BROAD AGENCY ANNOUNCEMENT
FOR EXTRAMURAL RESEARCH
(PROGRAM SPECIFIC)
for the
Department of Defense
Defense Health Program
Congressionally Directed Medical Research Programs
Defense Medical Research and Development Program

Joint Program Committee-1/
Medical Simulation and Information Sciences Research Program

Adaptive Tutor Using Methodologies for Neuroplasticity
Funding Opportunity Number: W81XWH-15-DMRDP-MSIS-ATUMN
Catalog of Federal Domestic Assistance Number: 12.420
Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Proposal/Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), September 10, 2015
- **Invitation to Submit a Proposal/Application:** October 21, 2015
- **Proposal/Application Submission Deadline:** 11:59 p.m. ET, December 17, 2015
- **End of Proposal/Application Verification Period:** 5:00 p.m. ET, December 22, 2015
- **Peer Review:** March 2016
- **Programmatic Review:** April 2016

*This Broad Agency Announcement is one of two documents with instructions to prepare and submit a proposal/application for this funding opportunity. The second document, the General Submission Instructions, is available for downloading from Grants.gov.*
Program Announcement

for the

Department of Defense
Defense Health Program
Congressionally Directed Medical Research Programs
Defense Medical Research and Development Program

Joint Program Committee-1/Medical Simulation and Information Sciences Research Program

Medical Decision Aids – Predictive Markers (SimMarkers)

Funding Opportunity Number: W81XWH-15-DMRDP-MSIS-SIMMARKERS
Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), July 29, 2015
- **Invitation to Submit an Application:** September 9, 2015
- **Application Submission Deadline:** 11:59 p.m. ET, November 12, 2015
- **End of Application Verification Period:** 5:00 p.m. ET, November 18, 2015
- **Peer Review:** February 2016
- **Programmatic Review:** March 2016

*The CDMRP eReceipt System has been replaced with the electronic Biomedical Research Application Portal (eBRAP). Principal Investigators and organizational representatives should register in eBRAP as soon as possible. All pre-applications must be submitted through eBRAP. In addition, applications submitted through Grants.gov will now be available for viewing, modification, and verification in eBRAP prior to the end of the application verification period.*

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

BEFORE APPLYING, PLEASE NOTE: THIS PROGRAM ANNOUNCEMENT/FUNDING OPPORTUNITY IS INTENDED FOR EXTRAMURAL INVESTIGATORS ONLY.

A separate announcement for intramural investigators is available at https://cdmrp.org/Program_Announcements_and_Forms/.

- An extramural investigator is defined as all those not included in the definition of an intramural investigator below.

- An intramural investigator is defined as a Department of Defense (DoD) military or civilian employee working within a DoD laboratory, DoD military treatment facility, or working in a DoD activity embedded within a civilian medical center. Intramural investigators are directed to apply through eReceipt (https://cdmrp.org/Program_Announcements_and_Forms/).

- Submissions from intramural investigators to this program announcement/funding opportunity will be rejected. It is permissible, however, for an intramural investigator to be named as a collaborator in an application submitted by an extramural investigator. For more information, refer to the General Application Instructions, Section II.C.5., Research & Related Budget.

A. Program Description

Applications to the Fiscal Year 2016 (FY16) Joint Program Committee 1 (JPC-1) Medical Simulation and Information Science (MSIS) 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 and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. Through the US Army Medical Research and Materiel Command (USAMRMC), the Congressionally Directed Medical Research Programs (CDMRP) provides Defense Medical Research and Development Program (DMRDP) execution management support for DHP core research program areas, including JPC-1/MSIS. This program announcement and subsequent awards will be managed and executed by CDMRP with strategic oversight from JPC-1/MSIS.

The mission of the JPC-1/MSIS is to explore the implications of models and technology for medical education and 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.

Per guidance from DoD Instruction 5000.02, “Operation of the Defense Acquisition System,” dated January 7, 2015, the outcomes of the research will be used to support the solution assessments/material considerations for materiel development of a SimMarkers tool kit or assessment system. The government plans to use research outcomes in assessing critical technology elements and technology maturity, system integration risk, future manufacturing feasibility, and, where necessary, technology maturation and demonstration needs.
The JPC-1/MSIS Medical Readiness Initiative (MRI): Medical Decision Aids – Predictive Markers

The JPC-1/MSIS MRI focuses on research and development of medical training methods, technologies, systems, and competency assessment tools for the attainment and sustainment of military medical readiness. MRI also includes methodologies, techniques, and tools that will allow for ethical, accurate, and appropriate pre-intervention rehearsal with input of authorized and personalized medical information into simulation models. Evidence-based efforts with measurable outcomes and reliable assessments also fall under the MRI.

The evolution of military medicine over the past 25 years has led to significant advancements in the ability to provide excellent care in a wide range of environmental and situational settings. Military medical personnel are trained and capable of providing care across the health continuum in support of disaster response, humanitarian relief, and contingency operations across the globe. While traditional military training platforms have served the military well in the past, an opportunity exists to more effectively understand and apply individualized instructional design strategies to select, train, sustain, and remediate adult learners at all levels of the military medical health system. Non-military medical professionals have several, but not all, of the same issues as their military counterparts. Non-military medical professionals support disaster response and humanitarian relief, and take sabbaticals; depending on the duration of time away from their practice, they may encounter decay (or degradation) of some of their healthcare skills. Training strategies will need to be identified to effectively enhance an individual’s ability to assess, perform, and communicate medical response activities across a wide range of clinical, operational, and environmental situations. The ability to effectively train individuals to care for patients will not only require a solid foundational knowledge but the ability to identify predictive markers (psychosocial, behavioral, etc.) that can be used to enhance the care and management of patients across the biopsychosocial model.

In many settings, the biopsychosocial training model is applied in a tiered approach. The foundation of this approach is built upon a solid understanding of anatomy and physiology, whereby the student is faced with correct and incorrect answers. As training progresses, students are required to apply critical thinking to align psychosocial issues with foundational knowledge in the development of differential diagnoses and management plans. The differential diagnosis and management plan, while founded in basic anatomy and physiology, is influenced by a wider variety of factors (some known and some unknown) in which the term “the art of medicine” comes into play. Many training programs utilize clinical immersion as a means to develop the “art of medicine” skill. Programs with longer training periods (i.e., MD, DO) typically result in individuals “self-selecting” their career track congruent with their ability and personal preferences to perform within the biopsychosocial model. The same is not true for members of the healthcare team at entry-level training programs. Individuals in entry-level training programs are required to attain a wide range of foundational information and expected to integrate psychosocial aspects often with limited immersive opportunities. The time and ability to effectively integrate aspects of the biopsychosocial model typically results in wide variation in applying the knowledge and skills in a variety of settings.

The DoD is already investigating opportunities to use electronic health records (EHR) and psychomotor simulation task devices to detect skill decay and degradation. The intent of the current DoD research is to assess whether an objective mathematical model, one that is yet to be
created, can be used to detect skill decay patterns for individual users. The assumption is that the development of these models would provide a means to deliver individually based sustainment and remediation to enhance overall clinical quality and patient safety. The application of these models may also benefit acquisition of knowledge and skills to tailor individualized learning. The application of these models should have broad availability, not only in content but also with the underlying architecture, by incorporating open source or open architectures that may inhibit systems communicating with other systems. While the intent is that these anticipated mathematical models hold promise to monitor skill acquisition and decay, the question remains, what other markers (i.e., psychological, biometric, socio-economic, spiritual, sociologic, age, gender, and experience) may be leveraged to enhance training acquisition, sustainment, and rehabilitation?

This FY16 announcement is requesting applications to identify markers that may be harnessed to effectively raise the ability, confidence, and proficiency of entry-level healthcare team members on the acquisition, sustainment, and remediation of skills. Are there individually based markers (i.e., personality types, learning strategies, experiences) associated with application of knowledge to applied tasks? If markers do exist, are there means to modify instructional design settings to enhance or overcome learning barriers to “accelerate” this process? Do measurable markers exist (i.e., stress markers, cognitive testing, problem-solving strategies) that could be used to monitor an individual’s ability and capacity to learn new material? Do measurable markers exist that could be leveraged to create predictable metrics and evaluation criteria related to training objectives? Are there common behavioral, environmental, and observational markers that could be deconstructed to create predictable evaluation criteria and inserted into a skill acquisition, maintenance, or decay model that has yet to be created? Are there common and predictive markers that can be deconstructed to clearly discriminate healthcare providers defined as competent from those defined as proficient?

This announcement is seeking alternate predictive markers, aside from information from an EHR or from use of currently available simulation systems that assess psychomotor skills. This announcement is seeking predictive markers that could be deconstructed into objective, or at least reliable, observational metrics and/or evaluation criteria that could eventually be inserted into computational models to select, train, sustain, and remediate healthcare professionals, initially at the entry-level healthcare team member. Eventually the long-term goal is that there will be computational models that could possibly be applicable to all healthcare providers, at any experience level. These markers should be task/procedure/skill agnostic, if at all possible, but need to provide enough detail and specifics to demonstrate, through a domain-specific proof of concept, that the markers indeed show some level of predictability. A pilot test in an entry-level medical domain-specific area is needed as an outcome of this research, in addition to the research information and evidence-based methodologies, to demonstrate feasibility of the skill acquisition, maintenance, or decay/degradation model. Linkage of data within the computational algorithms must also be demonstrated as a proof of concept.

B. Award Information

The FY16 JPC-1/MSIS Medical Decision Aids - Predictive Markers (SimMarkers) is seeking research that improves healthcare professionals’ cognitive and performance skill acquisition or minimizes his/her skill decay. This research is seeking objective markers that could be inserted
into a predictive model (one that has not been currently developed) to accurately and appropriately assess a healthcare professional’s cognitive and performance status. These cognitive and performance-type markers must be evidence-based and need to align with the respective credentialing or certifying healthcare organization. These cognitive and performance-type markers must also align with regional, local, and organization-specific recommendations, guidelines, and standards, especially if they exceed the credentialing or certifying healthcare organization-specific recommendations, guidelines, and standards.

It is anticipated that this research will minimize the use of data/information using hospital EHR and will not concentrate on psychomotor skills; current work sponsored by the DHP is already underway in those areas.

It is anticipated that this research will uncover information that clearly delineates the cognitive training differences between training to competency versus training to proficiency, as defined by Kirkpatrick.* It is anticipated that from this research there will be clear metrics/evaluation criteria that have been deconstructed that will discriminate between competency and proficiency. It is anticipated that from this research common environmental and/or behavioral factors will be able to be deconstructed to form metrics/evaluation criteria that could be used as markers that will assist in measuring cognitive skill acquisition and minimization of skill decay.

The research could use resources, such as crowdsourcing, using evidence-based methodologies, meta-analysis approaches, or other well-known evidence-based methodologies. A pilot study to test the markers is required. The pilot study may be in the medical domain at the discretion of the prospective Principal Investigator (PI) but should have significant applicability to military and government healthcare providers. Information about the pilot study needs to be incorporated in both the preproposal and full application. Items such as proposed methodologies, type of recruits, recruitment numbers, anticipated drop-out rate, assessment criteria, inter-rater reliability, intended medical domain(s) (or discipline[s]), control groups, and statistical protocols are just a few of the anticipated items for incorporation in the full application.

- The outcomes of research supported by the FY16 JPC-1/MSIS SimMarkers Project are as follows (in no particular order):
  - A list of contact references and sources for the information that support the proposed markers, the anticipated methodologies proposed, and the methodologies to support the proposed pilot study;
  - A report, document, and/or list of the terminology and respective definitions used for the markers, proposed metrics/evaluation criteria, and the chosen domain. Terminology and definitions are needed for the environments, behaviors, characteristics, competency, proficiency, etc., should also be provided;
  - A report or document containing the information about and analyzed data of the actual postulated markers that best fit the meaning of medical decision aids that could be used to help identify skill acquisition or minimization of skill decay in healthcare personnel.

○ A report or document detailing how the pilot study analyzed data, study methodologies, recruitment size, inter-rater reliability, assessment criteria, results, conclusions, and potential next-step recommendations;

○ A video provided on compact disc (CD) that presents the proof of concept model using the markers that could be considered to effectively raise the ability, confidence and proficiency of healthcare team members on the acquisition, sustainment, and remediation of skills. Video reports must comply with the following specifications:
  – Maximum run length: <= 6 minutes
  – Audio codec: AAC
  – Sample audio bit rate: 64 kbit/s (mono acceptable)
  – Video codec: H.264
  – Video resolution: <= 480 vertical lines
  – Format: MPEG-4 (mp4) container
  – Accepted formats: (mov, avi, mpg, mpeg, mp4, wmv)
  – A fully vetted abstract and the intended publication for which results will be published

NOTE: This Program Announcement/Funding Opportunity is not about creating, developing, and analyzing patient surveys to evaluate medical professionals skills; this is not about analyzing data/information using hospital EHR and will not concentrate on psychomotor skills acquisition or minimization of decay.

This Program Announcement/Funding Opportunity is not about developing a fully integrated healthcare provider cognitive skill acquisition or minimization of skill mathematical/computational predictive model that could be inserted into a system. However, the selected markers, metrics, and evaluation criteria are intended to be used as information to be inserted into a proof concept in order to conceptualize the utility of the chosen markers.

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), in addition to the local Institutional Review Board (IRB) of record. Local IRB 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. Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes. Refer to the General Application Instructions, Appendix 5, and the Human Subject Resource Document available on the eBRAP “Funding Opportunities & Forms” web page (https://ebrap.org/eBRAP/public/Program.htm) for additional information.
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. 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 3 to 4 months for regulatory review and approval processes for animal studies. Refer to General Application Instructions, Appendix 5, for additional information.

The CDMRP and JPC-1/MSIS intend that information, data, and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 3, Section L.

C. Eligibility Information

- Independent extramural investigators at all academic levels (or equivalent) are eligible to submit applications.
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, nonprofit, public, and private organizations.
- Intramural investigators are directed to apply through CDMRP eReceipt at https://cdmrp.org/Program_Announcements_and_Forms/.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is 18 months.
- The anticipated total costs budgeted for the entire period of performance will not exceed $600,000. Associated indirect costs can be budgeted in accordance with the organization’s negotiated rate. No budget will be approved by the Government exceeding $600,000 total costs or using an indirect rate exceeding the organization’s negotiated rate.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum 18 months.

Refer to the General Application Instructions, Section II.C.5., for budget regulations and instructions for the Research & Related Budget. For all Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in Section II.C.5. of the General Application Instructions.
For this award mechanism, direct costs must be requested for:

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

May be requested for (not all-inclusive):

- Salary
- Research-related subject costs
- Support for multidisciplinary collaborations
- Equipment
- Research supplies
- Travel between collaborating organizations, including travel to military/Government facilities
- Travel costs to attend scientific/technical meetings in addition to the required IPR meeting described above

This Program Announcement/Funding Opportunity is intended for extramural investigators only. Intramural investigators are required to apply to the JPC-1/MSIS Medical Decision Aids: Predictive Markers for Intramural Research Program Announcement/Funding Opportunity through CDMRP eReceipt at https://cdmrp.org/Program_Announcements_and_Forms/.

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. It is permissible for an intramural investigator to be named as a collaborator in an application submitted by an extramural investigator under this Program Announcement/Funding Opportunity. In such cases, the extramural investigator must include a letter from the intramural collaborator’s Commander or Commanding Officer that authorizes the involvement of the intramural collaborator.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Sub-awards to intramural agencies and other Federal agencies may be executed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR] or Funding Authorization Document [FAD] process). Direct transfer of funds from the recipient to a Federal agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.5. Research & Related Budget, for additional information on budget considerations for applications involving Federal agencies.

The JPC-1/MSIS expects to allot approximately $2.4M of the FY16 DHP appropriation to fund approximately four intramural and/or extramural JPC-1/MSIS SimMarkers Project applications, depending on the quality and number of applications received from intramural and extramural agencies and organizations. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of
Federal funds for this program. NOTE: Applications received in response to both the SimMarkers intramural and extramural Program Announcements/Funding Opportunities will be evaluated and considered for funding together. The Government reserves the right to fund any combination of intramural and/or extramural applications.

II. SUBMISSION INFORMATION

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

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance. A key feature of eBRAP is the ability of an organization’s representatives and PIs to view and modify the Grants.gov application submissions associated with them. eBRAP will validate Grants.gov application files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in an email to the PI and in the Full Application Files tab in eBRAP. It is the applicant’s responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement/Funding Opportunity.

PIs should ensure that their name and email address are the same as the name and email address that will be provided on the SF-424 Form of the Grants.gov application package submitted to Grants.gov. The organization, Business Officials, PI(s), and eBRAP log number named in the full application submitted to Grants.gov must match those named in the pre-application in eBRAP.

Application viewing, modification, and verification in eBRAP is strongly recommended, but not required. The Project Narrative and Budget cannot be changed after the application submission deadline. Any other application component cannot be changed after the end of the application verification period.

Where to Obtain the Grants.gov Application Package

To obtain the Grants.gov application package, including all required forms, perform a basic search using the Funding Opportunity Number W81XWH-15-DMRDP-MSIS-SIMMARKERS in Grants.gov (http://www.grants.gov/).

A. Pre-Application Submission Content

All pre-application components must be submitted by the PI through eBRAP (https://eBRAP.org/). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.
PIs and organizations identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

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

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**
  - Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF-424 form). The Business Official must either be selected from the eBRAP list or invited in order for the pre-application to be submitted.
  - It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.
- **Collaborators and Key Personnel – Tab 3**
  - Enter the name, organization, and role of all key personnel (including co-investigators, mentors, collaborators, consultants, and subrecipients/subawardees) associated with the application.
  - Federal agency personnel involved in the review process and/or with making funding recommendations are prohibited from being involved in the research proposed or assisting in any pre-application, including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation.
  - JPC-1 Medical Modeling, Simulation, and Training Working Group members and advisors (listed in the Appendix, below) should not be involved in any pre-application or application. For questions related to the JPC-1 Medical Modeling, Simulation, and Training Working Group members and advisors and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.
- **Conflicts of Interest (COIs) – Tab 4**
  - 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).
- **Pre-Application Files – Tab 5**
  
  *Note: Upload document(s) as individual PDF files unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.*
Preproposal Narrative (10-page limit): The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

The Preproposal Narrative should include the following:

- **Problem(s) 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 objectives, will provide information on proposed methods and analysis/evaluation strategies, and is based on sound rationale. Clearly articulate how the proposed work and research are derived from evidence-based, best-of-class, well-documented, and/or well-adopted designs to best solve the question of which markers, metrics, and evaluation criteria should be used in assessing healthcare provider cognitive skill acquisition or the minimization of skill decay.
  - **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. Include research design, methods, and analysis/evaluation strategies as well as materials anticipated to be used during the research. If applicable, include a description of animal and/or human use in the proposed project. For studies involving animals and/or 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 how the proposed research is relevant to the goal developing methodologies that will support sustainment of cognitive processes that assist inpatient assessment, clinical reasoning, clinical judgment, and clinical diagnosis and treatment.

  - **Innovation**: Explain how the proposed project is innovative and not an incremental advancement of previous work.

- **Proposed Study Design/Plan**: Provide the intended research methodology that will support the pilot study. Provide preliminary information such as anticipated type of recruits, number of recruits, control group, anticipated assessment criteria, inter-rater reliability, and statistical protocols. Refer to Award Information,
**Section I.B.** for additional information on the research areas of interest for this Program Announcement/Funding Opportunity.

- **Military Impact:** Describe the anticipated short- and/or long-term outcomes of the proposed project and their potential impact on improving healthcare training and patient safety in the military health system. Refer to Award Information, **Section I.B.,** for additional information on the anticipated outcomes sought by this Program Announcement/Funding Opportunity.

- **Personnel and Facilities:** Describe the role for the PI, co-PIs (if applicable), key personnel, sub-awards (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.

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

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

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

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

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

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

**Submit Pre-Application – Tab 6**

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

**Pre-Application Screening**

**Pre-Application Screening Criteria**

All pre-applications received in response to this Program Announcement/Funding Opportunity and those received in response to the SimMarkers Intramural Program Announcement/Funding Opportunity will be screened by the JPC-1 Medical Modeling, Simulation, and Training Working Group members to determine technical merit and relevance to the mission of the DHP and JPC-1/MSIS. Pre-applications will be screened based on the following criteria, listed in descending order of importance:
Theoretical Rationale, Scientific Methods, and Research: To what degree the research approach for accomplishing the specific aims is feasible, will accomplish the objectives, will provide information on proposed methods and analysis/evaluation strategies, and is based on sound rationale. To what degree the proposed work and research are derived from evidence-based, best-of-class, well-documented, and/or well-adopted designs to best solve which markers, metrics, and evaluation criteria will be determined in assessing healthcare provider (especially entry-level) cognitive skill acquisition or minimization of skill decay.

Significance, Relevance, and Innovation: To what degree the proposed research is relevant to the types of markers (such as competency vs. proficiency, environmental, behavior) used to assess a healthcare provider’s (especially entry-level) skill acquisition and minimization of skill decay, especially with respect to patient safety, patient outcomes, and clinical outcomes. To what degree the proposed work is innovative and novel, including whether the proposed research is duplicative of existing research.

Study Design/Plan: To what degree the proposed pilot study methodologies, anticipated type of recruits, number of recruits, control group, anticipated assessment criteria, inter-rater reliability, and statistical protocols will justify and support the intended outcomes of the proposed research.

Military Impact: To what degree the project’s anticipated short- and/or long-term outcomes will impact the military and a future training program in healthcare delivery and patient safety in the military health system in a way that is consistent with the program’s goals.

Personnel, Facilities, Timelines, and Budget: To what degree the expertise, experience, and knowledge of the key research personnel (including co-PIs, if applicable), sub-awards (if applicable), and consultants (if applicable) are appropriate and complementary for achieving the research goals. To what degree the prime facility will be able to perform the proposed research.

Notification of Pre-Application Screening Results

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

B. Full Application Submission Content

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

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

Each application submission must include the completed Grants.gov application package provided in Grants.gov for this Program Announcement/Funding Opportunity. The Grants.gov
application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (http://www.grants.gov/).

*Note: The Project Narrative and Budget Form cannot be changed after the application submission deadline.* If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or Budget Form needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID *prior to the application submission deadline.*

**Grants.gov application package components:** For the FY16 JPC-1/MSIS SimMarkers Project, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

1. **SF-424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

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

   - **Attachment 1: Project Narrative (20-page limit):** Upload as “ProjectNarrative.pdf.” The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, 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 the ideas and reasoning behind the proposed research; include relevant literature citations or preliminary data. Justify the rationale for the markers intended for investigation and how they will be able to discriminate between healthcare providers as they are acquiring cognitive skills and how to minimize cognitive skill decay. Justification must also be provided as to how and why the intended markers will greatly benefit patients, through patient safety, patient outcomes, or clinical outcomes. 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.
Clearly support the choice of study variables and explain the basis for the study questions and/or study hypotheses. Establish the relevance of the study and explain the applicability of the proposed findings.

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

- **Specific Aims:** Concisely explain the project’s specific aims. If this application is part of a larger study, present only tasks that this award would fund.

- **Study Design:** Describe the experimental design, methods, and analyses/evaluations providing sufficient detail for analysis.
  - Identify and describe the hypothesis to be studied and the projected outcome of the proposed research.
  - Define the pilot study variables and describe 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 a plan for data access.
  - Address any potential barriers and plans for addressing potential delays. Provide a risk management plan to address barriers to plans. As relevant, describe plans for addressing issues unique to working within the military health system.
  - 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.

*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.*

- 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.

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

For animal studies, allow at least 2 to 3 months for regulatory review and approval by the USAMRMC ACURO; this does not include the additional time required for local IACUC review and approval.

Refer to the General Application Instructions, Appendix 5, 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: 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.

○ Publications and/or Patent Abstracts: 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.

○ 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.

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

- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If the project involves collaboration with a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center), special requirements apply. A 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. (Refer to the General Application Instructions, Section II.C.8, for additional information.)

- Intellectual Property
  - Background and Proprietary Information: All software and data first produced under the award are subject to a Federal purpose license. Provide a list of all background intellectual property to be used in the project or provide a statement that none will be used. If applicable, state and identify the proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the Federal purpose license.
  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations. Identify which potential components will be open source/open architecture versus proprietary in the proposed framework, design, and/or plan of a possible biopsychosocial training model and how the proposed model would integrate/communicate with other systems.
  - Commercialization Strategy (if applicable): Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.

- 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 3, Section L, for more information about the CDMRP expectations for making data and research resources publicly available.

Abstracts of all funded applications may be publicly posted; therefore, proprietary information should not be included in the abstract.

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

- **Background:** Provide a brief statement of the ideas and theoretical reasoning behind the proposed work.
- **Objective/Hypothesis:** State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- **Specific Aims:** State concisely the specific aims of the study.
- **Study Design:** Briefly describe the study design.
- **Impact:** Provide a brief statement explaining the potential relevance of the proposed work to improving patient safety and healthcare outcomes in the military health system and/or to the general public.

**Attachment 4: Lay Abstract (one-page limit):** Upload as “LayAbs.pdf.” Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Not required at this time. Leave Attachment 4 space blank.

**Attachment 5: Statement of Work (SOW) (two-page limit):** Upload as “SOW.pdf.” The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (https://ebrap.org/eBRAP/public/Program.htm). For the JPC-1/MSIS SimMarkers mechanism, use the SOW format example titled “SOW Generic.” The SOW must be in PDF format prior to attaching. Refer to the General Application Instructions, Section II.C.3., for detailed guidance on creating the SOW.

**Attachment 6: Outcomes and Impact Statement (one-page limit):** Upload as “Impact.pdf.” Explain in detail why the proposed research project is important, as follows:

- **Describe the short-term impact:** Describe the anticipated outcome(s)/results(s), design, and/or plan that will be directly attributed to the results of the proposed research.
- **Describe the long-term impact:** Describe the anticipated long-term gains from the proposed research, including the long-term anticipated advantages that the new understanding may ultimately contribute. Articulate how the anticipated outcomes will contribute to providing the markers, metrics, evaluation criteria that could be inserted into a predictive model that then could be used to assess the healthcare provider cognitive skill acquisition and minimization of skill decay.
- **Military Relevance:** Clearly articulate how the proposed research is relevant to the goal of providing medical decision aids (markers, metrics, and evaluation
criteria) that could be inserted into a predictive model that then could be used to assess the healthcare provider cognitive skill acquisition and minimize skill decay. State precisely the estimates as to the immediate and/or long-range usefulness of this study to the Armed Forces, as distinguished from general advancement of knowledge in medicine.

- **Public Purpose:** Provide a concise, detailed description on how this research 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: Collaborating DoD Military Facility Budget Form(s), if applicable:** Upload as “MFBudget.pdf.” If a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the Collaborating DoD Military Facility Budget Form (available for download on the eBRAP “Funding Opportunities & Forms” web page), including a budget justification, for each Military Facility as instructed. Refer to the General Application Instructions, Section II.C.8., for detailed information.

3. **Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.4., for detailed information. Note: Some of the items in this attachment may be made available for programmatic review.

- 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 National Institutes of Health Biographical Sketch may also be used.

- 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.”
4. **Research & Related Budget:** Refer to the General Application Instructions, Section II.C.5., for detailed information.
   
   - **Budget Justification (no page limit):** Upload as “BudgetJustification.pdf.” The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.

5. **Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C.6., for detailed information.

6. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.7., for detailed information.

C. **Applicant Verification of Grants.gov Submission in eBRAP**

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of an application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant’s responsibility to review all application components and ensure proper ordering as specified in the Program Announcement/Funding Opportunity. **If either the Project Narrative or the budget fails eBRAP validation, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID prior to the application submission deadline.** The Project Narrative and Budget Form cannot be changed after the application submission deadline.

D. **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 application rejection.

E. **Other Submission Requirements**

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

All applications must be submitted through Grants.gov. Applicant organizations and all subrecipient organizations must have a Data Universal Numbering System (DUNS) number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the System for Award Management (SAM) with an “Active” status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Section II.A., for information on Grants.gov registration requirements.
III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applicants are evaluated by scientists, clinicians, and consumer advocates using 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 Office of the Assistant Secretary of Defense for Health Affairs, based on (a) technical merit and (b) the relevance to the mission of the DHP and JPC-1/MSIS and to the specific intent of the award mechanism. The highest-scoring applications from the first tier of review are not automatically recommended for funding. 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 scored criteria, which are listed in decreasing order of importance:

   - **Theoretical Rationale and Scientific Methods**
     - To what degree the research approach for accomplishing the specific aims are 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 from evidence-based, best-of-class, well-documented, and/or well-adopted designs to best solve which markers, metrics, and evaluation criteria will be determined in assessing healthcare provider (especially entry-level) cognitive skill acquisition or minimization of skill decay.
     - To what degree the proposed research is relevant to the types of markers (such as competency vs. proficiency, environmental, behavior) used to assess a healthcare provider’s (especially entry-level) skill acquisition and minimization of skill decay, especially with respect to patient safety, patient outcomes, and clinical outcomes.
○ How well the study aims, hypotheses or objectives, experimental design, methods, and analyses are designed to clearly answer the research questions.

○ Whether the proposed research and work provide a listing of evidence-based definitions, nomenclature, or lexicon that supports the proposed methodologies for determining which markers, metrics, and evaluation criteria should be investigated, and why.

○ How well the proposed methodologies, type of recruits, recruitment numbers, anticipated drop-out rate, assessment criteria, inter-rater reliability, intended medical domain(s) (or discipline[s]), control groups, statistical protocols, etc., supporting the pilot study are presented and aligned with the proposed study outcomes.

○ Whether there is evidence of an adequate contingency plan, such as a risk mitigation plan, to resolve potential delays.

**Relevance, Innovation, and Impact:**

○ How the proposed research is relevant to the goal of incorporating evidence-based methodologies and techniques and how and why the proposed markers, metrics, and evaluation criteria are relevant to and impactful on patient safety, patient outcomes, and clinical outcomes while presenting novel and innovative ways to potentially track how healthcare provider cognitive skills are acquired and skill decay is minimized.

○ How the proposed work is innovative and novel, including whether the proposed research is duplicative of existing research.

○ To what degree the proposed research, domain, and pilot study are relevant to the goal of this Program Announcement/Funding Opportunity.

○ To what degree the proposed markers, metrics, and evaluation criteria are relevant compared to healthcare facilities other than the PI’s organization. Are the proposed markers, metrics, and evaluation criteria locally applicable or do they have broader applications?

○ To what degree the anticipated short- and long-term outcomes resulting from the proposed study will contribute to the goal of improving patient safety and healthcare outcomes.

**Personnel and Facilities:**

○ How the composition and balance of the research team (including other organization personnel, sub-awards, and consultants, as applicable) are appropriate.

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

○ To what degree the levels of effort by the PI and other key personnel are appropriate to ensuring the success of proposed research.
To what degree the research environment and the accessibility of institutional resources support the proposed study (including collaborative arrangements). Whether there is evidence for appropriate institutional commitment. In addition, the following unscored criteria will also contribute to the overall evaluation of the application:

- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
  - Whether the proposed timeline is appropriate and tasks outlined in the application are logical in their progression.

- **Intellectual Property and Commercialization Plan**
  - If applicable, to what degree the intellectual property plan is appropriate.
  - If applicable, to what degree the commercialization plan is appropriate.

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

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

   a. Ratings and evaluations of the peer reviewers
   b. Relevance to the mission of the DHP and JPC-1/MSIS, as evidenced by the following:
      - Adherence to the intent of the award mechanism
      - Programmatic relevance & portfolio balance
      - Relative impact, innovation, and novelty
      - Degree of public accessibility of outcomes
      - Military relevance

C. **Recipient Qualification**

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

D. **Application Review Dates**

All application review dates and times are indicated on the title page of this Program Announcement/Funding Opportunity.
E. Notification of Application Review Results

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

IV. ADMINISTRATIVE ACTIONS

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

A. Rejection

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

- The pre-application is submitted by an intramural organization.
- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds 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 Preproposal Narrative and Project Narrative.
- Documents not requested will be removed.

C. Withdrawal

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

- A JPC-1 Medical Modeling, Simulation, and Training Working Group 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 JPC-1 Medical Modeling, Simulation, and Training Working Group members can be found in the Appendix.
- The pre-application or 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).

• Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.

• Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.

• The application budget differs significantly from the budget included in the pre-application.

• The invited full application does not propose the same research project described in the pre-application.

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 the USAMRAA Grants Officer for a determination of the final disposition of the application.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2017. Refer to the General Application Instructions, Appendix 3, for additional award administration information.

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

B. Administrative Requirements

Refer to the General Application Instructions, Appendix 3 for general information regarding administrative requirements.

C. National Policy Requirements

Refer to the General Application Instructions, Appendix 4 for general information regarding national policy requirements.
D. Reporting

Refer to the General Application Instructions, Appendix 3, Section I, for general information on reporting requirements.

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

E. Award Transfers

Refer to the General Application Instructions, Appendix 3, Section M, for general information on organization or PI changes.
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 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

B. Grants.gov Contact Center

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

Phone: 800-518-4726
Email: support@grants.gov

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

<table>
<thead>
<tr>
<th>Grants.gov Application Components</th>
<th>Upload Order</th>
<th>Action</th>
<th>Completed</th>
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<tr>
<td>SF-424 (R&amp;R) Application for Federal Assistance</td>
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<td>Complete form as instructed.</td>
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<tr>
<td>Attachments Form</td>
<td>1</td>
<td>Project Narrative: Upload as Attachment 1 with file name “ProjectNarrative.pdf.”</td>
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<td>2</td>
<td>Supporting Documentation: Upload as Attachment 2 with file name “Support.pdf.”</td>
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<td>3</td>
<td>Technical Abstract: Upload as Attachment 3 with file name “TechAbs.pdf.”</td>
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<td>Lay Abstract: Not required, leave Attachment 4 blank.</td>
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<td>5</td>
<td>Statement of Work: Upload as Attachment 5 with file name “SOW.pdf.”</td>
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<td>6</td>
<td>Outcomes and Impact Statement: Upload as Attachment 6 with file name “Impact.pdf.”</td>
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<td>7</td>
<td>Innovation Statement: Upload as Attachment 7 with file name “Innovation.pdf.”</td>
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<td>8</td>
<td>Collaborating DoD Military Facility Budget Form(s): If applicable, upload as Attachment 8 with file name “MFBudget.pdf.”</td>
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<tr>
<td>Research &amp; Related Senior/Key Person Profile (Expanded)</td>
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<td>Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.</td>
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<td>Confidential Letters of Recommendation</td>
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**APPENDIX:**

**JPC-1/MSIS WORKING GROUP MEMBERS AND ADVISORS**

*List of FY16 JPC-1 Medical Modeling, Simulation, and Training Working Group Members and Advisors:*

<table>
<thead>
<tr>
<th>CAPT Arthur Anthony</th>
<th>COL Dan Irizarry</th>
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<tr>
<td>Mr. Wilson Ariza</td>
<td>CDR Typhanie Kinder</td>
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<td>LTC Jay Baker</td>
<td>Ms. Heidi King</td>
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<td>SGM F. Young Bowling</td>
<td>Dr. Kevin Kunkler</td>
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<td>Dr. Harry Burke</td>
<td>Dr. Lori Loan</td>
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<tr>
<td>Mr. Paul Chatelier</td>
<td>Dr. Joseph Lopreiato</td>
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<tr>
<td>COL Tamara Crawford</td>
<td>Dr. Haru Okuda</td>
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<tr>
<td>COL Shad Deering</td>
<td>Dr. Ray Perez</td>
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<td>LTC Dawn Fitzhugh</td>
<td>Ms. M. Beth Pettitt</td>
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<td>Col Meletios Fotinos</td>
<td>LTC Christopher Todd</td>
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<tr>
<td>COL Denise Hopkins-Chadwick</td>
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*Submissions that include a JPC-1/MSIS Working Group member or advisor as an investigator, consultant, collaborator, or in a key personnel role will not be considered.*
Program Announcement

for the

Department of Defense
Defense Health Program
Congressionally Directed Medical Research Programs
Defense Medical Research and Development Program

Joint Program Committee-1/Medical Simulation and
Information Sciences Research Program

Metrics: Transitioning Training to Reality
(RealMETRX)

Funding Opportunity Number: W81XWH-15-DMRDP-MSIS-REALMETRX
Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- Pre-Application Deadline: 5:00 p.m. Eastern time (ET), July 29, 2015
- Invitation to Submit an Application: September 9, 2015
- Application Submission Deadline: 11:59 p.m. ET, November 12, 2015
- End of Application Verification Period: 5:00 p.m. ET, November 18, 2015
- Peer Review: January 2016
- Programmatic Review: March 2016

The CDMRP eReceipt System has been replaced with the electronic Biomedical Research Application Portal (eBRAP). Principal Investigators and organizational representatives should register in eBRAP as soon as possible. All pre-applications must be submitted through eBRAP. In addition, applications submitted through Grants.gov will now be available for viewing, modification, and verification in eBRAP prior to the end of the application verification period.

This Program Announcement/Funding Opportunity is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.
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APPENDIX: JPC-1/MSIS Working Group Members and Advisors ................... 29
I. FUNDING OPPORTUNITY DESCRIPTION

BEFORE APPLYING, PLEASE NOTE: THIS PROGRAM ANNOUNCEMENT/FUNDING OPPORTUNITY IS INTENDED FOR EXTRAMURAL INVESTIGATORS ONLY.

A separate announcement for intramural investigators is available at https://cdmrp.org/Program_Announcements_and_Forms/.

- An extramural investigator is defined as all those not included in the definition of intramural investigators below.
- An intramural investigator is defined as a Department of Defense (DoD) military or civilian employee working within a DoD laboratory, DoD military treatment facility, or working in a DoD activity embedded within a civilian medical center. Intramural investigators are directed to apply through eReceipt (https://cdmrp.org/Program_Announcements_and_Forms/).
- Submissions from intramural investigators to this Program Announcement/Funding Opportunity will be rejected. It is permissible, however, for an intramural investigator to be named as a collaborator in an application submitted by an extramural investigator. For more information, refer to the General Application Instructions, Section II.C.5., Research & Related Budget.

A. Program Description

Applications to the Fiscal Year 2016 (FY16) Joint Program Committee 1 (JPC-1) Medical Simulation and Information Science (MSIS) 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, the DHA RDA Directorate manages and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. Through the US Army Medical Research and Materiel Command (USAMRMC), the Congressionally Directed Medical Research Programs (CDMRP) provides Defense Medical Research and Development Program (DMRDP) execution management support for DHP core research program areas, including JPC-1/MSIS. This program announcement and subsequent awards will be managed and executed by CDMRP with strategic oversight from JPC-1/MSIS.

The mission of the JPC-1/MSIS is to explore the implications of models and technology for medical education and 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 of which includes medical simulation and training.

The JPC-1/MSIS Medical Readiness Initiative (MRI): Metrics: Transitioning Training to Reality (RealMETRX) is a line of research that supports the MRI under the JPC-1 medical simulation and training portfolio. The JPC-1/MSIS MRI focuses on the research, and ultimately the development of, medical training methods, technologies, systems, and competency assessment tools for the attainment and sustainment of military medical readiness research and development efforts. MRI also includes research on methodologies, techniques, and tools that
will allow for ethical, accurate, and appropriate pre-intervention rehearsal with input of potential authorized personalized medical information into simulation models. Evidence-based efforts with measurable outcomes and reliable assessments also fall under the MRI.

**Background:** The evolution of medical simulation systems has vastly increased opportunities to enhance the ability to deliver a blended learning approach to knowledge and skills acquisition. The ability to focus on cognitive, psychomotor, and affective domains has provided a means to more effectively assess the effectiveness of training as well as potential impact on clinical processes and outcomes. The evolution of medical simulation systems is a significant improvement over the “see one, do one, teach one” approach used in medicine. While these advances hold promise, there continue to be many unanswered research questions regarding simulation expectations and their application in medical education and training. Why, for instance, do medical simulation systems undergo so much more scrutiny compared to previous models used for medical training? Unrealistic expectations are also related to the belief that providers trained with simulation systems will readily be able to translate enhanced knowledge and skills to improved patient outcomes. Over the years, conclusions have been published linking medical training using simulation systems to real-world psychomotor skills; however, there are fewer publications conclusively showing transference of cognitive skills. Using a combination of simulation systems is not proportional to caring for a real patient nor does it reveal the entire event of patient care given by the healthcare provider.

Another assumption is that training on medical simulation systems already replicates clinical experience. With simulation, a healthcare provider now has a greater advantage over their predecessors. Simulation allows providers to:

- “See many” with virtual scenarios/patients;
- “Do many” with virtual simulations; and
- “Teach many” using simulation systems as the educational tool.

Lingering questions remain regarding which simulated procedures actually equate to real task, skill, or procedure.¹ For example, if the simulated activity is performed well (as identified by the objective metrics within the respective simulation system), then does this training contribute to optimal provider performance and maximized patient outcomes? The answer is, “It depends.” It depends on the type of activity to understand how many simulated procedures equate to a real procedure. It also depends on whether the training curriculum is scientifically linked to positive outcomes and conducted to standard. There are discrepancies even when gaining experience with real patients. For example, insertion of a peripheral intravenous catheter on the proverbial young adult male probably takes less experience and less training compared to similar skill for a neonate, a morbidly obese patient, or a geriatric patient with underlying cardiopulmonary disease who is on a ventilator. It may also depend on the type of activity and if it is known to be associated with the intended patient outcomes. It depends if the respective activity is simulated via a commercially available or a prototype simulation system.

¹ For the purposes of this Program Announcement/Funding Opportunity, the combination use of words “task, skill, or procedure” will be referenced as “activity” unless otherwise specified.
A challenge with today’s training strategies, particularly when using medical simulation systems, is how to increase the understanding of the entire patient experience and how to take that into consideration prior to performing a respective simulated activity. Anticipating errors including type, number, and severity, and preventing these errors are just some of the attributes that experienced healthcare providers have over novices. Envisioning outcomes, planning the course and anticipating variables, and really understanding and appreciating the risk-to-benefit ratio, are additional advantages experienced personnel have; experienced personnel understand where to take some calculated risks and where not to. Medical simulation systems that accelerate the path from novice to experienced healthcare providers are needed.

Several questions arise when considering one of the components to accelerate the training path from a novice to an expert. What are the variables, metrics, and evaluation criteria needed in order to distinguish novice from experienced healthcare providers? What are the measurable attributes that experienced healthcare professionals have that novices and not-so novice healthcare providers have to produce positive patient outcomes? What are the variables, metrics, and evaluation criteria that an experienced healthcare provider uses when assessing the whole patient and not just the injury or the present illness versus that of novices? What are the metrics that best transition from training to practicing medicine?

B. Award Information

The FY16 JPC-1/MSIS RealMETRX is seeking research to determine, define, and validate the best indicators (metrics/evaluation criteria) of training proficiency that are amenable to appraisal using medical simulation systems and are empirically linked to optimal provision of patient care. What are some of the best metrics and evaluation criteria to measure effective decision making of novice or even not-so novice healthcare personnel to better measure the multitude of variables and patient outcome contributors that could occur from the first healthcare encounter, to the time of discharge and even near-term follow-up (such as within the first 6 months)? What are the best metrics/evaluation criteria that could be used to (1) accelerate acquisition of maturity and experience level for novice and not-so novice healthcare personnel and (2) compare them to similar high-performing colleagues considered to be experienced within their discipline?

It is expected that award recipients will use statistical approaches to determine the best metrics and evaluation criteria that will objectively assess and measure the transition from training using medical simulation systems to that of actual medical practice. It is expected that award recipients will concentrate their research within acute trauma care, critical care, and prolonged care.2 It is expected that the award recipients will consider healthcare scenarios and medical conditions in order to uncover common patient outcomes or training-sensitive outcome indicators versus those that are currently used to evaluate tasks, skills, and procedures. Metrics produced should include as many aspects of the continuum of care as possible and should focus on acute trauma care, critical care, and prolonged care. Military-relevant injuries and conditions should be considered, but should not constitute the entirety of the variables, metrics, and evaluation criteria. It is anticipated that many of these variables, metrics, and evaluation criteria will transcend across the military, Veterans Health Administration, academic, inpatient,

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2 For the purposes of this Program Announcement/Funding Opportunity, prolonged care is care sustained until the patient arrives at the next appropriate level of care and often is under conditions where limited resources exist.
outpatient clinics, rural healthcare settings, private and public hospitals, and international healthcare situations.

A pilot study lasting at a minimum of 6 months to collect data for confirmation of proposed variables, metrics, and evaluation criteria is required. 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) (or discipline(s)), control groups, and statistical protocols are just a few of the anticipated items for incorporation in the full application. For the purposes of this study, subjects should not include students. Examples of subjects that may be considered: medics, corpsmen, pararescuers, emergency medical technicians, other technicians (such as radiology technicians, etc.), licensed nurses, physician assistants, residents, fellows, and licensed physicians.

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 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 between architecture or model and other systems.

Applications should address potential future public uses of the proposed research outcomes. It is anticipated that research outcomes, analysis, methodologies, and conclusions be disseminated and propagated to the Military and the Government, but also to the public at large. Public benefits from this research are encouraged.

The anticipated long-term vision includes but is not limited to: (1) influencing future commercial simulation systems to include many of the proposed metric and evaluation criteria in-and-above what are already being integrated; (2) possibility of several medical simulation systems connected together within a System of Systems concept and allow data from several systems to be analyzed to formulate more holistic and predictive metrics that better represent patient outcomes and not the disease, or the activity; and (3) coupling multitudes of well-constructed (from a learning and reliability perspective) appropriate fidelity simulation systems in order for medical educators to have assessment tools to compare training results versus actual evidence-based outcomes relative to patient safety and patient outcomes.

It is expected that as a result of the RealMETRX research findings there will be an increased level of learner's confidence to significantly advance a novice's training to the level closer to an experienced provider and, additionally, that his/her performance is more predictive of positive patient/clinical outcomes after use of training on simulation systems that have integrated the proposed metrics and evaluation criteria. It is also expected that findings will shift simulation systems concentrating their assessments on tasks, skills, and procedures to those that encompass a broader and more holistic assessment of the entire patient.

- The outcomes of research supported by the FY16 JPC-1/MSIS RealMETRX Initiative Award are as follows (in no particular order):
A validated list supported by contacts, references, and sources that support the proposed methodologies that underpin the determination of the anticipated variables, metrics, and evaluation criteria.

A report, document, and list of the terminology and respective definitions used for the variables, metrics, and evaluation criteria and how they were deconstructed. Objective measurements are preferred, but subjective measurements that have rigorous reliability, repeatability, and robustness will be considered.

A report or document with the information and analyzed data of the actual postulated variables, metrics, and evaluation criteria that best fits the meaning of transitioning from training to practicing medicine.

The pilot study specific aims, methodologies, sample and sample size, inter-rater reliability, assessment criteria, analyzed results, conclusions, and potential next-step recommendations.

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), in addition to the local Institutional Review Board (IRB) of record. Local IRB 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. Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes. Refer to the General Application Instructions, Appendix 5, and the Human Subject Resource Document available on the eBRAP “Funding Opportunities & Forms” web page (https://ebrap.org/eBRAP/public/Program.htm) for additional information.

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. Principal Investigators (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 3 to 4 months for regulatory review and approval processes for animal studies. Refer to General Application Instructions, Appendix 5, for additional information.

The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 3, Section L.
C. Eligibility Information

- Independent extramural investigators at all academic levels (or equivalent) are eligible to submit applications.
- Intramural investigators are directed to apply through CDMRP eReceipt at https://cdmrp.org/Program_Announcements_and_Forms/.
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, nonprofit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is 30 months.
- The anticipated total costs budgeted for the entire period of performance will not exceed $1.6 million (M). Associated indirect costs can be budgeted in accordance with the organization’s negotiated rate. No budget will be approved by the Government exceeding $1.6M total costs or using an indirect rate exceeding the organization’s negotiated rate.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum 30 months.

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

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

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

May be requested for (not all-inclusive):

- Salary
- Research-related subject costs
- Clinical research 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

*This Program Announcement/Funding Opportunity is intended for extramural investigators only.* Intramural investigators are required to apply to the Metrics: Training Transition to Reality for Intramural Research Program Announcement/Funding Opportunity through CDMRP eReceipt at [https://cdmrp.org/Program_Announcements_and_Forms/](https://cdmrp.org/Program_Announcements_and_Forms/).

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. It is permissible for an intramural investigator to be named as a collaborator on an application submitted by an extramural investigator under this Program Announcement/Funding Opportunity. In such cases, the extramural investigator must include a letter from the intramural collaborator’s Commander or Commanding Officer that authorizes the involvement of the intramural collaborator.

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural agencies and other Federal agencies may be executed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR] or Funding Authorization Document [FAD] process). Direct transfer of funds from the recipient to a Federal agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.5. Research & Related Budget, for additional information on budget considerations for applications involving Federal agencies.

The JPC-1/MSIS expects to allot approximately $3.2M of the FY16 DHP MSIS appropriation to fund approximately two intramural and/or extramural JPC-1/MSIS RealMETRX Initiative Award applications, depending on the quality and number of applications received from intramural and extramural agencies and organizations. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program. NOTE: Applications received in response to both the RealMETRX intramural and extramural Program Announcements/Funding Opportunities will be evaluated and considered for funding together. The Government reserves the right to fund any combination of intramural and/or extramural applications.

II. SUBMISSION INFORMATION

Submission is a two-step process requiring both (1) pre-application submission through the electronic Biomedical Research Application Portal (eBRAP) ([https://eBRAP.org/](https://eBRAP.org/)) and (2) application submission through Grants.gov ([http://www.grants.gov/](http://www.grants.gov/)). Refer to the General Application Instructions, Section II.A. for registration and submission requirements for eBRAP and Grants.gov.
eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance. A key feature of eBRAP is the ability of an organization’s representatives and PIs to view and modify the Grants.gov application submissions associated with them. eBRAP will validate Grants.gov application files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in an email to the PI and in the Full Application Files tab in eBRAP. It is the applicant’s responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement/Funding Opportunity.

PIs should ensure that their name and email address are the same as the name and email address that will be provided on the SF-424 Form of the Grants.gov application package submitted to Grants.gov. The organization, Business Officials, PI(s), and eBRAP log number named in the full application submitted to Grants.gov must match those named in the pre-application in eBRAP.

Application viewing, modification, and verification in eBRAP is strongly recommended, but not required. The Project Narrative and Budget cannot be changed after the application submission deadline. Any other application component cannot be changed after the end of the application verification period.

A. Where to Obtain the Grants.gov Application Package

To obtain the Grants.gov application package, including all required forms, perform a basic search using the Funding Opportunity Number W81XWH-15-DMRDPM-MSIS-REALMETRX in Grants.gov (http://www.grants.gov/).

B. Pre-Application Submission Content

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

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

A change in PI or organization after submission of the pre-application may be allowed after review of a submitted written appeal (contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507) and at the discretion of the USAMRAA Grants Officer.

The pre-application consists of the following components, which are organized in eBRAP by separate tabs (refer to the General Application Instructions, Section II.B., for additional information on pre-application submission):
• **Application Information – Tab 1**

• **Application Contacts – Tab 2**
  - Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF-424 Form). The Business Official must either be selected from the eBRAP list or invited in order for the pre-application to be submitted.
  - It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

• **Collaborators and Key Personnel – Tab 3**
  - Enter the name, organization, and role of all key personnel (including co-investigators, mentors, collaborators, consultants, and subrecipients/subawardees) associated with the application.
  - Federal agency personnel involved in the review process and/or with making funding recommendations are prohibited from being involved in the research proposed or assisting in any pre-application, including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation.
  - JPC-1 Medical Modeling, Simulation, and Training Working Group members and advisors (listed in the Appendix) should not be involved in any pre-application or application. For questions related to the JPC-1 Medical Modeling, Simulation, and Training Working Group members and advisors and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

• **Conflicts of Interest (COIs) – Tab 4**
  - 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).

• **Pre-Application Files – Tab 5**

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

  **Preproposal Narrative (10-page limit):** The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.
The Preproposal Narrative should include the following:

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

- **Theoretical Rationale, Scientific Methods, and Research**
  - **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. Include research design, methods, and analysis/evaluation strategies as well as materials anticipated to be used during the research. If applicable, include a description of animal and/or human use in the proposed project. For studies involving animals and/or 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 how the proposed research is relevant to the goal of formulating variables, metrics, and evaluation criteria that will assist in transitioning from training to real medical practice with the overall goal of improving patient safety and healthcare outcomes in in public health systems, especially the military health system.
  - **Innovation:** Explain how the proposed project is innovative and not an incremental advancement of previous work.

- **Proposed Study Design/Plan:** Provide the intended research methodology that will support the pilot study. Provide information such as specific aims, methodologies, sample and sample size, inter-rater reliability, assessment criteria, analyzed results, conclusions, and potential next-step recommendations. Refer to Section I.B.1., for additional information on the research areas of interest for this Program Announcement/Funding Opportunity.

- **Military Impact:** Describe the anticipated short- and/or long-term outcomes of the proposed project and their potential impact on improving healthcare training and patient safety in the military health system. Refer to Section I.B.1., for additional information on the anticipated outcomes sought by this Program Announcement/Funding Opportunity.

- **Personnel and Facilities:** Describe the role for 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.

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

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

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

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

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

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

**Submit Pre-Application – Tab 6**
- This tab must be completed for the pre-application to be accepted and processed.

**Pre-Application Screening**

**Pre-Application Screening Criteria**

All pre-applications received in response to this Program Announcement/Funding Opportunity and those received in response to the RealMETRX intramural Program Announcement/Funding Opportunity will be screened by the JPC-1 Medical Modeling, Simulation, and Training Working Group members and advisors to determine technical merit and relevance to the mission of the DHP and JPC-1/MSIS. Pre-applications will be screened based on the following criteria, listed in descending order of importance:

- **Theoretical Rationale, Scientific Methods, and Research:** To what degree the research approach for accomplishing the specific aims is feasible, will accomplish the objectives, will provide information on proposed methods and analysis/evaluation strategies, and is based on sound rationale. To what degree the proposed work and research is derived from evidence-based, best-of-class, well-documented, and/or well-adopted designs to formulate variables, metrics, and evaluation criteria that would facilitate transition from training using simulation systems to that of medical practice.

- **Significance, Relevance, and Innovation:** To what degree the proposed research is relevant to the goal of delivering variables, metrics, and evaluation criteria that would best transition from training using simulation systems to that of medical
practice. To what degree the proposed work is innovative and novel, including whether the proposed research is duplicative of existing research.

- **Study Design/Plan:** To what degree the proposed pilot study methodologies, anticipated type of recruits, number of recruits, control group, anticipated assessment criteria, inter-rater reliability, and statistical protocols will justify and support the intended outcomes of the proposed research.

- **Military Impact:** To what degree the project’s anticipated short- and/or long-term outcomes will impact the military and a future training program in healthcare delivery and patient safety in the military health system in a way that is consistent with the program’s goals.

- **Personnel and Facilities:** 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. To what degree the prime facility will be able to perform the proposed research.

- **Budget:** The pre-application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted

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

C. **Full Application Submission Content**

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

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

Each application submission must include the completed Grants.gov application package provided in Grants.gov for this Program Announcement/Funding Opportunity. The Grants.gov application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (http://www.grants.gov/).

**Note:** *The Project Narrative and Budget Form cannot be changed after the application submission deadline.* If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or Budget Form needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID **prior to the application submission deadline**.
Grants.gov application package components: For the FY16 JPC-1/MSIS RealMETRX Initiative Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

1. **SF-424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

2. **Attachments Form**

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

   - **Attachment 1: Project Narrative (20-page limit):** Upload as “ProjectNarrative.pdf.” The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, 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 the ideas and reasoning behind the proposed research; include relevant literature citations, preliminary data, previous highly regarded metrics/evaluation criteria and the justification for use, and/or other evidence that led to the development of the proposed study. Describe previous experience most pertinent to this project. Any preliminary data, if available, should be from the laboratory of the PI or member(s) of the collaborating team. Clearly support the choice of study variables and explain the basis for the study questions and/or study hypotheses. Establish the relevance of the study and explain the applicability of the proposed findings.

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

   - **Specific Aims:** Concisely explain the project’s specific aims. If this application is part of a larger study, present only tasks that this award would fund.
○ **Study Design:** Proposed pilot studies should be at least 6 months in duration. Describe the experimental design, methods, and analyses/evaluations in sufficient detail for analysis.

  - Identify and describe the hypothesis to be studied and the projected outcome of the proposed research.
  
  - Define the study variables and describe 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 a plan for data access.
  
  - Address any potential barriers and plans for addressing potential delays. Provide a risk management plan to address barriers to plans. As relevant, describe plans for addressing issues unique to working within the military health system.
  
  - 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.

*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.*

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

For animal studies, allow at least 3 to 4 months for regulatory review and approval by the USAMRMC ACURO; this does not include the additional time required for local IACUC review and approval.

Refer to the General Application Instructions, Appendix 5, 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: 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.
- Publications and/or Patent Abstracts (five-document limit): Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then a copy/copies of the published manuscript(s) must be included in Attachment 2. Extra items will not be reviewed.
- 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.
- Letters of Organizational Support: Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. (Letters of support not requested in the Program Announcement/Funding Opportunity, such as those from members of Congress, do not impact application review or funding decisions.)
- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. **If the project involves collaboration with a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity facility)**
embedded with a civilian medical center), special requirements apply. A 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. (Refer to the General Application Instructions, Section II.C.8, for additional information.)

○ Intellectual Property
  - Background and Proprietary Information: All software and data first produced under the award are subject to a Federal purpose license. Provide a list of all background intellectual property to be used in the project or provide a statement that none will be used. If applicable, state and identify the proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the Federal purpose license. 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 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 between architecture or model and other systems.

  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations. Identify which potential components will be open source/open architecture versus proprietary in the proposed framework, design, and/or plan of a possible biopsychosocial training model and how the proposed model would integrate/communicate with other systems.

  - Commercialization Strategy (if applicable): Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.

○ 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 3, Section L for more information about the CDMRP expectations for making data and research resources publicly available.


  Abstracts of all funded applications may be publicly posted; therefore, proprietary information should not be included in the abstract.
The technical abstract should be clear and concise and, at a minimum, provide the following information:

- **Background:** Provide a brief statement of the ideas and theoretical reasoning behind the proposed work.
- **Objective/Hypothesis:** State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- **Specific Aims:** State concisely the specific aims of the study.
- **Study Design:** Briefly describe the study design.
- **Impact:** Provide a brief statement explaining the potential relevance of the proposed work to improving patient safety and healthcare outcomes in the military health system and/or to the general public.

- **Attachment 4: Lay Abstract (one-page limit):** Upload as “LayAbs.pdf.” Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. Not required at this time. Leave Attachment 4 space blank.

- **Attachment 5: Statement of Work (SOW) (two-page limit):** Upload as “SOW.pdf.” The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & Forms” web page (https://ebrap.org/eBRAP/public/Program.htm). For the JPC-1/MSIS RealMETRX Initiative Award mechanism, use the SOW format example titled “SOW Generic.” The SOW must be in PDF format prior to attaching. Refer to the General Application Instructions, Section II.C.3., for detailed guidance on creating the SOW.

- **Attachment 6: Outcomes and Impact Statement (one-page limit):** Upload as “Impact.pdf.” Explain in detail why the proposed research project is important, as follows:
  - **Short-Term Impact:** Describe the anticipated outcome(s)/results(s), design, and/or plan that will be directly attributed to the results of the proposed research.
  - **Long-Term Impact:** Describe the anticipated long-term gains from the proposed research, including the long-term anticipated advantages that the new understanding may ultimately contribute. Articulate how the anticipated outcomes will contribute to provide variables, metrics, and evaluation criteria that best fit the meaning of transitioning from training to medical practice. Explain how the anticipated outcomes will help patients have increased confidence that their future healthcare providers see them as a whole individual instead of as a procedure or disease.
  - **Military Relevance:** Clearly articulate how the proposed research is relevant to the goal of enhancing team performance in delivery of variables, metrics, and evaluation criteria that best fit the meaning of transitioning from training to medical practice. State precisely the estimates as to the immediate and/or long-
range usefulness of this study to the Armed Forces, as distinguished from general advancement of knowledge in medicine.

○ **Public Purpose:** Provide a concise, detailed description on how this research 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: Collaborating DoD Military Facility Budget Form(s), if applicable:** Upload as “MFBudget.pdf.” If a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the Collaborating DoD Military Facility Budget Form (available for download on the eBRAP “Funding Opportunities & Forms” web page), including a budget justification, for each Military Facility as instructed. Refer to the General Application Instructions, Section II.C.8., for detailed information.

3. **Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.4., for detailed information. Note: Some of the items in this attachment may be made available for programmatic review.

- 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 National Institutes of Health Biographical Sketch may also be used.

- 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.”

4. **Research & Related Budget:** Refer to the General Application Instructions, Section II.C.5., for detailed information.

- Budget Justification (no page limit): Upload as “BudgetJustification.pdf.” The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.
5. **Project/Performance Site Location(s) Form**: Refer to the General Application Instructions, Section II.C.6., for detailed information.

6. **R & R Subaward Budget Attachment(s) Form (if applicable)**: Refer to the General Application Instructions, Section II.C.7., for detailed information.

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

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of an application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant’s responsibility to review all application components and ensure proper ordering as specified in the Program Announcement/Funding Opportunity. *If either the Project Narrative or the budget fails eBRAP validation, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID prior to the application submission deadline.* The Project Narrative and Budget Form cannot be changed after the application submission deadline.

**E. Submission Dates and Times**

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

**F. Other Submission Requirements**

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

All applications must be submitted through Grants.gov. Applicant organizations and all subrecipient organizations must have a Data Universal Numbering System (DUNS) number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the system for Award Management (SAM) with an “Active” status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Section II.A., for information on Grants.gov registration requirements.

**III. APPLICATION REVIEW INFORMATION**

**A. Application Review and Selection Process**

All applicants are evaluated by scientists, clinicians, and consumer advocates using 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 Office of the Assistant
Secretary of Defense for Health Affairs, based on (a) technical merit and (b) the relevance to the mission of the DHP, JPC-1/MSIS, and to the specific intent of the award mechanism. The highest-scoring applications from the first tier of review are not automatically recommended for funding. 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 scored criteria, which are listed in decreasing order of importance:

   • **Theoretical Rationale and Scientific Methods**
     - How well the rationale for the proposed study is supported by preliminary data (if provided), critical review and analysis of the literature, previous highly regarded metrics/evaluation criteria and the justification for use, and/or other evidence-based information/data that supports the proposed research, methods, and anticipated outcomes.
     - How well the study aims, hypotheses or objectives, experimental design, methods, and analyses are designed to clearly answer the research questions.
     - Whether the proposed research and work provides a listing of evidence-based definitions, nomenclature, or lexicon that supports the proposed methodologies on determining which metrics/evaluation criteria should be investigated and why.
     - How well the proposed specific aims, methodologies, sample and sample size, inter-rater reliability, assessment criteria, analyzed results, conclusions, and potential next-step recommendations, 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. Pilot studies should be at least 6 months in duration.
     - Whether there is evidence of an adequate contingency plan, such as a risk mitigation plan, to resolve potential delays.
• **Relevance, Innovation, and Impact**
  o How the proposed research is relevant to the goal of enhancing metrics/evaluation criteria that best transition from training to medical practice.
  o How the proposed work is innovative and novel, including whether the proposed research is duplicative of existing research.
  o To what degree the proposed plan will enable medical educators to identify the best metrics that transition to reality and have confidence that the learners have significantly advanced to a more experienced level, have advanced to having more predictable positive patient/clinical outcomes, and that patients have increased confidence that their future healthcare providers see them as a whole individual instead of as a procedure or disease.
  o To what degree the anticipated short- and long-term outcomes resulting from the proposed study will contribute to the goal of improving patient safety and healthcare outcomes in public health systems, especially the military health system.

• **Personnel and Facilities**
  o How the composition and balance of the research team (including other organization personnel, subawards, and consultants, as applicable) are appropriate.
  o To what degree the PI’s and research team’s backgrounds and expertise are appropriate and complementary to accomplishing the proposed work.
  o To what degree the levels of effort by the PI and other key personnel are appropriate to ensuring the success of the proposed research.
  o To what degree the research environment and the accessibility of institutional resources support the proposed study (including collaborative arrangements).
  o Whether there is evidence for appropriate institutional commitment.
  o If applicable, to what degree the intellectual property plan is appropriate.
  o If applicable, to what degree the commercialization plan is appropriate.

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

• **Budget**
  o Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
  o Whether the proposed timeline is appropriate and tasks outlined in the application are logical in their progression.

• **Intellectual Property and Commercialization Plan**
  o If applicable, to what degree the intellectual property plan is appropriate.
  o If applicable, to what degree the commercialization plan is appropriate.
Application Presentation

- To what extent the writing, clarity, and presentation of the application components influence the review.

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

a. Ratings and evaluations of the peer reviewers

b. Relevance to the mission of the DHP and JPC-1/MSIS, as evidenced by the following:
   - Adherence to the intent of the award mechanism
   - Programmatic relevance and program portfolio balance
   - Relative impact, innovation, and novelty
   - Degree of public accessibility of outcomes
   - Military relevance

C. Recipient Qualification

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

D. Application Review Dates

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

E. Notification of Application Review Results

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

IV. ADMINISTRATIVE ACTIONS

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

A. Rejection

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

- The pre-application is submitted by an intramural organization.
- Preproposal Narrative is missing.
The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds 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 Preproposal Narrative and Project Narrative.
- Documents not requested will be removed.

C. Withdrawal

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

- A FY16 JPC-1 Medical Modeling, Simulation, and Training Working Group member or advisor 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 JPC-1 Medical Modeling, Simulation, and Training Working Group members and advisors can be found in the Appendix.
- 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).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The application budget differs significantly from the budget included in the pre-application.
- The invited application does not propose the same research project described in the pre-application.
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 the USAMRAA Grants Officer for a determination of the final disposition of the application.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2017. Refer to the General Application Instructions, Appendix 3, for additional award administration information.

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

B. Administrative Requirements

Refer to the General Application Instructions, Appendix 3 for general information regarding administrative requirements.

C. National Policy Requirements

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

D. Reporting

Refer to the General Application Instructions, Appendix 3, Section I, for general information on reporting requirements.

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

E. Award Transfers

Refer to the General Application Instructions, Appendix 3, Section M, for general information on organization or PI changes.
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 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

B. Grants.gov Contact Center

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

   Phone: 800-518-4726
   Email: support@grants.gov

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

<table>
<thead>
<tr>
<th>Grants.gov Application Components</th>
<th>Upload Order</th>
<th>Action</th>
<th>Completed</th>
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<tbody>
<tr>
<td>SF-424 (R&amp;R) Application for Federal Assistance</td>
<td></td>
<td>Complete form as instructed.</td>
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</tr>
<tr>
<td>Attachments Form</td>
<td>1</td>
<td>Project Narrative: Upload as Attachment 1 with file name “ProjectNarrative.pdf.”</td>
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<td></td>
<td>2</td>
<td>Supporting Documentation: Upload as Attachment 2 with file name “Support.pdf.”</td>
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<td></td>
<td>3</td>
<td>Technical Abstract: Upload as Attachment 3 with file name “TechAbs.pdf.”</td>
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<td>Lay Abstract: Not required; leave Attachment 4 blank.</td>
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<td>Statement of Work: Upload as Attachment 5 with file name “SOW.pdf.”</td>
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<td>6</td>
<td>Outcomes and Impact Statement: Upload as Attachment 6 with file name “Impact.pdf.”</td>
<td></td>
</tr>
<tr>
<td></td>
<td>7</td>
<td>Innovation Statement: Upload as Attachment 7 with file name “Innovation.pdf.”</td>
<td></td>
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<tr>
<td></td>
<td>8</td>
<td>Collaborating DoD Military Facility Budget Form(s): Upload Attachment 8 with file name “MFBudget.pdf,” if applicable.</td>
<td></td>
</tr>
<tr>
<td>Research &amp; Related Senior/Key Person Profile (Expanded)</td>
<td></td>
<td>Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.</td>
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</tr>
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<td></td>
<td></td>
<td>Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.</td>
<td></td>
</tr>
<tr>
<td>Research &amp; Related Budget</td>
<td></td>
<td>Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.</td>
<td></td>
</tr>
<tr>
<td>Project/Performance Site Location(s) Form</td>
<td></td>
<td>Complete form as instructed.</td>
<td></td>
</tr>
<tr>
<td>R &amp; R Subaward Budget Attachment(s) Form</td>
<td></td>
<td>Complete form as instructed.</td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX:
JPC-1/MSIS WORKING GROUP MEMBERS AND ADVISORS

List of FY16 JPC-1 Medical Modeling, Simulation, and Training Working Group Members and Advisors:

<table>
<thead>
<tr>
<th>CAPT Arthur Anthony</th>
<th>LTC (P) Dan Irizarry</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mr. Wilson Ariza</td>
<td>CDR Typhanie Kinder</td>
</tr>
<tr>
<td>LTC Jay Baker</td>
<td>Ms. Heidi King</td>
</tr>
<tr>
<td>SGM F. Young Bowling</td>
<td>Dr. Kevin Kunkler</td>
</tr>
<tr>
<td>Mr. Paul Chatelier</td>
<td>Dr. Lori Loan</td>
</tr>
<tr>
<td>COL Tamara Crawford</td>
<td>Dr. Joseph Lopreiato</td>
</tr>
<tr>
<td>LTC(P) Shad Deering</td>
<td>Dr. Haru Okuda</td>
</tr>
<tr>
<td>LTC Dawn Fitzhugh</td>
<td>Dr. Ray Perez</td>
</tr>
<tr>
<td>Col Meletios Fotinos</td>
<td>Ms. M. Beth Pettitt</td>
</tr>
<tr>
<td>COL Denise Hopkins-Chadwick</td>
<td>LTC(P) Christopher Todd</td>
</tr>
</tbody>
</table>

Submissions that include a JPC-1/MSIS Working Group member or advisor as an investigator, consultant, collaborator, or in a key personnel role will be administratively withdrawn and not considered.
NOTE:

This program is open to Army Medical Department (AMEDD) personnel only. Collaboration with industry, academia and other military services is permitted, however the Submitter must be an AMEDD person and the funding must go to an AMEDD facility or command.

Instructions on How to Create Your AAMTI Account

To create your account you will need to complete the System Authorization Access Request (SAAR), Form DD2875. The SAAR must be completed and an electronic copy emailed to: willie.e.wright.ctr@mail.mil and AAMTI_PMs@TATRC.ORG. A PDF can be downloaded from the TATRC website at http://www.tatrc.org/www/labs-and-programs/aamti/. There are instructions on how to complete this document attached with the download. In addition there are parts of this document that will need to be completed by your on post security officer. Your account will be generated within 2 to 4 business days. When completing this form please make special note of item 9 where you will enter your email address. Only .mil addresses allowed as this will be the primary form of contact with you.
PREFACE

The AMEDD Advanced Medical Technology Initiative (AAMTI) plays a vital role in identifying solutions to medical problems of importance to the American war fighter at home and abroad. Through this program Army Medical Department leaders have the resources to conduct advanced technology development, demonstration and validation of important new technologies that can enhance the ability of the U.S. Army component of the TRICARE system to address emerging Force Health Protection requirements.

This document defines policy and procedure for the execution of the FY2016 program. The FY2016 program will enhance the management, accountability and reporting of medical technology demonstrations. The execution plan incorporates a Request for Submission (RFS), with two layers of submission and evaluation. The initial submission will be in the form of a Pre-proposal. Each submission will be evaluated based upon scientific/technical, medical, and military applicability. Those submitters whose proposals are deemed to be of greatest importance/interest will be invited to submit a full proposal, which will be evaluated by an AAMTI Vision Setting Panel.

Included within this RFS is a general description of the AMEDD Advanced Medical Technology Initiative, including specific areas of interest; the evaluation and selection criteria; and submission preparation instructions and formats. Submission eligibility is limited to AMEDD organizations. Any amendments of this submission system will be advertised on this site.

Questions concerning the preparation of submissions can be emailed to the AAMTI PM: Mr. John Winston (john.p.winston2.ctr@mail.mil). Telephonic inquiries can be made by calling 301-619-7674. The appropriate mailing address is:

U.S. Army Medical Research and Materiel Command
Telemedicine and Advanced Technology Research Center
ATTN: MCMR-TT
Mr. John Winston
504 Scott Street
Fort Detrick, MD 21702-5012
U.S. Army Medical Research and Materiel Command
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I. PROGRAM OVERVIEW

The objectives of the AMEDD Advanced Medical Technology Initiative are to increase beneficiary access to healthcare, improve the quality and safety of healthcare, improve force readiness, and reduce the cost of delivering healthcare.

To achieve these objectives, candidate advanced medical technology projects are subjected to a two-tiered evaluation process. This process includes submission of project Pre-proposals, peer evaluation of pre-proposals, invitation to submit full proposals for selected projects, full proposal evaluation and final selection.

FUNDS FOR THIS PROGRAM ARE DHP O&M (P8) DOLLARS AND ALL FUNDS MUST BE OBLIGATED NO LATER THAN COB 30 SEPTEMBER 2015. FINAL REPORTS ARE DUE EIGHTEEN (18) MONTHS AFTER FAD/MIPR OF FUNDS TO THE RECEIVING ORGANIZATION.

TATRC monitors the progress of funded projects throughout execution. A Final Report MUST be submitted electronically in accordance with guidance provided after project funding. The final results may be presented to a MEDCOM senior officer panel at a time and location to be determined. Each funded site is responsible for all costs related to this presentation, to include (but not limited to) travel, lodging, per diem, etc. TATRC will evaluate final reports and formulate recommendations for The Surgeon General (TSG) of the U.S. Army. The TSG will decide which project(s) has potential for incorporation into the operational Army medical department setting.

Please note: This program is designed to foster and encourage new projects that reflect "medical technology entrepreneurship”. OMA or acquisition efforts are not eligible for this program and will not be considered. Infrastructure, equipment, personnel, etc should be obtainable in a reasonable amount of time from the award date.

II. FY2016 PROGRAM AREAS OF INTEREST

The scope of the FY2016 program includes identification, exploration, and demonstration of key technologies and enabling biomedical principles required to overcome technological barriers that are medically and militarily unique. The goals of this effort are to: 1) provide technologies needed to enhance full spectrum force health protection and readiness; 2) reduce the cost of delivering care; 3) reduce the time it takes to access care and critical specialty intervention; 4) improve the skills and efficiency of care providers; and 5) improve the quality and safety of care throughout the TRICARE healthcare continuum.

Achieving these goals will require the application of existing and emerging technologies to health-related problems, as well as the integration of medical technology with other DoD modernization initiatives in the areas of information systems and telecommunications. As a result, submissions are sought in the following areas:
A. **Clinical Applications**

The FY2016 program seeks a broad range of clinical submissions. All manner of clinical submissions are encouraged. In the final analysis, funding will depend on matching the technology to appropriate clinical needs across the axis of cost, access, quality, and safety of care. Broadly defined, successful submissions will feature the use of clinically relevant procedural protocols and technology to improve cost, access, quality, and safety of care and force readiness. **Implied in the above is the requirement that any IM/IT technologies demonstrated through this program must be able to interface with appropriate enterprise solutions.**

B. **Medical Informatics**

The FY2016 program seeks a broad range of medical informatics submissions. These submissions will include, but are not limited to, proposals that leverage healthcare information technologies to streamline and enhance the documentation of medical encounters, allow the content of diverse, heterogeneous databases of medical information to be queried for research into evidence based medicine, information analysis that leads to better disease management, the integration of speech recognition technology into the health care delivery environment, and development and demonstration of novel approaches to the acquisition, fusion, distribution and interfacing with medical information. Of particular interest are medical informatics technologies that facilitate individual and aggregate predictive diagnostics that utilize tailored, natural language information and object oriented, intelligent agents for search and retrieval of medical data and wireless medical applications that provide access to practice guidelines, patient confirmation, learning tools and other medical information. Submissions that utilize advanced medical modeling and simulation to provide senior leaders with the capability to perform what if analysis of the impact of technology on the performance of complex integrated health care delivery networks are encouraged. **Any technologies (if applicable) demonstrated through this program must be able to interface with enterprise level solutions.**

C. **FY2016 Areas of Particular Interest**

For FY2016, the following areas are of particular interest:

- Demonstration/Development of technologies that improve education for both patients and providers.

- Applications involving the use of cell phones and other ubiquitous technologies to:
  - Deliver care
  - Monitor patients
  - Provide patients with information

- Integration of clinical functionality into AHLTA.
• Demonstration of technologies that support/enable medical care to remote and underserved populations within the AMEDD.

• Demonstration of technologies that reduce the administrative burden associated with the provision of care in the AMEDD and support efforts to improve the safety of care and force readiness.

• Tele-Surgical applications to include real-time surgical consultation from theatre, telementoring (using theatre surgeries), consultation and telementoring between and among AMEDD medical facilities and activities.

III. GENERAL INFORMATION

A. USAMRMC FADs and MIPRs

The USAMRMC will support the execution of this demonstration program by transferring funds to selected AMEDD organizations via FADs or MIPRs. A submitter must submit a pre- and (if invited) a full proposal through, and be employed by, an AMEDD organization to receive support. Contractors are not eligible to submit pre- or full proposals and may not act as a project lead.

A recipient should meet certain minimum standards pertaining to institutional support, financial resources, prior record of performance, integrity, organization, experience, operational controls, facilities, etc. Additionally, a full proposal submitter must include a list of infrastructure, equipment, personnel and subjects that would have to be acquired with an estimated time needed to acquire each. There should also be a disclosure of how soon the project could start from the provision of funds, based upon the above acquisition requirements. The local IMO and 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. Conflict of Interest

Submitters are cautioned that awards are made to institutions. Should the lead of a funded project leave the recipient institution, contact the AAMTI Program Manager as soon as possible to discuss transition to a new project lead.

C. Preparation of Submissions

The AAMTI does not fund preparation of submissions.
D. Information Service

Submitters may contact the AAMTI Program Office (AAMTI_PMs@tatrc.org) to acquire information regarding existing research to avoid duplication of scientific and engineering efforts.

E. Two-Tiered Submission Process

1) Pre-proposal Submission Preparation

Submissions will be made according to a two-tiered process. Initial submissions will be in the form of an online pre-proposal submission system. Pre-proposals may be submitted by any who meet the submission eligibility requirement: the submitter must be an AMEDD employee (employed at an AMEDD facility/activity). Upon evaluation of the pre-proposals by AMEDD representatives, pre-proposals that merit further exploration will be invited for further consideration via the submission of a full proposal. Full proposal submission is by invitation only based upon that decision.

All pre-proposals will be assigned an identification number after receipt. Brochures or other descriptions of general organizational or individual capabilities will not be accepted as a submission. The submitter should receive a decision letter or electronic mail on the submission within 30 to 45 days of the closing date of the pre-proposal submission period. A copy of the electronic pre-proposal submission form can be found below.

2) Pre-proposal Submission Form

Proposal Title: [Limit to 120 characters]

Principle Investigator: (Last Name, First Name, Degree, Specialty, Duty Title, Corps, Military Rank)
AMEDD Facility:
AMEDD Address:
Day Phone:
FAX:
E-mail:

Secondary Organizational POC: (Last Name, First Name)
Day Phone:
E-mail:

Cost: [Estimated cost]

Short Description: [Abstract LIMIT-1000 HTML CHARACTERS]
Project Purpose and Deliverables: [What is the purpose of this project and what will be the final deliverables? CONOPS- to include skillsets, specific personnel, program process, sites to be included, etc. Identify the significant milestones that must be met (IMIT issues, approvals for content and access, etc.) Identify the benefit in terms of impact on Cost, Access, Quality, and Safety of Care]

Problem Being Addressed/including Literature Support: [What is problem we are trying to solve (to include prevalence/severity)? LIMIT-7500 HTML CHARACTERS]

Military Relevance: [How is this relevant to Military Medicine? LIMIT-7500 HTML CHARACTERS]

Methods (to include Human/Animal Use): [What methods will be used to complete this study? Will there be any human or animal use? If so, explain. LIMIT-7500 HTML CHARACTERS]

Description of Metrics/Outcome Measures: [What metrics will you be using to prove your methods? Identify the ultimate goal and the next step towards that goal (assuming initial success through the AAMTI). LIMIT-7500 HTML CHARACTERS]

Infrastructure, Equipment, Personnel, and Subjects Needed: [What are the resources needed for this project? Provide detail regarding budget and required sub-contracts. LIMIT-7500 HTML CHARACTERS]

Partner Institutions: [Identify any other partners. LIMIT-7500 HTML CHARACTERS]

3) Full Proposal Submission Preparation

Upon evaluation and scoring by an AMEDD peer panel, those pre-proposals that merit further consideration will be invited for full proposal submission. Full proposal submission is by invitation only. The full proposals will be submitted via the same secure web site used for the pre-proposal submission. The submitter should receive a decision letter or electronic mail within 45 to 60 days of the closing date of the full proposal submission period. A copy of the full proposal submission form can be found below.
4) **Full Proposal Submission Form**

Proposal Title: [Same as Pre-proposal]

Cost:

Period of Performance Start and End Dates:

Problem to be Addressed: [LIMIT-7500 HTML CHARACTERS]

Military Relevance: [How will the military benefit, what military requirements does it address? LIMIT-7500 HTML CHARACTERS]

Technology to be demonstrated: [What is the technology, what is your study/demonstration design? LIMIT-7500 HTML CHARACTERS]

Significance and/or Uniqueness of the Demonstrated Technology: [LIMIT-7500 HTML CHARACTERS]

Metrics to be used to Prove Efficacy: [How do you intend to measure the success of the proposed demonstrations? What criteria will be used and how will the data be measured, verified and analyzed? LIMIT-7500 HTML CHARACTERS]

Participating Personnel & Man Hours: [Name, Title, Role, Effort (%)]

Expected Time from Award to Commencement (from receipt of funds): [When will you be able to start once funds are provided? LIMIT-7500 HTML CHARACTERS]

Institutional Evaluation Board (IRB) and Regulatory Oversight: [What are the human or animal use issues attendant to this project? Have you established a plan to deal with these issues? Show that you are aware of, and are prepared to address, any human/animal use issues as part of your IRB approval requirement. LIMIT-7500 HTML CHARACTERS]

Human Use: [Y/N]
Animal Use: [Y/N]

Information Management Office and Commander Concurrence: [Have you notified the IMO and Commander's office regarding the proposal? Has IMO confirmed that the technical infrastructure exists to allow for success for completion of this project? Is your Commander aware of the project and it's time requirements should you be funded?]}

PI's Curriculum Vitae: [One page]

Partner Institutions: [LIMIT-7500 HTML CHARACTERS]
Will this project require time to completion beyond the proposed work and Period of Performance? If so, how much time?: [LIMIT-7500 HTML CHARACTERS]

Impact: [What is the expected impact of the technology or system being demonstrated and is it a local, regional, MEDCOM–wide, or MHS-wide impact? LIMIT-7500 HTML CHARACTERS]

Literature Search: [List all sources used to research this technology. LIMIT-7500 HTML CHARACTERS]

Contracting POC: (If funds are to be executed by your Resource Management office provide the RM POC contact information-Name, Day Phone, Email)

DoDAAC [for WAWF/invoice payments]

Have you received previous AAMTI funding for a related project?: [Y/N, if yes, provide title and PI.]

Budget: [A budget link, located at the bottom of your proposal page opens an Excel spreadsheet to be used to itemize your budget elements. The total cost provided by these budget items should equal the total for your proposal.]

F. Evaluation and Selection

1) Request for Pre-proposal Submissions

The AMEDD Advanced Medical Technology Initiative will be conducted as a single funding effort. To allow additional flexibility, partnerships between the civilian sector and AMEDD institutions and personnel are permitted. However, all submissions must be submitted by an AMEDD organization.

2) Two-Tier Evaluation Process

All pre-proposals will be evaluated for scientific merit and relevance to military medical programs using the following criteria: military and program relevance, objectives, and scientific excellence. A panel of AMEDD personnel representing various AMEDD activities will evaluate each pre-proposal. Full proposals will be invited for proposals that merit further evaluation. Full proposals will be evaluated for consistency with the pre-proposal by a panel of AMEDD personnel using the following criteria: military and program relevance, proposed objective, scientific excellence, potential for AMEDD-wide adoption, and metrics. Awards will also be dependent upon adequate demonstration by the applicant that they have considered administrative issues related to interfaces with legacy systems or enterprise solutions (existing and planned), research involving human subjects/anatomical substances, research involving animals, etc.. As a consequence, awardees should initiate IRB procedures in accordance with their
local command authority standard operating procedures at their earliest convenience. Once local IRB approval is received, the Clinical Investigations Research Office (CIRO) will evaluate the approval and protocol. **A funded project may not enroll subjects until CIRO has evaluated and approved the local IRB approval and documentation.**

3) **Schedule**

The Director, TATRC, will retain authority for final source selection, execution of procurement actions and subsequent program management. TATRC will execute the program in accordance with the following milestones (dates subject to change):

<table>
<thead>
<tr>
<th>Date(s)</th>
<th>Milestone</th>
</tr>
</thead>
<tbody>
<tr>
<td>3 FEB 2015</td>
<td>Opening Date for Pre-Proposal Submission</td>
</tr>
<tr>
<td>3 JUN 2015</td>
<td>Closing Date for Pre-Proposal Submissions</td>
</tr>
<tr>
<td>8 JUN – 13 JUL 2015</td>
<td>Pre-Proposal Evaluation</td>
</tr>
<tr>
<td>20 JUL 2015</td>
<td>Opening Date for Full Proposal Submissions (Invitation Only)</td>
</tr>
<tr>
<td>20 AUG 2015</td>
<td>Closing Date for Full Proposal Submissions</td>
</tr>
<tr>
<td>29 SEP 2015</td>
<td>Full Proposal Evaluation Order of Merit List Prepared</td>
</tr>
<tr>
<td>TBD</td>
<td>Funding Recommendation Approved</td>
</tr>
</tbody>
</table>

4) **Evaluation Factors**

Submissions will be evaluated by an AMEDD panel for scientific/technical merit and military relevance using the factors listed below.

(a) **Pre-proposal Evaluations**

Military and Program Relevance
- Does the Pre-proposal clearly address a relevant and significant military-related problem that can be solved by the technology to be demonstrated?
- Does the proposed project meet stated AMEDD Areas of Interest as mentioned in the above descriptions?

Project Objective
- Is the stated objective clear, valid, and logical?
- Is the technology or system to be demonstrated innovative?

Scientific Excellence
- Does the work merit further evaluation via a Full Proposal?
- Is there potential for AMEDD-wide adoption?
• Are the identified metrics potentially capable of supporting an AMEDD-wide deployment decision?

(b) Full Proposal Evaluations

Military and Program Relevance:
• Does the Pre-proposal clearly address a relevant and significant military-related problem that can be solved by the technology to be demonstrated?
• Does the proposed project meet stated AMEDD Areas of Interest as mentioned in the above descriptions?

Proposed Objective
• Is the stated objective clear, valid and logical?
• Is the project innovative?

Scientific Excellence
• Are the plans, methods, techniques and procedures feasible, clear, valid, adequately referenced and state-of-the-art?
• Has the PI identified vigorous metrics to prove success?

Qualifications
• Are the qualifications, capabilities, and experience of the proposed PI and other key personnel sufficient to achieve the proposed objectives?

Facilities
• Are the proposed facilities and equipment, or unique combinations of these, adequate for the proposed objectives?

G. Award Administration

1) Information Release

Recipients are required to agree to the release of information pertaining to the research and development supported by the USAMRMC instrument. Statements (a) and (g) shall be included in all such releases; Statements (b)-(f) shall be included if relevant to the project being conducted:

(a) "This work was supported by the US Army Medical Research and Materiel Command. Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the US Army."

(b) "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, forms and descriptions as outlined in Appendix 10.

(c) "In conducting research using humans and/or human anatomical substances, the investigator is required to include approvals, forms, and descriptions as outlined in Appendix 9 of this announcement."

(d) "In the conduct of research utilizing recombinant DNA, the investigator adhered to NIH Guidelines for research involving recombinant DNA molecules (http://www.nih.gov/od/orda/toc.htm)."

(e) "In the conduct of research involving hazardous organisms, the investigator adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories (http://www.cdc.gov/od/ohs/biosfty/bmbl/bmbl-l.htm)."

(f) "Information" includes, and is not limited to, new releases, articles, manuscripts, brochures, advertisements, still and motion pictures, speeches, trade association meetings and symposia.

(g) “This work was funded by the AMEDD Advanced Technology Initiative (AAMTI), through the Telemedicine and Advanced Technology Research Center (TATRC)."

2) Freedom of Information Act Requests

The Freedom of Information Act (FOIA) (5 USC 552) provides a statutory basis for public access to official Government records. "Records" are defined to include documentation received by the government in connection with the transaction of public business. Records must be made available to any person requesting them unless the records fall under one of nine exceptions to the Act (http://www.aclu.org/library/foia.html). When a FOIA request asks for information contained in a successful Submission that has been incorporated into an award document, the submitter will be contacted and given an opportunity to object to the release of all or part of the information that was incorporated. A valid legal basis must accompany each objection to release. Each objection will be evaluated by USAMRMC in making its final determination concerning which information is or is not releasable. If information requested is releasable, the submitter will be given notice of USAMRMC’s intent to release and will be provided a reasonable opportunity to assert available action.

3) Site Visits

The USAMRMC Program Manager may, at his or her discretion, visit each funded project site during the project lifecycle.
4) Reporting Requirements

Participation in this program will require the timely delivery of reports during the effort. The award instrument will state the necessary reports that are due to TATRC. Reports should be submitted in an email attachment to the Programmatic POCs (contact information is listed below). The report templates are given in the attached appendices.

(a) Types of Reports

Interim Report: The interim report shall provide a brief, factual, and informal overview (positive or negative) of the project. The report is due halfway through the project, which is approximately nine months from the date of funding. A template can be found in Appendix A.

Final Report: The final report shall provide a complete summary of the project's results (positive or negative). The report shall be of sufficient length to provide a thorough description of the work including accomplishments and future initiatives. The report is due at the completion of the project, which is approximately 18 months from the date of funding. A template can be found in Appendix B.

[Optional] Project Update Report: At the discretion of the AAMTI Program Manager, a project update report may be requested. A project update report shall provide a brief, factual, and informal overview (positive and negative) of the project. The report will typically be requested between the mid-term and final report, and submitted in a timely manner to the Program Manager. A template can be found in Appendix C.

[Optional] Final Presentation: A final presentation may be required at a time and place to be determined. This presentation (if scheduled) would typically occur in the calendar year following the obligation date of project funds, thus each funded AMEDD Activity will be responsible for all costs associated with the final presentation.

(b) Reporting Schedule

<table>
<thead>
<tr>
<th>Report Type</th>
<th>Requirement</th>
<th>Due Date (est.)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Interim report</td>
<td>REQUIRED</td>
<td>JUL 2016</td>
</tr>
<tr>
<td>Final report</td>
<td>REQUIRED</td>
<td>APR 2017</td>
</tr>
<tr>
<td>Project update</td>
<td>As requested by the PM</td>
<td>TBD</td>
</tr>
</tbody>
</table>
5) **Project Management Files**

All correspondence related to the submission, evaluation, selection, and execution of projects will be maintained by the TATRC. Questions regarding official project management files should be sent to AAMTI_PMs@tatrc.org.

6) **Programmatic POCs**

Program Manager: Mr. John Winston (john.p.winston2.ctr@mail.mil)
Assistant Program Manager: Ms. Sharon Garlena (sharon.garlena.ctr@mail.mil)
Appendix A: Interim Report Template

AMEDD ADVANCED MEDICAL TECHNOLOGY INITIATIVE (AAMTI)

INTERIM REPORT

Title:

FY:

Principal Investigator (PI):
PI Email:
PI Phone:

Co-Investigator (Co-PI):
Co-PI Email:
Co-PI Phone:

PI Organization:

Report Date:

Type of Report: Interim

Prepared for: U.S. Army Medical Research and Materiel Command (USAMRMC), Telemedicine and Advanced Technology Research Center (TATRC), Fort Detrick, Maryland 21702-5012

Distribution Statement: Approved for Public Release; Distribution Unlimited

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Principal Investigator Signature:___________________________________________

Date:________________________________________________________________
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      i. What is the status of your funding obligations? Are there any issues?
      ii. Do you have the necessary contract(s) in place for your project? If yes, please forward a copy to the Program Manager.
      iii. Provide a budget showing expenditures to date, planned expenditures, and remaining funds.
   c. Personnel:
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      ii. Who is the back-up POC?
   d. Protocol:
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      iii. Are there any issues you foresee?
6. Key Accomplishments/Problems Encountered
7. Reportable Outcomes
8. Conclusions
Appendix B: Final Report Template

AMEDD ADVANCED MEDICAL TECHNOLOGY INITIATIVE (AAMTI)

FINAL REPORT

Title:

FY:

Principal Investigator (PI):
PI Email:
PI Phone:

Co-Investigator (Co-PI):
Co-PI Email:
Co-PI Phone:

PI Organization:

Report Date:

Type of Report: Interim

Prepared for: U.S. Army Medical Research and Materiel Command (USAMRMC), Telemedicine and Advanced Technology Research Center (TATRC), Fort Detrick, Maryland 21702-5012

Distribution Statement: Approved for Public Release; Distribution Unlimited

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Appendix A: Technical Summary
Appendix B: Funded Personnel and Participants
Appendix C: Supporting Documentation
Appendix D: Presentations, Posters, Publications

SF298: Separate Attachment
Appendix C: Project Update Report Template

AMEDD ADVANCED MEDICAL TECHNOLOGY INITIATIVE (AAMTI)

PROJECT UPDATE REPORT

Title:

FY:

Principal Investigator (PI):
PI Email:
PI Phone:

Co-Investigator (Co-PI):
Co-PI Email:
Co-PI Phone:

PI Organization:

Report Date:

Type of Report: Interim

Prepared for: U.S. Army Medical Research and Materiel Command (USAMRMC), Telemedicine and Advanced Technology Research Center (TATRC), Fort Detrick, Maryland 21702-5012

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      iii. Provide a budget showing expenditures to date, planned expenditures, and remaining funds.
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6. Conclusions
APPENDIX D: SF298 Template

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<td>1b9. TELEPHONE NUMBER (Include area code)</td>
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</table>

Standard Form 298 (Rev. 8/98)
Dr. John F. Glenn
Principal Assistant for Research and Technology
US Army Medical Research and Material Command
301 619 7363
john.glenn@us.army.mil

Biosketch:
Dr. John Frazier Glenn was selected to the Senior Executive Service in October 2005. He previously served as an officer in the U.S. Army Medical Service Corps, retiring as a Colonel with 30 years of service in 2004. Since October 2005, he has served as the Principal Assistant for Research and Technology at the U.S. Army Medical Research and Materiel Command at Fort Detrick, Maryland where he exercises scientific oversight and direction Command’s Science and Technology programs ($1.3B in FY07) in Military Operational Medicine, Combat Casualty Care, Advanced Technology, Medical Chemical and Biological Defense, and Congressional Special Interest Research Programs, as well as in oversight of the Command’s worldwide laboratory system (6 CONUS and 3 OCONUS).

Specialties: Leadership; planning, management and oversight of research and development programs; problem solving; policy and process development and implementation. Experience includes electrophysiology research; animal and human use review; team building; management and/or oversight of drug, vaccine, device, and medical information product development; financial planning at the project, program and strategic levels.

Oct 2005 – Present Principal Assistant for Research and Technology, USAMRMC
Provides senior executive-level oversight and management of the Command’s medical science and technology investment strategy, developing policies and plans, integrating and coordinating execution of all functions and activities involved in providing support for the Command’s programs, and ensuring that all DoD and Army research and technology requirements are fully integrated to achieve a balanced program. Provides authoritative direction and guidance to the Program/Project Managers of the USAMRMC and resolves and/or recommends appropriate action concerning priorities between Program/Project Managers and subordinate commands of the USAMRMC (approximately 5,226 personnel, with an annual operating budget of approximately $1.326 billion). Serves as a senior executive-level representative at meetings and other decision-making forums at MEDCOM, DA, DoD, other Government agencies, Congressional offices, academia and private industry.

Oct 2004 – Oct 2005 Technical Director, USAMRMC
As an Intergovernmental Personnel Act Assignee from Georgetown University Medical Center, report directly to the Commanding General, US Army Medical Research and Materiel Command. Implement a program of broad biomedical research, development, and acquisition goals and objectives, as well as priorities and policies consistent with Congressional, Defense, Army, Assistant Secretary of the Army for Acquisition, Logistics and Technology, and US Army Medical Command guidance and directives. In my role as Technical Director, conduct scientific oversight and direction of the offices of the Deputy for Research Technology, Deputy
for Congressionally Directed Medical Research Programs, Deputy for Advanced Technology and Telemedicine, and the Director of Plans and Programs. Also oversee Research Area Directors and the scientific programs of all subordinate laboratories and centers. Access classified materials up to and including top secret.

Jul 2004 – Oct 2004   Research Assoc Prof, Georgetown Univ Medical Center
Worked under contract to the U. S. Army in support of the Medical Joint Cross Service Group’s Medical-Dental RDA Working Group in the 2005 Base Realignment and Closure process. Also served as technical advisor to the Deputy for Research and Technology and Commanding General, U. S. Army Medical Research and Materiel Command. Was detailed to the U. S. Army Medical Research and Materiel Command as an assignee under the provisions of the Intergovernmental Personnel Act beginning in October 2004.

Feb 2000 – Oct 2004  Deputy for Research and Development, USAMRMC
Served as Technical Director for Army Medical Research and Development programs ($135M) and Army executed Department of Defense Medical Chemical and Biological Defense programs ($110M), reporting directly to the Commanding General, USAMRMC. Supervised, coordinated, integrated the activities of Headquarters Staff Directors for Infectious Disease, Combat Casualty Care, Military Operational Medicine, Medical Chemical and Biological Defense, Plans and Programs, and Strategic Partnerships. Provided executive-level oversight of the world-wide research activities of subordinate laboratories, including Walter Reed Army Institute of Research and its overseas labs, the Medical Research Institute of Infectious Diseases, the Medical Research Institute of Chemical Defense, the Research Institute for Environmental Medicine, and the Aeromedical Laboratory.

Independently, and with a broad range of personal authority, directed the Plans, Programs, Analysis and Evaluation Directorate in support of the total acquisition lifecycle management program under the Deputy for Medical systems, Office of the Assistant Secretary of the Army for Research, Development, Acquisition, and the Commanding General, U. S. Army Medical Research and Materiel Command. Coordinated planning, programming, review, evaluation, analysis and liaison activities for the Command’s assigned programs ($730M total in FY99). Provided expert guidance and support for the execution of special projects such as Section 912c, FAA’s and reorganization initiatives. Served as Army’s representative to the ASBREM Committee Secretariat, as well as Command representative to the ASTWG Technical Council, and Command lead for National Performance Review reinvention and Defense Science and Technology Reliance activities.

Education
Ph.D, Biological Psychology from Duke University in 1974
A.B., Psychology from University of North Carolina at Chapel Hill in 1969

Illustrative Publications Reflecting Personal Research Interests:
Preface
Glenn, John F.
Neuroimage 54, S16-S16    JAN 2011
Gastric Modulation Of Gustatory Afferent Activity
GLENN, JF; ERICKSON, RP
Physiology & Behavior 16(5), 561-568 1976

Gastric Modulation Of Gustatory Afferent Activity
Glenn, John Frazier.
Presentation for National Association of College and University Business Officers

Dr. John F. Glenn, SES
Principal Assistant for Research and Technology (PART), USAMRMC

The views expressed in this presentation are those of the authors and may not necessarily be endorsed by the U.S. Army.

The appearance of commercial products or company names does not constitute endorsement by the U.S. Army.
Webinar Topics

U.S. Army Medical Research and Materiel Command (USAMRMC)

- Mission/Vision
- Military Health Threats and Change Drivers
- USAMRMC Organization
- Research Program Areas
- Research Investment Decision Making
- Interfacing with USAMRMC
U.S. Army Medical Research and Materiel Command

MISSION

Responsively and responsibly create and deliver medical information and products for the warfighting family.

VISION

A trusted partner for leading biomedical research and materiel innovation for global health.
USAMRMC Responds to Medical Threats to Warfighters

Environmental Hazards
- Heat and Cold
- Altitude
- Toxic Industrial Chemicals & Materials

Endemic Disease Threats
- Parasitic Diseases
- Bacterial Diseases
- Viral Diseases

Chemical/Biological Warfare Threats
- Bacterial Threats
- Viral Threats
- Toxin Threats
- Nerve Agents
- Vesicant Agents
- Blood Agents

Combat Injuries
- Hemorrhage
- Head Trauma
- Blast Injury

Operational Stressors
- Sleep Deprivation
- Traumatic Stress and Situational Stressors
- Physical Work Load
- Cognitive Burden & Operational Complexity

Battle Sequelae
- Loss of limbs
- Loss of tissue
- Loss of vision
- Pain

System Hazards
- Laser
- Blast
- Biomechanical Insults and Stresses
- Noise
What is driving change in the military R&D environment?

Contemporary War Casualties

• Current war casualties are driving changes in health care needs and therefore changes in R&D
• Specific types of casualties driving changes:
  – Traumatic Brain Injury (TBI)
  – Blast Injuries
  – Amputations
  – Other Trauma (Eye/Ear injuries)
  – Post Traumatic Stress Disorder (PTSD)

<table>
<thead>
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<th>% Body Area</th>
<th>WWII</th>
<th>Korea</th>
<th>Vietnam</th>
<th>OIF/OEF</th>
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<tr>
<td>Head &amp; Neck</td>
<td>12%</td>
<td>21%</td>
<td>21%</td>
<td>16%</td>
<td>29%</td>
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<tr>
<td>Chest</td>
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<td>14%</td>
<td>10%</td>
<td>13%</td>
<td>6%</td>
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<tr>
<td>Abdomen</td>
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<td>8%</td>
<td>8%</td>
<td>9%</td>
<td>11%</td>
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<tr>
<td>Extremities</td>
<td>61%</td>
<td>58%</td>
<td>60%</td>
<td>61%</td>
<td>54%</td>
</tr>
</tbody>
</table>

Owens, J Trauma FEB 2008
USAMRMC: Customer-Focused Program and Outcomes

**CORE RDA OUTCOMES**

**CORE RDA PROGRAMS**

**RESEARCH**
Medical Research & Technology Program

- (1) Basic Research, (2) Applied Research, and (3) Advanced Technology Development to prove tech-base concepts for medical products (drugs, biologics & devices) and information

**DEVELOPMENT**
Medical Advanced Development Program

- (4) Advanced Component Development & Prototypes and (5) System Development & Demonstration of tech-base concepts or commercial products into FDA-approved war-ready medical products

**ACQUISITION**
Medical Logistics Program

- Acquire, field, distribute, centrally manage, sustain/maintain and dispose of medical products, supplies and equipment from the tech base, advanced development, or from commercial sources

**SPECIAL PROGRAMS**

**Congressional Special Interest Programs**
Programs directed by Congress

**SPECIAL OUTCOMES**

**Targeted Outcomes**

- Armed Forces Medical Examiner
  - DoD Medical Examiner
- National Museum of Health and Medicine
  - DoD Medical Museum

- Identification, Cause of Death
- Knowledge Resource
USAMRIID Ft Detrick, MD
US Army Medical Research Institute of Infectious Diseases

USARIEM Natick, MA
US Army Research Institute of Environmental Medicine

WRAIR Forest Glenn, MD
Walter Reed Army Institute of Research
- Armed Forces Research Institute of Medical Sciences (AFRIMS) – Thailand
- US Army Research Unit, Europe (USAMRU-E) – Germany
- US Army Research Unit, Kenya (USAMRU-K) – Kenya

USAMRICD Aberdeen PG, MD
US Army Medical Research Institute of Chemical Defense
- US Army Center for Environmental Health Research (USACEHR) - Ft. Detrick, MD

USAISR Ft Sam Houston, TX
US Army Institute of Surgical Research
- US Army Dental and Trauma Research Detachment (USADTRD) – Ft. Sam Houston, TX
- US Army Medical Research Detachment (USAMRD) – Ft. Sam Houston, TX

USAARL Ft Rucker, AL
US Army Aeromedical Research Laboratory
**Military Infectious Diseases Research Program**

**Disease Prevention**
- Vaccines research against malaria, bacterial diarrhea, rickettsia, dengue, and hantavirus
- HIV clinical trial sites

**Treatment and Prophylaxis**
- Antimalarials
  - (Treatment) Malarone or Artesunate
  - (Prophylaxis) Malarone or Tafenoquine
- Antileishmanial – Topical Paramomycin

**Diagnostics (platforms and kits)**
- Malaria detection – Binax Now
- Dengue and leishmania – Rapid Diagnostic Devices
- JBAIDS – Dengue Assay

**Insect Vector Control**
- Repellants and bednets
- Vector Detection Assays (within arthropod vector) – Rift Valley Fever Virus, West Nile Virus, Dengue Virus, Leishmania
- Identification Key – medically relevant arthropod

**Rapid Screening of Fresh Whole Blood, Wound Infection Prevention and Management, Antimicrobial Countermeasure**
- Screen fresh whole blood for HIV, Hepatitis B, and Hepatitis C
- Fundamental and applied research to prevent infections and/or guide clinical wound management decisions
- Fundamental and applied research to develop therapies to treat wound infections
Military Operational Medicine Research Program

**Physiological Health**
- Nutrition interventions to mitigate adverse effects of repeated combat missions, operational and training stressors
- Near real-time SPARTAN network-enabled predictions of Soldier hydration and thermal states using physiological and biophysical data
- Maintain/build/apply high-performance computing applications to support Army medical research
- Model of key determinants of individual fatigue resistance for individualized alertness/performance predictions

**Environmental Health and Protection**
- Environmental Sentinel Biomonitor system to rapidly identify acute toxic hazards from industrial chemicals in water
- Suite of biomarkers for militarily relevant chemicals and identify toxicity pathways
- In vivo heat stroke model to evaluate pharmacological interventions
- Probabilistic models for altitude illness risk, acclimatization status, and operational effectiveness following rapid ascents to 7K and 14K feet
- Validated noninvasive hydration assessment sensors

**Injury Prevention and Reduction**
- Assessment criteria for prediction of head, facial/eye injury
- Improved standards/performance requirements for Warfighter ocular protective gear
- Software to estimate physical/cognitive impairment due to inhalation of toxic gases
- Upgraded blast lung injury estimation software to include improved thoracic response characteristics
- Characterize current injury trends contributing to lost duty time, reduced mission effectiveness, and occupational disability

**Psychological Health and Resilience**
- Initial and long-term effects of concussion/mTBI on cognitive performance and neurophysiological functioning
- Resiliency/vulnerability factors for PTSD symptoms and depression in deployers and nondeployers
- Suicide education and training addressing suicidal intent and related behaviors, and a clinical intervention to treat Soldiers at risk for suicide
- Integrated mental health resilience training to reduce traumatic stress symptoms, anger, sleep problems, depression, alcohol problems, and relationship problems
Combat Casualty Care Research Program

**Hemorrhage and Resuscitation**
- Hemorrhage control
- Blood products
- Complement inhibition
- Resuscitation fluids

**Traumatic Brain Injury**
- Penetrating injury
- Diagnostic device
- Neuroprotective drug
- Blast effects

**Forward Surgical/Intensive Care**
- Trauma vitals
- Critical care technology
- Decision support
- Closed loop control

**Treatments for Tissue Injury**
- Maxillofacial injury
- Ocular trauma
- Pain control
- Burn treatment
Clinical and Rehabilitative Medicine Research Program

**Regenerative Medicine and Transplants**
- Focus areas: Extremity injury, craniofacial injury, burns/scarring, and tissue transplantation
- Employ cells/tissues/scaffolds to
  - Repair, reconstruct, or regenerate tissue lost or damaged due to traumatic injury
  - Develop technologies that promote healing with minimal scarring
  - Develop technologies that restore lost limb/tissue structure and function

**Neuromusculoskeletal Injury (Incl. Amputee)**
- Address psycho-social recovery aspects
- Improve rehabilitation for limb salvage and spinal injury patients
- Exercise and fitness systems and strategies
- Improved orthotics, prosthetics, robotics to improve extremity function
- Incorporate neural interface/feedback

**Pain Management (Acute/Chronic/Battlefield)**
- Improve management of battlefield, acute and chronic pain
- Identify and treat pain generators
- Improve objective diagnostic tools for pain
- Develop strategies to empower patient in managing pain

**Sensory Systems (Vision/Hearing/Balance)**
- Repair damage to the eye and visual system
- Restore hearing
- Treat tinnitus
- Improve diagnostics
- Rehabilitate TBI-associated sensory dysfunction
Medical Training and Health Information Sciences Research Program

Seeks to increase patient safety and quality of care through simulation-based technologies/systems; addresses the needs of the Military Health System through theater and garrison research initiatives by focusing on capability gaps with emerging technologies based on stakeholder-driven priorities.

**Medical Simulation & Training**
- Combat Casualty Training Initiative
  - Examine the efficacy of live animal training versus modern simulator technology in training combat medics. In an effort to determine whether live animal training can be reduced in the future
- Medical Practice Initiative
  - Focuses on medical provider training systems and assessment of competence for sustained military medical readiness
- Patient-Focused Initiative
  - Advanced user interface and interactive technologies for healthy living, patient treatment, and rehabilitation
- Developer Tools for Medical Education
  - Effort to promote medical simulation-related technologies by providing tools for providers to easily develop new products and content. This is done by promoting software development kits for virtual humans and a public physiology engine

**Health Informatics**
- Force Health Protection & Readiness
  - Provide services to the Armed Forces to promote, improve, conserve, or restore the mental or physical well-being of personnel through improved information management and the use of emerging technologies
- Medical Resourcing
  - Improved delivery of health care resources around the globe
- Health Care Services
  - Directly impact the way health care is provided to the patient and improve the medical providers’ ability to treat patients and promote health
- Enterprise Information Management
  - Improve IT and communications infrastructure, architecture, and management structure
CONGRESSIONAL PROGRAMS:

- Manages extramural research programs directed by Congress
- Started in 1993 with breast cancer, now many diseases
- Congress specifies disease area, CDMRP determines research strategy and competitively selects the best projects
- Unique public/private partnership encompassing the military, scientists, disease survivors, advocates, consumers, and policy makers
- CDMRP funds high-impact, innovative medical research to find cures, reduce the incidence of disease and injury, improve survival, and enhance the quality of life for those affected

EXECUTION AGENT for the Research Area Directorates (RADs) and Joint Program Committees (JPCs) to support their military mission

Military Relevant Research Programs

- Peer Reviewed Medical
- Psychological Health/Traumatic Brain Injury
- Defense Medical R&D
- Peer Reviewed Orthopedic
- Spinal Cord Injury
- Gulf War Illness

Cancer Research Programs

- Breast Cancer
- Prostate Cancer
- Ovarian Cancer
- Lung Cancer
- Peer Reviewed Cancer

Other Medical Research Programs

- Neurofibromatosis
- Tuberous Sclerosis Complex
- Amyotrophic Lateral Sclerosis
- Autism
- Multiple Sclerosis
- Bone Marrow Failure

PROGRAM MANAGEMENT PROCESS:

- Proposal Receipt
- Peer Review
- Programmatic Review
- Approval of Commanding General
- Award Execution (1-5 years)
- Congressional Appropriation
- Release of Program Announcement
- Vision Setting

FY11 PROGRAMS
Telemedicine & Advanced Technology Research Center
Extramural Execution Management

Science and technology scouts for military medicine
Center of gravity for Army telemedicine initiatives
Leader for eHealth and mHealth research programs
Laboratory functional capability in health information technology
Simulation and computational biology are major research components
Accelerates R&D for commercial-off-the-shelf products through active assistance
Uses convergence science involving engineering, physics, and math for military medical problem solving
EXECUTION AGENT for the Research Area Directorates (RADs) and Joint Program Committees (JPCs) to support their military mission
Provides subject matter expert support to Defense Health Program Research, Development, Test & Evaluation (RDT&E) execution
Good Ideas: Can Come from Many Sources

DoD and the Services

Military Leaders

Private Industry

Congress

US Soldiers and Their Families

US Military Medical Personnel

Academia

Entrepreneurs

Innovations

6 billion Others

Salesmen
Making Research Investment Decisions

- Strategic Guidance
- Emerging Technology Opportunities
- User Requirements Pull
- Joint Gaps
- Existing Service Investments

Program Announcements
Broad Agency Announcements
Requests for Proposals
**Recommended Best Practice**

**Broad Agency and Program Announcements (BAAs and PAs)**

**Program Defined**

**Preproposal Submitted**

**TAM / PM / SME Review for Relevance and Impact**

**Full Proposal Requested and Received**

**Not Approved**

**Internal Programmatic Review**
- JPC/IIP/RAD conduct programmatic review and integration
  - Composed of Army, Air Force, Navy, DoD, NIH, VA, Others
  - RADs coordinate and integrate with each other, CDMRP, and TATRC
  - RADs maintain research portfolios for research areas
  - Evaluates programmatic relevance
  - Comparison-based evaluation
  - Evaluates proposals evaluated across multiple disciplines
  - Considers External Scientific Peer Review (criteria-based)
  - Integrates across research areas and capability gaps

**PI Responds to Review, If authorized in announcement**

**Recommended for Funding (Approval)**

**Not Approved**

**Approved**

**Recommended for Funding (Approval)**

**Not Approved**

**Approved**

**Not Approved**

**Approved**

**Not Approved**

**Approved**

**JPC: Joint Program Committee**
**IIPT: Integrating Integrated Products Team**
**RAD: Research Area Directorate**
US Army Medical Research Acquisition Activity (USAMRAA)

- USAMRAA is the contracting element of the USAMRMC
- Provides support to the Command headquarters and its worldwide network of laboratories and medical logistics organizations
- USAMRAA also supports the Fort Detrick Garrison and its military tenant activities, Army-wide projects sponsored by the Army Surgeon General, and numerous congressionally mandated programs
Office of Research Protections

- Oversees USAMRMC-supported research and Army Medical Department clinical investigations involving human subjects or animals to ensure they are conducted IAW Federal, DoD, Army, USAMRMC, local, and international regulatory requirements.
- Supports the *HQ USAMRMC Institutional Review Board* and the *Research Ethics Advisory Panel*

### Human Research Protection Office (HRPO)
- USAMRMC policy and compliance oversight for USAMRMC laboratories and institutes
- Compliance oversight for all USAMRMC-supported intramural and extramural research
- By MOA provide intramural and extramural oversight to other Army and DoD organizations
- Consults the USAMRMC Research Ethics Advisory Panel

### Clinical Investigation Regulatory Office (CIRO)
- Compliance oversight for all human research at all AMEDD MTFs
- Preapproval of studies involving medical products/devices to ensure FDA regulatory compliance
- Instrumental staff assistance via education series, SAVs, and real-time resource for problem solving

### Institutional Review Board Office (IRBO)
- Supports HQ USAMRMC IRB-the primary IRB for several USAMRMC labs/institutes
- Supports many Army/DoD institutions without their own IRBs
- CENTCOM in theater research
- Can serve as a Central IRB for DoD studies conducted at multiple sites

### Animal Care and Use Review Office (ACURO)
- Animal care and use review oversight for all Army-supported research involving animals
- Oversight for Army Combat Trauma Training involving live animals
- By MOA provide intramural and extramural oversight to other DoD organizations
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<td>W81XWH-12-DMDRP-IIRA</td>
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<td>DoD FY12 Duchenne Muscular Dystrophy Therapeutic Idea Award</td>
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<td>DoD Psychological Health and Traumatic Brain Injury Chronic Effects of Neurotrauma Consortium Award</td>
<td>W81XWH-12-PHTBI-CENC</td>
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<td>FY12 Militarily Relevant Peer Reviewed Alzheimer's Disease Research Program (MRPRA) Convergence Science Research Award</td>
<td>W81XWH-12-MRPRA-CSRA</td>
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* As of 24 October 2012; www.grants.gov
Online Resources About Funding Opportunities

**Program Announcements and Broad Agency Announcements**
[www.grants.gov](http://www.grants.gov) (search CFDA #12.420)

**Federal Business Opportunities (FEDBIZOPPS)**
[www.fbo.gov](http://www.fbo.gov)

**Congressionally Directed Medical Research Programs (CDMRP)**
[www.cdmrp.army.mil](http://www.cdmrp.army.mil)

**Fort Detrick Business Development Office**
[www.FDBDO.com](http://www.FDBDO.com)

**Office of Small Business Programs**
Lest We Forget Why We Are Here

FREEDOM
COL. Daniel R. Kral  
Director  
Telemedicine and Advance Technology Research Center  
301 619 7967

**Biosketch:**  
COL Dan Kral began his military career by enlisting in the Georgia Army National Guard (GAARNG) in 1984. Following 5 years of service as a Combat Teletype Operator with the 151st MI Battalion in Atlanta, GA, COL Kral graduated from North Georgia College in 1989 with a Bachelor in Business Administration (BBA) and was subsequently commissioned a 2LT in the United States Army Medical Service Corps. His military training includes the AMEDD Officer Basic and Advanced Courses, the Joint Medical Planners Course, Combined Arms Staff Support School, Resident Command and General Staff College, and the Combat Developer Course. He holds a Master's of Science in Management of Technology (MSMOT) from University of Texas San Antonio and is a member of the Army Acquisition Corps with Level 3 certification in IM/IT.

COL Kral's first Active Duty assignment was to the 2nd Armored Division, Fort Hood, TX where he served 3 years as Ambulance and Treatment Platoon Leader in C/502nd FSB, Tiger Brigade, including 9 months attached to 2nd Marine Division during Operations Desert Shield/Storm. Additional assignments include Chief Administrator, Yongsan Health Clinic, Seoul, Korea; Commander, 560th Medical Company (GA), Camp Humphreys, Korea; Instructor, Officer Basic Course, Fort Sam Houston, TX; Chief, Information Management Division, Fort Leonard Wood, MO; Executive Officer, Western Region Dental Command, Fort Lewis, WA; G6, 30th Medical Brigade, Heidelberg, GE and Baghdad, Iraq; Chief, Medical Information Systems Division, Directorate of Combat Doctrine Development, Fort Sam Houston, TX; AMEDD Chief Technology Officer (CTO), MEDCOM CIO/G6, Fort Sam Houston, TX, and AMEDD Capability Manager for Operational Communications and IM/IT, MEDCOM CIO/G6, Fort Sam Houston, TX. He currently serves as the Director for Telemedicine & Advanced Technology Research Center (TATRC), MRMC, Fort Detrick, MD.

**Education**  
MS in Management of Technology from UT San Antonio  
BA in Business Administration from North Georgia College in 1989
Mr. Ron Marchessault, Jr.
Program Manager
Technology Transfer/Commercialization GOR/IPA,
Telemedicine and Advanced Technology Research Center (TATRC)
US Army Medical Research and Material Command
Fort Detrick, Maryland 21702-5012
301-619-4016
ronald.marchessault@tatrc.org.

Three year old news article:
Only a small percentage of medical research projects result in a new product on the market. If Ron Marchessault has his way, the U.S. military will see more and more promising technologies put into use to improve the care of our service members.

Marchessault is the director of technology transfer and commercialization for the U.S. Army Medical Research and Materiel Command’s Telemedicine and Advanced Technology Research Center. TATRC’s goal is to translate research into new products to advance the care of the nation's warfighters.

TATRC is deeply aware that it must encourage that next breakthrough that will enhance military health -- while making the most effective use of the federal funds that it stewards.

For this reason, the center charged Marchessault with developing a comprehensive commercialization program for the more than 1,800 research projects it manages at universities, government labs and high-tech start-up companies. It's a charge he takes seriously since a funded research project is only half the journey to providing solutions for Soldiers while bringing the lessons learned from war to the benefit of the wider society.

"Developing commercially viable technology requires more than a quick marketing survey," says Marchessault. "To determine what we should fund, we must find out whether a new technology solves an important problem, and who would purchase it."

Marchessault has been managing technology research projects for TATRC since 1998. In 2009, he was asked to create a formal program to leverage federal investment with private sector capital to commercialize federal medical research and development technologies. Since then, he has developed an innovative technology transfer program. His holistic approach is helping TATRC assess and guide the commercial potential of new discoveries and technologies, connect researchers with investors, and evaluate the economic impact of the precious research dollars the center manages for the military.

His hope is that TATRC’s pilot program will become a blueprint for others in the DoD.

ASSESSING
Marchessault has sought out several strategic partners and resources to provide the business expertise that must marry with science to create a marketable product. The first two years have seen many successes.
Market Overview Analysis
Fifteen TATRC small business partners demonstrating technologies with strong commercial potential were selected in 2011 for market overview analyses by FirstLink, a DoD technology transfer partner. One company, Tursiop Technologies, has developed nanotechnology for magnetic resonance imaging that dramatically decreases the size of the magnet needed, thus reducing the cost. It has now obtained the third-party funding needed to seek U.S. Food and Drug Administration approval.

"Discovery to Market" Project
Student teams from the Johns Hopkins University Carey Business School Global MBA program presented commercialization plans for eight TATRC projects in December 2011, marking the first such DoD/university technology transfer partnership. TATRC projects included in the program ranged from an e-learning system for surgical skills to a wearable robotic arm to a mobile diabetes self-care system. The students gained vital experience in applying business theory to assist high-tech start-up companies, while the researchers gained intellectual property research and in-depth marketing analyses that easily could have cost them hundreds of thousands of dollars. Students in this year's "Discovery to Market" class are now working with a second group of TATRC-funded investigators.

Online Commercialization Assessment Tools
After exploring several online commercialization assessment programs, Marchessault has introduced TATRC partners to EquityNet, a proven, metric-based program for determining commercialization viability. Ten companies are now participating in the program, which includes a business plan analysis, expert business support and opportunity assessment research.

CONNECTING
For those technologies "ready for prime time," networking is another key part of TATRC's Technology Transfer Program. Marchessault has teamed with the National Association of Seed and Venture Funds to connect promising research with private investment.

Marketing Campaign to Private Sector Developers
Last year the NASVF developed a marketing campaign to aid in TATRC’s commercialization goals. Through careful messaging and positioning in the healthcare business ecosystem, TATRC-funded companies with commercially viable technologies are being promoted to investors.

Networking through NASVF
Select small business partners seeking private sector capital have had the opportunity to pitch their companies to angel investors and the venture capital community through two NASVF meetings co-sponsored by TATRC. In Baltimore in 2010, three companies presented, and Blacktoe Medical III obtained the funding needed to pursue FDA approval for its SonicEye® finger-mounted ultrasound technology. At an Arlington, Texas, meeting in August 2011, three additional companies presented products ranging from a system to
coordinate data from all devices in the operating room, to cloud computing technology for health information technology.

Four similar opportunities throughout the United States are planned for 2012.

EDUCATING
Marchessault believes the best way to help translate research into a commercial product is to consider the market potential from the outset. Several programs are underway to educate and encourage investigators as well as reviewers to incorporate business analyses throughout their project timetables.

Commercialization Assessment and Mentorship Program
In a program with the Larta Institute, a not-for-profit firm that has assisted several federal agencies with commercialization efforts, 10 TATRC projects were matched with external industry experts in early 2011. These experts evaluated the projects' commercialization potential, served as mentors, and developed strategies for future private sector investment. Several of the companies were contacted by outside investors. One company, Livedata, Inc., brought to market an integrated data system for patient safety that generated $5 million in sales by August 2011. A second group of 10 TATRC partners is now working with the Larta Institute.

Medical Technology Transfer Symposium
TATRC organized a two-day symposium with the University of Nebraska Medical Center in May 2011. The Midwest Medical Technology Exchange enabled TATRC researchers in the Midwest to network with regional investors and discuss critical elements of technology commercialization. In this purely educational exchange, inventors were the audience as investors presented perspectives and information pertaining to commercialization. The event was well received and generated ideas that will help TATRC prioritize future projects based on their commercial potential. Marchessault hopes to offer a similar symposium on the West Coast in the near future.

Technology Acceleration Website
To bring market analysis capabilities to all of TATRC's small business partners, Marchessault is working with the Jacob Tyler Creative Group to develop a microsite with customized content focused on commercialization strategies. The online "toolbox" will feature project management evaluation tools as well as educational and training resources for both researchers and reviewers. It is expected to be available through TATRC's website by the fall of 2012.

ECONOMIC IMPACT
With "accountability" as his watchword, Marchessault is also integrating a final pillar into TATRC's Technology Transfer Program. He has shown that of approximately 1,800 projects funded through TATRC since 2000, 2.3% have resulted in a commercial product, generating $209M in sales from a total federal investment of $74M.

Furthermore, in an extensive economic impact analysis project, Econsult Corporation is
gathering validated data on TATRC-funded medical research and development expenditures. Data includes job creation/retention, salaries, follow-on funding, published patents, state and federal tax revenue, and sales revenue.

The first report is expected to be completed by the fall of 2012.

Marchessault notes, "For TATRC, it's not enough to have good science alone. Projects must meet a clinical need and often have commercial viability."
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I. OVERVIEW OF THE FUNDING OPPORTUNITY

A. Administrative Overview

This Funding Opportunity Announcement is a Broad Agency Announcement (BAA) for the Fiscal Year 2016 (FY16) Joint Program Committee 1 (JPC-1) Medical Simulation and Information Sciences (MSIS) Research Program Adaptive Tutor Using Methodologies for Neuroplasticity (ATUMN). This BAA must be read in conjunction with the submission guidelines in Grants.gov/Apply for Grants (hereafter called Grants.gov/Apply). It must also be read in conjunction with the document titled “General Submission Instructions” available with this BAA in Grants.gov.

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

This BAA is intended for extramural investigators only. A separate FY16 JPC-1/MSIS ATUMN Program Announcement/Funding Opportunity for intramural investigators will be available at https://cdmrp.org/Program_Announcements_and_Forms/.

- An extramural investigator is defined as all those not included in the definition of intramural investigators below.

- An intramural investigator is defined as a Department of Defense (DoD) military or civilian employee working within a DoD laboratory, DoD military treatment facility, or working in a DoD activity embedded within a civilian medical center. Intramural investigators are directed to apply through eReceipt (https://cdmrp.org/Program_Announcements_and_Forms/).

- Submissions from intramural investigators to this BAA will be rejected. It is permissible, however, for an intramural investigator to be named as a collaborator in a proposal/application submitted by an extramural investigator. For more information, refer to the General Submissions Instructions, Section II.C.8.

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

- Pre-Proposals/Pre-Applications: To conserve both submitters’ and Federal Government resources, organizations are required to submit preliminary proposals/applications (pre-proposals/pre-applications) so that the Government can
determine whether a proposed research idea meets the mission and requirements described herein. All pre-proposals/pre-applications must be submitted through the electronic Biomedical Research Application Portal (eBRAP [https://eBRAP.org/]). A registration process through eBRAP must be completed before a pre-proposal/pre-application can be submitted.

- A Principal Investigator (PI) and the organization’s business official must register in eBRAP before submitting a pre-proposal/pre-application.
- Invited full proposals/applications (submitted through Grants.gov) will be available for viewing, modification, and verification in eBRAP, for a limited period.
- A full proposal/application will not be accepted if the PI has not submitted a pre-proposal/pre-application and received an invitation to submit a full proposal/application.

**Full Proposals/Applications:** To submit a full proposal/application, the PI must have received an invitation to submit from a Contracting or Grants Officer. An invited full proposal/application must be submitted electronically through Grants.gov (http://www.grants.gov/) using the SF-424 Research and Related (R&R) forms and the SF-424 (R&R) Application Guide. *Proposals/Applications will not be accepted by mail or in person.*

**B. Program Overview**

Proposals/applications to the Fiscal Year 2016 (FY16) JPC-1/MSIS ATUMN 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 and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The US Army Medical Research and Materiel Command (USAMRMC) Congressionally Directed Medical Research Programs (CDMRP) provides Defense Medical Research and Development Program (DMDRP) execution management support for DHP core research program areas, including JPC-1/MSIS. This BAA and subsequent awards will be managed and executed by CDMRP with strategic oversight from JPC-1/MSIS.

Per guidance from DoD Instruction 5000.02, “Operation of the Defense Acquisition System,” dated January 7, 2015, the outcomes of the research will be used to support the solution assessments/material considerations for materiel development of an ATUMN tool kit or assessment system of sorts. The Government plans to use research outcomes in assessing critical technology elements and technology maturity, system integration risk, future manufacturing feasibility, and, where necessary, technology maturation and demonstration needs.

**The JPC-1/MSIS Medical Readiness Initiative (MRI): Adaptive Tutor Using Neuroplasticity Methodologies**

The ATUMN is a line of research that supports the MRI under the JPC-1 medical simulation and training portfolio. The JPC-1/MSIS MRI focuses on the research and ultimately the development of medical training methods, technologies, systems, and competency assessment
tools for the attainment and sustainment of medical readiness research and development efforts for the military and the public. MRI also includes methodologies, techniques, and tools that will allow for ethical, accurate, and appropriate pre-intervention rehearsal with input of potential authorized personalized medical information into simulation models. Evidence-based efforts with measurable outcomes and reliable assessments also fall under the MRI.

The evolution of military medicine over the past decade and greater has led to significant advancements in the ability to provide world-class care in a wide range of environmental and situational settings. Military medical personnel are trained and capable of providing care across the health continuum (prevention, ambulatory, emergency, restorative, and rehabilitative care) in support of disaster response, humanitarian relief, and contingency operations across the globe. Modern military medicine requires personnel to integrate and process a tremendous amount of asynchronous information. The ability to render medical care is an additive requirement for individuals working in teams to effectively communicate during tactical operations. While traditional military training techniques, tactics, and protocols have served the military well, the explosion of medical advancements coupled with lessons learned have demonstrated that our ability to effectively assess, respond, care for, and mitigate the effects of injuries and illness will require an adaptive individual and team-based training capability.

The training platforms of the future will need to provide military medics with the ability to effectively assess, perform, and communicate medical response activities across a wide variety of clinical, tactical, and environmental situations. The means to rapidly adapt training platforms to changes in injury and illness patterns as well as to changes in equipment, pharmaceuticals, and clinical practice guidelines in a shared service environment will be critical in providing seamless care from the point of injury through rehabilitative care. These training platforms will need to provide synchronous and asynchronous training within a distributed global network and have the ability to accurately assess, monitor, and direct individual and team-based training to meet environmental, geographic, and operational requirements. A key performance parameter for training will be to effectively apply adult learning strategies to optimize retention, sustainment of baseline proficiencies, and effective means to integrate adaptive learning strategies to link new information to existing training techniques, tactics, and protocols. The training platforms of the future will allow planners and commanders to efficiently integrate medical support capability packages based on individual and team-based training performance to meet operational requirements.

Some current commercially available medical education and training technologies have concentrated on and emphasized the psychomotor component of military medical skills and procedures, but have minimally addressed the broad cognitive decision-making skills that are needed prior to or in support of the psychomotor skill/procedure. Furthermore, it appears that some of the most common assessments, treatments, and procedures that are performed in military medical contingencies have received minimal focus. These may include, but are not limited to, assessment of shock, traumatic brain injury, mental health assessment (i.e., post-traumatic stress, substance abuse), musculoskeletal diagnosis and treatment, wound management/debridement, external fixation of fractures, shock management, ventilator management, and advanced emergency care (i.e., lateral canthotomy, cranial decompression). While the DoD has developed clinical practice guidelines (CPG) for many of these conditions (http://www.healthquality.va.gov/policy/index.asp), standards continue to evolve and the ability
to readily integrate into training platforms has not been fully realized across all DoD training platforms. A standardized approach to train and assess the adoption of evidence-based training practices in virtual and live settings will provide a sound approach to optimizing the care and coordination of care related to peacetime and contingency operations. Ideally, the ability to establish and train individuals/teams on standardized subject matter expert-driven assessment and treatment algorithms coupled with sound data collection may shorten the time to refine, develop, and implement CPGs to meet emerging requirements.

The development and standardization of evidence-based practices have been touted as a means to improve quality care; however, our ability to readily measure an individual’s understanding and application of these practices is currently not possible. The typical one-size-fits-all educational approach is primarily geared to training to a minimum level of competency without the ability to enable individuals to collectively reach their highest potential. The adult learning model recognizes the variance between a learner’s ability to achieve, maintain, and apply information based on the mode of transmission, length of training, frequency of instruction, and application of knowledge to existing and new situations. This is where adaptive learning/tutoring comes into play: by understanding where the learner is currently within the learning curve, understanding what the learner needs to achieve, and facilitating an appropriate route(s) to enhance learning opportunities. The tutor needs to continuously evaluate the progress and re-plan/re-route as appropriate. This may be referred as a compensatory/adaptive approach.

This BAA targets many related challenges. These include, but are not limited to, the following, given in no particular order: seeking military medical adaptive tutoring platform research that can accurately classify an individual’s experience and knowledge; a training and educational training platform that is empirically based upon some form of neuroplasticity concept (such as adult learning, perceptual training, psychophysical staircase functionality, etc.) to increase the probability of sustaining knowledge, particularly for patient assessment, clinical reasoning, clinical judgment, and clinical diagnosis and treatment; an open source/license/architecture platform that allows for future flexibility and modularity; and a non-integrated proof of concept that will demonstrate the adaptive tutoring portion of the research and development. A pilot (preliminary validation) test of the non-integrated proof of concept is needed prior to the end of the research to demonstrate the preliminary capability and functionality. The domain is the test case to prove the concept.

C. Award Information

The FY16 JPC-1/MSIS ATUMN is seeking research, development, and testing on compensatory/adaptive medical tutor prototype(s). This includes evidence-based sustained learning methodologies that decrease the need for future technology dependence to retain the details of the cognitive processes that assist with patient assessment, clinical reasoning, clinical judgment, and clinical diagnosis and treatment. The tutor must accurately and appropriately understand where the learner is within the learning curve versus the course curricula, objectives, and anticipated outcomes, and understand where the learner needs to go versus the course curricula, objectives, and anticipated outcomes. The tutor must identify viable and course-appropriate route(s) on how to navigate from current position to end position. The proposed tutor needs to continuously evaluate the progress and re-plan/re-route as appropriate versus the course curricula, objectives, and anticipated outcomes.
The compensatory/adaptive medical tutor prototype needs to be modular, flexible, robust, and reliable, and needs to incorporate open source/license/architecture. The modularity, flexibility, robustness, and reliability does NOT have to be demonstrated in the prototype, but these capabilities MUST be incorporated into the designs and architecture of the anticipated platform. The pre-proposal/pre-application and proposal/application must disclose any background intellectual property interest in the proposal solution, including but not limited to, current ownership status of the intellectual property, the existence and type of license the applicant holds, or whatever name exists. The proposal/application may disclose the capability and interest in licensing arrangements with the Government if the project is successful. Refer to the General Submission Instructions, Appendix 3 for additional information.

This compensatory/adaptive medical tutor prototype must demonstrate sustainment of the cognitive information that was gained. The content may be domain-specific per the desire of the PI and team, but the PI needs to select a domain that can be related to the military, such as the assessment of shock, traumatic brain injury, mental health assessment, (i.e., post-traumatic stress, substance abuse), musculoskeletal diagnosis and treatment, wound management/debridement, external fixation of fractures, shock management, ventilator management, and advanced emergency care (i.e., lateral canthotomy, cranial decompression). The PI must outline a pilot study concept of the compensatory/adaptive medical tutor prototype in the pre-proposal/pre-application. A detailed protocol must be provided in the full proposal/application, 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 statistical protocols.

1. **The anticipated outcomes of research supported by the FY16 JPC-1/MSIS ATUMN Project are as follows, in no particular order:**

   - A validated list supported by contacts, references, and sources that support the proposed recommendation for sustainment of cognitive knowledge, patient assessment, clinical reasoning, clinical judgment, and clinical diagnosis and treatment intended to be integrated/incorporated into the compensatory/adaptive medical tutor prototype.

   - A report, document, and/or list of the terminology and respective definitions used for the compensatory/adaptive medical tutor prototype including, but not limited to, the chosen domain, the proposed metrics/evaluation criteria and how they are used to determine where the learner is within the learning curve versus the course curricula, objectives, and anticipated outcomes and understand where the learner needs to go versus the course curricula, objectives, and anticipated outcomes.

   - A report or document with the information of the open source/license/architecture versus intellectual property components. The report needs to provide information on items such as hardware and software requirements to support the respective components and provide a listing of the most common issues with the proposed components, anticipated updates (if applicable), typical maintenance issues with the proposed components, and intended maintenance fees and schedules with the proprietary components (if applicable).
• A report or document that describes in detail the fully integrated design that includes items such as modularity, flexibility, robustness, and reliability and provides the proposed timeline that would be needed if such additional modularity, flexibility, robustness, and reliability were indeed added.

• The pilot study-specific aims, methodologies, sample and sample size, inter-rater reliability, assessment criteria, analyzed results, conclusions, and potential next-step recommendations. Indicate the proposed duration of sustained cognitive knowledge, patient assessment, clinical reasoning, clinical judgment, and clinical diagnosis and treatment.

• A demonstration of the compensatory/adaptive medical tutor prototype; anticipate the demonstration to occur in the National Capital Area/Maryland/Northern Virginia area, but it could occur at a Government organization located in the contiguous United States.

• A submitted or presented abstract or a draft or accepted publication.

Use of Human Anatomical Substances, Human Subjects, or Human Cadavers: All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRMC Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) of record. Local IRB/EC approval at the time of submission is not required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB/EC. **Allow a minimum of 2-3 months for HRPO regulatory review and approval processes.** Refer to the General Submission Instructions, Appendix 5, for additional information.

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 proposal/application is selected for funding. The ACURO 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.” **Allow at least 2-3 months for regulatory review and approval processes for animal studies.** Refer to General Submission Instructions, Appendix 5, for additional information.

D. Eligibility Information

• Independent extramural investigators at all academic levels (or equivalent) are eligible to submit proposals/applications.

• Cost sharing/matching is not an eligibility requirement.
• Eligible extramural investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations.

• Intramural investigators are directed to apply through CDMRP eReceipt at https://cdmrp.org/Program_Announcements_and_Forms/.

• Refer to the General Submission Instructions, Appendix 1, for general eligibility information.

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

Investigators are cautioned that awards are made to organizations, not individuals. A PI must submit a proposal/application through an organization in order to receive support.

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

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

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

**E. Funding**

• The maximum period of performance is **2 years**.

• The anticipated total costs (direct and indirect) budgeted for the entire period of performance will not exceed **$1.5 million (M)**. Indirect costs are to be budgeted in accordance with the organization’s negotiated rate. No budget will be approved by the Government exceeding **$1.5M** total costs or using an indirect rate exceeding the organization’s negotiated rate.

• Option periods may be used on contracts, subject to the availability of funds.

• The applicant may request the entire maximum funding amount for a project that has a period of performance less than the maximum 2 years.
Refer to the General Submission Instructions, Section II.C.5., for budget regulations and instructions for the Research & Related Budget. *For all Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in Section II.C.5. of the General Submission Instructions.*

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

- Travel costs for the PI(s) to an In-Progress Review (IPR) anticipated to be held near the end of the 1-year anniversary of the award at a Government location (to be determined). For planning purposes, it should be assumed that a 2-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

*This BAA is intended for extramural investigators only. Intramural investigators are directed to apply through CDMRP eReceipt at [https://cdmrp.org/Program_Announcements_and_Forms/](https://cdmrp.org/Program_Announcements_and_Forms/).*

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.

It is permissible for an intramural investigator to be named as a collaborator in a proposal/application submitted by an extramural investigator under this BAA. *In such cases, the extramural investigator must include a letter from the intramural collaborator’s Commander or Commanding Officer that authorizes the involvement of the intramural collaborator.*

Sub-awards to intramural agencies and other Federal agencies may be executed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR] or Funding Authorization Document [FAD] process). Direct transfer of funds from the recipient to a Federal agency is not allowed except under very limited circumstances. Refer to the General Submission Instructions, Section II.C.5. Research & Related Budget, for additional information on budget considerations for proposals/applications involving Federal agencies.
The JPC-1/MSIS expects to allot approximately $3M of the FY16 DHP MSIS appropriation to fund approximately 2 intramural and/or extramural JPC-1/MSIS ATUMN proposals/applications, 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 BAA is contingent upon the availability of Federal funds for this program. NOTE: Proposals/applications received in response to both the JPC-1/MSIS ATUMN intramural Program Announcement and extramural 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.

F. Mechanisms of Support

The DHP executes its extramural research program primarily through the award of contracts and assistance agreements (grants and cooperative agreements). The type of instrument used to reflect the business relationship between the organization and the Government is at the discretion of the Government based on the Statement of Work submitted in the proposal/application.

The USAMRAA will negotiate the award types for proposals/applications selected for funding. The Federal Grant and Cooperative Agreement Act of 1977, 31 USC 6301-6308, provides the legal criteria to select a procurement contract or an assistance agreement. Refer to the General Submission Instructions, Appendix 3, for additional information.

Any assistance agreement (grant or cooperative agreement) awarded under this BAA will be governed by the award terms and conditions that conform to the DoD’s implementation of Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of awards made after December 26, 2014, may include revisions to reflect DoD implementation of new OMB guidance in 2 CFR part 200, “Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards.”

G. Other Review Information

The following information will be reviewed prior to the award of a contract or assistance agreement:

1. “Exclusions” Identified in SAM

To protect the public interest, the Federal Government ensures the integrity of Federal programs by striving to conduct business only with responsible organizations. The USAMRAA uses the “Exclusions” within the Performance Information functional area of the System for Award Management (SAM); data from the Federal Awardee Performance and Integrity Information System, a component within SAM, is used to verify that an organization is eligible to receive Federal awards. More information about the “Exclusions” reported in SAM is available at https://www.sam.gov/. Refer to the General Submission Instructions, Section II.A., for additional information.

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1 United States Code
2 Code of Federal Regulations
2. **Conflicts of Interest**

   All conflicts of interest (COIs) or potential COIs must be disclosed with the proposal/application submission, along with a plan to resolve them. All COIs on the part of an organization or individual investigators that could bias the research project must be resolved prior to the award of a contract or assistance agreement. Refer to the General Submission Instructions, Appendix 1, for additional information.

3. **Review of Risk**

   The following areas may be reviewed in evaluating the risk posed by the applicant: Financial stability; quality of management systems and operational controls; history of performance; reports and findings from audits; ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities; degree of institutional support; integrity; adequacy of facilities; and conformance with safety and environmental statutes and regulations.

4. **Subcontracting Plan**

   If the resultant award is a contract that exceeds $650,000 and the offeror is a large business or an institution of higher education (other than Historically Black Colleges and Universities/Minority Institutions), the contractor will be required to submit a subcontracting plan for small business and small disadvantaged business concerns, in accordance with FAR 19.7. A mutually agreeable plan will be incorporated as part of the resultant contract.

II. **SUBMISSION INFORMATION**

   A. **Where to Obtain the Submission Package**

   To obtain the complete Grants.gov proposal/application package (hereinafter, submission package), including all required forms, perform a basic search using the Funding Opportunity Number W81XWH-15-DMRDP-MSIS-ATUMN in Grants.gov (http://www.grants.gov).

   B. **Pre-Proposal/Pre-Application Submission Content**

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

   PIs and organizations identified in the pre-proposal/pre-application should be the same as those intended for the subsequent proposal/application submission. If any changes are necessary after submission of the pre-proposal/pre-application, the PI must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507. A change in PI or organization after submission of the pre-proposal/pre-application will be allowed only at the discretion of the USAMRAA Contracting or Grants Officer.
The organization, Business Official, and PI must register in eBRAP before submitting a pre-proposal/pre-application. Upon completion of an organization’s registration in eBRAP and approval by the CDMRP Help Desk, the organization name will be displayed in eBRAP to assist the organization’s Business Officials and PIs as they register. The organization, Business Officials, and PIs must all be registered and affiliated in eBRAP. (See eBRAP User Guide at https://ebrap.org/eBRAP/public/UserGuide.pdf)

Pre-proposals/pre-applications must be submitted by the deadline specified on the title page of this BAA. Proprietary information should not be included in the pre-proposal/pre-application.

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

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**
  - Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF-424 form). The Business Official must either be selected from the eBRAP list or invited in order for the pre-proposal/pre-application to be submitted.
  - It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.
- **Collaborators and Key Personnel – Tab 3**
  - Enter the name, organization, and role of all key personnel (including co-investigators, mentors, collaborators, consultants, and subrecipients/subawardees) associated with the proposal/application.
  - JPC-1 Medical Modeling, Simulation, and Training Working Group members and advisors (listed in Section VII) should not be involved in any pre-proposal/pre-application or proposal/application including, but not limited to, concept design, proposal/application development, budget preparation, and the development of any supporting documentation. For questions related to the JPC-1 Medical Modeling, Simulation, and Training Working Group members and advisors and pre-proposals/pre-applications or proposals/applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.
- **Conflicts of Interest (COIs) – Tab 4**
  - List all individuals other than collaborators and key personnel who may have a COI in the review of the proposal/application (including those with whom the PI has a personal or professional relationship).
  - Federal agency personnel involved in the review process and/or with making funding recommendations are prohibited from assisting in any proposal/application,
including, but not limited to, concept design, proposal/application development, budget preparation, and the development of any supporting documentation. If formal collaboration with Military Facility personnel is planned (i.e., included in the proposal/application in performance of the research), this prohibition is not applicable. However, these individuals may not be involved in the review process and/or with making funding recommendations.

- Pre-Application Files – Tab 5

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

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, etc.) 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:** 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 from evidence-based, best-of-class, well-documented, and/or well-adopted designs to best solve how to insert sound sustainment training using neuroplasticity type of methodologies into a compensatory/adaptive medical tutor prototype.
  - **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. Include research design, methods, and analysis/evaluation strategies as well as materials anticipated to be used during the research. If applicable, include a description of animal and/or human use in the proposed project. For studies involving animals and/or 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 how the proposed research is relevant to the goal of developing methodologies that will support sustainment of cognitive processes that assist with patient assessment, clinical reasoning, clinical judgment, and clinical diagnosis and treatment.

- **Innovation:** Explain how the proposed project is innovative and not an incremental advancement of previous work.

Proposed Study Design/Plan: Describe the pilot study concept of the compensatory/adaptive medical tutor prototype. Provide the intended research methodology that will support the pilot study. Provide preliminary information such as anticipated type of recruits, number of recruits, control group, anticipated assessment criteria, inter-rater reliability, and statistical protocols. Refer to Section I.B., Program Overview, for additional information on the research areas of interest for this BAA.

Military Impact: Describe the anticipated short- and/or long-term outcomes of the proposed project and their potential impact on improving healthcare training and patient safety in the military health system. Refer to Section I.B., Program Overview, for additional information on the anticipated outcomes sought by this BAA.

Personnel and Facilities: Describe the role of the PI, co-PIs (if applicable), key personnel, sub-awards (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.

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).

- **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.

• Submit Pre-Proposal/Pre-Application – Tab 6
   ○ This tab must be completed for the pre-proposal/pre-application to be accepted and processed.

Pre-Proposal/Pre-Application Screening

• Pre-Proposal/Pre-Application Screening Criteria
   All pre-proposals/pre-applications will be screened by the JPC-1 Medical Modeling, Simulation, and Training Working Group members to determine technical merit and relevance to the mission of the DHP, DMRDP, 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 is derived from evidence-based, best-of-class, well-documented, and/or well-adopted designs to best solve how to insert sound sustainment training using neuroplasticity type of methodologies into a compensatory/adaptive medical tutor prototype.
   ○ Significance, Relevance, and Innovation: To what degree the proposed research is relevant to the goal of delivering a compensatory/adaptive medical tutor that determines where the learner is within the learning curve versus the course curricula, objectives, and anticipated outcomes. To what degree the proposed work is innovative and novel, including whether the proposed research is duplicative of existing research.
   ○ Open Source/License/Architecture: Evaluate if 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 compensatory/adaptive medical tutor tool.
   ○ Study Design/Plan: To what degree the proposed pilot-study methodologies, anticipated sample and sample size, types of recruits, anticipated assessment criteria, inter-rater reliability, and statistical protocols will justify and support the intended outcomes of the proposed research.
   ○ Military Impact: To what degree the project’s anticipated short- and/or long-term outcomes will impact the military and a future training program in healthcare delivery and patient safety in the military health system 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), sub-awards (if applicable), and consultants (if applicable) are
appropriate and complementary for achieving the research goals. To what degree
the prime facility will be able to perform the proposed research.

- **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 BAA.

C. **Proposal/Application Submission Content and Forms**

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

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

Each proposal/application submission must include the completed Grants.gov application
package provided in Grants.gov for this BAA. The Grants.gov application package is submitted
by the Authorized Organizational Representative through the Grants.gov portal

After proposal/application submission to Grants.gov, eBRAP will retrieve and validate the
submission. eBRAP will notify the organizational representatives and PI via email and instruct
them to log into eBRAP to review, modify, and verify the proposal/application. During this
verification period, the PI may upload missing files (excluding those listed in [Section IV.A.,
Rejection](#)), replace files, and re-categorize files. These modifications must be completed by the
end of the verification period.

*Note: The Project Narrative and Budget Form cannot be changed after the
proposal/application submission deadline.* If either the Project Narrative or the budget fails
eBRAP validation or if the Project Narrative or Budget Form needs to be modified, an updated
Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected
Application” with the previous Grants.gov Tracking ID [prior to the proposal/application
submission deadline](#).

Proprietary information should [be included](#) in the full proposal/application only if necessary for
evaluation purposes. Conspicuously and legibly, mark any proprietary information that is
included in the full proposal/application.

**Grants.gov application package components:** For the FY16 JPC-1/MSIS ATUMN Project,
the Grants.gov application package includes the following components (refer to the General
Submission Instructions, Section II.C., for additional information on proposal/application
submission):

1. **SF-424 (R&R) Application for Federal Assistance Form:** Refer to the General
   Submission Instructions, Section II.C., for detailed information.
2. Attachments Form

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

- **Attachment 1: Project Narrative (20-page limit): Upload as “ProjectNarrative.pdf.”** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, 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 proposal/application.

Describe the proposed project in detail using the outline below.

- **Background:** Present the ideas and reasoning behind the proposed research; include relevant literature citations or preliminary data on the proposed sustainment techniques using neuroplasticity type of methodologies. Additionally, present the ideas, reasoning, and justification behind the proposed compensatory/adaptive tutor that is anticipated to accurately and appropriately understand where the learner is within the learning curve versus the course curricula, objectives, and anticipated outcomes. The tutor must also identify viable and appropriate course route(s) on how to navigate from current position to end point position. 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.

Clearly support the choice of study variables and explain the basis for the study questions and/or study hypotheses. Establish the relevance of the study and explain the applicability of the proposed findings.

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

- **Specific Aims:** Concisely explain the project’s specific aims. If this proposal/application is part of a larger study, present only tasks that this award would fund.

- **Study Design:** Describe the experimental design, methods, and analyses/evaluations in sufficient detail for analysis.
  - Identify and describe the hypothesis to be studied and the projected outcome of the proposed research.
- Provide a detailed protocol, including but not limited to proposed methodologies, type of recruits, recruitment numbers, anticipated drop-out rate, assessment criteria, inter-rater reliability, intended medical domain(s) or discipline(s), control groups, and statistical protocols.

- Define the study variables and describe 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 a plan for data access.

- 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. Discuss the perceived engineering/design strengths and flaws and recommendations for overcoming/preventing them.

- Address any potential barriers and plans for addressing potential delays. Provide a risk management plan to address barriers to plans. As relevant, describe plans for addressing issues unique to working within the military health system.

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

  o **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.

  o **Additional Information:** If human and/or animal subjects are included in the research, proposals/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.

  *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.*

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

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

For animal studies, allow at least 2 to 3 months for regulatory review and approval by the USAMRMC ACURO; this does not include the additional time required for local IACUC review and approval.

Refer to the General Submission Instructions, Appendix 5, 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 be removed and may result in administrative withdrawal of the proposal/application.**

- **Bibliography and References Cited:** List the references in the order they appear in the proposal/application narrative. Use a reference format that gives the title of the citation. Do not send or attach copies of articles in print. There is no form for this information. The attachments should be in PDF in accordance with the formatting guidelines specified for full proposal/application preparation.

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

- **Facilities and Other Resources:** Describe the facilities available for performance of the proposed request and any additional resources proposed for acquisition at no cost to the Government. Indicate if a Government-owned facility is proposed for use. Reference should be made to the original or present award under which the facilities or resources are now accountable. There is no form for this information. The attachments must be in PDF in accordance with the formatting guidelines outlined for full proposal/application preparation.

- **Equipment:** Include a description of existing equipment to be used for the proposed research project.

- **Publications and/or Patent Abstracts (five-document limit):** Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscript(s) may be included in Attachment 2.

- **Letters of Organizational Support:** Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming
the laboratory space, equipment, and other resources available for the project. A letter for each organization involved in the project should be provided.

- **Letters of Collaboration:** Provide letter(s) supporting stated collaborative efforts necessary for the project’s success, even if provided at no cost. *If the project involves collaboration with a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center), special requirements apply.* A 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 proposal/application. Refer to the General Submission Instructions, Section II.C.8, for additional information.

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

- **Intellectual Property:** Refer to the General Submission Instructions, Appendix 3, for additional information. Provide the following:
  - List all background intellectual property to be used in the project or provide a statement that none will be used.
  - All software and technical data first produced under the award are subject to a Federal purpose license. If applicable, state and identify the proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the Federal purpose license.
  - **Intellectual and Material Property Plan (if applicable):** Provide a plan for resolving intellectual and material property issues among participating organizations. Identify which potential components will be open source/open architecture versus proprietary in the proposed framework, design, and/or plan of a possible biopsychosocial training model and how the proposed model would integrate/communicate with other systems.
  - **Commercialization Strategy (if applicable):** Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.
Implementation Plan: If commercialization is not applicable, describe the implementation plan to transform the standard of care.

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 Submission Instructions, Appendix 3, Section J for more information about the CDMRP expectations for making data and research resources publicly available.


Abstracts of all funded proposals/applications may be publicly posted; therefore, proprietary information should not be included in the abstract.

- 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: State concisely the specific aims of the study.
- Study Design: Briefly describe the study design.
- Impact: Provide a brief statement explaining the potential relevance of the proposed work to improving patient safety and healthcare outcomes in the military health system and/or to the general public.

Attachment 4: Lay Abstract (one-page limit): Upload as “LayAbs.pdf.” Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. Lay abstracts should be written using the following outline.

Abstracts of all funded proposals/applications may be posted online; therefore, proprietary information should not be included in the abstracts.

- 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.
- Do not duplicate the technical abstract.
- Describe the ultimate applicability and potential impact of the research.
  - What types of patients will it help; and how will it help them?
  - What are the potential clinical applications, benefits, and risks?
  - What is the projected timeline for achieving the expected patient-related outcome?
- Briefly describe how the proposed project will benefit Service members, Veterans, and/or their family members.
• **Attachment 5: Statement of Work (SOW) (two-page limit): Upload as “SOW.pdf.”** The SOW outlines and establishes the PI’s and an organization’s performance expectations for the work to be funded under this award. The SOW in an assistance agreement award establishes general objectives. The SOW in a contract sets rather specific goals and conditions for each year of the contracted project; the PI and contractor are expected to meet the provisions and milestones of the SOW. The SOW for all award types will be incorporated into the award document and, as such, is subject to release under the Freedom of Information Act (FOIA).

A series of relatively short statements should be included that comprise the approach to each of the major goals or objectives of the proposed research. The statements should outline the specific tasks, systems, and materials that are reasonable estimates for testing the proposed hypotheses of the study. An outline should be included that shows the work statements to be accomplished in each year of the award. If this proposal/application is part of a larger study, present only tasks that this award would fund. Allow at least 2 to 3 months for the USAMRMC ORP regulatory review and approval processes for studies involving human subjects and 2 to 3 months for studies involving animal subjects.

• **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)/result(s), design, and/or plan that will be directly attributed to the results of the proposed research.

  ○ *Long-Term Impact:* Describe the anticipated long-term gains from the proposed research, including the long-term anticipated advantages that the new understanding may ultimately contribute. Articulate how the anticipated outcomes will contribute in providing a compensatory/adaptive medical tutor using an empirically based neuroplasticity concept (such as adult-learning, perceptual training, psychophysical staircase functionality, etc.) for sustainment of knowledge.

  ○ *Military Relevance:* Clearly articulate how the proposed research is relevant to the intent of the funding opportunity and to improving patient safety and healthcare outcomes in the public and military health systems. State precisely the estimates as to the immediate and/or long-range usefulness of this study to the Armed Forces, as distinguished from general advancement of knowledge in medicine.

  ○ *Public Purpose:* Provide a concise, detailed description on how this research 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. Identify which potential components will be open source/open architecture vs. proprietary.

- Attachment 8: Conflicts of Interest, if applicable: Upload as “COI.pdf.” Provide details with the proposal/application submission of all actual or potential COIs, along with a plan to resolve them. A contract or assistance agreement will not be awarded if it is determined by the Contracting or Grants Officer that a COI cannot be resolved.

Federal agency personnel involved in the review process and/or with making funding recommendations are prohibited from assisting in any proposal/application, including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. If formal collaboration with Military Facility personnel is planned (i.e., included in the proposal/application in performance of the research), this prohibition is not applicable. However, these individuals may not be involved in the review process and/or with making funding recommendations.

Questions related to this topic should be directed to the CDMRP Help Desk at help@eBRAP.org or 301-682-5507. Refer to the General Submission Instructions, Appendix 1, for additional information.

- Attachment 9: Collaborating DoD Military Facility Budget Form(s), if applicable: Upload as “MFBudget.pdf.” If a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in the performance of the project, complete the Collaborating DoD Military Facility Budget Form (available for download on eBRAP at https://ebrap.org/eBRAP/public/Program.htm), including a budget justification, for each Military Facility as instructed. Refer to the General Submission Instructions, Section II.C.8., for detailed information.

3. Research & Related Senior/Key Person Profile (Expanded): Refer to the General Submission Instructions, Section II.C.4., for detailed information. Note: Some of the items in this attachment may be made available for programmatic review.

- 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 National Institutes of Health Biographical Sketch may also be used.

- PI Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
4. **Research & Related Budget**: Refer to the General Submission Instructions, Section II.C.5., for detailed information.

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

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

- **For Federal Agencies**: Proposals/Applications from Federal agencies must include in their budget justifications a Federal Financial Plan (Plan). The Plan must address how all funds will be obligated before their period for obligation expires, and how funds will be available to cover research costs over the entire award period. The Plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years.

- **For Collaborating Military Facilities**: Proposals/Applications from organizations that include collaborations with DoD Military Facilities (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) must submit Collaborating DoD Military Facility Budget Form(s) as instructed. Refer to the General Submission Instructions, Section II.C.5., Research & Related Budget, for detailed information.

5. **Project/Performance Site Location(s) Form**: Refer to the General Submission Instructions, Section II.C.6., for detailed information.

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

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

Prior to the end of the proposal/application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of a proposal/application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific BAA requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant’s responsibility to review all proposal/application components and ensure proper ordering as specified in the BAA. **If either the Project Narrative or the budget fails eBRAP validation, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking**
ID prior to the proposal/application submission deadline. The Project Narrative and Budget Form cannot be changed after the proposal/application submission deadline.

E. Data Universal Number System Numbers, Commercial and Government Entity Code, and System for Award Management

All proposals/applications must be submitted through Grants.gov. An applicant organization and any subaward organization must have Data Universal Number System (DUNS) numbers (issued by Dun and Bradstreet) before submitting a proposal/application to Grants.gov. In addition, an applicant organization must have a CAGE (Commercial and Government Entity) Code. Also, the organization must be registered as an Entity with the SAM and have an “Active” status before submitting a proposal/application through Grants.gov or receiving an award from the Federal Government.

Refer to the General Submission Instructions, Section II.A.2, for additional information.

F. Submission Dates and Times

All submission dates and times are indicated on the title page of this BAA. Pre-proposal/pre-application and proposal/application submissions are required. Failure to meet either of these deadlines will result in proposal/application rejection.

G. Intergovernmental Review

This BAA is not subject to Executive Order (EO) 12372.

H. Funding Restrictions

Refer to the General Submission Instructions, Section II.C.5, “Research & Related Budget,” for discussion of allowable costs, including pre-award costs and collaborations with Military Facilities.

I. Other Submission Requirements

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

III. PROPOSAL/APPLICATION REVIEW INFORMATION

A. Proposal/Application Review and Selection Process

All proposals/applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is peer review of proposals/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 (a) technical merit and (b) the relevance to the mission of the DHP and JPC-1/MSIS, and to the specific intent of the award mechanism. The highest-scoring proposals/applications from the first tier of review are not automatically recommended for funding. 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 proposal/application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization’s proposal/application. Violations by panel members or applicants that compromise the confidentiality of the review 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. Proposals/Application Review Process

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

- **Theoretical Rationale and Scientific Methods**
  - 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 are derived from evidence-based, best-of-class, well-documented, and/or well-adopted designs to best solve how to insert sound sustainment training using neuroplasticity type of methodologies into a compensatory/adaptive medical tutor prototype.
  - To what degree the proposed approach will accomplish cognitive processes that assist with patient assessment, clinical reasoning, clinical judgment, and clinical diagnosis and treatment.
  - How well the study aims, hypotheses or objectives, experimental design, methods, and analyses are designed to clearly answer the research questions.
  - Whether the proposed research and work provides a listing of evidence-based definitions, nomenclature, or lexicon that supports the proposed methodologies on determining which metrics/evaluation criteria should be investigated and why.
  - How well the proposed methodologies, type of recruits, recruitment numbers, anticipated drop-out rate, assessment criteria, inter-rater reliability, intended medical domain(s) (or discipline[s]), control groups, statistical protocols, etc., to support the pilot-study are presented and align with the proposed study outcomes.
  - Whether there is evidence of an adequate contingency plan, such as a risk mitigation plan, to resolve potential delays.
  - Whether the proposed timeline is appropriate and tasks outlined in the proposal/application are logical in their progression.
• **Relevance, Innovation, and Impact**
  - How the proposed research is relevant to the goal of incorporating empirically based sustainment techniques such as neuroplasticity methodologies to retain the details of the cognitive processes that assist with patient assessment, clinical reasoning, clinical judgment, and clinical diagnosis and treatment.
  - How the proposed work is 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 compensatory/adaptive medical tutor that determines where a learner is within the learning curve versus the course curricula, objectives, and anticipated outcomes.
  - To what degree the anticipated short- and long-term outcomes resulting from the proposed study will contribute to the goal of improving patient safety and healthcare outcomes.

• **Open Source/License/Architecture**
  - To what degree the proposed design/plan of the anticipated compensatory/adaptive medical tutor incorporates open source/license/architecture and intellectual property components available for license. Evaluate where in the prototype or the design/plan the respective components are located and to what degree the intellectual property components would limit future flexibility or adaptation of the tool to meet future Government needs.

• **Personnel and Facilities**
  - How the composition and balance of the research team (including other organization personnel, sub-awards, 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 BAA.
• Intellectual Property and Commercialization Plan
  ○ If applicable, to what degree the intellectual property plan is appropriate.
  ○ If applicable, to what degree the commercialization 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. Relevance to the mission of the DHP and JPC-1/MSIS, as evidenced by the following:
     • Adherence to the intent of the award mechanism
     • Programmatic relevance
     • Program portfolio balance
     • Relative impact, innovation, and novelty
     • Degree of public accessibility of outcomes
     • Military relevance

C. Submission Review Dates

All submission review dates and times are indicated on the title page of this BAA.

D. Notification of Proposal/Application Review Results

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

IV. ADMINISTRATIVE ACTIONS

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

A. Rejection

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

• The pre-proposal/pre-application is submitted by an intramural organization or FFRDC.
• Pre-Proposal/Pre-Application Narrative exceeds page limit.
• Pre-Proposal/Pre-Application Narrative is missing.
The following will result in administrative rejection of the proposal/application:

- Submission of a proposal/application for which a letter of invitation was not received.
- Project Narrative exceeds 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 pre-proposal/pre-application or proposal/application:

- An FY16 JPC-1 Medical Modeling, Simulation, and Training Working Group member or advisor is named as being involved in the research proposed or is found to have assisted in the pre-proposal/pre-application or proposal/application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. For a current listing of these individuals, please refer to Section VII, Medical Modeling, Simulation, and Training Working Group Members and Advisors.
- The proposal/application fails to conform to this BAA 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).
- Inclusion of any employee of CDMRP review contractors in proposals/applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Submission Instructions, Section II.B., for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The proposal/application budget differs significantly from the budget included in the pre-proposal/pre-application.
- The invited proposal/application does not propose the same research project described in the pre-proposal/pre-application.
D. Withhold

Proposals/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 the USAMRAA Grants Officer for a determination of the final disposition of the proposal/application.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

The awarding agency will be the USAMRAA. The USAMRAA Contracting and Grants Officers are the only individuals authorized to obligate funds and bind the Federal Government. Authorization to begin performance will be received via an award document (contract, grant, or cooperative agreement, as applicable) signed by the USAMRAA Contracting or Grants Officer. No commitment on the part of the Government should be inferred from discussions with any other individual.

A recommended for funding notification is NOT an authorization to begin performance nor a guarantee of an award. Awards will be made no later than September 30, 2017. Refer to the General Submission Instructions, Appendix 3, for additional information.

B. Administrative Requirements

Refer to the General Submission Instructions, Appendix 3 for general information regarding administrative requirements.

C. National Policy Requirements

Refer to the General Submission Instructions, Appendix 4 for general information regarding national policy requirements.

D. Reporting Requirements

Refer to the General Submission Instructions, Appendix 3, for general information on reporting requirements.

Monthly and/or quarterly technical progress reports and quad charts will be required based on the award mechanism. In addition to written progress reports, in-person presentations will be requested. Reporting of contractor manpower is required for all contracts.

- Contractor Manpower Reporting (CMR)
  - CMR is now a requirement of all DoD contracts. Offerors are allowed to include a nominal fee in their cost/price proposal for providing this data. A “nominal fee” is defined as a computation of an administrative assistant equivalent labor category providing approximately 6-8 hours to complete data input. Offerors may opt to not
separately price this required annual data input. CMR costs/price will not be evaluated as part of the total evaluated proposal cost/price.

- The contractor shall report ALL contractor labor hours (including subcontractor labor hours) required for performance of services provided under each contract via a secure data collection site. The contractor is required to completely fill in all required data fields using the following web address: http://www.ecmra.mil/.

- Reporting inputs will be for the labor executed during the period of performance during each Government fiscal year (FY), which runs October 1 through September 30. While inputs may be reported any time during the FY, all data shall be reported no later than October 31 of each calendar year, beginning with 2013. Contractors may direct questions to the help desk at: contractormanpower@hqda.army.mil or via phone at 703-377-6199.

E. Changes of Principal Investigator and Organization

Refer to the General Submission Instructions, Appendix 3, Section N, for general information on organization or PI changes.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

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

- Phone: 301-682-5507
- Email: help@eBRAP.org

B. Grants.gov Contact Center

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

- Phone: 800-518-4726; (international) 1-606-545-5035
- Email: support@grants.gov

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

- Failure to enter an email address for change notifications under the BAA Funding Opportunity Announcement in Grants.gov for notifications on any modification made to the initial posting.
- Attachments are uploaded into the incorrect form on Grants.gov forms. (See Proposal/Application Submission Checklist below.)
- Failure to contact the Grants.gov Help Desk when needed.
- Failure to send attachments.
- Inability to locate attachment forms. (Select “Search Grants” at http://www.grants.gov and enter W81XWH-BAA-15-1 in the “Funding Opp #” block. When the Funding Opportunity appears, select the Funding Opportunity #. When you reach the “View Grant Opportunity” screen, select “Full Announcement.” The forms will be listed on the following screen.)
- Use of “illegal” characters in attachment titles.
- Attachments exceed size limits.
- Upload attempts of unacceptable attachments: bitmap, TIFF, etc.
- Duplicate upload of documents.
VII. FY16 JPC-1 MEDICAL MODELING, SIMULATION, AND TRAINING WORKING GROUP MEMBERS AND ADVISORS

<table>
<thead>
<tr>
<th>CAPT Arthur Anthony</th>
<th>CDR Typhanie Kinder</th>
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<tr>
<td>Mr. Wilson Ariza</td>
<td>Ms. Heidi King</td>
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<td>COL Michael Barnes</td>
<td>Dr. Kevin Kunkler</td>
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<td>SGM F. Young Bowling</td>
<td>Dr. Amber Linde</td>
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<td>Dr. Harry Burke</td>
<td>Dr. Lori Loan</td>
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<td>Mr. Paul Chatelier</td>
<td>Dr. Joseph Lopreiato</td>
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<td>COL Tamara Crawford</td>
<td>Dr. Haru Okuda</td>
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<td>LTC Dawn Fitzhugh</td>
<td>Dr. Ray Perez</td>
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<td>Col Meletios Fotinos</td>
<td>Ms. M. Beth Pettitt</td>
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<td>COL Denise Hopkins-Chadwick</td>
<td>LTC Christopher Todd</td>
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<td>COL Daniel Irizarry</td>
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Submissions that include an FY16 JPC-1 Medical Modeling, Simulation, and Training Working Group member or advisor as an investigator, consultant, collaborator, or in a key personnel role will not be considered.
### VIII. APPLICATION SUBMISSION CHECKLIST

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<thead>
<tr>
<th>Grants.gov Application Components</th>
<th>Upload Order</th>
<th>Action</th>
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<td>SF-424 (R&amp;R) Application for Federal Assistance</td>
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<td>Attachments Form</td>
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<td>Project Narrative: Upload as Attachment 1 with file name “ProjectNarrative.pdf.”</td>
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<td>2</td>
<td>Supporting Documentation: Upload as Attachment 2 with file name “Support.pdf.”</td>
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<td>Technical Abstract: Upload as Attachment 3 with file name “TechAbs.pdf.”</td>
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</table>
Mr. John Winston
Director, Research Review/Business Development
Program Manager, Advanced
TATRC
USAMRMC
Fort Detrick MD
301-619-7674
john.p.winston2.ctr@mail.mil

Biosketch:
Jul 2011 – Nov 2012   Dir, Research Review; Dir, Business Development; PM AAMTI at TATRC, General Dynamics Information Technology
Jun 2003 – Jul 2011   Dir, Research Review; Dir, Business Development; PM AAMTI at TATRC, IPA from The Henry M. Jackson Foundation for the Advancement of Military Medicine

Education
BA in Speech, Communications, Theatre from Frostburg State University in 1982