

# **Intramural Program Announcement**

**for the**

**Department of Defense**

**Defense Health Program**

**Congressionally Directed Medical Research Programs**

**Defense Medical Research and Development Program**

**Joint Program Committee 6/  
Combat Casualty Care Research Program**

**Joint En Route Care Award**

## **SUBMISSION AND REVIEW DATES AND TIMES**

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), October 15, 2015
- **Application Submission Deadline:** 5:00 p.m. ET, December 15, 2015
- **Peer Review:** January 2016
- **Programmatic Review:** March 2016

## TABLE OF CONTENTS

<b>I. Funding Opportunity Description.....</b>	<b>3</b>
A. Program Description .....	3
B. FY16 Joint En Route Care Research Focus Areas.....	4
C. Award Information.....	4
D. General Site Requirements .....	5
E. Eligibility Information .....	7
F. Funding .....	8
<b>II. Submission Information .....</b>	<b>10</b>
A. Pre-Application Submission Content.....	10
B. Full Application Submission Content.....	11
<b>III. Application Review Information .....</b>	<b>19</b>
A. Application Review and Selection Process.....	19
B. Application Review Process .....	20
C. Application Review Dates .....	21
D. Notification of Application Review Results .....	22
<b>IV. Administrative Actions.....</b>	<b>22</b>
A. Rejection .....	22
B. Modification.....	22
C. Withdrawal.....	22
D. Withhold .....	23
<b>V. Award Administration Information.....</b>	<b>23</b>
A. Award Notice .....	23
B. Reporting.....	23
C. Award Transfers.....	23
D. Site Visits .....	23
<b>VI. Agency Contacts.....</b>	<b>24</b>
A. CDMRP Help Desk.....	24
B. JPC-6/CCCRP Technical Point of Contact.....	24
<b>VII. Application Submission Checklist .....</b>	<b>25</b>
<b>APPENDIX 1 Formatting Guidelines .....</b>	<b>26</b>
<b>APPENDIX 2 Administrative Information .....</b>	<b>27</b>
<b>APPENDIX 3 Regulatory Requirements.....</b>	<b>30</b>
<b>APPENDIX 4 JPC-6/CCCRP Joint En Route Care Working Group Members .....</b>	<b>36</b>

## I. FUNDING OPPORTUNITY DESCRIPTION

***BEFORE APPLYING PLEASE NOTE: THIS IS AN INTRAMURAL AWARD MECHANISM. This Program Announcement/Funding Opportunity is intended for intramural investigators only.***

- An *intramural investigator* is defined as a Department of Defense (DoD) military or civilian employee working within a DoD laboratory, DoD military treatment facility (MTF), or working in a DoD activity embedded within a civilian medical center.
- An *extramural investigator* is defined as all those not included in the above definition of intramural investigators. 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 6/Combat Casualty Care Research Program (JPC-6/CCCRP) Joint En Route Care (J-ERC) Award 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 [OASD (HA)], the DHA RDA Directorate manages and executes the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The US 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-6/CCCRP. This Program Announcement/Funding Opportunity and subsequent awards will be managed and executed by CDMRP with strategic oversight from JPC-6/CCCRP. Additional information about CDMRP can be found on the website at <http://cdmrp.army.mil>.

The CCCRP is one of six major program areas within the DHA RDA Directorate. DHP RDT&E research funding is administered through CCCRP with oversight from JPC-6, which consists of DoD and non-DoD medical and military technical experts relevant to the program area. The CCCRP mission is to focus on providing optimal combat casualty care and reducing the morbidity and mortality of combat injuries. En Route Care is one of the key portfolio areas within JPC-6/CCCRP.

Joint Publication 4-02, Health Service Support, 26 July 2012, defines En Route Care as “the continuation of care during movement (evacuation) within the Health Service Support (HSS) continuum of care without clinically compromising the patient’s condition.” The Joint En Route Care Research Portfolio Working Group facilitates research and solution development for patient movement capability gaps from point of injury to point of definitive or rehabilitative care.

## **B. FY16 Joint En Route Care Research Focus Areas**

The FY16 J-ERC Award will support translational research targeting specific Focus Areas of En Route Care research. Translational research is defined as work that “translates” basic science concepts and ideas into clinically relevant solutions and meaningful health outcomes with a view toward evaluating the feasibility of diagnostic and therapeutic techniques, clinical guidance, emerging approaches and technologies, promising new products, and/or pharmacologic agents.

To meet the intent of the FY16 J-ERC award mechanism, each research project must specifically address one or more of the J-ERC Research Focus Areas listed below. Applicants are encouraged to incorporate projects addressing a diversity of Focus Areas.

### **The FY16 Joint En Route Care Research Focus Areas:**

- Research to understand the impact of transport on patient physiology (including dose response), the impact of transport on clinician human performance, and the best time to transport (i.e., when it is safe to transport a critically ill patient).
- Research to advance the development of automated and autonomous En Route Care for traumatically injured patients.
- Research to determine the appropriate patient–provider ratio, currency, and skill levels for En Route Care providers (medics, nurses, physicians, etc.) and the impact on patient outcomes.
- Research to support evidence-based decisions about intelligent tasking, the development of En Route Care protocols, the use of teleconsultation in the transport setting, and integrated systems that support safe patient care and hand-offs.
- Research on the continued development of En Route Care interventions and treatment, including resuscitation and forward surgical care (e.g., Damage Control Resuscitation/Damage Control Surgery), invasive procedures (e.g., Resuscitative Endovascular Balloon Occlusion of the Aorta/Extracorporeal Life Support), the appropriate environmental requirements to provide care, and the impact on patient outcomes.

## **C. Award Information**

The goal of this award mechanism is to establish Joint En Route Care-focused research sites within the DoD. The sites will conduct research relevant to the needs of Wounded Warriors who require transport from the point of injury to the next level of care. In addition, awardees will serve as a capability resource for the Joint En Route Care Working Group (J-ERC WG).

Each participating site will conduct a minimum of three (3) projects, with oversight by a single Principal Investigator (PI). Individual projects may be led by the site PI or a separate project PI, if appropriate. Specific responsibilities of PIs are described in [Section I.D., General Requirements](#). Each site will have responsibility for funds management and the execution of their approved research projects, regardless of where the actual work is performed. Collaborations with other institutions, particularly with other DoD laboratories and MTFs, are encouraged.

As a capability resource, PIs are expected to serve as subject matter experts in En Route Care research. Additionally, PIs are expected to align their research programs to the current or future needs of the Warfighter as defined in regular meetings with JPC-6/CCCRP. The research projects and the core competency function are both highly important aspects of this award.

***THIS IS A COMPETITIVE FUNDING OPPORTUNITY FOR A PERIOD OF FIVE (5) YEARS. APPLICATIONS MUST DEMONSTRATE ABILITY TO ACHIEVE THE GOALS OF THE J-ERC AWARD. EACH SITE WILL START WITH A MINIMUM OF THREE (3) RESEARCH PROJECTS. IT IS ENVISIONED THAT IN FUTURE YEARS MORE PROJECTS WILL BE ADDED AND PROJECTS MAY BE TERMINATED AS THEY ARE COMPLETED OR CLOSED. THE PERFORMANCE OF EACH SITE WILL BE REVIEWED BY THE J-ERC WG ANNUALLY.***

### **Military Relevance**

Relevance to the health care needs of military Service members and other 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 has direct relevance to combat casualty care.
- Use of military populations or data in the proposed research.
- Collaboration among DoD investigators.
- Involvement of military consultants (Army, Air Force) or specialty leaders (Navy, Marine Corps) to the Surgeons General in a relevant specialty area.

### **D. General Site Requirements**

The initial scope of each site will include a site PI and a minimum of three projects with a period of performance of five years.

The application should include the overarching strategy of adequately addressing all of the goals of the site. The application should describe available infrastructure and any shared laboratory facilities as well as project-specific facilities. The application should explain both the site's proposed research activities and how it can serve as an En Route Care capability resource for the DoD.

The application must include an initial set of at least three (3) proposed studies for consideration during the review and selection process. The J-ERC WG may recommend some or all of the individual projects for funding.

One of the goals of the J-ERC Award is to provide core competency for the DoD across the field of En Route Care research. Applicants are therefore encouraged to demonstrate a diversity of efforts at the proposed site by selecting a primary Focus Area and two secondary topics in the research projects submitted. However, if applicants choose to submit a set of projects concentrating on a narrow set of the Focus Areas, they should explain how the expertise of the PIs and teams at the site will still support the goal of providing comprehensive core competency in En Route Care research.

Funding selections will depend upon evaluation of the proposed site's strategic research design, site structure, record of productivity, available capabilities, and ability of the group to accomplish the overall award objectives.

Within the first year of the award, each of the awarded site PIs will develop a communication and coordination plan to ensure visibility of ongoing En Route Care research efforts and existing capabilities at other En Route Care research sites. All proposed follow-on projects utilizing funding from this award must align with the most current J-ERC research priorities and will require J-ERC WG review and approval prior to implementation.

### **Summary of Responsibilities**

#### Site PI:

- Serve as the point of contact for the site in communications with the DoD, JPC-6/CCCRP, J-ERC WG, and CDMRP.
- Ensure compliance with all regulatory and reporting requirements for the awards.
- Develop, organize, and submit semi-annual progress reports and final reports as projects are closed or completed.
- Actively engage with subject matter experts in the En Route Care community to ensure research efforts are mission relevant.
- Coordinate the submission of new projects to the J-ERC WG with other En Route Care research sites to avoid duplication of effort or the purchase of unnecessary equipment.
- Collaborate with other organizations engaged in En Route Care research to ensure synergy of effort.
- Present proposed follow-on efforts to the J-ERC WG for approval.
- Coordinate the preparation of written and oral briefings to the J-ERC WG and JPC-6/CCCRP.
- Serve as an expert capability resource on En Route Care research to the DoD including, but not restricted to, presenting at DoD meetings, attendance at non-DoD meetings, and conducting scientific and programmatic reviews for JPC-6/CCCRP, as requested.
- Submit SBIR<sup>1</sup> and STTR<sup>2</sup> topics to JPC-6/CCCRP, as appropriate.

#### Project PIs:

- Appropriately manage approved research project(s), in accordance with all regulatory and reporting requirements.
- Provide progress reports to the site PI for submission to the J-ERC WG when requested, but at least semi-annually.
- Submit new research proposals to the site PI for consideration at the J-ERC WG, as appropriate.
- Support and inform the site PI of any new developments and information.

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<sup>1</sup> Small Business Innovation Research

<sup>2</sup> Small Business Technology Transfer

## Other Requirements

**Rigor of Experimental Design:** All projects should adhere to accepted standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. Core standards are described in S.C. Landis et al., *A call for transparent reporting to optimize the predictive value of preclinical research*, Nature 2012, 490:187-191 (<http://www.nature.com/nature/journal/v490/n7419/full/nature11556.html>). While these standards were written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in research and should be applied consistently across basic and translational studies. Projects that include research on animal models are required to submit Component 6, [Animal Research Plan](#), as part of the application package to describe how these standards will be addressed. Applicants should consult the ARRIVE (Animal Research: Reporting In Vivo Experiments) guidelines to ensure relevant aspects of rigorous animal research are adequately planned for and, ultimately, reported. The ARRIVE guidelines can be found at <http://journals.plos.org/plosbiology/article?id=10.1371/journal.pbio.1000412>.

**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 regulatory requirements listed in [Appendix 3](#) for additional information.

**Use of Active Duty Military Populations:** If the proposed research plan involves access to active duty military patient populations or resources, the PI is responsible for establishing such access. If possible, access to target active duty military patient populations/resources should be confirmed at the time of application submission. If access cannot be confirmed at the time of application submission, JPC-6/CCCRP 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.

**The JPC-6/CCCRP and CDMRP intend that data and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community and to the public at large. For additional guidance, refer to [Appendix 2, Administrative Information](#).**

### E. Eligibility Information

- **Only intramural investigators are eligible to apply as site PIs.** For the purposes of this award mechanism, an intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or MTF or working in a DoD activity embedded within a civilian medical center. Contract investigators are not eligible to submit applications and may not serve as a site PI, but may contribute as a project PI or study team member for the individual projects.

- Investigators from extramural organizations are not eligible to apply to this funding opportunity. Should an intramural organization propose collaboration with an extramural 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.

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

## **F. Funding**

***Submissions selected for funding will be processed for award by USAMRMC. Awards are 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 initial period of performance is **5** years.
- The anticipated total costs budgeted for the entire period of performance will not exceed **\$750,000**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$750,000** total costs or using an indirect rate exceeding the organization's negotiated rate.
- Funds should be requested for the site and for a minimum of three projects.
- All direct and indirect costs of any proposed collaborator must be included in the total direct costs of the primary award.
- Applicants must 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 will be obligated by the deadlines shown below. The plan must include the funding mechanism(s) and contractual arrangements that will be used to carry over funds between fiscal years, if applicable.

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

- Travel costs for the site PI to attend one In Progress Review (IPR) and one additional DoD military research-related meeting [either the Military Health System Research Symposium or another approved by the J-ERC WG Chair]. Justification must be provided if additional personnel are included in the travel budget.
- The IPR will be held in conjunction with the annual J-ERC WG meeting, which will be held at varying locations. PIs are responsible for all costs for attending these meetings,

including airfare, hotel, etc., associated with these events. Anticipated travel costs should be built into the budget.

May be requested for (not all-inclusive):

- Salary, including contract personnel and Federal salaries, only if reimbursable
- Training costs
- Research-related subject costs
- Clinical research costs
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs to present preliminary or definitive results at scientific/technical meetings

*The JPC-6/CCCRP expects to allot \$3M of the FY16 DHP RDT&E appropriation to fund up to 4 sites for Joint En Route Care Awards for the first year, with continuing funding of \$3M per year for the remaining 4 years of the period of performance.*

Continued funding is dependent on annual assessments of performance based on factors including the In Progress Reviews and quarterly progress reports. **Funding can be withdrawn from any project or from an entire site if the J-ERC WG determines performance is unsatisfactory.** *Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of Federal funds for this program.*

Please note DHP RDT&E funds are typically not available until the second quarter of the fiscal year. The intent is to announce the J-ERC Award before May 2016.

**FUNDS FOR THIS PROGRAM ARE PROGRAM ELEMENT 6 (PE6.3 and PE6.4) DOLLARS.**

**FUNDS ARE TO BE DISTRIBUTED AS FY16, FY17, FY18, FY19, and FY20 FUNDS.**

**FY16 FUNDS MUST BE OBLIGATED NO LATER THAN COB 30 SEPTEMBER 2017.**

**FY17 FUNDS MUST BE OBLIGATED NO LATER THAN COB 30 SEPTEMBER 2018.**

**FY18 FUNDS MUST BE OBLIGATED NO LATER THAN COB 30 SEPTEMBER 2019.**

**FY19 FUNDS MUST BE OBLIGATED NO LATER THAN COB 30 SEPTEMBER 2020.**

**FY20 FUNDS MUST BE OBLIGATED NO LATER THAN COB 30 SEPTEMBER 2021.**

## 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 **site 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.

Site and project 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](mailto: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 site PI, the individual 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 site 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.

***Applications including a J-ERC WG member as an investigator, consultant, collaborator, or in a key personnel role will be considered, but must be clearly identified. These individuals will not participate in the final selection of J-ERC applications or funding recommendations of individual J-ERC projects, but will remain engaged in the J-ERC WG as appropriate. A list of J-ERC WG members is included in [Appendix 4](#).***

- **Letter of Intent (LOI) – Tab 4:** Upload a letter of intent as an individual PDF file. *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](#).
  - Provide the names of Project PIs and the titles of the projects. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions.
- **Submit Pre-Application – 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.*
- **Other Documents Tab:** This tab is not applicable during the pre-application submission process.

## B. Full Application Submission Content

*The pre-application (LOI) process in eReceipt must be completed before the application can be submitted.*

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.

Submit each of the following components as an individual PDF file under Tab 4, “Required Files,” in the CDMRP eReceipt System. 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.*

Each application submission must include the following components:

- **Component 1: Technical Abstract (one-page limit): Upload as “TechAbs.pdf.”** Describe the proposed research project using the outline below. Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. Proprietary or confidential information should not be included.

Describe the ability of the proposed site to meet the intent of the award mechanism in supporting research and providing capability in applied En Route Care science.

For each Project, briefly:

- State the specific aims of the study.
- Describe the study design including appropriate controls.

**Military Relevance:** Briefly describe how the proposed site, including the associated projects, will impact military health care. State how the proposed study complements ongoing DoD areas of research interest.

- **Component 2: Statement of Work (SOW) (three-page limit): Upload as “SOW.pdf.”** There is no limit to the number of specific aims, tasks, or subtasks to be described within the SOW page limit.

The SOW is an outline of specific aims defined within the proposed research project that establishes the PI’s performance expectations and timeline during the period of performance of the award. The SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks outlined step-by-step as they relate to the major tasks and milestones within the period of performance. The suggested SOW format and specific examples are available on the CDMRP eReceipt System “Program Announcement and Forms” web page ([https://cdmrp.org/Program Announcements and Forms/](https://cdmrp.org/Program%20Announcements%20and%20Forms/)). The Government reserves the right to request a revised SOW format and/or additional information.

The SOW should describe only the work for which funding is being requested by this application and, as applicable, the SOW should also:

- Include the following information for each study site/subaward site: Organization; organization address; investigator(s), collaborator(s), consultant(s); to be conducted at the site; and key personnel responsible for each major task and each subtask to be performed at the site.
- Identify methods to be applied for the given task.

- **Component 3: Site Structure and Personnel (three-page limit): Upload as “SiteNarrative.pdf.”** The page limit of the Site 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 Site Narrative and could confer an unfair competitive advantage is prohibited and will result in administrative withdrawal of the application.

**Plan of Operations (recommend one-page limit):**

- Include a description of the rationale behind the proposed Joint En Route Care focused research site including a description of how the individual projects and the site personnel will meet the overarching objectives of the J-ERC Award. A separate section (“Research Plan”) will be for applicants to propose individual projects.
- This Site Plan of Operations must include the following:
  - The overall plan and rationale for inclusion of the initial projects selected.
  - An explanation, with examples, of how the site research, resources, and personnel will allow it to act as a capability resource on En Route Care for the DoD.
  - A plan for how the site PI and project PIs will communicate internally and externally.
  - For the site and project PIs, include a personnel transition plan for how the goals of each project and of the site would be accomplished in the event of personnel leaving due to transfers or other job status changes.

### **Expertise and Resources (recommend two-page limit):**

- Identify key personnel, unique expertise, and other relevant resources of the proposed site. Provide an organizational chart identifying the site PI, each of the Project PIs, and key members of the study team including institution/site/department and each person's position on the project. While there is no specified format for this information, a table(s) or diagram is recommended.
  - Describe the research experience of the site PI highlighting design, implementation, and coordination of multi-project studies. Include qualifications for developing and maintaining a core capability team.
  - Describe the scientific and technical expertise of the site PI, project PIs, and other key personnel. Relevant supporting publications should be provided in Component 4.
  - Describe the resources and facilities that will be available for this effort, including a description of leveraged activities, distinguishing between what is already established versus what would be new requests to be supported.
  - Provide evidence of organizational commitment for the site, core laboratory facilities, and each participating Study Site for the use of facilities and resources in the conduct of the En Route Care Research focus site.
- **Component 4: Research Project Plan (six-page limit for each proposed Research Project): Upload as "ResearchNarrative.pdf."** The page limit of the Research 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 Research Narrative and could confer an unfair competitive advantage is prohibited and will result in administrative withdrawal of the application.

The application must include an initial set of at least three proposed studies for consideration during the review and selection process.

**Start each project on a new page headed by the name of the Project PI and title of the Project.**

Describe the proposed project using the outline below.

- **Background:** State the relevance of the applied research to at least one of the award mechanism Focus Areas and explain the applicability of the proposed findings. Present the ideas and reasoning behind the proposed work. Cite relevant literature and pilot or preliminary data. Describe previous experience most pertinent to this project.
- **Objectives/Specific Aims/Hypotheses:** Provide a description of the purpose and objectives of the study with detailed specific aims and/or study questions/hypotheses.
- **Research Strategy and Feasibility:** Describe the research strategy, methods, and analyses, including appropriate controls, in sufficient detail for analysis of its appropriateness and feasibility. Identify any innovative aspects of the project.

Describe the statistical plan as appropriate for the proposed research. Address potential problem areas and present alternative methods and approaches. If human subjects or human anatomical samples will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples.

- **Military Benefit and Impact:** Describe the short- and long-term impact of this study on the field of En Route Care research, including impact on the research field and on patient care and/or quality of life. Address the impact on one or more of the Focus Areas and provide justification for how the project addresses an important problem related to En Route Care. Describe how the proposed project will benefit Service members.
- **Component 5: 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 documents unless otherwise noted. Include only those items described below; inclusion of items not requested may result in the removal of those items or 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.
  - **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. There is no form for this information.
  - **Publications and/or Patent Abstracts (ten-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. URLs are preferred. If pdfs are provided, please scan and use at the lowest resolution (100-150 dpi).
  - **Letters of Organizational Support (two-page limit per letter, add/remove personnel as applicable):**
    - **Resource Manager/Comptroller:** Provide a letter of support from the applicant institution’s Resource Manager/Comptroller (or appropriate financial point of contact) assuring that the institution will be able to accept these funds, if awarded. If funds are to be sent to multiple sites, include a letter from each site.
    - **Commander(s):** Provide a letter(s) of support from appropriate Installation Commander or equivalent Commander/Director to ensure access to the facility, research population, and other necessary resources. The Commander should be aware of all submissions and should confirm that the proposed work is both

feasible from a technical perspective and relevant from a programmatic and command perspective.

- Letter of Recommendation for the site PI: Provide a letter from the appropriate Installation Commander or equivalent Commander/Director in support of the site PI. The letter should evaluate how well the site PI would both lead a multi-project research team and serve as a primary point of contact in communications within the larger DoD community, thus enabling the site to fulfill the goal of serving as a capability resource on En Route Care research. The letter should specifically reference the personal and professional qualities of the applicant, as well as previous experiences in similar roles to demonstrate his or her ability to serve in this capacity.
- Letters of Partnership/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.
- Letter(s) Confirming Access to Military or VA Staff and/or Patient Populations or Resources: If the proposed research plan involves access to active duty military and/or VA populations, patients, data or resources, include letter(s) of support, signed by the lowest ranking person with approval authority, confirming such access. If access cannot be confirmed at the time of application submission, the Government 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.
- Intellectual Property (if applicable):
  - 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 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.
- 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.
- Quad Chart: Provide a Quad Chart for each of the proposed projects. 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).
- **Component 6: Animal Research Plan (if applicable, two-page limit per project):** Start each project on a new page headed by the name of the Project PI and title of the Project. **Combine and upload as a single file named “AnimalResearchPlan.pdf.”**

When the proposed study involves animals, the applicant is required to submit a summary describing the animal research that will be conducted. Applicants should not submit a verbatim replica of the protocol(s) to be submitted to the Institutional Animal Care and Use Committee (IACUC) as the Animal Research Plan. The Animal Research Plan should address the following points for each proposed animal study:

- Briefly describe the research objective(s) of the animal study. Explain how and why the animal species, strain, and model(s) being used can address the scientific objectives and, where appropriate, the study's relevance to human biology.
  - Summarize the procedures to be conducted. Describe how the study will be controlled.
  - Describe the randomization and blinding procedures for the study and any other measures to be taken to minimize the effects of subjective bias during animal treatment and assessment of results. If randomization and/or blinding will not be utilized, provide justification.
  - Provide a sample size estimate for each study arm and the method by which it was derived, including power analysis calculations.
  - Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).
- **Component 7: Biographical Sketches:** Combine biographical sketches and current/pending support documentation for the site and project PIs and all key personnel into a single PDF file. **Upload the file 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/](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, period of performance, 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 8: 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/](https://cdmrp.org/Program_Announcements_and_Forms/)). Upload as "Budget.pdf."

*Submit a detailed budget and justification that covers the entire period of performance (not just the first year). All costs must be entered in U.S. dollars. The*

budget and budget justification must be sufficiently detailed so that the Government can determine the proposed costs to be allowable, allocable, and reasonable for the proposed research. ***The Government reserves the right to request a revised budget and budget justification and/or additional information. The budget should cover all costs for the site and for the submitted projects.***

**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). On page F-3, fill in the appropriate total amounts for each budget category for each additional year (or partial year) of support requested under “Budget for Entire Proposed Period of Performance.” Itemize all budget categories for the additional years and 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 per year.
  - Attendance at one DoD-sponsored scientific/technical meeting. 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 CCCRP.
- **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 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 intramural organization propose collaboration with an extramural 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. Itemize direct costs within each budget category for additional years of support requested beyond year one.
- **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 will be obligated by 30 September 2017. The plan must include the funding mechanism(s) that will be used to carry over funds between fiscal years, if applicable.

### III. APPLICATION REVIEW INFORMATION

#### A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumer advocates using a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. The second tier is a programmatic review that makes recommendations for funding to the DHA RDA Directorate and the OASD(HA), based on (a) technical merit and (b) the relevance to the mission of the DHP and JPC-6/CCCRP 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.

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. Applications will receive an overall score that combines the review of the site operation and impact, as well as the proposed research projects.

- **Operation and Impact**

- The ability and expertise of the proposed site PI, and any other administrative personnel, to ensure the successful management as a Joint En Route Care Focused Research Site.
- Appropriateness of the proposed plans for site management, including compliance with regulatory requirements, reporting, personnel transition, and communication among site members.
- Adequacy of the proposed plan for selection of new research projects.
- The expertise of the associated Project PIs and resources of the site to serve as a capability resource for the DoD.
- Evidence of the Site PIs' commitment to act as an En Route Care capability resource.
- A demonstrated effort to collaborate with outside research organizations and En Route Care subject matter experts.

The following criteria for evaluation will be applied to each of the proposed research projects, in decreasing order of importance.

- **Research Strategy and Feasibility**

- The degree to which the preliminary data (if provided) and scientific rationale support the research project.
- How well the hypotheses or objectives, aims, experimental design, methods, and analyses are developed and integrated into the project.
- To what extent the statistical plan, including sample size projections and power analysis, is adequate to achieve the study objectives and is appropriate to type and phase of study.
- Whether potential problems are acknowledged and alternative approaches are proposed to address these problems.

- **Impact**
  - How the proposed study addresses one or more of the J-ERC Research Focus Areas.
  - How the potential outcomes of the proposed work will advance the field of En Route Care research or patient care.
- **Personnel**
  - How the background and expertise of the Project PI(s) and key personnel demonstrate their ability to perform the proposed work.
  - How the levels of effort by the investigator(s) are appropriate to ensure success of this project.
  - How each investigator's record of accomplishment demonstrates his/her ability to accomplish the proposed work.

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

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

- a. Ratings and evaluations of the peer reviewers.**
- b. Relevance to the mission of the DHP and JPC-6/CCCRP as evidenced by the following:**
  - Adherence to the intent of the award mechanism
  - Military Relevance
  - Program portfolio composition
  - Programmatic relevance
  - Relative impact and innovation

### **C. Application Review Dates**

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

## **D. Notification of Application Review Results**

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

## **IV. ADMINISTRATIVE ACTIONS**

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

### **A. Rejection**

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

- Letter of Intent is missing.
- The pre-application is submitted by an extramural organization.

The following will result in administrative rejection of the application:

- Pre-application was not submitted.
- Project Narrative is missing.
- Budget is missing.

### **B. Modification**

- Pages exceeding the specific limits will be removed prior to review.
- 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 JPC-6/CCCRP J-ERC WG member 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 without appropriate acknowledgement to ensure he/she is not included in the review and selection of the application. **A list of JPC-6/CCCRP J-ERC WG members is included in [Appendix 4](#).**
- 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 fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.

- Total costs as shown on the Detailed Budget and Justification exceed the maximum allowed by this Program Announcement/Funding Opportunity.
- 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).
- An application submitted by a PI who does not meet the eligibility criteria will be withdrawn.

#### **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 CDMRP for a determination of the final disposition of the application.

### **V. AWARD ADMINISTRATION INFORMATION**

#### **A. Award Notice**

Awards will be made no later than 30 September 2016. Refer to [Appendix 2](#) for additional award administration information.

#### **B. Reporting**

- Refer to Appendix 2 for additional information on reporting requirements and publication.
- Quarterly technical progress reports and quad charts will be required.
- In addition to written progress reports, oral briefings will be expected.
- Open publication of results in peer-reviewed journals is highly encouraged.

#### **C. 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-6/CCCRP.

#### **D. Site Visits**

JPC-6/CCCRP and/or CDMRP personnel may, at their discretion, visit each PI during the award period of performance.

## **VI. AGENCY CONTACTS**

### **A. CDMRP Help Desk**

Questions related to Program Announcement/Funding Opportunity content or submission requirements as well as questions related to the submission of the pre-application through CDMRP eReceipt 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@eBRAP.org](mailto:help@eBRAP.org)

### **B. JPC-6/CCCRP Technical Point of Contact**

Scientific or technical questions regarding award mechanism intent and requirements should be directed to the JPC-6/CCCRP Portfolio Manager, Lt Col Jennifer Hatzfeld.

Phone: 301-619-0236

Email: [jennifer.j.hatzfeld.mil@mail.mil](mailto:jennifer.j.hatzfeld.mil@mail.mil)

## VII. APPLICATION SUBMISSION CHECKLIST

<b>Application Components</b>	<b>Action</b>	<b>Completed</b>
Component 1 – Technical Abstract	Upload as “TechAbs.pdf”	
Component 2 – Statement of Work	Upload as “SOW.pdf”	
Component 3 – Site Structure and Personnel	Upload as “SiteNarrative.pdf”	
Component 4 – Research Project Plan	Combine individual project plans and upload as “ResearchNarrative.pdf”	
Component 5 – Supporting Documentation	Combine individual documents and upload as “Support.pdf”	
Component 6 – Animal Research Plan	(If applicable) Combine required documents and upload as “AnimalResearchPlan.pdf”	
Component 7 – Biographical Sketches	Combine all Biographical Sketch and Previous/Current/Pending Support documents and upload as “Biosketch.pdf”	
Component 8 – Detailed Budget and Justification	Upload completed form as “Budget.pdf”	

## **APPENDIX 1 FORMATTING GUIDELINES**

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

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

## APPENDIX 2 ADMINISTRATIVE INFORMATION

### A. 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).

### B. Publication, Acknowledgement, and Public Release

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

- “In the conduct of research utilizing recombinant DNA, the investigator adhered to NIH Guidelines for research involving recombinant DNA molecules.” (<http://www.nih.gov>)
- “In the conduct of research involving hazardous organisms or toxins, the investigator adhered to the CDC-NIH Guide for Biosafety in Microbiological and Biomedical Laboratories.” (<http://www.cdc.gov/biosafety>)

### C. 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**<sup>3</sup> 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**<sup>4</sup> are defined as recorded factual material commonly accepted in the scientific community as necessary to document and support research findings. These are not the summary statistics or tables; rather, final research data are the data on which summary statistics and tables are based. Final research data do not include laboratory notes or notebooks, partial datasets, preliminary analyses, drafts of scientific papers, plans for future research, peer review reports, communications with colleagues, or physical objects, such as gels or laboratory specimens.
  - **Research Resources**<sup>5</sup> 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

<sup>3</sup> Adapted from [http://grants.nih.gov/grants/policy/data\\_sharing/data\\_sharing\\_guidance.htm](http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm)

<sup>4</sup> Adapted from [http://grants.nih.gov/grants/policy/data\\_sharing/data\\_sharing\\_guidance.htm](http://grants.nih.gov/grants/policy/data_sharing/data_sharing_guidance.htm)

<sup>5</sup> Adapted from <http://grants.nih.gov/grants/policy/policy.htm>

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/).***

## 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 Sep 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 US 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](https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.acuro_regulations) and DoDI 3216.02, “Protection of Human Subjects and Adherence to Ethical Standards in DoD-Supported Research,” as issued on November 8, 2011, and available at <http://www.dtic.mil/whs/directives/corres/pdf/321602p.pdf>.

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

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

#### 1. Research Involving Animal Use

Specific documents relating to the use of animals in the proposed research will be requested if the application is selected for funding. The ACURO, a component of the USAMRMC ORP, must review and approve all animal use prior to the start of working

with animals. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled “Research Involving Animals.” For guidance on which version of the appendix to use, as well as links to both, visit the ACURO website at: [https://mrmc.amedd.army.mil/index.cfm?pageid=Research\\_Protections.acuro\\_Animalappendix](https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.acuro_Animalappendix). *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](mailto: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](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](mailto: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](mailto: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 eBRAP website (<https://ebrap.org/eBRAP/public/Program.htm>). 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](mailto:usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil)), and/or the U.S. Food and Drug Administration (FDA) as appropriate. For in-depth information and to access HRPO protocol submission forms, refer to the ORP HRPO website ([https://mrmc.amedd.army.mil/index.cfm?pageid=Research\\_Protections.hrpo](https://mrmc.amedd.army.mil/index.cfm?pageid=Research_Protections.hrpo)).



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

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

During the regulatory review process for research involving human subjects, the ORP HRPO requirements must be addressed, and any changes to the already approved protocol must be approved as an amendment by the local IRB. It is strongly recommended that investigators carefully read the “Information for Investigators” found at [https://mrmc.amedd.army.mil/index.cfm?pageid=research\\_protections.hrpo](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](https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo).

1. **Assurance of Compliance:** Each institution engaged in non-exempt human subjects research must have a current Department of Health and Human Services Office for Human Research Protection (OHRP) Federalwide Assurance (FWA) or DoD Assurance.
2. **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.
3. **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.
4. **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](mailto:usarmy.detrick.medcom-usamrmc.other.hrpo@mail.mil) if further clarification regarding applicability of 10 USC 980 to the proposed research project is required.*

**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 (UPIRISO) 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.

**5. 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.

**6. 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](https://mrmc.amedd.army.mil/index.cfm?pageid=research_protections.hrpo).*

7. **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.

### C. Clinical Trial Registry

PIs are required to register clinical trials individually on <http://clinicaltrials.gov/> using a Secondary Protocol ID number designation of “CDMRP-eReceipt Log Number” (e.g., CDMRP-PC14#####). If several protocols exist under the same application, the Secondary Protocol ID number must be designated “CDMRP-eReceipt Log Number-A, B, C, etc.” (e.g., CDMRP-PC14#####-A). Clinical trials must be registered prior to enrollment of the first patient. All trials that meet the definition on the National Institutes of Health database (see <http://prsinfo.clinicaltrials.gov/>, click on “Data Element Definitions”) are required to register. Failure to do so may result in a civil monetary penalty and/or the withholding or recovery of grant funds as per U.S. Public Law 110-85.

**APPENDIX 4**  
**JPC-6/CCCRP JOINT EN ROUTE CARE WORKING GROUP MEMBERS**

*Please note that applications that include a JPC-6/CCCRP Joint En Route Care Working Group member as an investigator, consultant, collaborator, or in a key personnel role will be accepted, but these individuals will not participate in the final selection of the application. An application will be removed from further consideration if it is determined that a JPC-6/CCCRP Joint En Route Care Working Group member 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 without appropriate acknowledgement to ensure he/she is not included in the review and selection of the application.*

The names of the JPC-6/CCCRP Joint En Route Care Working Group Members are listed here:

CDR John Kevin Beasley	Dr. Kevin Kunkler
Lt Col Vikhyat Bebart	Lt Col Phil Mason
Dr. Timothy Bentley	Mr. Christopher McCammant
LTC Kimberlie Biever	SFC Bryan Miles
Dr. Sylvain Cardin	Maj Charles Morris
CDR Joe Coleman	Mr. Charles Paschal
CDR Kathryn Cook	CDR Dan Patterson
Dr. John Crowley	Dr. Keith Prusaczyk
Lt Col Susan Dukes	Dr. James Ross
Col Ray Fang	Col Tami Rougeau
COL Bob Gerhardt	LTC Randall Schaefer
Dr. Michael Given	MAJ Craig Stachewicz
CDR Carl Goforth	COL Bill Statz
Col Andrea Gooden	Mr. James Suttles
Mr. Calvin Griner	Mr. Mark Urrutic
Lt Col Jennifer Hatzfeld	CDR Paul Villaire
Mr. Steven Hawbecker	LCDR Ben Walrath
Dr. Richard Hersack	Col Bradford Williams
CDR Michele Huddleston	LTC Christopher Wilson
Dr. Jay Johannigman	Mr. Doug Wright
LTC Brian Krakover	Col Shawn Zarr