

Program Announcement

for the

Defense Health Program

Defense Medical Research and Development Program

Department of Defense

Clinical and Rehabilitative Medicine Research Program/Joint Program Committee 8

Regenerative Medicine Clinical Trial Award

Funding Opportunity Number: W81XWH-14-DMRDP-CRMRP-RMCTA

Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), November 25, 2013
- **Invitation to Submit an Application:** December 23, 2013
- **Application Submission Deadline:** 11:59 p.m. ET, February 11, 2014
- **Peer Review:** March 2014
- **Programmatic Review:** May 2014

This Program Announcement is one of two documents with instructions to prepare and submit an application for this funding opportunity. The second document, the General Application Instructions, is available for downloading from Grants.gov.

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I. FUNDING OPPORTUNITY DESCRIPTION

A. Program Description

Applications to the Defense Medical Research and Development Program (DMRDP) are being solicited for the Assistant Secretary of Defense for Health Affairs, Defense Health Program (DHP), by the U.S. Army Medical Research Acquisitions Activity (USAMRAA). The executing agents for this Program Announcement/Funding Opportunity are the Congressionally Directed Medical Research Programs (CDMRP) and the U.S. Army Medical Materiel Development Activity.

The goal of the DMRDP is to advance the state of medical science in those areas of most pressing need and relevance to today's battlefield experience. The objectives of the DMRDP are to discover and explore innovative approaches to protect, support, and advance the health and welfare of military personnel, families, and communities and the general public; to accelerate the transition of medical technologies into deployed products; and to accelerate the translation of advances in knowledge into new standards of care for injury prevention, treatment of casualties, rehabilitation, and training systems that can be applied in theater or in the clinical facilities of the Military Health System. Applications from investigators within the military services are highly encouraged, as are applications involving multidisciplinary collaborations among academia, industry, the military services, the Department of Veterans Affairs (VA), and other Federal Government agencies.

The Clinical and Rehabilitative Medicine Research Program (CRM RP) is one of six major program areas within the DMRDP. The CRM RP is administered with oversight from Joint Program Committee 8 (JPC-8), which consists of Department of Defense (DoD) and non-DoD medical and military technical experts relevant to the program area. The CRM RP mission is to focus on definitive and rehabilitative care innovations required to reset our wounded warriors, both in terms of duty performance and quality of life.

B. Award Information

The FY14 DMRDP CRM RP Regenerative Medicine Clinical Trial Award (RMCTA) is intended to support Phase I or II clinical trials focused on extremity regeneration, craniomaxillofacial regeneration, vascularized composite allografts, and/or genitourinary/lower abdomen reconstruction. ***Funding from this award mechanism cannot be used for preclinical research studies.*** All clinical trials must be responsive to the health care needs of military Service Members and Veterans, and all applications must specifically and clearly address the military relevance of the proposed research; however, the use of military populations in the proposed clinical trial(s) is not a requirement. Applications submitted to the FY14 DMRDP CRM RP RMCTA ***must*** specifically address one or more of the Focus Areas listed below.

Extremity Regeneration

- **Muscle loss and damage**
 - Cellular-, biologic-, and/or biomaterial-based therapies for the treatment and consequences of large volume muscle loss in the extremities and/or defects. The

- intent is to restore muscle volume and function, support neovascularization and reinnervation of regenerated muscle tissue, and promote structural and functional integration between the regenerated and native host tissues.
- Cellular-, biologic-, and/or biomaterial-based therapies that control inflammation, wound healing and scarring of remaining muscle mass after large volume muscle loss and provide for tissue bulking and muscle regeneration in order to improve muscle form and function
 - **Peripheral nerve loss and damage**
 - Off-the-shelf nerve guide technologies, as an alternative for autograft nerve harvest, for the repair of nerve gaps greater than 3 cm in length in motor or mixed peripheral nerves. These technologies would also provide an improvement in the rate and quality of nerve regeneration when compared to the current standard of care.
 - Cellular-, biologic-, and/or biomaterial-based therapies or device technologies that accelerate or direct muscle reinnervation and/or preserve muscle form and function during the re-establishment of neuromuscular junctions following denervation due to trauma
 - **Vascular loss and damage**
 - Off-the-shelf vascular graft technologies as an alternative for autograft harvest that address vascular loss or defects due to trauma and are able to address defects of a diversity of lengths and diameters
 - Cellular-, biologic-, and/or biomaterial-based therapies that promote a robust and durable revascularization of damaged tissue and between regenerated tissue and host vasculature

Craniomaxillofacial Regeneration

- **Craniomaxillofacial soft tissues**
 - Cellular-, biologic-, and/or biomaterial-based therapies that enable reconstruction of lip, eyelid, and nasal cartilage tissue following loss and damage due to trauma or burn injury
 - Cellular-, biologic-, and/or biomaterial-based therapies for the treatment and consequences of facial muscle loss and/or defects to restore both muscle volume and function and support neovascularization and reinnervation of regenerated muscle tissue as well as structural and functional integration between the regenerated and host tissues
 - Cellular-, biologic-, and/or biomaterial-based therapies or device technologies that promote resolution of injury-related inflammation and reduction of tissue fibrosis, scarring, and disfigurement
- **Bone regeneration**
 - Cellular-, biologic-, and/or biomaterial-based therapies that provide an alternative to autograft bone harvest for the treatment of craniomaxillofacial bone injury and/or loss. Technologies should target one or more of the following: (1) well-shaped bone

that maintains form and relevant mechanical properties for cranial and midface bone repair and reconstruction; (2) bone that maintains three-dimensional shape, is load-bearing, and may or may not include an articular process intended for mandible reconstruction; and (3) reconstruction and regeneration of alveolar bone that supports dentition.

Vascularized Composite Allotransplantation (VCA)

- **Immunosuppression, immunomodulation, and immunocloaking technologies**
 - Drug minimization approaches and mechanisms that result in reduced toxicity or side effects of long-term immunosuppression protocols
 - Prolongation of allograft preservation and/or mitigation of ischemic injury
- **Clinical monitoring of VCA recipients**
 - Minimally invasive technologies and protocols that enable the quick identification and treatment of tissue rejection

Genitourinary/Lower Abdomen Reconstruction

- **Pelvic reconstruction**
 - Technologies that address tissue loss and damage to the anus and to the pelvic floor to restore both form and function
- **Urogenital reconstruction**
 - Technologies that address tissue loss and damage to genital (penile or scrotal tissues) and perineal tissue to restore both form and function

Funding from this award mechanism must support a clinical trial and may not be used for preclinical research studies. A clinical trial is defined as a prospective accrual of human subjects where an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested on a human subject for a measurable outcome with respect to exploratory information, safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the human subject of that intervention or interaction. Principal Investigators (PIs) seeking funding for a preclinical research project should consider one of the other award mechanisms/funding opportunities being offered. The term “human subjects” is used in this Program Announcement/Funding Opportunity to refer to individuals who will be recruited for or who will participate in the proposed clinical trial. For more information, a Human Subject Resource Document is provided at https://cdmrp.org/Program_Announcements_and_Forms/.

If the study proposed involves the use of a drug or biologic that has not been approved by the Food and Drug Administration (FDA) for its investigational use, ***evidence that an Investigational New Drug (IND) exemption application has been submitted or will be submitted within 60 days of award*** is required. If the proposed study involves an Investigational Device that has not been approved or cleared by the FDA for its investigational clinical use, the study may be required to comply with the FDA Investigational Device Exemption (IDE) regulations and ***evidence that an IDE has been submitted or will be submitted within 60 days of the award date or that the device is exempt from an IDE*** is required. The Government reserves

the right to withdraw funding if the IND or IDE application has not been submitted to the FDA within 60 days of the DoD award date or if the documented status of the IND or IDE has not been obtained within 6 months of the award date.

The following are important aspects of submission for the Regenerative Medicine Clinical Trial Award:

- The proposed clinical trial is expected to begin no later than 12 months after the award date.
- The proposed intervention to be tested should offer significant potential impact for military Service Members and Veterans.
- Inclusion of preliminary data relevant to the proposed research project is required.
- In addition to requisite preliminary data, the proposed research project must be based on sound scientific rationale that is established through logical reasoning and critical review and analysis of the literature.
- The application should demonstrate availability of, and access to, a suitable patient population that will support a meaningful outcome for the study. The PI should discuss how accrual goals will be achieved and how standards of care may impact the study population. If not proposing to study military and or Veteran subjects, the study should clearly articulate how the results will be meaningful for these populations.
- The application should demonstrate documented availability of and access to the drug/compound, device, and/or other materials needed, as appropriate.
- The proposed clinical trial should include clearly defined, measureable, and appropriate endpoints.
- The application should include a clearly articulated statistical analysis plan, appropriate statistical expertise, and a power analysis reflecting sample size projections that will clearly answer the objectives of the study.
- The application should include a study coordinator(s) who will guide the clinical protocol through the local Institutional Review Board (IRB) of record and other regulatory approval processes, coordinate activities from all sites participating in the trial, and coordinate participant accrual.
- The application should include a Transition Plan (including potential funding and resources) showing how the product will progress to the next clinical trial phase and/or delivery to the market after the successful completion of the award.
- The application should clearly demonstrate strong institutional support.

Use of Human Subjects and Human Anatomical Substances: All DoD-funded research involving new and ongoing research with human subjects and human anatomical substances 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. Time and level of effort for local IRB approval(s) should be considered in planning. The HRPO is mandated to comply with specific

laws and directives governing all research involving human subjects that is supported by the DoD. These laws and directives are rigorous and detailed, and will require information in addition to that supplied to the local IRB. In addition to time for local IRB approval(s), allow for a minimum of 2 months for HRPO review and approval processes. Refer to the General Application Instructions, Appendix 5, for more information.

Multi-Institutional Research: Multi-institutional research projects are encouraged when combining the resources of two or more organizations will strengthen the research application. If the proposed research is multi-institutional, plans for communication and data transfer between the collaborating institutions, as well as how data, specimens, and/or imaging products obtained during the study will be handled, must be included in the Project Narrative. A separate intellectual and material property plan agreed upon by all participating institutions is also required for multi-institutional research. Participating institutions must be willing to resolve potential intellectual and material property issues and to remove any barriers that may interfere with achieving high levels of cooperation to ensure successful completion of this award.

DoD Collaboration and Alignment Encouraged: Relevance to the health care needs of the Armed Forces, their family members, and/or the U.S. Veteran population is a key feature of this award. Therefore, Principal Investigators (PIs) are strongly encouraged to collaborate, integrate, and/or align their research projects with military and/or VA research laboratories and programs. The following websites may be useful in identifying information about ongoing DoD areas of research interest:

Air Force Research Laboratory

<http://www.wpafb.af.mil/afrl>

Clinical and Rehabilitative Medicine
Research Program

<https://crmrp.amedd.army.mil/>

Congressionally Directed Medical
Research Programs

<http://cdmrp.army.mil>

Defense Advanced Research
Projects Agency

<http://www.darpa.mil/>

Defense Technical Information Center

<http://www.dtic.mil>

Naval Health Research Center

<http://www.med.navy.mil/sites/nhrc>

Naval Medical Research Center

www.med.navy.mil/sites/nmrc

Navy and Marine Corps Public
Health Center

<http://www.nmcphc.med.navy.mil/>

Office of Naval Research

<http://www.med.navy.mil/>

Office of the Under Secretary of Defense
for Acquisition, Technology and
Logistics

<http://www.acq.osd.mil/>

U.S. Army Medical Research
Acquisition Activity

<http://www.usamraa.army.mil>

U.S. Army Medical Research and
Materiel Command

<https://mrmc.amedd.army.mil>

U.S. Army Research Laboratory

<http://www.arl.army.mil>

U.S. Naval Research Laboratory

www.nrl.navy.mil

U.S. Department of Veterans Affairs,
Office of Research and Development

www.research.va.gov

Use of Military and VA Populations or Resources: If the proposed research involves access to military and/or VA population(s) and/or resource(s), the PI is responsible for establishing access. If possible, access to target military and/or VA patient population(s) should be confirmed at the time of application submission. A letter of support, signed by the lowest ranking person with approval authority, should be included for studies involving military Service Members, Veterans, military and/or VA-controlled study materials, and military and/or VA databases. Use Attachment 2 to provide this documentation (see Section II.C., Application Submission Content and Form, Supporting Documentation).

Reporting Guidelines: Proposed research projects should adhere to a core set of reporting standards for rigorous study design. CRMRP strongly encourages investigators to follow the ARRIVE (Animal Research: Reporting *In Vivo* Experiments) guidelines (<http://www.nc3rs.org.uk/page.asp?id=1357>). While these standards are written for animal studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies and should be applied to those projects as well.

The CRMRP intends that data and research resources generated under awards funded by this Program Announcement/Funding Opportunity be made available to the research community (which includes both scientific and consumer advocacy communities) and to the public at large. For additional guidance, refer to the General Application Instructions, Appendix 4, Section K.

C. Eligibility Information

- Independent investigators at all academic levels (or equivalent) are eligible to submit applications.
- Cost sharing/matching is not an eligibility requirement.
- Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations. Both intramural (i.e., U.S. Federal Government agency, department, laboratory, medical treatment facility, or a U.S. Government activity embedded within a civilian medical center) and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

D. Funding

- The maximum period of performance is **4** years.
- The maximum allowable total (direct and indirect) costs for the entire period of performance are **\$2.5 million (M)**.
- All direct and indirect costs of any subaward (subgrant or subcontract) must be included in the total direct costs of the primary award.
- The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **4** years.

- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable total costs. Indirect costs shall be proposed in accordance with the organization's negotiated rate agreement.

Refer to the General Application Instructions, Section II.C.4., for budget regulations and instructions for the Research & Related Budget. ***For all federal agencies or organizations collaborating with federal agencies, budget restrictions apply as are noted in Section II.C.4 of the General Application Instructions.***

In addition, for this award mechanism, direct costs:

Must be requested for:

- Travel costs for the PI(s) to attend one program review per year during the award period of performance. For planning purposes, it may be assumed that these program reviews will be held in the National Capital Region for approximately 2 days.

May be requested for (not all-inclusive):

- Salary of non-Government personnel (includes contract research personnel at Government facilities)
- Research-related subject costs
- Clinical research costs
- Equipment
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs of up to \$1,800 per year to attend scientific/technical meetings (in addition to the required meeting described above)

Shall not be requested for:

- Preclinical research studies
- Salary of Government personnel

Intramural (DoD) and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity. As required of all applicants to this Program Announcement, if PIs from federal agencies submit full applications, they must submit through Grants.gov. Therefore, federal applicants must be familiar with Grants.gov requirements, including the need for System for Award Management (SAM) and a Data Universal Numbering System (DUNS) number. Refer to Appendix 3 of the General Application Instructions for further information regarding Grants.gov requirements.

Awards to extramural organizations will consist solely of assistance agreements (cooperative agreements and grants). Awards to intramural organizations will be executed through a Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD)

process. Direct transfer of funds from the recipient to a federal organization or agency is not allowed except under very limited circumstances.

The CRM RP JPC-8 expects to allot approximately \$11.1M of the FY14 DMRDP appropriation to fund approximately 4-5 Regenerative Medicine Clinical Trial Award applications, depending on the quality and number of applications received. The funding estimated for this Program Announcement/Funding Opportunity is approximate and subject to realignment. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of federal funds for this program.

II. SUBMISSION INFORMATION

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

Submission of applications that are essentially identical or propose essentially the same research project to different funding opportunities within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application.

A. Where to Obtain the Application Package

To obtain the complete application package, including all required forms, perform a Grants.gov (<http://www.grants.gov/>) basic search using the Funding Opportunity Number: W81XWH-14-DMRDP-CRM RP-RMCTA.

B. Pre-Application Submission Content and Form

All pre-application components must be submitted by the PI through the CDMRP eReceipt System (<https://cdmrp.org/>). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

PIs 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 (refer to the General Application Instructions, Section II.B., for additional information on pre-application submission):

- **Application Information – Tab 1**
- **Application Contacts – Tab 2**

- **Collaborators and Conflicts of Interest (COI) – Tab 3**

FY14 CRM RP RMCTA Steering Committee members should not be involved in any pre-application or application. For questions related to Steering Committee members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP at help@cdmrp.org or 301-682-5507.

- **Required Files – Tab 4**

Preproposal Narrative (three-page limit): The Preproposal Narrative page limit applies to text and any figures, tables, graphs, photographs, diagrams, chemical structures, pictures, pictorials, and cartoons. 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 application.

Note: *At this time, eReceipt is unable to read files made with Adobe Acrobat PDFMaker version 9.0 and higher.*

The Preproposal Narrative should include the following:

- **Rationale:** State the ideas and reasoning on which the proposed clinical trial is based. Describe how the preliminary data and rationale support the research idea. State how this project meets the intent of the award mechanism.
- **Focus Area:** Note specifically which of the FY14 CRM RP RMCTA Focus Area(s) the proposed work addresses.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Research Strategy:** Clearly describe the research or clinical trial being proposed, and indicate the phase of trial and/or class of device and regulatory status as appropriate. Concisely state the project's objectives, specific aims, and ultimate endpoints. Describe the proposed methods and how they will accomplish the project's aims.
- **Personnel:** Briefly state the qualifications of the PI and key personnel to perform the described clinical trial.
- **Military Benefit:** Describe how the proposed work would impact the health care needs of military Service Members and/or U.S. Veterans recovering from traumatic injury as well as their families, caregivers, and/or communities.

Pre-Application Supporting Documentation: The 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.
- **Key Personnel Biographical Sketches (four-page limit per individual).**

- **Quad Chart:** The Quad Chart template is a one-page PowerPoint file that must be downloaded from the CDMRP eReceipt System at https://cdmrp.org/Program_Announcements_and_Forms/, completed, and saved as a PDF file using Adobe Acrobat Reader.
- **Submit Pre-Application – Tab 5**
This tab must be completed for the pre-application to be accepted and processed by the CDMRP.
- **Other Documents Tab**
No additional documents are required.

Pre-Application Screening

- **Pre-Application Screening Criteria**
To determine the technical merits of the pre-application and the relevance to the mission of the DHP, the DMRDP, and the CRM RP, pre-applications will be screened based on the following criteria:
 - **Alignment with Focus Areas:** How well the project addresses at least one of the FY14 DMRDP CRM RP RMCTA Focus Areas.
 - **Research Plan:** How well the proposed clinical trial addresses the intent of the award mechanism and the program. To what degree the rationale, objectives, and specific aims support the research idea. How the endpoints are appropriate for the proposed study. Whether the proposed methodology is appropriate.
 - **Personnel:** How the qualifications and expertise of the PI and key personnel are appropriate to perform the proposed research or clinical trial.
 - **Military Benefit:** How the proposed work would benefit the health care needs of military Service Members and/or U.S. Veterans recovering from traumatic injury as well as their families, caregivers, and/or communities.
- **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.

C. Application Submission Content and Form

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

Each application submission must include the completed application package of forms and attachments provided in Grants.gov for this Program Announcement/Funding Opportunity. The application package is submitted by the Authorized Organizational Representative through the Grants.gov portal (<http://www.grants.gov/>).

Grants.gov application package components: For the FY14 DMRDP CRM RP RMCTA, the Grants.gov application package includes the following components (refer to the General Application Instructions, Section II.C., for additional information on application submission):

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

The Project Narrative is NOT the formal clinical trial protocol. Instead, all essential elements of the proposed clinical trial necessary for scientific review must be included as directed in Attachment 1 (the Project Narrative) and Attachments 6-8 described below. Failure to submit these attachments as part of the application package will result in rejection of the entire application.

- **Attachment 1: Project Narrative (25-page limit):** Upload as “ProjectNarrative.pdf.” The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and will result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

- **Background:** State the relevance of the proposed clinical trial to at least one of the FY14 DMRDP CRM RP RMCTA Focus Areas and explain the applicability of the proposed findings. Describe in detail the rationale for the study and include a literature review, preliminary studies, and/or preclinical data that led to the development of the proposed clinical trial. Provide a summary of relevant clinical trials and distinguish how the proposed study differs from other relevant or recently completed clinical trials. Include a discussion of any current clinical use of the intervention under investigation, and/or details of its study in clinical trials for other indications (as applicable). Clearly support the choice of study variables and explain the basis for the study questions and/or study hypotheses. 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.
- **Study Design:** Describe the type of study to be performed (e.g., prospective, randomized, controlled) and outline the proposed methodology in sufficient detail to show a clear course of action. Describe potential challenges and alternative strategies where appropriate.
 - Identify the intervention to be tested and describe the projected outcomes, including how they will be measured.
 - Define the study variables and describe how they will be measured. Include a description of appropriate controls and the endpoints to be tested.

- Describe the methods that will be used to recruit a sample of human subjects from the accessible population (e.g., convenience, simple random, stratified random).
- Describe the human subject-to-group assignment process (e.g., randomization, block randomization, stratified randomization, age-matched controls, alternating group, or other procedures), if applicable. Explain the specific actions to accomplish the group assignment (e.g., computer assignment, use of table of random numbers). Discuss blinding procedures as applicable and how the blind will be maintained. Describe other methods to control for the introduction of potential bias into the study.
- **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives. Specify the approximate number of human subjects that will be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size is appropriate and sufficient to meet the objectives of the study.
- **Attachment 2: Supporting Documentation.** Start each document on a new page. Combine and upload as a single file named “Support.pdf.” If documents are scanned to pdf, the lowest resolution (100 to 150 dpi) should be used. ***There are no page limits for any of these components unless otherwise noted. Include only those components described below; 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. 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.
 - 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 in Attachment 2. Extra items will not be reviewed.
 - Letters of Organizational Support (two-page limit per letter): Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project.

- Letters of Collaboration (if applicable) (two-page limit per letter): 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) of Support for Use of Military and VA Populations or Resources (if applicable) (two-page limit per letter): Provide a letter(s) signed by the lowest ranking person with approval authority for studies involving military Service Members, Veterans, military and/or VA-controlled study materials, and military and/or VA databases.
- Intellectual and Material Property Plan (if applicable):
 - Provide a list of all background intellectual property relevant to the project. Identify any proprietary information that will be provided to the Government and whether the applicant will require a waiver of Government purpose rights; *and/or*
 - 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 the General Application Instructions, Appendix 4, for more information about expectations for making data and research resources publically available. The Government reserves the right to identify additional data sharing requirements and or repositories for submission of data for archive.
- Current Quad Chart: Provide a current Quad Chart in the same format as in the pre-application. If no changes have been made to the project, the same Quad Chart submitted with the pre-application may be used.
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.”
Use the outline below. (Proprietary or confidential information should *not* be included.)
 - Background: State how the proposed clinical trial addresses a FY14 DMRDP CRM RP RMCTA Focus Area. Present 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 the specific aims of the study.
 - Study Design: Briefly describe the study design, including appropriate controls.
 - Military Benefit: Briefly explain how the proposed project will have an immediate or potential long-term impact on the health and well-being of Service Members, Veterans, and/or their family members.

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

Lay abstracts should be written using the following outline. (Proprietary or confidential information should *not* be included.)

- Describe the objectives and rationale for the application in a manner that will be readily understood by readers without a background in science or medicine.
 - Do not duplicate the technical abstract.
- Describe the ultimate applicability of the clinical research.
 - What types of patients will it help, and how will it help them? (Include the current available statistics to the related injury/condition.)
 - What are the potential clinical applications, benefits, and risks?
 - What is the projected timeline it may take to achieve the expected patient-related outcome?
 - Briefly describe how the proposed project will benefit Service Members, Veterans, and/or their family members

- **Attachment 5: Statement of Work (SOW) (three-page limit):** Upload as “SOW.pdf.” Refer to the General Application Instructions, Section II.C., for detailed information, including guidance on appropriate SOW formats.

- **Attachment 6: Human Subject Recruitment and Safety Procedures (no page limit):** Upload as “HumSubProc.pdf.” The Human Subject Recruitment and Safety Procedures attachment should include the components listed below.

a. Study Population: Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site (population from whom the sample will be recruited/drawn). Demonstrate that the research team has access to the proposed study population. Furthermore, discuss past efforts in recruiting human subjects from the target population for previous clinical trials (if applicable). Address any potential barriers to accrual and plans for addressing unanticipated delays. Include justification of any age, race, ethnicity, or sex limitations provided.

b. Inclusion/Exclusion Criteria: List the inclusion and exclusion criteria for the proposed clinical trial. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide detailed justification for exclusions.

Inclusion of Women and Minorities in Study. Consistent with the Belmont Report, “Ethical Principles and Guidelines for the Protection of Human Subjects,” and Congressional legislation, special attention is given to inclusion of women and/or minorities in studies funded or supported by the USAMRMC. This policy is intended to promote equity both in assuming the burdens and in receiving the benefits of human subjects research. Include an appropriate justification if women and/or minorities will be excluded from the clinical trial.

- c. **Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, health care provider identification).
- Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.
 - Include a detailed description of and justification for the compensation plan if the human subjects will be compensated for participation in the study.
 - Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study.
- d. **Description of the Informed Consent Process:** Specifically describe the plan for obtaining informed consent from human subjects.
- ***For the proposed study, provide a draft, in English, of the Informed Consent Form.***
 - Identify who is responsible for explaining the study, answering questions, and obtaining informed consent. Include a plan for ensuring that human subjects' questions will be addressed during the consent process and throughout the trial.
 - Include information regarding the timing and location of the consent process.
 - Address issues relevant to the mental capacity of the potential human subject (e.g., altered capacity due to administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia, brain injury, stress/life situations, or human subject age), if applicable.
 - Address how privacy and time for decision making will be provided and whether or not the potential human subject will be allowed to discuss the study with anyone before making a decision.
 - Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study and describe any relevant procedures to assure continued consent.
 - Describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. Note: The PI must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed clinical trial to be in compliance with Title 10 United States Code Section 980 (10 USC 980) (<http://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf>). If applicable, please refer to the General Application Instructions, Appendix 5, for more information.

- **Assent.** If minors or other populations that cannot provide informed consent are included in the proposed clinical trial, a plan to obtain assent (agreement) from those with capacity to provide it, or a justification for a waiver of assent, should be provided. PIs should consult with their local IRB to identify the conditions necessary for obtaining assent.
- e. **Screening Procedures:** List and describe any evaluations (e.g., laboratory procedures, history, or physical examination) that are required to determine eligibility/suitability for study participation and the diagnostic criteria for entry. Please note that some screening procedures may require a separate consent or a two-stage consent process. Informed consent must be obtained prior to initiation of any procedures for the purpose of determining eligibility.
- f. **Risks/Benefits Assessment:**
 - **Foreseeable risks:** Clearly identify all study risks. Study risks include any risks that the human subject is subjected to as a result of participation in the clinical trial. Consider psychological, legal, social, and economic risks as well as physical risks. If the risks are unknown, this should be stated. If applicable, any potential risk to the study personnel should be identified.
 - **Risk management and emergency response:**
 - Describe all safety measures to minimize and/or eliminate risks to human subjects and study personnel or to manage unpreventable risks. Include safeguards and planned responses such as dose reduction or stopping criteria based on toxicity grading scales or other predetermined alert values.
 - Discuss the overall plan for provision of emergency care or treatment for an adverse event for study-related injuries, to include who will be responsible for the cost of such care.
 - Address any special precautions to be taken by the human subjects before, during, and after the study (e.g., medication washout periods, dietary restrictions, hydration, fasting, pregnancy prevention).
 - Describe any special care (e.g., wound dressing assistance, transportation due to side effects of study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study.
 - **Potential benefits:** Describe known and potential benefits of the study to the human subject, a specific community, or society.
- **Attachment 7: Intervention (no page limit):** Upload as “Intervention.pdf.” The Intervention attachment should include the components listed below.
 - a. **Description of the Intervention:** As applicable, the description of the intervention should include the following components: complete name and composition, storage and handling information, source, dose, schedule, administration route, washout period, duration of the intervention, and concomitant medications allowed.

Summarize key preclinical pharmacological findings, dosage studies, and other clinical studies (if applicable) that examine the safety of the intervention. Description of devices should include detailed operational instructions, any potential risks to users, and intended benefits. Other types of interventions should be fully described.

- b. Study Procedures:** Describe the interaction with the human subject to include the study intervention that he/she will undergo. Provide sufficient detail in chronological order for a person uninvolved in the study to understand what the human subject will undergo. Provide a schedule (e.g., flowchart or diagram) of study evaluations and follow-up procedures. Discuss how compliance with Good Clinical Practices, Good Manufacturing Practices, and other regulatory considerations will be established, monitored, and maintained, as applicable.
- **Attachment 8: Data Management (no page limit):** Upload as “Data_Manage.pdf.” The Data Management attachment should include the components listed below.
 - a. Data Management:** Describe all methods used for data collection to include the following:
 - **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.
 - **Confidentiality:**
 - Explain measures taken to protect the privacy of study human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.
 - Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of USAMRMC are eligible to review study records.
 - Address requirements for reporting sensitive information to state or local authorities.
 - **Disposition of data:** Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, and the length of time data will be stored.
 - **Sharing study results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether or not the results of screening and/or study participation will be shared with human subjects or their primary care provider, to include results from any screening or diagnostic tests performed as part of the study.
 - b. Laboratory Evaluations:**
 - **Specimens to be collected, schedule, and amount.** All specimens that will be collected for study purposes must be clearly stated. The collection schedule and amount of material collected must also be clearly described.

- **Evaluations to be made.** Describe all evaluations that will be made for study purposes. Explain how the results of laboratory evaluations will be used to meet the objectives of the study (or to monitor safety of human subjects).
- **Storage.** Describe specimen storage, to include location of storage, how long specimens will be stored, any special conditions required, labeling, and disposition. Outline the plan to store specimens for future use to include considerations for informed consent and providing human subjects with an opportunity to decline participation in the study.
- **Labs performing evaluations and special precautions.** Identify the laboratory performing each evaluation, as well as any special precautions that should be taken in handling the samples. Special precautions that should be taken by the human subject before, during, or after the laboratory procedure should be clearly defined. If transport of samples is required, describe provisions for ensuring proper storage during transport.
- **Attachment 9: Study Personnel and Organization (no page limit):** Upload as “Personnel.pdf.” The Study Personnel and Organization attachment should include the components listed below.
 - a. **Principal Investigator/Study Staff:** Provide an organizational chart identifying key members of the study team including institution/center/department. Briefly describe their roles on the project. A medical monitor (external to the study and not reimbursed by the study) and study coordinator(s) should be included.
 - b. **Study Management Plan:** Provide a plan for ensuring the standardization of procedures among staff and across sites (if applicable). If the proposed clinical trial is multi-institutional, plans for communication and data transfer between the collaborating institutions, as well as how data, specimens, and/or imaging products obtained during the study will be handled, should be included. Provide a plan for real-time communication among collaborating institutions (if applicable).
- **Attachment 10: Surveys, Questionnaires, and Other Data Collection Instruments, if applicable (no page limit):** Upload as “Surveys.pdf.” The Surveys, Questionnaires, and Other Data Collection Instruments attachment should include a copy of the most recent version of surveys, questionnaires, data collection forms, rating scales, interview guides, or other instruments. For each instrument, describe how the information collected is related to the objectives of the study.
- **Attachment 11: Military Benefit (one-page limit).** Upload as “MilBen.pdf.”
 - Describe how the proposed study is responsive to the health care needs of military Service Members and/or Veterans recovering from traumatic injury. Provide information about the incidence and/or prevalence of the disease or condition to be studied in military Service Members and/or Veterans, if appropriate and available. Show how the proposed study complements ongoing DoD and VA areas of research interest.

- If active duty military and/or Veteran population(s) will be used in the proposed research project or clinical trial, describe the population(s), the appropriateness of the population(s) for the proposed study, and the feasibility of accessing the population. If a non-military population will be used for the proposed research project, explain how the population simulates the targeted population (i.e., military Service Members or Veterans).
- Describe the short-term impact: Detail the anticipated outcomes that will be directly attributed to the results of the proposed clinical trial.
- Describe the long-term impact: Explain the long-range vision for implementation of the intervention in the clinic or field, and describe the anticipated long-term benefits for the targeted population.
- **Attachment 12: Transition Plan (one-page limit).** Upload as “Transition.pdf.” Provide information on the methods and strategies proposed to move the product to the next phase of clinical trials and/or delivery to the military or civilian market after successful completion of the award. The transition plan should include the components listed below.
 - Details of the funding strategy that will be used to bring the outcomes to the next level of clinical trials and/or delivery to the military or civilian market (e.g., specific potential industry partners, specific funding opportunities to be applied for).
 - A description of collaborations and other resources that will be used to provide continuity of development.
 - A brief schedule and milestones for bringing the outcome(s) to the next phase of clinical trials and/or delivery to the military or civilian market.
 - The involvement of appropriate intellectual property, licensing, and/or business professionals.
 - A risk analysis for cost, schedule, manufacturability, and sustainability.
- **Attachment 13: IND/IDE Documentation (if applicable):** If submitting multiple documents, start each document on a new page. Combine and upload as a single file named “IND-IDE.pdf.”
 - Complete the IND/IDE Documentation Form, which is available for download on the Full Announcement page for this Program Announcement/Funding Opportunity on Grants.gov.
 - Provide evidence that an IND or IDE has been submitted and include an explanation of the status of the IND or IDE (e.g., past the critical 30-day period, pending response to questions raised by the Agency, on clinical hold). Inclusion of a copy of the Agency meeting minutes is encouraged but not required. If an IND or IDE is not required for the proposed study, provide evidence in the form of communication from the FDA or the IRB of record to that effect.

- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C., for detailed information.
 - PI Biographical Sketch (four-page limit): Upload as “Biosketch_LastName.pdf.”
 - PI Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
 - Key Personnel Biographical Sketches (four-page limit each): Upload as “Biosketch_LastName.pdf.”
 - Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support_LastName.pdf.”
- 4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C., for detailed information.
 - Budget Justification (no page limit): Upload as “BudgetJustification.pdf.”
- 5. Project/Performance Site Location(s) Form:** Refer to the General Application Instructions, Section II.C., for detailed information.
- 6. R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C., for detailed information.

D. Submission Dates and Times

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 any one of the deadlines will result in application rejection.

E. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, for detailed formatting guidelines.

All applications must be submitted through Grants.gov. Applicant organizations and all subrecipient organizations must have a DUNS number to submit applications to Grants.gov. The applicant organization must also be registered in the Entity Management functional area of the SAM with an “Active” status to submit applications through the Grants.gov portal. Refer to the General Application Instructions, Appendix 3, for information on Grants.gov requirements.

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 a 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 Office of the Assistant Secretary of Defense for Health

Affairs, based on technical merit, the relevance to the mission of the DHP, DMRDP, and CRMRP and 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 review process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess>.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a non-disclosure 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 Criteria

- 1. Peer Review:** To determine technical merit, all applications will be evaluated according to the following scored criteria, which are of equal importance:
 - **Military Benefit**
 - How relevant the anticipated outcomes of the proposed clinical trial are to military Service Members and Veterans recovering from traumatic injury.
 - How well the sample population represents the targeted patient population that might benefit from the proposed intervention.
 - The potential immediate and/or long-term benefits of the proposed clinical trial on the health and well-being of Service Members, Veterans, and/or their families or communities.
 - **Ethical Considerations**
 - How the level of risk to human subjects is minimized and whether there is sufficient evidence of a monitoring plan that is appropriate for the level of risk.
 - How well the evidence shows that the procedures are consistent with sound research design and, when appropriate, that these procedures are already in use for diagnostic or treatment purposes.
 - To what degree privacy issues are appropriately considered.
 - To what degree the process for seeking informed consent is appropriate and whether safeguards are in place for vulnerable populations.
 - **Intervention**
 - Whether there is evidence indicating availability of the intervention from its source for the duration of the proposed clinical trial.

- To what degree the intervention addresses the clinical need(s) described.
- To what degree the PI has provided preclinical and/or clinical evidence to support the safety of the intervention.
- How the intervention compares with currently available interventions and/or standards of care.
- Whether a member of the study team holds the IND/IDE or whether the timeline proposed for IND/IDE application is appropriate (if applicable).
- For investigator-sponsored INDs, whether there is evidence of appropriate institutional support, including capabilities to ensure monitoring as required by the FDA.
- To what degree the data collection instruments (e.g., surveys, questionnaires), if applicable, are appropriate to the proposed study.
- **Recruitment, Accrual, and Usability**
 - How well the PI addresses the availability of human subjects for the clinical trial and the prospect of their participation.
 - Whether the PI has demonstrated access to the proposed human subjects population.
 - The degree to which the recruitment, informed consent, screening, and retention processes for human subjects will meet the needs of the proposed clinical trial.
 - How well the application identifies possible delays (e.g., slow accrual, attrition) and presents adequate contingency plans to resolve them.
 - To what extent the proposed clinical trial might affect the daily lives of the individual human subjects participating in the study (e.g., Will human subjects still be able to take their regular medications while participating in the clinical trial? Are human subjects required to stay overnight in a hospital?).
- **Research Strategy**
 - How well the scientific rationale for testing the intervention is supported by the preliminary data, critical review and analysis of the literature, and/or laboratory/preclinical evidence.
 - How well the study aims, hypotheses or objectives, experimental design, methods, data collection procedures, and analyses are designed to answer clearly the clinical objective.
 - How well the inclusion and randomization criteria meet the needs of the proposed clinical trial.
 - How well the exclusion criteria are justified.
 - How well plans for addressing ethical and regulatory considerations have been developed

- **Statistical Plan**
 - To what degree the statistical model and data analysis plan are suitable for the planned study.
 - How the statistical plan, including sample size projections and power analysis, is adequate for the study and all proposed correlative studies.
- **Transition Plan**
 - Whether the funding strategy described to bring the outcome(s) to the next level of clinical trials and/or delivery to the military or civilian market is appropriate.
 - Whether appropriate collaborations and other resources for providing continuity of development are established and/or well described.
 - How the schedule and milestones for bringing the outcome(s) to the next level of clinical trial and/or delivery to the military or civilian market are appropriate and feasible.
 - How well the potential risk analysis for cost, schedule, manufacturability, and sustainability is developed.
 - How well the application identifies intellectual property ownership, describes any appropriate intellectual and material property plan among participating organizations (if applicable), and addresses any impact of intellectual property issues on product development and subsequent Government access to products supported by this Program Announcement/Funding Opportunity.

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

- **Personnel and Communication**
 - Whether the composition of the study team (e.g., study coordinator, statistician) is appropriate.
 - To what degree the study team's background and expertise are appropriate to accomplish the proposed work (e.g., statistical expertise, expertise in the disease, and clinical studies).
 - How the levels of effort of the study team members are appropriate for successful conduct of the proposed trial.
 - How well the logistical aspects of the proposed clinical trial (e.g., communication plan, data transfer and management, standardization of procedures) meet the needs of the proposed clinical trial.
- **Environment**
 - To what degree the scientific environment, clinical setting, and the accessibility of institutional resources support the clinical trial at each participating center or institution (including collaborative arrangements).
 - Whether there is evidence for appropriate institutional commitment from each participating institution.

- If applicable, how the intellectual and material property plan that is agreed upon by each participating institution is appropriate for the proposed clinical trial.
- **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 influenced the review.

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

- **Ratings and evaluations of the peer reviewers**
- **Relevance to the mission of the DHP, DMRDP, and CRM RP as evidenced by the following:**
 - Adherence to the intent of the award mechanism
 - Military relevance
 - Program portfolio composition
 - Relative impact

C. Recipient Qualification

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 1.

D. Application Review Dates

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

E. Notification of Application Review Results

Each PI and organization will receive 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 from the CDMRP eReceipt System or applications from Grants.gov, the following administrative actions may occur:

A. Rejection

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

- Preproposal Narrative exceeds page limit.

- 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.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- Human Subject Recruitment and Safety Procedures (Attachment 6) is missing.
- Intervention (Attachment 7) is missing.
- Data Management (Attachment 8) is missing.

B. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents other than the Preproposal Narrative and 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 (excluding those listed in Section IV.A., Rejection). The missing documents must be provided by 5:00 p.m. ET on the second full business day following the date the email was sent. Otherwise, the application will be reviewed as submitted.

C. Withdrawal

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

- A FY14 CRMRP RMCTA Steering Committee 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 document. A list of the FY14 CRMRP RMCTA Steering Committee members can be found at <http://cdmrp.army.mil/dmrdp/panels/RMCTApanel14>
- The application does not conform to this Program Announcement/Funding Opportunity description to an extent that precludes appropriate review.
- Total costs as shown on the Research & Related Budget 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).

- Inclusion of any employee of CDMRP review contractors in applications for funding without adequate plans to mitigate conflicts of interest. Refer to the General Application Instructions, Section II.B., for detailed information.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review process to gain protected evaluation information or to influence the evaluation process.
- The proposed research is not a clinical trial.

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 USAMRAA Grants Officer for a determination of the final disposition of the application.

V. AWARD ADMINISTRATION INFORMATION

A. Award Notice

Awards will be made no later than September 30, 2015. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

B. Administrative and National Policy Requirements

Refer to the General Application Instructions, Appendix 4, Section D, for general information regarding administrative and national policy requirements.

C. Reporting

Refer to the General Application Instructions, Appendix 4, Section E, for general information on reporting requirements.

Quarterly technical progress reports and quad charts will be required.

In addition to written progress reports, oral briefings may be requested.

D. Award Transfers

The institutional transfer of an award supporting a clinical trial is strongly discouraged and in most cases will not be allowed. Approval of a transfer request will be on a case-by-case basis at the discretion of the Grants Officer.

Refer to the General Application Instructions, Appendix 4, Section F, for general information on organization or PI changes.

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 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

B. Grants.gov Contact Center

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

Phone: 800-518-4726

Email: support@grants.gov

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

VII. APPLICATION SUBMISSION CHECKLIST

Grants.gov Application Components	Action	Completed
SF-424 (R&R) Application for Federal Assistance Form	Complete form as instructed.	
Attachments Form	Upload Project Narrative (ProjectNarrative.pdf) as Attachment 1.	
	Upload Supporting Documentation (Support.pdf) as Attachment 2.	
	Upload Technical Abstract (TechAbs.pdf) as Attachment 3.	
	Upload Lay Abstract (LayAbs.pdf) as Attachment 4.	
	Upload Statement of Work (SOW.pdf) as Attachment 5.	
	Upload Human Subject Recruitment and Safety Procedures (HumSubProc.pdf) as Attachment 6.	
	Upload Intervention (Intervention.pdf) as Attachment 7.	
	Upload Data Management (Data_Manage.pdf) as Attachment 8.	
	Upload Study Personnel and Organization (Personnel.pdf) as Attachment 9.	
	Upload Surveys, Questionnaires, and Other Data Collection Instruments (Surveys.pdf), if applicable, as Attachment 10.	
	Upload Military Benefit (MilBen.pdf) as Attachment 11.	
	Upload Transition Plan (Transition.pdf) as Attachment 12.	
	Upload IND/IDE Documentation (IND-IDE.pdf), if applicable, as Attachment 13,.	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
	Attach Previous/Current/Pending Support (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field.	
Project/Performance Site Location(s) Form	Complete form as instructed.	
R & R Subaward Budget Attachment(s) Form	Complete form as instructed.	