

**Intramural Announcement
and
Application Instructions**

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-MAT

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:** 5:00 p.m. ET, March 6, 2017
- **Peer Review:** May 2017
- **Programmatic Review:** June 2017

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I. FUNDING OPPORTUNITY DESCRIPTION

THIS IS AN INTRAMURAL AWARD; BEFORE APPLYING, PLEASE NOTE:

- 1. This Announcement/Funding Opportunity is intended for intramural investigators only. An intramural investigator is defined as a Department of Defense (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.***
- 2. Awards to intramural organizations will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers.***
- 3. Extramural entities ARE NOT eligible to apply to this Announcement/ Funding Opportunity and submissions from extramural investigators will be rejected. Should an intramural organization propose collaboration with an extramural entity for part of the research effort, the intramural organization will receive all funds and is responsible for executing all necessary contractual or assistance funding awards to collaborating partners through their agency's procedures.***
- 4. It is expected that the majority of work funded through this Announcement/ Funding Opportunity will be performed within a DoD laboratory or Military Treatment Facility (MTF). Regardless of location, any work that is to be performed by associated non-DoD organizations must be limited to work performed under existing service contracts or under Cooperative Agreements or Material Transfer Agreements. The Government reserves the right to administratively withdraw any application that does not meet these eligibility criteria. Applications that require work to be performed by a non-DoD organization under a new service contract will not be considered for funding.***
- 5. Applicants must provide a detailed Federal Agency Financial Plan after the budget justification information in the Detailed Budget and Justification form. Applications must provide a plan delineating how all Fiscal Year 2017 (FY17) funds will be obligated by September 30, 2018. The plan must include the funding mechanism(s) and contractual arrangements that will be used to carry over funds between fiscal years, if applicable.***

Funds for this award are FY17 DHP RDT&E Program Element (PE) 6.3 dollars. Any FY17 funds not obligated by September 30, 2018 may be withdrawn by the issuing comptroller.
- 6. Applicants must provide Letters of Organizational Support from the following:***
 - a. Resource Manager/Comptroller: Provide a letter of support from the applicant institution's Resource Manager/Comptroller Office (or appropriate financial point of contact) assuring that the institution will be able to accept these funds, if awarded. If funds are to be sent to multiple sites, include a letter from each site.***

- b. Commander(s): Provide a letter (or letters) of support from appropriate MTF, Installation Commander, or equivalent Commanders/Directors 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.*

A. Program Description

Applications to the 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 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 Modeling, Simulation, and Training Steering Committee members](#) provided the strategy for which this 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 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 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 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 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/Funding Opportunity 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 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 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 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.

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

- 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.***

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.***

The CDMRP intends that information, data, and research resources generated under awards funded by this Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large.

D. Eligibility Information

- **Principal Investigator:** Independent intramural investigators are eligible to apply. 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.
- Submissions from extramural (non-DoD) investigators will be rejected. It is permissible, however, for an extramural investigator to be named as a collaborator in a submission from an intramural investigator. In such cases, the intramural organization will receive all funds and is responsible for executing all necessary existing contractual or assistance funding awards to collaborating partners through their agency's procedures. Note, regardless of location, any work that is to be performed by associated non-DoD organizations must be limited to work performed under existing service contract or under Cooperative Agreements or Material Transfer Agreements.
- Cost sharing/matching is not an eligibility requirement.
- **The majority of work funded through this Announcement/Funding Opportunity is required to be performed within a DoD laboratory or MTF. Regardless of location, any work that is to be performed by associated non-DoD organizations must be limited to work performed under existing service.**

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 Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program. As of the release date of this 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 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 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.

Refer to [Appendix 4](#) for budget regulations and instructions. For all Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in [Appendix 4](#).

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.

Subawards to intramural agencies and other Federal agencies may be executed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR], Funding Authorization Document [FAD] process, or Support Agreements [DD Form 1144]). Direct transfer of funds from the recipient to a Federal agency is not allowed except under very limited circumstances. Refer to [Appendix 4](#) for additional information on budget considerations for proposals/applications involving Federal agencies.

II. SUBMISSION INFORMATION

Submission is a two-step process requiring both (1) pre-application submission and (2) application submission through the electronic Biomedical Research Application Portal (eBRAP) (<https://eBRAP.org>). 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. It is the applicant's

responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Announcement/Funding Opportunity.

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

Start the submission process early. eBRAP has a number of required steps that must be completed before submissions will be accepted. Be sure to allow adequate time for completion of all pre-application and application steps by their respective deadlines.

A. 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.

All pre-application components must be submitted by the PI through eBRAP (<https://eBRAP.org/>). Material submitted after the deadline, unless specifically requested by the Government, will not be forwarded for processing.

PIs, collaborators, mentors, 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:

- **Tab 1 – Application Information**
 - Enter the application information as described in eBRAP before continuing the pre-application.
- **Tab 2 – Application Contacts**
 - Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration. 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>). 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.

- **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).

- **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-Proposal/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/Funding Opportunity 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.

B. Full Application Submission Content

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

The pre-application process in eBRAP must be completed before the application can be submitted. After pre-application submission, go to “My Applications” and click on “Start Full Application” for the log number under which the pre-application was submitted.

All application components must be submitted by the indicated deadline by the PI through eBRAP (<https://eBRAP.org/>). Material submitted after the deadline, unless specifically requested by the Government, will not be forwarded for processing. *The organization’s Business Official or Authorized Organization Representative (or Resource Manager/ Comptroller) must approve/verify the full application submission prior to the verification/approval deadline.*

eBRAP application package components: For the **FY17 JPC-1/MSIS MATADOR (W81XWH-16-DMRDP-MSIS-MAT)** Award, the eBRAP application package includes the following components, which are organized in eBRAP by separate tabs. **To access these tabs, go to “My Applications” and click on “Start Full Application”** for the log number under which the pre-application was submitted.

- **Tab 1 – Summary:** Provides a summary of the application information.
- **Tab 2 – Application Contacts:** This tab will be populated by eBRAP. Add Authorized Organization Representative.
- **Tab 3 – Full Application Files:** Under each Application Component in eBRAP, upload each as an individual PDF file. Refer to [Appendix 1](#), for detailed formatting guidelines.

1. Application Component: Attachments: Each attachment must be uploaded as an individual PDF file unless otherwise stated.

- **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/application. 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 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 [Appendix 2](#) 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.

- **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.

- **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 [Appendix 3](#) for more information.*

- **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.

- **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.
- **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>).
- **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.
- **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.
- **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 [Appendix 3](#) 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.
 - **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.
- **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: Letters of Support (no page limit; limit each letter to two pages): Combine and upload as a single file named “Letters.pdf.** Start each document on a new page.
 - Resource Manager/Comptroller: Provide a letter of support from the applicant institution's Resource Manager/Comptroller (or appropriate financial point of contact) assuring that the institution will be able to accept and obligate these funds, if awarded. If funds are to be sent to multiple sites, include a letter from each site.
 - Commander(s): Provide a letter(s) of support from 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. The letter(s) should provide clear evidence of organizational commitment for the coordinating administrative tasks and for the use of facilities and resources necessary for the proposed work at each participating study site.
 - Partnership/Collaboration (if applicable):
 - If the project includes collaboration with a non-DoD site, provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
 - If the project involves collaboration with another Military Facility (e.g., military health system facility, research laboratory, treatment facility, dental treatment facility, a DoD activity embedded with a civilian medical center), the collaborating DoD researcher must obtain a letter from his/her commanding officer or Military Facility director authorizing his/her participation in the research project. This letter must be included with the application.
 - Access to Military or Department of Veterans Affairs (VA) Populations and/or Resources (if applicable): If the proposed research plan involves access to active duty military and/or VA populations, patients, data or resources, include letter(s) of support, signed by the lowest ranking person with approval authority, confirming such access. If access cannot be confirmed at the time of application submission, the Government reserves the right to withhold or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resources.
- **Attachment 11: 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.

2. Research & Related Senior/Key Person Profile (Expanded):

Each attachment must be uploaded as an individual PDF file unless otherwise stated. The Biographical Sketches and the Previous/Current/Pending Support for the PI and Key Personnel may either be attached to the Research & Related Senior/Key Person Profile (Expanded) Form or uploaded as individual files in the “Key Personnel” Application Component.

- Research & Related Senior/Key Person Profile (Expanded) Form: Upload the completed Research & Related Senior/Key Person Profile (Expanded) Form as “Key Personnel.pdf.”
- 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 six-page NIH Biographical Sketch may also be used. All biographical sketches should be submitted in the portable document format (pdf) that is not editable.

Biographical Sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

- PI Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
- Key Personnel Biographical Sketches (six-page limit each): Upload as “Biosketch_LastName.pdf.”
- Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”

3. Application Component: Budget: Use the DoD Military Budget Form available on the “Funding Opportunity and Forms” page in eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). Refer to [Appendix 4](#) for detailed information on completing this form.

- Upload the DoD Military Budget Form as “Budget_LastName.pdf.”
- Budget Justification (no page limit): Upload as “BudgetJustification_LastName.pdf.” The budget justification must include a Federal Agency Financial Plan as described in [Appendix 4](#).
- Subaward Budget: Include all Subaward budgets. Complete a separate detailed Budget using the DoD Military Budget Form including a budget justification for

each subaward (subgrant or subcontract) in accordance with the instructions listed above. Title each individual subaward, “Budget,” and “Budget Justification,” with the name of the subawardee/subrecipient organization,

4. Application Component: Project/Performance Site Location(s) Form: Use the Project/Performance Site Location(s) Form available on the “Funding Opportunity and Forms” page in eBRAP (<https://ebrap.org/eBRAP/public/Program.htm>). Upload as “Performancesites.pdf.”

- On the Project/Performance Site Location(s) Form, indicate the primary site where the work will be performed. If a portion of the work will be performed at any other site(s), include the name and address for each collaborating location in the data fields provided. Add more sites as necessary using the “Next Site” button. If more than eight performance site locations are proposed, provide the requested information in a separate file and attach it to this form. Each additional research site requesting funds will require a subaward budget.

- **Tab 4 – Application and Budget Data:**

Review and edit Proposed Project Start Date, Proposed End Date, and Budget data pre-populated from the Budget Form.

- **Tab 5 – Submit/request Approval Full Application**

Once all components have been uploaded and prior to the full application submission deadline, enter your password in the space provided next to “Enter Your Password Here” and press the “Submit Full Application” button. eBRAP will validate files against the Announcement/Funding Opportunity requirements and discrepancies will be noted. If no discrepancies are noted, press the “Confirm Submission” button to complete the application submission. **eBRAP will notify your Resource Manager/Comptroller or equivalent Business Official by email to log into eBRAP to review and to approve prior to the Approval deadline.**

C. Submission Dates and Times

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

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 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>.

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 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 Announcement/Funding Opportunity.
- Whether the budget is appropriate for the proposed research and within the limitations of this 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. Application Review Dates

All application review dates and times are indicated on the [title page](#) of this Announcement/Funding Opportunity.

D. Notification of Application Review Results

Each PI and organization will receive email notification of the funding recommendation. 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 and applications from CDMRP eBRAP, 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](http://cdmrp.army.mil/dmrpd/jpc1msisrp) can be found at <http://cdmrp.army.mil/dmrpd/jpc1msisrp>.*
- The application fails to conform to this 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>). 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.
- 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.

Any assistance instrument awarded under this 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 [Appendix 2](#) for general information regarding administrative requirements.

C. Reporting and Deliverables

Refer to [Appendix 2](#), Administrative Information, for Reporting and Deliverable requirements for this award.

- Quarterly, annual, and final technical progress reports and quad charts will be required.
- In addition to written progress reports, oral briefings may be requested.

D. Award Transfers

Transfer of an award to another institution is not allowed. The award may be transferred to another PI within the same institution. Approval of a PI transfer request will be on a case-by-case basis at the discretion of the FY16 JPC-1/MSIS Program Manager.

E. Site Visits

CDMRP personnel may, at their discretion, visit each PI during the award period of performance.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

Questions related to Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application through CDMRP 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

VII. APPLICATION SUBMISSION CHECKLIST

Application Components	Upload Order	Action	Completed
Attachments	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 (if applicable): Upload as Attachment 8 with file name "HumSubProc.pdf."	
	9	Data Management: Upload as Attachment 9 with file name "DataManage.pdf." Letters of Support:	
	10	Upload as Attachment 10 with file name "Letters.pdf."	
	11	Collaborating DoD Military Facility Budget Form(s), <i>if applicable</i> : Upload as Attachment 11 with file name "MFBudget.pdf."	
Key Personnel		Research & Related Senior/Key Person Profile (Expanded): Upload as "Key Personnel.pdf."	
		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.	
Budget		Upload Budget (Budget_LastName.pdf) and Budget Justification (BudgetJustification_LastName.pdf), and Subaward Budgets and Budget Justifications as applicable.	
Project/Performance Site Location(s) Form		Upload Project/Performance Site Location(s) Form as "Performancesites.pdf."	

APPENDIX 1 FORMATTING GUIDELINES

All pre-application and application documents must be legible and should conform to the formatting guidelines described below. The font size, spacing, page size, and margins may differ between the word processing, PDF, and printed versions. These guidelines apply to the document properties of the electronic version of the PDF file(s) as viewed on a computer screen.

- **Document Format:** All attachments must be in PDF.
- **Font Size:** 12 point, 10 pitch.
- **Font Type:** Times New Roman.
- **Spacing:** Single space or no more than six lines of type within a vertical inch (2.54 cm).
- **Page Size:** No larger than 8.5 inches x 11.0 inches (21.59 cm x 27.94 cm).
- **Margins:** At least 0.5 inch (1.27 cm) in all directions.
- **Print Area:** 7.5 inches x 10.0 inches (19.05 cm x 25.40 cm).
- **Color, High-Resolution, and Multimedia Objects:** Project narratives and pre-application files may include color, high-resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF files; however, these objects should not exceed 15 seconds in length and a size of 10 MB. Photographs and illustrations must be submitted in JPEG format; bit map or TIFF formats are not allowed.
- **Scanning Resolution:** 100 to 150 dots per inch.
- **Internet URLs:** URLs directing reviewers to websites that contain additional information about the proposed research are not allowed in the application or its components. Inclusion of such URLs may be perceived as an attempt to gain an unfair competitive advantage. However, links to publications referenced in the application are encouraged.
- **Language:** All documents must be submitted in English, unless otherwise specified in the Announcement/Funding Opportunity (e.g., foreign transcripts submitted with English translations).
- **Headers and Footers:** Should not be used. Pre-existing headers and footers on required forms are allowed.
- **Page Numbering:** Should not be used.
- **Recommended Component Size:** Each attachment should not exceed 20 MB.

APPENDIX 2 ADMINISTRATIVE INFORMATION

A. Reporting Requirements

Reporting requirements and deliverables will be determined prior to award funding and may vary depending on the research being conducted. Anticipated reporting requirements and deliverables may include the following:

- **Progress Reports:** Quarterly, annual and final reports will be required. These reports will present a detailed summary of scientific issues and accomplishments. A final report will be submitted within 30 days of the end of the award period and will detail the findings, their potential impact to the Military or Veteran population, and other issues for the entire project. The format for the progress reports is available on eBRAP at <https://ebrap.org/eBRAP/public/Program>
- **Quad Charts:** Quad Charts that outline the specific aims, approach, timeline and costs, and goals/milestones will be required with every quarterly report. The format for the quad chart is available on eBRAP at <https://ebrap.org/eBRAP/public/Program>

B. Publication, Acknowledgement, and Public Release

- **Publication of Findings:** Publication of findings is a requirement of this submission. It is expected that at study completion researchers will submit their findings to an appropriate peer-reviewed journal for publication. Copies of all scientific publications, presentations, and reports resulting from this funding mechanism shall be submitted to CDMRP when published or completed even if beyond the period of performance to allow reporting to the Defense Health Program and Congress on the accomplishments of the program.
- **Acknowledgment:** The recipient agrees that in the release of information relating to this award such release shall include the statements below, as applicable. “Information” includes, but is not limited to, news releases, articles, manuscripts, brochures, advertisements, still and motion pictures, speeches, trade association meetings, and symposia.
 - “This work was supported by the Defense Health Agency, Research, Development, and Acquisition Directorate through the Clinical Research Intramural Initiative Program. Opinions, interpretations, conclusions and recommendations are those of the author and are not necessarily endorsed by the Department of Defense.”
 - “In conducting research using animals, the investigator(s) adheres to the laws of the United States and regulations of the Department of Agriculture.” Include required assurances, approvals, documents and information specified on the Animal Care and Use Review Office (ACURO) website (https://mrmc.detrick.army.mil/index.cfm?pageid=Research_Protections.acuro&rn=1).
 - “In the conduct of research utilizing recombinant DNA, the investigator adhered to NIH Guidelines for research involving recombinant DNA molecules.” (<http://www.nih.gov>)

- “In the conduct of research involving hazardous organisms or toxins, the investigator adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.” (<http://www.cdc.gov/biosafety>)

C. Sharing of Data and Research Resources

- It is the intent of the Department of Defense that data and research resources generated by this funded research be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large.
- Expectations for sharing of data and research resources apply to all basic research, clinical studies, surveys, and other types of research funded through this award. This includes all data and research resources generated during the project’s period of performance through grants, cooperative agreements, or contracts. It is critically important to share unique data and research resources that cannot be readily replicated, including but not limited to the following:
 - **Unique Data**² are defined as data that cannot be readily replicated. Examples of unique data include large surveys that are expensive to replicate; studies of unique populations, such as patients to whom access is not widely available; studies conducted at unique times, such as during military conflict; studies of rare phenomena, such as rare diseases.
 - **Final Research Data**³ are defined as recorded factual material commonly accepted in the scientific community as necessary to document and support research findings. These are not the summary statistics or tables; rather, final research data are the data on which summary statistics and tables are based. Final research data do not include laboratory notes or notebooks, partial datasets, preliminary analyses, drafts of scientific papers, plans for future research, peer review reports, communications with colleagues, or physical objects, such as gels or laboratory specimens.
 - **Research Resources**⁴ include, but are not limited to, the full range of tools that scientists and technicians use in the laboratory, such as cell lines, antibodies, reagents, growth factors, combinatorial chemistry, DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines.
- ***Data and research resources generated from this funded research should be made as widely available as possible while safeguarding the privacy of participants, and protecting confidential and proprietary data, and third-party intellectual property.*** By sharing and leveraging data and research resources, duplication of very expensive and time-consuming efforts can be avoided, allowing for the support of more investigators with Federal funds. Such sharing allows for a more expeditious translation of research results into knowledge, products, and procedures to improve human health.
- ***The PI may be required to participate in the following:***

² Adapted from https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#unique

³ Adapted from https://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#final

⁴ Adapted from <http://www.gpo.gov/fdsys/pkg/FR-1999-12-23/pdf/99-33292.pdf>

- Traumatic Brain Injury: If the project includes traumatic brain injury (TBI) research, the PI may be required to make TBI data generated via an award available to the research community by depositing de-identified research data into the Federal Interagency TBI Research (FITBIR) informatics System (<https://fitbir.nih.gov>).
- Clinical Trials: If the project includes a clinical trial(s), the PI may be required to register the clinical trial(s) individually on the registry and database Clinical Trials.gov (<https://www.clinicaltrials.gov/>).
- Systems Biology: If the project includes systems biology (SB)-related research, the PI may be required to make SB data, generated via an award, available to the research community by depositing research data into the SysBioCube system (<https://sysbiocube-abcc.ncifcrf.gov/>).
- ***For additional information on data-sharing, refer to the document titled “Congressionally Directed Medical Research Programs: Policy on Sharing Data and Research Resources,” available on eBRAP under Reference Material at <https://ebrap.org/eBRAP/public/Program>***

APPENDIX 3 REGULATORY REQUIREMENTS

A. Surety, Safety, and Environmental Requirements

Based on recent changes to Department of Defense (DoD) compliance requirements (DA PAM 385-69, **DA PAM 385-10**, 32 CFR 651 6 September 2012), provisions previously requested for Safety and Environmental Compliance have been removed. However, in certain instances, compliance review may require submission of additional documentation prior to the awarding of any assistance agreement. Such instances may include use of Army-provided infectious agents or toxins, select biological agents or toxins, select chemical agent(s), or pesticides outside of an established laboratory. The U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Surety, Safety, and Environment will identify any need for compliance review and documents must be submitted upon request.

B. Research Protections Review Requirements – Use of Human Subjects, Human Anatomical Substances, Human Data, Human Cadavers, and Animals

The USAMRMC Office of Research Protections (ORP) ensures that research conducted, contracted, sponsored, supported, or managed by the USAMRMC and involving human subjects, human anatomical substances, human data, human cadavers, and animals are conducted in accordance with Federal, DoD, Army, USAMRMC, and international regulatory requirements.

Principal Investigators (PIs) and applicant organizations **may not commence performance** of research involving the above, **or expend funding** on such efforts, until and unless regulatory documents are submitted and approved by the USAMRMC ORP to ensure that DoD regulations are met. All expectations described below are consistent with the DoD Instruction (DoDI) 3216.01, “Use of Animals in DoD Programs,” as issued 13 September 2010, available at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.acuro_regulations and DoDI 3216.02, “Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research,” as issued on 8 November 2011, and available at <http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf>.

The ORP Animal Care and Use Review Office (ACURO) is responsible for administrative review, approval, and oversight of all animal research protocols, including all changes made during the life of the protocol.

The ORP Human Research Protection Office (HRPO) is responsible for administrative review, approval, and oversight of research involving human subjects, human anatomical substances or data, and use of human cadavers. ***Research involving use of human data and/or specimens that is anticipated to be exempt from human subjects protections regulations requires a determination from the PI’s institution as well as the ORP HRPO at USAMRMC.*** A timeframe for submission of the appropriate protocols and required approvals will be established during negotiations.

1. Research Involving Animal Use

Specific documents relating to the use of animals in the proposed research will be requested if the application is selected for funding. The ACURO, a component of the USAMRMC ORP, must review and approve all animal use prior to the start of working with animals. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the Animal Use Appendix titled “Research Involving Animals.” For guidance on which version of the appendix to use, as well as links to both, visit the ACURO website at: https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.acuro_Animalappendix. *Allow at least 3 to 4 months for regulatory review and approval processes for animal studies.*

For additional information, send questions via email to ACURO (usarmy.detrick.medcom-usamrmc.other.acuro@mail.mil).

2. Use of Human Cadavers or Human Anatomical Substances Obtained from Human Cadavers

Research, development, test and evaluation (RDT&E), education or training activities involving human cadavers shall not begin until approval is granted in accordance with the Army Policy for Use of Human Cadavers for RDT&E, Education, or Training, 20 April 2012 (https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.overview). The USAMRMC ORP is the Action Office (usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil) for this policy. Award recipients must coordinate with the supporting/funding Army organization to ensure that proper approvals are obtained. Written approvals to begin the activity will be issued under separate notification to the recipient. Questions regarding submission of cadaver research for USAMRMC ORP review and approval should be directed to the ORP at usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil.

3. Research Involving Human Subjects, Human Subjects Data, or Human Anatomical Substances



In addition to local Institutional Review Board (IRB) review, investigators must submit all USAMRMC-funded research protocols involving human subjects and human anatomical substances for review and approval by the USAMRMC ORP HRPO prior to implementation of the research. The focus of this review is to validate IRB review as appropriate and ensure that DoD, Army, and USAMRMC regulatory requirements have been met.

Human subject research definitions, categories, and resource information may be found in the Human Subject Resource Document on the eBRAP website (<https://ebrap.org/eBRAP/public/Program.htm>). This information is a guide only; it is not intended to be a source for human subject protection regulations. Questions regarding applicable human subject protection regulations, policies, and guidance should be directed to the local IRB, the ORP HRPO (usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil), and/or the U.S. Food and Drug Administration (FDA) as appropriate. For in-depth information and to access HRPO

protocol submission forms, refer to the ORP HRPO website (https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.hrpo).



ORP HRPO-required language must be inserted into the consent form, and compliance with DoD regulations may require additional information be included in the protocol.

The ORP HRPO ensures that DoD-supported and/or -conducted research complies with specific DoD laws and requirements governing research involving human subjects. These laws and requirements may require information in addition to that supplied to the local IRB.

During the regulatory review process for research involving human subjects, the ORP HRPO requirements must be addressed, and any changes to the already approved protocol must be approved as an amendment by the local IRB. It is strongly recommended that investigators carefully read the “Information for Investigators” found at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo. The time to approval depends greatly on adherence to the requirements described within. If the protocol has not been submitted to the local IRB at the time of award negotiation, these guidelines should be considered before submission.

Documents related to the use of human subjects or human anatomical substances will be requested if the application is recommended for funding. ***Allow at least 2 to 3 months for regulatory review and approval processes for studies involving human subjects.***

Specific requirements for research involving human subjects or human anatomical substances can be found at https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo.

- 4. Assurance of Compliance:** Each institution engaged in non-exempt human subjects research must have a current Department of Health and Human Services Office for Human Research Protection (OHRP) Federal-wide Assurance (FWA) or DoD Assurance.
- 5. Training:** Personnel involved in human subjects research must have appropriate instruction in the protection of human subjects. Documentation confirming completion of appropriate instruction may be required during the regulatory review process.
- 6. Informed Consent Form:** The following must appear in the consent form:
 - A statement that the U.S. Department of Defense is providing funding for the study.
 - A statement that representatives of the DoD are authorized to review research records.
 - In the event that a Health Insurance Portability and Accountability Act (HIPAA) authorization is required, the DoD must be listed as one of the parties to whom private health information may be disclosed.
- 7. Intent to Benefit:** The requirements of Title 10 of the United States Code Section 980 (10 USC 980), which are applicable to DoD-sponsored research, must be considered. 10 USC

980 requires that “Funds appropriated to the Department of Defense may not be used for research involving a human being as an *experimental subject* unless (1) the informed consent of the subject is obtained *in advance*; or (2) in the case of research intended to be beneficial to the subject, the informed consent may be obtained from a legal representative of the subject.”

An individual not legally competent to provide informed consent (e.g., incapacitated individuals, cognitively impaired, minors) may not be enrolled as an *experimental subject* in a DoD-supported study unless the research is intended to benefit each subject enrolled in the study, to include subjects enrolled in study placebo arms. Studies designed in a manner that permits all subjects to potentially benefit directly from medical treatment or enhanced surveillance beyond the standard of care can meet the 10 USC 980 requirements. Note that the definition of *experimental subject* as defined in the DoDI 3216.02 has a much narrower definition than *human subject*. Research with experimental subjects must involve an intervention or interaction where the primary purpose of the research is to collect data regarding the effects of the intervention or interaction.



10 USC 980 is only applicable to certain intervention studies. It does not apply to retrospective studies, observational studies, studies that involve only blood draws, and tissue collections. Contact the HRPO at usarmy.detrick.medcom-usarmmc.other.hrpo@mail.mil if further clarification regarding applicability of 10USC 980 to the proposed research project is required.

8. **Research Monitor Requirement:** *For research determined to be greater than minimal risk, DoDI 3216.02 requires that the IRB approve, by name, an independent research monitor with expertise consonant with the nature of risk(s) identified within the research protocol.* The IRB must approve a written summary of the monitors’ duties, authorities, and responsibilities.

The research monitor’s duties should be based on specific risks or concerns about the research. The research monitor may perform oversight functions and report his/her observations and findings to the IRB or a designated official. The research monitor may be identified from within or outside the PI’s institution. Research monitor functions may include:

- Observing recruitment and enrollment procedures and the consent process for individuals, groups or units;
- Overseeing study interventions and interactions;
- Reviewing monitoring plans and Unanticipated Problems Involving Risk to Subjects or Others (UPIRISO) reports; and/or
- Overseeing data matching, data collection, and analysis.

There may be more than one research monitor (e.g., if different skills or experiences are necessary). The monitor may be an ombudsman or a member of the data safety monitoring board. At a minimum, the research monitor:

- May discuss the research protocol with the investigators, interview human subjects, and consult with others outside of the study about the research;
- Shall have authority to stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor's report; and
- Shall have the responsibility for promptly reporting his or her observations and findings to the IRB or other designated official and the HRPO.

A curriculum vitae or biographical sketch and human subjects protection training for the research monitor must be provided. There should be no apparent conflict of interest, and the research monitor cannot be under the supervision of the PI, other investigators, or research staff associated with the proposed research project. If the duties of the research monitor could require disclosure of subjects' Protected Health Information outside a covered entity (i.e., the research monitor is not an agent of the covered entity), the PI's institution may require the identity and location of the research monitor to be described in the study HIPAA authorization. It is acceptable to provide appropriate compensation to the research monitor for his or her services.

9. Military Personnel Volunteers: The following is important information for research projects proposing to include military personnel as volunteers.

- **Recruitment of Military Personnel:** Civilian investigators attempting to access military volunteer pools are advised to seek collaboration with a military investigator familiar with service-specific requirements.

A letter of support from Commanders of military units in which recruitment will occur or the study will be conducted will be requested by the HRPO. Some military sites may also require that each volunteer seek written permission from their supervisor prior to participation in research studies.

Special consideration must be given to the recruitment process for military personnel. The Chain of Command must not be involved in the recruitment of military personnel and cannot encourage or order service members to participate in a research study.

For greater than minimal risk research, an ombudsman must be employed when conducting group briefings with active duty personnel to ensure that volunteers understand that participation is voluntary; this ombudsman may be recommended in other situations as well, especially when young enlisted service members, who by virtue of their age and enlistment status are trained to follow orders, are being recruited. Service members are trained to act as a unit, so peer pressure should also be considered and minimized, if possible.

- **Payment to Federal Employees and Military Personnel:** Under 24 USC 30, payment to Federal employees and active duty military personnel for participation in research while on duty is limited to blood donation and may not exceed \$50 per blood draw. These individuals may not receive any other payment or non-monetary

compensation for participation in a research study unless they are off duty or on leave during the time they are participating in the protocol.

- **Confidentiality for Military Personnel:** Confidentiality risk assessment for military personnel requires serious consideration of the potential to affect the military career. Medical and psychological diagnoses can lead to limitation of duties and/or discharge from active duty. Information regarding alcohol or drug abuse, drunk driving, and sexual or spousal abuse can lead to actions under the Uniform Code of Military Justice, including incarceration and dishonorable discharge.

10. **Site Visits:** The USAMRMC ORP HRPO conducts site visits as part of its responsibility for compliance oversight.

Accurate and complete study records must be maintained and made available to representatives of the USAMRMC as a part of their responsibility to protect human subjects in research. Research records must be stored in a confidential manner so as to protect the confidentiality of subject information.



Additional information pertaining to the human subjects regulatory review process, guidelines for developing protocols, and suggested language for specific issues can be found at: https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo.

11. **Protocol Submission Format:** The ORP HRPO accepts protocol submissions in the format required by the local IRB. The IRB protocol application, if separate from the protocol itself, should be included with protocol submissions. A HRPO protocol submission form should be completed and submitted with each protocol.

APPENDIX 4 BUDGET FORM INSTRUCTIONS

Complete the DoD Military Budget Form and Justification form. Begin by entering the PI name, eBRAP Log number, and period of performance fields at the top of the DoD Military Budget Form. **DoD Civilian and Military Personnel:** Personnel involved in the project should be listed in this section; however, this award is not intended to provide salary support for any Federal employee, as those costs were to have been included in infrastructure costs. If salary support is requested, sufficient justification must be provided in the budget justification section.

- **Name:** Beginning with the PI, list all participants who will be involved in the project during the initial budget period, whether or not salaries are requested. Include all collaborating investigators, research associates, individuals in training, mentor (if applicable) and support staff.
- **Role on Project:** Identify the role of each personnel listed. Describe his/her specific functions in the proposed research in the budget justification.
- **Type of Appointment (Months):** List the number of months per year reflected in an individual's contractual appointment with the applicant organization. The Government assumes that appointments at the applicant organization are full time for each individual. If an appointment is less than full time (e.g., 50%), note this with an asterisk (*) and provide a full explanation in the budget justification. Individuals may have split appointments (e.g., for an academic period and a summer period). For each type of appointment, identify and enter the number of months on separate lines.
- **Annual Base Salary:** Enter the annual organizational base salary (based on a full-time appointment) for each individual listed for the project.
- **Effort on Project:** List the percentage of each appointment to be spent on this project for all staff members including unpaid personnel.
- **Salary Requested:** Enter the salary for each position for which funds are requested. This is calculated automatically from the data provided. If you do not wish this to be calculated for you, uncheck the small "Calculate Salary" checkbox in the bottom of the field. Calculate the salary request by multiplying an individual's organizational base salary by the percentage of effort on the project.
- **Fringe Benefits:** Enter the fringe benefits requested for each individual in accordance with organizational guidelines.
- **Totals:** Calculated automatically from the data provided.
- **Major Equipment:** Provide an itemized list of proposed equipment, showing the cost of each item. Equipment is any article of nonexpendable tangible property having a useful life of more than 1 year and an acquisition cost of \$5,000 or more per unit.
- **Materials, Supplies, and Consumables:** The budget justification for supporting material and supply (consumable) costs should include a general description of expendable material and supplies.

- **Travel Costs:** PIs are responsible for budgeting for all costs associated with travel, including airfare, hotel, etc., associated with the trip. Anticipated travel costs should be built into the budget at current or projected DoD per diem rates. Travel costs must include:

- Travel costs for the PI to attend the required IPR meeting each year.

Travel costs may include:

- Travel costs for up to 1 investigator to travel to 1 scientific/technical meeting per year.
- Travel costs between collaborating organizations.
- **Research-Related Subject Costs:** Include itemized costs of subject participation in the proposed research. These costs are strictly limited to expenses specifically associated with the proposed research.
- **Other Direct Costs:** Itemize other anticipated direct costs such as publication and report costs, equipment rental (provide hours and rates), communication costs, and organizationally provided services. Unusual or expensive items should be fully explained and justified. Estimate the costs of publishing and reporting research results, including direct charges for clerical preparation, illustrations, reprints, and distribution. Organizationally provided services should be supported by the organization's current cost/rate schedule. These items should be described in detail and clearly justified.
- **Subcontract Costs (Partnership/Collaboration Costs):** Should an intramural organization propose collaboration with an extramural entity for part of the research effort, the intramural organization will receive all funds and is responsible for executing all necessary contractual or assistance funding awards to collaborating partners through the agency's procedures. **All direct and indirect costs of any partnership/ collaboration costs must be included in the total direct costs of the primary award.** The nature of the partnership/collaboration should be described in the Budget Justification section.
- **Total Direct Costs:** Calculated automatically from the data provided for the initial budget period on page F-2 and for the entire proposed period of support on page F-3.
- **Total Indirect Costs:** If funds for indirect costs are requested, sufficient justification must be provided in the budget justification section. The Government reserves the right to disallow any indirect costs not sufficiently justified. All direct and indirect costs of any proposed collaborator must be included in the total direct costs of the primary award. (See Section I.F., Funding.)
- **Total Costs:** This section is calculated automatically from the data provided.
- **Fee:** A profit or fixed fee is not allowable on awards or on subawards.

Budget Justification Instructions: Provide a clear budget justification for each item in the budget over the entire period of performance in the Justification section) of the DoD Military Budget Form. Itemize direct costs within each budget category for additional years of support requested beyond year one.

- **Federal Agency Financial Plan (required):** Provide a detailed Federal Agency Financial Plan after the budget justification information in the DoD Military Budget Form. The plan delineates how all FY16 funding will be obligated by **September 30, 2017**. The plan must include the funding mechanism(s) or contractual arrangements that will be used to carry over funds between fiscal years, if applicable. Any FY16 funding not obligated by September 30, 2017 may be withdrawn by the issuing Comptroller.