

# **Program Announcement**

**for the**

**Department of Defense**

**Defense Health Program**

**Congressionally Directed Medical Research Programs**

**Defense Medical Research and Development Program**

## **Joint Program Committee 1 (JPC-1) – Medical Simulation and Information Sciences Research Program (MSIS)**

**Translational Simulation Research (TRANSfeR) Award**

**Funding Opportunity Number: W81XWH-16-DMRDP-MSIS-TRA**

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

### **SUBMISSION AND REVIEW DATES AND TIMES**

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), October 13, 2016
- **Invitation to Submit an Application:** November 22, 2016
- **Application Submission Deadline:** 5:00 p.m. ET, February 2, 2017
- **End of Application Verification Period:** 5:00 p.m. ET, February 8, 2017
- **Peer Review:** April 2017
- **Programmatic Review:** May 2017

*This Program Announcement/Funding Opportunity is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.*

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## **I. FUNDING OPPORTUNITY DESCRIPTION**

### **A. Program Description**

Applications to the Fiscal Year 2017 (FY17) Joint Program Committee-1 (JPC-1)/Medical Simulation and Information Sciences (MSIS) Research Program are being solicited for the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) 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 RDA Directorate 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 Defense Medical Research and Development Program (DMRDP) management support for DHP core research program areas, including the JPC-1/MSIS. This Program Announcement/Funding Opportunity and subsequent awards will be managed by CDMRP with strategic oversight from the JPC-1/MSIS.

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

The mission of the JPC-1/MSIS is to explore the implications of models and technology for medical education and training plus 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 two areas of research. One area is focused on improving military medical training through medical modeling, simulation, and educational training tools. The second area is focused on improving the use and sharing of health-related data for better strategic planning, process development, and software applications.

### **B. Medical Readiness Initiative (MRI): Translational Simulation Research (TRANSfeR): Medical Simulation Modeling to Assess Translation Skills from Training to Clinical Practice**

The Translational Simulation Research (TRANSfeR): Medical Simulation Modeling to Assess Translation Skills from Training to Clinical Practice is a line of research that supports the Medical Readiness Initiative (MRI) under the JPC-1/MSIS Medical Simulation and Training portfolio. The JPC-1/MSIS MRI focuses on the research and development (R&D) of medical training methods, technologies, systems, and competency assessment tools for the attainment and sustainment of military medical readiness R&D efforts. MRI also includes methodologies, techniques, and tools that will allow for ethical, accurate, and appropriate pre-intervention rehearsal with input of potential authorized personal medical information into simulation models. Evidence-based efforts with measurable outcomes and reliable assessments also fall under the MRI. The outcomes of the research are intended to be used to support the solution assessments/material considerations for guidelines or curriculum development of TRANSfeR foundation concepts. The research outcomes will be used in assessing critical technology

elements and technology maturity, system integration risk, future manufacturing feasibility, and, where necessary, technology maturation and demonstration needs.

## Background

The training of the U.S. Military medical personnel using simulation methods has increased as technology improvements have made simulators more sophisticated, precise, and cost-effective. Medical simulation has established a research record over the last 40 years showing that simulation-based learning is an effective tool in medical training and education. However, most of these studies have focused on success under simulated conditions and not on patient outcomes in the real clinical world. As medical simulators have become more commonly accepted as training devices in schools and hospitals, it is very important to determine the benefit that simulation-based training has on direct patient care and, where appropriate, within the Military Health System (MHS) populations. The downstream effect that training has on the health and well-being of Service members and the Armed Forces is the most important outcome that can be measured in any medical training system.

According to Cook et al., even though many simulation training studies can be found in the literature, the ability to determine the effectiveness of such training is limited due to the difficulty in comparing these studies with similar studies; study limitations have proven to be many, thus rendering many of the systematic reviews inconclusive.<sup>1,2</sup> However, the common theme of these studies is simulation training which is significantly associated with improved learning outcomes.

According to McGaghie et al., there are several outcomes that can be measured in simulation-based training. McGaghie draws on parallels to clinical science in which translational research is emphasized.<sup>3,4</sup> Translational research aims to take the advances made in the laboratory and rapidly move them to the bedside to positively impact patient outcomes. In translational science, outcomes are based on three levels: T1, T2, and T3. T1 outcomes are those variables that can be measured in the simulation laboratory or under simulated clinical conditions. Research outcomes such as enhanced skill before and after a simulated training session fall into the T1 category. Many successful T1 studies have been conducted and reported.<sup>5</sup>

T2 research should generate outcome data that show clinical effectiveness at the level of the patient. T2 simulation outcomes are variables that can be measured in patients, such as operating time, adherence to treatment guidelines, and patient complications. The goal in T2 research is to inform healthcare providers on how to deliver better patient care delivery practices (e.g.,

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<sup>1</sup> Cook DA, Hatala R, Brydges R, Zendejas B, Szostek JH, Wang AT, Erwin PJ, and Hamstra SJ. 2011. Technology-enhanced simulation for health professions education: A systematic review and meta-analysis. *JAMA* 306(9):978-988.

<sup>2</sup> Barsuck JH, Cohen ER, and Feinglass J. 2009. Use of simulation based education to reduce catheter related bloodstream infections. *Arch Intern Med* 169(15):1420-1423.

<sup>3</sup> McGaghie WC, Draycott TJ, and Dunn WF. 2011. Evaluating the impact of simulation on translational patient outcomes. *Simul Healthc* August; 6 Suppl:S42-S47.

<sup>4</sup> McGaghie WC, Issenberg SB, Barsuk JH, and Wayne DB. 2014. A critical review of simulation-based mastery learning with translational outcomes. *Med Educ* 48(4):375-385.

<sup>5</sup> Anderson LW. 1975. [Major Assumptions of Mastery Learning](#). Annual Meeting of the Southeast Psychological Association.

emergency skills, obstetrical skills, surgical skills, airway skills, communication skills and decision making skills).

The purpose of T3 research is to generate outcomes that improve public health and health care delivery systems such as faster surgical recovery times, less bleeding, lower infection rates, lower procedure complication rates, less handover errors, lower re-admission rates, improved population health measures, just to name a few.

Some successful T2 and T3 studies have been reported. For example, Barsuk et al. conducted simulation-based training studies that measured T1, T2, and T3 outcomes in central line training.<sup>6</sup> Using simulation training, Barsuk showed improvement in central line catheter placement techniques (T1 outcomes) among physicians trained in the simulation laboratory. Extending his research, he showed that rates of patient complications, infections, and time to placement all decreased in the real clinical world after the introduction of simulation-based training as compared with controls (T2 outcomes). The research also revealed that overall rates of infection in all catheter placements improved with practice and mastery of catheter placement skills after simulation training and re-training (T3 outcomes).<sup>7</sup>

More T2 and T3 studies are needed that demonstrate success in combat casualty and garrison medical care; specifically, research is needed on topics relevant to the MHS to validate the effectiveness of simulation-based training. Award recipient(s) are expected to use valid approaches to determine the best metrics and evaluation criteria that can objectively assess translation of skill for T2 and T3 research.

The following are examples of outcomes that are directly related to translational research in simulation training:

- Time to procedure completion in the clinical world
- Skill in the operating room or field hospital
- Adherence to guidelines
- Complication rates of a procedure in real patients (i.e., during or post-intervention complications, re-admission rates, etc.)

### **C. Award Information**

The FY17 JPC-1/MSIS TRANSfeR Award Program Announcement/Funding Opportunity is seeking research to determine whether the medical skill learned on a simulation system has a downstream beneficial effect to patients and/or the MHS in the real clinical world.

The Program Announcement/Funding Opportunity seeks applications for research to demonstrate that simulation-based medical training has a measurable outcome on patient care. Previous T1 studies have shown improvement in skills in the simulated environment when deliberate practice and mastery learning (a set of group-based, individualized, learning strategies

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<sup>6</sup> Barsuck, 2009, *op cit.*

<sup>7</sup> Cohen ER, Feinglass J, and Barsuk JH. 2010. Cost savings from reduced catheter related bloodstream infections after simulation based education for residents in a medical intensive care unit. *Simulation in Healthcare* 5: 98-102.

based on the belief that students will achieve a high level of understanding in a given area when given enough time)<sup>8</sup> occur as part of training. The next set of studies should measure whether these same techniques translate to patient care and affect systems of care such as return-to-duty rates and morbidity and mortality statistics. Such research will involve taking the lessons learned in the laboratory and measuring outcomes in the patients who are cared for either in an operational environment or medical treatment facility. Historical patient outcome data does exist for the way medical professionals are trained now, so the variable being introduced in new studies would be simulation-based training.

The application should propose work to develop a model(s) that can measure translational outcomes as a result of a simulation-based program in the following areas:

- Adverse outcomes, for example, near-misses, harms, morbidity and mortality
- Return-to-duty rates
- Task and cognitive workload as it affects clinical performance
- Improved supervisor satisfaction as reflected in subordinate performance
- Improved team environment (i.e., inter-professional environments) as reflected in improved team task performance
- Time to completion (without sacrificing bulleted items listed immediately above) of time-sensitive clinical tasks

Efforts should be made, as feasible, to control for variables that could influence translational outcome (e.g., policy changes, technology upgrades, changes in medical education methodologies). Note that measuring effects only due to simulation training will be difficult to measure, and thus a strong study design is expected.

Simulation-based T2 and T3 studies do not need to be limited to medical procedures. The ability for the trainee to communicate effectively with patients, enroute care members, and hospital teams are skills that can be practiced in simulation and evaluated in the real clinical world for simulation training effectiveness.

Valid diagnostic reasoning is necessary for the proper management of patients and it can be measured as an outcome in patient care. Finally, effective outcomes such as trainee cognitive load and burnout, which are critical to long-term success in medical care, can also be measured in the real clinical world. All of these outcomes can be subjected to rigorous research using simulation-based training as an independent variable and clinician and/or patient outcomes as a dependent variable.

It is anticipated that applicants will incorporate the following in both the pre-applications and, in more detail, in the full applications (full application submissions are by invitation only). The items listed below are not in rank order:

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<sup>8</sup> *Ibid.*

- Studies should provide empirical definitions to the metrics and evaluation criteria that will be objectively or subjectively collected (i.e., infection rate, patient satisfaction, incorrect diagnosis, re-admission rates, etc.), and provide the measurement tools used;
  - In addition to measurements that the Principal Investigator (PI)/Organization wishes to measure, the PI/organization need to provide metrics and respective measurement tools for translational outcomes as a result of a simulation-based program as mentioned
- Studies should use existing commercial simulation training tools to determine the downstream beneficial effect of medical simulation training for T2 and T3.
- This award is not limited to a specific medical domain and all areas of medicine are encouraged to submit (i.e., dental, dermatology, obstetrics, ophthalmology, and surgical fields); however, medical domains that have higher alignment with treatment of traumatic and acute injuries will be factored in the decision.
- Proposed research should collect real patient outcomes data. The goal is not to collect data on how the student/clinician performed the learned skill but how the patient(s) did after the procedure was conducted.
- Studies should develop a model that can measure translational outcomes as a result of a simulation-based program that can be used across the Services.
- It is anticipated that many of these variables, metrics, and evaluation criteria will be applicable across the military, Veterans Health Administration, academic, inpatient, outpatient clinics, rural healthcare settings, private and public hospitals, and international healthcare situations.
- It is anticipated that 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. Public benefits from this research are encouraged.
- It is expected that any downstream patient effects (e.g., safety, outcomes, quality of life), whether beneficial, detrimental, or neutral (i.e., no difference) will be analyzed and recorded in the reports and, eventually, in the final report.

It is anticipated that any proof-of-concept tool (knowledge or materiel tool) resulting from research funded by this Program Announcement/Funding Opportunity will be provided to the military near the end of the award. Instructions on the use of the tool as well as definitions, measuring devices used, range of acceptable metrics/evaluation criteria, and a draft user manual will be provided to the Government.

### **Pilot Study**

While not required, a pilot study lasting a minimum of six (6) months may be conducted for collection of data to confirm proposed variables, metrics, and evaluation criteria that were researched and incorporated into the proof-of-concept measurable outcome of the patient care tool.

Applications that propose a pilot study should include a description of proposed methodologies, conceptual and operational definitions, type and number of subjects, recruitment numbers,

anticipated dropout rate, assessment criteria, generalizability, validity, reliability, intended medical domain(s) control groups, and statistical methods.

The submitter should demonstrate efforts to recruit their sample using National Guard, active military Service members, patients from a Military Treatment Facility, or military medical student / residency programs. A submitter who is granted permission to recruit from these sample populations must provide a Commander's Support Letter, in the event a Full Application is invited. If the submitter is unable to sample from the above populations for the pilot study, a description of the sample chosen and justification of how the sample compares to the military must be provided.

### **Intellectual Property**

While the proposed research may include proprietary tools, appropriate justification for incorporating proprietary tools must be included. Proposed proprietary intellectual property components should be clearly and legibly marked in the full application. The proposed research outcomes are intended to have broad availability not only with the content but also with underlying architecture or models to allow more open communication for now as well as the future. The results from this research are expected to be submitted in a peer-reviewed journal for dissemination.

### **Long-Term Vision**

The anticipated long-term vision includes but is not limited to:

- Incorporation of proposed metrics/evaluation criteria and their respective definitions into future announcements with the intent to integrate and implement commercial simulation systems. Either direct outcomes or modifications to the tools used to measure the proposed metrics/evaluation criteria might also be incorporated in future requests for proposals. It is anticipated that the outcomes of this research, development, and testing could be integrated and incorporated into an assessment tool for translational simulation research in future military and public medical research.
- Possibility of developing a repository of lessons learned in translational simulation research to share with the public and services that can promote higher standards of medical simulation training outcomes.
- Possibility of changing or modifying existing policies and/or military medical training curricula and/or objectives.

### **Anticipated Outcomes**

The anticipated outcomes of research supported by the FY17 JPC-1/MSIS TRANSfeR Award are as follows (not in rank order):

- A validated list of means of support by contacts, references, and sources that endorse the proposed methodologies underpinning the determination of the anticipated variables, metrics, and evaluation criteria for TRANSfeR.

- A report, document, or list of the terminology and respective definitions used for the variables, metrics, and evaluation criteria and how they were deconstructed. 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 TRANSfeR determinants of task performance to better understand how to assess T1-T2-T3 translational skills for specific tasks. Emphasis on T3 is particularly desired.
- A detailed translational medical research model that incorporates task determinants, along with a description of the metrics/evaluation criteria for the model. This should include objective measurements that determine the utility of the model and how the utilization of TRANSfeR pertains to measuring the effectiveness of medical simulation training for specific tasks and how they are transitioned to patient outcomes in the real clinical world.
- A report or document with the information and analyzed data of the actual postulated variables, metrics, and evaluation criteria that best fit the meaning of translation from medical task training to practicing medicine on a patient.
- 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 translation medical research assessment model that incorporates how utilization of TRANSfeR pertains to measuring the effectiveness of medical simulation training for specific tasks.
- A description of the components of the proof of concept that are proprietary and ones that are Open Source/Open Architecture. Explain 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 to create an improved translational assessment model that assesses T1-T2-T3 translation effects. Emphasis on T3 is particularly desired;
- A set of draft instructions for the developed proof of concept.

For the purpose of this announcement, the anticipated Technology Readiness Level (TRL) desired by the end of the research should constitute evidence that the proof-of-concept model may 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 lab type environment. Preliminary interface should be created. This will constitute the definition of a TRL 5 for the remainder of this announcement.

### **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), in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) of record. 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.*** Refer to the General Application Instructions, Appendix 6, 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.

Principal Investigators (PIs) 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, or laboratory animals until applicable regulatory documents are approved by the USAMRMC to ensure that DoD regulations have been met.

**Research Involving Animals:** All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRMC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is not required. Specific documents relating to the use of animals in the proposed research will be requested if the application is selected for funding. The ACURO must review and approve all animal use prior to the start of working with animals, including amendments to ongoing projects. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled “Research Involving Animals.” Allow at least 2 to 3 months for ACURO regulatory review and approval processes for animal studies. Refer to General Application Instructions, Appendix 6, for additional information.

The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement/Funding Opportunity 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 Application Instructions, Appendix 4, Section K.

### **D. Eligibility Information**

***This Program Announcement/Funding Opportunity is intended for extramural investigators only. There is a separate Program Announcement/Funding Opportunity for intramural investigators applying through intramural organizations that is available through the electronic Biomedical Research Application Portal (eBRAP) (<https://eBRAP.org/>) under the funding opportunity number W81XWH-16-DMRDP-MSIS-TRA.***

- Independent investigators at all academic levels (or equivalent) are eligible to submit applications.

- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or medical treatment facility, or working in a DoD activity embedded within a civilian medical center. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.

## **E. Funding**

***The JPC-1/MSIS expects to allot approximately \$1.8 million (M) of the anticipated FY17 DHP RDT&E appropriation to fund one JPC-1/MSIS-TRANSfeR application, depending on the quality and number of applications received from intramural agencies and extramural organizations. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program. As of the release date of this Program Announcement/Funding Opportunity, the FY17 Defense Appropriations Bill has not been passed and there is no guarantee that any funds will be made available to support this program. The funding estimated for this Program Announcement/Funding Opportunity is approximate and subject to realignment.***

***NOTE: Applications received in response to both the JPC-1/MSIS TRANSfeR intramural and extramural program announcements will be evaluated and considered for funding together. The Government reserves the right to fund any combination of intramural and/or extramural applications.***

- The maximum period of performance is 2 years, 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 **\$1.8M**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$1.8M** total costs or using an indirect rate exceeding the organization's negotiated rate.
- All direct and indirect costs of any subaward (subgrant 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 2 years.

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

- Travel costs for the PI(s) 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.

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 2 investigators to attend 2 scientific/technical meetings per year in addition to the required IPR meeting described above.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural (DoD) agencies and other Federal agencies may be managed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR]; Funding Authorization Document [FAD] process; or DD Form 1144 (Support Agreement)). Direct transfer of funds from the recipient to a DoD agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.4., for budget regulations and instructions for the Research & Related Budget. ***For Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in Section II.C.4. of the General Application Instructions.***

## II. SUBMISSION INFORMATION

Submission is a two-step process requiring both (1) pre-application submission through the electronic Biomedical Research Application Portal (eBRAP) (<https://eBRAP.org/>) and (2) application submission through Grants.gov (<http://www.grants.gov/>). Refer to the General Application Instructions, Section II.A., for registration and submission requirements for eBRAP and Grants.gov.

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration and a Data Universal Numbering System (DUNS) number. Refer to Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements. eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications

and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance. A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the Grants.gov application submissions associated with them. eBRAP will validate Grants.gov application files against the specific Program Announcement/Funding Opportunity 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 application components for accuracy as well as ensure proper ordering as specified in this Program Announcement/Funding Opportunity.

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

Application viewing, modification, and verification in eBRAP is strongly recommended, but not required. ***The Project Narrative and Budget cannot be changed after the application submission deadline.*** Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the [application verification period](#). After the end of the application verification period, the full application cannot be modified.

#### **A. Where to Obtain the Grants.gov Application Package**

To obtain the complete Grants.gov application package, including all required forms, perform a basic search using the Funding Opportunity Number **W81XWH-16-DMRDP-MSIS-TRA** in Grants.gov (<http://www.grants.gov/>)

#### **B. Pre-Application Submission and Content**

***The pre-application process should be started early to avoid missing deadlines. There are no grace periods. During the pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed during the application process on Grants.gov.***

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

PIs and organizations identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at [help@eBRAP.org](mailto:help@eBRAP.org) or 301-682-5507.

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

- **Tab 1 – Application Information**
  - Enter the information as described in eBRAP before continuing the pre-application.
- **Tab 2 –Application Contacts**
  - Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (or equivalent). This is the individual listed as “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF424 (R&R) form. The Business Official must either be selected from the eBRAP list or invited in order for the pre-application to be submitted.
  - If the organization’s Business Official is not in eBRAP, an invitation to the Business Official to register in eBRAP must be sent. In addition, it is recommended that the PI identify an Alternate Submitter in the event that assistance with the pre-application submission is needed.
  - 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 either be selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.
- **Tab 3 – Collaborators and Key Personnel**
  - Enter the name, organization, and role of all collaborators and key personnel associated with the application (including co-investigators, mentors, collaborators, consultants, and subrecipients/subawardees).
  - [FY16 JPC-1 Medical Modeling, Simulation, and Training Steering Committee members](#) should not be involved in any pre-application or application including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. For questions related to JPC-1 Medical Modeling, Simulation, and Training Steering Committee members and pre-applications or applications, refer to [Section IV.C., Withdrawal](#), or contact the CDMRP at [help@eBRAP.org](mailto: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 application preparation, research, or other duties for submitted applications. For FY16, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Government. Refer to the General Application 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 application (including those with whom the PI has a personal or professional relationship). Refer to Appendix 1, Section C, of the General Application Instructions, for further information regarding COIs.

- **Tab 5 – Pre-Application Files**

*Note: Upload document(s) 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.*

**Preproposal Narrative (10-page limit):** The Preproposal Narrative page limit applies to text and non-text elements (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 Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

The Preproposal 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.
- **Theoretical Rationale, Scientific Methods, and Research:** 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. Describe how the proposed work and research will support the knowledge research on how to better understand task performance to assess T1-T2-T3 translational skills and the development of a translational medical research model that incorporates task determinants along with a description of the metrics/evaluation criteria for the model.
  - **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.
  - **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-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 TRANSfeR translational medical research model that would appropriately support assessing T1-T2-T3 translational skills. The proposed design needs to address the long-term goals mentioned in this application 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 pilot study concept to demonstrate effectiveness and efficiency of the TRANSfeR proof of concept. 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.
- **Military Impact:** Describe the anticipated short- and/or long-term outcomes of the proposed project and their potential impact on improving healthcare training in the MHS. Explain what the potential of this proposed work is for improving current clinical practices, patient outcomes and decreasing medical errors. Refer to [Section I.A., Program Description](#) for additional information on the anticipated outcomes sought by this Program Announcement/Funding Opportunity.
- **Personnel and Facilities:** Describe the role of the PI, co-PIs (if applicable), key personnel, subawards (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-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application *must be uploaded as individual PDF documents* and are limited to:

- **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal 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). Please include military and civilian research in the review of the literature.

- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
  - **PI and Key Personnel Biographical Sketches (five-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.
- **Tab 6 - Submit Pre-Application**
    - This tab must be completed for the pre-application to be accepted and processed.

## Pre-Application Screening

- **Pre-Application Screening Criteria**

All pre-applications will be screened by the JPC-1 Medical Modeling, Simulation, and Training Steering Committee members to determine technical merit and relevance to the mission of the DHP and JPC-1/MSIS. Pre-applications will be screened based on the following criteria, listed in descending order of importance:

- **Theoretical Rationale, Scientific Methods, and Research:** 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. To what degree the proposed work and research will support the knowledge research on how to better understand task performance to assess T1-T2-T3 translational skills and the development of a translational medical research model. To what degree the research is derived from evidence-based, best-of-class, well-documented, and/or well-adopted designs. To what degree the metrics will measure translational outcomes as a result of a simulation-based program as outlined under Section I.C., Award Information.
- **Significance, Relevance, and Innovation:** To what degree the proposed research is relevant, innovative, and novel, including whether the proposed research is duplicative of existing research. To what degree the proposed research is relevant to the goal of delivering a TRANSfeR proof of concept that aligns to the context of this Program Announcement/Funding Opportunity.
- **Open Source/License/Architecture:** Evaluate 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 TRANSfeR proof-of-concept model. Evaluate the proposed Open Source/Architecture and where these are proposed within the design/plan.

- **Study Design/Plan:** To what degree the methodology proposed of a TRANSfeR proof-of-concept model can be adapted not only into the military but also into public purpose. To what degree the engineering/technical design that will be used to achieve the project goals demonstrates the feasibility of the proposed TRANSfeR proof-of-concept model.
- **Military Impact:** To what degree the project’s anticipated short- and/or long-term outcomes will impact the MHS in a way that is consistent with the intent of the award mechanism.
- **Personnel, Facilities, Timelines, and Budget:** To what degree the expertise, experience, and knowledge of the key research personnel (including co-PIs, if applicable), subawards (if applicable), and consultants (if applicable) are appropriate and complementary for achieving the research goals. Appropriateness of preliminary budget will be evaluated.
- **Notification of Pre-Application Screening Results**

Following the pre-application screening, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated on the [title page](#) of this Program Announcement.

### C. Full Application Submission Content

The application process should be started early on Grants.gov to avoid missing deadlines. There are no grace periods. Verify the status of the applicant’s organization’s Entity registration in the SAM well in advance of the application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. Refer to the General Application Instructions, Section II, for additional information.

*Applications will not be accepted unless the PI has received an invitation to submit.*

*All contributors and administrators to the application must use matching compatible versions of Adobe software when editing and preparing application components. The use of different software versions will result in corruption of the submitted file. See Section II.C. of the General Application Instructions for details on compatible Adobe software.*

*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 application submission must include the completed submissions package of forms and attachments provided in Grants.gov for this Program Announcement. The Grants.gov application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (<http://www.grants.gov/>). Refer to the General Application Instructions, Section II, for submission information.

**Note: The Project Narrative and Budget Form cannot be changed after the application submission deadline.** If either the Project Narrative or the budget fails eBRAP validation or if

the Project Narrative or Budget Form needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID *prior to the application submission deadline*.

The Grants.gov application package must be submitted using the unique eBRAP log number to avoid delays in application processing.

**Grants.gov Application Package Components:** For the **FY17 JPC-1/MSIS TRANSfeR** Program Announcement (**W81XWH-16-DMRDP-MSIS-TRA**), the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

**1. SF424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

**2. Attachments Form**

Each attachment to the Grants.gov application forms must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in Appendix 2 of the General Application Instructions. For all attachments, ensure that the file names are consistent with the guidance. Grants.gov will reject attachments with file names longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire Grants.gov application package may not exceed 200 MB.

- **Attachment 1: Project Narrative (20-page limit): Upload as “ProjectNarrative.pdf.”** The page limit of the Project Narrative applies to text and non-text elements (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 Project Narrative and could confer an unfair competitive advantage is prohibited and will result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

- **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 TRANSfeR proof-of-concept model and identify the data-driven information used to support the proposed TRANSfeR proof-of-concept model. 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 application is part of a larger study, present only tasks this award would fund.
- **Project Design:** Describe and define the experimental design, methods, and analyses/evaluations in sufficient detail for analysis.
  - Identify and describe the hypothesis or research question(s) to be studied and the projected outcome(s) of the proposed research.
  - 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 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.
  - Provide a detailed process, including but not limited to proposed methodology on how the proposed TRANSfeR proof of concept will be tested and evaluated to demonstrate that the concept could support the items listed in this Program Announcement/Funding Opportunity as well as potentially supporting the future needs. Include separate test and evaluation plans applicable for software and hardware approaches.
  - 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 barriers and provide plans for addressing potential delays and unexpected events. Provide a risk management plan to address barriers to plans.
  - Document the availability and accessibility of the study materials (including data) needed as applicable.

- **Project Milestones:** Identify timelines for critical events that must be accomplished in order for the project to be successful in terms of cost, schedule, and performance.
- **Additional Information:** If human and/or animal subjects are included in the research, applications may be submitted without human and/or animal use protocols and institutional approvals. However, protocols with required institutional approvals must be submitted 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 and/or animal 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.

***The following need to be addressed as applicable:***

- For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.
  - Identify cell line(s) and commercial or organizational source(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.
  - 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 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/EC review and approval.
  - For animal studies, allow at least 2 to 3 months for regulatory review and approval by the USAMRMC ACURO; this does not include the additional time required for local IACUC review and approval.
  - Refer to the General Application Instructions, Appendix 6, for additional regulatory information.
- **Attachment 2: Supporting Documentation: Start each document on a new page. Combine and upload as a single file named “Support.pdf.”** If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no page limits for any of these components unless otherwise noted. Include only those components described below; items not requested will be removed and may result in administrative withdrawal of the application.***
    - **References Cited (five citation limit):** 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 request and any additional resources proposed for acquisition at no cost to the Government. Indicate if a Government-owned facility is proposed for use. Reference should be made to the original or present award under which the facilities or resources are now accountable. There is no form for this information.
- **Publications and/or Patent Abstracts (five-document limit):** Include 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. A letter for each organization involved in the project should be provided.
- **Letters of Collaboration:** Provide letter(s) supporting stated collaborative efforts necessary for the project's success, even if provided at no cost. *If the project involves collaboration with a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center), special requirements apply.* A collaborating DoD researcher must include a letter from his/her commanding officer or Military Facility director authorizing his/her participation in the research project.
- **Intellectual Property:**
  - 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 project, 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;
    - Identify the cost to the Federal government for use or license of such property if applicable; or
    - Provide a statement that no property meeting this definition will be used on this project.
  - Intellectual and Material Property Plan (if applicable): If applicable, provide a plan for resolving intellectual and material property issues among participating organizations.

- **Data and Research Resources Sharing Plan:** Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 4, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.
- **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.

  - **Background:** Provide a brief statement of the ideas and theoretical reasoning behind the proposed work.
  - **Objective/Hypothesis:** State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
  - **Specific Aims/Milestones:** State concisely the specific aims/milestones of the project.
  - **Project Design:** Briefly describe the project design.
  - **Impact:** Provide a brief statement explaining the potential impact of the proposed work to advancing the standard of care for injured Service members and/or the general public.
- **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 following outline. *Do not duplicate the technical abstract.*

  - Describe the objectives and rationale for the application in a manner that will be readily understood by readers without a background in science or medicine.
  - Describe the ultimate applicability and potential 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?
- **Attachment 5: Statement of Work (SOW) (two-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 FY17 JPC-1/MSIS TRANSfeR Award mechanism, use the SOW format example titled “SOW Generic Format” or “SOW for Clinical Research (Including Trials, Special Populations).” The SOW must be in PDF format prior to attaching. Refer to the General Application Instructions, Section II.C.2., for detailed guidance on creating the SOW.

- **Attachment 6: Outcomes and Impact Statement (one-page limit): Upload as “Impact.pdf.”** Explain in detail why the proposed research project is important, as follows:
  - **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. Describe the product that the project will lead toward transforming training and education and explain how.
  - **Military Relevance:** Clearly articulate how the proposed project or product meets the needs of injured Service members and either allows them to return to duty or resume a fully active lifestyle.
  - **Public Purpose:** 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 (no page limit): Upload as “HumSubProc.pdf.”** The Human Subject Recruitment and Safety Procedures attachment should include the components listed below.
  - a. **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 Application Instructions, Appendix 6, for more information.*

- b. 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 and the standard of care for that patient population. 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.

- c. Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, 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.
- d. 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 trial.
- 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 administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia, brain injury, stress/life situations, or human subject age), 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 Application Instructions, Appendix 6, 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. PIs should consult with their local IRB/EC to identify the conditions necessary for obtaining assent.
- e. 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 and the diagnostic criteria for entry. Please 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.
- f. 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, 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 and must be addressed in Attachment 8d.*
- **Attachment 9: Data Management (no page limit): Upload as “DataManage.pdf.”** The Data Management attachment should include the components listed below.

**Data Management:** 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.

- The planned indication for the product label and an outline of the development plan required to support that indication.
- The anticipated regulatory strategy (e.g., additional nonclinical or clinical studies anticipated/required, FDA or regulatory authority meetings desired, industry partnerships) for movement of the research into later phases of development and to support a potential marketing application (e.g., New Drug Application, Biologics License Application, Premarket Approval Application, 510(k)).
- 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: Collaborating DoD Military Facility Budget Form(s), if applicable:** Upload as “MFBudget.pdf.” If a Military Facility (MHS facility, research laboratory, 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 Collaborating 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 Application Instructions, Section II.C.7., for detailed information.

**3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.3., 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.
- PI Previous/Current/Pending Support (three-page limit 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 (three -page limit each): Upload as “Support\_LastName.pdf.”
- 4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C.4., 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.

***NOTE: For all Federal agencies or organizations collaborating with Military Facilities, special restrictions apply to the budget and are described below.***

- **For Federal Agencies:** Applications from **Federal agencies** must include in their budget justifications a **Federal Financial Plan (Plan)**. The Plan must address how all funds will be obligated before their period for obligation expires, and how funds will be available to cover research costs over the entire award period. The Plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years.
  - **For Collaborating Military Facilities:** Applications from organizations that include **collaborations with DoD Military Facilities** (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) must submit Collaborating DoD Military Facility Budget Form(s) as instructed in Attachment 11.
- 5. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.5., for detailed information.
- 6. R & R Subaward Budget Attachment(s) Form, if applicable:** Refer to the General Application Instructions, Section II.C.6., for detailed information.

Collaborating DoD Military Facilities Form: A Military Facility collaborating in the performance of the project should be treated as a subaward for budget purposes. However, do not complete the Grants.gov R & R Subaward Budget Attachment Form; instead, complete the Collaborating DoD Military Facility Budget Form (use Attachment 11, Collaborating DoD Military Facility Budget Form) to show all direct and indirect costs. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section II.C.7., for detailed information

#### **D. Applicant Verification of Grants.gov Submission in eBRAP**

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of an application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify

the Grants.gov application submission. eBRAP will validate retrieved files against the specific Program Announcement 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 application components and ensure proper ordering as specified in the Program Announcement. ***If either the Project Narrative or the budget fails eBRAP validation, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID prior to the application submission deadline.*** The Project Narrative and Budget Form cannot be changed after the application submission deadline.

#### **E. Submission Dates and Times**

All submission dates and times are indicated on the [title page](#) of this Program Announcement/Funding Opportunity. Pre-application and application submissions are required. Failure to meet either of these deadlines will result in submission rejection.

#### **F. Other Submission Requirements**

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All extramural applications must be submitted through Grants.gov. Applicant organizations and all subrecipient organizations must have a DUNS number to submit 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 applications through the Grants.gov portal. Refer to the General Application Instructions, Section II.A., for information on Grants.gov registration requirements.

### **III. APPLICATION REVIEW AND SELECTION INFORMATION**

#### **A. Application Review and Selection Process**

All applications are evaluated by scientists, clinicians, and consumers, using a two-tier review process. The first tier is a peer review of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding to the DHA RDA Directorate and the OASD(HA), based on technical merit, the relevance to the mission of the DHP and JPC-1/MSIS, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement/Funding Opportunity. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in [Section III.B.2., 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 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 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 application. Violations by panel members or applicants that compromise the confidentiality of the review 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 Title 18 United States Code 1905.

## **B. Application Review Process**

**1. Peer Review:** To determine technical merit, all 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.
  - To what degree the proposed work and research is derived to create and produce effective metrics and evaluation criteria that will objectively produce a T1-T2-T3 translational model that will effectively measure medical simulation training from training to clinical practice. To what degree the measurements of a simulation-based program are considered.
  - 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. To what degree the recruited population either has military personnel or has a population that aligns with military personnel skill sets and responsibilities.
  - 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 application are logical in their progression.
  - To what degree the references cited within the application support the background, the proposed methodologies, and/or the proposed pilot study methodologies.
  - Whether the medical specialty (domain) aligns with the treatment of traumatic and acute injuries.

- **Relevance, Significance, Innovation, and Impact**
  - How the proposed research is relevant to the goal of delivering better patient care delivery practices (e.g., emergency skills, obstetrical skills, surgical skills, airway skills, communication skills, and decision making skills) and generating outcomes that improve public health and health care delivery systems such as faster surgical recovery times, less bleeding, lower infection rates, lower procedure complication rates, less handover errors, lower re-admission rates, improved population health measures, just to name a few.
  - How the proposed work is innovative, including whether the proposed research is duplicative of existing research.
  - To what degree the proposed research is relevant of delivering a proof-of-concept integrated assessment tool for translational simulation research in future medical research.
  - To what degree the anticipated short- and long-term outcomes resulting from the proposed study will contribute to the goal of improving military medical downstream effects, and whether benefit 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, subawards, and consultants, as applicable) are appropriate.
  - 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 application:

- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.

- Whether the proposed timeline is appropriate; whether tasks outlined in the application are logical in their progression; 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.
  - **Application Presentation**
    - To what extent the writing, clarity, and presentation of the application components influence the review.
- 2. Programmatic Review:** To make funding recommendations, the following criteria are used by programmatic reviewers:
- a. Ratings and evaluations of the peer reviewers**
  - b. Open Source/License/Architecture**
    - The anticipated Government rights of the proposed task performance assessment tool.
    - 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.
  - c. Relevance to the mission of the DHP and JPC-1/MSIS as evidenced by the following:**
    - To what degree the proposed research is relevant to the goal of delivering a proof-of-concept TRANSfeR model as described in this announcement.
    - Adherence to the intent of the award mechanism by delivering a proof-of-concept TRANSfeR model TRL 5 or greater.
    - Programmatic relevance, and significance
    - Program portfolio balance
    - Relative innovation and impact
    - Proposed project timelines

### **C. Recipient Qualification**

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

### **D. Application Review Dates**

All application review dates and times are indicated on the [title page](#) of this Program Announcement.

## **E. Notification of Application Review Results**

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 application.

## **IV. ADMINISTRATIVE ACTIONS**

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

### **A. Rejection**

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

- Pre-Application Narrative exceeds page limit.
- Pre-Application Narrative is missing.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds the page limit.
- Project Narrative is missing.
- Budget is missing.

### **B. Modification**

- Pages exceeding the specific limits may be removed prior to review for all documents other than the Pre-Application Narrative and Project Narrative.
- Documents not requested will be removed.

### **C. Withdrawal**

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

- An FY16 JPC-1/MSIS Medical Modeling, Simulation, and Training Steering Committee member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. *A list of the FY16 JPC-1/MSIS Medical Modeling, Simulation, and Training Steering Committee members can be found at: <http://cdmrp.army.mil/dmrp/jpc1msisrp>.*
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- 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 applications. For FY16, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess>). 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 Application Instructions, Appendix 1, 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 application does not propose the same research project as described in the pre-application.
- The application budget differs significantly from the budget included in the pre-application.
- Pre-Application or application proposes research involving a comparison with live tissue training.

#### **D. Withhold**

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 application.

### **V. AWARD ADMINISTRATION INFORMATION**

#### **A. Award Notice**

Awards will be made no later than September 30, 2018. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

Any assistance instrument awarded under this Program Announcement/Funding Opportunity will be governed by the award terms and conditions, which conform to DoD's implementation of the Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of new awards made after December 26, 2014 may include revisions to reflect DoD implementation of new OMB guidance in the Code of Federal Regulations, Title 2, Part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" (2 CFR part 200).

## **B. Administrative Requirements**

Refer to the General Application Instructions, Appendix 4, for general information regarding administrative requirements.

## **C. National Policy Requirements**

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

## **D. Reporting Requirements**

Refer to the General Application Instructions, Appendix 4, Section H, for general information on reporting requirements.

Quarterly technical progress reports and quad charts will be required. In addition to written progress reports, in-person presentations will be requested.

## **E. 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 Grants Officer. An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

Refer to the General Application Instructions, Appendix 4, Section L, for general information on organization or PI changes.

## **VI. VERSION CODES AND AGENCY CONTACTS**

### **A. Program Announcement/Funding Opportunity and General Application Instructions Version**

Questions related to this Program Announcement/Funding Opportunity should refer to the Program name, the Program Announcement/Funding Opportunity name, and the Program Announcement/Funding Opportunity version code [20160210j]. The Program Announcement/Funding Opportunity numeric version code will match the General Applications Instructions version code [20160210].

### **B. CDMRP Help Desk**

Questions related to Program Announcement content or submission requirements as well as questions related to the submission of the 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. Eastern Time. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: [help@eBRAP.org](mailto:help@eBRAP.org)

### **C. Grants.gov Contact Center**

Questions related to 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](mailto:support@grants.gov)

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

## VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Package Components	Upload Order	Action	Completed
SF424 (R&R) Application for Federal Assistance		Complete 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	Outcomes and Impact 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."	
	9	Data Management: Upload as Attachment 9 with the file name "DataManage.pdf."	
	10	Post-Award Project Transition Plan: Upload as Attachment 10 with the file name "Transition.pdf."	
	11	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 11 with the 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.	
Research & Related Budget		Attach Budget Justification (BudgetJustification.pdf) to the appropriate field. Complete form as instructed.	
Project/Performance Site Location(s) Form		Complete form as instructed.	
R&R Subaward Budget Attachment(s) Form (if applicable)		Complete form as instructed.	