Program Announcement

for the

Defense Health Program

Defense Medical Research and Development Program

Department of Defense

Congressionally Directed Medical Research Programs

Peer Reviewed Medical Research Program

Focused Program Award

Funding Opportunity Number: W81XWH-14-PRMRP-FPA

Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), June 25, 2014
- **Invitation to Submit an Application:** July 2014
- **Application Submission Deadline:** 11:59 p.m. ET, November 13, 2014
- **End of Application Verification Period:** 5:00 p.m. ET, November 18, 2014
- **Peer Review:** January 2015
- **Programmatic Review:** March 2015

Change for Fiscal Year 2014: *The CDMRP eReceipt System has been replaced with the electronic Biomedical Research Application Portal (eBRAP). Principal Investigators and organizational representatives should register in eBRAP as soon as possible. All pre-applications must be submitted through eBRAP. In addition, applications submitted through Grants.gov will now be available for viewing, modification, and verification in eBRAP prior to the end of the application verification period.*

This Program Announcement/Funding Opportunity 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 Fiscal Year 2014 (FY14) Peer Reviewed Medical Research Program (PRMRP) 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 PRMRP was initiated in fiscal year 1999 (FY99) to provide support for military health-related research of exceptional scientific merit. Appropriations for the PRMRP from FY99 through FY13 totaled $644.5 million (M). The FY14 appropriation is $200M. The PRMRP is administered by the U.S. Army Medical Research and Materiel Command (USAMRMC) through the Congressionally Directed Medical Research Programs (CDMRP).

The vision of the FY14 PRMRP is to improve the health and well-being of all military service members, Veterans, and beneficiaries. The PRMRP challenges the scientific and clinical communities to address at least one of the FY14 Topic Areas with original ideas that foster new directions along the entire spectrum of research and clinical care. The program seeks applications in laboratory, clinical, behavioral, epidemiologic, and other areas of research to advance knowledge in disease etiology, improve detection, diagnosis, treatment, and quality of life for those affected by a relevant disease or condition, and to develop and validate clinical care or public health guidelines.

B. FY14 PRMRP Congressionally Directed Topic Areas

All applications for PRMRP funding must specifically address at least one of the Topic Areas as directed by Congress, and must be directly relevant to the health care needs of military service members, Veterans, and/or beneficiaries. If the proposed research does not specifically address at least one of the FY14 PRMRP Topic Areas, the Government reserves the right to administratively withdraw the application. The Government also reserves the right to reassign the application's Topic Area if submitted under an inappropriate Topic Area. ***Applications to the FY14 PRMRP Focused Program Award are restricted to the Topic Areas listed below:***

- Acupuncture
- Congenital Heart Disease
- Illnesses Related to Radiation Exposure (excludes cancer)
- Metabolic Disease
- Neuroprosthetics
- Psychotropic Medications
- Respiratory Health (excludes lung cancer and mesothelioma)
- Segmental Bone Defects

Focused Program Award applications addressing any of the above Topic Areas are of interest to the program. Some of the Topic Areas have gaps and priority research areas that have been identified by the Department of Defense (DoD) and the Department of Veterans Affairs (VA). The list may be found in the Appendix of this document. Applicants are encouraged to read and

consider these research areas before preparing their applications. The information provided is not exhaustive, and applicants are not restricted to submitting applications that address the identified gaps. Any aspect of research relevant to any of the designated FY14 PRMRP Focused Program Award Topic Areas may be considered for funding.

Applicants seeking funding in a FY14 PRMRP Topic Area not included in the list above should apply to one of the other FY14 PRMRP Program Announcements/Funding Opportunities, which may be found at http://cdmrp.army.mil/funding/ or at www.grants.gov.

C. Award Information

The PRMRP Focused Program Award is being offered for the first time in FY14. The intent of the Focused Program Award is to optimize research and accelerate the solution for a critical question related to a designated FY14 PRMRP Focused Program Award Topic Area through a synergistic, multidisciplinary research program.

Key aspects of this award include:

Overarching Goal: Focused Program Award applications must describe a unifying, overarching goal or question that will be addressed by a set of research projects. The overarching goal must be relevant to a critical problem or question in the field of research and/or patient care in at least one of the FY14 PRMRP Focused Program Award Topic Areas.

Research Projects: Applicants are encouraged to submit a minimum of four research projects designed to address the overarching question; additional studies are allowed. Proposed projects should complement each other, but also be capable of standing on their own scientific merit. The exploration of multiple hypotheses or viewpoints of the same line of questioning is encouraged. Individual research projects may range from exploratory, hypothesis-developing studies through small-scale clinical trials (e.g., up to and including Phase II or equivalent). There must be an emphasis on and progression toward translational/clinical work over the course of the effort.

Implementation: The overarching goal must be supported by a detailed plan that identifies critical milestones; outlines the knowledge, resources, and technical innovations that will be utilized to achieve the milestones; and explains how the outcomes will be translated to patients. A robust statistical plan and statistical expertise should be included where applicable. A plan for assessing individual project performance toward the overarching goal must be included in the implementation plan. For multi-institutional collaborations, plans for communication and data transfer among the collaborating institutions, as well as how data, specimens, and/or imaging products obtained during the study will be handled, must be included. An intellectual and material property plan agreed to by participating institutions is required in the application's supporting documentation.

Research Team: The overall effort will be led by a Principal Investigator (PI) with demonstrated success in leading large, focused projects. The PI is required to devote a minimum of 20% effort to this award. The PI should create an environment that fosters and supports collaboration and innovation in a way that engages all members of the team in all aspects of the research plan. The research team assembled by the PI should be highly qualified and multidisciplinary, with identified project leaders for each of the complementary research

projects. The resources and expertise brought to the team by each project leader should combine to create a robust, synergistic collaboration. The PRMRP Science Officer assigned to any resulting award must be invited to participate in periodic research team meetings. The plan for such meetings should be noted in the application.

Milestone Meeting: The PI will be required to present an update on progress toward accomplishing the goals of the award at a Milestone Meeting to be held in the National Capital Region after the conclusion of Year 2 of the period of performance. The PI may bring up to three additional members of the research team to the meeting. The Milestone Meeting will be attended by members of the PRMRP Joint Programmatic Review Panel (JPRP), CDMRP staff, and the Grants Officer.

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

- Explanation of how the project addresses an aspect of the target disease/condition that has direct relevance to military service members, Veterans, or other military health system beneficiaries
- Use of military or Veteran populations or data in the proposed research
- Collaboration with DoD or VA investigators
- Involvement of military consultants (Army, Air Force) or specialty leaders (Navy, Marine Corps) to the Surgeons General in a relevant specialty area

PIs are strongly encouraged to collaborate, integrate, and/or align their research projects with DoD and/or VA research laboratories and programs. While not a complete list, the following websites may be useful in identifying additional information about ongoing DoD and VA areas of research interest or potential opportunities for collaboration within the FY14 PRMRP Focused Program Award Topic Areas:

Air Force Research Laboratory
http://www.wpafb.af.mil/afrl

Armed Forces Radiobiology Research Institute
http://www.usuhs.edu/afrri/

Clinical and Rehabilitative Medicine Research Program
https://crmrp.amedd.army.mil

Combat Casualty Care Research Program
https://ccc.amedd.army.mil

Congressionally Directed Medical Research Programs
http://cdmrp.army.mil

Defense Advanced Research Projects Agency
http://www.darpa.mil/

Defense Medical Research and Development Program
http://dmrdp.fhpr.osd.mil/home.aspx

Defense Technical Information Center
http://www.dtic.mil

Military Infectious Disease Research Program
https://midrp.amedd.army.mil

Military Operational Medicine Research Program
https://momrp.amedd.army.mil

Naval Health Research Center
http://www.med.navy.mil/sites/nhrc

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/

Uniformed Services University of the Health Sciences
http://www.usuhs.edu/research.html

U.S. Army Medical Research Acquisition Activity
https://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. Department of Defense Blast Injury Research Program
https://blastinjuryresearch.amedd.army.mil/

U.S. Department of Veterans Affairs, Office of Research and Development
http://www.research.va.gov

U.S. Naval Research Laboratory
http://www.nrl.navy.mil

Walter Reed Army Institute of Research
http://wrair-www.army.mil

Use of Active Duty Military and VA Populations: If the proposed research plan involves access to active duty military and/or VA patient populations or resources, the PI is responsible for establishing such access. If possible, access to target active duty military and/or VA patient populations/resources should be confirmed at the time of application submission by inclusion of a letter of support, signed by the lowest ranking person with approval authority, for studies involving active duty military service members, Veterans, military- and/or VA-controlled study materials, and military and/or VA databases. 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. Note that access to a Veteran population for clinical studies may only be obtained by either collaboration with a VA investigator where the VA investigator has a substantial role in the research, or by advertising to the general public.

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 U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO), in addition to the local Institutional Review Board (IRB) of record. Local IRB approval at the time of submission is ***not*** required. The HRPO is mandated to comply with specific laws and requirements governing all research involving human anatomical substances, human subjects, or human cadavers that is supported by the DoD. These laws and requirements will necessitate information in addition to that supplied to the IRB. Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes. Refer to the General Application Instructions, Appendix 6, for additional information.

Guidelines for Animal Research: All projects should adhere to a core set of standards for rigorous study design and reporting to maximize the reproducibility and translational potential of preclinical research. The standards are described in Landis, S. C., et al. A call for transparent reporting to optimize the predictive value of preclinical research. *Nature* 2012, 490: 187-191 (www.nature.com/nature/journal/v490/n7419/full/nature11556.html). While these standards are

written for preclinical studies, the basic principles of randomization, blinding, sample-size estimation, and data handling derive from well-established best practices in clinical studies. 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://www.nc3rs.org.uk/page.asp?id=1357.

The Congressionally Directed Medical Research Programs (CDMRP) 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 L.

D. Eligibility Information

- The PI must be an independent investigator at or above the level of Full Professor (or equivalent).
- Cost sharing/matching is not an eligibility requirement.
- Eligible investigators must apply through an organization. Organizations eligible to apply include national, international, for-profit, non-profit, public, and private organizations.
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

E. Funding

- The maximum period of performance is **5** years.
- The maximum allowable total costs for the entire period of performance are **$10M**.
- 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 **5** 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***.

For this award mechanism, direct costs:

Must be requested for:

- Travel for the PI and up to three additional members of the research team to attend a 1-day Milestone Meeting to be held in the National Capital Area during the award period of performance. This meeting will be held to provide a presentation on progress. Costs associated with travel to this meeting, up to $1,800 per person, should be included in Year 3 of the budget. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary
- Research-related subject costs
- Clinical research costs
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Travel costs of up to $3,600 per year to attend scientific/technical meetings in addition to the required meeting described above

Intramural (DoD), other federal agency, and extramural investigators are encouraged to apply to this Program Announcement/Funding Opportunity. An intramural investigator is defined as a DoD military or civilian employee working within a DoD laboratory or medical treatment facility, or working in a DoD activity embedded within a civilian medical center. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers. It is permissible for an intramural investigator to be named as a collaborator on an application submitted by an extramural investigator. In such cases, the extramural investigator must include a letter from the intramural collaborator's Commander or Commanding Officer that authorizes the involvement of the intramural collaborator.

As required of all applicants to this Program Announcement/Funding Opportunity, if PIs from federal agencies submit applications, they must submit through Grants.gov. Therefore, federal applicants must be familiar with Grants.gov requirements, including the need for an active System for Award Management (SAM) registration 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 agencies and other federal agencies will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Direct transfer of funds from the recipient to a federal agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.4. Research & Related Budget, for additional information on budget considerations for applications involving federal agencies.

The CDMRP expects to allot approximately $20M of the $200M FY14 PRMRP appropriation to fund approximately two Focused Program Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement/Funding Opportunity is contingent upon the availability of federal funds for this program.

II. SUBMISSION INFORMATION

Submission is a two-step process requiring both (1) pre-application submission through the electronic Biomedical Research Application Portal (eBRAP) (https://eBRAP.org/) and (2) application submission through Grants.gov (http://www.grants.gov/).

New for FY14: ***The CDMRP has replaced its eReceipt System with eBRAP.*** Submission remains a two-step process requiring both pre-application and application submission.

PIs must be registered in eBRAP in order to submit a pre-application and receive notification of the status of a pre-application or application. A key feature of eBRAP is that an organization's representatives and PIs are able to view and modify the Grants.gov application submissions associated with them, but only if the organization, Business Officials, and PIs are registered and affiliated to the organization in eBRAP (see *eBRAP User Guide* at *https://ebrap.org/eBRAP/public/UserGuide.pdf)*. Upon completion of an organization's registration in eBRAP and approval by the CDMRP Help Desk, the organization name will be displayed in eBRAP to assist the organization's business officials and PIs as they register.

Note: Submission of either the pre-application to eBRAP or application to Grants.gov does not require registering an organization and affiliating its Business Officials and PIs in eBRAP; however, the ability to view and modify the Grants.gov application in eBRAP is contingent upon the registration and affiliation. ***Application viewing, modification, and verification in eBRAP is strongly recommended, but not required. The Project Narrative and Budget cannot be changed after the application submission deadline. Any other application component cannot be changed after the end of the application verification period.*** If verification is not completed by the end of the application verification period, the application will be reviewed as submitted through Grants.gov, provided there is no cause for administrative rejection of the application (see Section IV.A., Rejection).

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-PRMRP-FPA.

B. Pre-Application Submission and Content Form

All pre-application components must be submitted by the PI through eBRAP (https://eBRAP.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@eBRAP.org or 301-682-5507.

A change in PI or organization after submission of the pre-application will be allowed only at the discretion of the US Army Medical Research Acquisition Activity (USAMRAA) Contracting/Grants Officer.

The pre-application consists of the following components, which are organized in eBRAP 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**
    - It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.
- **Collaborators and Conflicts of Interest (COI) – Tab 3**

  FY14 PRMRP JPRP members should not be involved in any pre-application or application. For questions related to JPRP members and pre-applications or applications, refer to Section IV.C., Withdrawal, or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.
- **Required Files – Tab 4**

  Notes: Upload document(s) as individual PDF files unless otherwise noted. eBRAP will not allow a file to be uploaded if the number of pages exceeds the limit specified below.

  Preproposal Narrative (five-page limit): The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings, etc.) used to describe the project. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

  The Preproposal Narrative should include the following:

    - **Topic Area:** Indicate how the proposed project relates to at least one of the designated FY14 PRMRP Focused Program Award Topic Areas (as noted in Section I.B.).

- **Overarching Goal:** Describe the overarching goal or question and how it is relevant to a critical problem or question in the field of research and/or patient care of the designated FY14 PRMRP Focused Program Award Topic Area(s). Clearly articulate the rationale for the overarching goal; include relevant preliminary data and literature citations.
- **Research Strategy:** The FY14 PRMRP Focused Program Award requires a minimum of four complementary research projects be proposed to address the overarching goal. For each proposed project, state the hypothesis to be tested or the objective to be reached and the specific aims and briefly describe the experimental approach. Describe how the projects are complementary to each other and align with the overarching goal.
- **Impact:** Describe the potential short-term and long-term impact of the results of the proposed research on at least one of the FY14 PRMRP Focused Program Award Topic Areas and its related research field(s) and patient population(s). Explain how the effort is relevant to the health care needs of military service members, Veterans, and/or beneficiaries.
- **Research Team:** Briefly describe the composition, expertise, and organization of the research team and each team member's role in the projects, with additional emphasis on the leadership role of the PI. Briefly describe how these features will facilitate the success of the key aspects of the projects.
- **Clinical Trial (if applicable):** If the proposed research includes a clinical trial(s), briefly state the clinical intervention(s), subject population(s), and the type and phase of the clinical trial(s). Describe the objectives of the clinical trial(s), how it addresses the overarching goal, and how it complements the other proposed projects. ***Only small-scale (e.g., up to and including Phase II or equivalent) clinical trials are allowed.***

Pre-Application Supporting Documentation: The items to be included as supporting documentation for the pre-application ***must be uploaded as individual documents*** and 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).

- **Submit Pre-Application – Tab 5**

  This tab must be completed for the pre-application to be accepted and processed.

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 and the FY14 PRMRP, pre-applications will be screened based on the following criteria:

  - **Overarching Goal:** How well the overarching goal or question addresses a critical problem or question in the field of research and/or patient care of the designated FY14 PRMRP Focused Program Award Topic Area(s). How well the rationale supports the overarching goal.
  - **Research Strategy:** How well the specific aims are defined for each proposed project and to what extent each project's approach will address these aims. How well the proposed projects complement each other and address the overarching goal.
  - **Impact:** Whether the potential immediate and long-range outcome(s)/product(s) (intellectual and/or tangible) of the proposed research, if successful, will impact a central critical problem or question in the field of research and/or patient care in the FY14 PRMRP Topic Area(s) addressed. To what degree the project is relevant to the health care needs of military service members, Veterans, and/or beneficiaries.
  - **Research Team:** To what degree the background and expertise of the PI and key personnel are appropriate with respect to their abilities to successfully complete the projects work and the extent to which the PI is well prepared and committed to lead the research team and proposed projects.

- **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 Forms

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/).

New for FY14: ***Applications submitted through and validated by Grants.gov will be retrieved and processed by eBRAP to allow for review, modification, and verification.*** The PI and organizational representatives will receive an email request from eBRAP to review, modify, and verify the application submitted to Grants.gov. During this verification period, the PI may

upload missing files (excluding those listed in Section IV.A., Rejection), replace files, and re-categorize files. These modifications must be completed by the end of the verification period.

Note: Changes to either the Project Narrative or Budget are not allowed in eBRAP; if such changes are required, the entire application package must be submitted through Grants.gov as a "Changed/Corrected Application" with the Previous Grants.gov Tracking ID ***prior to the application submission deadline (which occurs earlier than the end of the application verification period).***

Grants.gov application package components: For the Focused Program Award, 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**

   - **Attachment 1: Project Narrative (40-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 effort in detail using the outline below.

     - **Overarching Goal:** Describe the overarching goal or question and how it is relevant to a critical problem or question in the field of research and/or patient care of the designated FY 14 PRMRP Focused Program Award Topic Area(s). Clearly articulate the rationale for the overarching goal; include relevant literature citations. Clearly describe how the proposed research projects will complement each other and accelerate toward a solution through a synergistic, multidisciplinary research program.

     - **Research Plan: Provide the following details for each proposed research project, organizing each project clearly and separately:**

       - **Background:** Briefly describe the ideas and reasoning on which the proposed work is based. Provide sufficient preliminary data to support the feasibility of work proposed. If the project is exploratory/hypothesis-developing, preliminary data may not be required. For all projects, the PI must demonstrate logical reasoning and provide a sound scientific rationale for the proposed projects as established through a critical review and analysis of published literature. If proposing translational or clinical research, it is important to describe the studies showing proof of concept and, if applicable, efficacy in an in vivo system to support the translational feasibility and promise of the approach.

- **Hypotheses/Specific Aims:** State the hypothesis to be tested or the objective(s) to be reached. Concisely explain the project's specific aims.
- **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for analysis. Explain how the research strategy will address the overarching goal and meet appropriate milestones. Address potential problem areas and present alternative methods and approaches. Clearly describe the statistical plan and the rationale for the statistical methodology as well as an appropriate power analysis, if applicable. If animal studies are proposed, describe how they will be conducted in accordance with the ARRIVE guidelines (http://www.nc3rs.org.uk/page.asp?id=1357). If human subjects will be recruited or human biological samples will be used, describe the study population and include a detailed plan for the recruitment of human subjects or the acquisition of samples.

- **Implementation Plan:** Provide an overall strategic plan for completing the proposed projects that identifies critical milestones. Outline the knowledge, expertise, and technical innovations that the investigative team will utilize to make decisions, allocate resources, and accomplish the milestones. Describe and/or provide evidence that the research can be initiated without delay once the award is made. Describe how individual project performance will be assessed during the course of the award, including progression toward defined milestones and realization of study objectives and the overarching goal. Present an overall management plan to facilitate consistent and intensive interactions by all team members in the project(s), including aspects such as adherence to regulatory requirements, administrative support, and oversight to accelerate translation of the project's outcomes to patients and/or for clinical use. Describe plans for communication, data transfer among the collaborating institutions, and how data, specimens, and/or imaging products obtained during the study will be handled. If applicable, describe how Standard Operating Procedures will be created, reviewed, implemented, and modified during the course of the award.
- **Research Team and Environment:** Describe how the PI's research experience, leadership skills, and commitment to making an impact in the field of research and/or patient care in the FY14 PRMRP Focused Program Award Topic Area(s) addressed provide substantial qualifications to coordinate this collaborative effort. Describe the PI's demonstrated success in leading large, focused projects. Discuss the qualifications of the full research team, their specific contributions to the projects, and how the assembled expertise is necessary to address the overarching goal and enable the success of the proposed projects. Describe the research environment(s) and how the facilities and resources will support the research requirements and the collaboration.
- **Clinical Trial (if applicable):** ***Only small-scale (e.g., up to and including Phase II or equivalent) clinical trials are allowed.*** Provide detailed plans for initiating and conducting the clinical trial during the course of this award. As appropriate, outline a plan for applying for and obtaining Investigational New Drug/Investigational Device Exemption (IND/IDE) status (or other Food and

Drug Administration [FDA] approvals). Describe the rationale for the trial and summarize the previous work that led to the development of the proposed clinical trial. Describe the type of clinical trial to be performed (e.g., prospective, randomized, controlled) and indicate the phase of trial and/or class of device, as appropriate. 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.
- 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). Provide information on the inclusion and exclusion criteria, the availability of and access to the appropriate patient population(s), as well as the ability to accrue a sufficient number of subjects for the clinical trial.
- 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).
- Describe the statistical model and data analysis plan with respect to the study objectives. Specify the 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 to meet the objectives of the study.
- Provide evidence of documented availability of and access to all critical reagents, and describe how quality control will be addressed. Include a description of how compliance with Good Laboratory Practices (GLP), Good Manufacturing Practices (GMP), and Good Clinical Practices (GCP) will be established, monitored, and maintained, as applicable.
- Describe the composition of the clinical trial team. Provide details on how the team (including investigator(s), study coordinator, statistician) possesses the appropriate expertise in conducting clinical trials.

- **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 (eight-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: 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: 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.
- Letters Confirming Access to Military or VA Patient Populations or Resources (if applicable): If the proposed research plan involves access to active duty military and/or VA patient populations or resources, include a letter 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
  - Background and Proprietary Information: All software and data first produced under the award are subject to a federal purpose license in accordance with applicable DoD Grant and Agreement Regulations (DoDGAR) requirements. Provide a list of all background intellectual property to be used in the project or provide a statement that none will be used. If applicable, state and identify the proprietary information that will be provided to the Government and indicate whether the applicant will require a waiver of the federal purpose license.
  - Intellectual and Material Property Plan (if applicable): Provide a plan for resolving intellectual and material property issues among participating organizations.

- **Attachment 3: Technical Abstract (one-page limit):** Upload as "TechAbs.pdf."

  The technical abstract is used by all reviewers as a description of the project's key aspects. Therefore, clarity and completeness within the space limits of the technical abstract are highly important.

  Describe the proposed research effort including the following elements:

  Overarching Goal: Identify the unifying, overarching goal or question that will be addressed by the research plan, and describe how it relates to a critical problem or question in one or more of the FY14 PRMRP Focused Program Award Topic Areas.

  Background: Briefly articulate the rationale for the overarching goal and the proposed research.

  Research Plan: Provide a brief description of the studies proposed, including hypotheses/objectives and scientific approach.

  Impact: Briefly describe the potential short-term and long-term impact of the results of the proposed research on at least one of the designated FY14 PRMRP Focused Program Award Topic Areas and its related research field(s) and patient population(s).

  Military Relevance: Explain how the effort is relevant to the health care needs of military service members, Veterans, and/or beneficiaries.

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

  State the FY14 PRMRP Focused Program Award Topic Area(s) addressed by the proposed research project. Include a comprehensive overview of the effort that can be ***readily understood by readers without a background in science or medicine.*** Clearly describe the central critical problem or question to be addressed and the ultimate applicability and impact of the research. Do not duplicate the technical abstract.

- **Attachment 5: Statement of Work (SOW) (eight-page limit):** Upload as "SOW.pdf." Refer to the General Application Instructions, Section II.C.2., for detailed guidance on creating the SOW.

  The suggested SOW format and examples specific to different types of research projects are available on the eBRAP "Program Announcement and Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). For the Focused Program Award mechanism, use the SOW format example titled "SOW for Collaborative PI Projects." The SOW must be in PDF format prior to attaching.

- **Attachment 6: Impact Statement (one-page limit):** Upload as "Impact.pdf."

  Explain why the proposed research project is important and relevant to understanding the cause or progression of the disease or condition, and/or to developing improvements in detection, diagnosis, patient care, or quality of life in the FY14 PRMRP Focused Program Award Topic Area(s) addressed. Describe how the study will address a central critical problem or question in the relevant Topic Area(s), and how it will progress toward translational/clinical work over the

course of the effort**.** Explain how the outcomes of the projects will ultimately be translated to patients.

Describe the short-term impact: Detail the anticipated outcome(s)/product(s) (intellectual and/or tangible) that will be directly attributed to the results of the proposed research.

Describe the long-term impact: Explain the anticipated long-term gains from this research. Compare to the information known/products currently available, if applicable. Explain the long-range vision for how the research will impact clinical care.

- **Attachment 7: Military Relevance Statement (one-page limit):** Upload as "MilRel.pdf."

  Describe how the proposed study is responsive to the health care needs of military service members, Veterans, and/or beneficiaries. Provide information about the incidence and/or prevalence of the disease or condition to be studied in military service members, Veterans, and/or beneficiaries.

  If active duty military, military families, and/or Veteran population(s) or dataset(s) will be used in the proposed research project, describe the population(s)/dataset(s), the appropriateness of the population(s)/dataset(s) for the proposed study, and the feasibility of accessing the population(s)/dataset(s). 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, Veterans, and/or beneficiaries).

  If applicable, show how the proposed research project aligns with DoD and/or VA areas of research interest.

- **Attachment 8: Transition Plan (one-page limit):** Upload as "Transition.pdf."

  Provide information on the methods and strategies proposed to move the outcomes of the project to clinical use. The transition plan should include the components listed below.

  - A description of the expected outcome(s) that will result after completion of the proposed research project. Outcomes should be specific, measurable, and should include a definition of the end user.
  - Details of the funding strategy that will be used to bring the outcomes to the next phase of development and/or delivery to market (e.g., specific potential industry partners, specific funding opportunities to be applied for, etc.).
  - 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 delivery to market.

- **Attachment 9: Data and Research Resource Sharing Plan (one-page limit):** Upload as "Sharing.pdf."

  Describe how data and resources generated during the performance of the proposed research project will be shared with the research community. This includes cases where pre-existing data or research resources will be utilized and/or modified during the course of the proposed project. Specifically describe a plan to make animal models, tissue samples, and other resources developed as part of the proposed research project available to the scientific community. If there are limitations associated with a pre-existing agreement for the original data or research resources that preclude subsequent sharing, the applicant should explain this in the data- and/or research resource-sharing plan. Refer to the General Application Instructions, Appendix 4, Section L, for more information about the CDMRP expectations for making data and research resources publicly available.

  In preparing requested budgets, applicants may include anticipated costs associated with data- and research resource-sharing (i.e., making a large dataset available to the public or developing an important resource for the scientific community).

- **Attachment 10: IND/IDE Documentation:** ***Only applicable for applications that include a clinical trial(s).*** If submitting multiple documents, start each document on a new page. Combine and upload as a single file named "IND-IDE.pdf."
  - State whether the trial(s) requires regulation by the FDA. If FDA regulation is required, describe the planned indication for the proposed product and whether an IND/IDE is necessary.
  - If an IND or IDE application is required, indicate when it was submitted to the FDA and provide an explanation of the status of the IND or IDE application (e.g., past the critical 30-day period, pending response to questions raised by the Agency, on clinical hold). If the IND or IDE application has not been submitted to the FDA yet, provide a detailed timeline with appropriate milestones for application preparation and submission. Identify any consultants or experts who will assist in the regulatory application, if applicable, and include a copy of any curricula vitae or biographical sketches in the Key Personnel Biographical Sketches section of the application. Provide a summary of previous meetings with the FDA on development of this product, if appropriate. A copy of the Agency meeting minutes should be included if available. Provide copies of communications from the FDA relevant to the most recent status of the IND or IDE application.
  - If an IND or IDE is not required for the proposed trial(s), 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.3., 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.4., 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.5., for detailed information.

6. **R & R Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section II.C.6., for detailed information.

D. Verification of Grants.gov Application in eBRAP

For FY14, a new process has been initiated whereby organizational representatives and PIs can view their applications as submitted through Grants.gov and prior to peer review of the application. This will enable applicants to make modifications prior to scientific and programmatic evaluation of applications, provided the modifications are made by either the end of the application verification period or, for changes to the Project Narrative or Budget, by the application submission deadline.

After application submission to Grants.gov, eBRAP will retrieve and validate the application submission. eBRAP will notify the organizational representatives and PI via email and instruct them to log into eBRAP to review, modify, and verify the application. Files that fail eBRAP validation will be noted in both the email and in the Full Application Files tab. eBRAP does not validate the accuracy or completeness of content in the files. PIs are strongly encouraged to review all application components. If either the Project Narrative or the Budget fail eBRAP validation, an updated Grants.gov application package must be submitted via Grants.gov prior to the application submission deadline, which occurs earlier than the end of the application verification period. ***The Project Narrative and Budget cannot be changed after the application submission deadline. Any other application component cannot be changed after the end of the application verification period.***

E. 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 either of these deadlines will result in application rejection.

F. 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 applicants 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 Office of the Assistant Secretary of Defense for Health Affairs, based on (a) technical merit and (b) the relevance to the mission of the DHP and PRMRP and to the specific intent of the award mechanism. The highest-scoring applications from the first tier of review are not automatically recommended for funding. Additional information about the two-tier process used by the CDMRP can be found at http://cdmrp.army.mil/about/fundingprocess.

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 Process

1. **Peer Review:** To determine technical merit, all applications will be evaluated according to the following scored criteria, which are of equal importance:

    - **Impact**
        - To what degree the overarching goal addresses a critical problem or question in a designated FY14 PRMRP Focused Program Award Topic Area.

- To what degree the proposed project could, if successful, make a significant impact on the lives of relevant patient populations in the short-term or long-term.
- How well the proposed research will, if successful:
  - Make important scientific advances in the relevant field of research,
  - Promote greater understanding of the causes and progression of the relevant disease(s)/condition(s),
  - Promote the development of improvements in patient care, and/or
  - Promote the development of improvements in quality of life.

- **Research Strategy and Feasibility**
  - How well the research projects are integrated, complement each other, and provide a synergistic, multidisciplinary approach to solving a critical problem.
  - How well the scientific rationale supports the research and its feasibility, as demonstrated by a critical review and analysis of the literature, the presentation of preliminary data (where applicable), and logical reasoning.
  - How well the hypotheses, objectives, aims, experimental design, methods, endpoints, and analyses are developed and integrated into the projects.
  - How well potential problems are acknowledged and alternative approaches are addressed.
  - If animal studies are included, how well they are designed to achieve reproducible and rigorous results.
  - If applicable, to what degree the statistical plan and power analysis are appropriate for the proposed project.
  - Whether there is sufficient evidence to support availability and accessibility of the populations, samples, or other resources required for the study, if applicable.
- **Implementation Plan**
  - How the proposed projects are supported by a detailed plan that identifies critical milestones and explains how these milestones will be achieved.
  - To what extent the plans to assess individual project performance during the course of the award are appropriate.
  - How well the overall management plan will facilitate consistent and intensive interactions by all team members in the projects.
  - How the proposed plans for communication, data and specimen collection, data transfer, and periodic meetings are appropriate and robust.
  - To what extent the plans for creating, reviewing, implementing, and modifying Standard Operating Procedures are appropriate, if applicable.

- How well the application identifies intellectual property ownership, and whether there is sufficient evidence of a plan to resolve intellectual and material property issues, if applicable.

- **Personnel**
  - To what degree the PI's is experienced in successfully leading large, focused projects and is therefore well-positioned to lead the research team in achieving the overarching goal of the proposed effort.
  - Whether the PI will devote a minimum of 20% effort to this award.
  - To what degree the research team's background and expertise are appropriate with respect to its ability to perform the proposed work, including whether there is evidence of sufficient expertise for all aspects of the work and whether there is evidence of strong commitment to the projects.
  - If a clinical trial is proposed, how well the PI has assembled an appropriate and robust clinical team with the combined backgrounds and expertise needed to enable successful conduct of the clinical trial.
  - To what degree the levels of effort are appropriate for successful conduct of the proposed work.
- **Transition Plan**
  - The degree to which the strategy proposed to bring the outcomes to the next level of development, including milestones and schedule, is appropriate.
  - Whether appropriate collaborations and other resources for providing continuity of development are established and/or well described.

Applications with a clinical trial will also be evaluated on the following criterion, which is of equal importance:

- **Clinical Strategy**
  - To what extent the type of clinical trial (e.g., prospective, randomized, controlled) proposed is appropriate to meet the project's objectives.
  - How well the clinical trial is designed with appropriate study variables, controls, and endpoints.
  - How well the application demonstrates the availability of and access to the appropriate patient population(s), as well as the ability to accrue a sufficient number of subjects.
  - Whether the clinical trial design, methods, and analysis plan meet the requirements for applying for and obtaining IND/IDE status (or other FDA approvals), if appropriate.
  - Whether there is documented availability of, access to, and quality control for all critical reagents.
  - Whether there are resources available for the development of sufficient quantities of critical reagents under GMP or GLP, if applicable.

- To what degree the data analysis plan is suitable for the planned study.
- To what extent the statistical plan, including sample size projections and power analysis, is adequate for the study and all proposed correlative studies (if applicable).
- Whether potential challenges and alternative strategies are appropriately identified.

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

- **Environment**
  - To what degree the scientific environment(s) is appropriate for the proposed research.
  - How well the research requirements are supported by the availability of and accessibility to facilities and resources (including patient populations, samples, and collaborative arrangements).
  - To what degree the quality and extent of organizational support are appropriate for the proposed research.
- **Data and Resource Sharing**
  - To what degree the plan for sharing of project data and research resources is appropriate and reasonable to facilitate use by the wider research community.
- **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 criteria are used by programmatic reviewers:

   a. **Ratings and evaluations of the peer reviewers**

   b. **Relevance to the mission of the DHP and FY14 PRMRP, as evidenced by the following:**
      - Adherence to the intent of the award mechanism
      - Military Relevance
      - Program portfolio composition
      - Relative impact
      - Relevance to program objectives

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

IV. ADMINISTRATIVE ACTIONS

After receipt of pre-applications from eBRAP 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.

B. Modification

- Pages exceeding the specific 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 application submission to Grants.gov, the PI will receive an email request from eBRAP to review, modify, and verify the application submitted to Grants.gov. During this verification period, the PI may upload missing documents (excluding those listed in Section IV.A., Rejection), replace files, and re-categorize files. These

modifications must be completed by the end of the application verification period; 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 PRMRP JPRP member is named as being involved in the research proposed or is found to have assisted in the pre-application or application processes including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation. A list of the FY14 PRMRP JPRP members can be found at http://cdmrp.army.mil/prmrp/panels/panel14.
- 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 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 PI does not meet the eligibility criteria.
- The proposed research project is not relevant to any of the designated FY14 PRMRP Focused Program Award Topic Areas.

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 Requirements

Refer to the General Application Instructions, Appendix 4 for general information regarding administrative requirements.

C. National Policy Requirements

Refer to the General Application Instructions, Appendix 5 for general information regarding national policy requirements.

D. Reporting

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

Quarterly technical progress reports and quad charts will be required.

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

E. Award Transfers

Changes in PI are not allowed, except under extenuating circumstances that will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

The institution 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 M, 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 eBRAP should be directed to the CDMRP Help Desk, which is available Monday through Friday from 8:00 a.m. to 5:00 p.m. ET. Response times may vary depending upon the volume of inquiries.

Phone: 301-682-5507

Email: help@eBRAP.org

B. Grants.gov Contact Center

Questions related to application submission through 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	Complete form as instructed.	
Attachments Form	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf."	
	Military Relevance: Upload as Attachment 7 with file name "MilRel.pdf."	
	Transition Plan: Upload as Attachment 8 with file name "Transition.pdf."	
	Data and Research Resources Sharing Plan: Upload as Attachment 9 with file name "Sharing.pdf."	
	IND/IDE Documentation: Upload as Attachment 10 with file name "IND-IDE.pdf," if applicable.	
Research & Related Senior/Key Person Profile (Expanded)	Attach PI Biographical Sketch (Biosketch_LastName.pdf) to the appropriate field.	
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field.	
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field.	
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field.	
Research & Related Budget	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.	

APPENDIX

IDENTIFIED GAPS AND RESEARCH PRIORITIES

Applications addressing any of the FY14 PRMRP Focused Program Award Topic Areas are of interest to the program. Some of the Topic Areas have gaps and priority research areas that have been identified by the DoD and the VA and are listed below. Applicants are encouraged to read and consider these research areas before preparing their applications. The information provided is not exhaustive, and applicants are not restricted to submitting applications that address the identified gaps. Any aspect of research relevant to any designated FY14 PRMRP Focused Program Award Topic Area may be considered for funding.

Acupuncture:

- Definitive studies to determine the effectiveness of acupuncture for pain associated with traumatic neuromusculoskeletal injuries.
- Research on the role of acupuncture in pain management following traumatic brain injury, spinal cord injury, and/or peripheral nerve injury.
- Research on the use of acupuncture as prevention of or treatment for mental health disorders such as post-traumatic stress, depression, suicide, substance abuse, agitation, anxiety, and other co-morbid disorders.

Illnesses Related to Radiation Exposure (excludes cancer):

- Research addressing acute radiation syndrome (ARS).
- Research addressing the delayed effects of acute radiation exposure (DEARE).
- Research related to qualification of drug development tools (biomarkers, clinical outcome assessments, or animal models).
- Research on prototype countermeasures with the intent to develop data to support FDA approval.

Neuroprosthetics:

- Advancement of efferent control, i.e., control of multi degree-of-freedom (DOF) prostheses. This could include an upper extremity with fine motor movements, or a lower extremity to provide a biologically accurate gait.
- Development of device afferent communication, science of proprioception and pressure sensing and how to communicate this information to the user. The end goal of this research would be for the user to obtain natural feedback from a terminal device.

Psychotropic Medications:

- Identification and/or development of therapies that can completely or selectively reverse the effects of psychotropic medications.

- Research into the use of psychotropic medications for the treatment of mental health disorders including post-traumatic stress, suicide, substance abuse, and other co-morbid disorders.
- Research to determine and test psychological interventions related to mental health issues specific to women in the military.

Respiratory Health (excludes lung cancer and mesothelioma):

- Development of an innovative, next-generation Adenovirus vaccine, ideally one that may be modified for different adenovirus serotypes, for the prevention of acute respiratory illness caused by Adenovirus.
- Research into opportunistic infections that will assist in understanding their basic metabolism, create ex vivo growth systems or small animal models where there are none available, and/or develop new agents with which to treat them as it relates to respiratory disease.
- Technology- and/or therapeutic-based treatments for acute lung injury due to an inhalational injury.
- Preventive techniques and therapeutics to reduce the incidence of acute respiratory syndrome after acute lung injury in trauma patients.
- Research on the prevalence, cause, treatment, and prevention of respiratory symptoms and ailments possibly associated with deployed and re-deployed military personnel, including acute eosinophilic pneumonia, constrictive bronchiolitis, asthma, allergies, and other chronic lung diseases and breathing problems.

Segmental Bone Defects:

- Technologies addressing segmental/large bone defects in the craniomaxillofacial body region.
- Controlled release/extended release of growth factors for bone regeneration.
- Technologies that enable enhanced recruitment of endogenous cell populations for bone regeneration.
- Technologies that repair the soft tissue envelope to enhance bone regeneration.