

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

Discovery Award

Funding Opportunity Number: W81XWH-14-PRMRP-DA

Catalog of Federal Domestic Assistance Number: 12.420

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Deadline:** 5:00 p.m. Eastern time (ET), July 16, 2014
- **Application Submission Deadline:** 11:59 p.m. ET, July 30, 2014
- **End of Application Verification Period:** 5:00 p.m. ET, August 4, 2014
- **Peer Review:** September 2014
- **Programmatic Review:** November 2014

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 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. The FY14 PRMRP Topic Areas are listed below.

- Acupuncture
- Arthritis (other than post-traumatic osteoarthritis and rheumatoid arthritis)
- Chronic Migraine and Post-Traumatic Headaches
- Congenital Heart Disease
- DNA Vaccine Technology for Post-exposure Prophylaxis
- Dystonia
- Epilepsy
- Food Allergies
- Fragile X Syndrome
- Hereditary Angioedema
- Illnesses Related to Radiation Exposure (excludes cancer)
- Inflammatory Bowel Disease
- Interstitial Cystitis
- Lupus
- Malaria
- Metabolic Disease
- Neuroprosthetics
- Pancreatitis

- Polycystic Kidney Disease
- Post-Traumatic Osteoarthritis
- Psychotropic Medications
- Respiratory Health (excludes lung cancer and mesothelioma)
- Rheumatoid Arthritis
- Segmental Bone Defects
- Tinnitus

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 FY14 PRMRP Topic Area may be considered for funding.

C. Award Information

The intent of the PRMRP Discovery Award is to support innovative, untested, high-risk/potentially high-reward research that will provide new insights, paradigms, technologies, or applications. Studies supported by this award are expected to lay the groundwork for future avenues of scientific investigation. The proposed research project should include a well-formulated, testable hypothesis based on a sound scientific rationale and study design.

The proposed research project should be novel and innovative. Innovative research may introduce a new paradigm, challenge existing paradigms, look at existing problems from new perspectives, or exhibit other highly creative qualities. Research that is an incremental advance upon published data is not considered innovative and is not consistent with the intent of this award mechanism.

Inclusion of preliminary data is strongly discouraged. The outcome of research supported by this award should be the generation of robust preliminary data that can be used as a foundation for future research projects to understand the mechanisms of initiation or progression and/or improving patient care for a disease or condition. ***The Discovery Award is not intended to support a logical progression of an already established research project or other types of ongoing work;*** therefore, inclusion of preliminary data other than serendipitous findings or in small amounts is not consistent with the exploratory nature of this award. The presentation of substantial preliminary data suggests that the proposed research project would be more appropriately submitted to a different award mechanism.

Reviewers at both tiers of review will be blinded to the identity of the Principal Investigator (PI), collaborators, and their organizations. Young/early career investigators are encouraged to apply.

Research involving human subjects and human anatomical substances is permitted; however, this award may not be used to conduct clinical trials. 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. PIs seeking funding for a clinical trial should apply to the FY14 PRMRP Clinical Trial Award mechanism. For more information on how to distinguish clinical research from clinical trials, see the Human Subject Resource Document at <https://ebrap.org/eBRAP/public/Program.htm>. PIs seeking funding for a clinical trial should apply to the FY14 PRMRP Clinical Trial Award mechanism (W81XWH-14-PRMRP-CTA).

Military Relevance: Relevance to the health care needs of military service members, Veterans, and beneficiaries is a key feature of this award. Applications are required to include an explanation of how the proposed project has military relevance. Examples include the use of military or Veteran populations or data in the proposed research, and/or an explanation of how the project addresses an aspect of the target disease/condition/technology that has direct relevance or is unique to military service members, Veterans, or military beneficiaries. PIs are encouraged to integrate and/or align their research projects with DoD and/or VA research laboratories and programs. Collaboration with the DoD or VA is also encouraged; however, as the peer and programmatic reviewers will not have access to the identity of the PI, collaborators, and their organizations, collaboration cannot be taken into consideration for funding decisions.

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 Topic Areas:

Air Force Research Laboratory

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

Armed Forces Radiobiology Research Institute

<http://www.usuhs.edu/afri/>

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 Human Anatomical Substances, Human Subjects, or Human Cadavers: All Department of Defense (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.

New for FY14: 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

- Investigators at all levels are eligible to submit applications.
- 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 **18** months.
- The maximum allowable direct costs for the entire period of performance are **\$200,000** plus indirect costs.
- 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(s) may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **18** months.
- Regardless of the period of performance proposed, the applicant may not exceed the maximum allowable direct 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 costs of up to \$1,800 for the PI to disseminate project results at one DoD to be specified by the CDMRP during the award performance period. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary
- Research supplies
- Equipment
- Clinical research costs (clinical trials not allowed)
- 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

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 \$12M of the \$200M FY14 PRMRP appropriation to fund approximately 40 Discovery 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. As an exception, applicants may submit the research project described in their Discovery Award application as part of an application to the FY14 PRMRP Focused Program Award (W81XWH-14-PRMRP-FPA); however, accepting multiple awards to support the same project will not be allowed.

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-DA.

B. Pre-Application Submission and Content Form

All pre-application components must be submitted by the PI through eBRAP (<https://eBRAP.org/>).

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.

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 Joint Programmatic Review Panel (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**

Letter of Intent (LOI) (one-page limit): Provide a brief description of the research to be conducted. Include the FY14 PRMRP Topic Area under which the application will be submitted. LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review sessions.

- **Submit Pre-Application – Tab 5**

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

C. Application Submission Content and Forms

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).*

Reviewers at both tiers of review will be blinded to the identity of the PI, collaborators, and their organization(s). Due to the blinded nature of the review process, identifying or making references to the PI, collaborators, or their organization(s) in the Project Narrative, Technical and Public Abstracts, Military Relevance Statement, References Cited, or List of Abbreviations, Acronyms, and Symbols, is prohibited and will result in administrative rejection of the application. In addition, the use of “I,” “we,” “our,” “this organization” or similar phrases that refer to the PI, collaborators, or their organization(s) through the references listed or the use of formatting (e.g., bolding, underlining, names in headers/footers), inclusion of citations to unpublished manuscripts, or in any other way highlighting the names of the PI, collaborators, or their institutions, is prohibited and will result in administrative rejection of the application and preclude invitation to submit a full application.

Although required, the Statement of Work, Letters of Support, Research & Related Budget, R & R Subaward Budget Attachment(s) Form (if applicable), biographical sketch(es), previous/current/pending support, and Project/Performance Site Location(s) Form will not be forwarded for peer review or programmatic review. These documents will be used for administrative purposes only.

Grants.gov application package components: For the Discovery 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 (five-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. ***Do not include URLs or other information that identify the PI, collaborator(s), or their organization(s).***

- **Background:** Present the ideas and reasoning behind the proposed work. Cite relevant literature. Inclusion of preliminary data is strongly discouraged.
- **Hypothesis or Objective:** State the hypothesis to be tested or the objective to be reached.
- **Specific Aims:** Concisely explain the project’s specific aims. If the proposed work is part of a larger study, present only aims that the DoD award would fund.
- **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for scientific evaluation. Describe the statistical and other data analyses to be used to justify the number of research subjects (animal or human) and assess the collected data. Address potential problem areas and present alternative methods and approaches. 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 or human anatomical substances will be used, describe the study population and include a detailed plan for the recruitment of subjects or the acquisition of samples. ***Clinical trials are not allowed under the Discovery Award mechanism.***
- **Innovation:** Describe how the proposed research is novel and innovative, including how it will provide new insights, paradigms, technologies, or applications to the research field and/or patient care. Investigating the next logical step of an existing line of research or providing an incremental advance on published data is not considered innovative.
- **Significance/Relevance:** Describe how the proposed research addresses at least one of the FY14 PRMRP Topic Areas. State the expected results from the

proposed research and how they will be used as a foundation for future research projects. Describe the potential near- or long-term applicability to patient care.

- **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 (10-citation limit): 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). *Do not include URLs that identify the organization(s) of the PI or collaborator(s).*
 - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols. *Do not include information that will identify the organization(s) of the PI or collaborator(s).*
- **Attachment 3: Technical Abstract (one-page limit):** Upload as “TechAbs.pdf.” State the FY14 PRMRP Topic Area(s) addressed by the proposed research project. Clearly describe the proposed research including the idea to be studied and the objectives, the innovative aspect of the research, the study design, the expected results, and how the results will be used as a foundation for future research projects. *Do not include information that identifies the PI, collaborator(s), or their organization(s).*
- **Attachment 4: Lay Abstract (one-page limit):** Upload as “LayAbs.pdf.” State the FY14 PRMRP Topic Area(s) addressed by the proposed research project. Include an overview of the proposed research project that will be *readily understood by readers without a background in science or medicine.* Clearly describe the central critical problem or question to be addressed, the innovation of the idea, and the ultimate applicability and impact of the research. *Do not duplicate the technical abstract. Do not include information that identifies the PI, collaborator(s), or their organizations.*
- **Attachment 5: Statement of Work (SOW) (three-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 Discovery Award mechanism, use the SOW format example titled “SOW (Statement of Work) Generic Format.” The SOW must be in PDF format prior to attaching.
- **Attachment 6: 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. ***Do not include information that identifies the PI, collaborator(s), or their organization(s).***

- **Attachment 7: Letters of Support:** Start each document on a new page. Combine and upload as “Letters.pdf.” Two-page limit per letter is recommended. Letters will not be forwarded for peer or programmatic review.
 - 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. The letter should reflect the availability of laboratory space, equipment, and other resources available for the project.
 - Letters of Collaboration (if applicable): Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.
- 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.shtml>. For this Program Announcement/Funding Opportunity, reviewers at both tiers of review will be blinded to the identity of the PI, collaborator(s), and their organization(s).

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:
 - **Research Strategy and Feasibility**
 - How well the scientific rationale supports the proposed research project and its feasibility.
 - To what extent the experimental design, methods, and analyses are appropriate to test the hypothesis or support the objective(s).
 - Whether the proposed research project can be completed within an 18-month performance period.
 - How well potential problems and alternative approaches are addressed.
 - If applicable, to what degree the statistical plan and power analysis are appropriate for the proposed project.
 - If animal studies are included, how well they are designed to achieve reproducible and rigorous results.

- To what extent the research has the potential to generate robust preliminary data that can be used as a foundation for future research projects.
- **Innovation**
 - To what extent the proposed research will provide new insights, paradigms, technologies, or applications with the potential to impact the research field and/or patient care.
 - To what extent the proposed research represents more than an incremental advance upon published data or more than the next logical step in a research project.
- **Significance/Relevance**
 - How well the proposed research project addresses an important scientific question relevant to at least one of the FY14 PRMRP Topic Areas.
 - How well the proposed research will, if successful, make an original and important contribution toward advancing research and/or patient care.

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

- **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 innovation
 - 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 applications from Grants.gov, the following administrative actions may occur:

A. Rejection

The following will result in administrative rejection of the application:

- Pre-application was not submitted.
- 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.
- The PI, collaborators, or their organization(s) are identified or referenced in the Project Narrative, Technical and Public Abstracts, Military Relevance Statement, or List of Abbreviations, Acronyms, and Symbols.
- Use of “I,” “we,” “our,” “this organization,” or similar phrases that refer to the PI, collaborators, or their organization(s) through the references listed, or the use of formatting (e.g., bolding, underlining, names in headers/footers), inclusion of citations to unpublished manuscripts, or in any other way highlighting (and therefore revealing) the names of the PI, collaborators, or their institutions.

B. Modification

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Project Narrative.
- Documents not requested will be removed.
- Following 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 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.shtml>.
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- Direct 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, or requests funding for, a clinical trial.
- The proposed research project is not relevant to any of the Congressionally directed FY14 PRMRP 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 with quad charts may be required.

E. Award Transfers

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."	
	Military Relevance Statement: Upload as Attachment 6 with file name "MilRel.pdf."	
	Letters of Support: Upload as Attachment 7 with file name "Letters.pdf."	
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 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 FY14 PRMRP 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.

Chronic Migraine and Post-Traumatic Headache:

- Epidemiological/natural history studies of post-trauma headache to determine specific types of headache encountered, the pathobiology behind these headaches (such as the role of cortical spreading depression acutely after injury as a risk factor for chronic headaches of a migrainous type) as well as risk factors that might predispose people to certain types of post-traumatic headache.
- Double-blind placebo-controlled trials in the post-traumatic headache population in order to determine whether similar phenotypes in primary headache disorders and post-traumatic headache will respond similarly to treatment.
- Research on the optimal approaches to acute and chronic pain management for chronic migraine and post-traumatic headache, with a focus on assessing and eliminating adverse outcomes.
- Research on the utility of the Patient Centered Medical Home model in care of patients with chronic migraine or post-traumatic headache.
- Research to investigate, develop, and validate biomarkers useful in diagnosing and monitoring traumatic brain injury patients with chronic migraine or post-traumatic headache.

DNA Vaccine Technology for Post-Exposure Prophylaxis:

- The design and manufacture of a cost-efficient DNA vaccine that is simple to manufacture, stable without the need for refrigeration or freezing, can be used in both immune-competent and immune-compromised individuals, and expresses a highly conserved, chimeric protein antigen displaying multiple antigenic domains of key virulence factors of enteric pathogens.

- Development of innovative approaches to cure HIV (human immunodeficiency virus) using multiple therapeutic modalities in acute HIV infection. Additionally, there is a need to optimize antibody responses using novel adjuvants for HIV vaccine.
- Development of mechanisms or devices for mucosal delivery of a DNA vaccine for enteric pathogens. This includes research to understand and improve the mechanisms to stimulate immune responses with a cost-efficient DNA vaccine for enteric pathogens that is simple to manufacture and stable without the need for refrigeration or freezing.
- Research leading to a better understanding of the immune mechanisms involved in the clearance of enteric pathogens that would most likely be stimulated by a DNA vaccine. There is a need to evaluate humoral immune responses after DNA vaccination and to determine immunological correlates of protection, including both antibodies and cellular immune mechanisms in reproducible small animal models.

Epilepsy:

- Epidemiological and pathobiological studies that will inform early diagnosis, monitoring and evidence-based treatment guidelines for seizure disorders.
- Pharmacologic and non-pharmacologic interventions demonstrating objective improvement in measureable outcomes of decreased seizure frequency.
- Development of technologies that can identify prodromal markers of epileptiform activity so that the patient can medicate and/or find a safe place to rest before the seizure occurs.

Illnesses Related to Radiation Exposure:

- 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.

Inflammatory Bowel Disease:

- Studies on the long-term health consequences of acute enteric infection as they relate to IBD in the areas of epidemiology, animal model development, understanding disease pathogenesis, and development of effective preventive and clinical management modalities.
- Studies designed specifically to examine disease markers (genetic, microbiomic, immunologic) of severity or risk of IBD after acute enteric infections.
- Mechanistic studies in relevant post-infectious inflammatory disease animal models to elucidate the interactions among genomics, microbiome, and immune mechanisms behind infection and chronic health consequences.
- Studies of well-defined post-infectious IBD patients are needed to provide estimates of illness-associated disability, health care costs, and symptom duration from a military health system and societal perspective.

Malaria:

- Development and optimization of multi-platform based (i.e. protein, DNA, viral vector or live-attenuated) pre-erythrocytic based malaria vaccines to increase efficacy and enable identification of correlates of protection in preclinical studies and clinical trials.
- Identification of novel pre-erythrocytic stage *Plasmodium vivax* antigens and assessment of potential predictors of candidate vaccine efficacy in preclinical studies and clinical trials.
- Development of orally administered, bioavailable, novel chemical entities or alternative formulations of known anti-malarial drugs suitable for weekly prophylaxis, radical cure, treatment of severe/complicated disease indications, and to replace artemisinin class drugs in targeting immature blood stage parasites.
- Identification of modes of action of new generation anti-malarial drugs, optimization of drug partnering strategies for new malaria therapeutics and prophylaxis indications, and characterization of interactions between 8-aminoquinoline class anti-malarial drugs and cytochrome p450 2D6 enzyme to optimize development of next-generation anti-malarial drugs.

Neuroprosthetics:

- Advancement of efferent control, i.e., control of multi degree-of-freedom 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.

Post-Traumatic Osteoarthritis:

- Development of best practices to maximize function and evaluation of multidisciplinary team (orthopaedics, pain, rehabilitation, etc.) approaches evaluating the success of treatment algorithms.
- Technologies that restore joint stability after injury (e.g., connective tissues such as ligament/tendon/meniscus structures).
- Sustained release, intra-articular injectable steroidal, non-steroidal, or disease-modifying therapies that offer two or more months of symptomatic relief of pain and/or inflammation in a single injection.
- Development of preventive therapies and/or techniques to minimize the progression of post-traumatic osteoarthritis after traumatic injury to the joint.

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:

- 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.

Tinnitus:

- Research to understand the mechanisms of tinnitus, its relationship to noise-induced hearing loss, and progression to chronic tinnitus.
- Identification of effective non-invasive interventions to include neuromodulation and tinnitus retraining therapy for tinnitus treatment.
- Identification of novel therapies for early interventions to prevent tinnitus, including new uses for existing drugs, nutritional and pharmaceutical based strategies, and acoustic, electrical, and other stimulation technologies.
- Improvement of objective tools to diagnose and characterize tinnitus (e.g., imaging techniques to identify functional and structural changes in the brain).