

Intramural Program Announcement and Application Instructions

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-TRA

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 8, 2017
- **Peer Review:** April 2017
- **Programmatic Review:** May 2017

TABLE OF CONTENTS

- I. Funding Opportunity Description..... 3**
 - A. Program Description 3
 - B. Medical Readiness Initiative (MRI): Translational Simulation Research (TRANSfer): Medical Simulation Modeling to Assess Translation Skills from Training to Clinical Practice..... 4
 - C. Award Information..... 7
 - D. Eligibility Information 12
 - E. Funding 12
- II. Submission Information 13**
 - A. Pre-Application Submission Content..... 14
 - B. Full Application Submission Content..... 19
 - C. Submission Dates and Times 31
- III. Application Review Information 31**
 - A. Application Review and Selection Process..... 31
 - B. Application Review Process 32
 - C. Application Review Dates 34
 - D. Notification of Application Review Results 34
- IV. Administrative Actions..... 35**
 - A. Rejection 35
 - B. Modification..... 35
 - C. Withdrawal..... 35
 - D. Withhold 36
- V. Award Administration Information..... 36**
 - A. Award Notice 36
 - B. Administrative Requirements 36
 - C. Reporting and Deliverables..... 36
 - D. Award Transfers..... 36
 - E. Site Visits 37
- VI. Agency Contacts..... 37**
 - A. CDMRP Help Desk..... 37
- APPENDIX 1 Formatting Guidelines 39**
- APPENDIX 2 Administrative Information 40**
- APPENDIX 3 Regulatory Requirements..... 43**
- APPENDIX 4 Budget Form Instructions 49**

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.

THIS IS AN INTRAMURAL AWARD; BEFORE APPLYING, PLEASE NOTE:

- 1. This Program Announcement/Funding Opportunity is intended for intramural investigators only. An intramural investigator is defined as a Department of Defense (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.***
- 2. Awards to intramural organizations will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers.***
- 3. Extramural entities ARE NOT eligible to apply to this Program Announcement/Funding Opportunity and submissions from extramural investigators will be rejected. Should an intramural organization propose collaboration with an extramural entity for part of the research effort, the intramural organization will receive all funds and***

is responsible for executing all necessary contractual or assistance funding awards to collaborating partners through their agency's procedures.

4. *It is expected that the majority of work funded through this Program Announcement/ Funding Opportunity will be performed within a DoD laboratory or Military Treatment Facility (MTF). Regardless of location, any work that is to be performed by associated non-DoD organizations must be limited to work performed under existing service contracts or under Cooperative Agreements or Material Transfer Agreements. The Government reserves the right to administratively withdraw any application that does not meet these eligibility criteria. Applications that require work to be performed by a non-DoD organization under a new service contract will not be considered for funding.*
5. *Applicants must provide a detailed Federal Agency Financial Plan after the budget justification information in the Detailed Budget and Justification form. Applications must provide a plan delineating how all FY17 funds will be obligated by September 30, 2018. The plan must include the funding mechanism(s) and contractual arrangements that will be used to carry over funds between fiscal years, if applicable.*

Funds for this award are FY17 DHP RDT&E Program Element (PE) 6.3 dollars. Any FY17 funds not obligated by September 30, 2018, may be withdrawn by the issuing comptroller.

6. *Applicants must provide Letters of Organizational Support from the following:*
 - a. *Resource Manager/Comptroller: Provide a letter of support from the applicant institution's Resource Manager/Comptroller Office (or appropriate financial point of contact) assuring that the institution will be able to accept these funds, if awarded. If funds are to be sent to multiple sites, include a letter from each site.*
 - b. *Commander(s): Provide a letter (or letters) of support from appropriate MTF, Installation Commander, or equivalent Commanders/Directors to ensure access to the facility, research population, and other necessary resources. The Commander should be aware of all submissions and should confirm that the proposed work is both feasible from a technical perspective and relevant from a programmatic and Command perspective.*

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.^{1,2} 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.^{3,4} 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

¹ 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.

² 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.

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

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

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.⁵

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., 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.⁶ 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).⁷

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.)

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

⁶ Barsuck, 2009, *op cit*.

⁷ 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.

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 based on the belief that students will achieve a high level of understanding in a given area when given enough time)⁸ 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.

⁸ *Ibid.*

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:

- 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 U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO) prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is *not* required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB/EC. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Refer to the regulatory requirements listed in [Appendix 3](#) 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.

D. Eligibility Information

- **Principal Investigator:** Independent intramural investigators are eligible to apply. 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.
- Submissions from extramural (non-DoD) investigators will be rejected. It is permissible, however, for an extramural investigator to be named as a collaborator in a submission from an intramural investigator. In such cases, the intramural organization will receive all funds and is responsible for executing all necessary existing contractual or assistance funding awards to collaborating partners through their agency's procedures. Note, regardless of location, any work that is to be performed by associated non-DoD organizations must be limited to work performed under existing service contract or under Cooperative Agreements or Material Transfer Agreements.
- Cost sharing/matching is not an eligibility requirement.
- **The majority of work funded through this Program Announcement/Funding Opportunity is required to be performed within a DoD laboratory or MTF. Regardless of location, any work that is to be performed by associated non-DoD organizations must be limited to work performed under existing service.**

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 proposal/application, depending on the quality and number of proposals/applications received from intramural agencies and extramural organizations. Funding of proposals/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 available to support this program. The funding estimated for this Program Announcement/Funding Opportunity is approximate and subject to realignment.

NOTE: Proposals/applications received in response to both the JPC-1/MSIS TRANSfeR Intramural Program Announcement and Extramural Funding Announcement/BAA will be evaluated and considered for funding together. The Government reserves the right to fund any combination of intramural and/or extramural proposals/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.
- Option periods may be used on contracts.
- 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.

Refer to [Appendix 4](#) for budget regulations and instructions. For all Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in [Appendix 4](#).

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/Maryland/Northern Virginia 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 to attend scientific/technical meetings in addition to the required IPR meeting described above

Subawards to intramural agencies and other Federal agencies may be executed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR], Funding Authorization Document [FAD] process, or Support Agreements [DD Form 1144]). Direct transfer of funds from the recipient to a Federal agency is not allowed except under very limited circumstances. Refer to [Appendix 4](#) for additional information on budget considerations for proposals/applications involving Federal agencies.

II. SUBMISSION INFORMATION

Submission is a two-step process requiring both (1) pre-application submission and (2) application submission through the electronic Biomedical Research Application Portal (eBRAP) (<https://eBRAP.org/>).

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 application rejection.

Start the submission process early. eBRAP has a number of required steps that must be completed before submissions will be accepted. Be sure to allow adequate time for completion of all pre-application and application steps by their respective deadlines.

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. 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.

A. Pre-Application Submission 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.

All pre-application components must be submitted by the indicated deadline by the PI through eBRAP (<https://eBRAP.org/>). Material submitted after the deadline, unless specifically requested by the Government, will not be forwarded for processing.

PIs, collaborators, mentors, 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 or 301-682-5507.

The pre-application consists of the following components, which are organized in eBRAP by separate tabs:

- **Tab 1 – Application Information**
 - Enter the application information as described in eBRAP before continuing the pre-application.
- **Tab 2 – Application Contacts**
 - Enter contact information for the PI.
 - Enter the organization's Resource Manager/Comptroller or equivalent Business Official and Authorized Business Official or equivalent responsible for sponsored program administration. The Business Official and must either be selected from the eBRAP list or invited in order for the pre-application to be submitted.
 - Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI), 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.
- It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-proposal/pre-application submission is needed.
- [FY16 JPC-1/MSIS Medical Modeling, Simulation, and Training Steering Committee members](#) should not be involved in any pre-proposal/pre-application or proposal/application including, but not limited to, concept design, proposal/application development, budget preparation, and the development of any supporting documentation. For questions related to JPC-1/MSIS Medical Modeling, Simulation, and Training Steering Committee members and pre-proposals/pre-applications or proposals/applications, refer to [Section IV.C., Withdrawal](#), or contact the CDMRP at help@eBRAP.org or 301-682-5507.
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in 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.shtml>). 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.
- **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).
- **Tab 5 – Pre-Application Files**

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

Pre-Proposal/Pre-Application Narrative (10-page limit): The Pre-Proposal/Pre-Application 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 Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-proposal/pre-application.

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.C., Background](#) 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-Proposal/Pre-Application Supporting Documentation: The items to be included as supporting documentation for the pre-proposal/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 Pre-Proposal/Pre-Application Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate). 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 Pre-Proposal/Pre-Application 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-Proposal/Pre-Application Screening

- **Pre-Proposal/Pre-Application Screening Criteria**

All pre-proposals/pre-applications will be screened by the JPC-1/MSIS 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-proposals/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.](#)
- **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-Proposal/Pre-Application Screening Results**

Following the pre-proposal/pre-application screening, PIs will be notified as to whether or not they are invited to submit proposals/applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-proposal/

pre-application. The estimated timeframe for notification of invitation to submit a proposal/application is indicated on the [title page](#) of this PA.

B. Full Application Submission Content

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

The pre-application process in eBRAP must be completed before the application can be submitted. After pre-application submission, go to “My Applications” and click on “Start Full Application” for the log number under which the pre-application was submitted.

All application components must be submitted by the indicated deadline by the PI through eBRAP (<https://eBRAP.org/>). Material submitted after the deadline, unless specifically requested by the Government, will not be forwarded for processing. *The organization’s Business Official or Authorized Organization Representative (or Resource Manager/Comptroller) must approve/verify the full application submission prior to the verification/approval deadline.*

eBRAP application package components: For the **FY17 JPC-1/MSIS TRANSfeR (W81XWH-16-DMRDP-MSIS-TRA)** Award, the eBRAP application package includes the following components, which are organized in eBRAP by separate tabs. **To access these tabs, go to “My Applications” and click on “Start Full Application”** for the log number under which the pre-application was submitted.

- **Tab 1 – Summary:** Provides a summary of the application information.
- **Tab 2 – Application Contacts:** This tab will be populated by eBRAP. Add Authorized Organization Representative.
- **Tab 3 – Full Application Files:** Under each Application Component in eBRAP, upload each as an individual PDF file. Refer to [Appendix 1](#), for detailed formatting guidelines.
 1. **Application Component: Attachments:** Each attachment must be uploaded as an individual PDF file unless otherwise stated.
 - **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, etc.) 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 may 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 [Appendix 3](#), 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; inclusion of items not requested will result in the removal of those items or 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 project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.
 - **Publications and/or Patents (five document limit):** Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
 - **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 program, pre-existing, legally protected and perfected intangible property and for which no Federal funds had been used in the development of said property, the applicant must:
 - Clearly identify all such property;
 - 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): 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.”** Abstracts of all funded research projects will be posted publicly. *Do not include proprietary or confidential information.* Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.
The technical abstract is used by all reviewers and should be clear and concise and written using the outline below.
 - **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 outline below. *Do not duplicate the technical abstract.*

- Describe the objectives and rationale for the proposal/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>). There is no limit to the number of specific aims, tasks, or subtasks to be described within the SOW page limit. 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.
- **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:** If appropriate, provide a concise, detailed description on how this project will benefit the general public.
- **Attachment 7: Innovation Statement (two-page limit): Upload as “Innovation.pdf.”** Describe how the proposed project is innovative. Research deemed innovative may introduce a new paradigm, challenge current paradigms, look at existing problems from new perspectives, or exhibit other creative qualities. Investigating the next logical step or incremental advancement on published data is not considered innovative. This may include a proposed conceptual framework, design, and/or plan of key components and how they integrate/communicate with each other.
- **Attachment 8: Letters of Support (no page limit; limit each letter to two pages): Combine and upload as a single file named “Letters.pdf.** Start each document on a new page.
 - Resource Manager/Comptroller: Provide a letter of support from the applicant institution's Resource Manager/Comptroller (or appropriate financial point of contact) assuring that the institution will be able to accept and obligate these funds, if awarded. If funds are to be sent to multiple sites, include a letter from each site.

- Commander(s): Provide a letter(s) of support from appropriate Installation Commander or equivalent Commander/Director to ensure access to the facility, research population, and other necessary resources. The Commander should be aware of all submissions and should confirm that the proposed work is both feasible from a technical perspective and relevant from a programmatic and command perspective. The letter(s) should provide clear evidence of organizational commitment for the coordinating administrative tasks and for the use of facilities and resources necessary for the proposed work at each participating study site.
- Partnership/Collaboration (if applicable):
 - If the project includes collaboration with a non-DoD site, provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
 - If the project involves collaboration with another Military Facility (e.g., military health system facility, research laboratory, treatment facility, dental treatment facility, a DoD activity embedded with a civilian medical center), the collaborating DoD researcher must obtain a letter from his/her commanding officer or Military Facility director authorizing his/her participation in the research project. This letter must be included with the application.
- Access to Military or VA Populations and/or Resources (if applicable): If the proposed research plan involves access to active duty military and/or VA populations, patients, data or resources, include letter(s) of support, signed by the lowest ranking person with approval authority, confirming such access. If access cannot be confirmed at the time of application submission, the Government reserves the right to withhold or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resources.
- **Attachment 9: Human Subject Recruitment and Safety Procedures (if applicable, no page limit): Upload as “HumSubProc.pdf.”** Human Subject Recruitment and Safety procedures *are required* for all studies recruiting human subject and 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(s) (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 clinical trials (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, refer to [Appendix 3](#), for more information.*

- b. Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed **clinical** trial. 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 clinical research.

- 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 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 clinical trial to be in compliance with Title 10 United States Code Section 980 (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 clinical trial, 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 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. 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, including potential safety concerns and adverse events. Study risks include any risks that the human subject is subjected to as a result of participation in the clinical trial. 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 10: 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 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 the DoD 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 11⁹ is required.
- **Sharing study results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether or not

⁹ Code of Federal Regulations, Title 21, Part 11

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 11: 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 12: Collaborating DoD Military Facility Budget Form(s), if applicable: Upload as “MFBudget.pdf.”** If a Military Facility will be a collaborator in performance of the project complete the Collaborating DoD Military Facility Budget Form including a budget justification for each year. If more than one Military Facility is proposed, submit a separate budget form for each site.

2. Application Component: Key Personnel

Each attachment must be uploaded as an individual PDF file unless otherwise stated. The Biographical Sketches and the Previous/Current/Pending Support for the PI and Key Personnel may either be attached to the Research & Related

Senior/Key Person Profile (Expanded) Form or uploaded as individual files in the “Key Personnel” Application Component.

- Research & Related Senior/Key Person Profile (Expanded) Form: Upload the completed Research & Related Senior/Key Person Profile (Expanded) Form as “Key Personnel.pdf.”
- PI Biographical Sketch (five-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 five-page NIH Biographical Sketch may also be used. All biographical sketches should be submitted in the portable document format (pdf) that is not editable.

Biographical Sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

- PI Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
- Key Personnel Biographical Sketches (five-page limit each): Upload as “Biosketch_LastName.pdf.”
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”

3. Application Component: Budget: Use the DoD Military Budget Form available on the “Funding Opportunity and Forms” page in eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). Refer to [Appendix 4](#) for detailed information on completing this form.

- Upload the DoD Military Budget Form as “Budget_LastName.pdf.”
- Budget Justification (no page limit): Upload as “BudgetJustification_LastName.pdf.” The budget justification must include a Federal Agency Financial Plan as described in [Appendix 4](#).
- Subaward Budget: Include all Subaward budgets. Complete a separate detailed Budget using the DoD Military Budget Form including a budget justification for each subaward (subgrant or subcontract) in accordance with the instructions listed above. Title each individual subaward, “Budget,” and “Budget Justification,” with the name of the subawardee/subrecipient organization,

4. Application Component: Project/Performance Site Location(s) Form: Use the Project/Performance Site Location(s) Form available on the “Funding Opportunity and Forms” page in eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). Upload as “Performancesites.pdf.”

- On the Project/Performance Site Location(s) Form, indicate the primary site where the work will be performed. If a portion of the work will be performed at any other site(s), include the name and address for each collaborating location in the data fields provided. Add more sites as necessary using the “Next Site”

button. If more than eight performance site locations are proposed, provide the requested information in a separate file and attach it to this form. Each additional research site requesting funds will require a subaward budget.

- **Tab 4 – Application and Budget Data:**

Review and edit Proposed Project Start Date, Proposed End Date, and Budget data pre-populated from the Budget Form.

- **Tab 5 – Submit/request Approval Full Application**

Once all components have been uploaded and prior to the full application submission deadline, enter your password in the space provided next to “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will validate files against the Program Announcement/Funding Opportunity requirements and discrepancies will be noted. If no discrepancies are noted, press the “Confirm Submission” button to complete the application submission. **eBRAP will notify your Resource Manager/Comptroller or equivalent Business Official by email to log into eBRAP to review and to approve prior to the Approval deadline.**

C. 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.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. 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 CRII, and the specific intent of the award mechanism. ***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.shtml>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a nondisclosure 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 criteria, which are of equal 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 proposal/application:

- **Budget**
 - Whether the budget is appropriate for the proposed research and within the limitations of this Funding Opportunity/PA.
 - Whether the proposed timeline is appropriate and tasks outlined in the proposal/application are logical in their progression and how well the budget aligns with the proposed timeline and overall deliverables.
- **Intellectual Property and Transition Plan**
 - If applicable, to what degree the intellectual property plan is appropriate.

- If applicable, to what degree the transition plan is appropriate.
 - **Proposal/Application Presentation:**
 - To what extent the writing, clarity, and presentation of the proposal/application components influence the review.
- 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 to 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. Application Review Dates

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

D. Notification of Application Review Results

Each PI and organization will receive email notification of the funding recommendation. 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 and applications from CDMRP eBRAP, the following administrative actions may occur:

A. Rejection

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

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

B. Modification

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

C. Withdrawal

The following may result in administrative withdrawal of the 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.shtml>.*
- 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.shtml>). 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.

- 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 institutional investigation. The institution will be required to provide the findings of the investigation to CDMRP 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 [Appendix 2](#) for additional award administration information.

B. Administrative Requirements

Refer to [Appendix 2](#) for general information regarding administrative requirements.

C. Reporting and Deliverables

Refer to [Appendix 2](#), Administrative Information, for Reporting and Deliverable requirements for this award.

- Quarterly, annual, and final technical progress reports and quad charts will be required.
- In addition to written progress reports, oral briefings may be requested.

D. Award Transfers

Transfer of an award to another institution is not allowed. The award may be transferred to another PI within the same institution. Approval of a PI transfer request will be on a case-by-case basis at the discretion of the FY16 JPC-1/MSIS Program Manager.

E. Site Visits

CDMRP personnel may, at their discretion, visit each PI during the award period of performance.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

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

Phone: 301-682-5507

Email: help@eBRAP.org

VII. APPLICATION SUBMISSION CHECKLIST

Application Components	Upload Order	Action	Completed
Attachments	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	Letters of Support: Upload as Attachment 8 with file name "Letters.pdf."	
	9	Human Subject Recruitment and Safety Procedures (if applicable): Upload as Attachment 9 with file name "HumSubProc.pdf."	
	10	Data Management: Upload as Attachment 10 with file name "DataManage.pdf."	
	11	Transition Plan: Upload as Attachment 11 with file name "Transition.pdf."	
	12	Collaborating DoD Military Facility Budget Form(s), <i>if applicable</i> : Upload as Attachment 13 with file name "MFBudget.pdf."	
Key Personnel		Research & Related Senior/Key Person Profile (Expanded): Upload as "Key Personnel.pdf."	
		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.	
Budget		Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.	
		Upload Budget (Budget_LastName.pdf) and Budget Justification (BudgetJustification_LastName.pdf), and Subaward Budgets and Budget Justifications as applicable.	
Project/Performance Site Location(s) Form		Upload Project/Performance Site Location(s) Form as "Performancesites.pdf."	

APPENDIX 1 FORMATTING GUIDELINES

All pre-application and application documents must be legible and should conform to the formatting guidelines described below. The font size, spacing, page size, and margins may differ between the word processing, PDF, and printed versions. These guidelines apply to the document properties of the electronic version of the PDF file(s) as viewed on a computer screen.

- **Document Format:** All attachments must be in PDF.
- **Font Size:** 12 point, 10 pitch.
- **Font Type:** Times New Roman.
- **Spacing:** Single space or no more than six lines of type within a vertical inch (2.54 cm).
- **Page Size:** No larger than 8.5 inches x 11.0 inches (21.59 cm x 27.94 cm).
- **Margins:** At least 0.5 inch (1.27 cm) in all directions.
- **Print Area:** 7.5 inches x 10.0 inches (19.05 cm x 25.40 cm).
- **Color, High-Resolution, and Multimedia Objects:** Project narratives and pre-application files may include color, high-resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF files; however, these objects should not exceed 15 seconds in length and a size of 10 MB. Photographs and illustrations must be submitted in JPEG format; bit map or TIFF formats are not allowed.
- **Scanning Resolution:** 100 to 150 dots per inch.
- **Internet URLs:** URLs directing reviewers to websites that contain additional information about the proposed research are not allowed in the application or its components. Inclusion of such URLs may be perceived as an attempt to gain an unfair competitive advantage. However, links to publications referenced in the application are encouraged.
- **Language:** All documents must be submitted in English, unless otherwise specified in the Program Announcement (e.g., foreign transcripts submitted with English translations).
- **Headers and Footers:** Should not be used. Pre-existing headers and footers on required forms are allowed.
- **Page Numbering:** Should not be used.
- **Recommended Component Size:** Each attachment should not exceed 20 MB.

APPENDIX 2 ADMINISTRATIVE INFORMATION

A. Reporting Requirements

Reporting requirements and deliverables will be determined prior to award funding and may vary depending on the research being conducted. Anticipated reporting requirements and deliverables may include the following:

- **Progress Reports:** Quarterly, annual and final reports will be required. These reports will present a detailed summary of scientific issues and accomplishments. A final report will be submitted within 30 days of the end of the award period and will detail the findings, their potential impact to the Military or Veteran population, and other issues for the entire project. The format for the progress reports is available on eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>.
- **Quad Charts:** Quad Charts that outline the specific aims, approach, timeline and costs, and goals/milestones will be required with every quarterly report. The format for the quad chart is available on eBRAP at <https://ebrap.org/eBRAP/public/Program.htm>.

B. Publication, Acknowledgement, and Public Release

- **Publication of Findings:** Publication of findings is a requirement of this submission. It is expected that at study completion researchers will submit their findings to an appropriate peer-reviewed journal for publication. Copies of all scientific publications, presentations, and reports resulting from this funding mechanism shall be submitted to CDMRP when published or completed even if beyond the period of performance to allow reporting to the Defense Health Program and Congress on the accomplishments of the program.
- **Acknowledgment:** The recipient agrees that in the release of information relating to this award such release shall include the statements below, as applicable. “Information” includes, but is not limited to, news releases, articles, manuscripts, brochures, advertisements, still and motion pictures, speeches, trade association meetings, and symposia.
 - “This work was supported by the Defense Health Agency, Research, Development, and Acquisition Directorate through the Clinical Research Intramural Initiative Program. Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Department of Defense.”
 - “In conducting research using animals, the investigator(s) adheres to the laws of the United States and regulations of the Department of Agriculture.” Include required assurances, approvals, documents and information specified on the Animal Care and Use Review Office (ACURO) website (https://mrmc.detrick.army.mil/index.cfm?pageid=Research_Protections.acuro&rn=1).
 - “In the conduct of research utilizing recombinant DNA, the investigator adhered to NIH Guidelines for research involving recombinant DNA molecules.” (<http://www.nih.gov>)
 - “In the conduct of research involving hazardous organisms or toxins, the investigator adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.” (<http://www.cdc.gov/biosafety>)

C. Sharing of Data and Research Resources

- It is the intent of the Department of Defense that data and research resources generated by this funded research be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large.
- Expectations for sharing of data and research resources apply to all basic research, clinical studies, surveys, and other types of research funded through this award. This includes all data and research resources generated during the project's period of performance through grants, cooperative agreements, or contracts. It is critically important to share unique data and research resources that cannot be readily replicated, including but not limited to the following:
 - **Unique Data**¹⁰ are defined as data that cannot be readily replicated. Examples of unique data include large surveys that are expensive to replicate; studies of unique populations, such as patients to whom access is not widely available; studies conducted at unique times, such as during military conflict; studies of rare phenomena, such as rare diseases.
 - **Final Research Data**¹¹ are defined as recorded factual material commonly accepted in the scientific community as necessary to document and support research findings. These are not the summary statistics or tables; rather, final research data are the data on which summary statistics and tables are based. Final research data do not include laboratory notes or notebooks, partial datasets, preliminary analyses, drafts of scientific papers, plans for future research, peer review reports, communications with colleagues, or physical objects, such as gels or laboratory specimens.
 - **Research Resources**¹² include, but are not limited to, the full range of tools that scientists and technicians use in the laboratory, such as cell lines, antibodies, reagents, growth factors, combinatorial chemistry, DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines.
- ***Data and research resources generated from this funded research should be made as widely available as possible while safeguarding the privacy of participants, and protecting confidential and proprietary data, and third-party intellectual property.*** By sharing and leveraging data and research resources, duplication of very expensive and time-consuming efforts can be avoided, allowing for the support of more investigators with Federal funds. Such sharing allows for a more expeditious translation of research results into knowledge, products, and procedures to improve human health.
- ***The PI may be required to participate in the following:***
 - **Traumatic Brain Injury:** If the project includes traumatic brain injury (TBI) research, the PI may be required to make TBI data generated via an award available to the research community by depositing de-identified research data into the Federal Interagency TBI Research (FITBIR) informatics System (<https://fitbir.nih.gov>).

¹⁰ Adapted from https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#unique

¹¹ Adapted from https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#final

¹² Adapted from <http://www.gpo.gov/fdsys/pkg/FR-1999-12-23/pdf/99-33292.pdf>

- Clinical Trials: If the project includes a clinical trial(s), the PI may be required to register the clinical trial(s) individually on the registry and database Clinical Trials.gov (<https://www.clinicaltrials.gov/>).
- Systems Biology: If the project includes systems biology (SB)-related research, the PI may be required to make SB data, generated via an award, available to the research community by depositing research data into the SysBioCube system (<https://sysbiocube-abcc.ncifcrf.gov/>).
- ***For additional information on data-sharing, refer to the document titled “Congressionally Directed Medical Research Programs: Policy on Sharing Data and Research Resources,” available on eBRAP under Reference Material at <https://ebrap.org/eBRAP/public/Program.htm>.***

APPENDIX 3 REGULATORY REQUIREMENTS

A. Surety, Safety, and Environmental Requirements

Based on recent changes to Department of Defense (DoD) compliance requirements (DA PAM 385-69, **DA PAM 385-10**, 32 CFR 651.6 September 2012), provisions previously requested for Safety and Environmental Compliance have been removed. However, in certain instances, compliance review may require submission of additional documentation prior to the awarding of any assistance agreement. Such instances may include use of Army-provided infectious agents or toxins, select biological agents or toxins, select chemical agent(s), or pesticides outside of an established laboratory. The U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Surety, Safety, and Environment will identify any need for compliance review and documents must be submitted upon request.

B. Research Protections Review Requirements – Use of Human Subjects, Human Anatomical Substances, Human Data, Human Cadavers, and Animals

The USAMRMC Office of Research Protections (ORP) ensures that research conducted, contracted, sponsored, supported, or managed by the USAMRMC and involving human subjects, human anatomical substances, human data, human cadavers, and animals are conducted in accordance with Federal, DoD, Army, USAMRMC, and international regulatory requirements.

Principal Investigators (PIs) and applicant organizations **may not commence performance** of research involving the above, **or expend funding** on such efforts, until and unless regulatory documents are submitted and approved by the USAMRMC ORP to ensure that DoD regulations are met. All expectations described below are consistent with the DoD Instruction (DoDI) 3216.01, “Use of Animals in DoD Programs,” as issued 13 September 2010, available at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.acuro_regulations and DoDI 3216.02, “Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research,” as issued on 8 November 2011, and available at <http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf>.

The ORP Animal Care and Use Review Office (ACURO) is responsible for administrative review, approval, and oversight of all animal research protocols, including all changes made during the life of the protocol.

The ORP Human Research Protection Office (HRPO) is responsible for administrative review, approval, and oversight of research involving human subjects, human anatomical substances or data, and use of human cadavers. ***Research involving use of human data and/or specimens that is anticipated to be exempt from human subjects protections regulations requires a determination from the PI’s institution as well as the ORP HRPO at USAMRMC.*** A timeframe for submission of the appropriate protocols and required approvals will be established during negotiations.

1. Research Involving Animal Use

Specific documents relating to the use of animals in the proposed research will be requested if the application is selected for funding. The ACURO, a component of the USAMRMC ORP, must review and approve all animal use prior to the start of working with animals. 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.” For guidance on which version of the appendix to use, as well as links to both, visit the ACURO website at: https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.acuro_Animalappendix. *Allow at least 3 to 4 months for regulatory review and approval processes for animal studies.*

For additional information, send questions via email to ACURO (usarmy.detrick.medcom-usamrmc.other.acuro@mail.mil).

2. Use of Human Cadavers or Human Anatomical Substances Obtained from Human Cadavers

Research, development, test and evaluation (RDT&E), education or training activities involving human cadavers shall not begin until approval is granted in accordance with the Army Policy for Use of Human Cadavers for RDT&E, Education, or Training, 20 April 2012 (https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.overview).

The USAMRMC ORP is the Action Office (usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil) for this policy. Award recipients must coordinate with the supporting/funding Army organization to ensure that proper approvals are obtained.

Written approvals to begin the activity will be issued under separate notification to the recipient. Questions regarding submission of cadaver research for USAMRMC ORP review and approval should be directed to the ORP at usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil.

3. Research Involving Human Subjects, Human Subjects Data, or Human Anatomical Substances



In addition to local Institutional Review Board (IRB) review, investigators must submit all USAMRMC-funded research protocols involving human subjects and human anatomical substances for review and approval by the USAMRMC ORP HRPO prior to implementation of the research. The focus of this review is to validate IRB review as appropriate and ensure that DoD, Army, and USAMRMC regulatory requirements have been met.

Human subject research definitions, categories, and resource information may be found in the Human Subject Resource Document on the eBRAP website (<https://ebrap.org/eBRAP/public/Program.htm>). This information is a guide only; it is not intended to be a source for human subject protection regulations. Questions regarding applicable human subject protection regulations, policies, and guidance should be directed to the local IRB, the ORP HRPO (usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil), and/or the U.S. Food and Drug Administration (FDA) as appropriate. For in-depth information and to access HRPO protocol submission forms, refer to the ORP HRPO website (https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.hrpo).



ORP HRPO-required language must be inserted into the consent form, and compliance with DoD regulations may require additional information be included in the protocol.

The ORP HRPO ensures that DoD-supported and/or -conducted research complies with specific DoD laws and requirements governing research involving human subjects. These

laws and requirements may require information in addition to that supplied to the local IRB.

During the regulatory review process for research involving human subjects, the ORP HRPO requirements must be addressed, and any changes to the already approved protocol must be approved as an amendment by the local IRB. It is strongly recommended that investigators carefully read the “Information for Investigators” found at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo. The time to approval depends greatly on adherence to the requirements described within. If the protocol has not been submitted to the local IRB at the time of award negotiation, these guidelines should be considered before submission.

Documents related to the use of human subjects or human anatomical substances will be requested if the application is recommended for funding. ***Allow at least 2 to 3 months for regulatory review and approval processes for studies involving human subjects.***

Specific requirements for research involving human subjects or human anatomical substances can be found at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo.

4. **Assurance of Compliance:** Each institution engaged in non-exempt human subjects research must have a current Department of Health and Human Services Office for Human Research Protection (OHRP) Federal-wide Assurance (FWA) or DoD Assurance.
5. **Training:** Personnel involved in human subjects research must have appropriate instruction in the protection of human subjects. Documentation confirming completion of appropriate instruction may be required during the regulatory review process.
6. **Informed Consent Form:** The following must appear in the consent form:
 - A statement that the U.S. Department of Defense is providing funding for the study.
 - A statement that representatives of the DoD are authorized to review research records.
 - In the event that a Health Insurance Portability and Accountability Act (HIPAA) authorization is required, the DoD must be listed as one of the parties to whom private health information may be disclosed.
7. **Intent to Benefit:** The requirements of Title 10 of the United States Code Section 980 (10 USC 980), which are applicable to DoD-sponsored research, must be considered. 10 USC 980 requires that “Funds appropriated to the Department of Defense may not be used for research involving a human being as an *experimental subject* unless (1) the informed consent of the subject is obtained ***in advance***; or (2) in the case of research intended to be beneficial to the subject, the informed consent may be obtained from a legal representative of the subject.”

An individual not legally competent to provide informed consent (e.g., incapacitated individuals, cognitively impaired, minors) may not be enrolled as an ***experimental subject*** in a DoD-supported study unless the research is intended to benefit each subject enrolled in the study, to include subjects enrolled in study placebo arms. Studies designed in a manner that permits all subjects to potentially benefit directly from medical treatment or enhanced surveillance beyond the standard of care can meet the 10 USC 980 requirements. Note that

the definition of ***experimental subject*** as defined in the DoDI 3216.02 has a much narrower definition than ***human subject***. Research with experimental subjects must involve an intervention or interaction where the primary purpose of the research is to collect data regarding the effects of the intervention or interaction.



10 USC 980 is only applicable to certain intervention studies. It does not apply to retrospective studies, observational studies, studies that involve only blood draws, and tissue collections. Contact the HRPO at usarmy.detrick.medcom-usarmc.other.hrpo@mail.mil if further clarification regarding applicability of 10USC 980 to the proposed research project is required.

- 8. Research Monitor Requirement:** *For research determined to be greater than minimal risk, DoDI 3216.02 requires that the IRB approve, by name, an independent research monitor with expertise consonant with the nature of risk(s) identified within the research protocol.* The IRB must approve a written summary of the monitors' duties, authorities, and responsibilities.

The research monitor's duties should be based on specific risks or concerns about the research. The research monitor may perform oversight functions and report his/her observations and findings to the IRB or a designated official. The research monitor may be identified from within or outside the PI's institution. Research monitor functions may include:

- Observing recruitment and enrollment procedures and the consent process for individuals, groups or units;
- Overseeing study interventions and interactions;
- Reviewing monitoring plans and Unanticipated Problems Involving Risk to Subjects or Others (UPIRTSO) reports; and/or
- Overseeing data matching, data collection, and analysis.

There may be more than one research monitor (e.g., if different skills or experiences are necessary). The monitor may be an ombudsman or a member of the data safety monitoring board. At a minimum, the research monitor:

- May discuss the research protocol with the investigators, interview human subjects, and consult with others outside of the study about the research;
- Shall have authority to stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor's report; and
- Shall have the responsibility for promptly reporting his or her observations and findings to the IRB or other designated official and the HRPO.

A curriculum vitae or biographical sketch and human subjects protection training for the research monitor must be provided. There should be no apparent conflict of interest, and the research monitor cannot be under the supervision of the PI, other investigators, or research staff associated with the proposed research project. If the duties of the research monitor could require disclosure of subjects' Protected Health Information outside a covered entity (i.e., the research monitor is not an agent of the covered entity), the PI's

institution may require the identity and location of the research monitor to be described in the study HIPAA authorization. It is acceptable to provide appropriate compensation to the research monitor for his or her services.

9. Military Personnel Volunteers: The following is important information for research projects proposing to include military personnel as volunteers.

- **Recruitment of Military Personnel:** Civilian investigators attempting to access military volunteer pools are advised to seek collaboration with a military investigator familiar with service-specific requirements.

A letter of support from Commanders of military units in which recruitment will occur or the study will be conducted will be requested by the HRPO. Some military sites may also require that each volunteer seek written permission from their supervisor prior to participation in research studies.

Special consideration must be given to the recruitment process for military personnel. The Chain of Command must not be involved in the recruitment of military personnel and cannot encourage or order service members to participate in a research study.

For greater than minimal risk research, an ombudsman must be employed when conducting group briefings with active duty personnel to ensure that volunteers understand that participation is voluntary; this ombudsman may be recommended in other situations as well, especially when young enlisted service members, who by virtue of their age and enlistment status are trained to follow orders, are being recruited. Service members are trained to act as a unit, so peer pressure should also be considered and minimized, if possible.

- **Payment to Federal Employees and Military Personnel:** Under 24 USC 30, payment to Federal employees and active duty military personnel for participation in research while on duty is limited to blood donation and may not exceed \$50 per blood draw. These individuals may not receive any other payment or non-monetary compensation for participation in a research study unless they are off duty or on leave during the time they are participating in the protocol.
- **Confidentiality for Military Personnel:** Confidentiality risk assessment for military personnel requires serious consideration of the potential to affect the military career. Medical and psychological diagnoses can lead to limitation of duties and/or discharge from active duty. Information regarding alcohol or drug abuse, drunk driving, and sexual or spousal abuse can lead to actions under the Uniform Code of Military Justice, including incarceration and dishonorable discharge.

10. Site Visits: The USAMRMC ORP HRPO conducts site visits as part of its responsibility for compliance oversight.

Accurate and complete study records must be maintained and made available to representatives of the USAMRMC as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner so as to protect the confidentiality of subject information.



Additional information pertaining to the human subjects regulatory review process, guidelines for developing protocols, and suggested language for specific issues can be found at: https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo.

- 11. Protocol Submission Format:** The ORP HRPO accepts protocol submissions in the format required by the local IRB. The IRB protocol application, if separate from the protocol itself, should be included with protocol submissions. A HRPO protocol submission form should be completed and submitted with each protocol.

APPENDIX 4 BUDGET FORM INSTRUCTIONS

Complete the DoD Military Budget Form and Justification form. Begin by entering the PI name, eBRAP Log number, and period of performance fields at the top of the DoD Military Budget Form. **DoD Civilian and Military Personnel:** Personnel involved in the project should be listed in this section; however, this award is not intended to provide salary support for any Federal employee, as those costs were to have been included in infrastructure costs. If salary support is requested, sufficient justification must be provided in the budget justification section.

- **Name:** Beginning with the PI, list all participants who will be involved in the project during the initial budget period, whether or not salaries are requested. Include all collaborating investigators, research associates, individuals in training, mentor (if applicable) and support staff.
- **Role on Project:** Identify the role of each personnel listed. Describe his/her specific functions in the proposed research in the budget justification.
- **Type of Appointment (Months):** List the number of months per year reflected in an individual's contractual appointment with the applicant organization. The Government assumes that appointments at the applicant organization are full time for each individual. If an appointment is less than full time (e.g., 50%), note this with an asterisk (*) and provide a full explanation in the budget justification. Individuals may have split appointments (e.g., for an academic period and a summer period). For each type of appointment, identify and enter the number of months on separate lines.
- **Annual Base Salary:** Enter the annual organizational base salary (based on a full-time appointment) for each individual listed for the project.
- **Effort on Project:** List the percentage of each appointment to be spent on this project for all staff members including unpaid personnel.
- **Salary Requested:** Enter the salary for each position for which funds are requested. This is calculated automatically from the data provided. If you do not wish this to be calculated for you, uncheck the small "Calculate Salary" checkbox in the bottom of the field. Calculate the salary request by multiplying an individual's organizational base salary by the percentage of effort on the project.
- **Fringe Benefits:** Enter the fringe benefits requested for each individual in accordance with organizational guidelines.
- **Totals:** Calculated automatically from the data provided.
- **Major Equipment:** Provide an itemized list of proposed equipment, showing the cost of each item. Equipment is any article of nonexpendable tangible property having a useful life of more than 1 year and an acquisition cost of \$5,000 or more per unit.
- **Materials, Supplies, and Consumables:** The budget justification for supporting material and supply (consumable) costs should include a general description of expendable material and supplies.

- **Travel Costs:** PIs are responsible for budgeting for all costs associated with travel, including airfare, hotel, etc., associated with the trip. Anticipated travel costs should be built into the budget at current or projected DoD per diem rates. Travel costs must include:

- Travel costs for the PI to attend the required IPR meeting each year.

Travel costs may include:

- Travel costs for up to 1 investigator to travel to 1 scientific/technical meeting per year.
 - Travel costs between collaborating organizations.
 - **Research-Related Subject Costs:** Include itemized costs of subject participation in the proposed research. These costs are strictly limited to expenses specifically associated with the proposed research.
 - **Other Direct Costs:** Itemize other anticipated direct costs such as publication and report costs, equipment rental (provide hours and rates), communication costs, and organizationally provided services. Unusual or expensive items should be fully explained and justified. Estimate the costs of publishing and reporting research results, including direct charges for clerical preparation, illustrations, reprints, and distribution. Organizationally provided services should be supported by the organization's current cost/rate schedule. These items should be described in detail and clearly justified.
 - **Subcontract Costs (Partnership/Collaboration Costs):** Should an intramural organization propose collaboration with an extramural entity for part of the research effort, the intramural organization will receive all funds and is responsible for executing all necessary contractual or assistance funding awards to collaborating partners through the agency's procedures. **All direct and indirect costs of any partnership/ collaboration costs must be included in the total direct costs of the primary award.** The nature of the partnership/collaboration should be described in the Budget Justification section.
 - **Total Direct Costs:** Calculated automatically from the data provided for the initial budget period on page F-2 and for the entire proposed period of support on page F-3.
 - **Total Indirect Costs:** If funds for indirect costs are requested, sufficient justification must be provided in the budget justification section. The Government reserves the right to disallow any indirect costs not sufficiently justified. All direct and indirect costs of any proposed collaborator must be included in the total direct costs of the primary award. (See Section I.F., Funding.)
 - **Total Costs:** This section is calculated automatically from the data provided.
 - **Fee:** A profit or fixed fee is not allowable on awards or on subawards.
- Budget Justification Instructions:** Provide a clear budget justification for each item in the budget over the entire period of performance in the Justification section) of the DoD Military Budget Form. Itemize direct costs within each budget category for additional years of support requested beyond year one.
- **Federal Agency Financial Plan (required):** Provide a detailed Federal Agency Financial Plan after the budget justification information in the DoD Military Budget Form. The plan delineates how all FY16 funding will be obligated by

September 30, 2017. The plan must include the funding mechanism(s) or contractual arrangements that will be used to carry over funds between fiscal years, if applicable. Any FY16 funding not obligated by September 30, 2017 may be withdrawn by the issuing Comptroller.