultimate goal of this research is to identify psychological and physiological limitations of AR medical simulation training in the diverse high pressure and stressful context anticipated in the various military echelons of care, which will help ensure optimal development and utilization of AR technology to address the identified capability gaps in military medical simulation training.

**Technology Focus Areas**

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/MSIS 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 AR is a significant piece of the VPS, at point of injury (POINTS) and point of demand across the complete chain of evacuation (JETS).

Offerors will be allowed to submit more than one solution brief. Solution briefs will be expected to address the following (subject to change):

- Propose a human study that focuses on one 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;
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- 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 will be separated into two tasks.

- Task 1 includes all planning tasks for the human subjects study, including but not limited to, IRB/HRPO approvals or exemptions, 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 onto Task 2.
- Task 2 includes execution of the human subjects study. Task 2 will have a maximum period of performance of 18 months.

Proposed studies are not limited to a specific medical domain and all areas of medicine are encouraged for submission (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 are preferential.

This upcoming 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 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):

- Complete a human study that evaluates the physiological or psychological effects of AR, and/or assesses cognitive load, and/or determines conditions that would contraindicate AR exposure.
- 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 510(k) applications or provide post-mark surveillance data for FDA-cleared AR technology.

Potential Funding Availability
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 a qualified team to accomplish all tasks. Up to four awards may be made, contingent on the availability of additional funds.

**Acquisition Strategy:**
The MTEC will use a streamlined, accelerated approach for this acquisition. This approach will consist of the following steps:

**Step 1:** MTEC members who wish to offer a solution to the RPP must submit a Solutions Brief. The Solutions Brief will contain the MTEC Offeror’s technical concept and approach along with their viability toward the specific effort. To meet the statutory requirement of the Other Transaction authority, Offeror Solutions Briefs will also have to address the significant participation of a Nontraditional Defense Contractor or Nonprofit Research Organization on the team or the willingness to provide 1/3 cost share to the project. The Offeror will also be expected to present a rough order of magnitude (ROM) cost and schedule.

**Step 2:** As part of the Government review of the Solutions Brief, MTEC members who have submitted a favorable Solutions Brief based on the RPP criteria may be invited to present and discuss their solution with the Government sponsors for the research via a virtual or in-person “pitch” of the proposed project along with a SOW/Milestone Payment Schedule and cost information.

**Step 3:** MTEC Offeror(s) will be notified of the down select recommendation(s), and if selected, will be invited to submit a detailed Cost Proposal in accordance with the MTEC Proposal Preparation Guide (PPG).

Because of the nature of the requirements set forth in the forthcoming RPP, this streamlined, interactive approach is anticipated to be a better means to highlight company methodologies and skills and 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 they would approach and solve such an action. The full description of this contracting approach is included in the RPP.

**MTEC:**
The MTEC mission is to assist the U.S. Army Medical Research and Materiel Command (USAMRMC) by providing cutting-edge technologies and effective materiel life cycle management to transition medical solutions to industry that protect, treat, and optimize Warfighters’ health and performance across the full spectrum of military operations. MTEC is a biomedical technology consortium collaborating with multiple government agencies under a 10-year renewable Other Transaction Agreement (OTA), Agreement No. W81XWH-15-9-0001, with the U.S. Army Medical Research Acquisition Activity (USAMRAA). MTEC is currently recruiting a broad and diverse membership that includes representatives from large businesses, small businesses, “nontraditional” government contractors, academic research institutions and not-for-profit organizations.
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Administrative Information:
The RPP will be posted to the MTEC website and a notice will be posted on FedBizOpps.gov to notify interested parties. MTEC membership is required for the submission of a Solution Brief in response to this upcoming MTEC RPP. To join MTEC, please visit http://mtec-sc.org/how-to-join/.

For inquiries regarding this pre-announcement, please direct your correspondence to the following contacts:
• Technical questions – Dr. Lauren Palestrini, MTEC Director of Research, lauren.palestrini@officer.mtec-sc.org
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• Membership questions - Ms. Stacey Lindbergh, MTEC Executive Director, execdirect@mtec-sc.org

Sincerely,
MTEC Project Team