Intramural Program 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/Medical Simulation and Information Sciences Research Program

A Predictive Personality & Emotional State Performance Determinants for Training (PREEMPT)

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), May 11, 2016
- **Invitation to Submit an Application:** June 15, 2016
- **Application Submission Deadline:** 5:00 p.m. ET, August 22, 2016
- **End of Proposal/Application Verification Period:** 5:00 p.m. ET, August 29, 2016
- **Peer Review:** October 2016
- **Programmatic Review:** November 2016

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I. FUNDING OPPORTUNITY DESCRIPTION

BEFORE APPLYING, PLEASE NOTE: THIS PROGRAM ANNOUNCEMENT/FUNDING OPPORTUNITY IS INTENDED FOR INTRAMURAL INVESTIGATORS ONLY.

A separate announcement for extramural investigators is available at Grants.gov (http://www.grants.gov) under the Funding Opportunity Number **W81XWH-16-R-MSI1.**

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

A. Program Description

Proposals/applications to the FY16 JPC-1/MSIS PREEMPT are being solicited for the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate by the U.S. Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs [OASD(HA)], the DHA RDA Directorate manages and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The 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 JPC-1/MSIS. CDMRP is the execution management agent for this BAA and will provide management support for subsequent awards with strategic oversight from JPC-1/MSIS.

The mission of the JPC-1/MSIS is to explore the implications of models and technology for medical education and for the provision, management, and support of health services in the military. The JPC-1/MSIS plans, coordinates, and oversees a responsive world-class, tri-service science and technology program. The JPC-1/MSIS is responsible for programming research in two distinct areas: Medical Simulation & Training and Health Information Sciences. This committee works with the Services and joint agencies to address gaps and requirements as identified by the Military Health System.

The JPC-1/MSIS Combat Casualty Training Initiative (CCTI): PREEMPT is a line of research that supports the CCTI under the JPC-1/MSIS Medical Simulation and Training portfolio. The JPC-1/MSIS CCTI focuses on research advancing the entire continuum of care for combat casualty training through research and development. CCTI research involves, but is not limited to: gap analysis for technology based approaches; validation of training metrics and outcomes; and development of next-generation tools and systems to appropriately and continuously provide

a high state of readiness for military healthcare providers. CCTI also investigates simulated "tissue" behaviors and characteristics to better represent virtual models and material properties related to simulation training systems. The effort includes research to integrate best practices into trauma training to improve warfighter performance under stress as would be experienced in-theatre. It also includes team (i.e., collective) training research.

Per guidance from DoD Instruction 5000.02, "Operation of the Defense Acquisition System," dated January 7, 2015, the outcomes of the research are intended to be used to support the solution assessments/material considerations for guidelines or curriculum development of PREEMPT foundation concepts. The government plans to use research outcomes in assessing critical technology elements and technology maturity, system integration risk, future manufacturing feasibility, and, where necessary, technology maturation and demonstration needs.

B. Award Information

PREEMPT seeks the development of a proof-of-concept task performance assessment tool that incorporates personality and emotional state as determinant components to predict an individual's performance and overall stress level under a wide range of potential combat casualty care scenarios, environments, and other stressful situations relevant to patient care. For this award, it is anticipated that the various components will be integrated for initial testing purposes in a laboratory setting to evaluate how the components work together. The FY16 JPC-1/MSIS PREEMPT is seeking research on two (2) of the several predictors of an individual's performance: personality and emotional state. This knowledge can be used to:

- Assess an individual's overall performance and stress levels during combat casualty care scenarios;
- Deconstruct overall performance into its personality and emotional state determinants and assess each;
- Combine the determinants to predict the person's overall performance on known tasks, especially as it applies to performance under stress.

For the purposes of this announcement, personality will be defined as that set of non-physical characteristics which distinguishes one individual from another.

For the purposes of this announcement, emotional states are interpretations of complex states that best describe a person's subjective response to a person, thing, or situation. Emotional states indirectly affect behavior.

The focus of the research should concentrate on those wishing to become military combat medics, corpsmen, pararescuemen, or special operations combat medics, but could consider other populations that are nearly equivalent. The pilot study should consider an individual's performance compared against currently used standards for military entry within the respective area. If unable to use a standard for military entry, then the applicant should justify the proposed standard that the organization perceives as nearly equivalent, especially if there are data-driven outcomes for individuals who have trained using standards vs. those who have not. The

assessment tool(s) could also potentially be used for sustainment of task performance and overall stress level assessment in refresher / sustainment courses.

For completeness, task difficulty needs to be described and defined and, if applicable, evaluation criteria provided with a description of the measurement tool. Task difficulty and conditions should be held constant in the proposed project.

In summary, an individual's performance on a task in a specific environment at a moment in time can be specified in terms of the individual's personality, emotional state, and task difficulty. This means that the observed task performance is the final common pathway of the complex interplay of the task determinants. The goal of this program is to identify the personality and emotional state determinants of individual performance in order to determine how to better select the right people for specific tasks in certain scenarios, environments, and stressful situations and how to improve individual performance across tasks and environments.

Anticipated Future Goals

It is anticipated that the outcomes of this research, development, and testing could be integrated and incorporated into an assessment tool for future military medical personnel at any level. As mentioned above, initial consideration will be targeting the military combat medics, corpsmen, pararescuemen, or special operations combat medics. In the future, determinants of performance assessment model will be needed to assess an individual's ability to optimally perform in environments such as, but not limited to, the treatment of multiple casualties with multiple injuries; pandemic events; and seeing one's fellow Service member inflicted with horrific injuries.

Anticipated Outcomes

- Explanation, including definitions and descriptions, of the personality and emotional state determinants of task performance to better understand how to assess an individual's performance capabilities for specific tasks and in difficult scenarios, environments, and stressful situations;

- Detailed performance model that incorporates the task determinants. A description of the metrics / evaluation criteria for the model. This needs to include the "objective" measurements that determine the utility of model and how the personality and emotional states pertain to an individual's performance capabilities for specific tasks and in difficult scenarios, environments, and stressful situations;

- Completion of preliminary / pilot empirical evaluation of the developed proof-of-concept task performance assessment model that incorporates personality and emotional states as components and assesses an individual's future performance;

- Describe the gaps that were uncovered during this research on personality and emotional states as they pertain to an individual's performance and provide anticipated next steps / recommendations to create an improved task performance assessment model that assesses an individual's performance and predicts future task performance for various tasks and environments;

- Provide a suggested list of Terminal Learning Objectives for possible inclusion in instructor military medical training courses. These potential courses could be used as a way to determine which learners will do well or will struggle and/or may identify optimal styles of learning.

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 to 3 months for HRPO regulatory review and approval processes***. Refer to the General Submission Instructions, Appendix 5, for additional information.

C. Eligibility Information

- Independent intramural investigators at all academic levels (or equivalent) are eligible to submit applications.
- Cost sharing/matching is not an eligibility requirement.
- Extramural investigators are directed to apply through CDMRP eBRAP at https://eBRAP.org/.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

It is expected that the majority of work funded through this Program Announcement/Funding Opportunity will be performed within a DoD laboratory or medical 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.

D. Funding

The JPC-1/MSIS expects to allot approximately $2.5 million (M) of the FY16 DHP RDT&E appropriation to fund approximately two JPC-1/MSIS-PREEMPT proposals/applications, depending on the quality and number of proposals/applications received from intramural agencies and extramural organizations. Funding of proposals/applications received in response to this BAA is contingent upon the availability of Federal funds for this program. As of the release date of this Program Announcement/Funding Opportunity, the FY17 Defense Appropriations Bill has not been passed and there is no guarantee that any additional funds will be made available to support this program. The funding estimated for this Program Announcement/Funding Opportunity is approximate and subject to realignment.

NOTE: Proposals/applications received in response to both the JPC-1/MSIS PREEMPT intramural Program Announcement and extramural BAA will be evaluated and considered for funding together. The Government reserves the right to fund any combination of intramural and/or extramural proposals/applications.

- The maximum period of performance is **2** years.
- The anticipated **total** costs (direct and indirect) budgeted for the entire period of performance will not exceed **$1.25M**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **$1.25M** 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.
- Option periods may be used on contracts.

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

- Travel costs for the PI(s) to an In-Progress Review (IPR) anticipated to be held near the end of the 1-year anniversary of the award at a Government location (to be determined). For planning purposes, it should be assumed that the meeting will be held in the National Capital Area/Maryland/Northern Virginia. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary, including contract personnel (Federal salaries paid by the parent organization may not be reimbursable)
- Research-related subject costs
- Support for multidisciplinary collaborations
- Equipment
- Research supplies
- Travel between collaborating organizations, including travel to military/Government facilities
- Travel costs to attend scientific/technical meetings in addition to the required IPR meeting described above

Submissions selected for funding will be processed for award by USAMRMC and awards made to organizations, not individuals. 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.

This Program Announcement/Funding Opportunity is intended for intramural investigators only. Extramural investigators are directed to apply through Grants.gov (http://www.grants.gov/) under the Funding Opportunity Number W81XWH-16-R -MSI1.

An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or MTF, or working in a DoD activity embedded within a civilian medical center.

It is permissible for an extramural investigator to be named as a collaborator in an application submitted by an intramural investigator under this Program Announcement/Funding Opportunity. ***In such cases, 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.***

II. SUBMISSION INFORMATION

Submission is a two-step process requiring both (1) pre-application submission and (2) application submission through the CDMRP eReceipt System (https://cdmrp.org/).

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

Start the submission process early. The CDMRP eReceipt System 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

All pre-application components must be submitted by the indicated deadline by the PI through the CDMRP eReceipt System (https://cdmrp.org/). Material submitted after the deadline, unless specifically requested by the government, will not be forwarded for processing.

PIs, collaborators, 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@cdmrp.org or 301-682-5507.

The pre-application consists of the following components, which are organized in the CDMRP eReceipt System by separate tabs:

- **Application Information – Tab 1**
    - Enter the application information as described in the CDMRP eReceipt System before continuing the pre-application.

- **Application Contacts – Tab 2**
  - Enter contact information for the PI responsible for the overall scientific and technical direction of this application and the organization's Resource Manager/Comptroller or equivalent personnel responsible for sponsored program administration. This contact information is ***required*** in the CDMRP eReceipt System. The pre-application will not be accepted without it. However, the CDMRP does not require approval of the pre-application by the PI's organization.

- **Collaborators and Conflicts of Interest (COIs) – Tab 3:**
  - Enter the name, organization, and role of all collaborators and key personnel associated with the application (including co-investigators, mentors, collaborators, consultants, and subrecipients/subawardees) associated with the proposal/ application. Enter the organization's Business Official responsible for sponsored program administration (the "person to be contacted on matters involving this application" in Block 5 of the Grants.gov SF-424 form). The Business Official must either be selected from the eBRAP list or invited in order for the pre-proposal/pre-application to be submitted.
  - It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.
  - ***Pre-applications that designate a JPC-1 Medical Modeling, Simulation, and Training Working Group member or advisor (listed in Appendix 4) as an investigator, consultant, collaborator, or in a key personnel role will not be considered.*** For questions related to the JPC-1 Medical Modeling, Simulation, and Training Working Group members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at help@CDMRP.org or 301-682-5507.
  - To preserve the integrity of its peer and programmatic review process, 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 identies of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess.shtml). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage Conflicts of Interest (COIs) are provided and deemed appropriate by the Government. Refer to the General Application Instructions Appendix 1, for detailed information.

- **Conflicts of Interest – Tab4:**
  - List all individuals other than collaborators and key personnel who may have a COI in the review of the proposal/application (including those with whom the PI has a personal or professional relationship). Refer to the General Application Instructions Appendix 1, Section C for further information regarding COIs.

- **Required Files – Tab 5:** ***Note: At this time, the CDMRP eReceipt System is unable to read files made with Adobe Acrobat PDFMaker version 9.0 and higher.*** The documents should conform to the formatting guidelines outlined in Appendix 1.

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

  Include the following:

  - **Problem to Be Studied:** Describe the perceived issue(s) and the problems to be studied. This section should serve as an abstract of the proposed work.
  - **Theoretical Rationale, Scientific Methods, and Research:** Describe the research approach for accomplishing the specific aims is feasible, what will accomplish the proposed objectives, will provide information on proposed methods and analysis/ evaluation strategies, and is based on sound rationale. Describe how the proposed work and research will create and produce a proof-of-concept task performance assessment tool that incorporates personality and emotional state as determinant components to assess an individual's performance and overall stress level.
    - **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 preliminary data should be from the laboratory of the PI or member(s) of the collaborating team.
    - **Hypothesis/Objective and Specific Aims:** State the proposed project's hypothesis and/or objectives and the specific aims/tasks of the proposed research.
    - **Approach/Methodology:** Describe the research approach. Include research design, methods, and analysis/evaluation strategies as well as materials anticipated to be used during the research. If applicable, include a description of human use in the proposed project. For studies involving human subjects, include a description of the size, characteristics, and partnering organizations of the subject population that will be employed.
  - **Significance, Relevance, and Innovation of the Proposed Effort**
    - **Significance and Relevance:** Clearly articulate how the proposed research is relevant to the goal of developing a proof of concept task performance assessment tool that incorporates personality and emotional state as determinant components to assess an individual's performance and overall stress level during combat casualty care scenarios.

- **Innovation:** Explain how the proposed project is innovative and not an incremental advancement of previous work.

- **Proposed Study Design/Plan:** Describe the pilot study concept of the compensatory/adaptive medical tutor prototype. Provide the intended research methodology that will support the pilot study. Provide preliminary information such as anticipated type of recruits, number of recruits, control group, anticipated assessment criteria, inter-rater reliability, and statistical protocols. Refer to Section I.B., Award Information for additional information on the research areas of interest for this PA.
- **Military Impact:** Describe the anticipated short- and/or long-term outcomes of the proposed project and their potential impact on improving healthcare training and patient safety in the military health system. Refer to Section I.B., Award Information, for additional information on the anticipated outcomes sought by this PA.
- **Personnel and Facilities:** Describe the role of the PI, co-PIs (if applicable), key personnel, sub-awards (if applicable), and consultants (if applicable) in the research team, including the expertise each brings to the proposed project. Explain how the team's expertise is appropriate and complementary for achieving the research goals. Also, briefly provide information on the primary facility where the research is expected to be performed.
- **Open Source/License/Architecture**: Describe the intellectual property that is intended to be incorporated within the design/plan and identify any additional costs, such as licensing, which may be needed to ensure flexibility or adaption of a compensatory/adaptive inter-professional medical team teaching guidelines or curriculum.

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

- **References Cited (one-page limit):** List the references cited (including URLs if available) in the Pre-Proposal/Pre-Application Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Pre-Proposal/Pre-Application Narrative.
- **PI and Key Personnel Biographical Sketches (five-page limit per individual):** Upload as "Biosketch_LastName.pdf." Bold or highlight publications relevant to the proposed project.
- **Budget Summary: Upload as "BudgetSummary.pdf."** Complete the two-page Pre-Application Budget Summary Form (available for download in eBRAP) as instructed.

- **Quad Chart: Upload as "QuadChart.pdf."** Complete the one-page Quad Chart Form (available for download in eBRAP) as instructed.

- **Submit Pre-Application – Tab 6:**

  - This tab must be completed for the pre-proposal/pre-application to be accepted and processed.

Pre-Application Screening

- **Pre-Proposal/Pre-Application Screening Criteria**

  All pre-proposals/pre-applications will be screened by the JPC-1 Medical Modeling, Simulation, and Training Steering Committee members to determine technical merit and relevance to the mission of the DHP, DMRDP, and JPC-1/MSIS. Pre-proposals/pre-applications will be screened based on the following criteria, listed in descending order of importance:

  - **Theoretical Rationale, Scientific Methods, and Research:** To what degree the research approach for accomplishing the specific aims is feasible, will accomplish the objectives, will provide information on proposed methods and analysis/ evaluation strategies, and is based on sound rationale. To what degree the proposed work and research will create and produce a proof-of-concept task performance assessment tool that incorporates personality and emotional state as determinant components to assess an individual's performance and overall stress level.
  - **Significance, Relevance, and Innovation:** To what degree the proposed research is relevant, innovative, and novel, including whether the proposed research is duplicative of existing research.
  - **Open Source/License/Architecture:** Evaluate if intellectual property that is proposed for incorporation is located in key areas within the design/plan which could impact future flexibility or adaptation of a task performance assessment tool to assess an individual's performance and overall stress level compensatory.
  - **Study Design/Plan:** To what degree the proposed pilot-study methodologies, anticipated sample and sample size, types of recruits, anticipated assessment criteria, inter-rater reliability, and statistical protocols will justify and support the intended outcomes of the proposed research.
  - **Military Impact:** To what degree the project's anticipated short- and/or long-term outcomes will impact the military and a future training program in team-based healthcare delivery and patient safety in the military health system in a way that is consistent with the intent of the award mechanism.
  - **Personnel, Facilities, Timelines, and Budget:** To what degree the expertise, experience, and knowledge of the key research personnel (including co-PIs if applicable), sub-awards (if applicable), and consultants (if applicable) are appropriate and complementary for achieving the research goals. To what degree the prime facility will be able to perform the proposed research.

Notification of Pre-Proposal/Pre-Application Screening Results

Following the pre-proposal/pre-application screening, PIs will be notified as to whether or not they are invited to submit proposals/applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-proposal/ pre-application. The estimated timeframe for notification of invitation to submit a proposal/application is indicated on the title page of this Program Announcement/Funding Opportunity.

B. Full Application Submission Content

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

All application components must be submitted by the indicated deadline by the PI through the CDMRP eReceipt System (https://cdmrp.org/). Material submitted after the deadline, unless specifically requested by the government, will not be forwarded for processing.

The application consists of the following components, which are organized in the CDMRP eReceipt System by separate tabs. To access these tabs, go to "My Applications" and click on "View/Edit Application Information" for the log number of the application that has been invited for submission.

- **Application Information – Tab 1:** This tab will be populated by eReceipt. Do not change.

- **Application Contacts – Tab 2:** This tab will be populated by eReceipt. Do not change.

- **Collaborators and Conflicts of Interest (COIs) – Tab 3:** This tab will be populated by eReceipt. To avoid COIs during application screening and review processes, review and update (if needed) the names of all scientific participants in the proposed research project, including co-investigators, mentors, collaborators, consultants, and subrecipients/subawardees. In addition, add all individuals outside of the application who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship) and choose "COI" from the drop-down list.

  Applications that designate a JPC-1 Medical Modeling, Simulation, and Training Working Group member or advisor as an investigator, consultant, collaborator, or in a key personnel role will not be considered. A list of JPC-1/MSIS Working Group members and advisors is included in Appendix 4.

- **Required Files – Tab 4:** Submit each component as an individual PDF file. Refer to Appendix 1, for detailed formatting guidelines. ***Note: At this time, the CDMRP eReceipt System is unable to read files made with Adobe Acrobat PDFMaker version 9.0 and higher.***

  Component 1: Project Narrative (20-page limit): Upload as "ProjectNarrative.pdf." The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical

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

Describe the proposed project in detail using the outline below.

- **Background:** Present the ideas and reasoning behind the proposed research; include relevant literature citations or preliminary data on the proposed sustainment techniques using neuroplasticity type of methodologies. Additionally, present the ideas, reasoning, and justification behind the proposed compensatory/adaptive tutor that is anticipated to accurately and appropriately understand where the learner is within the learning curve versus the course curricula, objectives, and anticipated outcomes. The tutor must also identify viable and appropriate course route(s) on how to navigate from current position to end point position. Describe previous experience most pertinent to this project. Any preliminary data should be from the laboratory of the PI or member(s) of the collaborating team.
  - Clearly support the choice of study variables and explain the basis for the study questions and/or study hypotheses. Establish the relevance of the study and explain the applicability of the proposed findings.
- **Hypotheses/Objectives:** State the hypotheses/study questions and overall objective(s) to be reached.
- **Specific Aims:** Concisely explain the project's specific aims. If this application is part of a larger study, present only tasks that this award would fund.
- **Study Design:** Describe the experimental design, methods, and analyses/ evaluations in sufficient detail for analysis.
  - Identify and describe the hypothesis to be studied and the projected outcome of the proposed research.
  - Provide a detailed protocol, including but not limited to proposed methodologies, type of recruits, recruitment numbers, anticipated drop-out rate, assessment criteria, inter-rater reliability, intended medical domain(s) or discipline(s), control groups, and statistical protocols.
  - Define the study variables and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested. Describe how data will be collected and analyzed in a manner that is consistent with the study objectives. Describe a plan for data access.
  - For development of devices and technologies, discuss the engineering/technical design that will be used to achieve the project goals demonstrating the feasibility of the proposed product development. Discuss the perceived engineering/design strengths and flaws and recommendations for overcoming/preventing them.
  - Address any potential barriers and plans for addressing potential delays. Provide a risk management plan to address barriers to plans. As relevant,

describe plans for addressing issues unique to working within the military health system.

- Document the availability and accessibility of the study materials (including data) needed as applicable.

- **Project Milestones:** Identify timelines for critical events that must be accomplished in order for the project to be successful in terms of cost, schedule, and performance.

- **Additional Information:** If human and/or animal subjects are included in the research, applications may be submitted without human and/or animal use protocols and institutional approvals. However, protocols with required institutional approvals must be submitted no later than 60 days after award to demonstrate continued progress and ensure continuation of payment. The Contracting or Grants Officer may make exceptions in situations where human and/or animal use is not expected to begin until after the first year of the research project. In such cases, a timeframe for submission of the appropriate protocols and institutional approvals will be established prior to award.

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

  - For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.
  - Identify cell line(s) and commercial or organizational source(s) to be used. If human anatomical substances (including cell lines) will be used, specify whether or not identifiable information is accessible to the research team by any means.
  - If applicable, indicate time required for submission and/or approval of documents (e.g., Investigational New Drug and Investigational Device Exemption) to the U.S. Food and Drug Administration or appropriate government agency.
  - For studies involving human subjects, allow at least 2 to 3 months for regulatory review and approval by the USAMRMC HRPO; this does not include the additional time required for local IRB/EC review and approval.
  - For animal studies, allow at least 2 to 3 months for regulatory review and approval by the USAMRMC ACURO; this does not include the additional time required for local IACUC review and approval.
  - Refer to Appendix 3 for additional regulatory information.

Component 2: Supporting Documentation. Start each document on a new page. Combine and upload as a single file named "Support.pdf." If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no***

page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested will result in the removal of those items or may result in administrative withdrawal of the application.

- **Bibliography and References Cited:** List the references in the order they appear in the proposal/application narrative. Use a reference format that gives the title of the citation. Do not send or attach copies of articles in print. There is no form for this information. The attachments should be in PDF in accordance with the formatting guidelines specified for full proposal/application preparation.
- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
- **Facilities and Other Resources:** Describe the facilities available for performance of the proposed request and any additional resources proposed for acquisition at no cost to the government. Indicate if a government-owned facility is proposed for use. Reference should be made to the original or present award under which the facilities or resources are now accountable. There is no form for this information. The attachments must be in PDF in accordance with the formatting guidelines outlined for full proposal/application preparation.
- **Equipment:** Include a description of existing equipment to be used for the proposed research project.
- **Publications and/or Patent Abstracts (five-document limit):** Include relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscript(s) may be attached.
- **Letters of Organizational Support:** Provide a letter (or letters, if applicable) from the following:
  - 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 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.
- **Letters of Collaboration:** Provide letter(s) supporting stated collaborative efforts necessary for the project's success, even if provided at no cost. ***If the project involves collaboration with a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center), special requirements apply.*** A DoD researcher must obtain a letter from his/her commanding officer or Military Facility director authorizing his/her participation in the research project. This letter must be included with the application.

- **Joint Sponsorship (if applicable):** Describe present or prospective joint sponsorship of any portion of the program outlined in the proposal/application. In the absence of agreements among sponsors for joint support, the proposal/application should be structured so that the research can be carried out without the resources of any other sponsor. If, however, it is desirable to request partial support from another agency, the proposed plan should be stated and the reasons documented. If the plan cannot be formulated at the time the proposal/application is submitted, information should be sent later as an addendum to the proposal/application. Prior approval from both agencies must be secured for research to be undertaken under joint sponsorship. Provide letters of support related to recruitment, subject access, and data access plans.
- **Intellectual Property:**
  - 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:
    1. Clearly identify all such property;
    2. Identify the cost to the Federal government for use or license of such property if applicable; or
    3. Provide a statement that no property meeting this definition will be used on this project."
  - Intellectual and Material Property Plan: If applicable, provide a plan for resolving intellectual and material property issues among participating organizations.
  - All software and technical data first produced under the award are subject to a Federal purpose license. If applicable, state and identify the proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the Federal purpose license.
- **Implementation Plan:** If commercialization is not applicable, describe the implementation plan to improve combat casualty care.
- **Data and Research Resources Sharing Plan:** Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to Appendix 2 for more information about the CDMRP expectations for making data and research resources publicly available.

Component 3: Technical Abstract (one-page limit): Upload as "TechAbs.pdf."

Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. Use the outline below. Abstracts of all funded proposals/applications will be posted publicly; ***therefore, proprietary information should not be included in the abstracts.***

- **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/Milestones:** State concisely the specific aims/milestones of the project.
- **Project Design:** Briefly describe the project design.
- **Impact:** Provide a brief statement explaining the potential impact of the proposed work to improving combat casualty care for injured Service members and/or the general public.

Component 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf." Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. Abstracts of all funded proposals/applications will be posted publicly; ***therefore, proprietary information should not be included in the abstracts.***

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

- Describe the objectives and rationale for the proposal/application in a manner that will be readily understood by readers without a background in science or medicine.
- Describe the ultimate applicability and potential impact of the research.
  - What types of patients will it help, and how will it help them? Include the current available statistics to the related injury/condition.
  - What are the potential clinical applications, benefits, and risks?
  - What is the projected timeline it may take to achieve the expected patient-related outcome?
- Briefly describe how the proposed project will benefit Service members, Veterans, and/or their family members.

Component 5: Statement of Work (SOW) (two-page limit): Upload as "SOW.pdf." The SOW outlines and establishes the PI's and an organization's performance expectations for the work to be funded under this award. The SOW in an assistance agreement award establishes general objectives. The SOW in a contract sets rather specific goals and conditions for each year of the contracted project; the PI and contractor are expected to meet the provisions and milestones of the SOW. The SOW for all award types will be incorporated into the award document and, as such, is subject to release under the Freedom of Information Act (FOIA).

A series of relatively short statements should be included that comprise the approach to each of the major goals or objectives of the proposed research. The statements should outline the specific tasks, systems, and materials that are reasonable estimates for testing the proposed hypotheses of the study. An outline should be included that shows the work statements to be accomplished in each year of the award. If this proposal/application is part of a larger study, present only tasks that this award would fund. Allow at least 2 to 3

months for the USAMRMC ORP regulatory review and approval processes for studies involving human subjects and 2 to 3 months for studies involving animal subjects.

Component 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)/theoretical framework, design, and/or plan that will be directly attributed to the results of the proposed research.
- ***Long-Term Impact:*** Describe the anticipated long-term clinical/ patient gains or commercial end product from the proposed project. What is the indication and will the project lead toward improving combat casualty care? Are there non-trauma-related indications that would expand the market for the proposed product?
- ***Military Relevance:*** Clearly articulate how the proposed project or product meets the needs of military medical providers and injured Service members during combat casualty care.
- ***Public Purpose:*** If appropriate, provide a concise, detailed description on how this project will benefit the general public.

Component 7: Innovation Statement (two-page limit): Upload as "Innovation.pdf." Describe how the proposed project is innovative. Research deemed innovative may introduce a new paradigm, challenge current paradigms, look at existing problems from new perspectives, or exhibit other creative qualities. Investigating the next logical step or incremental advancement on published data is not considered innovative. This may include a proposed conceptual framework, design, and/or plan of key components and how they integrate/communicate with each other. Identify which potential components will be open source/open architecture vs. proprietary.

Component 8: Human Subject Recruitment and Safety Procedures (no page limit): Upload as "HumSubProc.pdf." The Human Subject Recruitment and Safety Procedures attachment should include the components listed below.

a. Study Population: Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site (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 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.

b. Inclusion/Exclusion Criteria: List the inclusion and exclusion criteria for the proposed 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 study.

c. Description of the Recruitment Process: Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, health care provider identification).

- Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.
- Include a detailed description of and justification for the compensation plan if the human subjects will be compensated for participation in the study.
- Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study.

d. Description of the Informed Consent Process: Specifically describe the plan for obtaining informed consent from human subjects.

For the proposed study, provide a draft, in English, of the Informed Consent Form.

- Identify who is responsible for explaining the study, answering questions, and obtaining informed consent. Include a plan for ensuring that human subjects' questions will be addressed during the consent process and throughout the trial.
- 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/EC 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 study to be in compliance with 10 USC 980 (http://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf). If applicable, please refer to the General Submission Instructions, Appendix 5, for more information.

- Assent. If minors or other populations that cannot provide informed consent are included in the proposed 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/EC to identify the conditions necessary for obtaining assent.

e. Screening Procedures: List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry. Please note that some screening procedures may require a separate consent or a two-stage consent process. Informed consent must be obtained prior to initiation of any procedures for the purpose of determining eligibility.

f. Risks/Benefits Assessment:

- **Foreseeable risks:** Clearly identify all study risks. Study risks include any risks that the human subject is subjected to as a result of participation in the study. Consider psychological, legal, social, and economic risks as well as physical risks. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.
- **Risk management and emergency response**
  - Describe how safety surveillance and reporting to the IRB and FDA (if applicable) will be managed and conducted.
  - Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values.
  - Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, to include who will be responsible for the cost of such care.
  - Address any special precautions to be taken by the human subjects before, during, and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention).
  - Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study.
- **Potential benefits:** Describe known and potential benefits of the study to the human subject, a specific community, or society**.** ***Note: Payment and/or other***

compensation for participation are not considered to be benefits and must be addressed in Attachment 8c.

Component 9: Data Management (no page limit): Upload as "DataManage.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 study 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 USAMRMC are eligible to review study records.
    - Address requirements for reporting sensitive information to state or local authorities.
- **Disposition of data:** Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, and the length of time data will be stored. For FDA-regulated studies, compliance with 21 CFR 11 is required.
- **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.

Component 10: Post-Award Project Transition Plan (three-page limit). Upload as "Transition.pdf." Provide information on the methods and strategies proposed to move the product or knowledge outcomes to the next project phase of studies, commercialization, and/or delivery to the civilian or military market after successful completion of the award. The transition plan should include, as applicable, the components listed below.

a. The planned indication for the product label and an outline of the development plan required to support that indication.

b. The anticipated regulatory strategy (e.g., additional nonclinical or clinical studies anticipated/required, FDA or regulatory authority meetings desired, industry partnerships) for movement of the research into later phases of development and to support a potential marketing application [e.g., New Drug Application, Biologics License Application, Premarket Approval Application, 510(k)].

c. Details of the funding strategy that will be used to bring the outcomes to the next level of development and/or commercialization (e.g., specific potential industry partners, specific funding opportunities to be applied for).

d. For knowledge products, a description of how the knowledge will be further developed, disseminated, and incorporated into clinical care.

e. A description of collaborations and other resources that will be used to provide continuity of development.

f. A brief schedule and milestones for bringing the outcome(s) to the next phase of studies, commercialization, and/or delivery to the military or civilian market, including when it can be anticipated to be transitioned to an industry partner or approved by the FDA.

g. A risk analysis for cost, schedule, manufacturability, and sustainability.

Component 11: Conflicts of Interest, *if applicable*: Upload as "COI.pdf." Provide details with the proposal/application submission of all organizational or individual investigator COIs, or potential COIs, along with a plan to resolve them. A contract or assistance agreement will not be awarded if it is determined by the respective Contracting or Grants Officer that a COI cannot be resolved.

Personnel involved in the review process and/or with making funding recommendations are prohibited from assisting in any proposal/application, including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. ***If formal collaboration with Military Facility personnel is planned (i.e., included in the proposal/application in performance of the research), this prohibition is not applicable. However, these individuals may not be involved in the review process and/or with making funding recommendations.***

Component 12: Collaborating DoD Military Facility Budget Form(s), *if applicable*: Upload as "MFBudget.pdf." If a Military Facility will be a collaborator in performance of the project complete the Collaborating DoD Military Facility Budget Form (available for download on eBRAP "Funding Opportunities and Forms" web page), including a budget justification for each year. If more than one Military Facility is proposed, submit a separate budget form for each site.

Component 13: Biographical Sketches: Combine biographical sketches and current/pending support documentation for the PI and all key personnel into a single PDF file and upload as "Biosketches.pdf."

- The suggested biographical sketch format is available on the "Program Announcement and Forms" page in the CDMRP eReceipt System (https://cdmrp.org/Program_Announcements_and_Forms/). Use of this document is optional.
- **Current/Pending Support:** For all current and pending research support, include the title, time commitments, supporting agency, name and address of the funding agency's procuring Contracting/Grants Officer, performance period, level of funding, brief description of the project's goals, and list of the specific aims. If

applicable, identify where the proposed project overlaps with other current and pending research projects. Clearly state if there is no overlap. If there is no current or pending support, enter "None." An updated current and pending support document will be required during award negotiations.

Component 14: Budget and Budget Justification: Use the Detailed Budget and Justification form available on the "Program Announcement and Forms" page in the CDMRP eReceipt System (https://cdmrp.org/Program_Announcements_and_Forms/). **Upload as "Budget.pdf."**

Submit a detailed budget and budget justification that cover the entire period of performance (not just the first year). All costs must be entered in U.S. dollars. The budget and budget justification must be sufficiently detailed so that the Government can determine the proposed costs to be allowable, allocable, and reasonable for the proposed research. ***The Government reserves the right to request a revised budget and budget justification and/or additional information.***

***Budget Instructions*:** Complete the Detailed Budget and Justification form. Begin by entering the PI name, CDMRP log number, and period of performance fields at the top of page F-1 of the Detailed Budget and Justification form. Following the guidelines below, enter the required information under "Detailed Budget for Year One" on pages F-1 (Senior/Key Person and Other Personnel) and F-2 (Other Direct Costs). Clearly justify each budget item for the entire period of performance in the Justification section on page F-4.

- **Senior/Key Person and Other 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 previously provided. 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, and support staff.
  - **Role in Project:** Identify the role of each participant listed. Describe his/her specific functions 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.

- **Other Direct Costs:** Itemize and clearly justify all additional direct costs as components of the budget categories listed below. Enter the itemized budget information for the first year on page F-2.
- **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.
- **Travel Costs:** Travel costs may include:
  - Required attendance at one 1-day IPR meeting, to be held in the National Capital Region.
  - Attendance at scientific/technical meetings. Include the meeting name, purpose, location, and date, if known, in the budget justification.
  - Travel associated with the execution of the proposed work (if applicable). Reasonable costs for travel between collaborating organizations should be included and are not subject to the yearly cost limitation on travel to scientific/ technical meetings. International travel may be requested but must be well justified, requested no less than 180 days before travel, and is subject to approval by the CDMRP.
- **Materials, Supplies, and Consumables:** The budget justification for supporting material and supply (consumable) costs should include a general description of expendable material and supplies. If animals are to be purchased, state the species, strain (if applicable), number to be used, cost per animal, and proposed vendor. If human cell lines are to be purchased, state the source, cost, and description.
- **Consultant Costs:** Whether or not funds are requested, include in the budget justification the names and organizational affiliations of all consultants, and include the daily consultant fee, travel expenses, nature of the consulting effort, and why consultants are required for the proposed research project.
- **Partnership/Collaboration Costs**: Should an extramural organization propose collaboration with an intramural 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. 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.**

- **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 Expenses:** 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.
- **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:** This award is not intended to provide funds for indirect costs to the applicant organization. All direct and indirect costs of any proposed collaborator must be included in the total direct costs of the primary award. 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.
- **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 (page F-4) of the Detailed Budget and Justification form.

- **Federal Agency Financial Plan (required):** 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 funds (FY16) 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.
- PIs must plan to have 90% of FY16 funds disbursed and/or obligated by September 30, 2016. Any funding not obligated by September 30, 2017 may be withdrawn by the issuing Comptroller.

- **Submit – Tab 5:** Once all components have been uploaded, enter your password in the space provided next to "Enter Your Password Here" and press the "Submit" button. Press the "Confirm Submission" button to complete the application submission.

  This tab MUST be completed for the application to be accepted and processed by eReceipt.

- **Other Documents Tab:** This tab is not applicable during the application submission process.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that makes recommendations for funding to the DHA RDA Directorate and the [OASD(HA)], based on (a) technical merit and (b) the relevance to the mission of the DHP and JPC-1/MSIS and to the specific intent of the award mechanism. The highest-scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier process used by the CDMRP can be found at http://cdmrp.army.mil/about/fundingprocess.shtml.

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

B. Application Review Process

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

   - **Theoretical Rationale and Scientific Methods**
     - To what degree the research approach for accomplishing the specific aims is feasible, will accomplish the objectives, and is based on sound rationale.
     - Whether the proposed proof-of-concept task performance assessment model adequately incorporates personality and emotional state as determinant components to assess an individual's performance and overall stress level.

- How well the study aims, hypotheses or objectives, experimental design, methods, and analyses are designed to clearly answer the research questions.
- How well the proposed methodologies, evaluation strategy, type of recruits, recruitment numbers, anticipated drop-out rate, assessment criteria, inter-rater reliability, intended medical domain(s) (or discipline[s]), control groups, statistical protocols, etc., to support the pilot-study are presented and align with the proposed study outcomes.
- Whether there is evidence of an adequate contingency plan, such as a risk mitigation plan, to resolve potential delays.
- Whether the proposed timeline is appropriate and tasks outlined in the proposal/application are logical in their progression.
- To what degree the references cited within the proposal/application supports the background, the proposed methodologies, and/or the proposed pilot study methodologies.

- **Relevance, Innovation, and Impact:**
  - How the proposed research is relevant to the goal of incorporating personality and emotional state as determinant components and how the proposed work will impact the development of an assessment tool for an individual's performance and overall stress level.
  - How the proposed work is innovative and novel, including whether the proposed research is duplicative of existing research.
  - To what degree the proposed research is relevant to the goal of delivering a task performance assessment tool.
  - To what degree the anticipated short- and long-term outcomes resulting from the proposed study will contribute to the goal of improving patient safety and healthcare outcomes.
- **Open Source/License/Architecture**
  - To what degree the proposed task performance assessment tool incorporates open source/license/architecture and intellectual property components available for license.
  - To what degree the intellectual property components may impact future flexibility or adaptation of the tool to meet future Government needs.
  - Identify within the proposal the anticipated Government rights of the proposed task performance assessment tool.
- **Personnel and Facilities**
  - How the composition and balance of the research team (including other organization personnel, sub-awards, and consultants, as applicable) are appropriate.

- To what degree the PI's and research team's backgrounds and expertise are appropriate and complementary to accomplishing the proposed work.
- To what degree the levels of effort by the PI and other key personnel are appropriate to ensuring the success of proposed research.
- To what degree the research environment and the accessibility of institutional resources support the proposed study (including collaborative arrangements).
- Whether there is evidence for appropriate institutional commitment.

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

- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
- **Intellectual Property and Commercialization Plan**
  - If applicable, to what degree the intellectual property plan is appropriate.
  - If applicable, to what degree the commercialization plan is appropriate.
- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influence the review.

2. **Programmatic Review:** To make funding recommendations, the following criteria are used by programmatic reviewers:

   a. Ratings and evaluations of the peer reviewers

   b. Open Source/License/Architecture

   - Identify within the proposal/application anticipated Government rights of the proposed task performance assessment tool.
   - To what degree the intellectual property components may impact future flexibility or adaptation of the tool to meet future Government needs.
   - Degree of public accessibility of outcomes.

   c. Relevance to the mission of the DHP and JPC-1/MSIS, as evidenced by the following:

   - Adherence to the intent of the award mechanism
   - Programmatic relevance
   - Program portfolio balance
   - Relative innovation and impact
   - Proposed project timelines

C. Application Review Dates

All application review dates and times are indicated on the title page of this Program 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 eReceipt, the following administrative actions may occur:

A. Rejection

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

- The pre-application is submitted by an extramural organization.
- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

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

B. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Preproposal Narrative and Project Narrative.
- Documents not requested will be removed.
- Following the application deadline, the PI may be contacted by CDMRP via email with a request to provide certain missing supporting documents. The missing documents must be provided by the deadline specified. Otherwise, the application will be reviewed as submitted.

C. Withdrawal

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

- An FY16 JPC-1 Medical Modeling, Simulation, and Training Working Group member or advisors is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to,

concept design, application development, budget preparation, and the development of any supporting documentation. A list of the JPC-1 Medical Modeling, Simulation, and Training Working Group Members and Advisors can be found in Appendix 4.

- The pre-application and/or application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The application budget differs significantly from the budget included in the pre-application.
- The invited application does not propose the same research project described in the pre-application.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending institutional investigation. The institution will be required to provide the findings of the investigation to the CDMRP and JPC-1/MSIS for a determination of the final disposition of the application.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2017. Refer to Appendix 2 for additional award administration information.

B. Administrative Requirements

Refer to Appendix 2 for general information regarding administrative requirements.

C. Reporting

Refer to Appendix 2 for general information on reporting requirements.

Monthly and/or Quarterly technical progress reports and quad charts will be required based on the award mechanism. In addition to written progress reports, in-person presentations will be requested. Reporting of contractor manpower is required for all contracts.

- Contractor Manpower Reporting (CMR)
    - CMR is now a requirement of DoD contracts. Offerors are allowed to include a nominal fee in their cost/price proposal for providing this data. A "nominal fee" is defined as a computation of an administrative assistant equivalent labor category providing approximately 6-8 hours to complete data input. Offerors may opt to not separately price this required annual data input. CMR costs/price will not be evaluated as part of the total evaluated proposal cost/price.

    - The contractor shall report ALL contractor labor hours (including subcontractor labor hours) required for performance of services provided under each contract via a secure data collection site. The contractor is required to completely fill in all required data fields using the following web address: http://www.ecmra.mil/.

    - Reporting inputs will be for the labor executed during the period of performance during each Government fiscal year (FY), which runs October 1 through September 30. While inputs may be reported any time during the FY, all data shall be reported no later than October 31 of each calendar year, beginning with 2013. Contractors may direct questions to the help desk at: contractormanpower@hqda.army.mil or via phone at 703-377-6199.

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 CDMRP and JPC-1/MSIS.

E. Site Visits

JPC-1/MSIS and/or 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 Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application and/or application through the CDMRP eReceipt system 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@cdmrp.org

VII. APPLICATION SUBMISSION CHECKLIST

Application Components	Action	Completed
Component 1 – Project Narrative	Upload as "ProjectNarrative.pdf."	
Component 2 – Supporting Documentation	Upload as "Support.pdf."	
Component 3 – Technical Abstract	Upload as "TechAbs.pdf."	
Component 4 – Lay Abstract	Upload as "LayAbs.pdf."	
Component 5 – Statement of Work	Upload as "SOW.pdf."	
Component 6 – Outcomes and Impact Statement	Upload as "Impact.pdf."	
Component 7 – Innovation Statement	Upload as "Innovation.pdf."	
Component 8 – Human Subject Recruitment and Safety Procedures	Upload as "HumSubProc.pdf."	
Component 9 – Data Management	Upload as "DataManage.pdf."	
Component 10 – Post-Award Project Transition Plan	Upload as "Transition.pdf."	
Component 11 – Conflicts of Interest	Upload as "COI.pdf."	
Component 12 – Collaborating DoD Military Facility Budget Forms	Upload as "MFBudget.pdf."	
Component 13 – Biographical Sketches	Upload as "Biosketches.pdf."	
Component 14 – Budget and Budget Justification	Upload as "Budget.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 Program Announcement (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. Disclosure of Proprietary Information

Do not include proprietary information in a pre-application or abstract. Proprietary information should only be included in a full application if necessary for evaluation.

Proprietary information submitted in an application may be disclosed outside the government for the sole purpose of technical evaluation. Evaluators must agree that proprietary information in the proposal/application will be used for evaluation purposes only and will not be further disclosed or used.

All applications may be subject to public release under the Freedom of Information Act (FOIA) to the extent that they are incorporated into an award document; applications that are not selected for funding will not be subject to public release.

B. Marking of Proprietary Information

Conspicuously and legibly mark any proprietary information that is included in the application.

C. 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 the Congressionally Directed Medical Research Programs (CDMRP) eReceipt System at https://cdmrp.org/Program_Announcements_and_Forms.

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 the CDMRP eReceipt System at https://cdmrp.org/Program_Announcements_and_Forms.

D. 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 Assistant Secretary of Defense for Health Affairs through the Defense Health Agency, Research, Development, and Acquisition Directorate. 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)

E. 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**[1] 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**[2] 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

[1] Adapted from http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#unique
[2] Adapted from http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#fin

papers, plans for future research, peer review reports, communications with colleagues, or physical objects, such as gels or laboratory specimens.

- **Research Resources**[3] 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.

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 the CDMRP eReceipt System under Reference Material at https://cdmrp.org/Program_Announcements_and_Forms/.

[3] Adapted from https://grants.nih.gov/grants/intell-property_64FR72090.pdf

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 September 13, 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 November 8, 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 2 to 3 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 eReceipt System (https://cdmrp.org/Program_Announcements_and_Forms) under Regulatory Information and Forms. 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-usamrmc.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 (UPIRTSO) 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
FY16 JPC-1 MEDICAL MODELING, SIMULATION, AND TRAINING WORKING GROUP MEMBERS AND ADVISORS

CAPT Arthur Anthony	Dr. Kevin Kunkler
Mr. Wilson Ariza	Dr. Amber Linde
SGM F. Young Bowling	Dr. Joseph Lopreiato
Dr. Harry Burke	CDR (s) Kazmer Meszaros
Dr. Paul Chatelier	COL Steven Middlecamp
MSG James Dominguez	Dr. Haru Okuda
LTC Dawn Fitzhugh	Dr. Ray Perez
Col Meletios Fotinos	Ms. M. Beth Pettitt
Mr. Ruben Garza	Dr. James Petro
COL Denise Hopkins-Chadwick	LTC Kevin Snyder
COL Daniel Irizarry	LTC(P) Christopher Todd
CDR Typhanie Kinder	

Submissions that include an FY16 JPC-1 Medical Modeling, Simulation, and Training Working Group member or advisor as an investigator, consultant, collaborator, or in a key personnel role will not be considered.