I. OVERVIEW OF THE FUNDING OPPORTUNITY

Broad Agency Announcement for Extramural Research (Program Specific) for the Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Joint Program Committee-1 (JPC-1)/Medical Simulation and Information Sciences (MSIS) Research Program

Psychological Health/Traumatic Brain Injury Research Program (PH/TBIRP)

Trauma Resiliency Immersive Adaptive Gaming Environment (TRIAGE) Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-18-S-MSI1

Catalog of Federal Domestic Assistance Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Proposal/Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), June 25, 2018
- **Invitation to Submit a Proposal/Application:** July 17, 2018
- **Proposal/Application Submission Deadline:** 11:59 p.m. ET, September 17, 2018
- **End of Proposal/Application Verification Period:** 5:00 p.m. ET, September 24, 2018
- **Peer Review:** November 2018
- **Programmatic Review:** January 2019

This Broad Agency Announcement/Funding Opportunity Announcement (BAA) must be read in conjunction with the General Submission Instructions, which are available for downloading from Grants.gov. The General Submission Instructions are located under the "package tab" and can be downloaded by selecting the "Download Instructions" icon when previewing the submission package.

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

***New for* 2018: Proposal/Application submission by extramural organizations through Grants.gov requires use of the Workspace interface, which separates the proposal/ application package into individual forms. Applicants must create a Workspace in Grants.gov, complete the required forms, and submit their proposal/application Workspace package.**

This Funding Opportunity Announcement is a Broad Agency Announcement (BAA) for the Fiscal Year 2018 (FY18) Psychological Health/Traumatic Brain Injury Research Program (PH/TBIRP) Trauma Resiliency Immersive Adaptive Gaming Environment (TRIAGE) Award. For the remainder of the announcement, this BAA will be referenced as TRIAGE. Specific submission information and additional administrative requirements can be found in the document titled "General Submission Instructions," available in Grants.gov along with this BAA.

This BAA (Program Specific) is intended to solicit extramural research and development ideas and is issued under the provisions of the Competition in Contracting Act (CICA) of 1984 (Public Law 98-369), as implemented in Federal Acquisition Regulation (FAR) 6.102(d)(2) and 35.016 and in Department of Defense (DoD) Grant and Agreement Regulations (DoDGARs) 22.315. In accordance with FAR 35.016, projects funded under this BAA must be for basic and applied research and that part of development not related to the development of a specific system or hardware procurement. Projects must be for scientific study and experimentation directed toward advancing the state-of-the-art or increasing knowledge or understanding rather than focusing on a specific system or hardware solution. Research and development funded through this BAA is intended and expected to benefit and inform both military and civilian medical practice and knowledge.

This BAA is intended for extramural applicants only. For definitions and additional information, see Section II.C.1. (There is a separate BAA for intramural applicants applying through intramural organizations that is available through the eBRAP [https://eBRAP.org/] under the funding opportunity number W81XWH-18-DMRDP-MSIS-TRI).

- In accordance with FAR 35.017, Federally Funded Research and Development Centers (FFRDCs) are not eligible to directly receive awards under this BAA. However, teaming arrangements between FFRDCs and eligible organizations are allowed if permitted under the sponsoring agreement between the Federal Government and the specific FFRDC.

II.A. PROGRAM DESCRIPTION

Proposals/Applications to the FY18 PH/TBIRP are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The U.S. Army Medical Research and Materiel Command (USAMRMC) Congressionally Directed Medical Research Programs (CDMRP) provides PH/TBIRP management support aligned with specific DHA

research program areas, including the Joint Program Committee 1 (JPC-1)/Medical Simulation and Information Sciences (MSIS) Research Program. This BAA and subsequent awards will be managed and executed by CDMRP with strategic oversight from the JPC-1/MSIS.

The PH/TBIRP was established by Congress in FY07 in response to the devastating impact of traumatic brain injury (TBI) and psychological health (PH) issues, including post-traumatic stress disorder (PTSD), on our deployed Service members in Iraq and Afghanistan. The PH/TBIRP mission is to establish, fund, and integrate both individual and multiagency research efforts that will lead to improved prevention, detection, and treatment of PH issues and TBI. The vision of the PH/TBIRP is to prevent, mitigate, and treat the effects of traumatic stress and TBI on function, wellness, and overall quality of life for Service members as well as their caregivers and families.

The mission of the JPC-1/MSIS 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/MSIS plans, coordinates, and oversees a responsive world-class, tri-Service science and technology program focused on three portfolios of research: (1) Medical Simulation (Med Sim), focused on improving military medical training through medical modeling, simulation, and educational training tools; (2) Health Information Technology (HIT), 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.

The JPC-1/MSIS Medical Simulation and Training Technologies Steering Committee provides programmatic funding recommendations for DHP RDT&E medical research dollars related to medical training and education efforts to advance the development and integration of simulation-based training systems. The Steering Committee provided the strategy for which this BAA's topic was conceived.

II.A.1. Research Area of Interest

The FY18 JPC-1/MSIS PH/TBIRP TRIAGE Award is seeking proposals/applications developing and evaluating an innovative protocol for virtual immersive gaming interoperable components that will increase medical care provider performance, adaptability, and agility in stress-inducing contexts related to Roles of Care 1-3. These resulting TRIAGE proof-of-concept models should be developed for relevancy to medical simulation training across the continuum of care and address the needs and priorities of the military medical training community, with applicability to civilian groups as well.

TRIAGE is a line of research that maps to DHA's Warfighter Preparation, Resilience, Enhancement and Protection (WarPREP) program, under the JPC-1/MSIS Med Sim portfolio. It

addresses the capability gap to provide resiliency training prior to deployment to better elicit higher performance under pressure. The ultimate goal of this research is to increase medical care providers' readiness and resiliency through increases in performance, adaptability, and agility in the diverse high pressure and stressful context anticipated in Roles of Care 1-3 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. Role 2 also includes en route care, defined as 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.

TRIAGE is not aimed at resiliency training *prior* to stress exposure in order to mitigate stress-induced performance loss; instead, it seeks a gaming interoperable component that elicits cognitively demanding problem-solving and decision-making under high-stress scenarios in order to increase performance, adaptability, and agility that also translates to real-world scenarios. By using virtual, gaming simulations, medical care providers can undergo exercises under high-stress scenarios in diverse, relevant settings before their skills are needed in the field. The current announcement focuses on high-stress, immersive three-dimensional (3D) gaming interoperable components that increase participant performance, adaptability, and agility through repeated rehearsals of a medical scenario in which the participants can learn to adapt their behavior to:

- Alter the course of the scenario;

- Influence scenario outcomes; and

- Reduce or control the level of stress presented to the participant.

For the purposes of this BAA, the research is *not* for the development of a new gaming platform; instead, it should leverage existing, validated platforms to develop a new interoperable component. Reliance on open source and accessible platforms is preferred. Anticipated technology readiness level (TRL) desired by the end of the base year of research is TRL 4, which constitutes evidence that the proof-of-concept model can be implemented into a data/knowledge system whose components are integrated and work together, and the proof-of-concept model has been evaluated within a laboratory-type environment. A preliminary interface will be created, and information the accessibility of this proof-of-concept and if there are open source or publicly accessible components should also be stated.

This award is not limited to research in a specific medical domain; all areas of medicine are encouraged to submit (dental, dermatology, obstetrics, ophthalmology, surgical fields, etc.).

However, medical domains that have higher alignment with treatment of traumatic and acute injuries/multi-casualties will be more favorably viewed.

The outcomes of the research will allow data/information/knowledge into the proof-of-concept model. The model needs to be tested in a laboratory-type environment, ***preferably by a subawardee with no active participation in the development of the model***. Actual interfaces will need to be described and defined in the outcome, but functionality of the entire defined interface does not need to be demonstrated in the delivered proof-of-concept.

Proposal/Application submissions to the FY18 PH/TBIRP TRIAGE Award should not only include the design and the methodologies to create the TRIAGE proof-of-concept interoperable component, but also include a protocol for a resiliency model that is embedded within a stressful medical scenario and evaluation of the resiliency effectiveness in relevant contexts in a pilot group of participants, using wearable or non-wearable sensors or other assays to measure stress, performance, and other relevant metrics.

The proposal/application objectives should be focused on the development of an interoperable component that aims to include all of the following attributes, in order of importance:

- Stress-inducing immersive scenarios where the stress-level can be unpredictable, varied or dosed;
- Repeated exposure to scenarios where participant behavior and decisions influence the course of the scenario to tailor the scenario to the participant; and
- Increases in performance that can be objectively measured.

It is encouraged that applicants include the following features in the model:

- Adaptive coaching component that can give feedback based on the phase of learning or turned off to allow participants to play through; and
- Simulations on medical safety issues seen in the field (e.g., triaging).

The proposed research outcomes are intended to have broad applicability not only with the content, but also with underlying architecture or models to allow more open communication now as well as in future efforts. Although discouraged, the proposed research *may* include proprietary tools. The results from this research are expected to be submitted to a peer-reviewed journal for dissemination and be made available for Government use.

II.A.2. Award Background

For additional background information please see the references listed below.

Emergency and traumatic scenarios require medical care providers to maintain performance in the face of intense stress. This ability to maintain performance during and after high pressure or traumatic scenarios composes the concept of resiliency and is essential to the maintenance of a fit and ready Force. Resiliency related to maintaining cognitive performance during stress

includes the ability to maintain adaptability, agility, decision-making and problem-solving skills, mental flexibility, attention, and memory. As many of these cognitive skills are integral to the delivery of effective care in complex medical scenarios, such as in mass casualty events, it is important to gradually build these skills under stress exposure while undergoing medical training. Preparation programs using medical simulation can incorporate stress exposure to scenarios in order to practice strategies to maintain cognitive performance in order to build and strengthen resiliency skills. Ideally, the gains in performance under stress obtained in training are long-lasting and generalize to diverse settings and challenges anticipated in real-world scenarios and the operational space.

The ability to prepare for increased agility and adaptability will likely become increasingly important in anticipated future deployments to variable and diverse operational settings. Considerable attention is being paid to developing new and modifying existing training aimed at promoting personal readiness and resilience in "training on demand" formats that are more amenable to the operational landscape. The DoD has put an emphasis on developing resilience in its Force, as specified in the DoD Instruction 6490.09 subject: DoD Directors of Psychological Health. The emphasis on the performance building aspects of resiliency are reiterated in the Headquarters, Department of the Army, Executive Order (HQDA EXORD) 086-16 (Human Dimension 22 DEC 15), which states that "The Army has the capability and capacity to optimize the human performance of every Soldier and civilian…" Objective 1.3 of this health and fitness goal states a priority to "Enhance soldier and army civilian health and physical readiness through an individualized training system that improves human performance and resilience…" and to "train teams of army professionals to improve and thrive in ambiguity and chaos." Efforts to prepare for increased decision-making, problem-solving, adaptability, and agility are integral to success in these ever-changing, ambiguous, chaotic, and diverse operational environments. The ability to maintain medical skills in high-stress scenarios extends beyond the military as civilian organizations are faced with mass casualty events from natural disasters, mass shootings, and other mass casualty events facing the public.

Ongoing efforts in this concept of Stress Management Training (SMT) have shown growing evidence for efficacy in reducing the negative outcomes of stress on performance and health (see Pallavicini et al., 2016, and Leppin et al., 2014, for review). While resiliency exposure in the absence of stress has demonstrated efficacy in decreased performance losses for future stress exposure, this announcement is focused on Stress Exposure Training (SET) or Stress Inoculation Training (SIT) paradigms that use training under stress. Similar paradigms in SET or SIT have been used by multiple programs to train military members on both combat and medical skills, such as in Squad Overmatch; virtual reality adaptive simulation (VRAS); and Stress Resilience in Virtual Environments (STRIVE) (Rizzo et al., 2012). The outcomes of these programs can be influenced by the content of the exercise, as well as the structure of the setting, timing of stress, format of delivery, sequence of events, number, or repetition of stress exposure, and the type or perceived controllability of the stressor. Ideally, these programs would cause long-lasting gains in performance, adaptability, and agility in participants as compared to subjects not exposed to stress, and these gains would translate to contexts beyond the scenarios.

Animal studies on resilience have demonstrated that repeated exposure to stress in certain formats, namely in controllable or escapable stress scenarios, can lead to long-lasting resilience that generalizes beyond the initial stress context to novel adverse events (Seligman and Maier,

1967; Maier and Watkins, 2005). Conversely, animals exposed to the same stressor, but without the ability to control or turn off the stressor, eventually demonstrated learned helplessness and behaviors related to anxiety- and depression-like behaviors in subsequent assays. The animals with the option to learn how to control or escape a stressor over repeated iterations not only showed protection for the negative effects of stress exposure, but also in some cases, improved performance as compared to a non-stressed comparison group (Maier and Watkins, 2010). Some initial work has demonstrated similar behavioral effects of controllable stress in humans; however, more work is needed (Hartley et al., 2015).

Simulation of stressful scenarios provides an ideal opportunity to provide repeated, safe exposure to controllable or uncontrollable stressors. Virtual simulation provides a unique opportunity to control stress exposure to participants in combat care scenarios and allows for relevant scenarios to be explored. Virtual simulation allows for a diversity of scenarios; preliminary evidence shows it can reduce participants' responses to stress (for review, see Pallavicini et al., 2016). Initial attempts to implement SET with virtual or gaming simulations have been conducted; however, more data are needed on the aspects of stress controllability and ability to generalize performance gains to novel scenarios. Additionally, simulation provides an opportunity for participants to learn over multiple iterations how to control the scenario, and therefore stress exposure, through their actions and performance in the simulation. Allowing the participant to actively alter the stress of the scenario through his or her own actions provides an opportunity to replicate the controllable stress paradigms. Virtual simulation provides a unique opportunity to control stress exposure to participants in combat care scenarios and allows for a diversity of scenarios; preliminary evidence shows it can reduce participants' responses to stress (for review, see Pallavicini et al., 2016).

The anticipated long-term vision includes, but is not limited to: (1) incorporation of an existing, live, virtual gaming platform; (2) scalable, modular, interoperable, flexible preparation proof-of-concept component that can be adapted for diverse military or civilian needs; (3) interoperability with existing virtual gaming platforms; (4) sustainable maintenance and updates of the interoperable component; (5) opportunities for commercialization; and (6) possibility of changing or modifying existing policies and/or military medical preparation curricula and/or objectives.

References:

1. Pallavicini, F., Argenton, L., Toniazzi, N., Aceti, L., and Mantovani, F. 2016. Virtual reality applications for stress management training in the Military. *Aerospace Medicine and Human Performance*, 87(12): 1021-1030. PMID: 28323588.

2. Leppin, A.L., Bora, P.R., Tilburt, J.C., Gionfriddo, M.R., Zeballaos-Palacios, C., Dulohery, M.M., Sood, A., Erwin, P.J., Brito, J.P., Boehmer, K.R., and Montori, V.M. 2014. The efficacy of resiliency training programs: a systemic review and meta-analysis of randomized trials. *PLoS One*, 9(10): e111420. PMID: 25347713.

3. Rizzo, A., Buckwalter, J.G., John, B., Newman, B., Parsons, T., Kenny, P, and Williams, J. 2012. STRIVE: Stress resilience in virtual environments: a pre-deployment VR system for

training emotional coping skills and assessing chronic and acute stress responses. *Studies in Health Technology and Informatics*, 173: 379-385. PMID: 22357022.

4. Seligman, M.E. and Maier, S.F. 1967. Failure to escape traumatic shock. *Journal of Experimental Psychology*, 74(1):1-9. PMID: 6032570.

5. Maier, S.F. and Watkins, L.R. 2005. Stressor controllability and learned helplessness: the roles of the dorsal raphe nucleus, serotonin, and corticotropin-releasing factor. *Neuroscience and Biobehavioral Reviews*, 29(4-5): 829-841. PMID: 15893820.

6. Maier, S.F. and Watkins, L.R. 2010. Role of the medial prefrontal cortex in coping and resilience. *Brain Research*, 1355: 52-60. PMID: 20727864.

7. Hartley, C.A., Gorun, A., Reddan, M.C., Ramirez, F., and Phelps, E.A. 2014. Stressor controllability modulates fear extinction in humans. *Neurobiology of Learning and Memory*, 113: 149-156. PMID: 24333646.

II.A.3. Anticipated Outcomes

The anticipated outcomes of research supported by the FY18 PH/TBIRP TRIAGE Award are described below (in no particular order).

- A proof-of-concept simulation.
- Empirical definitions to the outcome measures and metrics that will be objectively or subjectively collected and provide the measurement tools used.
- A description of the scenarios or explanation of how scenarios can be easily customized or adapted.
- Plans to evaluate gains in outcome measures.
- Evaluation of effects on outcome measures (performance, ability, adaptability, stress levels) whether positive, negative, or neutral, which will be analyzed and recorded in the technical reports and, eventually, in the final report.
- Instructions on the use of the tool as well as definitions, descriptions of measuring devices used, range of acceptable metrics/evaluation criteria, and a draft user manual that will be provided to the Government.
- Plans for sustainable maintenance and updates of the interoperable component including possible commercialization pathways.
- An interoperable component that can be or is designed to be scalable to incorporate scenarios with multiple players (team setting).
- An interoperable component that can be used across the Military Services. Research outcomes, analysis, methodologies, and conclusions will be disseminated and propagated not

only to the military and the Government but also to the public at large through publication in peer-reviewed journals. It is anticipated that scenarios could be relevant across the military, Department of Veteran Affairs (VA), academic, inpatient, outpatient clinics, rural healthcare settings, private and public hospitals, and international healthcare situations.

II.B. AWARD INFORMATION

The anticipated total costs budgeted for the entire period of performance for an FY18 TRIAGE Award will not exceed $1.3 million (M). Refer to Section II.D.6, Funding Restrictions, for detailed funding information.

The USAMRAA will negotiate the award types for proposals/applications selected for funding. The Federal Grant and Cooperative Agreement Act of 1977, United States Code, Title 31, Sections 6301-6308 (31 USC 6301-6308), provides the legal criteria to select a procurement contract or an assistance agreement.

Extramural Organizations: An assistance agreement (grant or cooperative agreement) is appropriate when the Federal Government transfers a "thing of value" to a "state, local government," or "other recipient" to carry out a public purpose of support or stimulation authorized by a law of the United States, instead of acquiring property or service for the direct benefit and use of the U.S. Government. An assistance agreement can take the form of a grant or cooperative agreement. If "no substantial involvement" on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305) and the award will identify the specific substantial involvement. Substantial involvement may include collaboration, participation, or intervention in the research to be performed under the award. A contract is required when the principal purpose of the instrument is to acquire property or services for the direct benefit or use of the U.S. Government. The award type, along with the start date, will be determined during the negotiation process.

Please see Appendix 2 of the General Submission Instructions for more information.

Research involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRMC Office of Research Protections (ORP), Human Research Protection Office (HRPO), prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is not required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB/EC. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Additional time for regulatory reviews may be needed for clinical studies taking place in international settings. When possible, protocols should be written for research with human subjects and/or human anatomical substances that are specific to the DoD-supported effort outlined in the submitted proposal/application as a stand-alone study. Submission to HRPO of protocols involving more

than the scope of work in the DoD-funded award will require HRPO review of the entire protocol (DoD and non-DoD funded). DoD human subjects protection requirements may be applied to non-DoD funded work and necessitate extensive revisions to the protocol. Refer to the General Submission Instructions, Appendix 1, and the Human Subject Resource Document available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for additional information.

Use of DoD or Department of Veterans Affairs (VA) Resources: If the proposed research involves access to active duty military patient populations and/or DoD resources or databases, the applicant is responsible for demonstrating such access at the time of proposal/application submission and should develop a plan for maintaining access as needed throughout the proposed research. Access to target active duty military patient population(s) and/or DoD resource(s) or database(s) should be confirmed by including a letter of support, signed by the lowest-ranking person with approval authority.

If the proposed research involves access to VA patient populations, VA study resources and databases, and/or VA research space and equipment, VA applicants must have a plan for obtaining and maintaining access throughout the proposed research. Access to VA patients, resources, and/or VA research space should be confirmed by including a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief. If appropriate, the proposal/application should identify the VA-affiliated non-profit corporation (NPC) as the applicant institution for VA applicants. If the VA NPC is not identified as the applicant institution for administering the funds, the proposal/application should include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

Access to certain DoD or VA patient populations, resources, or databases may only be obtained by collaboration with a DoD or VA investigator who has a substantial role in the research and may not be available to a non-DoD or non-VA investigator if the resource is restricted to DoD or VA personnel. Applicants should be aware of which resources are available to them if the proposed research involves a non-DoD or non-VA investigator collaborating with the DoD and/or VA. If access cannot be confirmed at the time of proposal/application submission, the Government reserves the right to withdraw or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resource(s). Refer to Section II.D.2.b.ii, Full Proposal/Application Submission Components, for detailed information.

The CDMRP intends that information, data, and research resources generated under awards funded by this BAA be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Submission Instructions, Appendix 2, Section K.

II.C. ELIGIBILITY INFORMATION

II.C.1. Eligible Applicants

- An ***extramural applicant*** is defined as all those not included in the definition of intramural applicants below.

- An ***intramural applicant*** is defined as a DoD military or civilian employee working within a DoD laboratory, DoD military treatment facility, or working in a DoD activity embedded within a civilian medical center. This BAA is intended for extramural applicants only. (There is a separate BAA for intramural applicants applying through intramural organizations that is available through the eBRAP [https://eBRAP.org/] under the funding opportunity number W81XWH-18-DMRDP-MSIS-TRI). Applicants submitting through their intramural organizations are reminded to coordinate receipt and commitment of funds through their respective resource managers.

- Submissions from intramural applicants to this BAA will be rejected. ***It is permissible, however, for an intramural investigator to be named as a collaborator on a proposal/application submitted through an extramural organization. In this case, the proposal/application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.*** For more information, refer to the General Submission Instructions, Section II.C.

II.C.1.a. Organization: All extramural organizations, including international organizations, are eligible to apply.

Awards are made to organizations only. Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations. Refer to the General Submission Instructions, Appendix 3, for general eligibility information.

NOTE: In accordance with FAR 35.017, FFRDCs are not eligible to directly receive awards under this BAA. However, teaming arrangements between FFRDCs and eligible organizations are allowed so long as they are permitted under the sponsoring agreement between the Federal Government and the specific FFRDC.

The USAMRMC is committed to supporting small businesses. Small business, Veteran-owned small business, Service-disabled Veteran-owned small business, HUBZone small business, small disadvantaged business, and woman-owned small business concerns must be given the maximum practical opportunity to participate through subawards on research proposals/ applications submitted through the BAA.

Government Agencies Within the United States: Local, state, and Federal Government agencies are eligible to the extent that proposals/applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their proposals/ applications do not overlap with their internal programs.

Proposals/Applications for this BAA may only be submitted by extramural organizations. Applicants from an intramural organization should apply through eBRAP under the funding opportunity number W81XWH-18-DMRDP-MSIS-TRI. These terms are defined below.

Extramural Organization: An eligible non-DoD organization. Examples of extramural organizations include academia, biotechnology companies, foundations, Government, and research institutes.

Intramural DoD Organization: A DoD laboratory, DoD military treatment facility, and/or DoD activity embedded within a civilian medical center. ***If an investigator at an intramural organization is named as a collaborator on a proposal/application submitted through an extramural organization, the proposal/application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.***

Note: Proposals/Applications from an intramural DoD organization or from an extramural non-DoD Federal organization may be submitted through a research foundation.

The USAMRAA makes awards to eligible organizations, not to individuals.

II.C.1.b. Principal Investigator

Independent investigators at all academic levels of professorship appointments (or industrial equivalent) are eligible to submit proposals/applications. Training fellows, at the graduate or postdoctoral level, are not eligible to apply for this solicitation.

An eligible PI, regardless of ethnicity, nationality, or citizenship status, must be employed by, or affiliated with, an eligible organization.

The CDMRP encourages all applicants to participate in a digital identifier initiative through Open Researcher and Contributor ID, Inc. (ORCID). Registration for a unique ORCID identifier can be done online at http://orcid.org/.

II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

II.C.3. Other

Organizations must be able to access **.gov** and **.mil** websites in order to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

Each investigator may submit only one FY18 PH/TBIRP TRIAGE Award proposal/application as a PI.

Subcontracting Plan: If the resultant award is a contract that exceeds $700,000 and the offeror is other than a small business, the contractor will be required to submit a subcontracting plan for small business and small disadvantaged business concerns, in accordance with FAR 19.704 and

Defense Federal Acquisition Regulation Supplement, Subpart 219.704 (DFARS 219.704). A mutually agreeable plan will be incorporated as part of the resultant contract.

For general information on required qualifications for award recipients, refer to the General Submission Instructions, Appendix 3.

In addition to other information provided herein, by submitting a proposal/application and accepting an award, the organization is: (1) certifying that the applicants' credentials have been examined and (2) verifying that the applicants are qualified to conduct the proposed study and to use humans as research subjects, if proposed. Applicants include all individuals, regardless of ethnicity, nationality, or citizenship status, who are employed by, or affiliated with, an eligible organization.

Refer to Section II.H.1, Administrative Actions, for a list of administrative actions that may be taken if a pre-proposal/pre-application or proposal/application does not meet the administrative, eligibility, or ethical requirements defined in this BAA.

II.D. PROPOSAL/APPLICATION AND SUBMISSION INFORMATION

II.D.1. Address to Request Proposal/Application Package

eBRAP is a multifunctional web-based system that allows applicants to submit their pre-proposals/pre-applications electronically through a secure connection, to view and edit the content of their pre-proposals/pre-applications and full proposals/applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance.

Extramural Submissions: Pre-proposal/Pre-application content and forms must be accessed and submitted at eBRAP.org. Full proposal/application packages must be accessed and submitted at Grants.gov.

Intramural DoD Submissions: Pre-proposal/Pre-application content and forms and full proposal/application packages for funding opportunity number W81XWH-18-DMRDP-MSIS-TRI must be accessed and submitted at eBRAP.org.

Contact information for the CDMRP Help Desk and the Grants.gov Contact Center can be found in Section II.G, Federal Awarding Agency Contacts.

II.D.2. Content and Form of the Proposal/Application Submission

Submission is a two-step process requiring both ***pre-proposal/pre-application*** and ***full proposal/application*** as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods.

Pre-Proposals/Pre-Application Submissions: All pre-proposals/pre-applications for both extramural and intramural organizations must be submitted through eBRAP (https://eBRAP.org/).

Full Proposal/Application Submissions: Full proposals/applications must be submitted through the online portals as described below.

Submitting Extramural Organizations: Full proposals/applications from extramural organizations must be submitted through a Grants.gov Workspace. Proposals/Applications submitted by extramural organizations (e.g., research foundations) on behalf of intramural DoD or other Federal organizations or investigators will be considered extramural submissions. Proposals/Applications from extramural organizations, including non-DoD Federal organizations, received through eBRAP will be withdrawn. See definitions in Section II.C.1, Eligible Applicants.

Submitting Intramural DoD Organizations: Intramural DoD organizations may submit full proposals/applications for funding opportunity number W81XWH-18-DMRDP-MSIS-TRI to either eBRAP or Grants.gov. Intramural DoD organizations that are unable to submit to Grants.gov should submit through eBRAP. Intramural DoD organizations with the capability to submit through Grants.gov may submit following the instructions for extramural submissions through Grants.gov or may submit to eBRAP.

For Both Extramural and Intramural Applicants: A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the full proposal/application submissions associated with them. eBRAP will validate full proposal/application files against the specific BAA requirements, and discrepancies will be noted in an email to the PI and in the "Full Application Files" tab in eBRAP. It is the applicant's responsibility to review all proposal/application components for accuracy as well as ensure proper ordering as specified in this BAA.

The proposal/application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-proposal/pre-application and full proposal/application submission process. Inconsistencies may delay proposal/application processing and limit or negate the ability to view, modify, and verify the proposal/application in eBRAP. If any changes need to be made, the applicant should contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 prior to the proposal/application submission deadline.

II.D.2.a. Step 1: Pre-Proposal/Pre-Application Submission Content

Pre-proposals/Pre-applications should describe specific ideas or projects that pertain to any of the areas described under "Program Description" in this BAA. A pre-proposal/pre-application must include a brief description of the scientific methods and design to address the problem as described below. Brochures or other descriptions of general organizational or individual capabilities will not be accepted as a pre-proposal/pre-application. ***DO NOT include any proprietary information in the pre-proposal/pre-application.***

During the pre-proposal/pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed during the full proposal/application submission process.

To begin the pre-proposal/pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel (*the selection chosen should be "extramural" as only extramural applicants are eligible to apply to this BAA*). **Incorrect selection of extramural or intramural submission type will delay processing.**

If an error has been made in the selection of extramural versus intramural and the pre-proposal/ pre-application submission deadline has passed, the PI or Business Official must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 to request a change in designation.

All pre-proposal/pre-application components must be submitted by the applicant through eBRAP (https://eBRAP.org/). Because the invitation to submit a proposal/application is based on the contents of the pre-proposal/pre-application, applicants should not change the title or research objectives after the pre-proposal/pre-application is submitted.

Applicants and organizations identified in the pre-proposal/pre-application should be the same as those intended for the subsequent proposal/application submission. If any changes are necessary after submission of the pre-proposal/pre-application, the applicant must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

Applicants with an ORCID identifier should enter that information in the appropriate field in the "My Profile" tab in the "Account Information" section of eBRAP.

The pre-proposal/pre-application consists of the following components, which are organized in eBRAP by separate tabs (refer to the General Submission Instructions, Section II.B, for additional information on pre-application submission):

- **Tab 1 – Application Information**

  Submission of proposal/application information includes assignment of primary and secondary research classification codes, which may be found at https://ebrap.org/eBRAP/public/Program.htm. Note that the codes have recently been revised. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

- **Tab 2 – Application Contact**

  Enter contact information for the PI. Enter the organization's Business Official responsible for sponsored program administration (the "person to be contacted on matters involving this application" in Block 5 of the Grants.gov SF424 Form). The Business Official must either be selected from the eBRAP list or invited for the pre-proposal/pre-application to be submitted.

  Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 (R&R) Form), and click on "Add Organizations to this Pre-application." The organization(s) must be either selected from the eBRAP drop-down list or invited in order for the pre-proposal/pre-application to be submitted.

It is recommended that an Alternate Submitter is identified in the event that assistance with pre-proposal/pre-application submission is needed.

- **Tab 3 – Collaborators and Key Personnel**

  Enter the name, organization, and role of all collaborators and key personnel associated with the pre-proposal/pre-application.

  FY18 JPC-1/MSIS Medical Simulation and Training Technologies Steering Committee members should not be involved in any pre-proposal/pre-application or proposal/application including, but not limited, to concept design, proposal/application development, budget preparation, and the development of any supporting documentation. For questions related to the Steering Committee members and pre-proposals/pre-applications or proposals/applications, refer to Section II.H.2.c, Withdrawal, or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

  To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in proposal/application preparation, research, or other duties for submitted proposals/ applications. For FY18, the identity of the peer review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess.shtml). The programmatic review is performed by the FY18 JPC-1.MSIS Medical Simulation and Training Technologies Steering Committee. Pre-proposals/Pre-applications or proposals/applications that include names of personnel from either the peer review contractor or steering committee member will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Government. Refer to the General Submission Instructions, Appendix 1, for detailed information.

- **Tab 4 – Conflicts of Interest**

  List all individuals other than collaborators and key personnel who may have a COI in the review of the pre-proposal/pre-application (including those with whom the PI has a personal or professional relationship).

  Federal agency personnel involved in the review process and/or with making funding recommendations are prohibited from being involved in the research proposed or assisting in any pre-proposal/pre-application, including, but not limited to, concept design, proposal/application development, budget preparation, and the development of any supporting documentation. ***If formal collaboration with Military Facility personnel is planned (i.e., included in the proposal/application in performance of the research), this prohibition is not applicable. Military Facility is defined as Military Health System (MHS) facility, research laboratory, medical treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center. However, these Military Facility personnel cannot be involved in the review process and/or with making funding recommendations.***

Refer to the General Submission Instructions, Appendix 3, for additional information. For questions related to COI, contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

- **Tab 5 – Pre-Application Files**

  NOTE: Upload documents as individual PDF files unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.

  Pre-Proposal/Pre-Application Narrative (eight-page limit): The Pre-Proposal/ Pre-Application Narrative page limit applies to text and non-text components (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Pre-Proposal/ Pre-Application Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

  The Pre-Proposal/Pre-Application Narrative should include the following:

  - **Problem to Be Studied:** Describe the perceived issue(s) and the problems to be studied. This section should serve as an abstract of the proposed work.

  - **Background/Rationale:** Clearly present the ideas and reasoning behind the proposed research. Include relevant literature citations, preliminary and/or pilot data, and/or other evidence that led to the development of the proposed research. Any preliminary data should be from the laboratory of the PI or member(s) of the collaborating team. Briefly, describe how the proposed work and research will support how to increase performance through stressful simulation.

  - **Hypothesis/Objective and Specific Aims:** State the proposed project's hypothesis and/or objectives and the specific aims/tasks of the proposed research.

  - **Approach/Methodology:** Describe the research approach and development plan. Include research design, methods, and analysis/evaluation strategies as well as materials anticipated to be used during the research. Provide a list of methods planned to be used in the test and evaluation study that will provide the data/information needed to answer research questions or successfully complete aims of study. Include in the pre-proposal/ pre-application any relevant procedures/skills anticipated to be included in the proof-of-concept. If applicable, include a description of human use in the proposed project. For studies involving human subjects, include a description of the size, characteristics, and partnering organizations of the subject population that will be employed.

  - **Significance, Relevance, and Innovation of the Proposed Effort**

    - **Significance and Relevance:** Clearly articulate, using a theoretical construct, how the proposed research and development are relevant to the goal of developing a proof-of-concept preparation interoperable component that would appropriately support assessing performance gains after stress-inducing simulation. The proposed design

needs to address the long-term goals mentioned in this BAA within the proposed model design/architecture.

- **Innovation:** Explain how the proposed project is innovative and not an incremental advancement of previous work and has the potential to improve current practices and patient outcomes and decrease medical errors.

- **Proposed Study Design/Plan:** Describe the proposed pilot study to demonstrate effectiveness and efficiency of the TRIAGE proof-of-concept, preferably to be conducted by a subawardee not involved in the development of the model. Provide the intended research methodology that will support the pilot study. If applicable, provide preliminary information such as anticipated type of recruits, number of recruits, control group, anticipated assessment criteria, inter-rater reliability, and statistical approaches. Refer to Section II.A, Program Description for additional information on the research areas of interest for this BAA.

- **Military Impact:** Describe the anticipated short- and/or long-term outcomes of the proposed project and their potential impact on improving simulation-based medical provider training in the MHS. Explain what the potential of this proposed work is for improving current practices and patient outcomes and decreasing medical errors. Refer to Section II.A, Program Description for additional information on the anticipated outcomes sought by this BAA.

- **Personnel and Facilities:** Describe the role of the PI, co-PIs (if applicable), key personnel, subawardees (if applicable), and consultants (if applicable) in the research team, including the expertise each brings to the proposed project. Explain how the team's expertise is appropriate and complementary for achieving the research goals. Also, briefly provide information on the primary facility where the research is expected to be performed.

- **Open Source/License/Architecture:** Describe the intellectual property that is intended to be incorporated within the design/plan of the proposed model and identify any additional costs, such as licensing, that may be needed to ensure flexibility or adaptation of the research project for Government use. Additionally, provide what is intended to be open source/architecture within the proposed proof-of-concept.

- **Pre-Proposal/Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-proposal/pre-application ***must be uploaded as individual files*** and are limited to the following:

  - References Cited (one-page limit): List the references cited (including URLs if available) in the Pre-Proposal/Pre-Application Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate). Include both military and civilian research in the review of the literature, as applicable.

- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols used in the Pre-Proposal/Pre-Application Narrative.

- PI and Key Personnel Biographical Sketches (six-page limit per individual): Upload as "Biosketch_LastName.pdf." Bold or highlight publications relevant to the proposed project.

- Budget Summary: Upload as "BudgetSummary.pdf." Complete the two-page Pre-Application Budget Summary Form (available for download in eBRAP) as instructed.

- Quad Chart: Upload as "QuadChart.pdf." Complete the one-page Quad Chart Form (available for download in eBRAP) as instructed.

Refer to the General Submission Instructions, Section II.C, for detailed information.

- **Tab 6 – Submit Pre-Application**

  This tab must be completed for the pre-proposal/pre-application to be accepted and processed.

Pre-Proposal/Pre-Application Screening

Pre-Proposal/Pre-Application Screening Criteria

All pre-proposals/pre-application will be screened by the FY18 JPC-1/MSIS Medical Simulation and Training Technologies Steering Committee members to determine technical merit and relevance to the mission of the DHP, PH/TBIRP, and JPC-1/MSIS. Pre-proposals/ Pre-applications will be screened based on the following criteria:

- **Rationale, Scientific Methods, and Research:**

  - How well the research approach for accomplishing the specific aims is feasible, will accomplish the objectives, will provide information on proposed methods and analysis/ evaluation strategies, and is based on sound rationale.

  - How well the proposed work and research will support the knowledge research on how to better understand task performance to assess translational skills and the development of a translational medical research model.

  - How well the research is derived from evidence-based, best-of-class, well-documented, and/or well-adopted designs.

- **Significance, Relevance, and Innovation:**

  - How well the proposed research is relevant, innovative, and novel, including whether the proposed research is duplicative of existing research.

- How well the proposed research is relevant to the goal of delivering a TRIAGE proof-of-concept that aligns to the context of this BAA.

- **Open Source/License/Architecture:**

  - Whether intellectual property that is proposed for incorporation is located in key areas within the design/plan that would limit future flexibility or adaptation of a TRIAGE proof-of-concept model. If applicable, whether the proposed open source/architecture and locations for incorporation are appropriate.

- **Study Design/Plan:**

  - How well the methodology proposed of a TRIAGE proof-of-concept model can be adjusted to include scenarios relevant to military training.

  - How well the engineering/technical design that will be used to achieve the project goals demonstrates the feasibility of the proposed TRIAGE proof-of-concept model.

- **Military Impact:** How well the project's anticipated short- and/or long-term outcomes are relevant to the military in a way that is consistent with the intent of the award mechanism.

- **Personnel, Facilities, Timelines, and Budget:** How well the expertise, experience, and knowledge of the key research personnel (including co-PIs, if applicable), subawardees (if applicable), and consultants (if applicable) are appropriate and complementary for achieving the research goals.

Notification of Pre-Proposal/Pre-Application Screening Results

Following the pre-proposal/pre-application screening, applicants will be notified as to whether or not they are invited to submit proposals/applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-proposal/pre-application. The estimated timeframe for notification of invitation to submit a proposal/application is indicated on the Section I, Overview of the Funding Opportunity of this BAA.

II.D.2.b. Step 2: Full Proposal/Application Submission Content

Proposals/Applications will not be accepted unless the PI has received notification of invitation.

The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.

Each proposal/application submission must include the completed full proposal/application package for this BAA. The full proposal/application package is submitted by the Authorized Organizational Representative through Grants.gov (http://www.grants.gov/) for extramural organizations or through eBRAP (https://ebrap.org/) for intramural organizations. See Table 1 below for more specific guidelines.

II.D.2.b.i. Full Proposal/Application Guidelines

Extramural organizations must submit full proposals/applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the proposal/application components to be completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out webforms in the Workspace. A compatible version of Adobe Reader must be used to view, complete, and submit a proposal/application package consisting of PDF forms. If more than one person is entering text into a proposal/application package, the same version of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user's computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Submission Instructions, Section III, and the "Apply For Grants" page of Grants.gov (https://www.grants.gov/web/grants/applicants/apply-for-grants.html) for further information about the Grants.gov Workspace submission process. Submissions of extramural proposals/ applications through eBRAP may be withdrawn.

Table 1. Full Proposal/Application Submission Guidelines

Proposal/Application Package Location
Download proposal/application package components for W81XWH-18-S- MSI1 from Grants.gov (http://www.grants.gov) and create a Grants.gov Workspace. The Workspace allows online completion of the proposal/application components and routing of the proposal/application package through the applicant organization for review prior to submission.
Full Proposal/Application Package Components
SF424 (R&R) Application for Federal Assistance Form: Refer to the General Submission Instructions, Section III.A.1, for detailed information.
Descriptions of each required file can be found under Full Proposal/Application Submission Components: • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • R&R Subaward Budget Attachment(s) Form (if applicable)

Proposal/Application Package Submission
Create a Grants.gov Workspace. Add participants (applicants and Business Officials) to the Workspace, complete all required forms, and check for errors before submission. **Submit a Grants.gov Workspace Package.** A proposal/application may be submitted through Workspace by clicking the "Sign and Submit" button on the "Manage Workspace" page, under the "Forms" tab. Grants.gov recommends submission of the proposal/application package **at least 24-48 hours prior to the close date** to allow time to correct any potential technical issues that may disrupt the proposal/application submission. Note: If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget needs to be modified, an updated Grants.gov proposal/application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID prior to the proposal/application submission deadline.
Proposal/Application Verification Period
The full proposal/application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the proposal/application verification period. During the proposal/application verification period, the full proposal/application package, ***with the exception of the Project Narrative and Budget Form,*** may be modified.
Further Information
Tracking a Grants.gov Workspace Package. After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the "Confirmation" page that is generated after submission. Refer to the General Submission Instructions, Section III, for further information regarding Grants.gov requirements.

Proposal/Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. ***The Project Narrative and Budget cannot be changed after the proposal/application submission deadline.*** Prior to the full proposal/application deadline, a corrected or modified full proposal/application package may be submitted. Other proposal/application components may be changed until the end of the proposal/application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the proposal/application verification period. If these components are missing, upload them to eBRAP before the end of the proposal/application verification period. After the end of the proposal/application verification period, the full proposal/application cannot be modified.

Material submitted after the end of the proposal/application verification period, unless specifically requested by the Government, will not be forwarded for processing.

The full proposal/application package must be submitted using the unique eBRAP log number to avoid delays in proposal/application processing.

II.D.2.b.ii Full Proposal/Application Submission Components

The Grants.gov submission package includes the following components (refer to the General Submission Instructions, Section III, for additional information on proposal/application submission).

- **SF424 (R&R) Application for Federal Assistance Form:** Refer to the General Submission Instructions, Section III, for detailed information.

  Attachments:

  Each attachment to the full proposal/application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Submission Instructions, Appendix 4.

  For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are longer than 50 characters or if they have incorrect file names, i.e., containing characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire full submission package may not exceed 200 MB.

  - **Attachment 1: Project Narrative (20-page limit):** Upload as "ProjectNarrative.pdf." There is no form for this information. The attachments must be PDF files in accordance with the formatting guidelines specified for full proposal/application preparation. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and will result in administrative withdrawal of the proposal/application.

    A detailed description of the research to be undertaken should be submitted. This should include the areas provided below and address their relationship to the state of knowledge in the field and to comparable work in progress elsewhere. Evaluation of the proposed research will be influenced by the adequacy of this information.

    The following general outline should be followed:

    - **Background:** Present theoretical framework behind the proposed research; include relevant literature citations or preliminary data on the proposed methodologies. Additionally, present the ideas, reasoning, justification, and stakeholder needs that will influence the design and development of the proposed TRIAGE proof-of-concept model and identify the data-driven information used to support the proposed TRIAGE proof-of-concept model. Describe how the proposed work and research will support the knowledge research on how to increase performance through stressful simulation. Describe previous experience most pertinent to this project. Any preliminary data should be from the laboratory of the PI or member(s) of the collaborating team.

    - **Hypotheses/Objectives:** State the hypotheses or research/evaluation questions and overall objective(s) to be reached.

- **Specific Aims:** Concisely explain the project's specific aims to include expected timeframe of each aim. If this proposal/application is part of a larger study, present only tasks this award would fund. Describe how the research approach for accomplishing the specific aims is feasible, will accomplish the proposed objectives, will provide information on proposed methods and analysis/evaluation strategies, and is based on sound rationale.

- **Project Design:** Describe and define the experimental design, methods, and analyses in sufficient detail for evaluation.

  - Identify and describe the hypothesis or research question(s) to be studied and the projected outcome(s) of the proposed research.

  - State the virtual gaming platform used for the preparation of the interoperable component.

  - Provide the proposed procedures/skills that are anticipated to be included in the proof-of-concept. Explain why the proposed procedures/skills align with the proposed methodology, and describe those components of the proposed procedures/skills that would be difficult to integrate into the proof-of-concept.

  - Provide a detailed process, including but not limited to, proposed methodology on how the proposed TRIAGE proof-of-concept will be tested and evaluated to demonstrate that the concept could support the items listed in this BAA as well as potentially supporting the future needs. Include separate test and evaluation plans applicable for software and hardware approaches.

  - Provide a detailed protocol, including, but not limited to, proposed methodologies, type of recruits, recruitment numbers, anticipated dropout rate, assessment criteria, inter-rater reliability, intended medical domain(s) or discipline(s), control groups, and defined statistical models, if applicable. Explain how the known, and even unanticipated unknown, variables will be addressed.

  - Define the study variables (independent/dependent) and define how they will be measured. Include a description of appropriate controls and the endpoints to be tested. Describe how data will be collected and analyzed in a manner that is consistent with the study objectives. Describe the measurement tools and provide definitions as well as the tolerance ranges that the tools are designed to measure.

  - For development of devices and technologies, discuss the engineering/technical design that will be used to achieve the project goals, demonstrating the feasibility of the proposed product development. Describe end user context need and how feedback will allow device/technology to be intuitive to the end user. Discuss the perceived engineering/design strengths and flaws and recommendations for overcoming/preventing them.

  - Address all potential risks/barriers and provide plans for addressing potential delays and unexpected events. Provide a risk management plan to address

barriers to plans with objective, easily and independently measured metrics for Cost, Schedule, and Performance. As relevant, describe plans for addressing potential issues unique to working within the MHS.

- Document the availability and accessibility of the study materials (including data) needed as applicable.

– **Additional Information:** If human subjects are included in the research, proposals/applications may be submitted without human use protocols and institutional approvals. However, protocols with required institutional approvals must be submitted for approval no later than 60 days after award to demonstrate continued progress and ensure continuation of payment. The Contracting or Grants Officer may make exceptions in situations where human use is not expected to begin until after the first year of the research project. In such cases, a timeframe for submission of the appropriate protocols and institutional approvals will be established prior to award.

Applicants and collaborating organizations may not use, employ, or subcontract for the use of any human participants, including the use of human anatomical substances, human data, and/or human cadavers until applicable regulatory documents are reviewed and approved by the USAMRMC ORP to ensure that DoD regulations have been met.

○ **Attachment 2: Supporting Documentation:** Combine and upload as a single file named "Support.pdf." Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative.

There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested or viewed as an extension of the Project Narrative will result in the removal of those items or may result in administrative withdrawal of the proposal/application.

– References Cited: List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

– List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.

– Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under

which the facilities or equipment items are now accountable. There is no form for this information.

- Publications and/or Patent Abstracts (five-document limit): Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

- Letters of Organizational Support: Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the BAA, such as those from members of Congress, do not impact proposal/application review or funding decisions.

- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on a proposal/application submitted through an extramural organization, the proposal/application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.

- Intellectual Property: Information can be found in Code of Federal Regulations, Title 2, Part 200.315 (2 CFR 200.315), "Intangible Property."

  - An appropriate justification for incorporating proprietary tools *must* be included. ***Proposed proprietary intellectual property components must be clearly and legibly marked in the full proposal/application. Failure to clearly and legibly list, describe, justify, and mark proprietary property will result in full forfeiture of any and all proprietary claims.***

  - Open source and open architecture components must be highlighted. Proposals/Applications must fully demonstrate that all necessary permissions have been obtained from any third parties.

  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.

  - Intangible property acquired, created, or developed under this award will be subject to all rights and responsibilities established at 2 CFR 200.315. Should the applicant intend to use, in the performance of this program, pre-existing, legally protected and perfected intangible property and for which no Federal funds had been used in the development of said property, the applicant must:

    - Clearly identify all such property; and

- ❖ Identify the cost to the Federal Government for use or license of such property, if applicable;

- Describe how the proposed task performance assessment tool incorporates open source/license/architecture and intellectual property components available for license. Indicate where in the proof-of-concept or the design the respective proprietary or open source/architecture components are located.

– **Use of DoD Resources (if applicable):** Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active duty military patient populations and/or DoD resources or databases.

– **Use of VA Resources (if applicable):** Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the ACOS/R&D or Clinical Service Chief confirming access to VA patients, resources, and/or VA research space. For VA applicants, if the VA NPC is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

– *If the project involves collaboration with a Military Facility, special requirements apply.* A DoD researcher, to include collaborating DoD applicants, must obtain a letter from his/her commanding officer or Military Facility director authorizing his/her participation in the research project. This letter must be included with the proposal/application.

– Joint Sponsorship: Describe present or prospective joint sponsorship of any portion of the program outlined in the proposal/application. In the absence of agreements among sponsors for joint support, the proposal/application should be structured so that the research can be carried out without the resources of any other sponsor. If, however, it is desirable to request partial support from another agency, the proposed plan should be stated and the reasons documented. If the plan cannot be formulated at the time the proposal/application is submitted, information should be sent later as an addendum to the proposal/application. Prior approval from each organization must be secured for research to be undertaken under joint sponsorship. Provide letters of support related to recruitment, subject access, and data access plans.

○ **Attachment 3: Technical Abstract (one-page limit):** Upload as "TechAbs.pdf." The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

The structured technical abstract should be clear and concise and, at a minimum, provide the following information:

– Background: Provide a brief statement of the ideas and theoretical reasoning behind the proposed work.

- Objective/Hypothesis: State the objective to be reached/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.

- Specific Aims: State concisely the specific aims of the study.

- Study Design: Briefly describe the study design.

- Relevance: Provide a brief statement explaining the potential relevance of the proposed work to addressing the intent of this BAA, which is a gaming interoperable component that elicits cognitively demanding problem-solving and decision-making under high-stress scenarios in order to increase performance, adaptability, and agility that also translates to real-world scenarios.

- **Attachment 4: Lay Abstract (one-page limit):** Upload as "LayAbs.pdf." The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

  Lay abstracts should be written using the outline below. Do not duplicate the technical abstract.

  - Clearly describe the objectives and theoretical reasoning behind the proposed work in a manner readily understood by readers without a background in science or medicine.

  - Clearly describe the problem or question to be addressed and the ultimate applicability and impact of the research.

    - What types of patients will it help, and how will it help them? Include the current available statistics to the related injury/condition.

    - What are the potential clinical applications, benefits, and risks?

    - What is the projected timeline it may take to achieve the expected patient-related outcome?

    - Describe how the proposed project will benefit Service members, Veterans, and/or their family members.

- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as "SOW.pdf." The suggested SOW format and examples specific to different types of research projects are available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). For the FY18 PH/TBIRP TRIAGE Award mechanism, use the SOW format example titled "SOW (Statement of Work) Generic Format" or "SOW for Clinical Research (Including Trials, Special Populations)," as appropriate. Include a Gantt chart depicting project schedule timeline, including objectives that must be accomplished in order for the project to be successful. The SOW

must be in PDF format prior to attaching. Refer to the General Submission Instructions, Section II.C.2, for detailed guidance on creating the SOW.

- For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.

- For use of human anatomical substances, identify the commercial or organizational source(s) of the material. For cell lines, identify cell line(s) to be used. If human anatomical substances (including cell lines) will be used, specify whether or not identifiable information is accessible to the research team by any means.

- If applicable, indicate time required for submission and/or approval of documents (e.g., Investigational New Drug and Investigational Device Exemption) to the U.S Food and Drug Administration (FDA) or appropriate Government regulatory agency.

- For studies involving human subjects, allow at least 2 to 3 months for regulatory review and approval by the USAMRMC HRPO; this does not include the additional time required for local IRB review and approval, as stated above.

- Refer to the General Submission Instructions, Appendix 1, for additional regulatory information.

- **Attachment 6: Impact/Outcomes Statement (one-page limit):** Upload as "Impact.pdf." Explain the potential impact of the research in the field, the significance of this impact, and when it can be anticipated. Explain how the results of this research are expected to impact the intended beneficiaries. Expand upon the dual (military and public) purpose for the research, as appropriate.

  - ***Short-Term Impact:*** Describe the anticipated outcome(s)/results(s)/theoretical framework, design, and/or plan that will be directly attributed to the results of the proposed research.

  - ***Long-Term Impact:*** Describe the anticipated long-term clinical/patient gains or commercial end product from the proposed project. Explain how and why the project outcomes will transform medical provider preparation and education.

  - ***Military Relevance:*** Clearly articulate how the proposed project meets the needs of injured Service members and either allows them to return to duty or resume a fully active lifestyle in the civilian sector.

  - ***Public Purpose:*** If appropriate, provide a concise, detailed description on how this project will benefit the general public.

- **Attachment 7: Innovation Statement (two-page limit):** Upload as "Innovation.pdf." Describe how the proposed project is innovative. Research deemed innovative may introduce a new paradigm, challenge current paradigms, look at existing problems from new perspectives, or exhibit other creative qualities. Investigating the next logical step or incremental advancement on published data is not considered innovative. This may

include a proposed conceptual framework, design, and/or plan of key components and how they integrate/communicate with each other.

- **Attachment 8: Human Subject Recruitment and Safety Procedures (if applicable; no page limit):** Upload as "HumSubProc.pdf." The Human Subject Recruitment and Safety Procedures attachment should include the components listed below.

  - **Study Population:** Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site (population from whom the sample will be recruited/drawn). Demonstrate that the research team has access to the proposed study population. Furthermore, discuss past efforts in recruiting human subjects from the target population for previous studies (if applicable). Address any potential barriers to accrual and plans for addressing unanticipated delays. Include justification of any age, race, ethnicity, or sex limitations provided. ***For studies proposing to include military personnel as volunteers, refer to the General Submission Instructions, Appendix 1, for more information.***

  - **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed study. Inclusion/Exclusion criteria should take into consideration the specific risk profile of the studies to be conducted. Provide detailed justification for exclusions.

    Inclusion of Women and Minorities in Study. Consistent with the Belmont Report, "Ethical Principles and Guidelines for the Protection of Human Subjects," and Congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRMC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects' research. Include an appropriate justification if women and/or minorities will be excluded from the study.

  - **Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, and health care provider identification).

    - Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.

    - Include a detailed description of and justification for the compensation plan if the human subjects will be compensated for participation in the study.

    - Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study.

- **Description of the Informed Consent Process:** Specifically describe the plan for obtaining informed consent from human subjects.

  For the proposed study, provide a draft, in English, of the Informed Consent Form.

  - Identify who is responsible for explaining the study, answering questions, and obtaining informed consent. Include a plan for ensuring that human subjects' questions will be addressed during the consent process and throughout the study.

  - Include information regarding the timing and location of the consent process.

  - Address issues relevant to the mental capacity of the potential human subject (e.g., altered capacity due to brain injury, stress/life situations, human subject age, or administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia), if applicable.

  - Address how privacy and time for decision-making will be provided and whether or not the potential human subject will be allowed to discuss the study with anyone before making a decision.

  - Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study and describe any relevant procedures to assure continued consent.

  - Describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB/EC of record should be consulted for guidance regarding who can serve as LAR for research at the study site. Note: The PI must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed study to be in compliance with 10 USC 980 (http://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf). If applicable, refer to the General Submission Instructions, Appendix 1, for more information.

  - Assent: If minors or other populations that cannot provide informed consent are included in the proposed study, a plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent, should be provided. Applicants should consult with their local IRB/EC to identify the conditions necessary for obtaining assent.

- **Screening Procedures:** List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study participation. Note that some screening procedures may require a separate consent or a two-stage consent process. Informed consent must be obtained prior to initiation of any procedures for the purpose of determining eligibility.

- **Risks/Benefits Assessment**

  - **Foreseeable risks:** Clearly identify all study risks. Study risks include any risks that the human subject is subjected to as a result of participation in the study. Consider psychological, legal, social, and economic risks as well as physical risks. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.

  - **Risk management and emergency response**

    - Describe how safety surveillance and reporting to the IRB and FDA (if applicable) will be managed and conducted.

    - Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values.

    - Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, to include who will be responsible for the cost of such care.

    - Address any special precautions to be taken by the human subjects before, during, and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, and pregnancy prevention).

    - Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study.

  - **Potential benefits:** Describe known and potential benefits of the study to the human subject, a specific community, or society. ***Note: Payment and/or other compensation for participation are not considered to be benefits***.

- **Attachment 9: Data Management (no page limit):** Upload as "DataManage.pdf." The Data Management attachment should include the components listed below.

  Describe all methods used for data collection to include the following:

  - **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.

  - **Confidentiality:** Explain measures taken to protect the privacy of study human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.

- Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of USAMRMC are eligible to review study records.

- Address requirements for reporting sensitive information to state or local authorities.

– **Disposition of data:** Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, and the length of time data will be stored. For FDA-regulated studies, compliance with 21 CFR 11 is required.

– **Sharing study results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether or not the results of screening and/or study participation will be shared with human subjects or their primary care provider, to include results from any screening or diagnostic tests performed as part of the study.

○ **Attachment 10: Post-Award Project Transition Plan (three-page limit):** Upload as "Transition.pdf." Provide information on the methods and strategies proposed to move the product or knowledge outcomes to the next project phase of studies, commercialization, and/or delivery to the civilian or military market after successful completion of the award. The transition plan should include, as applicable, the components listed below.

– Details of the funding strategy that will be used to bring the outcomes to the next level of development and/or commercialization (e.g., specific potential industry partners, specific funding opportunities to be applied for).

– For knowledge products, a description of how the knowledge will be further developed, disseminated, and incorporated into clinical care.

– A description of collaborations and other resources that will be used to provide continuity of development.

– A brief schedule and milestones for bringing the outcome(s) to the next phase of studies, commercialization, and/or delivery to the military or civilian market, including when it can be anticipated to be transitioned to an industry partner or approved by the FDA.

– A risk analysis for cost, schedule, manufacturability, and sustainability.

○ **Attachment 11: Representations:** Upload as "MandatoryReps.pdf." All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Submission Instructions, Appendix 5, Section B, Representations.

○ **Attachment 12: Collaborating DoD Military Facility Budget Form(s), *if applicable*:** Upload as "MFBudget.pdf." If a Military Facility (MHS facility, research laboratory,

medical treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the DoD Military Facility Budget Form, available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm), including a budget justification, for each military facility as instructed. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Submission Instructions, Section III.A, for detailed information.

To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC A§1681 et seq.), the DoD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in proposals/applications in science, technology, engineering, or mathematics (STEM) disciplines. To enable this assessment, each proposal/application must include the following forms completed as indicated.

Research & Related Personal Data: For extramural submissions (via Grants.gov), refer to the General Submission Instructions, Section III.A.3, for detailed information.

Research & Related Senior/Key Person Profile (Expanded): Refer to the General Submission Instructions, Section III.A.4, for detailed information.

- PI Biographical Sketch (six-page limit): Upload as "Biosketch_LastName.pdf." The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in the PDF format that is not editable.

- PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

- Key Personnel Biographical Sketches (six -page limit each): Upload as "Biosketch_LastName.pdf."

- Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

Research & Related Budget: For extramural submissions (via Grants.gov), refer to the General Submission Instructions, Section III.A.5 for detailed information.

Budget Justification (no page limit): Upload as "BudgetJustification.pdf." The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.

Project/Performance Site Location(s) Form: Refer to the General Submission Instructions, Section III.A.6, for detailed information.

R & R Subaward Budget Attachment(s) Form (if applicable): Refer to the General Submission Instructions, Section III.A.7, for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Submission Instructions, Section III.A, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the proposal/application verification period. If these components are missing, upload them to eBRAP before the end of the proposal/ application verification period.

Intramural DoD Collaborator(s): Complete the DoD Military Budget Form and upload to Grants.gov attachment form as Attachment 12. (Refer to the General Submission Instructions, Section III.A, for detailed information.) Intramural DoD Collaborator(s) costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs.

NOTE: Proposals/Applications from **Federal agencies** must include a **Federal Financial Plan** in their budget justifications. Proposals/Applications from organizations that include **collaborations with DoD Military Facilities** must comply with special requirements. Refer to the General Submission Instructions, Section III.A.5, Research & Related Budget, for detailed information.

II.D.3. Dun and Bradstreet Data Universal Numbering System (DUNS) and System for Award Management (SAM)

Applicant organizations and all subrecipient organizations must have a DUNS number to submit proposals/applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an "Active" status to submit proposals/ applications through the Grants.gov portal. Verify the status of the applicant's organization's Entity registration in SAM well in advance of the proposal/application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant. Refer to the General Submission Instructions, Section III, for further information regarding Grants.gov requirements.

II.D.4. Submission Dates and Times

All submission dates and times are indicated on the Section I, Overview of the Funding Opportunity of this BAA. Pre-proposal/Pre-application and proposal/application submissions are required. The pre-proposal/pre-application and proposal/application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

Applicant Verification of Full Proposal/Application Submission in eBRAP

Following retrieval and processing of the full proposal/application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full proposal/application submission. eBRAP will validate retrieved files against the specific BAA requirements, and discrepancies will be noted in both the email and in the "Full Application Files" tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all proposal/application components and ensure proper ordering as specified in the BAA. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full proposal/application package must be submitted prior to the proposal/application submission deadline.*** The Project Narrative and Budget Form cannot be changed after the proposal/application submission deadline.

The full proposal/application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the proposal/application verification period. During the proposal/ application verification period, the full proposal/application package, ***with the exception of the Project Narrative and Budget Form***, may be modified.

For All Submissions: Verify that subaward budget(s) with budget justification are present in eBRAP during the proposal/application verification period. If these components are missing, upload them to eBRAP before the end of the proposal/application verification period.

II.D.5. Intergovernmental Review

This BAA is not subject to Executive Order (EO) 12372, "Intergovernmental Review of Federal Programs." The EO provides for state and local government coordination and review of proposed Federal financial assistance and direct Federal development. The EO allows each state to designate an entity to perform this function. This coordination and review is not required under this BAA.

II.D.6. Funding Restrictions

NOTE: Proposals/Applications received in response to both the JPC-1/MSIS TRIAGE Award extramural and intramural BAAs will be evaluated and considered for funding together. The Government reserves the right to fund any combination of extramural and/or intramural proposals/applications.

The JPC-1/MSIS expects to allot approximately **$2.6M** of the FY18 PH/TBIRP appropriation to fund up to two TRIAGE Award proposals/applications, depending on the quality and number of proposals/applications received from extramural organizations and intramural organizations. Funding of proposals/applications received in response to this BAA is contingent upon the availability of Federal funds for this program. The funding estimated for this BAA is approximate and subject to realignment.

- The maximum period of performance is **18 months**, which includes the testing and evaluation of the proof-of-concept and the results from the test and evaluation.

- The anticipated total costs (direct and indirect) budgeted for the entire period of performance will not exceed **$1.3M**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **$1.3M** total costs or using an indirect rate exceeding the organization's negotiated rate.

- All direct and indirect costs of any subaward, contract, or subcontract must be included in the total direct costs of the primary award.

- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **18 months**.

For this award mechanism, direct costs must be requested for:

- Travel costs for the PI to attend an In-Progress Review (IPR) meeting anticipated to be held near the end of 1-year anniversary of the award at a Government location (to be determined). For planning purposes, it should be assumed that a 1-day IPR meeting will be held in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings. All planned travel during the period of performance must be itemized by trip, in the full proposal/application.

May be requested for (not all-inclusive):

- Salary

- Research-related subject costs

- Support for multidisciplinary collaborations

- Equipment

- Research supplies

- Travel between collaborating institutions, including travel to military/Government facilities

- Travel costs for up to two investigators to attend two scientific/technical meetings in addition to the required IPR meeting described above

Refer to the General Submission Instructions, Section III.A.5, for budget regulations and instructions for the Research & Related Budget. ***For Federal agencies or organizations collaborating with Federal organizations, budget restrictions apply as are noted in Section III.A.5 of the General Submission Instructions***.

Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. The time is considered when establishing the award's period of performance. It is anticipated that awards made from this funding opportunity will be funded with FY18 funds, which will expire for use on September 30, 2024.

II.D.7. Other Submission Requirements

Refer to the General Submission Instructions, Appendix 4, for detailed formatting guidelines.

II.E. PROPOSAL/APPLICATION REVIEW INFORMATION

II.E.1. Criteria

II.E.1.a. Peer Review

Peer Review: To determine technical merit, all proposals/applications will be evaluated according to the following scored criteria, which are listed in decreasing order of importance:

- **Theoretical Rationale and Scientific Methods**
    - How well the study aims, hypotheses or objectives, experimental design, methods, and analyses are designed to clearly answer the research questions.
    - To what degree the research approach for accomplishing the specific aims is feasible, will accomplish the objectives, will provide information on proposed methods and analysis/evaluation strategies, and is based on sound rationale.
    - How well the study aims, hypotheses or objectives, experimental design, methods, and analyses are designed to clearly answer the research questions.
    - How well the proposed methodologies, evaluation strategy, type of recruits, recruitment numbers, anticipated dropout rate, assessment criteria, inter-rater reliability, intended medical domain(s) (or discipline[s]), control groups, statistical protocols, etc., to support the pilot study are presented and align with the proposed study outcomes.
    - Whether there is evidence of an adequate contingency plan, such as a risk mitigation plan, to resolve potential delays.
    - Whether the proposed timeline is appropriate and tasks outlined in the proposal/ application are logical in their progression.
    - To what degree the references cited within the proposal/application support the background, the proposed methodologies, and/or the proposed pilot study methodologies.
- **Relevance, Significance, Innovation, and Impact**
    - Whether the proposed work is innovative, including whether the proposed research is duplicative of existing research.
    - To what degree the proposed research is relevant to delivering a proof-of-concept interoperable component for increasing medical provider performance in high-stress medical care scenarios.

- To what degree the anticipated short- and long-term outcomes resulting from the proposed study will contribute to the goal of improving the downstream effects of medical care; whether beneficial to the patient (e.g., improved patient safety, improved patient outcomes, improved patient quality of life), detrimental, or neutral (i.e., no difference) will be analyzed and recorded.

- **Open Source/License/Architecture**

  - To what degree the proposed task performance assessment tool incorporates open source/license/architecture and intellectual property components available for license. Evaluate where in the proof-of-concept or the design the respective proprietary or open source/architecture components are located.

- **Personnel and Facilities**

  - How the composition and balance of the research team (including other organization personnel, subawardees, and consultants, as applicable) are appropriate. Whether MHS medical providers and facilities are included as collaborators and, if not, how the proposed personnel and facilities might compare to MHS medical providers and facilities.

  - To what degree the PI's and research team's backgrounds and expertise are appropriate and complementary to accomplishing the proposed work.

  - To what degree the levels of effort by the PI and other key personnel are appropriate to ensuring the success of proposed research.

  - To what degree the research environment and the accessibility of institutional resources support the proposed study (including collaborative arrangements).

  - Whether there is evidence for appropriate institutional commitment.

In addition, the following unscored criteria will also contribute to the overall evaluation of the proposal/application:

- **Budget**

  - Whether the budget is appropriate for the proposed research and within the limitations of this BAA.

  - How well the budget aligns with the proposed timeline and overall deliverables.

- **Intellectual Property and Transition Plan**

  - If applicable, to what degree the intellectual property plan is appropriate.

  - If applicable, to what degree the transition plan is appropriate.

- **Proposal/Application Presentation**
    - To what extent the writing, clarity, and presentation of the proposal/application components influence the review.

II.E.1.b. Programmatic Review

To make funding recommendations and select the proposal(s)/application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

- **Ratings and evaluations of the peer reviewers**
- **Open source/license/architecture**
    - Whether the proposal/application identifies the anticipated Government rights of the proposed interoperable component
    - To what degree the intellectual property components may limit future flexibility or adaptation of the tool to meet future Government needs
    - Degree of public accessibility of outcomes
- **Relevance to the mission of the DHP, PH/TBIRP, and JPC-1/MSIS as evidenced by the following:**
    - Adherence to the intent of the award mechanism to assess a proof-of-concept TRIAGE model
    - Programmatic relevance and significance
    - Program portfolio balance
    - Relative innovation and impact

II.E.2. Proposal/Application Review and Selection Process

All proposals/applications are evaluated by scientists, and clinicians in a two-tier review process. The first tier is peer review of proposals/applications against established criteria for determining technical merit. Each proposal/application is evaluated for its own merit, independent of other proposals/applications. The second tier is a programmatic review that makes recommendations for funding to the Commanding General, USAMRMC, on behalf of the DHA and the OASD(HA), based on technical merit, the relevance to the mission of the DHP, JPC-1/MSIS, and the PH/TBIRP, the specific intent of the award mechanism, and to other specified evaluation criteria in the BAA. Programmatic review is a comparison-based process in which proposals/applications with scientific and technical merit compete in a common pool. ***The highest-scoring proposals/applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described***

in Section II.E.1.b, Programmatic Review. Additional information about the two-tier process used by the CDMRP can be found at http://cdmrp.army.mil/about/fundingprocess.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement that proposal/application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review and approval process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's proposal/application. Violations by panel members or applicants that compromise the confidentiality of the review and approval process may also result in suspension or debarment from Federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with 18 USC 1905.

II.E.3. Integrity and Performance Information

Prior to making an award where the Federal share is expected to exceed the simplified acquisition threshold (currently $150,000) over the period of performance, the Federal awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (FAPIIS).

An applicant, at its option, may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about itself that a Federal awarding agency previously entered and is currently available in FAPIIS.

The Federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics, and record of performance under Federal awards when determining an organization's qualification prior to award, according to the qualification standards of the DoDGARs or the FAR.

II.E.4. Anticipated Announcement and Federal Award Dates

All proposal/application review dates and times are indicated in Section I, Overview of the Funding Opportunity.

Each PI and organization will receive email notification of posting of the funding recommendation in eBRAP. Each PI will receive a peer review summary statement on the strengths and weaknesses of the proposal/application.

II.F. FEDERAL AWARD ADMINISTRATIVE INFORMATION

II.F.1. Federal Award Notices

Awards will be made no later than September 30, 2019. Refer to the General Submission Instructions, Appendix 2, for additional award administration information.

After email notification of proposal/application review results through eBRAP, and if selected for funding, a representative from the USAMRAA will contact the business official authorized to negotiate on behalf of the PI's organization.

Only an appointed USAMRAA Contracting/Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government should be inferred from discussions with any other individual. The award document signed by the Contracting/Grants Officer is the official authorizing document.

Federal Organizations: Awards to Federal Government organizations will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural collaborators are reminded to coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

After email notification of proposal/application review results through eBRAP, and if selected for funding, a representative from the CDMRP will contact the business official authorized to negotiate on behalf of the PI's organization.

II.F.1.a. PI Changes and Award Transfers

An organizational transfer of an award is discouraged and will be evaluated on a case-by-case basis and only allowed at the discretion of the Contracting/Grants Officer. Refer to the General Submission Instructions, Appendix 2, for general information on changes to applicants and organizational transfers.

Should the PI of a funded project leave the award organization, both the PI and organization must contact the USAMRAA as soon as possible to discuss options for continued support of the research project. Every effort should be made to notify the USAMRAA prior to the PI leaving the organization.

II.F.2. Administrative and National Policy Requirements

In-person IPR presentations will be requested. Applicable requirements in the DoDGARs found in 32 CFR, Chapter 1, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this BAA.

Applicable requirements in the FAR, found in 48 CFR, Chapter 1, DFARS, found in 48 CFR Chapter 2, and AFARS, found in 48 CFR Chapter 51, apply to contracts resulting from this BAA.

Refer to the General Submission Instructions, Appendix 2, for general information regarding administrative requirements.

Refer to the General Submission Instructions, Appendix 5, for general information regarding national policy requirements.

II.F.3. Reporting

Refer to the General Submission Instructions, Appendix 2, Section A, for general information on reporting requirements. ***If there are technical reporting requirement delinquencies for any existing USAMRAA-sponsored awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.***

Quarterly and annual technical progress reports and quad charts will be required.

- Quarterly quad charts including:
    - Objective, measurable, and easily independently verifiable assessment of metrics to measure progress regarding project cost, schedule, performance, risk, and opportunity.
    - Risk and opportunity assessment of project cost, schedule, and performance. Risk assessments will use objective, measurable, and easily independently verifiable metrics; mitigation plans; triggering event; latest potential successful mitigation date; and impacts of unmitigated risks. Opportunity assessments will use objective, measurable and easily independently verifiable metrics; exploitation plans; triggering event; latest potential successful exploitation; and impact of successful opportunity exploitation.
    - Integrated project Gantt chart with all progress to date, supported by the cost, performance, risk, and opportunity assessments.
    - Budget chart with burn rate, demonstrating funding expended against time, funds remaining, and planned expense plan through the rest of the project schedule against planned milestones.
- Quarterly and annual technical reports including the following:
    - Full description of architecture and content of new interoperable component, description of scenarios developed, results and method of pilot study.
    - A report, document, or list of the terminology and respective definitions used for the variables, metrics, and evaluation criteria and how they were deconstructed. It must provide the measuring tools and, if needed, how they were used to obtain the metric/evaluation criteria. Objective measurements are preferred, but subjective measurements that have rigorous reliability, repeatability, and robustness will be considered.
    - Explanation, including definitions and descriptions, of TRIAGE determinants of performance and agility. A report or document with the information and analyzed data of the actual postulated variables, metrics, and evaluation criteria.
    - Analyzed pilot study data and the specific aims, methodologies, sample and sample size, inter-rater reliability, assessment criteria, statistical methods, analyzed results, conclusions, and potential next-step recommendations.

- Completion of preliminary/pilot empirical evaluation of the developed proof-of-concept;
- A description of the components of the proof-of-concept that are proprietary and ones that are open source/open architecture. Explanation of Government rights and/or proposed pricing structure to the Government (if applicable).
- Documentation of the translational parameters and the respective definitions (if applicable).
- Description of the gaps that were uncovered during this research as it pertains to the success or improvement measured and an outline of anticipated next steps or recommendations.

- Yearly IPRs reporting on progress

Awards resulting from this BAA will incorporate additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than $10,000,000 are required to provide information to FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a Federal award. Recipients are required to disclose, semiannually, information about criminal, civil, and administrative proceedings as specified in the applicable Terms and Conditions (see General Submission Instructions, Appendix III.A).

II.G. FEDERAL AWARDING AGENCY CONTACTS

II.G.1. CDMRP Help Desk

Questions related to BAA content or submission requirements as well as questions related to the submission of the pre-proposal/pre-application through eBRAP should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions related to full proposal/application submission through the Grants.gov portal should be directed to the Grants.gov Contact Center, which is available 24 hours a day, 7 days a week (closed on U.S. Federal holidays). Note that the CDMRP Help Desk is unable to provide technical assistance with Grants.gov submission.

Phone: 800-518-4726 (International: 1-606-545-5035)

Email: support@grants.gov

Sign up on Grants.gov for "send me change notification emails" by following the link on the Synopsis page for the BAA or by responding to the prompt provided by Grants.gov when first downloading the submission package. If the submission package is updated or changed, the original version of the submission package may not be accepted by Grants.gov.

II.H. OTHER INFORMATION

II.H.1. Administrative Actions

After receipt of pre-proposals/pre-applications or proposals/applications from Grants.gov, the following administrative actions may occur:

II.H.1.a. Rejection

The following will result in administrative rejection of the pre-proposal/pre-application:

- Pre-Proposal/Pre-Application Narrative exceeds the page limit.
- Pre-Proposal/Pre-Application Narrative is missing.

The following will result in administrative rejection of the proposal/application:

- Submissions from intramural applicants to this BAA will be rejected.
- Submission of a proposal/application for which a letter of invitation was not received.
- Project Narrative exceeds the page limit.
- Project Narrative is missing.
- Budget is missing.
- For proposals/applications including human subjects, the following may result in administrative rejection:
    - Human Subject Recruitment and Safety Procedures (Attachment 8) is missing.

II.H.1.b. Modification

- Pages exceeding the specific limits may be removed prior to review for all documents other than the Pre-Proposal/Pre-Application Narrative and Proposal/Application Project Narrative.
- Documents not requested may be removed.
- Following proposal/application submission to Grants.gov, the PI will receive an email request from eBRAP to review, modify, and verify the proposal/application submitted to Grants.gov. During this verification period, the PI may upload missing documents (excluding those listed above, Section II.H.2.a, Rejection), replace files, and re-categorize files. These modifications must be completed by the end of the proposal/application

verification period; otherwise, the proposal/application will be reviewed as submitted. If either the Project Narrative exceeds the page limit or the Budget form contains only zeros, an updated Grants.gov submission package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID.

II.H.1.c. Withdrawal

The following may result in administrative withdrawal of the pre-proposal/pre-application or proposal/application:

- An FY18 JPC-1 Medical Simulation and Training Steering Committee member is named as being involved in the research proposed or is found to have assisted in the pre-proposal/ pre-application or proposal/application processes including, but not limited to, concept design, proposal/application development, budget preparation, and the development of any supporting documentation. ***A list of the Steering Committee members can be found at: http://cdmrp.army.mil/dmrdp/jpc1msisrp.shtml.***

- The proposal/application fails to conform to this BAA description to the extent that appropriate review cannot be conducted.

- An investigator at an intramural organization is named as a collaborator on a proposal/application submitted through an extramural organization, but the proposal/application does not include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.

- The resultant award is a contract that exceeds $700,000 and the offeror is other than a small business, but the contractor did not submit a subcontracting plan for small business and small disadvantaged business concerns, in accordance with FAR 19.704 and DFARS 219.704.

- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.

- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted proposals/applications. For FY18, the identity of the peer review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess.shtml). The programmatic review is performed by the FY18 JPC-1.MSIS Medical Simulation and Training Technologies Steering Committee. Proposals/Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Government. Refer to the General Submission Instructions, Appendix 3, for detailed information.

- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The invited proposal/application does not propose the same research project as described in the pre-proposal/pre-application.
- The proposal/application budget differs significantly from the budget included in the pre-proposal/pre-application.
- Proposals/Applications proposing research involving a comparison with live tissue training.
- Applications may be administratively withdrawn from further consideration if the applicant cannot demonstrate access to the relevant study population and resources.

II.H.1.d. Withhold

Proposals/Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization will be required to provide the findings of the investigation to the USAMRAA Contracting or Grants Officer for a determination of the final disposition of the proposal/application.

II.I. PROPOSAL/APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Upload Order	Action	Completed
SF424 (R&R) Application for Federal Assistance		Complete form as instructed.	
Attachments Form	1	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	2	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	3	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	4	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	5	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	6	Impact/Outcomes Statement: Upload as Attachment 6 with file name "Impact.pdf."	
	7	Innovation Statement: Upload as Attachment 7 with file name "Innovation.pdf."	
	8	Human Subject Recruitment and Safety Procedures: Upload as Attachment 8 with file name "HumSubProc.pdf" (if applicable; required for all studies recruiting human subjects).	
	9	Data Management: Upload as Attachment 9 with file name "DataManage.pdf" (if applicable; required for all studies recruiting human subjects).	
	10	Post-Award Project Transition Plan: Upload as Attachment 10 with file name "Transition.pdf."	
	11	Representations: Upload as Attachment 11 with file name "MandatoryReps.pdf."	
	12	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 12 with file name "MFBudget.pdf," if applicable.	
Research & Related Senior/Key Person Profile (Expanded)		Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
		Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
		Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
		Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.	

Grants.gov Application Components	Upload Order	Action	Completed
Research & Related Budget		Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form		Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form		Complete form as instructed.	

APPENDIX I: ACRONYMS AND ABBREVIATIONS

ACOS/R&D	Associate Chief of Staff for Research and Development
BAA	Broad Agency Announcement
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CICA	Competition in Contracting Act
COI	Conflict of Interest
DFARS	Defense Federal Acquisition Regulation Supplement
DHA	Defense Health Agency
DHP	Defense Health Program
DoD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
DUNS	Data Universal Numbering System
eBRAP	Electronic Biomedical Research Application Portal
EC	Ethics Committee
EO	Executive Order
ET	Eastern Time
EXORD	Executive Order
FAD	Funding Authorization Document
FAPIIS	Federal Awardee Performance and Integrity Information System
FAR	Federal Acquisition Regulation
FDA	U.S. Food and Drug Administration
FFRDC	Federally Funded Research and Development Center
FY	Fiscal Year
HIT	Health Information Technology
HQDA	Headquarters, Department of the Army
HRPO	Human Research Protection Office
IPR	Interim Progress Review
IRB	Institutional Review Board
JPC-1	Joint Program Committee 1
LAR	Legally Authorized Representative
M	Million
Med Sim	Medical Simulation
MHS	Military Health System
MIPR	Military Interdepartmental Purchase Request

MSIS	Medical Simulation and Information Sciences
MSISRP	Medical Simulation and Information Sciences Research Program
NPC	Non-Profit Corporation
OASD(HA)	Office of the Assistant Secretary of Defense for Health Affairs
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PAR	Patient at Risk
PH	Psychological Health
PH/TBIRP	Psychological Health/Traumatic Brain Injury Research Program
PI	Principal Investigator
PTSD	Post-Traumatic Stress Disorder
RDT&E	Research, Development, Test, and Evaluation
SAM	System for Award Management
SET	Stress Exposure Training
SIT	Stress Inoculation Training
SMT	Stress Management Training
SOW	Statement of Work
STEM	Science, Technology, Engineering, and Mathematics
STRIVE	Stress Resilience in Virtual Environments
TBI	Traumatic Brain Injury
TRIAGE	Trauma Resiliency Immersive Adaptive Gaming Environment
TRL	Technology Readiness Level
USAMRAA	U.S. Army Medical Research Acquisition Activity
USAMRMC	U.S. Army Medical Research and Materiel Command
USC	United States Code
VA	Department of Veterans Affairs
VRAS	Virtual Reality Adaptive Simulation
WarPREP	Warfighter Preparation, Resilience, Enhancement and Protection