Intramural Program Announcement

and

Application Instructions

for the

Department of Defense
Defense Health Program
Congressionally Directed Medical Research Programs
Defense Medical Research and Development Program

Joint Program Committee-1/Medical Simulation and Information
Sciences Research Program
Health Informatics/Information Technology

SUBMISSION AND REVIEW DATES AND TIMES

- Pre-Application Deadline: 11:59 p.m. Eastern time (ET), August 6, 2015
- Invitation to Submit an Application: October 1, 2015
- Application Submission Deadline: 5:00 p.m. ET, December 1, 2015
- Peer Review: January 2016
- Programmatic Review: March 2016
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I. FUNDING OPPORTUNITY DESCRIPTION

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

- An **intramural investigator** is defined as a U.S. Department of Defense (DoD) military or civilian employee working within a DoD laboratory, DoD military treatment facility, or working in a DoD activity embedded within a civilian medical center.

- An **extramural investigator** is defined as all those not included in the definition of intramural investigators above. Submissions from extramural investigators to this Program Announcement/Funding Opportunity will be rejected. *It is permissible, however, for an extramural investigator to be named as a collaborator in an application submitted by an intramural investigator.* In such cases, the intramural organization will receive all funds and is responsible for executing all necessary contractual or assistance funding awards to collaborating partners through their agency’s procedures.

A. Program Description

Applications to the Fiscal Year 2016 (FY16) Joint Program Committee 1 (JPC-1)/Medical Simulation and Information Sciences (MSIS) Research Program are being solicited for the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate. As directed by the Office of the Assistant Secretary of Defense for Health Affairs, the DHA RDA Directorate manages and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. Through the US Army Medical Research and Materiel Command (USAMRMC), the 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. This program announcement and subsequent awards will be managed and executed by CDMRP with strategic oversight from JPC-1/MSIS.

The mission of the JPC-1/MSIS is to explore the implications of models and technology for medical education and for the provision, management, and support of health services in the military. The JPC-1/MSIS plans, coordinates, and oversees a responsive world-class, tri-Service science and technology program focused on two areas of research. One area is focused on improving military medical training through medical modeling, simulation, educational gaming, assessment systems, and objective training metrics. The second area is focused on improving the use and sharing of health-related data for better strategic planning, process development, and software applications. It is organized into two portfolios, one for each of the two focus areas.

The JPC-1/MSIS Health Information Technology and Informatics portfolio includes research to support the DoD, with the role of strategic planning, programming, and budgeting DHP Health Informatics and Information Technology (HIT) research funding. The focus of this research supports the functional community of end users in the areas of Theater Health Services and Support, Healthcare Services and Population Health, Health Operations Resourcing, and the Health Enterprise Infrastructure.
B. Award Information

Research applications should be applicable to one or more of the areas of interest as prioritized by the JPC-1/MSIS HIT Working Group:

1. Theater/Operational Medicine
   i. Research to support the valuation of different biosensors and telehealth technologies. In conjunction, research to be conducted around the transmission, storage, and retrieval of this high-volume, high-velocity, and high-variety patient data.
   ii. Research on better technology platforms for improved physiologic monitoring during evacuation including enhancements to predictive algorithms and well as improvement of core logistics systems to include information systems, automatic identification technologies and tracking, and medical material management, including those with specific environmental handling requirements (e.g., blood, oxygen, etc.).

2. Medical Resourcing
   i. Research technologies to streamline the access to and management of educational systems across the Military Health System (MHS), providing increased efficiency and effectiveness in the way education is delivered.

3. Healthcare Services
   i. Research to help support the normalization, analysis, and visualization of personal health data for the purpose of aggregating said data to monitor and support population health decisions. This early-stage research will help inform stakeholders of the best tools and techniques in support of the acquisition of said tools.
   ii. Research to support the economic and recall knowledge ability of “just in time” mobile training at the Medical Education Training Campus (METC) and in the non-deployed and deployed environments as compared to the traditional classroom settings.

4. Enterprise Infrastructure Management
   i. Research to support the MHS’s goal of total interoperability within the enterprise. In support of this Cloud computing, universal exchange languages and semantic interoperability tools will be evaluated and considered as feasible tools for a highly integrated MHS enterprise.

Multi-Organizational Studies

If the proposed research is multi-organizational, plans for communication and data transfer among the collaborating organizations, as well as how resources used and obtained during the study will be handled, should be included in the appropriate sections of the application.
Military Relevance

Relevance to the healthcare needs of military Service members, Veterans, and beneficiaries is a key feature of this award. Investigators are encouraged to consider the following characteristics as examples of how a project may demonstrate military relevance:

- Explanation of how the project addresses an aspect of healthcare that has direct relevance to the DoD, U.S. Department of Veterans Affairs (VA), Service members, or other military beneficiaries.
- Use of data relevant to military or Veteran personnel in the proposed research; data used in research projects will be synthetic or de-identified.
- Collaboration among DoD and/or VA investigators.
- Involvement of military consultants (Army, Air Force) or specialty leaders (Navy, Marine Corps) to the Surgeons General in a relevant specialty area.

Use of Military Resources

The Principal Investigator (PI) is responsible for establishing access to the proposed military resources such as facilities, data, personnel, equipment, or supplies. Access and approvals should be confirmed at the time of application submission by inclusion of a letter of support, signed by the approval authority. If access cannot be confirmed at the time of application submission, JPC-1 reserves the right to withhold or revoke funding until the PI has demonstrated support for and access to the relevant population(s) and/or resources.

Defense Business Information Technology Certification: All DHP research investments funded by JPC-1 require Defense Business Information Technology certification (DBITC). This certification is a high-level certification requiring limited information on the JPC-1 process, and then when individual projects are selected, each will be described and entered into a tracking system at DHA. JPC-1’s current portfolio DBITC certification only applies to research in a laboratory environment and does not cover research in operational/clinical environments. Research can be done in an operational/clinical environment; however, this will require a complete certification that would include Program Element 6.5 RDT&E – not just the 6.4 funding in the limited certification. If the project includes plans for any research in the operational/clinical environment (e.g., includes patients or healthcare workers or is conducted at a medical facility), the applicant will need to work with the appropriate program office Composite Health Care System (CHCS), Armed Forces Health Longitudinal Technology Application (AHLTA), Theater Medical Information Program (TMIP), etc.) for the required certification. An out-of-cycle certification may take up to 6 months and will be required before the project can be funded.

Research Involving 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 U.S. Army Medical Research and Materiel Command (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 Appendix 3 for additional information.

C. Eligibility Information

- Independent intramural investigators at all academic levels (or equivalent) are eligible
to submit applications.

It is expected that the majority of work funded through this Program Announcement/Funding
Opportunity will be performed within a DoD facility. Regardless of location, any work that is to
be performed by associated non-DoD organizations must be limited to work performed under
service contracts, Cooperative Agreements or Material Transfer Agreements. **The Government
reserves the right to administratively withdraw any application that does not meet these
eligibility criteria. Applications requesting distribution of funds to a non-DoD organization
will not be considered.**

D. Funding

*Submissions selected for funding will be processed for award by USAMRMC, and awards
made to organizations, not individuals. Awards to intramural organizations will be executed
through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization
Document (FAD) process. Transfer of funds is contingent upon appropriate safety and
administrative approvals. Intramural applicants and collaborators are reminded to coordinate
receipt and commitment of funds through their respective Resource Managers.*

- The maximum period of performance is 2 years.
- Applications are not restricted to a predetermined cost limit. The requested budget must
  be justified and appropriate to the scope of work proposed.
- Associated indirect costs can be budgeted in accordance with the organization’s
  negotiated rate. No budget will be approved by the Government using an indirect rate
  exceeding the organization’s negotiated rate.

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

- Travel costs for the PI(s) to one In-Progress Review (IPR) per year, anticipated to be
  held at a Government location (to be determined) on date(s) determined by JPC-1. 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, including contract personnel (Federal salaries paid by the parent organization
  may not be reimbursable)
- Research-related subject costs
• Support for multidisciplinary collaborations
• Equipment
• Research supplies
• Travel between collaborating organizations
• Travel costs to attend scientific/technical meetings in addition to the required IPR meeting described above

This Program Announcement/Funding Opportunity is intended for intramural investigators only.

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

It is permissible for an extramural investigator to be named as a collaborator in an application submitted by an intramural investigator under this Program Announcement/Funding Opportunity. In such cases, the intramural organization will receive all funds and is responsible for executing all necessary contractual or assistance funding awards to collaborating partners through their agency’s procedures.

The JPC-1 expects to allot approximately $5M of the FY16 DHP appropriation to fund approximately 6-8 applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.

FUNDS FOR THIS PROGRAM ARE PROGRAM ELEMENT 6.4 DOLLARS.

FUNDS ARE TO BE DISTRIBUTED AS FY16 FUNDS.

FY16 FUNDS MUST BE OBLIGATED NO LATER THAN CLOSE OF BUSINESS SEPTEMBER 30, 2017.

II. SUBMISSION INFORMATION

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

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

Start the submission process early. The CDMRP eReceipt System has a number of required steps that must be completed before submissions will be accepted. Be sure to allow adequate time for completion of all pre-application and application steps by their respective deadlines.
A. Pre-Application Submission Content

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

PIs, collaborators, and organizations identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the PI must contact the CDMRP Help Desk at help@cdmrp.org or 301-682-5507.

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

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

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

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

  *Pre-applications that designate a JPC-1/MSIS HIT Working Group member as an investigator, consultant, and collaborator or in a key personnel role will not be considered. A list of JPC-1/MSIS HIT Working Group members is included in Appendix 4.* For questions related to the JPC-1/MSIS HIT Working Group members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at help@cdmrp.org or 301-682-5507.

- **Required Files – Tab 4:** Note: *At this time, the CDMRP eReceipt System is unable to read files made with Adobe Acrobat PDFMaker version 9.0 and higher.* The documents should conform to the formatting guidelines outlined in Appendix 1.

  **Preproposal Narrative (10-page limit):** The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application. *Proprietary information should not be included in the pre-application.*
The Preproposal Narrative should include the following:

- **Problem to Be Studied:** Describe the perceived issue(s) and the problems to be studied. This section should serve as an abstract of the proposed work.

- **Theoretical Rationale, Scientific Methods, and Research**
  - **Background/Rationale:** Clearly present the ideas and reasoning behind the proposed research. Include relevant literature citations, preliminary and/or pilot data, and/or other evidence that led to the development of the proposed research. Any preliminary data should be from the laboratory of the PI or member(s) of the collaborating team.
  - **Hypothesis/Objective and Specific Aims:** State the proposed project’s hypothesis and/or objectives and the specific aims/tasks of the proposed research.
  - **Approach/Methodology:** Describe the research approach. Include research design, methods, and analysis/evaluation strategies as well as materials anticipated to be used during the research.

- **Significance, Relevance, and Innovation of the Proposed Effort**
  - **Significance and Relevance:** Clearly articulate how the proposed research is relevant to the goal of improving health informatics and information technology in the military health system to support the functional community of end users in the areas listed in Section I.B.
  - **Innovation:** Explain how the proposed project is innovative and not an incremental advancement of previous work.

- **Proposed Study Design/Plan:** Provide the intended research methodology that will support the proposed research plan. Provide information such as specific aims, methodologies, sample and sample size, inter-rater reliability, assessment criteria, analyzed results, conclusions, and potential next-step recommendations. Refer to Section I.B., for additional information on the areas of interest for this Program Announcement/Funding Opportunity.

- **Military Impact:** Describe the anticipated short- and/or long-term outcomes of the proposed project and their potential impact on improving health informatics and information technology in the military health system.

- **Personnel and Facilities:** Describe the role for the PI, co-PIs (if applicable), key personnel, subawards (if applicable), and consultants (if applicable) in the research team, including the expertise each brings to the proposed project. Explain how the team’s expertise is appropriate and complementary for achieving the research goals. Also, briefly provide information on the primary facility where the research is expected to be performed.

**Pre-Application Supporting Documentation:** Combine and upload the pre-application supporting documentation as a single PDF file. Items to be included as supporting documentation for the pre-application are limited to:
- References Cited (one-page limit): List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.

- PI and Key Personnel Biographical Sketches (five-page limit per individual): Bold or highlight publications relevant to the proposed project.

- Budget Summary: Complete the three-page Budget Summary Form (available for download in the CDMRP eReceipt System at https://cdmrp.org/Program_Announcements_and_Forms) as instructed.

- Quad Chart: Provide a one-page Quad Chart that summarizes the proposed project. The format for the quad chart is available on the CDMRP eReceipt System at https://cdmrp.org/Program_Announcements_and_Forms.

- Submit – Tab 5: Enter your password in the space provided next to “Enter Your Password Here” and press the “Submit” button. Press the “Confirm Submission” button to complete the pre-application submission.

  This tab MUST be completed for the pre-application to be accepted and processed by the CDMRP eReceipt System.

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

Pre-Application Screening

- Pre-Application Screening Criteria

  All pre-applications will be screened to determine technical merit and relevance to the mission of the DHP and JPC-1/MSIS based on the following criteria, listed in descending order of importance:

  - Programmatic relevance: To what degree the proposed project addresses an identified area of interest in Theater/Operational Medicine, Medical Resourcing, Healthcare Services, and/or Enterprise Infrastructure Management as described in this Program Announcement/Funding Opportunity (see Section I.B.).

  - Military relevance: To what degree the anticipated short- and/or long-term outcomes of the proposed project will result in the improvement of health informatics and information technology in the military health system.

  - Scientific rigor: 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.

  - Utility: To what degree the proposed project will result in or lead to the development of a product or knowledge outcome that will improve the use of health informatics and information technology in the military health system.
• Notification of Pre-Application Screening Results

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

B. Full Application Submission Content

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

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

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

• Application Information – Tab 1: This tab will be populated by the CDMRP eReceipt System. Do not change.

• Application Contacts – Tab 2: This tab will be populated by the CDMRP eReceipt System. Do not change.

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

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

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

Component 1: Project Narrative (20-page limit): Upload as “ProjectNarrative.pdf.” The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to
expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application. Proprietary information should be included in the application only if necessary for evaluation purposes (see Appendix 2 for more information).

Describe the proposed project in detail using the outline below.

- **Background:** Provide a brief statement of ideas and reasoning behind the proposed study. Describe previous experience most pertinent to this project. Cite relevant literature references. Include discussion of any findings (if available) from relevant pilot or preliminary work or any related work underway. Describe into which current system or Program Management Objective this research effort will integrate or transition.

- **Hypothesis:** State the hypothesis to be tested and the expected results. For development of devices and technologies, discuss the technical feasibility of the proposed project including background of the problem, previous and current solutions, similar projects previously undertaken and related development activities.

- **Technical Objectives:** State concisely the question to be answered by each research objective.

- **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.

- **Military Significance:** State precisely the estimates as to the immediate and/or long-range usefulness of this study to the Armed Forces, as distinguished from general advancement of knowledge in medicine.

- **Public Purpose:** If appropriate, provide a concise, detailed description of how this research project will benefit the general public.

- **Methods:** Give details about the experimental design and methodology. If the methodology is new or unusual, describe in sufficient detail for evaluation. For development of devices and technologies, discuss the engineering/technical design 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. For studies involving human subjects, describe the recruitment plan and access to populations. The application should describe a plan for data access. Access to subjects and data is the sole responsibility of the investigator. As relevant, describe plans for addressing issues unique to working with military populations.

**Component 2: Supporting Documentation:** Start each document on a new page. Combine and upload as a single file named “Support.pdf.” If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested will be removed or may result in administrative withdrawal of the application.
○ References Cited: List the references cited (including URLs if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).

○ List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.

○ 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 included. Extra items will not be reviewed.

○ Facilities, Existing Equipment, and Other Resources: Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.

○ Letters of Organizational Support: Provide a letter (or letters, if applicable) from the following:
  – Resource Manager/Comptroller: Provide a letter of support from the applicant institution’s Resource Manager/Comptroller (or appropriate financial point of contact) assuring that the institution will be able to accept these funds, if awarded. If funds are to be sent to multiple sites, include a letter from each site.
  – Commander(s): Provide a letter(s) of support from the appropriate Installation Commander or equivalent Commander/Director to ensure access to the facility, research population, and other necessary resources. The Commander should be aware of all submissions and should confirm that the proposed work is both feasible from a technical perspective and relevant from a programmatic and Command perspective.

○ Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work. If the project involves collaboration with a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center), special requirements apply. A DoD researcher must obtain a letter from his/her commanding officer or Military Facility director authorizing his/her participation in the research project. This letter must be included with the application.

○ Joint Sponsorship (if applicable): Describe present or prospective joint sponsorship of any portion of the program outlined in the application. In the absence of agreements among sponsors for joint support, the 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 application is submitted, information should be sent later as an addendum to the 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
  - Background and Proprietary Information: All software and data first produced under the award are subject to a Federal purpose license in accordance with applicable DoD Grant and Agreement Regulations (DoDGAR) requirements. Provide a list of all background intellectual property to be used in the project or provide a statement that none will be used. If applicable, state and identify the proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the Federal purpose license.
  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.
  - Commercialization Strategy (if applicable): Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.

- Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community. Refer to Appendix 2 for more information about the CDMRP expectations for making data and research resources publicly available.


Abstracts of all funded applications may be publicly posted; therefore, proprietary information should not be included in the abstract.

The abstract should fully describe the proposed work, in a clear and concise overview, including the background, objective or hypothesis and its supporting rationale, significance of the proposed work to the program’s goals, specific aims of the study, and study design.

- Background: Provide a brief statement of the ideas and reasoning behind the proposed work.
- Objective/Hypothesis: State the objective/hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.
- Specific Aims: State concisely the specific aims of the study.
- Study Design: Briefly describe the study design.
Relevance: Provide a brief statement explaining the potential relevance of the proposed work to the specific topic area being addressed and its impact on health outcomes.


Not required at this time. Leave Component 4 space blank.

Component 5: Statement of Work (SOW) (one-page limit): Upload as “SOW.pdf.” The SOW outlines and establishes the PI’s and an organization’s performance expectations and timeline for the work to be funded under this award. Examples of different SOW formats can be found on the “Program Announcement and Forms” page in the CDMRP eReceipt System (https://cdmrp.org/Program_Announcements_and_Forms/). 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 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 Office of Research Protections’ regulatory review and approval processes for studies involving human subjects and 2 to 3 months for studies involving animal subjects.

Component 6: Biographical Sketches: Combine biographical sketches and current/pending support documentation for the PI and all key personnel into a single PDF file and upload as “Biosketches.pdf.”

The suggested biographical sketch format is available on the “Program Announcement and Forms” page in the CDMRP eReceipt System (https://cdmrp.org/Program_Announcements_and_Forms/). Use of this document is optional.

Current/Pending Support: For all current and pending research support, include the title, time commitments, supporting agency, name and address of the funding agency’s procuring Contracting/Grants Officer, performance period, level of funding, brief description of the project’s goals, and list of the specific aims. If applicable, identify where the proposed project overlaps with other current and pending research projects. Clearly state if there is no overlap. If there is no current or pending support, enter “None.” An updated current and pending support document will be required during award negotiations.

Component 7: Budget and Budget Justification: Use the Detailed Budget and Justification form available on the “Program Announcement and Forms” page in the CDMRP eReceipt System (https://cdmrp.org/Program_Announcements_and_Forms/). Upload as “Budget.pdf.”

Submit a detailed budget and budget justification that cover the entire period of performance (not just the first year). All costs must be entered in U.S. dollars. The
The government reserves the right to request a revised budget and budget justification and/or additional information.

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

- Senior/Key Person and Other Personnel: Personnel involved in the project should be listed in this section; however, this award is not intended to provide salary support for any Federal employee, as those costs were to have been included in infrastructure costs previously provided. If salary support is requested, sufficient justification must be provided in the budget justification section.
  - Name: Beginning with the PI, list all participants who will be involved in the project during the initial budget period, whether or not salaries are requested. Include all collaborating investigators, research associates, individuals in training, and support staff.
  - Role on Project: Identify the role of each participant listed. Describe his/her specific functions in the budget justification.
  - Type of Appointment (Months): List the number of months per year reflected in an individual’s contractual appointment with the applicant organization. The Government assumes that appointments at the applicant organization are full time for each individual. If an appointment is less than full time (e.g., 50%), note this with an asterisk (*) and provide a full explanation in the budget justification. Individuals may have split appointments (e.g., for an academic period and a summer period). For each type of appointment, identify and enter the number of months on separate lines.
  - Annual Base Salary: Enter the annual organizational base salary (based on a full-time appointment) for each individual listed for the project.
  - Effort on Project: List the percentage of each appointment to be spent on this project for all staff members including unpaid personnel.
  - Salary Requested: Enter the salary for each position for which funds are requested. This is calculated automatically from the data provided. If you do not wish this to be calculated for you, uncheck the small “Calculate Salary” checkbox in the bottom of the field. Calculate the salary request by multiplying an individual’s organizational base salary by the percentage of effort on the project.
  - Fringe Benefits: Enter the fringe benefits requested for each individual in accordance with organizational guidelines.
- **Totals:** Calculated automatically from the data provided.

- **Other Direct Costs:** Itemize and clearly justify all additional direct costs as components of the budget categories listed below. Enter the itemized budget information for the first year on page F-2.

- **Equipment:** Provide an itemized list of proposed equipment, showing the cost of each item. Equipment is any article of nonexpendable tangible property having a useful life of more than 1 year and an acquisition cost of $5,000 or more per unit.

- **Travel Costs:** Travel costs may include:
  - Required attendance at one 1-day IPR meeting, to be held in the National Capital Region.
  - Attendance at scientific/technical meetings. Include the meeting name, purpose, location, and date, if known, in the budget justification.
  - Travel associated with the execution of the proposed work (if applicable). Reasonable costs for travel between collaborating organizations should be included and are not subject to the yearly cost limitation on travel to scientific/ technical meetings. International travel may be requested but must be well justified, requested no less than 180 days before travel, and is subject to approval by the CDMRP.

- **Materials, Supplies, and Consumables:** The budget justification for supporting material and supply (consumable) costs should include a general description of expendable material and supplies. If animals are to be purchased, state the species, strain (if applicable), number to be used, cost per animal, and proposed vendor. If human cell lines are to be purchased, state the source, cost, and description.

- **Consultant Costs:** Regardless of whether funds are requested, include in the budget justification the names and organizational affiliations of all consultants, and include the daily consultant fee, travel expenses, nature of the consulting effort, and why consultants are required for the proposed research project.

- **Partnership/Collaboration Costs:** Should an extramural organization propose collaboration with an intramural entity for part of the research effort, the intramural organization will receive all funds and is responsible for executing all necessary contractual or assistance funding awards to collaborating partners through their agency’s procedures. All direct and indirect costs of any partnership/collaboration costs must be included in the total direct costs of the primary award. The nature of the partnership/collaboration should be described in the Budget Justification section.

- **Research-Related Subject Costs:** Include itemized costs of subject participation in the proposed research. These costs are strictly limited to expenses specifically associated with the proposed research.

- **Other Expenses:** Itemize other anticipated direct costs such as publication and report costs, equipment rental (provide hours and rates), communication costs, and organizationally provided services. Unusual or expensive items should be fully explained and justified. Estimate the costs of publishing and reporting research.
results, including direct charges for clerical preparation, illustrations, reprints, and distribution. Organizationally provided services should be supported by the organization’s current cost/rate schedule. These items should be described in detail and clearly justified.

- **Total Direct Costs:** Calculated automatically from the data provided for the initial budget period on page F-2 and for the entire proposed period of support on page F-3.

- **Total Indirect Costs:** This award is not intended to provide funds for indirect costs to the applicant organization. All direct and indirect costs of any proposed collaborator must be included in the total direct costs of the primary award. If funds for indirect costs are requested, sufficient justification must be provided in the budget justification section. The Government reserves the right to disallow any indirect costs not sufficiently justified.

- **Total Costs:** This section is calculated automatically from the data provided.

- **Fee:** A profit or fixed fee is not allowable on awards or on subawards.

**Budget Justification Instructions:** Provide a clear budget justification for each item in the budget over the entire period of performance in the Justification section (page F-4) of the Detailed Budget and Justification form.

- **Federal Agency Financial Plan (required):** Provide a detailed Federal Agency Financial Plan after the budget justification information in the Detailed Budget and Justification form. Applications must provide a plan delineating how all funds (FY16) will be obligated by September 30, 2017. The plan must include the funding mechanism(s) or contractual arrangements that will be used to carry over funds between fiscal years, if applicable.

- PIs must plan to have 90% of FY16 funds disbursed and/or obligated by September 30, 2016. Any funding not obligated by September 30, 2017 may be withdrawn by the issuing Comptroller.

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

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

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

### III. APPLICATION REVIEW INFORMATION

#### A. Application Review and Selection Process

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

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

B. Application Review Process

1. Peer Review: To determine technical merit, all applications will be evaluated according to the following scored criteria:

   • Scientific Merit
     o How well an explanation of current standard/state is presented.
     o To what degree the plan for delivering technology or product as stated in the research objectives/aims/hypothesis is feasible.
     o How well the rigor of the research plan, design, procedures and measures is described and is appropriate to the proposed study.
     o To what degree the sample size justification, recruitment/access to data strategies, and analysis plan are appropriate to the proposed study.

   • Military Relevance
     o How the research contributes to accelerating the fulfillment of military needs in health informatics and information technology.
     o To what degree the proposed research will inform future military strategy.
     o Whether there is near-term or midterm usability of proposed research findings.

   • Impact
     o How the proposed work is innovative and novel, including whether the proposed research is duplicative of existing research.
     o How well does the proposed study accelerate core research efforts.
How well the proposed study addresses at least one of the following areas of interest: Theater/Operational Medicine, Medical Resourcing, Healthcare Services, and/or Enterprise Infrastructure Management (as described in Section I.B.).

To what degree the anticipated short- and long-term outcomes resulting from the proposed study will result in the improvement of health informatics and information technology in the MHS.

- **Personnel, Resources, and Research Organization Quality**
  - How the composition and balance of the research team (including other organization personnel, subawards, 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 subawards and collaborative arrangements).
  - Whether there is evidence for appropriate institutional commitment.

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

- **Budget**
  - Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
  - Whether the proposed timeline is appropriate and tasks outlined in the application are logical in their progression.

- **Intellectual Property and Commercialization Plan**
  - If applicable, to what degree the intellectual property plan is appropriate.
  - If applicable, to what degree the commercialization plan is appropriate.

- **Application Presentation**
  - To what extent the writing, clarity, and presentation of the application components influence the review.

2. **Programmatic Review:** To make funding recommendations and select the application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

   a. **Ratings and evaluations of the peer reviewers**
   
   b. **Relevance to the mission of the DHP and JPC-1/MSIS, as evidenced by the following:**
• Adherence to the intent of the award mechanism
• Programmatic relevance
• Program portfolio balance
• Relative impact, innovation, and novelty
• Military relevance
• Cost and schedule
• Business risk analysis

C. Application Review Dates

All application review dates and times are indicated on the title page of this Program Announcement/Funding Opportunity.

D. Notification of Application Review Results

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

IV. AWARD ADMINISTRATION

After receipt of pre-applications and applications from the CDMRP eReceipt System, the following administrative actions may occur:

A. Rejection

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

• The pre-application is submitted by an extramural organization.
• Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

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

B. Modification

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

C. Withdrawal

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

• A FY16 JPC-1/MSIS HIT Working Group member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. A list of the JPC-1/MSIS HIT Working Group members can be found in Appendix 4.

• The pre-application and/or fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.

• Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.

• Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).

• Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest.

• Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.

• The application budget differs significantly from the budget included in the pre-application.

• The invited application does not propose the same research project described in the pre-application.

D. Withhold

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

E. Award Notice

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

F. Administrative Requirements

Refer to Appendix 2 for general information regarding administrative requirements.
G. Reporting

Refer to Appendix 3 for general information on reporting requirements.

Quarterly technical progress reports and quad charts will be required. In addition to written progress reports, in-person presentations may be requested.

H. Award Transfers

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

I. Site Visits

JPC-1/MSIS and/or CDMRP personnel may, at their discretion, visit each PI during the award period of performance.

V. AGENCY CONTACTS

A. CDMRP Help Desk

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application and/or application through the CDMRP eReceipt System should be directed to the CDMRP help desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

   Phone: 301-682-5507
   Email: help@cdmrp.org
VI. APPLICATION SUBMISSION CHECKLIST

<table>
<thead>
<tr>
<th>Application Components</th>
<th>Action</th>
<th>Completed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Component 1 – Project Narrative</td>
<td>Upload as “ProjectNarrative.pdf.”</td>
<td></td>
</tr>
<tr>
<td>Component 2 – Supporting Documentation</td>
<td>Upload as “Support.pdf.”</td>
<td></td>
</tr>
<tr>
<td>Component 4 – Lay Abstract</td>
<td>Not required; leave Component 4 blank.</td>
<td></td>
</tr>
<tr>
<td>Component 5 – Statement of Work</td>
<td>Upload as “SOW.pdf.”</td>
<td></td>
</tr>
<tr>
<td>Component 6 – Biographical Sketches</td>
<td>Upload as “Biosketches.pdf.”</td>
<td></td>
</tr>
<tr>
<td>Component 7 – Budget and Budget Justification</td>
<td>Upload as “Budget.pdf.”</td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX 1
FORMATTING GUIDELINES

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

- **Document Format:** All attachments must be in PDF.
- **Font Size:** 12 point, 10 pitch.
- **Font Type:** Times New Roman.
- **Spacing:** Single space or no more than six lines of type within a vertical inch (2.54 cm).
- **Page Size:** No larger than 8.5 inches x 11.0 inches (21.59 cm x 27.94 cm).
- **Margins:** At least 0.5 inch (1.27 cm) in all directions.
- **Print Area:** 7.5 inches x 10.0 inches (19.05 cm x 25.40 cm).
- **Color, High-Resolution, and Multimedia Objects:** Project narratives and pre-application files may include color, high-resolution, or multimedia objects (e.g., MPEG, WAV, or AVI files) embedded in the PDF files; however, these objects should not exceed 15 seconds in length and a size of 10 MB. Photographs and illustrations must be submitted in JPEG format; bit map or TIFF formats are not allowed.
- **Scanning Resolution:** 100 to 150 dots per inch.
- **Internet URLs:** URLs directing reviewers to websites that contain additional information about the proposed research are not allowed in the application or its components. Inclusion of such URLs may be perceived as an attempt to gain an unfair competitive advantage. However, links to publications referenced in the application are encouraged.
- **Language:** All documents must be submitted in English, unless otherwise specified in the Program Announcement (e.g., foreign transcripts submitted with English translations).
- **Headers and Footers:** Should not be used. Pre-existing headers and footers on required forms are allowed.
- **Page Numbering:** Should not be used.
- **Recommended Component Size:** Each attachment should not exceed 20 MB.
APPENDIX 2
ADMINISTRATIVE INFORMATION

A. Disclosure of Proprietary Information

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

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

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

B. Marking of Proprietary Information

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

C. Reporting Requirements

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

- **Progress Reports:** Quarterly, annual, and final reports will be required. These reports will present a detailed summary of scientific issues and accomplishments. A final report will be submitted within 30 days of the end of the award period and will detail the findings, their potential impact to the Military or Veteran population, and other issues for the entire project. The format for the progress reports is available on the Congressionally Directed Medical Research Programs (CDMRP) eReceipt System at [https://cdmrp.org/Program_Announcements_and_Forms](https://cdmrp.org/Program_Announcements_and_Forms).

- **Quad Charts:** Quad Charts that outline the specific aims, approach, timeline and costs, and goals/milestones will be required with every quarterly report. The format for the quad chart is available on the CDMRP eReceipt System at [https://cdmrp.org/Program_Announcements_and_Forms](https://cdmrp.org/Program_Announcements_and_Forms).

D. Publication, Acknowledgement, and Public Release

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

E. **Sharing of Data and Research Resources**

- It is the intent of the Department of Defense that data and research resources generated by this funded research be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large.

- Expectations for sharing of data and research resources apply to all basic research, clinical studies, surveys, and other types of research funded through this award. This includes all data and research resources generated during the project’s period of performance through grants, cooperative agreements, or contracts. It is critically important to share unique data and research resources that cannot be readily replicated, including but not limited to the following:
  
  ○ **Unique Data** are defined as data that cannot be readily replicated. Examples of unique data include large surveys that are expensive to replicate; studies of unique populations, such as patients to whom access is not widely available; studies conducted at unique times, such as during military conflict; studies of rare phenomena, such as rare diseases.

  ○ **Final Research Data** are defined as recorded factual material commonly accepted in the scientific community as necessary to document and support research findings. These are not the summary statistics or tables; rather, final research data are the data

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1 Adapted from [http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#unique](http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#unique)
2 Adapted from [http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#unique](http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm#unique)
on which summary statistics and tables are based. Final research data do not include laboratory notes or notebooks, partial datasets, preliminary analyses, drafts of scientific papers, plans for future research, peer review reports, communications with colleagues, or physical objects, such as gels or laboratory specimens.

○ **Research Resources**\(^3\) include, but are not limited to, the full range of tools that scientists and technicians use in the laboratory, such as cell lines, antibodies, reagents, growth factors, combinatorial chemistry, DNA libraries, clones and cloning tools (such as PCR), methods, laboratory equipment and machines.

- **Data and research resources generated from this funded research should be made as widely available as possible while safeguarding the privacy of participants, and protecting confidential and proprietary data, and third-party intellectual property.** By sharing and leveraging data and research resources, duplication of very expensive and time-consuming efforts can be avoided, allowing for the support of more investigators with Federal funds. Such sharing allows for a more expeditious translation of research results into knowledge, products, and procedures to improve human health.

- **For additional information on data-sharing, refer to the document titled “Congressionally Directed Medical Research Programs: Policy on Sharing Data and Research Resources,” available on the CDMRP eReceipt System under Reference Material at** [https://cdmrp.org/Program_Announcements_and_Forms/](https://cdmrp.org/Program_Announcements_and_Forms/).

\(^3\) Adapted from [https://grants.nih.gov/grants/intell-property_64FR72090.pdf](https://grants.nih.gov/grants/intell-property_64FR72090.pdf).
APPENDIX 3
REGULATORY REQUIREMENTS

A. Surety, Safety, and Environmental Requirements

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

4. **Assurance of Compliance:** Each institution engaged in non-exempt human subjects research must have a current U.S. Department of Health and Human Services Office for Human Research Protection (OHRP) Federal-wide Assurance (FWA) or DoD Assurance.

5. **Training:** Personnel involved in human subjects research must have appropriate instruction in the protection of human subjects. Documentation confirming completion of appropriate instruction may be required during the regulatory review process.

6. **Informed Consent Form:** The following must appear in the consent form:
   - A statement that the U.S. Department of Defense is providing funding for the study.
   - A statement that representatives of the DoD are authorized to review research records.
   - In the event that a Health Insurance Portability and Accountability Act (HIPAA) authorization is required, the DoD must be listed as one of the parties to whom private health information may be disclosed.

7. **Intent to Benefit:** The requirements of Title 10 of the United States Code Section 980 (10 USC 980), which are applicable to DoD-sponsored research, must be considered. 10 USC 980 requires that “Funds appropriated to the Department of Defense may not be used for research involving a human being as an experimental subject unless (1) the
informed consent of the subject is obtained in advance; or (2) in the case of research intended to be beneficial to the subject, the informed consent may be obtained from a legal representative of the subject.”

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

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

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

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

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

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

- May discuss the research protocol with the investigators, interview human subjects, and consult with others outside of the study about the research;
• Shall have authority to stop a research protocol in progress, remove individual human subjects from a research protocol, and take whatever steps are necessary to protect the safety and well-being of human subjects until the IRB can assess the monitor’s report; and

• Shall have the responsibility for promptly reporting his or her observations and findings to the IRB or other designated official and the HRPO.

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

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

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

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

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

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

• Payment to Federal Employees and Military Personnel: Under 24 USC 30, payment to Federal employees and active duty military personnel for participation in research while on duty is limited to blood donation and may not exceed $50 per blood draw. These individuals may not receive any other payment or non-monetary compensation for participation in a research study unless they are off duty or on leave during the time they are participating in the protocol.
• **Confidentiality for Military Personnel:** Confidentiality risk assessment for military personnel requires serious consideration of the potential to affect the military career. Medical and psychological diagnoses can lead to limitation of duties and/or discharge from active duty. Information regarding alcohol or drug abuse, drunk driving, and sexual or spousal abuse can lead to actions under the Uniform Code of Military Justice, including incarceration and dishonorable discharge.

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

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

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

11. **Protocol Submission Format:** The ORP HRPO accepts protocol submissions in the format required by the local IRB. The IRB protocol application, if separate from the protocol itself, should be included with protocol submissions. A HRPO protocol submission form should be completed and submitted with each protocol.
**APPENDIX 4**  
**JPC-1/MSIS HIT WORKING GROUP MEMBERS**

*List of FY16 JPC-1/MSIS Health Informatics and Information Technology Working Group Members:*

<table>
<thead>
<tr>
<th>Member</th>
<th>Position</th>
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<tbody>
<tr>
<td>Mr. (Leslie) Carl Barker (Alternate)</td>
<td>COL Nicole Kerkenbush (Alternate)</td>
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<tr>
<td>Col Al Bonnema</td>
<td>Dr. Lori Loan</td>
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<tr>
<td>Ms. Heather Burke</td>
<td>Dr. Terry Newton</td>
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<tr>
<td>Mr. Jim Copeland</td>
<td>CAPT Paul Miller</td>
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<tr>
<td>Mr. Russell Davis</td>
<td>MAJ Paul Roley</td>
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<tr>
<td>CDR Jody Dreyer (Alternate)</td>
<td>Mr. Frank Rowland</td>
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<tr>
<td>CDR James Ellzy</td>
<td>COL John Scott</td>
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<tr>
<td>Ms. Carol Fielder</td>
<td>Dr. Alan Smith</td>
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<tr>
<td>Mr. Richard Foster</td>
<td>COL Andy Smith</td>
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<tr>
<td>COL Thomas Greig</td>
<td>LTC Richard Wilson</td>
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<tr>
<td>Col Ray Jeter</td>
<td>CAPT Daniel Zinder</td>
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<td>COL Daniel Kral</td>
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*Submissions that include a JPC-1/MSIS HIT Working Group member as an investigator, consultant, collaborator, or in a key personnel role will not be considered.*