

**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/
Medical Simulation and Information Sciences Research Program**

**Health Information Technologies and Informatics
Theater/Operational Medicine Initiative (TOMI)**

Funding Opportunity Number: W81XWH-16-R-MSI3

**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 an Application:** June 15, 2016
- **Full 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
- **Scientific 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 Years 2016-2017 (FY16-FY17) Joint Program Committee-1 (JPC-1)/Medical Simulation and Information Sciences (MSIS) Research Program, Health Information Technologies and Informatics (HITI) Theater/Operational Medicine Initiative (TOMI). This BAA must be read in conjunction with the submission guidelines in [Grants.gov/Apply for Grants](https://www.grants.gov/Apply-for-Grants) (hereinafter called [Grants.gov/Apply](https://www.grants.gov/Apply)). It must also be read in conjunction with the document titled “General Submission Instructions” available with this BAA in Grants.gov.

This BAA is intended to solicit extramural research and development ideas and is issued under the provisions of the Competition in Contracting Act of 1984 (Public Law 98-369), as implemented in Federal Acquisition Regulation (FAR) 6.102(d)(2) and 35.016. 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 FY16-17 JPC-1/MSIS HITI TOMI Announcement/Funding Opportunity for intramural investigators will be available at [https://cdmrp.org/Program Announcements and Forms/](https://cdmrp.org/Program%20Announcements%20and%20Forms/).

- An *extramural investigator* is defined as all those not included in the definition of intramural investigators below.
- An *intramural investigator* is defined as a Department of Defense (DoD) military or civilian employee working within a DoD laboratory, DoD military treatment facility, or working in a DoD activity embedded within a civilian medical center. **Intramural investigators are directed to apply through CDMRP 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.D.
- 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: To conserve both submitters’ and Federal government resources, organizations are ***required to submit preliminary proposals/applications (pre-proposals/pre-applications)*** so that the government can determine whether a proposed

research idea meets the USAMRMC's mission and requirements described herein. All pre proposals/pre-applications must be submitted through Electronic Biomedical Research Application Portal (eBRAP) (<https://eBRAP.org/>). A registration process through eBRAP (<https://eBRAP.org>) 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 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>

B. General Program Overview

Proposals/applications to the FY16-FY17 JPC-1/MSIS TOMI are being solicited for the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate by the U.S. Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs [OASD(HA)], the DHA RDA Directorate manages and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The U.S. Army Medical Research and Materiel Command (USAMRMC), Congressionally Directed Medical Research Programs (CDMRP) provides Defense Medical Research and Development Program (DMRDP) execution management support for DHP core research program areas, including JPC-1/MSIS. CDMRP is the execution management agent for this BAA and will provide management support for subsequent awards with strategic oversight from JPC-1/MSIS.

The mission of the JPC-1/MSIS is to explore the implications of models, technology, and informatics for medical education, and for the provision, management, and support of healthcare services in the military. The JPC-1/MSIS Research Program plans, coordinates, and oversees a responsive world-class, tri-service science and technology program focused on two areas of research: (1) medical modeling, simulation and training, and (2) HITI.

The JPC-1/MSIS HITI portfolio facilitates scientific studies and promotes advances in software, information technology, medical informatics, and analytics in both garrison (fixed facilities) and theater (military combat and operational environments) settings. Advances generated will intersect with the Military Health System (MHS) Information Technology strategy at multiple points. The HITI portfolio is responsive to the evolving needs across the MHS enterprise. There are four research domains within the HITI:

- (1) Theater/Operational Medicine – Research to enhance the efficiency of healthcare operations in combat and operational environments to ensure the delivery of high-quality healthcare services by improving information accessibility and by providing better decision support for clinicians
- (2) Military Health Care Services – Research to promote, improve, conserve, or restore the mental or physical well-being of personnel through improved information management and technologies
- (3) Medical Resourcing – Research initiatives to improve the management of human and financial healthcare resources
- (4) Information Technology Infrastructure and Data Management – Research to improve the management of IT and communications infrastructure, healthcare data management, and architecture

This BAA focuses specifically on one of the four HITI domains: The Theater/Operational Medicine Initiative. The HITI Theater/Operational Medicine Initiative aims to provide technology solutions, software, decision support tools, algorithms, knowledge and HITI services to enhance the efficiency of healthcare operations in combat and operational environments to ensure the delivery of high-quality healthcare services by improving information accessibility and by providing better decision support for clinicians through improved information management and the use of emerging technologies. The government plans to use research outcomes from this award to assess critical technology elements and technology maturity, system integration risk, future use feasibility, and, where necessary, technology maturation and demonstration to fulfill critical capability gaps in Theater/Operational Medicine Healthcare delivery and support.

C. Award Information

To be considered for funding, proposals/applications to this BAA must specifically address at least one of the three FY17 JPC-1 HITI Theater and Operational Medicine Initiative Topic Areas, below.

1. Technology and Data for Joint Casualty Management (JCM) directly supports medical care in theater/operational environments and sustains a healthy and fit force. JCM delivers five of the seven joint Health Services Support capabilities outlined in the new Taxonomy Continuum of Health Care Capabilities developed in Joint Publication 4-02, Health Service Support. The capabilities delivered are expected to be technology and informatics solutions for First Responders, Forward Resuscitative Care, Theater Hospitalization, Definitive Care, and En Route Care.

The research Topic Areas within the JCM are:

- a. Demonstration and validation of solutions for synchronous audio/uni-directional video telementoring (i.e. GoPro Cam or other unique approaches). Proposed solutions should be able to provide documentation of the injury at or near the point of injury, and the data should be transferable to the current theater medical systems, and ultimately to the JOMIS system (Attachment 1).

- b. Solutions for Joint synchronous/asynchronous teleconsultations and telementoring for patients and/or deployed healthcare professionals at all levels of care. Research should provide a material solution for live/store and forward remote medical consultation and telementoring that integrates with service-level hardware and software, and will ultimately be transferable to the JOMIS system (Attachment 1). The demonstrated solutions will connect healthcare professionals to a network of consultants in theater and/or garrison. The goal is to improved care delivery via telementoring and teleconsultation at all levels of care in theater/opmed and during prolonged care in place when casualty evacuation is delayed. Telementoring will direct diagnostic and treatment assistance in theater to isolated providers who have limited medical skills.

2. Technology and Data for the Joint Medical Logistics Infrastructure Support (JMLIS) must establish the principles and practices that will move medical logistics into focused logistics. To integrate into the focused logistics system and to provide the highest quality of care, the medical logistics system must be able to accomplish two primary tasks. The first, accomplished in conjunction with service force management and force design organizations, is to ensure the medical supplies, material, and equipment with which our medical forces deploy include the latest technologies and advances in the medical field. The second task is to ensure medical supplies, material, and equipment is delivered to the right person, at the right place, and at the right time. JMLIS must incorporate new technologies and informatics solutions to provide real-time medical and operational capability and situational awareness of medical logistics operations within the joint area of operations. JMLIS technology and informatics will rapidly integrate advances in research, technology, and doctrine from science, medicine, engineering, information technology (IT), and other fields into fielded capabilities.

New approaches for projecting power will place a premium on enhancing U.S. active and passive defenses against missiles and chemical, biological, radiological, and nuclear (CBRN) weapons; distributing forces throughout a theater of operations and developing new net-centric concepts of operations; reducing the dependence of U.S. forces on major air and sea ports for insertion; increasing U.S. reliance on stealth, standoff, hypersonic, long-range, and unmanned systems for power projection; enhancing capabilities to project and sustain power directly from an integrated sea base; continuing to improve capabilities for littoral engagements; and developing ground forces that are more agile, more lethal, more versatile, more survivable, more sustainable, and rapidly deployable. These new approaches require equally new approaches to sustain U.S. forces in anti-access environments and to attain the DoD goal of reducing our logistics footprint by 50 percent.

The research Topic Area within the JMLIS is:

Demonstration of Passive Identification methods (i.e. sensors or other novel approaches) to solve Equipment tracking, inventory and other equipment Management Issues to support an agile force and attaining the DoD goal of reducing our logistics footprint by 50 percent. Proposed solutions should integrate with current and/or future logistics systems, including the Defense Medical Logistics Enterprise System (DMLES) and/or the Defense Medical Logistics Standard Support (DMLSS) Automated Information System (AIS).

3. Technology and Data for Joint Theater Medical Command and Control (C2) will research and validate a Joint Medical Command and Control (MedC2) solution that will synchronize and integrate health and medical force-related information from disparate databases and systems into one efficient, effective C2 capability. The resulting medical decision-based application will utilize intelligence, algorithms, decision support or other novel approaches to organize and synthesize planning information queried from existing databases. The data will eventually be migrated to a cloud solution to enable real-time response to anticipated, emerging, or contingency (crisis) situations. The research will enable direction, management, and/or coordination of assigned medical forces, assets and resources in the accomplishment of assigned missions. The DoD transformation strategy, called Military Transformation: A Strategic Approach, provides insights into how joint U.S. forces will organize and operate to meet future threats. This strategy calls for operational forces that are agile and net-centric, can take action from a forward position, be rapidly reinforced from other areas, and can defeat adversaries swiftly and decisively while conducting an active defense of U.S. territory.

- Net-centric operational forces will distribute forces more widely by increasing information sharing via a secure network that provides actionable information at all levels of command. This sharing, in turn, will create conditions for greater collaboration and coordination in real time, the results of which are greater speed of command, greater self-synchronization, and greater precision of desired effects.
- Small changes in the initial conditions result in enormous changes in outcome. Thus, speed will be a defining characteristic of the future joint force because the ability to decide and act faster than our opponent allows us to define or alter the initial conditions on terms favorable to our interests. The goal is to develop a dynamic situation, and in particular, one that is changing at a higher rate of speed than that with which an adversary can keep pace, while at the same time sharply narrowing the adversary's strategic options. Only certain kinds of forces are going to be able to accomplish that: forces oriented around speed. The necessary speed is not of the response but within it: speed of deployment, speed of organization, speed of employment, and speed of sustainment. This requires timely and decisive command information and decision-making capabilities.

The research Topic Area within the C2 is:

- Demonstration of Common Joint C2 systems user interface and decision-making capability. This topic includes research and validation for feasible solutions for Army, Navy, Air Force Joint Command and Control (C2) solutions that aggregate and present data in a unified user interface, providing algorithms, decision support, or other novel approaches to support C2 decision making. The research will investigate and demonstrate the aggregation of data from disparate applications that are currently used by the services for medical C2, and with a view toward integrating with the future JOMIS capability (Attachment 1).

Technical and Situational Overview

The DoD MHS has multiple legacy healthcare systems and data stores, developed over decades, which are in the process of being modernized. This modernization must ensure and enable sustainability, flexibility, and interoperability of the MHS while improving the continuity of

patient care. In May 2013 the Secretary of Defense (SECDEF) memorandum mandated DoD to competitively select a configurable, scalable, and modernized Off the Shelf (OTS) Electronic Health Record (EHR) System. The Cerner Millennium EHR System was selected in 2015, and it will replace MHS legacy clinical systems including, but not limited to, the Armed Forces Health Longitudinal Technology (AHLTA), Composite Health Care System (CHCS), and most components of the Theater Medical Information Program – Joint (TMIP-J). Currently, TMIP-J provides support for planning and delivery of healthcare services in Combatant Command (CCMD) Areas of Responsibility (AOR). It is a multi-Service Major Automated Information System (MAIS) that assists coordination, support and documentation of patient treatment in an electronic health record (EHR); medical command and control (MedC2); medical logistics (MEDLOG); medical situational awareness activities (MEDSA); and patient movement (PM) and evacuation. The Joint Requirements Oversight Council (JROC) validated TMIP-J functional requirements in the 1990's, which were updated in 2006. Recognizing the unique aspects of future theater and operational military needs, the Undersecretary of Defense for Acquisition, Technology and Logistics (USD[AT&L]) signed an acquisition decision memorandum (ADM) tasking the Director, Defense Health Agency (DHA) to conduct analysis of follow-on joint theater medical information requirements. The results of this effort will result in a Capability Development Document (CDD) (targeted for early 2016) to support development and fielding of a new Theater software application, the Joint Operational Medicine Information System (JOMIS). See Attachment 1 for further JOMIS information. The JOMIS office will work with the Deployment and Readiness Systems (D&RS) Program Office, which manages TMIP-J, and the Services' infrastructure program offices to deploy the Cerner EHR System to permanent and temporary operational environment platforms to meet capabilities required for each Role of Care, as defined in Joint Publication 4-02 Health Service Support. Operational platforms currently include 225 ships, 75 submarines, and 2 hospital ships; temporarily deployed operational medical units currently include approximately 6 Theater Hospitals, 450+ Forward Resuscitative Sites, 3 Aeromedical Staging Facilities (ASF) and numerous aeromedical evacuation teams to support military operations abroad. Theater/Operational Medicine must deliver and provide care in a complex, geographically dispersed, global enterprise in an extremely dynamic environment, and provide patient data to the Cerner EHR used in the garrison-level, Military Treatment Facilities (MTF's) fixed facilities.

Operational medical platforms are employed as needed to support the military mission; from deploying a Role 3 Theater Hospital to Afghanistan for a multi-year rotation, to deploying a Hospital Ship to New York City after tropical storm Sandy for humanitarian assistance. In the past, most operational medical platforms were contingent in nature; that is, they are on a standby status ready to support a mission when called upon. Equipment is staged and ready, and personnel are on a recall status. When called upon they mobilize from their home units (Segment 1 MTFs, or Guard and Reserve units) and deploy to the operational location to support the mission. When the mission or their rotation ends they return home. Naval ships are the exception, as their operational medical platforms are embedded within the ship and support the ship 24/7 during its operational life cycle. More recently, and in future projections, per the Joint Concept for Health Services, 31 August 2015, operational medicine platforms need to be more agile, with a smaller footprint, and have global reach to meet future military operations.

The theater/operational medicine capabilities are expected to function in a low/no communication environment, in support of the Roles of Care as defined below:

- (a) Role 1 – First responder capabilities including immediate lifesaving measures at the point of injury in deployed/operational environments.
- (b) Role 2 – Forward resuscitative care including advanced trauma/emergency medical treatment. Some Role 2 sites are expanded to include additional medical services and Ancillary support services (e.g., Laboratory, Pharmacy, Radiology) to provide more robust care for larger Patient at Risk (PAR) populations.
- (c) Role 3 – Theater hospitalization including robust care for resuscitation, surgery, and post-operative care.
- (d) Enroute Care – Care required to maintain the phase treatment initiated prior to evacuation and the sustainment of the patient’s medical condition during evacuation.

Care can range from in-flight skilled nursing care up to invasive Critical Care services from Critical Care Air Transport Teams (CCATT).

Key issues, specialties and environmental challenges related to theater and roles of care are depicted in Figure 1. JPC-1 is seeking research proposals offering unique solutions to meet these challenges.

FIGURE 1. ISSUES BY ROLES OF CARE		
ROLES	SPECIALTIES INCLUDED	DURABILITY/ENVIRONMENT
ROLE 1	Initial Trauma Response, Patient Stabilization and Evacuation	Austere Conditions; Fine dust, limited space, extreme variations in temperature (hot and cold), humidity and pressure. Limited power sources and high periods of low/no communications. Maneuverable.
ROLE 2	Trauma/Critical Care, Patient Stabilization and Movement to next level of care, some Lab Services, Dental, Mental Health and Medical Logistics Support	Austere Conditions; Fine dust, extreme variations in temperature (hot and cold), humidity and pressure. Limited power sources and constrained communication (limited bandwidth) with some prolonged periods of no communications. Stationary or maneuverable.
ROLE 3	Expanded Trauma Care, Dental, Basic Physical Therapy, Medical/Surgical Specialties & Ancillary Services*	Austere Conditions; Fine dust, extreme variations in temperature (hot and cold), humidity and pressure. Limited power sources and constrained communication (limited bandwidth) with some periods of No Communications. Stationary or maneuverable.
EN ROUTE CARE	Adult Critical Care, Medical Surgical Inpatient, Trauma Care, Peri-operative	Austere Conditions; Fine dust, limited space, extreme variations in temperature (hot and cold), humidity and pressure. Equipment must be light, safe to fly and provide mobility around aircraft. Typically no communication available in flight.

FIGURE 1. ISSUES BY ROLES OF CARE		
TRAINING SITES	Primary Care, Adult Critical Care, Emergency Care (trauma), Medical Surgical Inpatient, Peri-operative, Behavioral Health, Neonatal, OB-GYN, Pediatrics.	Dedicated servers/system at training/field exercise locations.
<i>*Medical/Surgical Specialties & Ancillary Services include:</i>		
<ul style="list-style-type: none"> • Otorhinolaryngology (ENT) • Infectious Disease Control • Mental Health Triage • Combat Stress Management • Neurosurgery 	<ul style="list-style-type: none"> • Pediatrics • Thoracic/ Vascular Surgery • Urology • Blood Support Center • Computed Tomography (CT) 	<ul style="list-style-type: none"> • OB/GYN • Ophthalmology • Oral and Maxillofacial Surgery • Diagnostic Radiology • Optometry

Figure 2 depicts the number of sites by Roles of Care in each of the services. A research goal is to provide HITI solutions that will meet JOINT MILITARY NEEDS, while still recognizing service specific requirements.

FIGURE 2. NUMBER OF SITES BY ROLES OF CARE						
SERVICE	ROLE 1	ROLE 2	ROLE 3	EN ROUTE CARE	TRAINING SITES	TOTAL
AIR FORCE	100	102	32	295	3	532
ARMY	1992	204	30		22	2248
MARINE CORPS	143					143
NAVY	279	39	13			331
TOTAL						3254

The goal of HITI research is to transfer research products for further usage within the MHS enterprise. As such, Attachment 2 provides sources of technical documentation, which provides guidance for some of the technical aspects that should be considered in proposed research solutions. Attachment 2 is not an inclusive list.

Strategic Guidance

The theater/operational strategic environment is changing, and guidance for employment of the Joint Force is evolving in response. Thus, medical care and support for deployed forces must

also change in response. Current large-scale operations in U.S. Central Command AOR have drawn down and the U.S. strategic focus is also changing to include a Pacific Rim focus. There are also evolving operational demands for the U.S. military to conduct sustained, distributed counterterrorist operations; maintain forward presence; and conduct foreign engagements to encourage regional stability. If these efforts to maintain stability fail, the U.S. must also be prepared to defeat regional adversaries in large-scale, multi-phased campaigns. Meeting these demands will require a future Joint Force that can rapidly mass unique Service and agency capabilities combine with mission partners across domains, echelons, geographic boundaries and organizational affiliations when appropriate, and project decisive military capabilities in different arrangements in both time and space. To ensure that the MHS is able to medically support the Joint Force in meeting the needs of the future Joint Force Commanders (JFC), new medical technologies, documentation, analysis, synthesis, and medical intelligence are necessary to fulfill support medical needs in operational environments.

Strategic guidance highlights the changing strategic environment and the evolving need for medical solutions to support operational demands for the Joint Force. These demands for more dynamic and, potentially, much more intense military activity all drive new demands for knowledge of theater medical information. The strategic guidance documents listed below are publicly available via the internet; the Joint Concept for Health Services, most recently published, is included as Attachment 3.

(1) Sustaining U.S. Global Leadership: Priorities for 21st Century Defense, January 2012.

This guidance articulates the priorities of the Joint Force to support U.S. strategic goals through its agility, flexibility, readiness, and technologically-advanced nature. The Joint Force's primary missions span the range of military operations, from effective operations in cyberspace and space to conducting counterterrorism and irregular warfare. The Joint Force must be prepared to conduct these operations globally, including operations that cross traditional geographic boundaries. In order to succeed in these missions on a global scale, the Joint Force and Joint Force Commanders (JFC) require assured identification and management of information necessary to support operational healthcare function activities.

(2) Quadrennial Defense Review (QDR) Report, 2014. In order to respond to a future security environment that is characterized by growing technological diffusion, dynamic and unpredictable challenges, and growing adversary capabilities across all domains, the QDR prioritizes three strategic pillars: defending the homeland; building security globally by projecting U.S. influence and deterring aggression; and remaining prepared to win decisively against any adversary should deterrence fail. These pillars drive information requirements in support of operational healthcare functions as geographic and functional Combatant Commanders (CCDRs) orient their operations and activities.

(3) Guidance for Employment of the Force (GEF), 2015. The GEF translates national security strategy and objectives and reflects and build upon the 2014 QDR. The GEF "issues both the President's guidance for contingency planning, and conveys the Secretary's guidance for near-term, steady-state plans and defense posture." The GEF provides guidance for the top priorities for planning, focusing on, among other things various geographic contingencies. These priorities drive functional requirements for health services as well as information requirements to support healthcare planning and execution.

- (4) The Military Health System Strategic Plan, 2014. The MHS Strategic Plan outlines the approach for an integrated MHS that supports warfighter requirements while delivering a coordinated continuum of preventative and curative services to beneficiaries. These efforts will require the effective management and synchronization of operational health and medical force information during operations.
- (5) Health Readiness Concept of Operations (CONOPS) 21 January 2010. The Health Readiness CONOPS details requirements needed to enhance DoD and our Nation's security by providing health support for the full range of military operations and sustaining the health of all those entrusted to our care. The Health Readiness CONOPS encompasses the following 3 CONOPS, which go into further details for requirements for military medical care and medical support requirements.
- (6) Force Health Protection CONOPS 17 November 2011 – Details what is needed for the ability to promote, improve, conserve and restore the mental and physical wellbeing of deployed forces.
- (7) Health Service Delivery CONOPS 22 February 2011 – Details what is needed for the ability to provide acute or long-term primary or specialty care capabilities to all eligible military beneficiaries outside the theater in either the direct or purchased care system.
- (8) Health System Support CONOPS 22 February 2011 – Details what is needed for the ability to perform healthcare administrative and support related functions to sustain and continuously improve MHS mission effectiveness through focused development of people.
- (9) The Joint Concept for Health Services (JCHS) 31 August 2015 – Describes in broad terms the Chairman of the Joint Chiefs of Staffs vision for what the future Joint Force will need to have from its collective medical enterprise in order to support Globally Integrated Operations. This concept encompasses the global employment of joint operational health services and the idea of interoperable Service capabilities guided by common standards and procedures, with the ability to tailor support to meet a wide variety of operational and strategic requirements. The recently published JCHS is included as Attachment 3.

Research proposals should address and meet the following characteristics and principles in whole or in part; they should be:

- (a) Joint solutions, i.e., applicable to Army, Navy, and Air Force.
- (b) Solutions that leverage or easily integrate with current and/or future service-provided and service-maintained information technologies including software, hardware devices, and tactical communication.
- (c) Solutions that leverage emerging information technologies.
- (d) Solutions that maximize security and minimize threats such as hacking, penetration, jamming, and electronic emanations especially for systems intended for use in tactical environments.
- (e) Solutions that enable generation and transmission of unclassified medical information within organizations or tactical environments that require information systems to operate on the SIPRNET.
- (f) Solutions that do or will integrate Army, Navy, Air Force Data into Joint IT System.

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) of record. Local IRB 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. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Refer to the General Application Instructions, Appendix 5, for additional information.

D. Eligibility Information

- Independent extramural investigators at all academic levels (or equivalent) are eligible to submit applications.
- Cost sharing/matching is not an eligibility requirement.
- Eligible extramural investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, 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, 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.

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 up to \$15M of the FY16 and anticipated FY17 DHP RDT&E appropriations to fund both TOMI and Hands-Free Electronic Health Record Data Entry Initiative (HFEHRI) proposals/applications. JPC-1/MSIS expects to fund approximately one to four TOMI proposals/applications, depending on the quality and number of proposals/applications received from intramural agencies and extramural organizations. Funding of proposals/applications received in response to this BAA/Funding Opportunity is contingent upon the availability of Federal funds for this program. As of the release date of this BAA/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 BAA/Funding Opportunity is approximate and subject to realignment.

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

- The maximum period of performance is 2 years.
- The anticipated **total** costs (direct and indirect) budgeted for the entire period of performance will not exceed \$ 2M. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding \$ 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 disseminate project results at one DoD in-progress review (IPR) meeting. Costs associated with travel to this meeting should be included in Year 1 of the budget. For planning purposes, it should be assumed that the meeting will be held in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary
- Research-related subject costs
- Clinical research costs
- Support for multidisciplinary collaborations
- Equipment
- Travel between collaborating organizations
- Travel costs to attend scientific/technical meetings in addition to the required meeting described above

Subawards to intramural agencies and other Federal agencies may be executed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR], Funding Authorization Document [FAD] process, or Interservice Support Agreements (DD form 1144)). Direct transfer of funds from the recipient to a Federal agency is not allowed except under very limited circumstances. Refer to 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 USC¹ 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) or contract awarded under this BAA will be governed by the award terms and conditions that conform to the DoD's implementation of Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of awards made after December 26, 2014, may include revisions to reflect DoD implementation of new OMB guidance in 2 CFR² 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.

¹ United States Code

² Code of Federal Regulations

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 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 after.

A. Where to Obtain the Submission Package

To obtain the complete Grants.gov proposal/application package (hereinafter, submission package), including all required forms, perform a basic search using the Funding Opportunity Number **W81XWH-16-R-MSI3** 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 HITI 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 HITI 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>). 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 (6-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, etc.) 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 Design:** Describe the research approach for accomplishing the specific aims is feasible, what will accomplish the objectives, will provide information on proposed methods and analysis/ evaluation strategies, and is based on sound rationale. Describe how the proposed work and research will create and produce a demonstration and validation/proof of concept to meet the subject Topic Area and improve Theater/Operational Medicine.
 - **Background/Rationale:** Clearly present the ideas and reasoning behind the proposed research. Include relevant military and civilian literature citations, preliminary and/or pilot data, and/or other evidence that led to the development of the proposed research. Any preliminary data should be from the laboratory of the PI or member(s) of the collaborating team.

- **Hypothesis/Objective and Specific Aims:** State the proposed project’s hypothesis and/or objectives and the specific aims/tasks of the proposed research.
- **Approach/Methodology:** Describe the research approach. Include research design, methods, and analysis/evaluation strategies as well as materials anticipated to be used during the research. Include a description of human use in the proposed project. For studies involving human subjects, include a description of the size, characteristics, and partnering organizations of the subject population that will be employed.
- **Significance, Relevance, and Innovation of the Proposed Effort**
 - **Significance and Relevance:** Clearly articulate how the proposed research is instrumental in addressing research gaps, meets military requirements, and has military relevance to improving theater/operational medicine.
 - **Innovation:** Explain how the proposed project is innovative and not an incremental advancement of previous work.
- **Proposed Study Design/Plan:** Describe the concept to demonstrate and validate the proposed technology/HITI solution. Provide the intended research methodology that will support the study. Provide preliminary information such as description and background of the technical solution, anticipated success criteria, research/test plan(s), and statistical protocols. 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 technologies, data and/or processes related to HITI for theater/operational medicine while decreasing medical morbidity and mortality in the military healthcare system. 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 the research project for Government use.

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

- **References Cited (one-page limit):** List the references cited (including URLs if available) in the Pre-Proposal/Pre-Application Narrative using a standard reference

format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Pre-Proposal/Pre-Application Narrative.
- **PI and Key Personnel Biographical Sketches (five-page limit per individual):** Upload as “Biosketch_LastName.pdf.” Bold or highlight publications relevant to the proposed project.
- **Budget Summary: Upload as “BudgetSummary.pdf.”** Complete the two-page Pre-Application Budget Summary Form (available for download in eBRAP) as instructed.
- **Quad Chart: Upload as “QuadChart.pdf.”** Complete the one-page Quad Chart Form (available for download in eBRAP) as instructed.
- **Submit Pre-Application – Tab 6:**
 - This tab must be completed for the pre-proposal/pre-application to be accepted and processed.

Pre-Proposal/Pre-Application Screening

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

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

- **Theoretical Rationale, Scientific Methods, and Research:** To what degree the research approach for accomplishing the specific aims is feasible, will accomplish the objectives, will provide information on proposed methods and analysis/evaluation strategies, and is based on sound rationale. To what degree the proposed work and research will create and produce a demonstration and validation/proof of concept to address one of the Topic Areas and improve theater/operational medicine.
- **Significance, Relevance, and Innovation:** To what degree the proposed research is relevant and innovative, including whether the proposed research is duplicative of existing research.
- **Open Source/License/Architecture:** Evaluate if intellectual property that is proposed for incorporation is located in key areas within the design/plan which could impact future flexibility or adaptation of the proposed technical/data solution(s).
- **Study Design/Plan:** To what degree the proposed demonstration and validation study methodologies, anticipated sample and sample size, test plan(s), anticipated success criteria, evaluation criteria/metrics, and statistical protocols will justify and support the intended outcomes of the proposed research.

- **Military Impact:** To what degree the project’s anticipated short- and/or long-term outcomes will impact the military and provide advancement in theater/operational medicine 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

A proposal/application 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 application package 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 FY16-FY17 JPC-1 MSIS TOMI BAA (W81XWH-16-R-MSI3), the Grants.gov application package includes the following components (refer to the General Submission Instructions, Section II.D., for additional information on proposal/application submission):

1. **SF-424 (R&R) Application for Federal Assistance Form:** Refer to the General Submission Instructions, Section II.D., 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, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and will result in administrative withdrawal of the proposal/application.

Describe the proposed project in detail using the outline below.

- **Background:** Present the ideas and reasoning behind the proposed research; include relevant literature citations or preliminary data on the proposed technical solution(s) and how they may have been utilized in similar environment(s). 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 research design, methods, and analyses/evaluations in sufficient detail for analysis.
 - Clearly support the choice of study variables/metrics 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.

- Provide a detailed protocol, including but not limited to, proposed methodologies, research/test plan(s) and criteria, intended medical domain(s) or discipline(s), control groups, and defined statistical models.
 - 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. 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, unexpected events, changes in key personnel, and ongoing adaptation of the application. 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 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.

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.
Note: For researchers who will require access to the Defense Healthcare Management Systems Modernization (DHMSM) Cerner Electronic Health Record (EHR) solution for testing related to research workflows and/or interfaces: Access will be provided through a research environment within the Program Executive Office (PEO) Defense Healthcare Management Systems (DHMS) Testing Infrastructure at Allegheny Ballistics Laboratory (ABL). This research enclave will be established, third quarter, FY16 and users will follow the PEO DHMS Testing Infrastructure Onboarding Guide to access the environment. Direct support from the DHMSM vendor will not be provided through the DHMSM contract. No one is authorized to engage the DHMSM contractor for this purpose. Research must remain in these stated bounds.

- **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.D., Research and Related Budget, 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 (if applicable):** 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.

- **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.
- **Relevance:** Provide a brief statement explaining the potential relevance of the proposed work to the specific topic area being addresses and its impact on health outcomes.
- **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 the abstracts.*

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

- Describe the objectives and rationale for the proposal/application in a manner that will be readily understood by readers without a background in science or medicine.
- Describe the ultimate applicability and potential impact of the research.
 - What types of patients will it help, and how will it help them? Include the current available statistics to the related injury/condition.
 - What are the potential clinical applications, benefits, and risks?

- What is the projected timeline it may take to achieve the expected patient-related outcome?
 - Briefly describe how the proposed project will benefit Service members, Veterans, and/or their family members.
- **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 military medical providers and injured Service members.
 - **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: Data and Research Resource-Sharing Plan (one-page limit): Upload as “Sharing.pdf.”** Describe how unique and/or final research data will be shared with the research community, along with any resulting research resources. This includes cases where pre-existing data or research resources will be utilized and/or modified during the course of the proposed project. If there are limitations associated with a pre-existing agreement for the original data or research resources that preclude subsequent sharing, the applicant should explain this in the data-and/or research resource-sharing plan. For projects involving clinical trials, PIs may be required to register their clinical trials on Clinicaltrials.gov (<https://clinicaltrials.gov/>). For projects involving TBI, PIs may be required to report data to the Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system (<http://fitbir.nih.gov/>). If the project includes systems biology-related research, the PI may be required to make the systems biology data, generated via an award, available to the research community by depositing research data into the SysBioCube system (<https://sysbiocube-abcc.ncifcrf.gov/>). Refer to the General Submission Instructions, Appendix 3, for additional information.

- **Attachment 9: Conflicts of Interest, if applicable: Upload as “COI.pdf.”** Provide details with the proposal/application submission of all potential or actual 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 managed.

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 10: 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 11: Post-Award Project Transition Plan (three-page limit). Upload as “Transition.pdf.”** Provide information on the methods and strategies proposed to move the project 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 the components listed below as applicable.
 - 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 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.D.8., for detailed information.

3. Research & Related Senior/Key Person Profile (Expanded): Refer to the General Submission Instructions, Section II.D.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.D.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 12.

5. **Project/Performance Site Location(s) Form:** Refer to the General Submission Instructions, Section II.D.6., for detailed information.
6. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Submission Instructions, Section II.D.7., for detailed information.

D. Application 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 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 Grants.gov 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>.

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 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, proposals/applications will be evaluated according to the following scored criteria, which are listed in decreasing order of importance:
 - **Theoretical Rationale and Scientific Methods**
 - To what degree the research approach for accomplishing the specific aims is feasible, will accomplish the objectives, and is based on sound rationale.

- To what degree the proposed work and research is derived to create and produce a demonstration and validation of a technology or data solution that will meet the defined Topic Area to improve Theater/Operational Medicine.
 - How well the study aims, hypotheses or objectives, experimental design, methods, and analyses are designed to clearly answer the research questions.
 - How well the technical feasibility of successfully demonstrating and validating the proposed solution is described.
 - How well the proposed methodologies, evaluation strategy, research/test plan(s), statistical protocols, etc., to support the demonstration and validation/proof of concept study are presented and align with the proposed study outcomes.
 - Whether there is evidence of an adequate contingency plan, such as a risk mitigation plan, to resolve potential delays.
 - Whether the proposed timeline is appropriate and tasks outlined in the proposal/application are logical in their progression.
 - To what degree the references cited within the proposal/application supports the background, the proposed methodologies, and/or the proposed study methodologies.
- **Relevance, Innovation, and Impact**
 - How the proposed research is relevant to the goals and challenges of theater/operational medicine as defined in the background documents provided.
 - How the proposed work is innovative, including whether the proposed research is duplicative of existing research.
 - To what degree the proposed research is relevant to the goal of providing high usability technical solution(s) to theater/operational medicine users.
 - To what degree the anticipated short- and long-term outcomes resulting from the proposed study will contribute to the goal of improving theater/operational medicine.
- **Open Source/License/Architecture**
 - To what degree the proposed research project incorporates open source / license/architecture and intellectual property components available for license.
 - Identify within the proposal the anticipated Government rights of the proposed research project.
- **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 demonstration and validation research and project development and within the limitations of this BAA.

- **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 will be used by programmatic reviewers:

a. Ratings and evaluations of the peer reviewers

b. Open Source/License/Architecture

- To what degree the proposed research project 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 research product to meet future Government needs.
- Degree of public accessibility of research project(s).

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 agency 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 or contains only zeros.

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/HITI Steering Committee member](#) (Section IX) is named as being involved in the research proposed or found to have assisted in the pre-proposal/pre-application or proposal/application processes, including, but not limited to, concept design, proposal/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 full 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. Awards will be made no later than September 30, 2017. 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 Application 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 Proposal/Application Submission Checklist below.)
- 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-MSI3** 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.

VIII. 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	Data and Research Resource-Sharing Plan: Upload as Attachment 8 with the file name "Sharing.pdf."	
	9	Conflicts of Interest: Upload as Attachment 9 with file name "COI.pdf," if applicable.	
	10	Data Management: Upload as Attachment 10 with file name "DataManage.pdf."	
	11	Post-Award Project Transition Plan: Upload as Attachment 11 with file name "Transition.pdf."	
	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.	
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.	

XI. FY16 JPC-1 HEALTH INFORMATION TECHNOLOGIES AND INFORMATICS STEERING COMMITTEE MEMBERS AND ADVISORS

Submissions that include an FY16 JPC-1 Health Information Technologies and Informatics Steering Committee member or advisor (listed below) as an investigator, consultant, collaborator, or in a key personnel role will not be considered.

LTC Mark Mellott (Chair)	Mr. Rich Franco
Ms. Heather Burke	Col Ray Jeter
Mr. Donald Dahlheimer	Dr. Terry Newton
Mr. Russell Davis	Dr. Loretta Schlachta-Fairchild
CDR James Ellzy	Dr. Alan Smith
COL Daniel Kral	Mr. Robert Bolluyt
Mr. Frank Rowland	Col Al Bonnema
Dr. Peter Marks	Ms. Carol Fielder
LTC Richard Wilson	LTC Kevin Peck
COL John Scott	Ms. Colleen Rye
CAPT Paul Miller	Mr. Richard Foster
COL Thomas Greig	Mr. Jim Copeland
Ms. Janet Fuller	Ms. Janine Oakley
Dr. Timothy B. Bentley	

Attachment 1
Joint Operational Medicine Information Systems Program Management Office

Attachment 2
Select Applicable Technical Documents

Attachment 3
Joint Concept for Health Services