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 Hands-Free Electronic Health Record Data Entry Initiative (HFEHRI)

Funding Opportunity Number: W81XWH-16-R-MSI4

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) <u>Hands-Free Electronic Health Record Data Entry Initiative</u> (HFEHRI). This BAA must be read in conjunction with the submission guidelines in <u>Grants.gov/Apply for Grants</u> (hereinafter called <u>Grants.gov/Apply</u>). 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-FY17 JPC-1/MSIS HITI HFEHRI Announcement/Funding Opportunity for intramural investigators will be available at <u>https://cdmrp.org/Program_Announcements_and_Forms/.</u>

- 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 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: All pre-proposals/pre-applications must be submitted through the electronic Biomedical Research Application Portal (eBRAP [https://eBRAP.org/]). A registration process through eBRAP must be completed before a pre-proposal/pre-application can be submitted.

- A Principal Investigator (PI) and the organization's business official must register in eBRAP before submitting a pre-proposal/pre-application.

- Full proposals/applications (submitted through Grants.gov) will be available for viewing, modification, and verification in eBRAP, for a limited period.

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

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

B.   General Program Overview

Proposals/applications to the FY16-17 JPC-1/MSIS HFEHRI 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 overall 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 mission of the JPC-1 HITI is to facilitate scientific studies and promote advances in software, information technology, medical informatics, and analytics in both garrison (fixed facilities) and theater (military combat and operational environments). Advances generated will intersect with the Military Health System (MHS) Information Technology strategy at multiple points. The HITI portfolio is developed, shaped, customized, and administered to address 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

C.   Focus Area: Theater/Operational Medicine – Hands-Free Electronic Health Record Initiative

This BAA focuses specifically on one of the four HITI domains: Theater/Operational Medicine. The Theater/Operational Medicine focus area provides 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.

The Theater/Operational Medicine – Hands-Free Electronic Health Record Initiative (HFEHRI) seeks to specifically focus on demonstrating and validating technology approaches that enable data entry/data capture to the electronic patient record at point-of-injury without the use of hand-operated input devices. Both in theater/operational care, and in day-to-day military healthcare in hospitals and clinics, the environment is often noisy, disruptive and fast moving. Corpsmen, medics, nurses, doctors, physician assistants and other providers have to move swiftly, conducting hands on interventions caring for patients to save life and limb. Stopping the flow of care to enter electronic health record data using keyboards or a stylus results in loss of time for direct patient care, and is often completely prohibitive in emergency environments, resulting in a loss of documentation.

Research with Natural Language Processing (NLP) has occurred, however NLP has not yet proven to be repeatedly reliable in noisy tactical/operational environments with factors such as aircraft noise and wind.   Key factors for a proposed solution is ability for providers to operate in challenging and rugged indoor and outdoor environments (noise, wind), able to be mobile and move about freely to care for patients, and minimal weight for carrying additional technologies or items on their person. Research is needed to demonstrate and validate hands-free data entry solutions.

D. Award Information

The FY16-FY17 JPC-1/MSIS HITI HFEHRI BAA seeks to support research relevant to the Hands-Free Electronic Health Record Initiative to demonstrate and validate technological approaches that enable data entry/data capture to the electronic patient record at point-of-care without the use of hand-operated input devices. Proposed research should explore solutions that will not degrade workflow, will be operable and reliable in complex, noisy environments, and should demonstrate a high-degree of usability to avoid interference with the flow of hands-on patient care, which can be interrupted with handheld device usage. Especially in theater/operational environments with high tempo, the ability to enter data/document care in a hands free manner is critical. Keeping provider's hands available for caring for casualties, moving patients for evacuation, and administering life- and limb-saving treatments is imperative. Solutions from other domains, such as industry, manufacturing, disability solutions, aerospace and other non-medical arenas are encouraged.

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 (MTFs) 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)   En Route 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
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

Medical/Surgical Specialties & Ancillary Services include:

• **Otorhinolaryngology (ENT)**	• **Pediatrics**	• **OB/GYN**
• **Infectious Disease Control**	• **Thoracic/ Vascular Surgery**	• **Ophthalmology**
• **Mental Health Triage**	• **Urology**	• **Oral and Maxillofacial Surgery**
• **Combat Stress Management**	• **Blood Support Center**	• **Diagnostic Radiology**
• **Neurosurgery**	• **Computed Tomography (CT)**	• **Optometry**

Figure 2 depicts the number of sites by Roles of Care in each of the services. A research goal is to provide the hands-free data entry, 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 – 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 that could be borrowed from other domains such as industry, manufacturing, disability technologies, aerospace or other arenas.

(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.

FY17 Hands-free Electronic Health Record data Entry Initiative Topic Area:

The FY16-FY17 JPC-1 HITI BAA seeks research to address Hands-free data entry for the following topic:

Demonstrate and validate technology products and/or services for hands-free electronic record data entry for medical/clinical/purposes even if the solution is not currently in use with medical systems. Research should propose to demonstrate and validate existing solutions for current technology or soon-to-be released technologies in the domain of hands-free electronic data entry. Research should examine methodologies for product implementation/integration into military medical environments including theater/combat/operational medicine and/or in peacetime healthcare delivery, determination of future technological barriers, and identification of probably risk mitigation strategies. The solutions will demonstrate added first responder and medic capabilities through the alleviation of the requirement to interface and input casualty care information using hand-operated input devices. The current data capture methods degrade the ability to document care in deployed and evacuation environments. The solution(s) will validate

effective data capture and entry approaches/technologies that are operable for data capture/data entry in fully disruptive Theater/operational environments.

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 Submission Instructions, Appendix 5, for additional information.

E.   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.

F.   Funding

The JPC-1/MSIS expects to allot up to $15M of the FY16 and anticipated FY17 DHP RDT&E appropriations to fund both HFEHRI and Theater/Operational Medicine Initiative (TOMI) proposals/applications. JPC-1/MSIS expects to fund approximately one to four HFEHRI 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 HFEHRI 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.

G.   Mechanisms of Support

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

The USAMRAA will negotiate the award types for proposals/applications selected for funding. The Federal Grant and Cooperative Agreement Act of 1977, 31 USC[1] 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 CFR[2] part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards."

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[1] United States Code
[2] Code of Federal Regulations

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.

H.   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-MSI4 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.shtml). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Government. Refer to 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 how 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. 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 adaption 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 the Topic Area 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 HFEHRI (W81XWH-16-R-MSI4), 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. For development of devices and technologies, discuss the timelines and provide a commercial strategy plan for the technology being developed.

- ○ **Additional Information**: If human subjects are involved in the research, proposals/applications may be submitted prior to human protocol 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 ORP 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 & 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.
  - ○ **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.

  a. The planned indication for the product label, if appropriate, 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, if applicable.

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.5., Research & Related Budget, 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."

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

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

B.   Peer and Programmatic Review

1. **Peer Review:** To determine technical merit, all proposals/applications will be evaluated according to the following scored criteria, which are listed in descending 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 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(s) 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 form 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/MSIS HITI Steering Committee Member 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 Submission Instructions, Appendix 3, for general information on reporting requirements.

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

- Contractor Manpower Reporting (CMR)
  - ○ CMR is now a requirement of all DoD contracts. Offerors are allowed to include a nominal fee in their cost/price proposal for providing these data. A "nominal fee" is defined as a computation of an administrative assistant equivalent labor category providing approximately 6-8 hours to complete data input. Offerors may opt to not separately price this required annual data input. CMR costs/price will not be evaluated as part of the total evaluated proposal cost/price.
  - ○ The contractor shall report ALL contractor labor hours (including subcontractor labor hours) required for performance of services provided under each contract via a secure data collection site. The contractor is required to completely fill in all required data fields using the following web address: http://www.ecmra.mil/.
  - ○ Reporting inputs will be for the labor executed during the period of performance during each Government fiscal year (FY), which runs October 1 through September 30. While inputs may be reported any time during the FY, all data shall be reported no later than October 31 of each calendar year, beginning with 2016. Contractors may direct questions to the help desk at: contractormanpower@hqda.army.mil or via phone at 703-377-6199.

E.   Changes of Principal Investigator and Organization

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

VI. AGENCY CONTACTS

A. CDMRP Help Desk

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

> Phone: 301-682-5507

> Email: help@eBRAP.org

B. Grants.gov Contact Center

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

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

> Email: support@grants.gov

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

C. Common Submission Problems

- Failure to enter an email address for change notifications under the BAA Funding Opportunity Announcement in Grants.gov for notifications on any modification made to the initial posting.
- Attachments are uploaded into the incorrect form on Grants.gov forms. (See 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-MSI4** 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

Joint Operational Medicine Information Systems Program Management Office

DHMS

Program Executive Office

DHMS ---- DHMSM
DMIX
DoD/VA IPO
JOMIS
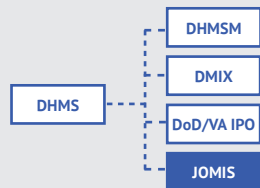
The mission of Joint Operational Medicine Information Systems (JOMIS) is to support the planning, procurement and deployment of the new EHR and follow-on theater capabilities to DoD expeditionary locations.

QUICK FACTS

Operational Medicine Footprint Today

5	Theater Hospitals
169	Forward Resuscitative Sites
141	Army
15	Navy
11	Air Force
2	Marine Corps
160	U.S. Navy Ships
43	Submarines
9M+	Orders of Ancillary Services (3/2007 to 4/2015)
7M+	Outpatient encounters (3/2007 to 4/2015)

TIMELINE

2014
» TMIP-J I2R3 receives ICD-10 codes update
» TMIP-J staff deploy and use AHLTA-T and TMDS to support healthcare documentation during EBOLA outbreak in Africa
» USD AT&L signs memo establishing JOMIS PMO on Dec. 23

2015
» Acquisition Strategy completed
» System Acceptance Reviews for final release of TMIP-J I2R3 completed

LEADERSHIP

Ms. Claire Evans
Program Manager (Incoming Sept. 2015)

COL John Ryan Bailey
Deputy Program Manager

- -

Defense Healthcare Management Systems
   Joint Operational Medicine Information
   Systems PMO
   1501 Wilson Boulevard, 6th floor
   Arlington, VA 22209
   T: 703-588-5860
   www.health.mil/dhms

As of July 21, 2015

ABOUT

On December 23, 2014, the Under Secretary of Defense for Acquisition, Technology, and Logistics (USD AT&L) issued an Acquisition Decision Memorandum (ADM) establishing the Joint Operational Medicine Information Systems (JOMIS) Program Management Office (PMO). The JOMIS PMO comprises the Theater Medical Information Program-Joint (TMIP-J) and elements of Medical Communications for Combat Casualty Care (MC4), TMIP-Air Force, TMIP-Maritime and TMIP-Marine Corps.

Operating under the Program Executive Office (PEO) Defense Healthcare Management Systems (DHMS), JOMIS will manage TMIP-J's legacy software suite. JOMIS will also work in collaboration with the Defense Healthcare Management Systems Modernization (DHMSM) new electronic health record (EHR) efforts.

In coordination with DHMS program offices, the Service's Infrastructure Offices and the Defense Health Agency, JOMIS will provide capabilities that allow medical personnel in any operational environment access to the most relevant medical data for medical services and medical situational awareness across the full range of military operations.

PROGRAM STRATEGY

The JOMIS PMO will focus on three efforts that directly provide information technology capabilities to support an operational medicine environment.

First, DoD's legacy operational medicine system, TMIP-J, is slated to enter into sustainment in December 2015 with the final release of TMIP-J Increment 2 Release 3 (TMIP-J I2R3) software. The JOMIS PMO will work with the Services to ensure legacy systems support operational medicine needs until the introduction of required operational environment improvements.

Secondly, the first release of JOMIS software will include the new EHR capabilities acquired by the DHMSM program. The JOMIS PMO will utilize the DHMSM EHR as the core application for accessing, capturing and documenting medical care in an operational environment.

Lastly, the JOMIS PMO is responsible for developing or acquiring any new capabilities to meet evolving operational requirements captured in an emerging Capabilities Development Document (CDD).

FY15 OBJECTIVES

• Develop and obtain approval for JOMIS PMO Acquisition Strategy
• Complete Multi-Service Operational Test and Evaluation for TMIP-J I2R3
• Perform a comprehensive product evaluation and gap analysis of the DHMSM new EHR with the emerging CDD immediately following contract award
• Begin preparation for joint testing with DHMSM for initial JOMIS release to the operational environment
• Conduct joint testing events with DHMSM to test new EHR in the operational environment

SYSTEMS UNDER JOMIS PMO

The final TMIP-J software release will be modernized using capabilities acquired under the DHMSM EHR modernization, at which time the new software baseline will be renamed "JOMIS" to differentiate it from the legacy TMIP-J software suite.

The current TMIP-J legacy systems support the military's continuum of care from the battlefield to the home front including health data sharing with the Department of Veterans Affairs for follow-on care.

CLINICAL SYSTEMS

AHLTA

AHLTA-Theater (AHLTA-T)
AHLTA-T is a fully compatible and deployable system with a similar look, feel and functionality as AHLTA, but tailored to operate in the Theater environment.

MCC

Mobile Computing Capability (MCC)
MCC empowers first responders and providers at Level I treatment facilities with handheld mobility for health care documentation. MCC records the history, physical exam and disposition in structured data terminology.

TMDS

Theater Medical Data Store (TMDS)
TMDS serves as the authoritative Theater database for service members' medical information. Clinicians and caregivers, in both Theater and CONUS facilities, can use TMDS to view individual inpatient and outpatient records for patients treated in Theater and patients receiving continuing care at Level IV facilities. Users can view all Theater clinical information, including progress notes, laboratory, drug and radiological history.

TC2

Theater Medical Information Program (TMIP) Composite Health Care System Caché (TC2)
TC2 provides military health care providers an environment to access and document inpatient health, ancillary services order-entry, and result reporting in a deployed environment. Using the TMIP Framework for transmission of data to the Theater Medical Data Store (TMDS), TC2 provides laboratory, radiology and pharmacy ordering and results retrieval capabilities.

TMIP

Theater Medical Information Program (TMIP) Reporting
TMIP Reporting provides reporting capabilities on patient demographics, clinical and other pertinent data utilizing the information residing in the AHLTA-T database.

MEDICAL AND LOGISTICS SUPPORT SYSTEMS

MMM

Maritime Medical Modules (MMM)
MMM is an automated, multi-user medical support application that tracks medical and dental readiness, environmental conditions, radiation exposure and medical supplies of operational units.

DTRS/TIR

Deployable Tele-Radiology System/Theater Image Repository (DTRS/TIR)
The DTRS/TIR provides health care clinicians in Theater access to radiographic images for tele-radiology and transfer back to definitive care military treatment facilities.

DMLSS

Defense Medical Logistics Standard Support (DMLSS) Customer Assistance Module (DCAM)
DCAM is a medical logistics ordering tool used by all Services that allows users to view their supplier's catalog and generate electronic orders. DMLSS is an automated and integrated information system with a comprehensive range of medical material, equipment, war reserve materiel and facilities management functions for the Military Health System.

PMITS

Patient Movement Items Tracking System (PMITS)
PMITS is an information technology system within the Defense Medical Logistics – Enterprise Solution (DML-ES) portfolio. The DML-ES portfolio provides a continuum of medical logistics support, and PMITS tracks the status and location of biomedical equipment used during aeromedical evacuations of patients.

COMMAND AND CONTROL SUPPORT SYSTEMS

MSAT

Medical Situational Awareness in the Theater (MSAT)
MSAT provides Joint Planners and Command and Control staff with actionable knowledge and enhanced medical situational awareness to assess risks, mitigate operational vulnerabilities and allocate scarce combat resources. MSAT links information that encompasses disease and non-battle related injuries, physical and psychological trauma, patient tracking, environmental health, weather and chemical/biological threats.

TRAC2ES

TRAC2ES Mobile
The Transportation Command (TRANSCOM) Regulating and Command & Control Evacuation System (TRAC2ES) Mobile is an application on MC4 laptops that helps deployed medical staff coordinate and monitor patient movement between medical treatment facilities during peacetime, contingencies and war, including mass casualty situations.

Attachment 2
Select Applicable Technical Documents

ATTACHMENT 2

Select Applicable Technical Documents

1. DoD 5200.2-R, "Personnel Security Program," current version

2. DoD Instruction 8500.01, "Cybersecurity", March 14, 2014

3. The DoD Open System Architecture (OSA) Contract Guidebook for Program Mangers, Version 1.1, June 2013

4. DoD Directive 8530.1, "Computer Network Defense (CND)", January 8, 2001

5. DoD Instruction 8510.01, "Risk Management Framework (RMF) for DoD Information Technology (IT)", March 12, 2014

6. MIL-STD-882E "Department of Defense Standard Practice System Safety" May 11, 2012

7. DoD Instruction "Sharing Data, Information, and Information Technology (IT) Services in the Department of Defense" (DODI 8320.02), issued August 5, 2013

8. OMB Circular A-130, Management of Federal Information Resources (November 28,2000)

9. National Institute of Standards and Technology: Federal Information Processing Standards (FIPS) http://www.nist.gov/itl/fipscurrent.cfm

10. DoDI 5000.64, Accountability and Management of DoD Equipment and Other Accountable Property, May 19, 2011

11. MIL-STD-130N, DoD Standard Practice Identification Marking of US Military Property, 16 November 2012

12. MIL-STD-881C, Department of Defense Standard: Work Breakdown Structures (WBSs) For Defense Materiel Items, October 3, 2011

13. Joint Publication (JP) 4-02, Health Service Support, July 26, 2012

14. DoD 5000.04-M-1 Cost and Software Data Reporting (CSDR) Manual, November 4, 2011

15. American National Standards Institute / Electronic Industries Alliance (ANSI/EIA) 748C, March 2013

16. Health Information Technology for Economic and Clinical Health Act, Feb 17, 2009

17. DoD Joint System Safety Engineering Handbook

18. PEO Risk Management Plan

19. DHMSM Deployment, Training, Change Management Plan

20. DHMSM Engineering Master Plan

21. DHMSM Test Strategy

22. DHMSM Government Approved Labs Plan

23. PEO Configuration Management Plan

24. PEO Requirements Management Plan

25. PEO Cybersecurity Strategy

26. PEO Data Management Strategy

27. PEO Release and Deployment Management Plan

28. DHMSM Data Communications Network and Enterprise Services Infrastructure Framework

29. DHMSM Interface Strategy

30. International Organization for Standardization (ISO) / International Electrotechnical Commission (IEC) 25010:2011, March 1, 2011

31. DoD AI-15 OSD Records and Information Management Program, May 3, 2013

32. DoD Manual 5220.22M National Industrial Security Program Operating Manual (NISPOM), February 28, 2006

33. Directive-Type Memorandum (DTM) 08-003, "Next Generation Common Access Card. (CAC) Implementation Guidance," December 1, 2008

34. DoDI 8500.2, Information Assurance (IA) Implementation, February 6, 2003

35. DISA Approved Product List (https://aplits.disa.mil/processAPList.do)

36. ISO/IEC 12207 IEEE Std. 12207-2008, Second edition 2008-02-01, "Systems and software engineering – Software life cycle processes"

37. Homeland Security Presidential Directive 12 (HSPD-12): Policy for a Common Identification Standard for Federal Employees and Contractors, August 27, 2004

38. Form I-9 "Employment Eligibility Verification" (http://www.uscis.gov/files/form/i-9.pdf) in OMB No. 115-0136

39. DoD 8570.01-M, December 19, 2005

40. DoD Directive 5205.02E, June 20, 2012

41. Office of Management and Budget (OMB) Memorandum 99-05, Attachment B

42. DoD Privacy Impact Assessment (PIA) Guidance, February 12, 2009

43. DD Form 2930, November 2008

44. DoD 5400.11-R, "DoD Privacy Program", May 14, 2007

45. DoDI 5200.44, November 5, 2012

Attachment 3
Joint Concept for Health Services

Joint Concept for Health Services
(JCHS)

31 August 2015

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FOREWORD

The *Joint Concept for Health Services (JCHS)* describes in broad terms the Chairman of the Joint Chiefs of Staff's 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 JCHS describes the fundamental purposes of comprehensive health services to deployed forces in an operating environment characterized by highly distributed operations and minimal, if any, pre-established health service infrastructure. This concept offers a way to address these challenges, defining a framework of key ideas to guide the provision of health services and to identify solutions to joint capability requirements that will enhance interoperability and global agility. This framework also establishes a perspective for joint health care to guide Combatant Command, Service, Defense Health Agency, and Joint Staff efforts to achieve unity of effort for joint health service operations.

Each Service has a vital role in providing health services that support Globally Integrated Operations. This concept was developed with representation from each of the Services and from across the Joint Staff in coordination with the Combatant Commands, multinational partners, and other key stakeholders.

The need for integrated medical support that keeps pace with the operational agility and organizational flexibility requirements to support Globally Integrated Operations is clear. The Joint Concept for Health Services is a critical step in ensuring that the Joint Force has the requisite capabilities to do so.

PAUL J. SELVA
General, U.S. Air Force
Acting Chairman

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EXECUTIVE SUMMARY

The *Capstone Concept for Joint Operations: Joint Force 2020* (CCJO) envisions a globally postured Joint Force that can quickly combine capabilities in a future security environment that may be more unpredictable, complex, and potentially dangerous than today's environment. These Globally Integrated Operations (GIO) will stress the Joint Force's ability to provide health services for deployed forces and mission partners. The *Joint Concept for Health Services (JCHS)* responds to these challenges, describing how the future Joint Force will provide health services in support of activities across the range of military operations.

Purpose and Scope. The JCHS seeks to apply the lessons learned from recent combat experiences as well as analysis of future concepts of operations (CONOPs) to shape future solutions to the many health-care challenges the Joint Force will face when conducting GIO. It applies to Combatant Commands, Services, the Joint Staff, and Combat Support Agencies and includes all medical components, active and reserve. While focused on Department of Defense (DoD) activities and capabilities, the concept acknowledges the likely participation of other interagency, foreign governmental, and nongovernmental mission partners during the conduct of military operations.

Future Operating Environment. This concept responds to a future security environment projected to remain uncertain and complicated with increasing trends of instability and conflict. In this environment the Quadrennial Defense Review and the CCJO envision a shift from the relatively static operations in Iraq and Afghanistan to sustained engagement and force projection/crisis response operations. These operations will require the future Joint Force to quickly combine capabilities; deploy long distances from multiple, widely dispersed locations; and conduct missions across the range of military operations, often in austere and contested environments.

Globalization and the proliferation of technology and information, however, will challenge the ability of U.S. Forces to maintain current capability advantages over state and non-state adversaries during these operations. These adversaries may well obtain equivalency or even superiority in the various operating domains, thereby increasing the threat to the health of the force, increasing operational risk, and potentially limiting Joint Force freedom of action.

The future operating environment and the Joint Force's GIO response pose several issues for the provision of health care. These issues include supporting forces that are dispersed over great distances and that must be able to rapidly aggregate/disaggregate, providing health services to forces that are increasingly being integrated at lower echelons than is currently the case, and integrating with non-DoD mission partners. These challenges must be addressed in a

strategic environment that is becoming more fiscally constrained while still meeting the high expectations for positive medical outcomes.

<u>Military Problem</u>. Faced with the challenges above, the JCHS seeks to address the following military problem:

How can the Joint Force provide comprehensive health services to deployed forces in an operating environment characterized by highly distributed operations and minimal, if any, pre-established health service infrastructure?

<u>Central Idea</u>. The future Joint Force will address this problem with Globally Integrated Health Services (GIHS). GIHS is the strategic management and global synchronization of joint operational health services that are sufficiently modular, interoperable, and networked to enable the Joint Force Commander to quickly and efficiently combine and synchronize capabilities. These future health services will be characterized by 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.

Seven core supporting ideas describe GIHS:

- **Integrated Joint Requirements in Medical Force Development** that mitigate threats to health services specifically, and the Joint Force generally, in contested environments.

- **Global Synchronization of Health Services** that plan, integrate, and sustain medical resources efficiently and quickly on a global scale.

- **Modular and Interoperable Medical Capabilities** that meet a core set of joint standards and requirements while also conforming to Service-specific requirements.

- **Global Network of Health Service Nodes** that incorporate mission partners and are flexible enough to rapidly mobilize and deploy medical capabilities and resources.

- **Tailored Medical Forces and Operations** that reduce lift requirements, sustainment requirements, and physical presence while improving quality of care.

- **Leaders Integrating Joint Medical Capabilities** who are adaptive, skilled, and can synchronize multiple efforts across multiple domains to ensure unity of health service efforts.

- **Improved Performance** through appropriate balance between sustainment of current readiness through healthcare delivery in medical beneficiary markets, targeted warfighting clinical education and training, and investment in future capabilities.

<u>Capability Requirements</u>. This concept identifies 16 capabilities required to employ and sustain comprehensive, responsive, and flexible health services in support of GIO. These capabilities will be further examined during follow-on assessment and implementation.

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Table of Contents

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1. **Introduction**

The *Joint Concept for Health Services (JCHS)* describes how the future Joint Force will provide health-care services in support of Globally Integrated Operations (GIO) as articulated in the *Capstone Concept for Joint Operations: Joint Force 2020* (CCJO). The CCJO requires a globally postured Joint Force to quickly combine capabilities in a future security environment that may be more unpredictable, complex, and potentially dangerous than today's. GIO will stress the Joint Force's ability to provide health services for deployed forces and mission partners.

Elements of Globally Integrated Operations (GIO)
• Mission command
• Seize, retain, and exploit the initiative
• Global agility
• Partnering
• Flexibility
• Cross-domain synergy
• Flexible, low signature capabilities
• Minimize unintended consequences

The Department of Defense (DoD) effort to improve "jointness" across the force has continued to challenge military health-care efforts to adapt, as each Military Department maintains nominal responsibility for the health of its respective Service members from point-of-injury through rehabilitative care. In practice, health services are applied to eligible patients, irrespective of Service (and at times nationality), in an unanticipated patchwork of Service and partner capabilities that begins with the first responder, proceeding through forward resuscitative and definitive care in a Joint Operations Area (JOA), and culminating with longer-term care at complex and robustly resourced fixed facilities able to apply the full spectrum of definitive/rehabilitative medical capabilities.

In recent operations, Service collaboration overcame shortcomings across the Joint Doctrine, Organization, Training, Materiel, Leadership, Personnel, Facilities, and Policy (DOTMLPF-P) spectrum for health services. This collaboration significantly advanced the provision of joint health services, especially in the prevention of disease and injury; delivery of combat casualty care to include wound care and hemorrhage control; and the provision of critical care during evacuation. However, increases in the efficiency and effectiveness of operational medical support resulted from ad hoc, temporary solutions. The JCHS seeks to apply the lessons learned from recent combat experiences to propose a joint concept that will shape future solutions to the many additional challenges the Joint Force will face when conducting GIO.

The military medical community's performance in Iraq and Afghanistan provided valuable insight on the types of changes, concerns, and medical capabilities required for the future Joint Force. To take advantage of these insights, the Department of Defense must better synchronize policies, procedures, andinvestments in health services to sustain the current quality of care while ensuring the Joint Force can support GIO. Disparate application of

the Services' respective medical capabilities makes supporting the Joint Force difficult and inefficient without increasing effectiveness.

2. **Purpose**

The purpose of this joint concept is to offer a way to address these challenges and guide future force development by:

- Establishing a framework for the provision of joint health services for use by senior policy makers, Warfighters, and the medical community of interest.

- Informing studies, wargaming, and experimentation resulting in recommendations to DOTMLPF-P.

- Establishing a joint medical context to guide Combatant Command (CCMD), Service, Joint Staff, and Defense Health Agency efforts to achieve unity of effort for joint health service operations.

3. **Scope**

The JCHS applies to CCMDs, Services, Joint Staff, and Combat Support Agencies and includes all medical components, active and reserve, across the range of military operations. While focused on the employment of the United States (U.S.) Joint Force, this concept acknowledges the likely participation of interagency, nongovernmental organizations (NGOs), and foreign partners in the provision of health services in joint operations. While the JCHS identifies capabilities required to implement the concept, it does not establish specific programmatic requirements.

4. **Health Service Challenges in the Future Operational Environment**

The CCJO envisions a future operating environment that is more unpredictable, complex, and potentially dangerous than today. The 2014 Quadrennial Defense Review and the CCJO envision a shift from the relatively static operations in Iraq and Afghanistan to sustained engagement and force projection/crisis response operations. The DOD will respond with GIO using smaller, more agile forces that combine quickly and integrate capabilities across domains, echelons, geographic boundaries, and organizational affiliations.

GIO require the Joint Force to quickly combine capabilities, deploy long distances from multiple, widely dispersed locations, and conduct missions across the range of military operations in austere and non-permissive environments. Diverse enemies will employ traditional, unconventional, and hybrid strategies to threaten U.S. security and vital interests. Anticipating the demands of future armed conflict requires an understanding of the nature of war as well as an appreciation for changes in the character of armed conflict.

Threats may emanate from nation states or non-state actors such as transnational terrorists, insurgents, and criminal organizations. These conditions may complicate medical support, especially forward resuscitative care, theater hospitalization, and the entire spectrum of patient evacuation. Wide dispersion also inherently complicates medical support as medical functions tend to benefit from economies of scale. It is generally simpler to provide medical support to a single unit on a single line of communication than multiple units operating on multiple, disparate lines of communication.

Providing health services support to GIO will require constant medical planning and execution to keep pace with rapid operational transitions and to address a wide range of health threats. GIO calls for distributed units to be able to aggregate quickly; converge and combine rapidly into larger formations, often across unit, Service, agency or even national boundaries in response to emerging crises; and then disaggregate and reconfigure as the situation changes. This rapid aggregation/disaggregation of forces will stress current medical operational relationships and the ability to treat, evacuate, conduct biosurveillance and protection, use information technology, and employ medical logistics systems.

The integration of combat units at lower echelons in support of GIO will require better integrated delivery of health services than previously required. Accordingly, the future medical force must be able to support Service-unique missions while also operating with an optimal degree of inter-Service integration. This integration begins with a base level of interoperability in which capabilities from more than one Service can operate together to accomplish assigned tasks at a joint theater-wide scale. It is furthered when the Services embed aims of enhancing interoperability in capability development areas such as medical equipment and logistics; clinical databases, patient administration and management systems; techniques and procedures; and, to some degree, medical research and technology development. Interoperability goals should be applied judiciously so Service-specific capabilities may persist to support unique operational environments or characteristics.

The growing sophistication and specialization of military medicine will generate a greater demand and wider variety of medical capabilities in theater. Advanced technologies, new diagnostic tools, innovative treatment protocols, and increased specialization have dramatically increased the capabilities of medical care. Magnetic Resonance Imaging and Computed Tomography scans are just a few of the resource-intensive capabilities in widespread use that previously were rarely available. It is expensive to develop, acquire, and manage these resource-intensive medical capabilities and costs will likely increase. Greater medical capability tends to generate increased medical requirements.

Another challenge is the perishable nature of medical skills and knowledge and the difficulty in sustaining these skills given the individual's scope of practice and DoD fiscal realities. Enhanced combat casualty care training curriculums and Clinical Practice Guidelines contributed to battlefield survivability, but are more resource-intensive. Additionally, medical research, sophisticated diagnostic equipment, advances in resuscitative and rehabilitative care, and medical research, development, test and evaluation have all significantly increased achievable patient outcomes of medical care, but also incurred the consequences of increased expectations, costs, and complexity.

The joint assessment of medical requirements, following acceptance of this concept, will inform and guide the Services with their force development and risk management by increasing inter-Service communication regarding the integration of capabilities; this will assist with prioritization of resources in support of reducing redundancy and improving processes. The growing cost of health care relative to overall defense spending should provide additional impetus to jointly innovate to maximize resources.

An additional challenge in the future operating environment is the increasing incorporation of potential interagency, NGO, and multinational partners who may not meet U.S. accepted standards of care. This will require increasing engagement with respective medical partners and leveraging access to external medical resources for joint forces. The role and the commitment of medical partners will vary from situation to situation according to a large number of factors, such as the wills, skills, and resources available to partners.

Some partners will contribute medical support to the overall effort, whether in support of their own elements or in lieu of other contributions. Their medical capabilities will vary, as will their standards of care, medical proficiency, and diagnostic and treatment protocols/equipment. Other partners will look to the U.S. Joint Force as the partner with the most resources for medical support. The exact combination of partner contributions and requirements will be unique to each situation. U.S. Forces should expect to be the largest medical contributor to a coalition force, potentially placing additional demands on the provision of health services.

Integrating all partner capabilities and requirements into the broader medical effort will be necessary, and the United States may potentially guide the integration. Given the variety of medical material, protocols, and casualty/patient information systems, integration will be crucial to providing medical support at all echelons, especially when supporting small units in remote locations.

The future operating environment will additionally complicate health-care delivery with a dynamic array of medical challenges such as new chemical, biological, and radiological threats; man-made nanotechnology and bio-

engineered threats; and new types of wounds caused by evolving weapons technology. The lack of mature medical infrastructure in operational areas and the adversary anti-access/area denial efforts will challenge the ability to provide health care at the point of injury and stage patients for evacuation, as well as increase the transit time to definitive care. Enemy threats and constraints of the environment will challenge the application of a "golden hour" standard in a medical treatment/evacuation paradigm. These challenges may increase the need for partnering to provide medical support at all echelons, especially when supporting small units in remote locations.

Last, the future operating environment will challenge health services as U.S. Forces may not have the benefit of both a robust theater medical infrastructure and domain dominance to enable forward positioned care without significant threat from enemy forces. Additionally, advancements in military medicine throughout recent conflicts create increased expectations for positive medical outcomes for combat-related trauma.

5. **The Military Problem**

Given the expected operational environment and future way of operating as described in the CCJO and other joint concepts, the JCHS seeks to address the following military problem:

How can the Joint Force provide comprehensive health services to deployed forces in a contested operating environment characterized by highly distributed operations and minimal, if any, pre-established health service infrastructure?

6. **The Central Idea**

Globally Integrated Health Services (GIHS) is the strategic management and global synchronization of joint operational health services that are sufficiently modular, interoperable, and networked to enable their quick and efficient combination and synchronization by a Joint Force Commander (JFC). GIHS also promulgates the idea that the provision of health services to the future Joint Force will be characterized by 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.

It is characterized by the following core supporting ideas (Figure 1):
- Integrated Joint Requirements in Medical Force Development
- Global Synchronization of Health Services
- Modular and Interoperable Medical Capabilities
- Global Network of Health Service Nodes
- Tailored Medical Forces and Operations

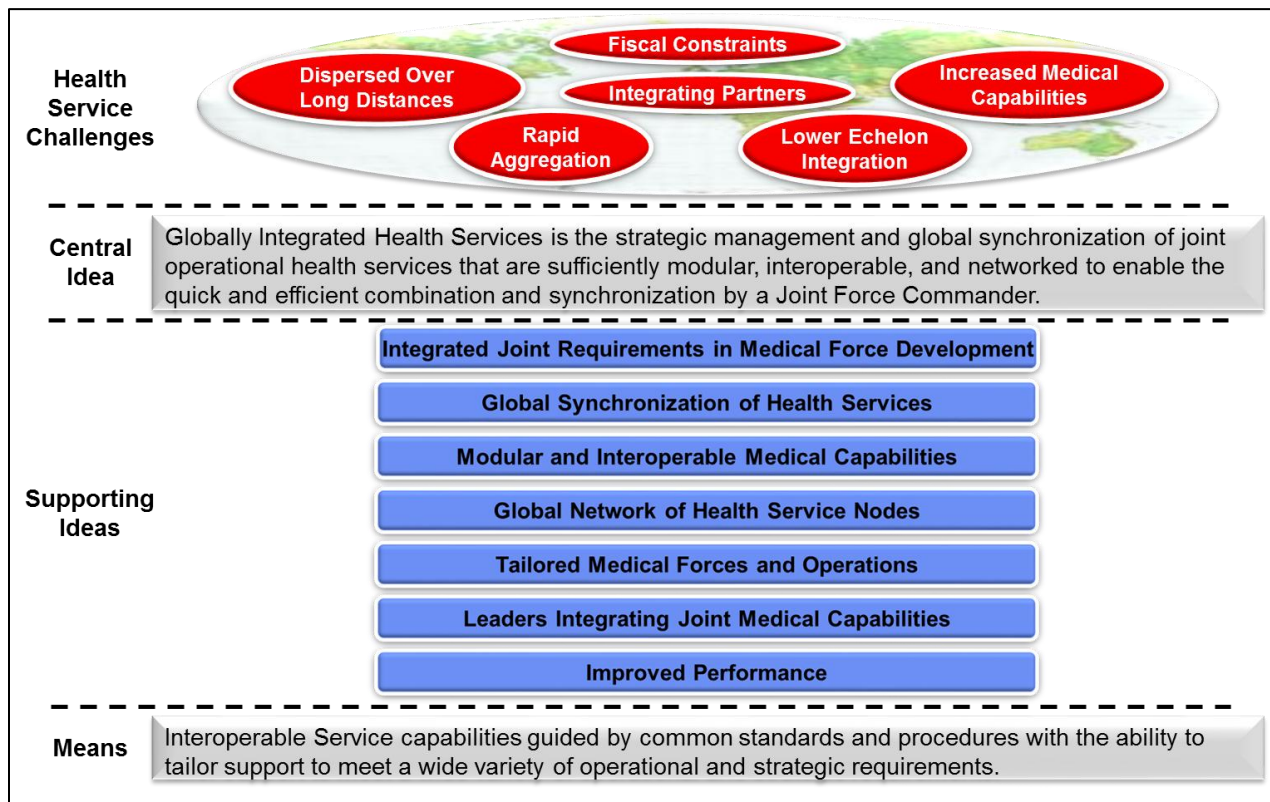- Leaders Integrating Joint Medical Capabilities

- Improved Performance

Figure 1. JCHS Visualization

While GIHS is a concept for providing joint medical operations, many required actions must occur well before the beginning of those operations. Examples include consideration of lessons learned from previous operations; advancement of medical issues in the research, development, and acquisition processes; identification of medical infrastructure requirements, including military medical treatment facilities (MTFs) and medical research laboratories; provision of education and training; inclusion of health service input into force development; and participation in contingency and operations planning to ensure alignment with strategic priorities.

The Joint Force will suffer casualties in the face of advanced and asymmetric threats. The enemy is unlikely to discriminate between combat and medical forces as targets. GIHS will allow medical forces to mitigate their possible attrition by selectively aggregating and disaggregating capabilities. Furthermore, medical integration will allow U.S. Forces to operate better in dispersed locations, thus complicating the enemy's area-denial efforts.

Another consideration is the evolving nature of battlespace geometry from a linear framework to one that is more multidimensional. Consequently, the

continuum of care must also break with its linear alignment and evolve to a networked configuration. Medical support must be capable of rapidly adapting to operational conditions, ensuring the right medical capabilities are available at the right place and right time. These medical capabilities will need to be provided through a scalable and interoperable joint health services network that puts a premium on prevention and mitigation; restoring health; and integrating life-, limb-, and eyesight-saving capabilities.

7. Supporting Ideas

a. Integrated Joint Requirements in Medical Force Development

Global agility, the foundation for GIO, comprises transporting and supporting combat power over extended distances from widely distributed locations. This makes GIO impractical without a joint integration of operational health services. Integrated force development will help mitigate the threats to health services specifically, and the Joint Force generally, in contested environments. Joint interoperable medical capabilities are the key to providing medical support to joint operations, especially in contested environments. Providing health services in contested environments will necessitate delivery of medical care that is not dependent upon existing facilities or new infrastructure. Interoperability and employment of complementary medical capabilities can reduce operational risk, especially when providing medical and surgical care that incorporates the latest medical technology.

Interoperable health service capabilities provide more options to support GIO. This may include use of medical capability solutions across Services, agencies, and coalition/national lines, where feasible. This may also minimize redundancies while sharing capabilities or alternating sources of the required capability (see Figure 2).
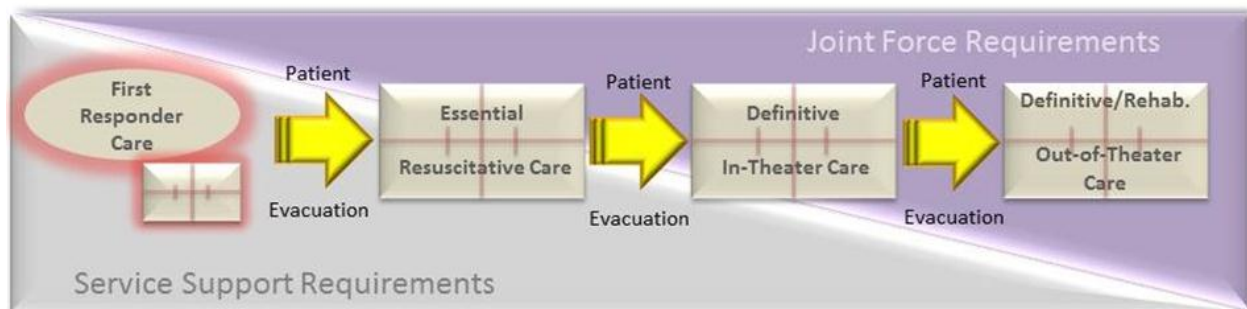

Figure 2. Consideration of Requirements for Medical Treatment Facility and Patient Evacuation Capabilities

Predictive joint analysis is another key aspect of force development. This means extracting information from existing data sets to determine medical patterns and predict future trends. These assessments, combined with health surveillance, develop robust global medical profiles that identify potential

health threats, provide data for regional and global biosurveillance, and assess a likely partner's medical capabilities. Expected threats may include trauma and burns as well as chemical, biological, radiological, nuclear, and explosives (CBRNE) agents and effects, which may also include naturally-occurring and biologically engineered emerging diseases. Adaptive adversaries combined with advances in technologies, including nanotechnology, may increase the risk to the Joint Force. Expected threats such as these should be assessed and mitigated with risk reduction measures through the application of health services and/or force development activities.

b. Global Synchronization of Health Services

This concept calls for mechanisms that can plan, integrate, and sustain medical resources efficiently and quickly on a global scale in support of the operational needs of the Combatant Commanders (CCDRs). Analysis of the future operational environment suggests that current methods of medical force management and allocation will likely be insufficient to meet the demands imposed by GIO. CCMDs will require systems and processes that can request tailored medical capabilities rather than a whole organization. This mechanism is an important part of the answer to the challenges of achieving global agility and maximizing efficient use of limited medical resources and capabilities.

This concept is agnostic to the form such mechanisms should take, whether procedures or organizations. Just as Global Force Management (GFM) strives for efficient and timely allocation and distribution of other functional capabilities, it must also pursue the same for medical capabilities. The intent is to ensure that CCMDs have better and timely access to any medical resources that could support their operations.

c. Modular and Interoperable Medical Capabilities

While acknowledging that the Services will continue to have different constraints for various capabilities, this concept advocates an optimal balance of Service modularity and inter-Service interoperability. This will permit Services to detach capabilities from a parent unit and employ them with sister Service capabilities in an interoperable format in potentially austere environments. This employment will require capability sets to meet a core set of joint standards and requirements while also conforming to Service-specific capability requirements. This is an essential idea for GIHS and requires medical capabilities that are scalable and agile enough to support rapid aggregation of forces from distributed units and for joint integration at all levels.

Current Service medical support configurations, primarily designed for a major war against a regional or global power, may struggle to match actual requirements for GIO. Hence, medical capabilities should achieve more than

the sum of independently developed Service programs by maximizing opportunities for interoperability, and attain a more seamless provision of capabilities through joint development and adoption of joint standards.

GIHS must be more responsive than current health services to support diverse contingency operations. The growing trend toward smaller Joint Force deployments, conducting a variety of missions with different medical requirements from engagement to combat, requires a "pick list" of joint medical capabilities for tailored support and economy of force. Without compromising support to Service-unique missions, these capabilities need to be further developed jointly and optimized to support joint health service operations across the contingency spectrum.

The notion of interoperability implies a level of standardization and commonality of technology, procedures, and a mutual lexicon. Joint interoperability is maximized by the joint development of Service medical capabilities with joint interoperability and scalability inherent from the beginning. Where this is impractical due to differing mission requirements of the Services, deliberate assessment should take place to identify opportunities for optimizing interoperability.

While Service medical capabilities may not be interchangeable, they may be interoperable and, in some cases, interdependent. In some circumstances, resources can be optimized and redundancies minimized without compromising medical capabilities that are needed to support Service-unique requirements.

In all cases, rapid and effective medical treatment must be delivered with an emphasis on providing initial stabilizing care followed by forward/resuscitative treatment. Theater treatment facilities must be task organized, with a minimized footprint and proportionally supported by patient evacuation and medical logistics assets. These joint capabilities must be light, agile, interoperable, and able to globally support highly mobile and dispersed Joint Force assets.

d. Global Network of Health Service Nodes

GIHS can be thought of as a network of multi-purpose health service delivery points (e.g., MTFs, clinics, mission partner facilities, deployable/modular capabilities). These delivery points, or "nodes," are connected by virtual and physical lines of communication to ensure that the Joint Force receives the medical support needed to maintain global agility.

This worldwide network must be flexible enough to rapidly reconfigure and respond to changing conditions and threats in the operational environment, with activities and lines of effort synchronized to ensure rapid mobilization and deployment of medical capabilities and resources in support of GIO. Once

deployed and established, this network of nodes must be able to provide health services for joint forces conducting concurrent distributed operations in multiple theaters or in multiple locations within a single theater, to include in anti-access or area denial situations.

This global network may include non-DoD mission partners (interagency, foreign governmental, or non-governmental), which will require expansion of health service coordination and synchronization efforts. This requires working with partners to identify the precise medical capabilities they can offer, how each of these capabilities can interface with other nodes and capabilities, and how these partners will sustain their contributions to create an integrated package. It also includes continued leadership in developing multinational interoperability through standardization agreements among mission partners. This does not mean everything has to be integrated into one medical package, or necessarily delivered in one place. It does mean arranging all health services so partner contributions are not disjointed and are easily accessible for employment. This will involve coordinating and managing medical elements into an integrated set of capabilities, to include interagency and multinational partners.

Assisting partners to develop and sustain their health service networks to ensure capabilities are suitable and accessible when needed will require extensive, persistent engagement as well as coordination to facilitate bilateral or multilateral-negotiated access with foreign governmental and/or private partners. Investments in global health engagement may support the development of an improved understanding of non-U.S. health systems to better inform these activities. Even then, access to mission partner health services will not be guaranteed. A foreign nation's decision to provide access may be contingent on political circumstances, so it will be important to have a wide network of potential options from which to build an operational health system within an area of operations.

Providing global health services requires consideration of all potential partners. This also includes domestic and foreign private sector service contract networks, potentially providing even greater flexibility and agility for projecting military power across all domains to resolve crises and defeat enemies.

e. Tailored Medical Forces and Operations

In recent conflicts, U.S. Forces enjoyed unimpeded patient evacuation and access to medical logistics, combined with robust trauma care resulting in unprecedentedly low morbidity/mortality rates. Medical operations in the much more restrictive conditions of a contested environment or in broadly dispersed locations with limited physical presence will be challenged to achieve this same degree of positive medical outcomes. In contested environments, higher casualty rates may create the need to conduct deliberate combat

operations to open patient treatment spaces or "windows of opportunity" for evacuation corridors. These conditions may also require more mobile medical force packages (i.e., smaller and lighter) by leveraging more robust "off-shore" capabilities in safe havens or sea-based platforms.

Supporting GIO will require new health service employment concepts and policies, exploiting emerging technology and new platforms for resuscitative care, hospitalization, and en route care, etc., to simultaneously support multiple dispersed operations. Responding to these challenges may require medical capabilities like advanced patient holding, advanced stabilization technologies and capabilities, robust initial-entry trauma treatment, and tiered Tactical Combat Casualty Care for nonmedical personnel (self-aid/buddy-aid) and for pre-hospital providers (medics/corpsmen) with a greater clinical scope for conducting trauma, primary care, and en route care.

Developing smaller, lighter, energy-efficient medical equipment and supplies that are interoperable will reduce lift requirements. Maximizing medical technology to augment medical care, such as telemedicine and autonomous systems that are bandwidth efficient and integrated into the joint information environment, can provide capabilities with less physical presence. Increasing the shelf life and decreasing special handling requirements for medical supplies and blood products will reduce logistics infrastructure and simplify distribution operations.

f. Leaders Integrating Joint Medical Capabilities

Critical to implementing GIHS are adaptive, skilled medical leaders and planners who can synchronize multiple efforts across multiple domains to ensure unity of effort. To best support GIHS in the future operational environment, these medical leaders and planners must be deliberately developed and equipped with tools that enable effective, agile, and adaptive medical planning. Key elements in this process include consideration of lessons learned from previous operations and inclusion of information about joint medical capabilities in all career courses and functional schools to promote understanding of the sustainment implications of medical capabilities in force design and employment. It also requires that all medical career paths include Joint Professional Military Education to understand the profession of arms. This education and training should be developed in tandem with development of a career progression model that identifies key assignments that impart the experience and knowledge crucial to understand and solve the complex and dynamic challenges associated with GIHS. These steps could produce medical leaders and staffs who understand how to plan, coordinate, and build synergy from medical capabilities inherent in all the Services, interagency, multinational partners, and NGOs. The ultimate outcomes will be medical professionals capable of operating within a joint framework and warfighting leaders informed of the force-multiplying capabilities of joint health services.

g. Improved Performance

Likewise, GIHS requires resource programming and investments driven by force management needs of joint and Service medical capabilities to improve performance of operations and delivery of healthcare. Well-informed investment in research and development, medical infrastructure, and future medical performance is critical. The medical community must achieve appropriate balance between the sustainment of current readiness through healthcare delivery in medical beneficiary markets, targeted warfighting clinical education and training, and investment in future capabilities. This requires rethinking the role of programmatic oversight and collaboration to create medical capabilities more effectively and efficiently, and in the integrated and synchronized manner intended by the JCHS. As an example, the Joint Theater Trauma System (JTTS), modeled after a civilian system, was established as a joint clinical performance management system chartered to improve medical outcomes. The JTTS contributed to the improved survival after battlefield injury and established the standard for trauma care. The JCHS calls for integrated resourcing and minimizing redundancies without compromising Service-unique requirements, while maintaining flexible options for supporting strategic end-states. Integrated performance must be supported with adequate resourcing.

Historical Vignette: Antietam

In June 1862, MG McClellan promoted Maj. Dr. Jonathan Letterman to Medical Director of the Army of the Potomac. By September, Maj. Letterman devised an efficient system of casualty management, beginning with first aid adjacent to the battlefield, removal of the wounded by an organized ambulance system to field hospitals for urgent and stabilizing treatment, and then referral to general hospitals for longer-term definitive management. This three-stage approach to casualty management, strengthened by effective and efficient transportation, proved invaluable.

On the morning of 17 September 1862, 130,000 soldiers were ready for battle. Total casualties on both sides, killed, missing and wounded, were 23,000—more Americans died on 17 September 1862 than on any other day in the Nation's military history, including World War II's D-Day. Within 24 hours of the battle, all Federal wounded were secured in hospitals, and within 48 hours the abandoned Confederate wounded were secured as well. This contrasted starkly with the aftermath of previous battles, such as First Bull Run, where the wounded languished on the field for more than a week, often dying from exposure. Advances in battlefield medicine and casualty management were a success.

Shortly after the Civil War, many of these advances were lost. Institutional memory lapses combined with a downsizing of the force caused the U.S. to relearn these lessons at great human expense in future conflicts. The lessons of military medicine are on display in the operations in Iraq and Afghanistan. The medical community's performance in Iraq and Afghanistan has provided valuable insights on the types of challenges and medical capabilities required to support future joint operations. The Joint Concept for Health Services seeks to institutionalize the many advances in medical operations achieved through collaboration in the war zone. Additionally, it will codify an approach to capture changing medical capabilities in response to the evolving requirements of the Joint Force.

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8. Concept Required Capabilities

The JCHS entails a set of both evolved and potentially novel required capabilities for force development. After analyzing inputs from across the community of interest, the following capabilities emerged as essential to implementation of this concept. They constitute an initial proposal, not an exhaustive or authoritative listing, of required capabilities for additional thought and development. Furthermore, the required capabilities have implications for DOTMLPF-P as well as for integration with interagency and multinational partners. Following concept approval, review and consideration of lessons learned in conjunction with subsequent analysis of these proposed capability requirements within the Joint Capabilities Integration and Development System (JCIDS) shall provide the basis for developing capability solutions to close the operational gap the concept addresses.

Required Capability #1. **Joint Medical Planning**.
Implement the ability to conduct Joint Force medical planning that integrates health service considerations across the JFC's staff; develop medical plans to support JFC intent; synchronize parallel planning at Service or subordinate levels, interagency, and multinational partners; and better support the conduct and sustainment of distributed operations.

Required Capability #2. **Joint Theater Directed Coordination, Synchronization, and Medical Situational Awareness.**
Improve the ability to ensure unity of medical effort in the JOA through joint processes and tools that facilitate medical communication, collaboration, and coordination as well as a common operating picture of health service capabilities and threats to enable a JFC to decide in real time. Medical systems need to be integrated with other DoD and interagency systems where possible.

Required Capability #3. **Monitor Patient Outcomes, Assess Clinical Effects, and Adapt Operations.**
Improve the ability to employ joint medical information systems that track clinical outcomes and trends as well as provide tools to inform and empower the JFC to dynamically adjust resources and capabilities.

Required Capability #4. **Joint Force Development Framework for Health Services.**
Improve the ability to support identification of joint and Service-specific medical force requirements and the development and preparation of medical capabilities in order to meet present and future Service-specific operational needs and, as practical, those of the Joint Force.

Required Capability #5. **Medical Mitigation of the Environment.**
Improve the ability to execute preventive medicine, public health, health surveillance, and health risk assessment that enable the Joint Force to predict, prevent, and mitigate the effects of climate, environment, or other health threats. The distributed nature of GIO may make it particularly difficult for certain mitigation capabilities, such as laboratory support, environmental science, and biosurveillance, which benefit from consolidated forces. This capability encompasses monitoring the health of populations, assessing human and animal disease effects, predicting the effects of the environment, and implementing required individual and patient protection measures and/or collective protection measures.

a. Apply joint technologies, practices, and procedures to create comprehensive preventive medicine, health disease risk assessment, and the ability to triage, treat, and transport individuals with diseases and/or injuries to effect early intervention and control strategies for all occupational and environmental health hazards and CBRNE threats.

b. Adopt joint processes for employment of medical countermeasures. This will minimize the incidence or the severity of disease or illness, including the protection of U.S. personnel against diseases or against CBRNE hazards through the application of uniform and timely Immuno- and Chemo-prophylaxis countermeasures as well as ensure effective use by the Joint Force.

c. Incorporate health risk assessment into all Joint Force planning to improve employment of Force Health Protection measures that may include medical countermeasures and exposure/threat avoidance or minimization through policies, guidance, standards, or criteria.

*Required Capability #6. **Joint Credentialing and Privileging**.* Establish the ability to confirm and communicate the qualifications of healthcare providers, as well as grant permissions and responsibilities to healthcare providers, within their scope of practice, among the Services and across the Department of Defense. This capability should seek to improve interoperability and clinical practice oversight in joint operational environments through development of joint standardized scopes of practice. This capability may also address coalition and interagency partners.

*Required Capability #7. **Medical Treatment Facilities (MTFs)**.* Improve the ability to employ a continuum of healthcare delivery units tailored and scaled for different domains, operational environments, and spectrums of conflict in support of Joint Force operations. MTFs function in multiple roles in support of joint health service support. MTFs provide the DoD's principal platform for attaining currency, as defined and managed by the Services, and developing and maintaining competency in addition to training affiliation agreements with civilian healthcare institutions that extend DoD's capability to train and sustain medical personnel with essential clinical skills.

a. Provide First Responder Care that meets joint clinical standards and promulgates best practices for initial triage and transition into patient status, and that balances the most advanced medical capabilities within the shortest possible time/distance from the point of injury.

b. Provide Essential Resuscitative Care for joint forces that may be integrated at lower echelons, such as battalion or group. This includes stabilizing the patient in preparation for transportation to higher capability treatment facilities.

c. Provide Definitive Care in the JOA to support joint or coalition patients as directed by the JFC, regardless of operational relationships through agile and mission-tailored capabilities that repair, restore, or stabilize patients. These include preparation for further evacuation, return to duty, or processes for rehabilitation, as appropriate.

d. Provide Definitive Care outside the JOA that is planned resourced, and accessed as a Joint Force support asset to improve the ability to provide long-term, complicated, or specialty care capabilities outside the JOA in a supporting CCMD areas of responsibility (AORs). These include the capabilities to repair, restore, stabilize, or rehabilitate the patient for return-to-duty,

improve patient status during planned evacuation stopovers, or prepare patient for transition out of the Department of Defense.

e. Integrate joint and Service clinical, as well as ancillary and support medicine, competency and training requirements, as defined and managed by the Services, into the resourcing and operation of fixed essential care and definitive care facilities and/or base support networks. This integration must account for the difference in training requirements between operational medical currency and garrison.

*Required Capability #8. **Patient Evacuation**.*
Advance the ability to integrate transportation, medical treatment, logistics, and command, control, communications, computers, and intelligence to provide effective en route care and efficient movement of patients to appropriate treatment facilities in support of joint operations. Effective patient evacuation ensures that patients are brought to definitive care as fast as necessary. En route care sustains or improves patient condition during evacuation.

a. Provide Joint Theater Patient Evacuation matching Service evacuation capabilities to Joint Force requirements and improving integration in the JOA by conducting joint planning, preparation, integrated execution, and assessment of performance until patient treatment needs exceed MTF capabilities and capacity in the JOA.

b. Provide Joint Global Patient Evacuation by conducting joint coordination and movement from a JOA to an appropriate definitive care facility with advanced staging and/or hospitalization, mission adjustable en route care, and globally directed management out of the JOA or among Geographic Combatant Command AORs.

*Required Capability #9. **Patient Management**.*
Improve the ability to effectively apply the required scope of health service capabilities for each casualty or injury accepted into care as a patient in order to achieve the lowest mortality and morbidity possible in support of Joint Force operations.

a. Adopt initial casualty and injury management protocols that meet joint outcome standards, apply jointly developed initial actions and practices at the point of injury by the individual, team, or unit non-medical personnel and leaders. This may include requesting medical evacuation, individual skills or collective drills, or employment of non-medical casualty evacuation to move casualties to medical care as required.

b. Ensure diagnosis processes that meet Joint standards, to the extent possible, for identification of a medical or dental condition, disease, or injury. Joint information systems should provide links between diagnostic procedures

and patient history, to include signs, symptoms, as well as results of physical examination for both ambulatory and inpatient diagnostic services.

c. Match treatment capabilities to patient needs by employing modular, scalable, deployable or fixed-facility, packaged elements, and by applying joint protocols that improve the ability to employ remedies to patients for a disease or injury.

d. Provide rehabilitation through aggregation of joint resources to restore skills and capabilities to a patient so they can regain maximum possible function as far forward in the operating environment, as necessary. This also requires application of joint standards and practices for addressing patients' physical, psychological, social, vocational, educational, and environmental needs.

Required Capability #10. ***Joint Medical Leader Development.*** Implement the ability to develop and manage Service medical leaders who can effectively plan and operate in the Joint Force environment, to include a process for joint qualification and JPME which accounts for the demands of health service leaders to provide JFCs with the best advice about potential health threats, the health readiness of the Joint Force, and the employment of joint medical capabilities.

Required Capability #11. ***Medical Intelligence.*** Improve the ability to collect, evaluate, analyze, and interpret foreign information on health systems, infectious disease, medical science and technology, and environmental health in order to support joint intelligence production and support biosurveillance objectives. Additionally, improve the ability to assess opportunities for leveraging partners to support GIO.

Required Capability #12. ***Joint and Service Medical Education and Training.*** Improve the ability to develop and implement capabilities-based individual and collective training for the Service medical forces in support of Joint Force requirements. These requirements may differ from those for garrison care. Joint and Service medical education that supports essential health service capabilities will prepare medical personnel to function in joint warfighting environments and enhance joint medical interoperability.

Required Capability #13. ***Joint Medical Research and Development.*** Enhance the ability to advance the state of medical science, technologies, and practices in areas relevant to GIO and to ensure the most promising medical solutions are developed and fielded for the future Joint Force.

a. Improve support for basic medical research directed toward greater knowledge and understanding of the fundamental principles of science and medicine that are relevant to the improvement of health services capabilities.

b. Improve joint refinement of biomedical technology concepts and ideas into potential solutions to military health and performance problems with a view towards evaluating technical feasibility and Joint Force requirements.

c. Improve support of promising medical technology candidate solutions that are selected for initial safety and efficacy testing in small-scale human clinical trials regulated by the U.S. Food and Drug Administration (FDA) prior to licensing for human use. This includes examining promising medical technology candidate solutions for initial safety and efficacy testing.

d. Improve Advanced Component Development support for medical products that are regulated by the U.S. FDA and the accelerated transition of FDA licensed and non-licensed (or FDA-unapproved) products and medical practice guidelines to the military operational user through clinical and field validation studies.

e. Improve development and demonstration of medical commodities delivered from Advanced Component Development efforts that are directed at meeting validated requirements prior to full-rate initial production and fielding, including initial operational test and evaluation and clinical trials.

f. Improve support for enhancement activities for fielded medical products and the pre-planned improvement of fielded medical products, including information management/information technology systems.

*Required Capability #14. **Medical Logistics**.*
Improve the ability to provide and synchronize joint medical logistics and infrastructure support (JMLIS) in accordance with the JFC's plans and priorities. This includes the ability to integrate, network, and tailor medical logistics capabilities of health service mission partners to efficiently and responsively meet the needs of the supported joint force and mission.

a. Establish joint interoperability, interchangeability, and interdependency as a requirement in materiel development of health service capabilities.

b. Develop the ability to predict and fulfill the medical supply and maintenance requirements of modular medical force elements as they aggregate and/or disaggregate with other modular elements provided by health service mission partners.

c. Improve the ability to orchestrate the provision of medical logistics support (e.g. medical supplies, medical equipment, medical maintenance, blood, optical, medical facilities, medical services, and/or medical contracting) to the Joint Force. This involves the ability to tailor medical logistics capabilities to the needs of the supported force and mission.

d. Improve the quality and availability of authoritative medical logistics data necessary to accurately forecast requirements, reduce variation, establish equivalencies, and efficiently integrate end-to-end JMLIS activities required to sustain medical capabilities in joint operations.

e. Improve the integration of Service JMLIS capabilities into a scalable, responsive framework that provides joint visibility of requirements and enables timely fulfillment.

Required Capability #15. **Health Services Contracts and Resource Programming**.
Improve the ability to augment and extend military health service capabilities through rapid and flexible acquisition and contract processes. This requires improved alignment of resource programmatic processes to enhance responsiveness to emergent Joint Force requirements and Service's priorities for medical force development.

Required Capability #16. **Global Health Services Network**.
Establish the ability to leverage non-DoD, foreign, and NGO partners to build a collective healthcare capability with global reach to support GIO in austere, urbanized, and denied environments.

a. Establish a flexible worldwide network of health service nodes/MTFs and a mechanism to coordinate their activities to ensure the ability to rapidly mobilize medical capabilities and resource in support of GIO.

b. Implement processes to assess potential partner medical capabilities sets, availability for use by U.S. Forces, and their capacity to support.

9. <u>Risks of Adopting this Concept</u>

The risks of implementing this concept reside in the following areas: medical capabilities and readiness, technology, and resources.

- *Integrated U.S. Military Medical Capabilities might become more vulnerable to interdiction or disruption*. Medically supporting GIHS relies on the ability to execute command, control, communications, computers, and intelligence solutions. Health services achieving the required level of integration may expose vulnerabilities concurrent with centralized information, coordination, or control.

- *Joint Medical Standards and Integration might drive homogeneity*. While standardization among Services can support improved safety and quality assurance of medical care, it may lead to medical capabilities which are less able to support the diversity, flexibility, versatility, and ultimately, effectiveness derived from the complementary employment of diverse Service capabilities. In addition, adoption of this concept in such a way to create an imbalance

between efficiency and redundancy creates a future force that may not be resilient enough for the future operating environment.

• ***Joint Force development priorities might lead to Service gaps in development of organic health service capabilities***. The Services and the Defense Health Agency may fail to balance joint, integrated medical force development and implementation frameworks with Service-specific requirements. This could lead to a disparate sprint toward joint capabilities resulting in unanticipated gaps for Service-driven resource management.

• ***Increased focus on how operational Health Services affect the ability of MTFs to provide care to non-uniformed beneficiaries***. Changes in force design to better provide forward-positioned advanced trauma care and the disparate nature of medical care competencies/specialties required to support operational requirements (vice non-uniformed beneficiary care) may make the current way of providing health benefits for non-uniformed beneficiaries unsustainable. Mitigating this risk will require close coordination between MTFs and purchased care in employing a comprehensive approach to design a medical force responsive to both operational employment and day-to-day readiness requirements of operational forces. Cost (both in training to sustain casualty care skills and to provide beneficiary care) and risk to maintaining combat capabilities for operational capabilities will be major considerations.

• ***Efforts to maintain or improve medical outcomes through technology may increase resource burdens on the Joint Force***. This concept puts a premium on technology to offset requirements for reduced physical presence and to sustain the ability to maintain positive medical outcomes. Developing and sustaining these technologies to enable this level of performance may stress the budget resources of the Joint Force.

• ***Force reductions with insufficient force modernization*** place at risk the medical community's efforts to compensate for a smaller footprint with increased technology. This may be compounded by the expected capabilities of allied or partner nations proving insufficient. Improved interoperability with joint, interagency, and multinational partners may provide additional methods to mitigate this risk by improving synergy across all domains.

10. <u>Conclusion</u>

GIO are inherently complex and will occur in fast-paced, contested operating environments. Supporting GIO will stress the operational agility and organizational flexibility for providing GIHS. This document provides a conceptual foundation for medical capability development in response to the future operating environment. This concept document contains sufficient detail to initiate a capabilities-based assessment via the JCIDS process.

Implementation will require experimentation to test the concept and refine capabilities.

11. **<u>Annexes</u>**

Annex A. References

Annex B. Acronyms

Annex C. Glossary

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Annex B. Acronyms

AOR	area of responsibility
CBRNE	chemical, Biological, Radiological, Nuclear and Explosive
CCDR	Combatant Commander
CCJO	Capstone Concept for Joint Operations
CCMD	Combatant Command
CONOPS	concept of operations
DoD	Department of Defense
DOTMLPF-P	doctrine, organization, training, materiel, leadership and education, personnel, facilities, and policy
FDA	Food and Drug Administration
GFM	Global Force Management
GIHS	Globally Integrated Health Services
GIO	Globally Integrated Operations
JCHS	Joint Concept for Health Services
JCIDS	Joint Capabilities Integration and Development System
JFC	Joint Force Commander
JMLIS	Joint Medical Logistics and Infrastructure Support
JOA	Joint Operations Area
JPME	Joint Professional Military Education
JTTS	Joint Theater Trauma System
MTF	Medical Treatment Facility
NGO	nongovernmental organization
U.S.	United States

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Annex C. Glossary

Biosurveillance. The process of gathering, integrating, interpreting, and communicating essential information related to all hazards, threats, or disease activity affecting human, animal, or plant health to achieve early detection and warning, contribute to overall situational awareness of the health aspects of an incident, and to enable better decision making at all levels. (*National Strategy for Biosurveillance*, July 2012)

Denied Area. An area under enemy or unfriendly control in which friendly forces cannot expect to operate successfully within existing operational constraints and force capabilities. (JP 3-05)

Domain. A sphere of activity or influence. (JCHS)

Force Health Protection. The ability to sustain and protect the health and effectiveness of the human centerpiece of the American military. Force Health Protection is composed of activities that promote human performance enhancement; provide for a healthy, fit, and protected force; engage in health surveillance; encompass casualty management in the JOA; and enhance mission set preparedness and support to Homeland Defense/Civil Support operations. (Force Health Protection Concept of Operations [CONOPS])

Health Services. Medical capabilities designed to perform, provide, or arrange the promotion, improvement, conservation, or restoration of human mental and physical well-being that may be utilized to support the National Military Strategy and the readiness of the Joint Force. (JCHS)

Health Service Support. All services performed, provided, or arranged to promote, improve, conserve, or restore the mental or physical well-being of personnel, which include, but are not limited to, the management of Health Services resources, such as manpower, monies, and facilities; preventive and curative health measures; evacuation of the wounded, injured, or sick; selection of the medically fit and disposition of the medically unfit; blood management; medical supply, equipment, and maintenance thereof; combat and operational stress control; and medical, dental, veterinary, laboratory, optometric, nutrition therapy, and medical intelligence services.. (JP 4-02)

Health Service Delivery. The ability to build healthy communities by managing and delivering the TRICARE health benefit. This ability includes clinical preventive medicine, clinical diagnostics, treatment, rehabilitation, and reintegration. (Health Service Delivery CONOPS)

Health System Support. The ability to organize and execute key capabilities required to support and continuously improves Health Service Delivery and Force Health Protection in fulfillment of the Military Health System mission. It includes activities associated with the education, research and development,

Health Services contract development, Health Services contract management, and partnership development among health service organizations outside the Military Health System. (Health Readiness CONOPS)

Interoperability. Systems, units, and forces shall be able to provide and accept data, information, materiel, and services to and from other systems, units, and forces and shall effectively interoperate with other U.S. Forces and coalition partners. (DoDD 5000.01)

Node. Physical location for delivering health services. These can be fixed (e.g., MTFs, clinics, mission partner facilities) or mobile (e.g., deployable/modular capabilities). (JCHS)

Operational Level of War. The level of war at which campaigns and major operations are planned, conducted, and sustained to achieve strategic objectives within theaters or other operational areas. (JP 3-0)

Synchronization. The arrangement of military actions in time, space, and purpose to produce maximum relative combat power at a decisive place and time. (JP 2-0)