

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/](https://cdmrp.org/Program%20Announcements%20and%20Forms/).

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

*Kirkpatrick DL and Kirkpatrick JD. 2007. *Implementing the Four Levels*, Berrett-Koehler Publishers, San Francisco, California.

- 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 of 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.
- **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.

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>.

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

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: Not required, leave Attachment 4 blank.	
	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	Collaborating DoD Military Facility Budget Form(s): If applicable, upload as Attachment 8 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.	
Confidential Letters of Recommendation		Confirm upload to eBRAP.	

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

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

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

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.