Program Announcement

for the

Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs
Defense Medical Research and Development Program

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

Developing Models for Military and/or Civilian Medical Training from Field Data Collected from Sensors (MATADOR) Award

Funding Opportunity Number: W81XWH-16-DMRDP-MSIS-MAT

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

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), November 14, 2016
- **Invitation to Submit an Application:** December 19, 2016
- **Application Submission Deadline:** 11:59 p.m. ET, March 1, 2017
- **End of Application Verification Period:** 5:00 p.m. ET, March 6, 2017
- **Peer Review:** May 2017
- **Programmatic Review:** June 2017

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

TABLE OF CONTENTS

I. FUNDING OPPORTUNITY DESCRIPTION

BEFORE APPLYING, NOTE: THIS PROGRAM ANNOUNCEMENT/FUNDING OPPORTUNITY IS INTENDED FOR EXTRAMURAL INVESTIGATORS ONLY. INTRAMURAL INVESTIGATORS ARE REQUIRED TO APPLY TO THE FY17 JPC-1/MSIS MATADOR INTRAMURAL ANNOUNCEMENT/FUNDING OPPORTUNITY THROUGH THE CDMRP ELECTRONIC BIOMEDICAL RESEARCH APPLICATION PORTAL eBRAP (https://eBRAP.org/).

- An *intramural investigator* is defined as a Department of Defense (DoD) military or civilian employee working within a DoD laboratory or military treatment facility, or working in a DoD activity embedded within a civilian medical center.
- An *extramural investigator* is defined as all those not included in the definition of intramural investigators above. Submissions from intramural investigators to this Program Announcement/Funding Opportunity will be rejected.

It is permissible, however, for an intramural investigator to be named as a collaborator in an application submitted by an extramural investigator. In such cases, the application from the extramural organization must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.

A. Program Description

Applications to the Fiscal Year 2017 (FY17) Joint Program Committee 1 (JPC-1)/Medical Simulation and Information Sciences (MSIS) Research Program Developing Models for Military and/or Civilian Medical Training from Field Data Collected from Sensors (MATADOR) Award are being solicited for the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA RDA Directorate manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The U.S. Army Medical Research and Materiel Command (USAMRMC) Congressionally Directed Medical Research Programs (CDMRP) provides Defense Medical Research and Development Program (DMRDP) execution management support for DHP core research program areas, including the JPC-1/MSIS. This Program Announcement/Funding Opportunity and subsequent awards will be managed and executed by CDMRP with strategic oversight from the JPC-1/MSIS.

The JPC-1/MSIS provides programmatic funding recommendations for OASD(HA) medical DHP RDT&E dollars related to medical training and education efforts to advance the development and integration of simulation-based medical training systems. The JPC-1/MSIS Medical Simulation and Training Steering Committee members provided the strategy for which this Program Announcement/Funding Opportunity's topic was conceived.

The mission of the JPC-1/MSIS is to explore the implications of models and technology for medical education and for the provision, management, and support of health services in the military. The JPC-1/MSIS plans, coordinates, and oversees a responsive world-class, tri-Service science and technology program focused on two areas of research. The first area, Medical

Simulation and Training, is focused on improving military medical training through medical modeling, simulation, and educational training tools. The second area, Health Informatics and Information Technologies, is focused on improving the use and sharing of health-related data for better strategic planning, process development, and software applications.

The outcomes of the research funded by this Program Announcement/Funding Opportunity are intended to take data and information already collected by existing sensors and measurement devices to be used to create and develop a model that better informs and assists in directing future military and civilian medical modeling, simulation, training, and education systems. The research outcomes will be used to better cross-link data-driven collected information from the field to be used as a cumulative data reference source to assist in strategic decisions on future research and development of military and/or civilian medical simulation systems and what components might be emphasized to reflect items such as changes in injury patterns, changes in regional diseases, and changes in stress factors that military and civilian healthcare professionals are facing. This proposed model could also assist in assessing critical technology elements and technology maturity, as examples, to better understand if future medical simulation systems could even be feasibly developed based upon critical pathways. All applications must specifically and clearly address the military and/or civilian relevance of the proposed research project.

B. Combat Casualty Training Initiative: Developing Models for Medical Training from Field Data Collected from Sensors

Developing Models for Military and/or Civilian Medical Training from Field Data Collected from Sensors (MATADOR) is a line of research that supports the Combat Casualty Training Initiative (CCTI) under the JPC-1/MSIS Medical Simulation and Training portfolio. The JPC-1/ MSIS CCTI focuses on research and development toward advancing combat casualty care training for the entire continuum of care.

The MATADOR Award Program Announcement/Funding Opportunity seeks to support research to develop a proof-of-concept strategic planning tool or model, based on data collected in diverse operational environments by sensors (which include biosensors) and biosurveillance measurement systems, to inform current practices in medical simulation training as well as the future development of medical curricula, training scenarios, and simulation. Research sought may be analogous to all of the data points, satellite information, etc., used to create meteorological models to better predict weather forecasting, which are used to provide options of possible weather patterns and can be used to train personnel on how they will respond to the events if they occur. Applications must include a pilot study to compare the proposed tool's/model's efficiency and effectiveness against current commercially available methods.

For the purposes of this Program Announcement/Funding Opportunity, the following definitions are used:

- A biosensor is defined as any device that senses and transmits information about a biological process. For the remainder of this Program Announcement/Funding Opportunity, "sensor" will be used to mean both a non-biosensor and a biosensor.

- Biosurveillance is defined as a system that gathers, incorporates, interprets, and communicates critical information related to all-hazards threats and/or disease activity.

For the purpose of the development of the conceptual model, the data selected should be able to be rapidly collected, analyzed, and incorporated into a military and/or civilian-relevant medical training model, which has yet to be developed but is intended to be created based upon the results of this research.

The JPC-1/MSIS Medical Simulation and Training portfolio is looking for a proof-of-concept tool to determine how the different and diverse data/information that is collected in the field from a variety of sensors and biosurveillance systems can be used and analyzed to develop a predictive model. Additionally this announcement is seeking whether this analyzed data/information can ultimately improve the development of future medical simulation systems in order to obtain improved patient outcomes, alignment with injury patterns or illnesses occurring in the field, etc., by decreasing the time it takes to develop medical curricula, medical scenarios, and simulation systems for training.

Using data/information collected from the field, analyzing it, and then synthesizing it into a strategic planning tool(s)/model(s) to support medical simulation training, the research should be able to demonstrate if it is possible to use data that are already being collected in the field and develop fast, accurate, efficient, and effective models to support medical simulation training. The emphasis on the proof of concept will help guide the simulation system developers to design training and education systems using live data or near real-time data to ensure the training reflects experiences that are currently happening in the field.

BACKGROUND

For years, the Services have extracted and utilized data points and information for the purposes of planning, coordinating, and implementing operations in support of field maneuvers. As it is presumed that data are already being collected by sensors and biosurveillance systems currently deployed in field operations, the foundational theory of this Program Announcement/Funding Opportunity is the assumption that data/information already being collected for planning, coordinating, and implementing operations in support of field maneuvers plus combining other data/information, such those for infectious disease gathering; physiological data from individuals; and other wearable sensor technologies could be used to develop and improve upon current medical curricula, medical training scenarios, and medical simulation training systems.

Currently, medical simulation training models do not adequately utilize field biosurveillance data/information. Instead, most tend to use data collected from controlled environments, information provided by individuals replaying a scenario and/or anecdotal information. Medical simulation training models also do not necessarily take into account other external factors that can affect the outcome of the simulated training experience when compared to the actual field experience; therefore, the development of a strategic planning tool(s)/model(s) that can capture and synthesize information collected by sensors/biosurveillance systems from the field is a novel concept and needs to be explored.

C. Award Information

The FY17 JPC-1/MSIS MATADOR Award seeks to support research for the development and preliminary validation of a conceptual predictive model with the ability to rapidly collect, analyze, and weigh sensor and/or biosurveillance data collected directly from the field (not be limited to a particular type of field environment) via a variety of sensors and/or biosurveillance systems. It is critical for research projects to create standards, specifications, format, and storage of the collected data/information as appropriate to the initial stages of the proposed working model.

The application should address the following:

- How much field data (such as to support operations, collecting for infectious disease, physiological data, and other wearable sensors) will need to be captured to accurately, effectively, and efficiently develop medical curricula, training scenarios, and medical simulation systems that operators can use in a near-real time implementation?
- How will data collected be weighted (i.e., determined to be critical or non-critical) for analysis?
- Will it be necessary to validate the collected sensors/biosurveillance field data with an independent dataset?
- What type of, and how much, analysis will need to go into the collected data prior to modeling?
- Where within the predictive modeling process might natural language processing and machine-learning algorithms be leveraged to insert data and query information from the large amounts of unstructured data collected from multiple sources?
- What is the best way to store the collected data/information in terms of the format, security, and modularity? How can some portions of data/information be allowed more access than others yet be stored in the same data warehouse?

For the purposes of this Program Announcement/Funding Opportunity, data/information related to chemical, biological, or nuclear hazard exposures should NOT be included. Radiological (i.e., background radiation in the environment) data/information is acceptable. For more information on chemical, biological, radiological, and nuclear environments, one may reference Joint Publication documents, such as Operations in Chemical, Biological, Radiological, and Nuclear Environments.[1] Note that Joint publications are regularly updated.

A proof-of-concept evaluation of the proposed model in a defined laboratory or model setting to demonstrate its functional capability is expected as an anticipated outcome of this research. For the purposes of this award, a proof of concept is aligned with Technology Readiness Level (TRL) 4, which, paraphrased, is a proof of concept that can be demonstrated in a defined laboratory setting or in defined models. Proposed models must use real field data/information

[1] Defense Technical Information Center (DTIC), Joint Publication 3-11; Operations in Chemical, Biological, Radiological, and Nuclear Environments (Oct 2013)

and its components must work together. The following aspects should be incorporated into the proposed project and clearly articulated in the application:

- Sensor/biosurveillance data should be collected from a variety of authentic operational field environments (i.e., desert, mountainous terrain, aircraft, water craft, etc.).
- Functional definitions of the model structures and parameter values, including how variable weighting will be determined within the dynamics of the model, should be provided.
- Statistical approaches should be used to determine the best metrics and evaluation criteria for objective development of a proof-of-concept model that rapidly incorporate sensor/biosurveillance data and complementary data.
- Functional definitions of the metrics and criteria that will be objectively or subjectively obtained (collected); respective measurement tools (either currently commercially available or to be developed via this anticipated award mechanism) should be provided.
- The proposed model should have open source communication, connectivity, and standardized formatting to allow other sensors/biosurveillance systems that have not been evaluated to input information.
- The design of the proof-of-concept model will have sufficient detail to function as a basis of a yet to be developed working predictive model and the design of the proof-of-concept model needs to have flexibility and modularity incorporated into the design of the strategic planning tool(s) / model(s).
- The outcomes of the research should provide raw data as well as the analyzed data/information on the model and how it was evaluated during the pilot study. Furthermore, the outcomes should elaborate on how the model may be used in practical settings and how actual decisions might be determined based upon both the sensor/biosurveillance data as well as the environment from which it was collected.
- The proposed design should provide details on how the data/information will be stored, what the format should be, what security should be attached, and how different components of the data/information may have different access levels depending upon type of data/information collected.

The development of the proof-of-concept model should not exceed a period of performance of 2 years, which also includes the pilot study, described as follows.

The pilot study should include all aspects of the assessment of the proposed model to include its classifiers, variables, metrics, and evaluation criteria. Applications should outline the pilot study's proposed methodologies, conceptual and operational functional definitions, algorithms, type of data collected, source of the data, assessment criteria, generalizability, validity, reliability, intended medical domain(s), control data, complementary data used, statistical protocols, and other information as relevant to the proposed research. Time, accuracy, effectiveness, and efficiency of the model should be represented. Pilot studies should be at least three (3) months in duration.

While the proposed research may include proprietary tools, appropriate justification for incorporating proprietary components must be included. Proposed proprietary intellectual

property components should be clearly and legibly marked in the full application. The anticipated research outcomes should have broad availability not only with the content but also with the underlying architecture or models to allow more open communication. The application must explain how open-sourced components will communicate with the proposed tool/model as well as clarifying the feasibility of completing the proof-of concept model.

Applications should be relevant to both military and/or civilian medical simulation system development. The data/information model is intended to assist in faster and more accurate development of future simulation systems relevant to the medical community. It would also provide the medical simulation developer community with access to an objective data/information model from which to better define and target specific capabilities and functionalities. It may also allow for better metrics and evaluation criteria leading to increased patient quality care and improved clinical outcomes as there will be a means to better align training with real-world data.

Results of the MATADOR research should demonstrate a proof-of-concept model that can incorporate field data collected from sensors and biosurveillance systems. At a minimum, the proof of concept must be implemented into data/knowledge systems and evaluated in a lab-type environment TRL4. The anticipated research outcomes of projects supported by the FY17 JPC-1/MSIS MATADOR Award are as follows (in no particular order):

- A validated list supported by contacts, references, and sources that support the proposed methodologies that underpin the determination of the anticipated variables, metrics, statistical methodology, and evaluation criteria for a proof-of-concept MATADOR model.
- A report, document, and list of the terminology and respective functional definitions of the different sensors and the data/information collected from them.
- A report, document, and list of the terminology and respective lexicon and functional definitions of the metrics and criteria collected and a description of the respective measurement tools that 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 and document of the data/information from the sensors and why and how much weight is carried by that data/information for a yet to be determined predictive model to support military medical scenarios within a medical simulation training system.
- An analytical report of the model structures and parameter used within the dynamics of the proof-of-concept model.
- A report, document, list of terminology that describes the system components (including the interfaces) and assumptions as well as data assumptions that were collected from the sensors and biosurveillance systems as well as complementary data if used.
- A report on the components that are proprietary and ones that are Open Source. Licensing rights and Government ownership need to be provided.

- A report and document of the outcomes (analyzed data/information) from the pilot study.
- A report and document of the algorithms, equations, definitions, and methodologies used to create the proof-of-concept model. Story boards, flow diagrams, designs, and specifications of the type of data/information intended to be collected and used for the models are requested as well as the specifications as to how the data/information should be stored.
- The research outcomes, analysis, methodologies, and conclusions should be prepared in a report, which may include images, flow diagrams, tables, links to a video that demonstrate the proof of concept, etc.
- **OPTIONAL:** Delivery of the proof of concept to the Government as well as the data package. The Government would then evaluate the proof of concept at a location that will be determined later.

Use of Human Anatomical Substances, Human Subjects, or Human Cadavers: All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRMC Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) of record. Local IRB/EC approval at the time of submission is ***not*** required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB/EC. ***Allow a minimum of 2-3 months for HRPO regulatory review and approval processes***. Refer to the General Application Instructions, Appendix 6, 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.

Principal Investigators (PIs) and collaborating organizations may not use, employ, or subcontract for the use of any human participants, including the use of human anatomical substances, human data, and/or human cadavers, or laboratory animals until applicable regulatory documents are approved by the USAMRMC to ensure that DoD regulations have been met.

Research Involving Animals: All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by USAMRMC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is not required. Specific documents relating to the use of animals in the proposed research will be requested **if the application is selected for funding**. The ACURO must review and approve all animal use prior to the start of working with animals, including amendments to ongoing projects. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled "Research Involving Animals." ***Allow at least 2 to 3 months for ACURO regulatory review and approval processes for animal studies.*** Refer to General Application Instructions, Appendix 6, for additional information.

The CDMRP intends that information, data, and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 4, Section K.

D. Eligibility Information

- ***This Program Announcement/Funding Opportunity is intended for extramural investigators only.*** Intramural (DoD) investigators are required to apply to the FY17 DMRDP JPC-1/MSIS MATADOR Intramural Announcement/Funding Opportunity through CDMRP eBRAP at ***(https://eBRAP.org/)***.
- Independent extramural investigators at all academic levels (or equivalent) are eligible to submit applications.
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include non-DoD Federal agencies, national, international, for-profit, nonprofit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

E. Funding

The JPC-1/MSIS expects to allot approximately $2.2 million (M) of the anticipated FY17 DHP RDT&E appropriation to fund approximately three (3) JPC-1/MSIS MATADOR Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program. As of the release date of this Program Announcement/Funding Opportunity, the FY17 Defense Appropriations Bill has not been passed and there is no guarantee that any funds will be available to support this program. The funding estimated for this Program Announcement/Funding Opportunity is approximate and subject to availability and realignment.

NOTE: Applications received in response to both the intramural and extramural JPC-1/MSIS MATADOR Award Program Announcements/Funding Opportunities will be evaluated and considered for funding together. The Government reserves the right to fund any combination of intramural and/or extramural applications.

- The maximum period of performance is **2** years. The proposed pilot study MUST be included within the proposed 2-year Statement of Work plan.
- The anticipated total costs budgeted for the entire period of performance will not exceed **$750,000**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **$750,000** 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.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum 2 years.
- The programmatic reviewers may recommend sections/components of the proposal to optimize government outcomes and to minimize redundancy.

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

- Travel costs for the PI(s) to attend In-Progress Review meetings anticipated to be held at 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
- Travel costs for up to two investigators to travel to two scientific/technical meetings per year in addition to the required meeting described above.

An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or medical treatment facility, or working in a DoD activity embedded within a civilian medical center. It is permissible for an intramural investigator to be named as a collaborator on an application submitted by an extramural investigator under this Program Announcement/Funding Opportunity. ***In such cases, the extramural investigator must include a letter from the intramural collaborator's Commander or Commanding Officer that authorizes the involvement of the intramural collaborator.***

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Subawards to intramural (DoD) agencies and other Federal agencies may be managed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR]; Funding Authorization Document [FAD] process; or DD Form 1144 Support Agreement). Direct transfer of funds from the recipient to a DoD agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.4., for budget regulations and instructions for the Research & Related Budget. ***For Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in Section II.C.4. of the General Application Instructions***.

II. SUBMISSION INFORMATION

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

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration and a Data Universal Numbering System (DUNS) number. Refer to Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

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

The 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-application and application submission process. Inconsistencies may delay application processing and limit the ability to view, modify, and verify the 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 application deadline.

Application viewing, modification, and verification in eBRAP is strongly recommended, but not required. ***The Project Narrative and Budget cannot be changed after the application submission deadline.*** Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

A. Where to Obtain the Grants.gov Application Package

To obtain the Grants.gov application package, including all required forms, perform a basic search using the Funding Opportunity Number W81XWH-16-DMRDP-MSIS-MAT in Grants.gov (http://www.grants.gov/).

B. Pre-Application Submission Content

The pre-application process should be started early to avoid missing deadlines. There are no grace periods. **During the pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed during the application process on Grants.gov.**

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

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

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

- **Tab 1 – Application Information**
- **Tab 2 – Application Contacts**
  - Enter contact information for the PI. Enter the organization's Business Official responsible for sponsored program administration (the "person to be contacted on matters involving this application" in Block 5 of the Grants.gov SF424 (R&R) Form). The Business Official must either be selected from the eBRAP list or invited in order for the pre-application to be submitted.
  - Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 (R&R) Form), and click on "*Add Organizations to this Pre-application.*" The organization(s) must either be selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.
  - It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.
- **Tab 3 – Collaborators and Key Personnel**
  - Enter the name, organization, and role of all collaborators and key personnel associated with the application.
  - FY16 JPC-1/MSIS Medical Modeling, Simulation, and Training Steering Committee members should NOT be involved in any pre-application or application including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. For questions related to 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 FY16, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess.shtml). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, for detailed information.

- **Tab 4 – Conflicts of Interest**
  - List all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship). Refer to Appendix 1, Section C, of the General Application Instructions for further information regarding COIs.

- **Tab 5 – Pre-Application Files**

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

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

  The Preproposal Narrative should include the following:

  - **Problem to Be Studied:** Describe the perceived issue(s) and the problems to be studied. This section should serve as an abstract of the proposed work.
  - **Theoretical Rationale, Scientific Methods, and Research:** 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 strategic planning tool(s)/model(s) that captures, analyzes, and synthesizes information collected by sensors/biosurveillance systems in the field to inform future planning and development of military and/or civilian medical curricula, training scenarios, and medical simulation systems.
  - **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 3 months in duration.
- **Military Impact:** Describe the anticipated short- and/or long-term outcomes of the proposed project and their potential impact on improving healthcare training and patient safety in the military health system.
- **Personnel and Facilities:** Describe the role of the PI, co-PIs (if applicable), key personnel, subawards (if applicable), and consultants (if applicable) in the research team, including the expertise each brings to the proposed project. Explain how the team's expertise is appropriate and complementary for achieving the research goals. Also, briefly provide information on the primary facility where the research is expected to be performed.
- **Open Source/License/Architecture**: Describe the intellectual property that is intended to be incorporated within the design/plan.

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

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

- Key Personnel Biographical Sketches (six-page limit per individual). ***All biographical sketches should be uploaded as a single combined file.***
- Quad Chart: Complete the Quad Chart template, a one-page PowerPoint file that must be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm, and saved using Adobe Acrobat Reader as a PDF file.

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

Pre-Application Screening

- **Pre-Application Screening Criteria**

  To determine the technical merits of the pre-application and the relevance to the mission of the DHP and the JPC-1/MSIS, 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. How well the proposed methodologies of the pilot study are outlined along with supportive information of number and type of recruitment.
  - **Significance, Relevance, and Innovation**: How well the pre-proposal addresses the potential significance and relevance as requested within this announcement and how innovative the concept and ideas are to propose the solutions requested.
  - **Personnel and Facilities:** To what extent the qualifications and expertise of the PI and key personnel are appropriate to perform the proposed research project.
  - **Military Relevance:** How well the proposed research project directly or indirectly benefits injured military Service members, Veterans, and/or their family members and caregivers.
  - **Open Source/ License/ Architecture:** How well the proposed research includes open source / license / architecture and where within the proposed design is the open source / license / architecture intended to be used or not used.

- **Notification of Pre-Application Screening Results**

  Following the pre-application screening, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. Invitations to submit a full application are based on the Pre-Application Screening Criteria as published above.

C. Full Application Submission Content

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

All contributors and administrators to the application must use matching compatible versions of Adobe software when editing and preparing application components. The use of different software versions will result in corruption of the submitted file. See Section II.C. of the General Application Instructions for details on compatible Adobe software.

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

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

Note: The Project Narrative and Budget Form cannot be changed after the application submission deadline.

If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or Budget Form needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID ***prior to the application submission deadline***.

Grants.gov application package components: For the FY17 JPC-1/MSIS MATADOR Award, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

1. **SF424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

2. **Attachments Form**

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

   - **Attachment 1: Project Narrative (20-page limit): Upload as "ProjectNarrative.pdf."** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs

that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

- **Background:** Present the ideas and reasoning behind the proposed research; include relevant literature citations, preliminary data, 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 model/tool and the proposed pilot study. Describe previous experience most pertinent to this project. Any preliminary data, if available, should be from the laboratory of the PI or member(s) of the collaborating team.

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

  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.

- **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.

  - 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). Proposed pilot study information will need to include proposed methodology, number of anticipated recruits, type of anticipated recruits, power analysis, study protocols, proposed assessment tool intended to be used, proposed evaluation metrics / criteria anticipated to be used, and interrater reliability (if applicable) as examples of information for inclusion in the full proposal. Reference 'Attachment 8' below for further information.

- **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.
  - For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.
  - Identify cell line(s) and commercial or organizational source(s) to be used. If human anatomical substances (including cell lines) will be used, specify whether or not identifiable information is accessible to the research team by any means.
  - If applicable, indicate time required for submission and/or approval of documents (e.g., Investigational New Drug and Investigational Device Exemption) to the U.S. Food and Drug Administration or appropriate Government agency.

- **Attachment 2: Supporting Documentation. Start each document on a new page. Combine and upload as a single file named "Support.pdf."** If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested will result in the removal of those items or may result in administrative withdrawal of the application.***
  - References Cited: List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
  - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
  - Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.
  - Publications and/or Patents: Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.

- Letters of Organizational Support: Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the Program Announcement/Funding Opportunity, such as those from members of Congress, do not impact application review or funding decisions.
- If an intramural (DoD) organization is included as a subaward, provide a letter(s) of support from the appropriate Installation Commander or equivalent Commander/Director to ensure access to the facility, research population, and other necessary resources. The Commander should be aware of all submissions and should confirm that the proposed work is both feasible from a technical perspective and relevant from a programmatic and Command perspective.
- Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
- Intellectual Property:
  - Intangible property acquired, created or developed under this award will be subject to all rights and responsibilities established at 2 CFR 200.315. Should the applicant intend to use, in the performance of this program, pre-existing, legally protected and perfected intangible property and for which no Federal funds had been used in the development of said property, the applicant must:
    - Clearly identify all such property;
    - Identify the cost to the Federal government for use or license of such property, if applicable; or
    - Provide a statement that no property meeting this definition will be used on this project.
  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
- Commercialization Strategy (if applicable): Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.
- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Application Instructions, Appendix 4, Section K, for more information about the CDMRP expectations for making data and research resources publicly available.

- Current Quad Chart: Provide a current Quad Chart in the same format as in the pre-application. If no changes have been made to the project, the same Quad Chart submitted with the pre-application may be used.

- **Attachment 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf."** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publicly. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

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

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

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf."** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publically. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. ***Do not duplicate the technical abstract.***

  Lay abstracts should be written using the outline below:

  - 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 MATADOR Award mechanism, 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 Application Instructions, Section II.C.2., for detailed guidance on creating the SOW.

- **Attachment 6: Outcomes and Impact Statement (one-page limit): Upload as "Impact.pdf."** Explain in detail why the proposed research project is important, as follows:
    - Short-term impact: Describe the anticipated outcome(s)/results(s), design, and/or plan that will be directly attributed to the results of the proposed research.
    - Long-term impact: Describe the anticipated long-term gains from the proposed research, including the long-term anticipated advantages that the new understanding may ultimately contribute toward the future development of a strategic planning tool(s)/model(s) for planning and development of medical curricula, training scenarios, and medical simulation systems that are informed by sensors/biosurveillance data gathered from various operational field environments. Explain how the proposed model if implemented would be able to predict complex working data/information sets that can enhance the efficiency, effectiveness, and accuracy of the experience of medical simulation training platforms.
    - Military Relevance: Clearly articulate how the proposed research is relevant to the goal of developing and pilot testing a strategic planning tool(s)/model(s) that captures, analyzes, and synthesizes information collected by sensors/ biosurveillance sensors from the field, which then allows for future planning and development of military medical curricula, training scenarios, and medical simulation systems. State precisely the estimates as to the immediate and/or long-range usefulness of this study to the Armed Forces, as distinguished from general advancement of knowledge in medicine.
    - Public Purpose: Provide a concise, detailed description on how this research project will benefit the general public.

- **Attachment 7: Innovation Statement (two-page limit): Upload as "Innovation.pdf."** Describe how the proposed project is innovative. Research deemed innovative may introduce a new paradigm, challenge current paradigms, look at existing problems from new perspectives, or exhibit other creative qualities. Investigating the next logical step or incremental advancement on published data is not considered innovative. This may include a description of the innovate 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 (if applicable, 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 Application Instructions, Appendix 6, 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 subjects 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, 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 administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia, brain injury, stress/life situations, or human subject age), if applicable.
- Address how privacy and time for decision making will be provided and whether or not the potential human subject will be allowed to discuss the study with anyone before making a decision.
- Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study and describe any relevant procedures to assure continued consent.
- Describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. Note: The PI must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed clinical study to be in compliance with Title 10 United States Code Section 980 (10 USC 980) (http://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf). If applicable, refer to the General Application Instructions, Appendix 6, for more information.
- ***Assent.*** If minors or other populations that cannot provide informed consent are included in the proposed clinical 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 U.S. Food and Drug Administration (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 Application Instructions, Appendix 6, 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 (if applicable, 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 (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the Collaborating DoD Military Facility Budget Form, available for download on the eBRAP "Funding Opportunities & Forms" web page (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 Application Instructions, Section II.C.7., for detailed information**.**

3. **Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.4., 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 (five-page limit each): Upload as "Biosketch_LastName.pdf."
   - Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf."

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

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

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

D. Applicant Verification of Grants.gov Submission in eBRAP

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of an application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the Program Announcement/Funding Opportunity. ***If either the Project Narrative or the budget fails eBRAP validation 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. Submission Dates and Times

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

F. Other Submission Requirements

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

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

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and engineers in a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding

to the DHA RDA Directorate and the OASD(HA), based on technical merit, the relevance to the mission of the DHP and JPC-1/MSIS, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement/Funding Opportunity. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in Section III.B.2., Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found at http://cdmrp.army.mil/about/fundingprocess.shtml.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Programmatic Panel members sign a statement that application and evaluation information will not be disclosed outside the panel. Violations of confidentiality can result in the dissolving of a panel(s) and other corrective actions. In addition, personnel at the applicant or collaborating organizations are prohibited from contacting persons involved in the review process to gain protected evaluation information or to influence the evaluation process. Violations of these prohibitions will result in the administrative withdrawal of the organization's application. Violations by panel members or applicants that compromise the confidentiality of the review process may also result in suspension or debarment from Federal awards. Furthermore, the unauthorized disclosure of confidential information of one party to another third party is a crime in accordance with Title 18 United States Code 1905.

Extramural and Intramural applications will be reviewed by the same peer review and programmatic review panels and evaluated by the same criteria.

B. Application Review Process

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

   - **Theoretical Rationale and Scientific Methods**
     - How well the 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.
     - How well the proposed specific aims, methodologies, sample and sample size, inter-rater reliability, assessment criteria, analyzed results, conclusions, and potential next-step recommendations, intended medical domain(s) or discipline(s), control groups, statistical protocols, etc., to support the pilot study are presented and align with the proposed study outcomes.

- 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 sensors/biosurveillance systems for the proposed research, including discussions on the type and format of data/information to be captured and transmitted by the sensors/biosurveillance systems, how the data/information components will be weighted and analyzed, and how the data/information should be stored. Applications that include chemical, biological, or nuclear data/information will be removed from the review process prior to the reviewers screening of the applications.
  - How well the application details the risk to human subjects, the collection of potential personally identifiable information (PII) and how they will handle and mitigate any release of PII within the research protocol.
- How well the application describes the proposed strategic planning tool(s)/ model(s) and how the tool/model will directly be used to determine future medical simulation curricula, scenario training, and medical simulation systems.

- **Significance, Relevance, and Innovation:**
  - To what degree the proposed research is relevant to the goal of delivering a proof-of-concept model/tool using data collected by sensors/biosurveillance sensors in diverse operational environments to inform the future development of military and/or civilian medical training curricula and simulation systems.
  - To what degree the proposed work is innovative, and not an incremental advancement or duplication of previous work.
  - To what degree the anticipated short- and long-term outcomes of the proposed study will contribute to the goal of this Program Announcement/Funding Opportunity.
- **Open Source/License/Architecture:**
  - To what degree the proposed sensors/biosurveillance sensors have open source data/information for potential incorporation into the proof-of-concept model.
  - To what degree the proposed proof-of-concept model incorporates open source vs. proprietary and, more importantly, where in the proof of concept the open source components are located. Evaluate where in the proof of concept or the design the respective proprietary or open source/architecture components are located.
- **Pilot Study Design/Plan:**
  - To what degree the proposed pilot study methodologies, including the proposed type and number of recruits, number of recruits, assessment criteria, inter-rater reliability criteria, and statistical analysis plan, are appropriate for the intended outcomes.
  - How well the application describes the Human Subject Recruitment and Safety Protocols that are proposed.
  - Whether the proposed pilot study is at least 3 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.
- **Budget**
  - Whether the total maximum costs are equal to or less than the allowable total maximum costs as published in the Program Announcement/Funding Opportunity.
  - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
- **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 and program portfolio balance
   - Open Source/License/Architecture
     - To what degree the intellectual property components may limit future flexibility or adaptation of the tool to meet future Government needs.
     - Degree of public accessibility of outcomes.
   - Adherence to the intent of the award mechanism
   - Relative innovation and impact
   - Proposed project timelines and proposed tasks with respect to the proposed budget
   - Military relevance and public purpose

C. Recipient Qualification

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

D. Application Review Dates

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

E. Notification of Application Review Results

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

IV. ADMINISTRATIVE ACTIONS

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

A. Rejection

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

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative exceeds page limit.
- Project Narrative is missing.
- Budget is missing.

B. Modification

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

C. Withdrawal

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

- An FY16 JPC-1/MSIS Medical Modeling, Simulation and Training Steering Committee member is named as being involved in the research proposed or is found to have assisted

in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. ***A list of the FY16 JPC-1/MSIS Medical Modeling, Simulation, and Training Steering Committee members can be found at http://cdmrp.army.mil/dmrdp/jpc1msisrp.shtml***.

- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY16, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess.shtml). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Government. Refer to the General Application 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.
- The application includes chemical, biological, or nuclear data/information.

D. Withhold

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

Awards will be made no later than September 30, 2018. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

Any assistance instrument awarded under this Program Announcement/Funding Opportunity will be governed by the award terms and conditions, which conform to DoD's implementation of the Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of new awards made after December 26, 2014 may include revisions to reflect DoD implementation of new OMB guidance in the Code of Federal Regulations, Title 2,

Part 200, “Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards” (2 CFR part 200).

B. Administrative Requirements

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

C. National Policy Requirements

Refer to the General Application Instructions, Appendix 5, for general information regarding national policy requirements.

D. Reporting

Refer to the General Application Instructions, Appendix 4, Section H, for general information on reporting requirements.

Quarterly technical progress reports and quad charts will be required.

In addition to written progress reports, in-person presentations may be requested.

E. Award Transfers

Approval of a transfer request will be on a case-by-case basis at the discretion of the 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.

Refer to the General Application Instructions, Appendix 4, Section L, for general information on organization or PI changes.

VI. VERSION CODES AND AGENCY CONTACTS

A. Program Announcement/Funding Opportunity and General Application Instructions Version

Questions related to this Program Announcement/Funding Opportunity should refer to the Program name, the Program Announcement/Funding Opportunity name, and the Program Announcement/Funding Opportunity version code 20160210j. The Program Announcement/ Funding Opportunity numeric version code will match the General Applications Instructions version code 20160210.

B. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application through eBRAP should be directed to the CDMRP Help Desk, which is available Monday through Friday

from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@eBRAP.org

C. Grants.gov Contact Center

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

Phone: 800-518-4726; 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 Program Announcement/Funding Opportunity or by responding to the prompt provided by Grants.gov when first downloading the Grants.gov application package. If the Grants.gov application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Upload Order	Action	Completed
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 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.	