BROAD AGENCY ANNOUNCEMENT

FOR EXTRAMURAL RESEARCH

(PROGRAM SPECIFIC)

for the

Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Defense Medical Research and Development Program

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

INter-professional TEam-based Learning in Early Stages of Learning (Team_INTEL)

Funding Opportunity Number: W81XWH-16-R-MSI2

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

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Proposal/Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), May 11, 2016
- **Invitation to Submit a Proposal/Application:** June 15, 2016
- **Proposal/Application Submission Deadline:** 11:59 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

This Broad Agency Announcement is one of two documents with instructions to prepare and submit a proposal/application for this funding opportunity. The second document, the Program-Specific Broad Agency Announcement General Submission Instructions, is available for downloading from Grants.gov.

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I. OVERVIEW OF THE FUNDING OPPORTUNITY

A. Administrative Overview

This Funding Opportunity Announcement is a Broad Agency Announcement (BAA) for the Fiscal Year 2017 (FY17) Joint Program Committee 1 (JPC-1)/Medical Simulation and Information Sciences (MSIS) Research Program Inter-professional Team-based Learning in Early Stages of Learning, for the remainder of the announcement this will be referenced as Team_INTEL]. This BAA must be read in conjunction with the submission guidelines in Grants.gov/Apply for Grants (hereinafter called Grants.gov/Apply). It must also be read in conjunction with the document titled "General Submission Instructions" available with this BAA in Grants.gov.

This BAA (Program Specific) is intended to solicit extramural research and development ideas and is issued under the provisions of the Competition in Contracting Act of 1984 (Public Law 98-369), as implemented in Federal Acquisition Regulation (FAR) 6.102(d)(2) and 35.016. In accordance with FAR 35.016, projects funded under this BAA must be for basic and applied research and that part of development not related to the development of a specific system or hardware procurement. Projects must be for scientific study and experimentation directed toward advancing the state-of-the-art or increasing knowledge or understanding rather than focusing on a specific system or hardware solution. Research and development funded through this BAA is intended and expected to benefit and inform both military and civilian medical practice and knowledge.

This BAA is intended for extramural investigators only. A separate FY17 JPC-1/MSIS-Team_INTEL Announcement/Funding Opportunity for intramural investigators will be available through eReceipt (https://cdmrp.org/Program_Announcements_and_Forms/).

- An ***extramural investigator*** is defined as all those not included in the definition of intramural investigators below.
- An ***intramural investigator*** is defined as a Department of Defense (DoD) military or civilian employee working within a DoD laboratory, DoD military treatment facility, or working in a DoD activity embedded within a civilian medical center. Intramural investigators are directed to apply through CDMRP eReceipt (http://cdmrp.org/).
- Submissions from intramural investigators to this BAA will be rejected. ***It is permissible, however, for an intramural investigator to be named as a collaborator in a proposal/application submitted by an extramural investigator.*** For more information, refer to the General Submissions Instructions, Section II.C.8.
- In accordance with FAR 35.017, Federally Funded Research and Development Centers (FFRDCs) are not eligible to directly receive awards under this BAA. However, teaming arrangements between FFRDCs and eligible organizations are allowed if permitted under the sponsoring agreement between the Federal Government and the specific FFRDC.

Pre-Proposals/Pre-Applications: All pre-proposals/pre-applications must be submitted through the electronic Biomedical Research Application Portal (eBRAP [https://eBRAP.org/]). A

registration process through eBRAP must be completed before a pre-proposal/pre-application can be submitted.

- A Principal Investigator (PI) and the organization's business official must register in eBRAP before submitting a pre-proposal/pre-application.
- Full proposals/applications (submitted through Grants.gov) will be available for viewing, modification, and verification in eBRAP, for a limited period.

Full Proposals/Applications: To submit a full proposal/application, the PI must have received an invitation to submit from a U.S. Army Medical Research Acquisition Activity (USAMRAA) Contracting or Grants Officer. An invited full proposal/application must be submitted electronically through Grants.gov (http://www.grants.gov/) using the SF-424 Research and Related (R&R) forms and the SF-424 (R&R) Application Guide. ***Proposals/Applications will not be accepted by mail or in person.***

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

B. General Program Overview

Proposals/applications to the FY17 JPC-1/MSIS Team_INTEL 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 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): Team_INTEL 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 Team_INTEL 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.

C. Award Information

There are existing gaps in research relating to early adoption of inter-professional team-based learning within military medical healthcare settings. The literature suggests that after training, foundation skills are required to perform a task[1]. However, individual skills (novice or expert) do not always translate to competency or proficiency. For the purposes of this announcement, a competency model refers to the deconstruction of training into skills, knowledge, and attitude and those changes in skills, knowledge, and attitude compared to one's peers. Proficiency (or a proficiency model) measures performance and the defined set of observable behaviors to what is produced and what the person must do to achieve those results.

Transitioning individual skills to team performance is a separate skill governed by expectations of what is going to happen within the team and ultimately dictated by group dynamics such as collaboration, trust, and respect between all members within the group.

For the purposes of this announcement, there are fundamentally two ways that teams could learn for training medical encounters:

- Patient risk factors versus the medical staff's individual skills (i.e., surgical, central line insertion, administration of anesthesia, diagnosis of disease/injury) and
- Patient risk factors versus the medical team assigned to the patient condition (i.e., communication, team process, safety, morale, leadership).

Within the medical community, the perception of communication is sadly misleading. A 2005 survey[2] showed that before team training, teamwork was initially perceived by the surgeon and attending surgeons as good, but anesthesiologist and operating room (OR) personnel perceived teamwork as poor. After the team training was implemented, only the surgeon's communication with the anesthesiologist improved significantly, not with the OR supporting personnel. This survey was conducted in a civilian medical environment, and, due to differences in military culture, it is unknown whether this survey or results of the survey would carry over into military medical settings.

Research has shown a connection in the cohesion of the team process when the patient is the center focus of any medical procedure (non-emergency and emergency settings)[3]. The pre-

[1] Learner, S., Magrane, D., & Freidman, E. (2009). Teaching teamwork in medical education. Mt Sinai J Med. Aug;76(4):318-29. doi: 10.1002/msj.20129

[2] Awad SS, Fagan SP, Bellow C, Albo D, Green-Rashad B, De la Garza M, and Berger DH. 2005. Bridging the communication gap in the operating room with medical team training. *American Journal of Surgery* 190(5):770-774.

[3] CAMH. (2015). Patient safety systems (ps). http://www.jointcommission.org/assets/1/18/PSC_for_Web.pdf

briefing before the procedure and the debriefing following the procedure are focused completely on patient safety and the patient outcomes. This approach results in a way forward for continuing improvement, discovering lessons learned, and process modification or correction to keep the pathway clear for lifelong learning, course correction, and ultimately an improvement in medical team processes to eliminate medical errors. Quality teams are encircled by a culture of trust and respect for all professional skillsets that builds excellence within the team during all phases of the team effort.

For the purposes of this announcement, there are two main schools of thought on team training.

- Medical Team Training (MTT)
- Medical Team-Based Learning (TBL)

The military and civilian sectors have utilized MTT in more advanced learning states in medical teams; TBL has not been integrated as well in the medical community[4]. TBL encourages the pursuance of adaptation, flexibility, and lifelong learning, all of which are essential for the medical professional to acclimate quickly in varying military medical environments. TBL has some similarities to MTT: TBL stresses understanding of roles and situation awareness beforehand; in other words, never assume everyone is automatically on the same page. It is very important the leadership role be identified, structure explained, goals understood, expectations of the upcoming encounter discussed, and, finally, Question & Answer discussions be incorporated in a "no fear" environment. After the medical procedure is conducted, it is followed by a debriefing. This step is not omitted and is extremely important as it promotes lessons learned and process improvements. The results are reflected in a decrease in errors and close calls, and a decrease in patient morbidity and mortality rates.

The FY17 JPC-1/MSIS Team_INTEL is seeking research to determine, define, and validate learning strategies that foster inter-professional team-based learning during the early stages i.e. when teams are forming and groups are becoming familiar with each other and are starting to implement their roles and responsibilities of medical skills training in order to eliminate the current culture of focusing on the individual's medical skills and leaving team training practice at a later date during "on the job training."

- It is expected that award recipients will use statistical approaches to determine the best metrics and evaluation criteria that will objectively assess a foundation on team-based learning training practice guideline(s);
- It is expected that award recipients will provide definitions to the metrics and evaluation criteria that will be objectively or subjectively collected, and provide the respective measurement tools (either currently commercially available or to be developed via this anticipated award mechanism);
- It is expected that award recipients will utilize inter-professional teams from different clinical practice skillsets (i.e., novice through experts; different areas of military services);

[4] Joo, P.A. (2013). Team-based learning: the quest for better ways to teach and learn. The Doctor's Tablet. Albert Einstein College of Medicine.

- It is encouraged that the validation of member team skills are not based solely on student learners, as team leaders are typically more advanced learners of a higher rank and need to be included to measure true effectiveness of the team effectiveness training program;
- It is expected that award recipients will include a model of training that should be able to be used across the services, throughout the continuum of care, and in various military team-based environments from Roles 1-4[5];
- It is expected that the Team_INTEL should be adaptive to teaching not only student learners new to a TBL environment but include those who have been in team environments and can influence and alter unproductive team behavior practices;
- It is anticipated that the outcomes of the research will result in a model that is implemented into data/knowledge systems and tested in a lab-type environment. Actual interfaces will need to be described and defined in the outcome;
- It is anticipated that many of these variables, metrics, and evaluation criteria will be employed across the military, Veterans Health Administration, academic, inpatient, outpatient clinics, rural healthcare settings, private and public hospitals, and international healthcare situations;
- It is anticipated that research outcomes, analysis, methodologies, and conclusions will be disseminated and propagated to the military and the Government, but also to the public at large. Public benefits from this research are encouraged.

Training Guidelines or Curriculum

It is anticipated, but not required, that an establishment of training guidelines or curriculum will incorporate pre-briefing, the simulated procedure (scenario), and debriefing parameters in addition to the above bulleted items. The scenario may be at the discretion of the organization and team, but consideration that such scenarios should transition to military healthcare teams is vital. The training strategy should not end with the debriefing but should provide the advancements of lessons learned from team discussions, e.g., reports sent and received by upper-level administration, to allow for system improvements that will encourage instillation of culture within the team and future combination of teams.

Pilot Study

A pilot study lasting a minimum of six (6) months to collect data for confirmation of proposed variables, metrics, and evaluation criteria is required.

Proposals/Applications should include proposed methodologies, conceptual and operational definitions, type and number of subjects, recruitment numbers, anticipated dropout rate, assessment criteria, generalizability, validity, reliability, intended medical domain(s) (or discipline(s)), control groups, and statistical protocols. These are just a few of the anticipated

[5]Roles of Medical Care (United States)
http://www.cs.amedd.army.mil/borden/FileDownloadpublic.aspx?docid=1a73495d-1176-4638-9011-9e7f3c6017d8

items for incorporation in the full application. Examples of subjects (from novices to experts) that may be considered but are not limited can include: combat medics, corpsmen, para-rescuers, emergency medical technicians, other technicians (such as radiology technicians, etc.), licensed physicians, licensed nurses, physician assistants, residents, and fellows. Student learners may be included but they should not be allowed to serve as team leaders.

Intellectual Property

While the proposed research may include proprietary tools, appropriate justification for incorporating proprietary tools must be included. Proprietary intellectual property components should be clearly and legibly marked in the full application. The proposed research outcomes are intended to have broad availability not only with the content but also with underlying architecture or models to allow more open communication.

JPC-1/MSIS Long-Term Vision

The anticipated long-term vision includes but is not limited to:

(1) Incorporation of proposed metrics / evaluation criteria and their respective definitions into future announcements with the intent of commercial simulation systems integration and implementation. 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.

(2) Possibility of developing foundation training practice guidelines or a curriculum that will be assimilated in team-based learning military medical personnel training education; and

(3) Coupling multitudes of well-constructed (from a learning and reliability perspective) appropriate fidelity simulation systems that will yield an assessment tool able to compare training results from Team_INTEL versus evidence-based outcomes that did not train with other early learning practices (such as TBL) relative to patient safety and patient outcomes.

Results of Team_INTEL research should demonstrate an increased level of learner confidence and competence to work effectively within an inter-professional team-based environment. Such ability to competently function within a team will significantly advance a novice's training closer to the level of an experienced provider and will allow the experienced team member to be able to share knowledge and experience with the team while aiming toward the common goal of a patient-based center of focus. It is expected that outcomes of this research will better prepare the military in team-based learning, better understanding of combination of personnel (combination of novice, competent, proficient, and expert) in preparation of teams prior to deployment; create a standard of working in an inter-professional medical team environment; and encourage lifelong learning through tools such as after-action debriefings that should serve as mechanisms to correct faulty processes that undermine team effectiveness and decrease patient safety.

Anticipate Outcomes

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

- A validated list of means of support by contacts, references, and sources that endorse the proposed methodologies that underpin the determination of the anticipated variables, metrics, and evaluation criteria for early inter-professional TBL;
- A report, document, or list of the terminology and respective definitions used for the variables, metrics, and evaluation criteria and how they were deconstructed. Must provide the measuring tools and, if needed, how they were used to obtain the metric / evaluation criteria. Objective measurements are preferred, but subjective measurements that have rigorous reliability, repeatability, and robustness will be considered;
- Explanation, including definitions and descriptions, of early inter-professional team-based learning determinates of task performance to better understand how to assess a team'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 should include objective measurements that determine the utility of the model and how the utilization of early inter-professional team-based learning pertain to a team's performance capabilities for specific tasks and in difficult scenarios, environment, and stressful situations;
- A report or document with the information and analyzed data of the actual postulated variables, metrics, and evaluation criteria that best fit the meaning of transitioning from training to practicing medicine in various inter-professional team settings;
- Analyzed pilot study data / information and the specific aims, methodologies, sample and sample size, inter-rater reliability, assessment criteria, analyzed results, conclusions, and potential next-step recommendations;
- Completion of preliminary / pilot empirical evaluation of the developed proof-of-concept task performance assessment model that incorporates early inter-professional team-based learning strategies as components and assesses an individual's assimilation in future team-based performance environments;
- A report or list of the components that are proprietary and ones that are Open Source / Open Architecture. Licensing rights need to be provided;
- Description of the components of the prototype that are proprietary and ones that are Open Source / Open Architecture. Explain Government rights and / or proposed pricing structure to the Government;
- Documentation of the pre-briefing, the simulated procedure (scenario), and debriefing parameters and the respective definitions (if applicable);
- A strategy plan for applying Team_INTEL training practice guidelines or curriculum across the Services;

- Provide a suggested list of Terminal Learning Objectives for possible inclusion in instructor military medical training courses. These potential courses could be used as early introductions in inter-professional team-based learning in military medicine to minimize the current culture of "on the job learning";

- Description of the gaps that were uncovered during this research into early inter-professional team-based learning as it pertains to the success or failure of team performance and provide anticipated next steps or recommendations to create an improved task performance assessment model that assesses inter-professional team performance and predicts future task performance for various tasks and environments;
- (Optional) The prototype system that was developed including a set of instructions that are needed for the prototype.

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.

D. Eligibility Information

- Independent extramural investigators at all academic levels (or equivalent) are eligible to submit proposals/applications.
- Cost sharing/matching is not an eligibility requirement.
- Eligible extramural investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations.
- Intramural investigators are directed to apply through CDMRP eReceipt at https://cdmrp.org/Program_Announcements_and_Forms/.
- Refer to the General Submission Instructions, Appendix 1, for general eligibility information.

Recipient Qualification: In addition to other information provided herein, by submitting a proposal/application and accepting an award, the organization is: (1) certifying that the investigators' credentials have been examined; and (2) verifying that the investigators are qualified to conduct the proposed study and to use humans or animals as research subjects, if proposed. Investigators include all individuals, regardless of ethnicity, nationality, or citizenship status, who are employed by, or affiliated with, an eligible organization.

Investigators are cautioned that awards are made to organizations, not individuals. A PI must submit a proposal/application through an organization in order to receive support. ***NOTE:*** In accordance with FAR 35.017, Federally Funded Research and Development Centers (FFRDCs) are not eligible to directly receive awards under this BAA. However, teaming arrangements between FFRDCs and eligible organizations are allowed so long as they are permitted under the sponsoring agreement between the Federal government and the specific FFRDC.

The USAMRMC is committed to supporting small businesses. Small business, Veteran-owned small business, service-disabled Veteran-owned small business, HUBZone small business, small disadvantaged business, and woman-owned small business concerns must be given the maximum practical opportunity to participate through subawards on research proposals/applications submitted through the BAA.

E. Funding

The JPC-1/MSIS expects to allot approximately $2.4 million (M) of the anticipated FY17 DHP RDT&E appropriation to fund two JPC-1/MSIS-Team INTEL proposal/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 Broad Agency Announcement/Funding Opportunity is contingent upon the availability of federal funds for this program. As of the release date of this Program Announcement/Funding Opportunity, the FY17 Defense Appropriations Bill has not been passed and there is no guarantee that any 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 Team INTEL 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, which includes the six (6) month pilot study.
- The anticipated **total** costs (direct and indirect) budgeted for the entire period of performance will not exceed **$1.2M**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **$1.2M** total costs or using an indirect rate exceeding the organization's negotiated rate.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- Option periods may be used on contracts.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **2** years.

Refer to the General Submission Instructions, Section II.D.5., for budget regulations and instructions for the Research & Related Budget. **For all Federal agencies or organizations**

collaborating with Federal agencies, budget restrictions apply as are noted in Section II.D.5.of the General Submission Instructions.

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

- Travel costs for the PI(s) to attend an In-Progress Review (IPR) meeting anticipated to be held near the end of 1-year anniversary of the award at a Government location (to be determined). For planning purposes, it should be assumed that a 2-day IPR meeting will be held in the National Capital Area/Maryland/Northern Virginia area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary
- Research-related subject costs
- Support for multidisciplinary collaborations
- Equipment
- Research supplies
- Travel between collaborating institutions, including travel to military/Government facilities
- Travel costs to attend scientific/technical meetings in addition to the required IPR meeting described above

Subawards to intramural agencies and other Federal agencies may be executed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR] or Funding Authorization Document [FAD] process). Direct transfer of funds from the recipient to a Federal agency is not allowed except under very limited circumstances. Refer to the General Submission Instructions, Section II.C.5. Research & Related Budget, for additional information on budget considerations for proposals/applications involving Federal agencies.

F. Mechanisms of Support

The DHP executes its extramural research program primarily through the award of contracts and assistance agreements (grants and cooperative agreements). The type of instrument used to reflect the business relationship between the organization and the Government is at the discretion of the Government based on the Statement of Work submitted in the proposal/application.

The USAMRAA will negotiate the award types for proposals/applications selected for funding. The Federal Grant and Cooperative Agreement Act of 1977, 31 USC[6] 6301-6308, provides the legal criteria to select a procurement contract or an assistance agreement. Refer to the General Submission Instructions, Appendix 3, for additional information.

Any assistance agreement (grant or cooperative agreement) awarded under this BAA will be governed by the award terms and conditions that conform to the DoD's implementation of Office

[6] United States Code

of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of awards made after December 26, 2014, may include revisions to reflect DoD implementation of new OMB guidance in 2 CFR part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards."

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

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

G. Other Review Information

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

1. ***"Exclusions" Identified in System for Award Management (SAM):*** To protect the public interest, the Federal Government ensures the integrity of Federal programs by striving to conduct business only with responsible organizations. The USAMRAA uses the "Exclusions" within the Performance Information functional area of the SAM; data from the Federal Awardee Performance and Integrity Information System, a component within SAM, is used to verify that an organization is eligible to receive Federal awards. More information about the "Exclusions" reported in SAM is available at https://www.sam.gov/. Refer to the General Submission Instructions, Section II.A.2., for additional information.

2. ***Conflicts of Interest: All awards must be free of Conflicts of Interest (COIs) that could bias the research results. Prior to award of an assistance agreement or contract, applicants will be required to disclose all potential or actual COIs along with a plan to manage them. An award may not be made if it is determined by the Grants Officer or Contracting Officer that a COI cannot be adequately managed.*** Refer to the General Submission Instructions, Appendix 1, for additional information.

3. ***Review of Risk:*** The following areas may be reviewed in evaluating the risk posed by the applicant: Financial stability; quality of management systems and operational controls; history of performance; reports and findings from audits; ability to effectively implement statutory, regulatory, or other requirements imposed on non-Federal entities; degree of institutional support; integrity; adequacy of facilities; and conformance with safety and environmental statutes and regulations.

4. ***Subcontracting Plan:*** If the resultant award is a contract that exceeds $650,000 and the offeror is other than a small business, the contractor will be required to submit a subcontracting plan for small business disadvantaged business concerns, in accordance with FAR 19.7. A mutually agreeable plan will be incorporated as part of the resultant contract.

II. SUBMISSION INFORMATION

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

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

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

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

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

A. Where to Obtain the Submission Package

To obtain the complete Grants.gov proposal/application package (hereinafter, submission package), including all required forms, perform a basic search using the Funding Opportunity Number **W81XWH-16-R-MSI2** in Grants.gov (http://www.grants.gov/)

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

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

PIs and organizations identified in the pre-proposal/pre-application should be the same as those intended for the subsequent proposal/application submission. If any changes are necessary after submission of the pre-proposal/pre-application, the PI must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507. A change in PI or organization after submission of the pre-proposal/pre-application will be allowed only at the discretion of the USAMRAA Contracting or Grants Officer.

The organization, Business Official, and PI must register in eBRAP before submitting a pre-proposal/pre-application. Upon completion of an organization's registration in eBRAP and approval by the CDMRP Help Desk, the organization name will be displayed in eBRAP to assist the organization's Business Officials and PIs as they register. The organization, Business Officials, and PIs must all be registered and affiliated in eBRAP. (See *eBRAP User Guide* at https://ebrap.org/eBRAP/public/UserGuide.pdf.)

Pre-proposals/pre-applications must be submitted by the deadline specified on the title page of this BAA. ***Proprietary information should not be included in the pre-proposal/pre-application.***

The pre-proposal/pre-application consists of the following components, which are organized in eBRAP by separate tabs. Refer to the General Submission Instructions, Section II.B., for additional information on pre-proposal/pre-application submission.

- **Application Information – Tab 1:** Enter the information as described in eBRAP before continuing the pre-proposal/pre-application.
- **Application Contacts – Tab 2:** Enter contact information for the PI and the organization's Business Official responsible for sponsored program administration (or equivalent). This is the individual listed as "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 named or invited in order for the pre-proposal/pre-application to be submitted. If the organization's Business Official is not in eBRAP, an invitation to the Business Official to register in eBRAP must be sent. In addition, it is recommended that the PI identify an Alternate Submitter in the event that assistance with pre-proposal/pre-application submission is needed.

  NOTE: The eBRAP system does not require an approval of the pre-proposal/ pre-application by the PI's organization.
- **Collaborators and Key Personnel – Tab 3:**
  - Enter the name, organization, and role of all collaborators and key personnel 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.
- FY16 JPC-1 Medical Modeling, Simulation, and Training Steering Committee members should not be involved in any pre-proposal/pre-application or proposal/application including, but not limited to, concept design, proposal/application development, budget preparation, and the development of any supporting documentation. For questions related to JPC-1 MSIS Steering Committee members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP at help@eBRAP.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 identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (http://cdmrp.army.mil/about/2tierRevProcess.shtml). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage Conflicts of Interest (COIs) are provided and deemed appropriate by the Government. Refer to General Submission Instructions, Appendix 1, for detailed information.

- **Conflicts of Interest – Tab 4:**
  - List all individuals other than collaborators and key personnel who may have a COI in the review of the proposal/application (including those with whom the PI has a personal or professional relationship). Refer to Appendix 1, Section C, of the General Submission Instructions for further information regarding COIs.
- **Pre-Application Files - Tab 5:**

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

  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 is derived to create and produce inter-professional early team based determinant components to assess a team's overall performance.
  - **Background/Rationale:** Clearly present the ideas and reasoning behind the proposed research. Include relevant literature citations, preliminary and/or pilot data, and/or other evidence that led to the development of the proposed research. Any preliminary data should be from the laboratory of the PI or member(s) of the collaborating team.
  - **Hypothesis/Objective and Specific Aims:** State the proposed project's hypothesis and/or objectives and the specific aims/tasks of the proposed research.
  - **Approach/Methodology:** Describe the research approach. Include research design, methods, and analysis/evaluation strategies as well as materials anticipated to be used during the research. Provide a list of methods planned to be used in the study that will provide the data/information needed to answer research questions or successfully complete aims of study. 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 using a theoretical construct as to how the proposed research is relevant to the goal of developing a proof of concept task of early inter-professional team-based learning performance module that incorporates determinant components to assess a team's performance.
  - **Innovation:** Explain how the proposed project is innovative and not an incremental advancement of previous work and has the potential to improve current practices and patient outcomes and decrease medical errors.
- **Proposed Study Design/Plan:** Describe the pilot study concept to demonstrate effectiveness and efficiency of the proof of concept or early inter-professional team based learning as determinant components to assess a team's performance. 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 approaches. Provide an evaluation strategy how the methodology can be adapted and improved upon during the development of criteria and explain how it can be adopted in various medical point of care environments (Roles 1-4). Refer to Section I.B., General Program Overview, for additional information on the research areas of interest for this BAA.

- **Military Impact:** Describe the anticipated short- and/or long-term outcomes of the proposed project and their potential impact on improving healthcare training, building medical teams that complement but not undermine military culture, and improve patient well-being while decreasing medical morbidity and mortality in the military healthcare system. Explain what the potential of this proposed work will have to improve current practices and patient outcomes and decrease medical errors. Refer to Section I.B., General Program Overview, for additional information on the anticipated outcomes sought by this BAA.
- **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 adaptation 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). Please include military and civilian research in your review of the literature.
- **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-Proposal/Pre-Application Screening

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

  All pre-proposals/pre-applications will be screened by the JPC-1 Medical Modeling, Simulation, and Training 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 is derived to create and produce a proof of concept early inter-professional team based learning curriculum that incorporates determinant components to assess a team's performance.
  - **Significance, Relevance, and Innovation:** To what degree the proposed research is relevant, and innovative, including whether the proposed research is duplicative of existing research or is a TBL-validated curriculum that will be researched and measured under this specified research context.
  - **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 compensatory/adaptive inter-professional medical team teaching guidelines or curriculum.
  - **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 models will justify and support the intended outcomes of the proposed research and show results are reproducible in a variety of early learning settings. To what degree the evaluation strategy of how the methodology can be adapted and improved upon during the development of criteria and how it can be adopted in various medical point of care environments (role 1-4).
  - **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 BAA.

C. Full Proposal/Application Submission Content and Forms

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

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

Each proposal/application submission must include the completed submissions package of forms and attachments provided in Grants.gov for this BAA. The submissions package is submitted by the Authorized Organizational Representative through the Grants.gov portal (http://www.grants.gov/). Refer to the General Submission Instructions, Section II, for submission information.

After proposal/application submission to Grants.gov, eBRAP will retrieve and validate the submission. eBRAP will notify the organizational representatives and PI via email and instruct them to log into eBRAP to review, modify, and verify the proposal/application. During this verification period, the PI may upload missing files (excluding those listed in Section IV.A., Rejection), replace files, and re-categorize files. These modifications must be completed by the end of the verification period.

Note: The Project Narrative and Budget Form cannot be changed after the proposal/application submission deadline. If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or Budget Form needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID ***prior to the application submission deadline***.

Proprietary information should ***be included*** in the full proposal/application ***only if necessary for evaluation purposes***. Conspicuously and legibly mark any proprietary information that is included in the proposal/application.

Grants.gov Application Package Components: For the **FY-17 JPC-1/MSIS Team_INTEL** BAA **(W81XWH-16-R-MSI2)**, the Grants.gov application package includes the following components (refer to the General Submission Instructions, Section II.C., for additional information on proposal/application submission):

1. **SF-424 (R&R) Application for Federal Assistance Form:** Refer to the General Submission Instructions, Section II.C., for detailed information.

2. **Attachments Form**

   Each attachment to the Grants.gov application forms must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in Appendix 2 of the General Submission Instructions. For all attachments, ensure that the file names are

consistent with the guidance. Grants.gov will reject attachments with file names longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire Grants.gov application package may not exceed 200 MB.

- **Attachment 1: Project Narrative (20-page limit): Upload as "ProjectNarrative.pdf."** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and will result in administrative withdrawal of the proposal/application.

  Describe the proposed project in detail using the outline below.

  - **Background:** Present theoretical framework behind the proposed research; include relevant literature citations or preliminary data on the proposed methodologies. Additionally, present the ideas, reasoning, justification, and stakeholder needs that will influence the study design how this can be used to research and/or develop an early inter-professional based team learning guidelines or curriculum. 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.
  - **Hypotheses/Objectives:** State the hypotheses or research/evaluation questions and overall objective(s) to be reached.
  - **Specific Aims:** Concisely explain the project's specific aims to include expected timeframe of each aim. If this proposal/ application is part of a larger study, present only tasks this award would fund.
  - **Project Design:** Describe and define the experimental design, methods, and analyses/ evaluations in sufficient detail for analysis.
    - Identify and describe the hypothesis or research question(s) to be studied and the projected outcome(s) of the proposed research.
    - Provide an evaluation protocol how the methodology can be adapted and improved upon during the development of criteria and explain how it can be adopted in various medical point of care environments (Roles 1-4).
    - 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 defined statistical models.
    - Clearly support the choice of study variables and explain the basis for the research questions and/or study hypotheses. Establish the relevance of the

study and explain the applicability of the proposed findings and how it knowledge will be disseminate.

- Define the study variables (independent/dependent) and define 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 and outcome dissemination.
- 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. Describe end user context need and how feedback will allow device/technology to be intuitive to the end user. Discuss the perceived engineering/design strengths and flaws and recommendations for overcoming/preventing them.
- Address all potential barriers and provide plans for addressing potential delays, and unexpected events. Provide a risk management plan to address barriers to plans. As relevant, describe plans for addressing potential 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, proposals/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 the General Submission Instructions, Appendix 5, for additional regulatory information.

- **Attachment 2: Supporting Documentation: Start each document on a new page. Combine and upload as a single file named "Support.pdf."** If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no page limits for any of these components unless otherwise noted. Include only those components described below; items not requested will be removed and may result in administrative withdrawal of the proposal/application.***

○ **Bibliography and References Cited:** List the references in the order they appear in the Project Narrative. Use a reference format that gives the title of the citation. Do not send or attach copies of articles in print. There is no form for this information. 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 a copy/copies of the published manuscript(s) must be attached.

○ **Letters of Organizational Support:** Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. A letter for each organization involved in the project should be provided.

- **Letters of Collaboration:** Provide letter(s) supporting stated collaborative efforts necessary for the project's success, even if provided at no cost. ***If the project involves collaboration with a Military Facility (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 collaborating DoD researcher must obtain a letter from his/her commanding officer or Military Facility director authorizing his/her participation in the research project. This letter must be included with the proposal/application. (Refer to the General Submission Instructions, Section II.C.8., for additional information.)
- **Joint Sponsorship (if applicable):** Describe present or prospective joint sponsorship of any portion of the program outlined in the proposal/application. In the absence of agreements among sponsors for joint support, the proposal/application should be structured so that the research can be carried out without the resources of any other sponsor. If, however, it is desirable to request partial support from another agency, the proposed plan should be stated and the reasons documented. If the plan cannot be formulated at the time the proposal/application is submitted, information should be sent later as an addendum to the proposal/application. Prior approval from both agencies must be secured for research to be undertaken under joint sponsorship. Provide letters of support related to recruitment, subject access, and data access plans.
- **Intellectual Property**: Refer to the General Submission Instructions, Appendix 3, for additional information. Provide the following:
  - Should the applicant intend to use, in the performance of this program, pre-existing, legally protected and perfected intangible property and for which no Federal funds had been used in the development of said property, the applicant must:
    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.
- **Data and Research Resources Sharing Plan**: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to the General Submission Instructions,

Appendix 3, Section J, for more information about the CDMRP expectations for making data and research resources publicly available.

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

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

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf**."

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

  Lay abstracts should be written using the following outline.

  - 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.
  - Do not duplicate the technical abstract.
  - 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.

- **Attachment 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.

  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's regulatory review and approval processes for studies involving human subjects and 2 to 3 months for studies involving animal subjects.

- **Attachment 6: Outcomes and Impact Statement (one-page limit): Upload as "Impact.pdf."** Explain in detail why the proposed research project is important, as follows:
  - ***Short-Term Impact:*** Describe the anticipated outcome(s)/results(s)/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 transforming the standard of 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 injured Service members and either allows them to return to duty or resume a fully active lifestyle.
  - ***Public Purpose:*** If appropriate, provide a concise, detailed description on how this project will benefit the general public.

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

- **Attachment 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.***

- **Attachment 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.

- **Attachment 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.

- **Attachment 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.

Questions related to this topic should be directed to the CDMRP Help Desk at help@eBRAP.org or 301-682-5507. Refer to the General Submission Instructions, Appendix 1, for additional information.

- **Attachment 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. Refer to the General Submission Instructions, Section II.C.8., for detailed information.

3. **Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Submission Instructions, Section II.C.4., for detailed information.
   - PI Biographical Sketch (five-page limit): Upload as "Biosketch_LastName.pdf." The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The five-page National Institutes of Health Biographical Sketch may also be used.
   - PI Previous/Current/Pending Support (three-page limit page limit): Upload as "Support_LastName.pdf."
   - Key Personnel Biographical Sketches (five-page limit each): Upload as "Biosketch_LastName.pdf."
   - Key Personnel Previous/Current/Pending Support (three -page limit each): Upload as "Support_LastName.pdf."

4. **Research & Related Budget:** Refer to the General Submission Instructions, Section II.C.5., for detailed information.
   - Budget Justification (no page limit): Upload as "BudgetJustification.pdf." The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.

   NOTE: For all Federal agencies or organizations collaborating with Military Facilities, special restrictions apply to the budget and are described below.

   - **For Federal Agencies:** Proposals/Applications from **Federal agencies** must include in their budget justifications a **Federal Financial Plan (Plan)**. The Plan must address how all funds will be obligated before their period for obligation expires, and how funds will be available to cover research costs over the entire award period. The Plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years.
   - **For Collaborating Military Facilities:** Proposals/Applications from organizations that include **collaborations with DoD Military Facilities** (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD

activity embedded with a civilian medical center) must submit Collaborating DoD Military Facility Budget Form(s) as instructed in Attachment 13.

5. **Project/Performance Site Location(s) Form:** Refer to the General Submission Instructions, Section II.C.6., for detailed information.

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

D. Applicant Verification of Grants.gov Proposal/Application in eBRAP

Prior to the end of the proposal/application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of a proposal/application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific BAA requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all proposal/application components and ensure proper ordering as specified in the BAA. ***If either the Project Narrative or the budget fails eBRAP validation, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID prior to the proposal/application submission deadline.*** The Project Narrative and Budget Form cannot be changed after the proposal/application submission deadline.

Refer to the General Submission Instructions, Section II.A.2., for additional information.

E. Data Universal Number System Numbers, Commercial and Government Entity Code, and System for Award Management

All proposals/applications must be submitted through Grants.gov. An applicant organization and any subaward organization must have Data Universal Number System (DUNS) numbers (issued by Dun and Bradstreet) before submitting a proposal/application to Grants.gov. In addition, an applicant organization must have a CAGE (Commercial and Government Entity) Code. Also, the organization must be registered as an Entity with the SAM and have an "Active" status before submitting a proposal/application through Grants.gov or receiving an award from the Federal Government.

F. Submission Dates and Times

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

G. Intergovernmental Review

This BAA is not subject to Executive Order (EO) 12372.

H. Funding Restrictions

Refer to the General Submission Instructions, Section II.D.5, "Research & Related Budget," for discussion of allowable costs, including pre-award costs and collaborations with Military Facilities.

I. Other Submission Requirements

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

III. PROPOSAL/APPLICATION REVIEW AND SELECTION INFORMATION

A. Proposal/Application Review and Selection Process

All proposals/applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is a peer review of proposals/applications against established criteria for determining technical merit. The second tier is a programmatic review that makes recommendations for funding to the DHA 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 proposals/applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier process used by the CDMRP can be found at http://cdmrp.army.mil/about/fundingprocess.shtml.

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

B. Peer and Programmatic Review

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

- 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 is derived to create and produce effective metrics and evaluation criteria that will objectively assess a foundation simulated inter-professional team-based learning training practice guidelines or curriculum that will make Team_INTEL an intuitive and normal practice in military team-based point of care.
- How well the study aims, hypotheses or objectives, experimental design, methods, and analyses are designed to clearly answer the research questions.
- How well the proposal addresses the incorporation early team-based learning as determinant components to assess a team's performance.
- 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.
- How well the proposal includes an establishment of training guidelines or curriculum that incorporates pre-briefing, the simulated procedure, and debriefing parameters and how it could be used across the services in various military team-based environments from Roles 1-4[7].
- How well the proposal is adaptive to teach not only student learners new in a TBL environment, but includes those who have previous experience in inter-professional team environments where the training can influence and alter unproductive current individual behavior practices within teams.
- 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 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 early inter-professional team-based learning determinant components and how the proposed work has the potential to improve a team's performance.
  - How the proposed work is innovative, including whether the proposed research is duplicative of existing research.

[7] Roles of Medical Care (United States)
http://www.cs.amedd.army.mil/borden/FileDownloadpublic.aspx?docid=1a73495d-1176-4638-9011-9e7f3c6017d8

- To what degree the proposed research is relevant to the goal of delivering an early inter-professional team-based training guidelines or curriculum.
- To what degree the anticipated short- and long-term outcomes resulting from the proposed study will contribute to the goal of improving military medical team training, 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 proposal/application:

- **Budget**
  - Whether the budget is appropriate for the proposed intervention outlined in the proposal and product development and within the limitations of this BAA.
  - Whether the proposed timeline is appropriate and tasks outlined in the proposal/application are logical in their progression.
- **Intellectual Property and Transition Plan**
  - If applicable, to what degree the intellectual property plan is appropriate.
  - If applicable, to what degree the transition plan is appropriate.
- **Proposal/Application Presentation:**
  - To what extent the writing, clarity, and presentation of the proposal/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

   - To what degree the proposed work and research is derived to create and produce effective metrics and evaluation criteria that will objectively assess a foundation simulated inter-professional team-based learning training practice guidelines or curriculum that will make Team_INTEL an intuitive and normal practice in military team-based point of care.

   b. Open Source/License/Architecture

   - Identify within the proposal the 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 Submission Review Dates

All submission review dates and times are indicated on the title page of this BAA.

D. Notification of Submission Review Results

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

IV. ADMINISTRATIVE ACTIONS

After receipt of proposals/applications from Grants.gov, the following administrative actions may occur:

A. Rejection

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

- The pre-proposal/pre-application is submitted by an intramural organization or FFRDC.

- Pre-Proposal/Pre-Application Narrative exceeds page limit.
- Pre-Proposal/Pre-Application Narrative is missing.

The following will result in administrative rejection of the proposal/application:

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

B. Modification

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

C. Withdrawal

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

- An FY16 JPC-1 Medical Modeling, Simulation, and Training Steering Committee member is named as being involved in the research proposed or is found to have assisted in the pre-proposal/pre-application or proposal/application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation.
- The proposal/application fails to conform to this BAA description to the extent that appropriate review cannot be conducted.
- Inclusion of any employee of CDMRP review contractors in pre-proposals/ pre-applications or full proposals/applications for funding without adequate plans to resolve conflicts of interest. Refer to General Submission Instructions, Appendix 1, for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The full proposal/application does not propose the same research project as described in the pre-proposal/pre-application.
- The proposal/application budget differs significantly from the budget included in the pre-proposal/pre-application.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.

D. Withhold

Proposals/Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization will be required to provide the findings of the investigation to the USAMRAA Contracting or Grants Officer for a determination of the final disposition of the proposal/application.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

The awarding agency will be the USAMRAA. The USAMRAA Contracting and Grants Officers are the only individuals authorized to obligate funds and bind the Federal Government. Authorization to begin performance will be received via an award document (contract, grant, or cooperative agreement, as applicable) signed by the USAMRAA Contracting or Grants Officer. No commitment on the part of the Government should be inferred from discussions with any other individual.

A recommended for funding notification is NOT an authorization to begin performance or a guarantee of an award. Contingent upon funding availability, awards will be made no later than **September 30, 2018**. Refer to the General Submission Instructions, Appendix 3, for additional information.

B. Administrative Requirements

Refer to the General Submission Instructions, Appendix 3 for general information regarding administrative requirements.

C. National Policy Requirements

Refer to the General Submission Instructions, Appendix 4 for general information regarding national policy requirements.

D. Reporting Requirements

Refer to the General Submission Instructions, Appendix 3, for general information on reporting requirements.

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

- Contractor Manpower Reporting (CMR)
    - CMR is now a requirement of all DoD contracts. Offerors are allowed to include a nominal fee in their cost/price proposal for providing these data. A “nominal fee” is defined as a computation of an administrative assistant equivalent labor category providing approximately 6-8 hours to complete data input. Offerors may opt to not

separately price this required annual data input. CMR costs/price will not be evaluated as part of the total evaluated proposal cost/price.

- The contractor shall report ALL contractor labor hours (including subcontractor labor hours) required for performance of services provided under each contract via a secure data collection site. The contractor is required to completely fill in all required data fields using the following web address: http://www.ecmra.mil/.
- Reporting inputs will be for the labor executed during the period of performance during each Government fiscal year (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 2016. Contractors may direct questions to the help desk at: contractormanpower@hqda.army.mil or via phone at 703-377-6199.

E. Changes of Principal Investigator and Organization

Refer to the General Submission Instructions, Appendix 3, for general information on changes to PIs and organizational transfers.

VI. AGENCY CONTACTS

A. CDMRP Help Desk

Questions related to BAA content or submission requirements as well as questions related to the submission of the pre-proposal/pre-application through eBRAP should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. Eastern Time. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@eBRAP.org

B. Grants.gov Contact Center

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

Phone: 800-518-4726; (international) 1-606-545-5035

Email: support@grants.gov

Sign up on Grants.gov for "send me change notification emails" by following the link on the Synopsis page for the BAA or by responding to the prompt provided by Grants.gov when first downloading the application package. If the application package is updated or changed, the original version of the application package may not be accepted by Grants.gov.

C. Common Submission Problems

- Failure to enter an email address for change notifications under the BAA Funding Opportunity Announcement in Grants.gov for notifications on any modification made to the initial posting.
- Attachments are uploaded into the incorrect form on Grants.gov forms. (See Section VII., Proposal/Application Submission Checklist.)
- Failure to contact the Grants.gov Help Desk when needed.
- Failure to send attachments.
- Inability to locate attachment forms. (Select "Search Grants" at http://www.grants.gov and enter **W81XWH-16-R-MSI2** in the "Funding Opp #" block. When the Funding Opportunity appears, select the Funding Opportunity #. When you reach the "View Grant Opportunity" screen, select "Full Announcement." The forms will be listed on the following screen.)
- Use of "illegal" characters (i.e., characters not available on a standard QWERTY keyboard, e.g., Greek letters) in attachment titles.
- Attachments exceed size limits.
- Upload attempts of unacceptable attachments: bitmap, TIFF, etc.
- Duplicate upload of documents.

VII. PROPOSAL/APPLICATION SUBMISSION CHECKLIST

Grants.gov Submission Package Components	Upload Order	Action	Completed
SF-424 (R&R) Application for Federal Assistance		Complete as instructed.	
Attachments Form	1	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	2	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	3	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	4	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	5	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	6	Outcomes and Impact Statement: Upload as Attachment 6 with file name "Impact.pdf."	
	7	Innovation Statement: Upload as Attachment 7 with file name "Innovation.pdf."	
	8	Human Subject Recruitment and Safety Procedures: Upload as Attachment 8 with file name "HumSubProc.pdf."	
	9	Data Management: Upload as Attachment 9 with the file name "DataManage.pdf."	
	10	Post-Award Project Transition Plan: Upload as Attachment 10 with the file name "Transition.pdf."	
	11	Conflicts of Interest: Upload as Attachment 11 with file name "COI.pdf," if applicable.	
	12	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 12 with the file name "MFBudget.pdf," if applicable.	
Research & Related Senior/Key Person Profile (Expanded)		Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
		Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
		Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
		Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.	

Grants.gov Submission Package Components	Upload Order	Action	Completed
Research & Related Budget		Attach Budget Justification (BudgetJustification.pdf) to the appropriate field. Complete form as instructed.	
Project/Performance Site Location(s) Form		Complete form as instructed.	
R&R Subaward Budget Attachment(s) Form (if applicable)		Complete form as instructed.	

VIII. FY16 JPC-1 MEDICAL MODELING, SIMULATION, AND TRAINING STEERING COMMITTEE MEMBERS AND ADVISORS

CAPT Arthur Anthony	Dr. Amber Linde
Mr. Wilson Ariza	Dr. Joseph Lopreiato
SGM F. Young Bowling	CDR (s) Kazmer Meszaros
Dr. Harry Burke	COL Steven Middlecamp
Dr. Paul Chatelier	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	Col Daniel Shoor
COL Daniel Irizarry	LTC Kevin Snyder
CDR Typhanie Kinder	LTC(P) Christopher Todd
Dr. Kevin Kunkler	

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