

**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.

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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](https://www.grants.gov/Apply-for-Grants) (hereafter called [Grants.gov/Apply](https://www.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/](https://cdmrp.org/Program%20Announcements%20and%20Forms/).

- 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/](https://cdmrp.org/Program%20Announcements%20and%20Forms/)).
- 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 (DMRDP) 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 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 to 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 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 drop-out 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/](https://cdmrp.org/Program%20Announcements%20and%20Forms/).
- 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%20Announcements%20and%20Forms/).

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 USC¹ 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 CFR² 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.

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 (<http://www.grants.gov/>).

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.
- **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, 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.
- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.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. Use the outline below.

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.

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

Lay abstracts should be written using the following outline.

- 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)/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 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.”

- 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 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>.

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

CAPT Arthur Anthony	CDR Typhanie Kinder
Mr. Wilson Ariza	Ms. Heidi King
COL Michael Barnes	Dr. Kevin Kunkler
SGM F. Young Bowling	Dr. Amber Linde
Dr. Harry Burke	Dr. Lori Loan
Mr. Paul Chatelier	Dr. Joseph Lopreiato
COL Tamara Crawford	Dr. Haru Okuda
LTC Dawn Fitzhugh	Dr. Ray Perez
Col Meletios Fotinos	Ms. M. Beth Pettitt
COL Denise Hopkins-Chadwick	LTC Christopher Todd
COL Daniel Irizarry	

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

Grants.gov Application Components	Upload Order	Action	Completed
SF-424 (R&R) Application for Federal Assistance		Complete form as instructed.	
Attachments Form	1	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	2	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	3	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	4	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	5	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	6	Outcomes and Impact Statement: Upload as Attachment 6 with file name "Impact.pdf."	
	7	Innovation Statement: Upload as Attachment 7 with file name "Innovation.pdf."	
	8	Conflicts of Interest (if applicable): Upload as Attachment 8 with file name "COI.pdf."	
	9	Collaborating DoD Military Facility Budget Form(s): If applicable, upload as Attachment 9 with file name "MFBudget.pdf."	
Research & Related Senior/Key Person Profile (Expanded)		Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
		Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
		Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
		Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget		Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form		Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form		Complete form as instructed.	