

**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 (JPC-1)/Medical Simulation and
Information Sciences (MSIS) Research Program**

**Utilizing Machine Learning and Artificial Intelligence for Medical
Training Needs (MACH Learning) Award**

Funding Opportunity Number: W81XWH-17-R-MSI1

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

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Proposal/Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), February 3, 2017
- **Invitation to Submit a Proposal/Application:** March 10, 2017
- **Proposal/Application Submission Deadline:** 11:59 p.m. ET, May 12, 2017
- **End of Proposal/Application Verification Period:** 5:00 p.m. ET, May 17, 2017
- **Peer Review:** July 2017
- **Programmatic Review:** August 2017

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 Program-Specific Broad Agency Announcement 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 2017 (FY17) Joint Program Committee-1 (JPC-1)/Medical Simulation and Information Sciences (MSIS) Research Program Utilizing Machine Learning and Artificial Intelligence for Medical Training Needs (MACH Learning) Award. For the remainder of the BAA this will be referenced as MACH Learning Award. This BAA must be read in conjunction with the submission guidelines in [Grants.gov/Apply for Grants](https://www.grants.gov/apply-for-grants) (hereinafter 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 and in DoD Grant and Agreement Regulations (DoDGARS) 22.315. In accordance with FAR 35.016, 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 are 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 FY17 JPC-1/MSIS-MACH Learning Award BAA/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 CDMRP electronic Biomedical Research Application Portal (eBRAP <https://eBRAP.org/>). Applicants submitting through their intramural organizations are reminded to coordinate receipt and commitment of funds through their respective resource managers.
- Submissions from intramural investigators to this BAA will be rejected. ***It is permissible, however, for an intramural investigator to be named as a collaborator on a proposal/application submitted through an extramural organization. In this case, the proposal/application must include a letter from the collaborator’s Commander or Commanding Officer at the intramural organization that authorizes the collaborator’s involvement.*** For more information, refer to the General Submission Instructions, Section II.C.
- 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: 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.

Full Proposals/Applications: To submit a full proposal/application, the PI must have received an invitation to submit from a U.S. Army Medical Research Acquisition Activity (USAMRAA) Contracting or Grants Officer. An invited full proposal/application must be submitted electronically through Grants.gov (<http://www.grants.gov/>) using the SF424 Research and Related (R&R) forms and the SF424 (R&R) Application Guide. ***Proposals/Applications will not be accepted by mail or in person.***

- Full proposals/applications (submitted through Grants.gov) will be available for viewing, modification, and verification in eBRAP, for a limited period.

A compatible version of Adobe is required for download from Grants.gov. For assistance downloading this or any Grants.gov package, contact Grants.gov Customer Support at <http://www.grants.gov/web/grants/support.html>.

B. General Program Overview

Proposals/Applications to the FY17 JPC-1/MSIS MACH Learning Award are being solicited for the Defense Health Agency (DHA) J9, Research and Development 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 manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The U.S. Army Medical Research and Materiel Command (USAMRMC) Congressionally Directed Medical Research Programs (CDMRP) provides Defense Medical Research and Development Program (DMRDP) management support for DHP core research program areas, including the JPC-1/MSIS. This BAA/Funding Opportunity and subsequent awards will be managed by CDMRP with strategic oversight from JPC-1/MSIS.

The mission of the JPC-1/MSIS is to explore the implications of models, technology and informatics for medical education/training, and for the provision, management, and support of healthcare services in the military. The JPC-1/MSIS plans, coordinates, and oversees a responsive world-class, tri-Service science and technology program focused on two areas of research: (1) improving military medical training through medical modeling, simulation, and educational training tools; and (2) improving the use and sharing of health-related data for better strategic planning, process development, and software applications. The JPC-1/MSIS Medical Modeling, Simulation and Training Steering Committee provided the strategy for which this Broad Agency Announcement/Funding Opportunity's topic was conceived.

Per guidance from DoD Instruction (DoDI) 5000.02,¹ the outcomes of research funded by this Broad Agency Announcement/Funding Opportunity will be used to better understand optimal algorithms and models to predict advancement of individuals as they are acquiring skills but also to assist in analyzing skill decay and assist in refresher training through machine learning and artificial intelligence approaches. These proposed machine learning models with artificial intelligence approaches would have substantial public purpose applications as an adjunct, objective way to provide additional information to instructors and faculty to advance students (medical, nursing, emergency medical technicians, etc.), as well as residents and licensed professionals, to more appropriate courses as those students acquire skills or the professionals refresh their own skills.

C. Background

MACH Learning is a line of research that supports the Medical Readiness Initiative (MRI) under the JPC-1/MSIS Medical Simulation and Training Technologies portfolio. The JPC-1/MSIS MRI focuses on research and ultimately the development of medical training methods, technologies, systems, and competency assessment tools for the attainment and sustainment of medical readiness for the military and the public. MRI also focuses on research methodologies, techniques, and tools that will allow for ethical, accurate, and appropriate pre-intervention rehearsal for medical providers with the input of authorized personalized medical information into simulation models.

Military medical personnel are trained and capable of providing care across the healthcare 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 in constantly changing environments (e.g., field hospitals, military treatment facilities [MTFs]). The ability to render medical care whenever and wherever a Service member is called to duty is a requirement for individuals working in the Military Health System (MHS). Medical practical skills used in the field do not necessarily translate to skills used in a controlled facility (hospital), making it essential for training of these skills to be proficient before deployment. In addition, retention of MTF- relevant skills after medical personnel return from a combat duty station or not having used hospital/MTF skills over a period of time needs to be addressed. New skill acquisition based upon existing core knowledge of fundamental information and definitions is also essential.

Recognized gaps, such as enhancement and sustainment of military healthcare professionals' cognitive performance to optimize decision making and modulating information flow to assist towards performance and decision making in this area of research include: (1) lack of appropriate metrics for assessing advancement of individuals as they are acquiring skills and sustaining those skills; and (2) inability to prevent decay of skills resulting from training loss due to transitional effects (clinical to theater and back to clinical setting) in military medicine. This Broad Agency Announcement/Funding Opportunity is soliciting research that may lead to algorithms for the creation of models for the identification of medical skills training needs utilizing machine

¹ Operation of the Defense Acquisition System, DoDI Number 5000.02, January 7, 2015.

learning and artificial intelligence that have the ability to synthesize information from a multitude of sources to predict the need for advancement of learners from one of competency to that of proficiency during acquisition of skills as well as refresher training to be offered before medical personnel are transitioned to a different medical environment. Possible research to be considered includes but is not limited to:

- Algorithms/models for the prediction of an individual’s cognitive and psychomotor competency and proficiency level in order to provide objective information to the educator/trainer to advance the trainee or have the trainee repeat specific components;
- Algorithms/models for the prediction of medical training needs based on available data sources to be used as a prediction tool for the educator to plan appropriate training when it matters;
- Algorithms/models that can be used to create refresher training curricula at reasonable time intervals before or after deployment.

Machine learning is defined as a type of artificial intelligence that allows computers to acquire knowledge without being programmed. It focuses on the development of programs that can “learn” when exposed to new data². Machine learning can be a powerful tool for predicting when a student (trainee) should advance from course to course with minimal instructor analysis or when refresher training is needed in order to improve the performance of the learner by optimizing a performance criterion using comparison data of peers or past experience and allowing the refresher courses to be on the current level of the learner to optimize the course experience.

The FY17 JPC-1/MSIS MACH Learning Award is intended to support research projects to develop machine learning/artificial intelligence modeling that can be used as predictive models for early detection of needed medical training during the acquisition of skills as well as refresher training. The research project should focus on an effective training surveillance system model that can address training requirements in the military medical community and that also has applicability for public purpose. The research must be able to mine a variety of training data reports in order to analyze training outcomes to determine level of competence/proficiency and model and predict training effectiveness as well as aligning training outcomes with that of curricula objectives in real time.

Advances in machine learning development are anticipated to make it possible for an artificial intelligence network with various sets of parameters to assist in planning the next level of course work for the trainee whether it is for acquisition of skills or for refresher training. Over time, the artificial intelligence network will be “smart” enough to distinguish a learner from a beginner/novice, or any other learner as defined by Benner³, by identifying simulation results and/or by comparing trends and critical metrics with known guidelines or comparing a similar, peer-level group’s outcomes with those of the trainee’s.

² A Smola and SVN Vishwanathan. 2008. Introduction to machine learning. *Cambridge University, UK*, 32, p.34.

³ P Benner. 1982. From novice to expert. *American Journal of Nursing* 82(3):402-407.

The anticipated long-term vision of this concept includes but is not limited to: (1) incorporating a predictive multi-use training model to be used across the Services for medical education and training; (2) developing more complex models to predict when training is needed to assist military medical personnel and/or training education organizations in those procedures that should be stressed, whether for an individual or for a team; and (3) coupling multitudes of well-constructed (from a learning and reliability perspective) appropriate fidelity simulation systems with the machine learning model and integrating those structures into the system to serve as real-time assessment tools to predict task outcomes compared to the training standards or against a comparable peer-level group.

D. Award Information

The FY17 JPC-1/MSIS MACH Learning Award supports research to determine, define, and validate predictive machine learning modeling systems that predict early stages of training needs in order to eliminate the current culture of just-in-time training or not being able to offer refresher training in an efficient manner. The intended outcomes are relevant for military and general public training and educational purposes.

The FY17 JPC-1/MSIS MACH Learning Award seeks metrics/evaluation criteria, the definition of those metrics/evaluation criteria, and specific measuring tools to obtain (collect) and potentially analyze the metrics/evaluation criteria needed to develop a sufficient algorithm for use in the prediction of training needs, both in the skill acquisition phase and in refresher training. It is also seeking a proof-of-concept and/or prototype (depending on award vehicle) in which the proposed predictive model works together with incoming data/information from different, well-evidenced sources. The models need to use real data/information/knowledge and need to compare against known guidelines within the relative medical discipline and a comparable, peer-level group.

The outcomes of the research will allow data/information/knowledge into the proof-of-concept and/or prototype (depending on award vehicle) model. The model needs to be tested in a laboratory-type environment, preferably by a subawardee with no active participation in the development of the model. Actual interfaces will need to be described and defined in the outcome, but functionality of the entire defined interface does not need to be demonstrated in the delivered proof-of-concept and/or prototype (depending on award vehicle).

Submissions to the FY17 JPC-1/MSIS MACH Learning Award should not only include the design and the methodologies to create the MACH Learning proof-of-concept/prototype, but should also include data/information that will or could be used as input into or output from a machine learning and artificial intelligence model. The submissions should include, but are not limited to, the following:

- Define classifiers that will be used in the developed model (i.e., learner classified as a novice, expert, etc.).
- Define the types of data being used to create the model (e.g., lists, sets, and matrices, images, video, trees/graphs, strings, and compound structures); define the assessment criteria, generalizability, validity, and reliability; and define how the types of data being used within the model will handle a variety of data that may vary widely in format.

Include a plan for how missing data would be handled and how it might impact accuracy and appropriateness of the model.

- Describe (1) the type(s) of learning problem to be used in the model (e.g., binary, multiclass, structured estimation, regression, novelty detection) and (2) the appropriate statistical methodology used with the learning problem chosen.
- Describe the modeling errors and corrections for covariate shift, co-training, mistakes of estimation, and missing variables within the model.
- Define the type(s) of algorithm being used in the model (e.g., ranking, collaborative filtering, automatic translation, named entity recognition, speech recognition).
 - The algorithm developed should be a continuous learning model that can be adapted to predict skill training for multiple military medical tasks. A simple model is acceptable under this Broad Agency Announcement/Funding Opportunity; however, elegance and complexity of a prediction model will be evaluated.
- Describe the selection of machine learning style that will be used in the model (i.e., supervised learning, unsupervised learning, or semi-supervised learning).
- Define the approach in using machine learning to generate algorithms/models that predict, in real-time, a learner's training needs for performing a medical procedure. The medical procedure should:
 - Be interventional (assessing combination of cognitive, psychomotor, and behavioral skills).
 - Establish very clear objectives, especially as related to clinical/patient outcomes and patient safety.
 - Maintain definitive objective metrics.
 - Be military-relevant but does not have to represent the treatment of a traumatic injury analogous to one endured during combat or in theatre.
- Include one or more of the following scenarios for incorporation within the proof-of-concept and/or prototype model (depending on award vehicle). Deviations from the scenarios below are acceptable if the applicant describes the series of skills/procedures that comprise competency/proficiency within that area and provides adequate justification of military relevance.
 - Hemorrhage control, amputation management, and fasciotomy;
 - Airway management (upper and lower) (e.g., intubation, needle decompression, cricothyroidotomy); and/or
 - Burn management (including escharotomy).
- Describe the pilot study, which should include but is not limited to:
 - Proposed methodologies, conceptual and operational definitions, intended medical domain(s) (or discipline[s]), control groups, and statistical protocols (in the full application).

- Research outcomes, analysis, methodologies, and conclusions are expected to be disseminated and propagated to the military and the Government. Public benefits from this research are encouraged, such as through published articles, as well as applying the machine learning algorithms to academic medicine, private practice medicine, and outpatient medicine.
- Compare the prediction model to currently used evaluation criteria that will allow novices to advance from one level of skill acquisition to the next, and compare refresher training standards and known medical guidelines (per respective disciplines) to show whether there is a necessity to predict needed training and when those training time periods should be held to maximize training benefits.

For the FY17 JPC-1/MSIS MACH Learning Award, the total duration of the research and testing will be no more than 30 months. At a minimum, 12 of those months are expected to be allotted to a pilot study that includes the proposed specific aims, methodologies, sample and sample size, inter-rater reliability, assessment criteria, analyzed results, conclusions, and potential next-step recommendations, etc.; an assessment of the model once the proof-of-concept and/or prototype (depending on award vehicle) has been completed; and a determination as to which classifiers, variables, metrics, evaluation criteria, and so forth are significantly relevant to determining outcomes. Recommendations as to which classifiers, variables, metrics, evaluation criteria, and so forth need future refinement must also be identified.

Results of MACH Learning Award research should demonstrate a predictive model that provides the foundation of utilizing machine learning in the MHS by methodically predicting the time when a learner needs appropriate refresher training depending on duty station needs. Such ability to predict training needs, including specifying the level of training needed, will reduce cost and time loss when training is not needed for a mission. Outcomes of this research are expected to better prepare military medical educators to provide refresher training at appropriate time periods, optimizing the training experience. In addition, the resultant predictive modeling is expected to help the learner identify his/her level of training needs and to seek appropriate refresher training.

Intellectual Property

While the proposed research may include proprietary tools, appropriate justification for incorporating proprietary tools must be included. Proposed proprietary components should be clearly and legibly marked in the full application. The proposed research outcomes are intended to have broad availability not only with the content but also with underlying predictive models to allow more medical simulation systems to use the proposed model. For the purpose of the public, the machine learning predictive models must be open source to allow organizations to insert their own generated data/information into the model without additional licenses or access limitations.

Anticipated Outcomes

The anticipated outcomes of research supported by the FY17 JPC-1/MSIS MACH Learning Award are as follows (in no particular order):

- Proof-of-concept and/or prototype (depending on funding award vehicle) that at a minimum achieves technology readiness level (TRL) four (4), which means that software/hardware/firmware components are needed to work together and the models need to use real data/information. The proof-of-concept and/or prototype (depending on award vehicle) need to address:
 - Classifiers that will be used in the developed model (i.e., learner classified as a novice, expert, etc.).
 - Demonstrate ability for novices to advance from one portion of their acquisition of skills to the next, and compare refresher training standards or known medical guidelines (per respective disciplines).
 - Demonstrate the type of learning problem implemented in the model (e.g., binary, multiclass, structured estimation, regression, novelty detection).
 - Demonstrate the types of data being used that created the model (e.g., lists, sets, and matrices, images, video, trees/graphs, strings and compound structures) and demonstrate the assessment criteria implemented.
 - Demonstrate the type of algorithm implemented in the model (e.g., ranking, collaborative filtering, automatic translation, named entity recognition, speech recognition).
 - Demonstration of the continuous learning model to predict skill training for multiple military medical tasks.
 - Demonstration of a military relevant skill / procedure:
 - Hemorrhage control, amputation management, and fasciotomy;
 - Airway management (upper and lower) (intubation, needle decompression, cricothyroidotomy, as examples); and/or
 - Burn management (including escharotomy).
- A validated report, document, and/or list with contacts, references, and sources that support the proposed methodologies that underpin the determination of the anticipated classifiers, variables, metrics, and evaluation criteria. The content needs to provide information and analyzed data of the actual postulated classifiers, variables, metrics, and evaluation criteria that best fit the machine learning model.
- A report, document, and/or list of the terminology and respective definitions for the data/information/knowledge inserted into the model.
- A report, document, and/or list that provides the measuring tools and, if needed, how they were used to obtain the metric/evaluation criteria. Objective measurements are preferred, but subjective measurements that have rigorous reliability, repeatability, and robustness will be considered.

- A report, document, and/or list of the definitions and weight (proportionality) of data/information/knowledge and the equations/algorithms used in the proposed predictive model. The content must provide when the equations have statistical relevance due to the amount and type of data versus when the equations may predict trends but not statistical significance.
- A report, document, and/or list (or table) that provides the curricula of the scenarios used within the proof-of-concept and/or prototype (depending on award vehicle) and explains the sequence of steps on how an individual progresses through the steps to obtain competency and then proficiency.
- Analyzed information and the specific aims, methodologies, sample and sample size, inter-rater reliability, assessment criteria, analyzed results, conclusions of the pilot study, and next-step recommendations based upon the results of the study.
- A report on the components that are proprietary and ones that are open source/open architecture. Government ownership and licensing rights need to be provided.
- A strategic plan for applying the MACH Learning model to additional medical training and education applications.

Research Involving Human Anatomical Substances, Human Subjects, or Human

Cadavers: All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRMC Office of Research Protections (ORP), Human Research Protection Office (HRPO) prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is *not* required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB/EC. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Refer to the General Submission 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, including amendments to ongoing projects. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled “Research Involving Animals.” ***Allow at least 2 to 3 months for ACURO regulatory review and approval processes for animal studies.*** Refer to the General Submission Instructions, Appendix 5, for additional information.

The CDMRP intends that information, data, and research resources generated under awards funded by this Broad Agency 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 Submission Instructions, Appendix 4, Section K.

E. 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 extramural investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, nonprofit, public, and private organizations.
- This Broad Agency Announcement/Funding Opportunity is intended for extramural investigators only. Intramural investigators are directed to apply through CDMRP eBRAP (<https://eBRAP.org/>).
- 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. **NOTE:** In accordance with FAR 35.017, FFRDCs are not eligible to directly receive awards under this Broad Agency Announcement/Funding Opportunity. However, teaming arrangements between FFRDCs and eligible organizations are allowed so long as they are 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.

F. Funding

The JPC-1/MSIS expects to allot approximately \$3.2 million (M) of the anticipated FY17 DHP RDT&E appropriation to fund approximately two (2) JPC-1/MSIS MACH Learning Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Broad Agency Announcement is contingent upon the

availability of Federal funds for this program. As of the release date of this Broad Agency Announcement, the FY17 Defense Appropriations Bill has not been passed and there is no guarantee that any funds will be available to support this program. The funding estimated for this Broad Agency Announcement is approximate and subject to realignment.

NOTE: Applications received in response to both the intramural JPC-1/MSIS MACH Learning Award BAA and the extramural JPC-1/MSIS MACH Learning Award Broad Agency Announcement will be evaluated and considered for funding together. The Government reserves the right to fund any combination of intramural and/or extramural applications.

- The maximum period of performance is **30 months**. The proposed pilot study *must* be included within the proposed 30-month Statement of Work plan and, at a minimum, must be 12 months in duration.
- The anticipated total costs budgeted for the entire period of performance will not exceed **\$1,600,000**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$1,600,000** total costs or using an indirect rate exceeding the organization's negotiated rate.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- Option periods may be used on contracts.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **30 months**.

Refer to the General Submission Instructions, Section II.C.4., 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.4. of the General Submission Instructions.**

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

- Travel costs for the PI(s) to attend In-Progress Review (IPR) meetings anticipated to be held at or near the end of Year 1 and Year 2. For planning purposes, it should be assumed that the meetings 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 supplies
- Research-related subject costs
- Travel between collaborating institutions, including travel to military/Government facilities
- Support for multidisciplinary collaborations, including travel

- Travel costs for up to two investigators to travel to two scientific/technical meetings per year in addition to the required IPR meetings described above.

Subawards to intramural agencies and other Federal agencies may be executed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR]; or Funding Authorization Document [FAD] process; or Interagency Support Agreement [DD form 1144]). 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.4., Research & Related Budget, for additional information on budget considerations for proposals/applications involving Federal agencies.

G. 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 determine the award types for proposals/applications selected for funding. The Federal Grant and Cooperative Agreement Act of 1977, 31 USC⁴ 6301-6308, provides the legal criteria to select a procurement contract or an assistance agreement. Refer to the General Submission Instructions, Appendix 3, for additional information.

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

Any contract awarded under this BAA will be governed by the Federal Acquisition Regulations (FAR) and other applicable federal regulations.

More information on these award instruments may be obtained from the USAMRAA website at <http://www.usamraa.army.mil>. No fee or profit is allowable under an assistance agreement.

H. Other Review Information

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

1. ***"Exclusions" Identified in System for Award Management (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 SAM; data from the Federal Awardee Performance and Integrity Information System, a component

⁴ United States Code

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.B, for additional information.

2. **Conflict of Interest (COI):** All awards must be free of COIs that could bias the research results. Prior to award of an assistance agreement or contract, applicants will be required to disclose all potential or actual COIs along with a plan to manage them. An award may not be made if it is determined by the Grants Officer or Contracting Officer that a COI cannot be adequately managed. 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 \$700,000 and the offeror is other than a small business, the contractor will be required to submit a subcontracting plan for small business 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

Submission is a two-step process requiring both (1) pre-proposal/pre-application submission through eBRAP (<https://eBRAP.org/>) and (2) full proposal/application submission through Grants.gov (<http://www.grants.gov/>).

The pre-proposal/pre-application and full proposal/application submission process should be started early to avoid missing deadlines. There are no grace periods. Applicants must be familiar with Grants.gov requirements, including the need for an active SAM registration and a Data Universal Numbering System (DUNS) number. Refer to Section II.D. of the General Submission Instructions for further information regarding Grants.gov requirements

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-proposals/pre-applications electronically through a secure connection, to view and edit the content of their pre-proposals/pre-applications and full proposals/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 proposal/application submissions associated with them. eBRAP will validate Grants.gov proposal/application files against the specific Broad Agency Announcement 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 proposal/application components for accuracy as well as ensure proper ordering as specified in this Broad Agency Announcement.

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

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

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-17-R-MSII in Grants.gov (<http://www.grants.gov/>).

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

All pre-proposal/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-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.C., for additional information on pre-proposal/pre-application submission):

- **Application Information – Tab 1:**

- Enter the information as described in eBRAP before continuing the pre-proposal/pre-application.

- **Application Contacts – Tab 2:**

- Enter contact information for the PI and the organization’s Business Official responsible for sponsored program administration (or equivalent). This is the individual listed as the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF424 (R&R) Form). The Business Official must either be named or invited in order for the pre-proposal/pre-application to be submitted. If the organization’s Business Official is not in eBRAP, an invitation to the Business Official to register in eBRAP must be sent. In addition, it is recommended that the PI identify an Alternate Submitter in the event that assistance with the pre-proposal/pre-application is needed.

Note: The eBRAP system does not require an approval of the pre-proposal/pre-application by the PI’s organization.

- **Collaborators and Key Personnel – Tab 3:**

- Enter the name, organization, and role of all collaborators and key personnel (including co-investigators, mentors, collaborators, consultants, and subrecipients/subawardees) associated with the proposal/ application. 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 SF424 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.
- FY17 JPC-1/MSIS Medical Modeling, Simulation and Training Steering Committee members should not be involved in any pre-proposal/pre-application or proposal/application including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. For questions related to FY17 [JPC-1/MSIS Medical Modeling, Simulation and Training Steering Committee](#) members 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.
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in application preparation, research, or other duties for submitted applications. For FY17, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess.shtml>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Government. Refer to the General Submission Instructions, Appendix 1, for detailed information.

- **Conflicts of Interest – 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). Refer to Appendix 1, Section C, of the General Submission Instructions for further information regarding COIs.

- **Pre-Application Files – Tab 5**

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

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

Include the following:

- **Problem to Be Studied:** Describe the perceived issue(s) and the problems to be studied. This section should serve as an abstract of the proposed work.
- **Theoretical Rationale, Scientific Methods, and Research:** Describe the research approach for accomplishing the specific aims that is feasible, will accomplish the proposed objectives, will provide information on proposed methods and analysis/evaluation strategies, and is based on sound rationale.
 - **Background/Rationale:** Clearly present the ideas and reasoning behind the proposed research. Include relevant military and civilian literature citations, preliminary and/or pilot data, and/or other evidence that led to the development of the proposed research. Any unpublished 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.
 - **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 human use in the proposed project, including 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 a proof-of-concept and/or prototype (depending on award vehicle) machine learning algorithm using artificial intelligence that includes the suggested scenarios (hemorrhage control, amputation management, and fasciotomy; airway management [upper and

lower]; and/or burn management [including escharotomy] or one that is proposed and justified by the award recipient) and explain how the proposed MACH Learning model assists in the decision-making process for progressing new trainees in acquiring skills or assists with refresher skills to minimize decay/degradation of skills.

- **Innovation:** Explain how the proposed project is innovative and not an incremental advancement or duplication of previous work.
- **Proposed Study Design/Plan:** Describe the pilot study that will support the preliminary evaluation of the strategic planning tool(s)/model(s). 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. Pilot studies should be at least 12 months in duration. Refer to [Section I.B., General 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 MHS. Refer to [Section I.B., General Program Overview](#), for additional information on the anticipated outcomes sought by this BAA.
- **Personnel:** Describe the role of the PI, co-PIs (if applicable), key personnel, subawards (if applicable), and consultants (if applicable) in the research team, including the expertise each brings to the proposed project. Explain how the team’s expertise is appropriate and complementary for achieving the research goals.
- **Open Source/License/Architecture:** Describe the intellectual property that is intended to be incorporated within the design/plan and describe components that are designed to be open source/architecture.

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 files* 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 (six-page limit per individual):** *All biographical sketches should be uploaded as a single combined file.* 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-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 Program Panel members to determine technical merit and relevance to the mission of the DHP and JPC-1/MSIS. Pre-proposals/pre-applications will be screened based on the following criteria:

- **Background/Research Problem:** How well the background and scientific rationale demonstrate sufficient evidence to support the proposed research project.
- **Specific Aims and Study Design:** How well the specific aims are stated and supported through scientific rationale and referenced literature and how well the proposed research project’s approach will address these aims.
- **Significance, Relevance, and Innovation:** How well the pre-proposal/pre-application addresses the potential significance and relevance of the proposed research as requested within this Broad Agency Announcement/Funding Opportunity and to what degree the proposed research is innovative. How well the pre-proposal/pre-application addresses open resource/architecture within the design.
- **Personnel:** 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.
- **Military Relevance:** How well the proposed research project directly or indirectly benefits injured military Service members, Veterans, and/or their family members and caregivers.
- **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 an application is indicated on the [title page](#) of this Broad Agency Announcement/Funding Opportunity.

C. Full Proposal/Application Submission Content and Forms

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

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 submission package of forms and attachments provided in Grants.gov Broad Agency Announcement/Funding Opportunity. The submission package is submitted by the Authorized Organizational Representative through the Grants.gov portal (<http://www.grants.gov/>). Refer to the General Submission Instructions, Section II, for submission information.

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 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.***

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 FY17 JPC-1/MSIS MACH Learning Award (W81XWH-17-R-MSI1), the Grants.gov application package includes the following components (refer to the General Submission Instructions, Section II.D., for additional information on proposal/application submission):

- 1. SF424 (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) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

- **Background:** Present the ideas and reasoning behind the proposed research; include relevant literature citations, preliminary data, if applicable, previous highly regarded metrics/evaluation criteria and the justification for use, and/or other evidence that led to the development of the proof-of-concept and/or prototype (depending on award vehicle) model/tool and the proposed pilot study. Describe previous experience most pertinent to this project and provide what rights, licensures, or government ownership those projects may have. Any preliminary data, if available, should be from the laboratory of the PI or member(s) of the collaborating team.

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

Provide a listing of evidence-based definitions, nomenclature, or lexicon associated with the proposed methodologies and explain how they support the proposed methodologies.

- **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 in sufficient detail for analysis.
 - 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 in and out of the proposed machine learning model.
 - Document the availability and accessibility of the study materials (including data) needed as applicable.

- Describe the pilot study and how the study will support the preliminary evaluation of the proposed strategic planning tool(s)/model(s).
- **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 within 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 (FDA) or appropriate Government agency.
- For studies involving human subjects, allow at least 2 to 3 months for regulatory review and approval by the USAMRMC HRPO; this does not include the additional time required for local IRB/EC review and approval.

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 result in the removal of those items or may result in administrative withdrawal of the application.*

- **Bibliography and References Cited:** List the references in the order they appear in the Project 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.
- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
- **Facilities and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.
- **Publications and/or Patent Abstracts (five documents limit):** Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then a copy/copies of the published manuscript(s) must be attached.
- **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 (MHS facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center), special requirements apply.* A collaborating DoD researcher must 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.D.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:
 - Should the applicant intend to use, in the performance of this program, pre-existing, legally protected and perfected intangible property and for which no Federal funds had been used in the development of said property, the applicant must:
 - Clearly identify all such property;
 - Identify the cost to the Federal Government for use or license of such property, if applicable; or
 - Provide a statement that no property meeting this definition will be used on this project.
 - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
 - All software and technical data first produced under the award are subject to a Federal purpose license. A term of the award requires the recipient to grant the Government all necessary and appropriate licenses, which could include licenses to background and proprietary information that have been developed at private expense.

Therefore, it is important to disclose/list any intellectual property (software, data, patents, etc.) that will be used in performance of the project or provide a statement that none will be used. If applicable, all proprietary information to be provided to the Government should be stated and identified; the applicant should indicate whether a waiver of the Federal purpose license will be required.
- **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 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 will be posted publicly; *therefore, proprietary information should not be included.*

- **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 relevance of the proposed work to improving patient safety and healthcare outcomes in the MHS 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 will be posted publicly; *therefore, proprietary information should not be included.*

Lay abstracts should be written using the outline below. Do not duplicate the technical abstract.

- Describe the objectives and rationale for the proposed study in a manner that will be readily understood by readers without a background in science or medicine.
 - Describe the ultimate applicability and impact of the research.
 - How might it improve patient safety and healthcare outcomes?
 - What are the potential clinical applications, benefits, and risks?
 - What types of military and/or civilian patients will it help, and how will it help them?
- **Attachment 5: Statement of Work (SOW) (three-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 MACH Learning Award, use the SOW format example titled “SOW for Advanced Tech Development Research.” The SOW must be in PDF format prior to attaching. Refer to the General Submission Instructions, Section II.D.3., for detailed guidance on creating the SOW.
 - The proposed pilot study must be included within the 30-month Statement of Work plan and, at a minimum, must be 12 months in duration.
 - **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 long-term anticipated advantages. Explain how the proposed model, if implemented, would be able to predict accurately and appropriately how and where individuals should be placed within future training courses, either during acquisition of skills or during refresher training, and would optimize the learner’s training outcomes toward improved patient wellbeing and clinical outcomes.
- **Military Relevance:** Clearly articulate how the proposed research is relevant to the military medicine’s goals and objectives. 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. Clearly articulate the relevance of the scenarios selected for integration into the proof-of-concept and/or prototype (depending on award vehicle) and why the selected curricula, metrics, evaluation criteria, etc., based upon those scenarios will optimize military medicine training and education.
- **Public Purpose:** Provide a concise, detailed description of how this research project will benefit the general public. Articulate different markets within medicine that the award recipient believes would have applicability of a machine learning model.
- **Attachment 7: Innovation, Relevance, and Novelty (two-page limit): Upload as “Innovation.pdf.”** Describe how the proposed project is innovative, relevant and its novelty. 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 description of the innovative, relevant and impactful features of the proposed conceptual framework, design, and/or plan of key components and how they integrate/communicate with each other.
- **Attachment 8: Human Subject Recruitment and Safety Procedures (required for all studies recruiting human subjects; no page limit): Upload as “HumSubProc.pdf.”** The Human Subject Recruitment and Safety Procedures attachment should include the components listed below.
 - a. **Study Population:** Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site(s) (population from whom the sample will be recruited/drawn). Demonstrate that the research team has access to the proposed study population. Furthermore, discuss past efforts in recruiting human subjects from the target population for previous clinical studies (if applicable). Address any potential barriers to accrual and plans for addressing unanticipated delays. Include justification of

any age, race, ethnicity, or sex limitations provided. *For clinical studies proposing to include military personnel as volunteers, refer to the General Submission Instructions, Appendix 5, Section E.5., for more information.*

- b. Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical study. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide detailed justification for exclusions.

Inclusion of Women and Minorities in Study. Consistent with the Belmont Report, “Ethical Principles and Guidelines for the Protection of Human Subjects,” and Congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRMC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subject(s) research. Include an appropriate justification if women and/or minorities will be excluded from the clinical study.

- c. Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, and healthcare provider identification).
- Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.
 - Include a detailed description of and justification for the compensation plan if the human subjects will be compensated for participation in the study.
 - Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study.
- d. Description of the Informed Consent Process:** Specifically describe the plan for obtaining informed consent from human subjects.
- *For the proposed study, provide a draft, in English, of the Informed Consent Form.*
 - Identify who is responsible for explaining the study, answering questions, and obtaining informed consent. Include a plan for ensuring that human subjects’ questions will be addressed during the consent process and throughout the study.
 - Include information regarding the timing and location of the consent process.
 - Address issues relevant to the mental capacity of the potential human subject (e.g., altered capacity due to brain injury, stress/life situations, human subject age, administration of any mind-altering substances such as tranquilizers, conscious sedation, or anesthesia,) if applicable.

- Address how privacy and time for decision making will be provided and whether or not the potential human subject will be allowed to discuss the study with anyone before making a decision.
 - Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study and describe any relevant procedures to assure continued consent.
 - Describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. Note: The PI must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed clinical study to be in compliance with 10 USC 980 (<http://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf>). If applicable, refer to the General Submission Instructions, Appendix 5, Section E.4., for more information.
 - **Assent.** If minors or other populations that cannot provide informed consent are included in the proposed clinical study, a plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent, should be provided. PIs should consult with their local IRB to identify the conditions necessary for obtaining assent.
- e. Screening Procedures:** List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry. Note that some screening procedures may require a separate consent or a two-stage consent process. Informed consent must be obtained prior to initiation of any procedures for the purpose of determining eligibility.
- f. Risks/Benefits Assessment:**
- **Foreseeable risks:** Clearly identify all study risks, including potential safety concerns and adverse events. Study risks include any risks that the human subject is subjected to as a result of participation in the clinical study. Consider psychological, legal, social, and economic risks as well as physical risks. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.
 - **Risk management and emergency response:**
 - Describe how safety surveillance and reporting to the IRB and FDA (if applicable) will be managed and conducted.
 - Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values.

- Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, to include who will be responsible for the cost of such care.
- Address any special precautions to be taken by the human subjects before, during, and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention).
- Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study.
- For a study in which the IRB determines there is greater than minimal risk to human subjects, the DoD requires an independent research monitor with expertise consonant with the nature of risk(s) identified within the research protocol. If applicable, refer to the General Submission Instructions, Appendix 5, Section F.4, for more information on study reporting authorities and responsibilities of the research monitor.
- **Potential benefits:** Describe known and potential benefits of the study to the human subject, a specific community, or society.
- **Attachment 9: Data Management (required for all studies recruiting human subjects; no page limit): Upload as “Data_Manage.pdf.”** The Data Management attachment should include the components listed below.
 - a. **Data Management:** Describe all methods used for data collection to include the following:
 - **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.
 - **Confidentiality:**
 - Explain measures taken to protect the privacy of human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.
 - Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of the DoD are eligible to review study records.
 - Address requirements for reporting sensitive information to state or local authorities.
 - **Data capture, verification, and disposition:** Describe how data will be captured and verified. Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, the process for locking the database at study completion, and the length of time data will be stored. Describe the proposed database, how it will be

developed and validated, and its capability to safeguard and maintain the integrity of the data. For FDA-regulated studies, compliance with 21 CFR 11 is required.

- **Data reporting:** Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.
- **Sharing study results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether or not the results of screening and/or study participation will be shared with human subjects or their primary care provider, to include results from any screening or diagnostic tests performed as part of the study.

b. Laboratory Evaluations:

- **Specimens to be collected, schedule, and amount:** All specimens that will be collected for study purposes must be clearly stated. The collection schedule and amount of material collected must also be clearly described.
- **Evaluations to be made:** Describe all evaluations that will be made for study purposes. Explain how the results of laboratory evaluations will be used to meet the objectives of the study (or to monitor safety of human subjects).
- **Storage:** Describe specimen storage, to include location of storage, how long specimens will be stored, any special conditions required, labeling, and specimen disposition. Outline the plan to store specimens for future use to include considerations for informed consent and providing human subjects with an opportunity to decline participation in the study.
- **Labs performing evaluations and special precautions:** Identify the laboratory performing each evaluation, as well as any special precautions that should be taken in handling the samples. Special precautions that should be taken by the human subject before, during, or after the laboratory procedure should be clearly defined. If transport of samples is required, describe provisions for ensuring proper storage during transport.
- **Attachment 10: Collaborating DoD Military Facility Budget Form(s), if applicable: Upload as “MFBudget.pdf.”** If a Military Facility (MHS facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the Collaborating DoD Military Facility Budget Form, available for download on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>), including a budget justification, for each Military Facility as instructed. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General 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.3., for detailed information.
- PI Biographical Sketch (six-page limit): Upload as “Biosketch_LastName.pdf.” The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in the portable document format (pdf) that is not editable.
- Biographical Sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.
- PI Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
 - Key Personnel Biographical Sketches (six-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.4., for detailed information.
- Budget Justification (no page limit): Upload as “BudgetJustification.pdf.” The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.
- NOTE: For all Federal agencies or organizations collaborating with Military Facilities, special restrictions apply to the budget and are described below.***
- **For Federal Agencies:** 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** (MHS facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) must submit Collaborating DoD Military Facility Budget Form(s) as instructed in Attachment 10.
- 5. Project/Performance Site Location(s) Form:** Refer to the General Submission Instructions, Section II.C.5., for detailed information.
- 6. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Submission Instructions, Section II.C.6., for detailed information.

Collaborating DoD Military Facilities Form: A Military Facility collaborating in the performance of the project should be treated as a subaward for budget purposes. However, do not complete the Grants.Gov R & R Subaward Budget Attachment Form; instead, complete the Collaborating DoD Military Facility Budget Form (use Attachment 10, Collaborating DoD Military Facility Budget Form) to show all direct and indirect costs. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Submission Instructions, Section II.C.8., for detailed information.

D. Applicant Verification of Grants.gov Proposal/Application 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 Broad Agency 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 Broad Agency Announcement/Funding Opportunity. *If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID prior to the application submission deadline.* The Project Narrative and Budget Form cannot be changed after the 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 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.

F. Submission Dates and Times

All submission dates and times are indicated on the [title page](#) of this Broad Agency Announcement/Funding Opportunity. Pre-application and application submissions are required. Failure to meet either of these deadlines will result in submission 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.4, “Research & Related Budget,” for discussion of allowable costs, including pre-award costs and collaborations with Military Facilities.

I. Other Submission Requirements

Proposals/applications must be submitted electronically to Grants.gov. Refer to the General Submission Instructions, Appendix 2, for detailed formatting guidelines.

III. PROPOSAL/APPLICATION REVIEW AND SELECTION INFORMATION

A. Proposal/Application Review and Selection Process

All applications are evaluated by scientists and clinicians in a two-tier review process. The first tier is a 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 and the OASD(HA), based on (a) technical merit and (b) the relevance to the mission of the DHP and JPC-1/MSIS and to the specific intent of the award mechanism. The highest-scoring proposals/applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess.shtml>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign agreements to protect the confidentiality of the information 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 by military personnel or employee of the Federal Government is a crime in accordance with 18 USC 1905.

B. Peer and Programmatic Review

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

- **Theoretical Rationale and Scientific Methods**
 - How well the proposed research, methods, and anticipated outcomes are supported by rationale, preliminary data (if provided), critical review and analysis of the literature, use of existing metrics/evaluation criteria justification (if applicable), and/or other evidence-based information/data.

- 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 provides a listing of evidence-based definitions, nomenclature, or lexicon associated with the proposed methodologies and explains how they support the proposed methodologies.
- Whether there is evidence of an adequate contingency plan, such as a risk mitigation plan, to resolve potential delays.
- Whether there is sufficient rationale for using the proposed data/information in the proposed machine learning model with artificial intelligence approaches and how that data/information is proposed to be used to generate the outputs of the proposed model and how that data/information correlates with the proposed outputs of the proposed model.
- How well the application describes the proposed machine learning model with artificial intelligence approaches, taking into account the proposed scenarios, curricula, metrics, evaluation criteria, weight of the metrics, and so forth to accurately and appropriately predict the level of an individual while acquiring skills or receiving refresher training.
- For research involving human subjects:
 - How well the PI describes the population(s) of interest, demonstrates access to these populations, has a viable plan for recruitment, consent, screening, and retention of appropriate subjects, and identifies sampling methods to gain a representative sample from the population(s) of interest.
 - How well plans for addressing ethical and regulatory considerations have been developed, including mitigation of risk, consideration of privacy issues, and the process for obtaining informed consent.
- For research involving animals:
 - How well the animal study (or studies) is designed to achieve the objectives, including the choice of model and endpoints/outcome measures to be used.
 - How well the study (or studies) is designed to achieve reproducible and rigorous results, including controls, sample size estimation, blinding, randomization and data handling.
- **Relevance, Innovation, Novelty and Impact**
 - To what degree the proposed research is relevant to the goal of delivering a proof-of-concept and/or prototype (depending on award vehicle) machine learning model with artificial intelligence approaches, and how relevant, from both quantitative and qualitative perspectives, are the data/information, methodologies proposed, and metrics/evaluation criteria proposed, toward creating the most optimal tool to accurately and appropriately predict where an individual should be along the learning curve while acquiring skills or receiving refresher training.

- To what degree the proposed work is innovative, and novel, and not an incremental advancement or duplication of previous work. To what degree the innovation and novelty is a departure from current paradigms, yet is grounded by sound scientific evidence and methodologies.
- To what degree the anticipated short- and long-term outcomes of the proposed study will contribute to the goals of this Broad Agency Announcement/Funding Opportunity and where largest anticipated impact to the public might occur. .
- **Open Source/License/Architecture**
 - To what degree the proposed proof-of-concept and/or prototype (depending on award vehicle) model incorporates open source vs. proprietary components, and, importantly, where in the proof-of-concept and/or prototype (depending on award vehicle) the open source components are located.
- **Pilot Study Design/Plan**
 - To what degree the proposed pilot study methodologies, including the proposed type and number of recruits, assessment criteria, inter-rater reliability criteria, and statistical analysis plan, are appropriate for the intended outcomes.
 - Whether the proposed pilot study is at least 12 months in duration.

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

- **Personnel and Facility**
 - Whether the levels of effort are appropriate for successful conduct of the proposed work.
 - To what degree the expertise, experience, and knowledge of the key research personnel, including co-PIs (if applicable), subawards (if applicable), and consultants (if applicable) are appropriate and complementary for achieving the research goals.
 - To what degree the prime facility will be able to perform the proposed research.
 - To what degree the collaborating military organizations, investigators, resources (if applicable) are appropriate and complementary for achieving the research goals.
- **Budget**
 - Whether the budget is appropriate for the proposed research and within the limitations of this Broad Agency Announcement/Funding Opportunity.
- **Proposal/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:**
 - Programmatic relevance, program portfolio balance and adherence to the intent of the award mechanism
 - Relative innovation and impact
 - Open source/license/architecture
 - The degree to which the intellectual property components may limit future flexibility or adaptation of the tool to meet future Government needs
 - Degree of public accessibility of outcomes
 - Military relevance
 - Proposed project timelines with respect to the proposed budget and anticipated outcomes/deliverables
 - The invited proposal/application does not propose the same research project as described in the pre-proposal/pre-application.
 - The invited proposal/application budget differs from the budget included in the pre-proposal/pre-application.

C. Recipient Qualification

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

D. Application Review Dates

All application review dates and times are indicated on the [title page](#) of this Broad Agency 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 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:

- Pre-Proposal/Pre-Application Narrative exceeds page limit.
- Pre-Proposal/Pre-Application Narrative is missing.
- The Pre-Proposal/Pre-Application was submitted by an intramural investigator.

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.

For applications recruiting human subjects:

- Attachment 8, Human Subject Recruitment and Safety Procedures, is missing.
- Attachment 9, Data Management, 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 FY17 JPC-1/MSIS Medical Modeling, Simulation and Training Steering Committee member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. *A list of the FY17 JPC-1/MSIS Medical Modeling, Simulation and Training Steering Committee members can be found at http://cdmrp.army.mil/dmrdp/panels/17jpc1_mmst.shtml.*
- The proposal/application fails to conform to this BAA description to the extent that appropriate review cannot be conducted.

- Inclusion of any employee of CDMRP review contractors in pre-proposals/ pre-applications or full proposals/applications for funding without adequate plans to resolve COIs. Refer to General Submission Instructions, Appendix 1, for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.

D. Withhold

Proposals/Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization will be required to provide the findings of the investigation to the USAMRAA Grants Officer for a determination of the final disposition of the 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 or a guarantee of an award. Awards will be made no later than **September 30, 2018**. Refer to the General Submission Instructions, Appendix 4, 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, Section H, for general information on reporting requirements.

Monthly and/or quarterly, annual and final technical progress reports and quad charts will be required. 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 these 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, which runs October 1 through September 30. While inputs may be reported any time during the fiscal year, 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.K, for general information on changes to PIs and organizational transfers.

The institution transfer of an award supporting a clinical trial is strongly discouraged and in most cases will not be allowed. Approval of a PI or organizational transfer request will be on a case-by-case basis at the discretion of the Contracting or Grants Officer. An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

Questions related to Broad Agency Announcement/Funding Opportunity 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 full 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 Broad Agency 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.

C. Common Submission Problems

- Failure to enter an email address for change notifications under the Broad Agency Announcement/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 [Section VII, Proposal/Application Submission Checklist](#).)
- 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-17-R-MSI1 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 (i.e., characters not available on a standard QWERTY keyboard, e.g., Greek letters) in attachment titles.
- Attachments exceed size limits.
- Upload attempts of unacceptable attachments: bitmap, TIFF, etc.
- Duplicate upload of documents.

VII. PROPOSAL/APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Upload Order	Action	Completed
SF424 (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, Relevance, and Impact Statement: Upload as Attachment 7 with file name "Innovation.pdf."	
	8	Human Subject Recruitment and Safety Procedures: Upload as Attachment 8 with file name "HumSubProc.pdf" (if applicable; required for all studies recruiting human subjects).	
	9	Data Management: Upload as Attachment 9 with file name "Data_Manage.pdf" (if applicable; required for all studies recruiting human subjects).	
	10	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 10 with file name "MFBudget.pdf," if applicable.	
Research & Related Senior/Key Person Profile (Expanded)		Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
		Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
		Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
		Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget		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.	