

Program Announcement

for the

Department of Defense

Defense Health Program

Congressionally Directed Medical Research Programs

Peer Reviewed Medical Research Program

Discovery Award

Funding Opportunity Number: W81XWH-16-PRMRP-DA

**Catalog of Federal Domestic Assistance Number: 12.420 Military Medical
Research and Development**

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application Submission Deadline:** 5:00 p.m. Eastern time (ET), July 7, 2016
- **Application Submission Deadline:** 11:59 p.m. ET, July 21, 2016
- **End of Application Verification Period:** 5:00 p.m. ET, July 26, 2016
- **Peer Review:** September 2016
- **Programmatic Review** November 2016

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 2016 (FY16) Peer Reviewed Medical Research Program (PRMRP) are being solicited for the Defense Health Agency, Research, Development, and Acquisition (DHA RDA) Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA RDA Directorate manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The managing agent for this Program Announcement/Funding Opportunity is the Congressionally Directed Medical Research Programs (CDMRP). The PRMRP was initiated in 1999 to provide support for military health-related research of exceptional scientific merit. Appropriations for the PRMRP from FY99 through FY15 totaled \$1.092 billion. The FY16 appropriation is \$278.7 million (M).

The vision of the FY16 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 FY16 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 prevention, 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. FY16 PRMRP 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 healthcare needs of military Service members, Veterans, and/or beneficiaries. If the proposed research does not specifically address at least one of the FY16 PRMRP Topic Areas, the Government will administratively withdraw the application. The Government reserves the right to reassign the application's Topic Area if submitted under an inappropriate Topic Area. The FY16 PRMRP Topic Areas are listed below.

- Acute Lung Injury
- Antimicrobial Resistance
- Chronic Migraine and Post-Traumatic Headache
- Congenital Heart Disease
- Constrictive Bronchiolitis
- Diabetes
- Dystonia
- Emerging Infectious Diseases
- Focal Segmental Glomerulosclerosis
- Fragile X Syndrome
- Hepatitis B
- Hereditary Angioedema
- Hydrocephalus
- Inflammatory Bowel Disease
- Influenza
- Integrative Medicine
- Interstitial Cystitis
- Lupus
- Malaria

- Metals Toxicology
- Mitochondrial Disease
- Nanomaterials for Bone Regeneration
- Non-Opioid Pain Management
- Pancreatitis
- Pathogen-Inactivated Dried Plasma
- Polycystic Kidney Disease
- Post-Traumatic Osteoarthritis
- Psychotropic Medications
- Pulmonary Fibrosis
- Respiratory Health
- Rett Syndrome
- Rheumatoid Arthritis
- Scleroderma
- Sleep Disorders
- Tinnitus
- Tuberculosis
- Vaccine Development for Infectious Disease
- Vascular Malformations
- Women's Heart Disease

Research relevant to one or more FY16 PRMRP Topic Areas may be considered for funding. ***Applicants should select the FY16 PRMRP Funding Opportunity most appropriate to the stage of the proposed research.*** Areas of Encouragement related to the FY16 PRMRP Topic Areas have been identified by the Department of Defense (DoD), the Department of Veterans Affairs (VA), and other relevant stakeholders ([Appendix 1](#)). Applicants are urged to read and consider these Areas of Encouragement before preparing their applications. ***The information provided is not exhaustive, and applicants are not restricted to submitting applications that address an Area of Encouragement on this list.***

C. Award Information

The intent of the PRMRP Discovery Award is to ***support innovative, non-incremental, 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.

Innovation is the most important review criterion. Innovative research may introduce a new paradigm, look at existing problems from new perspectives, or exhibit other highly creative qualities. Research that represents an incremental advancement on previously published work is not considered innovative. The following list, although not all-inclusive, provides examples of research that is ***not innovative***:

- Exploring a previously tested hypothesis in a different cell line or in a new population
- Using a published series of in-vitro assays to further characterize a model system
- Incorporating known biomarkers into in-vivo or clinical models of the disease or condition
- Investigating the next logical step or continuation of a previous research project
- Proposing work that is an incremental advancement of published data

The outcome of research supported by this award should be the generation of 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, ***preliminary data are not required.*** The presentation of substantial preliminary data suggests that the proposed research project would be more appropriately submitted to a different award mechanism. **Absence of preliminary data will not negatively affect scientific or programmatic review of the application.**

Reviewers at both tiers of review will be blinded to the identity of the Principal Investigator (PI), collaborators, and their organizations. Applications that identify the PI, collaborators, or their organizations in certain components of the application (see [Section II.C., Full Application Submission Content](#), for details) will be rejected for noncompliance. A document describing common blinding mistakes to avoid can be found on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>). 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.*** For information on how to distinguish clinical research from clinical trials, see the Human Subject Resource Document at <https://ebrap.org/eBRAP/public/Program> PIs seeking funding for a clinical trial should apply to the FY16 PRMRP Clinical Trial Award mechanism (W81XWH-16-PRMRP-CTA).

Military Relevance: Relevance to the healthcare 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:

- 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
- Description of how the knowledge, information, products, or technologies gained from the proposed research could be implemented in a dual-use capacity to benefit the civilian population and also address a military need
- Use of military or Veteran populations or datasets if appropriate to the proposed research

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. A list of websites that may be useful in identifying additional information about ongoing DoD and VA areas of research interest or potential opportunities for collaboration within the FY16 PRMRP Topic Areas can be found in [Appendix 2](#).

Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers: All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by

the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO) prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC 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/EC. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes.*** Refer to the General Application Instructions, Appendix 6, and the Human Subject Resource Document available on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) 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.elsevier.com/_data/promis_misc/622936arrive_guidelines.pdf.

All DoD-funded research involving new and ongoing research with animals must be reviewed and approved by the USAMRMC ORP Animal Care and Use Review Office (ACURO), in addition to the local Institutional Animal Care and Use Committee (IACUC) of record. IACUC approval at the time of submission is not required. Specific documents relating to the use of animals in the proposed research will be requested **if the application is selected for funding.** The ACURO must review and approve all animal use prior to the start of working with animals, including amendments to ongoing projects. PIs must submit the institutional animal use protocol, IACUC approval of that protocol, and a version of the animal use appendix titled “Research Involving Animals.” ***Allow at least 2 to 3 months for ACURO regulatory review and approval processes for animal studies.*** Refer to General Application Instructions, Appendix 6, for additional information.

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

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 Federal agencies, national, international, for-profit, nonprofit, public, and private organizations.
- 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. Submissions from intramural (DoD) organizations are allowed and encouraged for this Program Announcement/Funding Opportunity. Applicants submitting through their intramural organizations are reminded to coordinate receipt and commitment of funds through their respective resource managers. *If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.*
- Refer to the General Application Instructions, Appendix 1, for general eligibility information.

E. Funding

- The maximum period of performance is **18** months.
- The anticipated direct costs budgeted for the entire period of performance will not exceed **\$200,000**. Indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$200,000** direct costs or using an indirect rate exceeding the organization's negotiated rate.
- 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 has a period of performance less than the maximum **18** months.

For this award mechanism, direct costs may be requested for (not all-inclusive):

- Salary
- Research supplies
- Equipment
- Clinical research costs (clinical trials not allowed)
- Support for multidisciplinary collaborations, including travel
- Travel costs for up to 1 investigator to travel to 1 scientific/technical meeting per year

Shall not be requested for:

- Tuition

Awards to extramural organizations will consist solely of assistance agreements (Cooperative Agreements and Grants). Awards to intramural (DoD) agencies and other Federal agencies may

be managed through a direct fund transfer (e.g., the Military Interdepartmental Purchase Request [MIPR]; Funding Authorization Document [FAD] process; or DD Form 1144 Support Agreement). Direct transfer of funds from the recipient to a DoD agency is not allowed except under very limited circumstances. Refer to the General Application Instructions, Section II.C.4., for budget regulations and instructions for the Research & Related Budget. ***For Federal agencies or organizations collaborating with Federal agencies, budget restrictions apply as are noted in Section II.C.4. of the General Application Instructions.***

The CDMRP expects to allot approximately \$14.4M of the \$278.7M FY16 PRMRP appropriation to fund approximately 48 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 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(s). As an exception, applicants may submit the research project described in their Discovery Award application as part of an application to the FY16 PRMRP Focused Program Award (W81XWH-16-PRMRP-FPA); however, accepting multiple awards to support the same project will not be allowed.

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/>). Refer to the General Application Instructions, Section II.A., for registration and submission requirements for eBRAP and Grants.gov.

The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. 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.

eBRAP is a multifunctional web-based system that allows PIs to submit their pre-applications electronically through a secure connection, to view and edit the content of their pre-applications and full applications, to receive communications from the CDMRP, and to submit documentation during award negotiations and period of performance. A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the Grants.gov application submissions associated with them. eBRAP will validate Grants.gov application files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in an email to the PI and in the Full Application Files tab in eBRAP. It is the applicant's responsibility to review all application components for accuracy as well as ensure proper ordering as specified in this Program Announcement/Funding Opportunity.

The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent for the entire pre-application and application submission process. Inconsistencies may delay application processing and limit the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application deadline.

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.*** Prior to the full application deadline, a corrected or modified full application package may be submitted. Other application components may be changed until the end of the [application verification period](#). After the end of the application verification period, the full application cannot be modified.

A. Where to Obtain the Grants.gov Application Package

To obtain the Grants.gov application package, including all required forms, perform a basic search using the Funding Opportunity Number W81XWH-16-PRMRP-DA in Grants.gov (<http://www.grants.gov/>).

B. Pre-Application Submission Content

The pre-application process should be started early to avoid missing deadlines. There are no grace periods. During the pre-application process, each submission is assigned a unique log number by eBRAP. This unique eBRAP log number will be needed during the application process on Grants.gov.

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):

- **Tab 1 – Application Information**
 - Select the FY16 PRMRP Topic Area addressed by the proposed research. If the proposed research project is aligned with more than one FY16 PRMRP Topic Area, select the topic area of highest relevance as the required first choice.
- **Tab 2 – Application Contacts**
 - Enter contact information for the PI. Enter the organization’s Business Official responsible for sponsored program administration (the “person to be contacted on matters involving this application” in Block 5 of the Grants.gov SF424 (R&R)

Form). The Business Official must either be selected from the eBRAP list or invited in order for the pre-application to be submitted.

- Select the performing organization (site at which the PI will perform the proposed work) and the contracting organization (organization submitting on behalf of the PI, which corresponds to Block 5 on the Grants.gov SF424 (R&R) Form), and click on “*Add Organizations to this Pre-application.*” The organization(s) must either be selected from the eBRAP drop-down list or invited in order for the pre-application to be submitted.
- It is recommended that PIs identify an Alternate Submitter in the event that assistance with pre-application submission is needed.

- **Tab 3 – Collaborators and Key Personnel**

- Enter the name, organization, and role of all collaborators and key personnel associated with the application.
- FY16 PRMRP Programmatic Panel members should not be involved in any pre-application or application. For questions related to Panel 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.
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in application preparation, research, or other duties for submitted applications. For FY16, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage conflicts of interest (COIs) are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, for detailed information.

- **Tab 4 – Conflicts of Interest**

- List all individuals other than collaborators and key personnel who may have a COI in the review of the application (including those with whom the PI has a personal or professional relationship). Refer to Appendix 1, Section C, of the General Application Instructions for further information regarding COIs.

- **Tab 5 – Pre-Application Files**

Letter of Intent (LOI) (one-page limit): Provide a brief description of the research to be conducted. Include the FY16 PRMRP Topic Area(s) 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.

- **Tab 6 – Submit Pre-Application**

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

C. Full Application Submission Content

The application process should be started early on Grants.gov to avoid missing deadlines. There are no grace periods. Verify the status of the applicant's organization's Entity registration in the SAM well in advance of the application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. Refer to the General Application Instructions, Section II, for additional information.

All contributors and administrators to the application must use matching compatible versions of Adobe software when editing and preparing application components. The use of different software versions will result in corruption of the submitted file. See Section II.C. of the General Application Instructions for details on compatible Adobe software.

The CDMRP cannot make allowances/exceptions to its policies for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.

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

Note: The Project Narrative and Budget Form cannot be changed after the application submission deadline.

If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or Budget Form needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID ***prior to the application submission deadline.***

Reviewers 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(s), collaborator(s), or their organization(s) in the Project Narrative, Supporting Documentation, Technical and Public Abstracts, Military Relevance Statement, and Impact Statement 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(s), collaborator(s), 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, inclusion of URLs, or in any other way highlighting the names of the PI(s), collaborator(s), or their organization(s), is prohibited and will result in administrative rejection of the application and preclude invitation to submit a full application. A document describing common blinding mistakes to avoid can be found on the eBRAP "Funding Opportunities & Forms" web page (<https://ebrap.org/eBRAP/public/Program.htm>).

Although required, Statement of Work, Research & Related Budget, R & R Subaward Budget Attachment(s) Form (if applicable), Letter(s) of Support (if applicable), Collaborating Military DoD Facility Support Form (if applicable), biographical sketch, 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. **SF424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section II.C., for detailed information.

2. **Attachments Form**

Each attachment to the Grants.gov application forms must be uploaded as an individual PDF file in accordance with the formatting guidelines listed in Appendix 2 of the General Application Instructions. For all attachments, ensure that the file names are consistent with the guidance. Grants.gov will reject attachments with file names longer than 50 characters or incorrect file names that contain characters other than the following: A-Z, a-z, 0-9, underscore, hyphen, space, and period. In addition, Grants.gov has file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire Grants.gov application package may not exceed 200 MB.

- **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 may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below. *Reviewers will be blinded to the identity of the PI, collaborators, and their organization(s). Do not include names, URLs, or other information such as use of the terms “I,” “we,” “our,” “this organization,” or similar phrases that identify the PI, collaborator(s), or their organization(s).*

- **Background:** Describe how the proposed research project addresses one or more of the FY16 PRMRP Topic Areas. Present the ideas and reasoning behind the proposed work. Cite relevant literature. Inclusion of preliminary data is not required.
- **Hypothesis:** State the hypothesis to be tested.
- **Specific Aims:** Concisely explain the project’s specific aims and the objective(s) to be reached. If the proposed work is part of a larger study, present only aims that this DoD award would fund.
- **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for scientific evaluation. If cell lines or animals are to be used, justify why the proposed cell line(s) or animal model(s) were chosen. If applicable, describe the statistical and other data analyses to be used to justify the number of research subjects (animal or human) and assess the data collected. Address potential problem areas and

present alternative methods and approaches. ***Clinical trials are not allowed under the Discovery Award mechanism.***

- **Innovation:** Describe how the proposed research is innovative, including how it will provide new insights, 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.
- **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 will result in the removal of those items or may result in 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 PI(s), collaborator(s), or the organization(s) of the PI(s) or collaborator(s).***
 - List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols.
- **Attachment 3: Technical Abstract (one-page limit): Upload as “TechAbs.pdf.”** The technical abstract is used by all reviewers. Abstracts of all funded research projects will be posted publically. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

Clarity and completeness within the space limits of the technical abstract are highly important. Describe the proposed research project including the following elements:

State the FY16 PRMRP Topic Area(s) addressed by the proposed research project. Clearly describe the proposed research including the rationale, the hypothesis to be tested, the innovative aspects 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.”** The lay abstract is used by all reviewers. Abstracts of all funded research projects will be posted publically. ***Do not include proprietary or confidential information.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

State the FY16 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 organization(s).***

- **Attachment 5: Statement of Work (SOW) (two-page limit): Upload as “SOW.pdf.”** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP “Funding Opportunities & 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. Refer to the General Application Instructions, Section II.C.2., for detailed guidance on creating the SOW.

- **Attachment 6: Impact Statement (one-page limit): Upload as “Impact.pdf.”**
Explain why the proposed research project is important and relevant to the FY16 PRMRP Topic Area(s) addressed. Describe the critical problem or question in the relevant Topic Area(s) that is addressed in the proposed research. If applicable, describe how the project addresses an FY16 PRMRP Area of Encouragement ([Appendix 1](#)). Outline the potential short-term and long-term impact of the proposed research on the field of study and/or patient care.

Do not include information that identifies the PI, collaborator(s), or their organization(s).

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

Describe how the proposed study is responsive to the healthcare needs of military Service members, Veterans, and/or beneficiaries. Provide information about the incidence and/or prevalence of the disease or condition in the general population as well as 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 and/or patient care. Provide a description of how the knowledge, information, products, or technologies gained from the research could be implemented in a dual-use capacity to benefit the civilian population that also

addresses a military need, as appropriate. ***Do not include information that identifies the PI, collaborator(s), or their organization(s).***

- **Attachment 8: Letters of Support:** Start each document on a new page. Combine and upload as “Letters.pdf.” 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.

- **Attachment 9: Collaborating DoD Military Facility Budget Form(s), if applicable: Upload as “MFBudget.pdf.”**

If a Military Facility (military health system facility, research laboratory, treatment facility, dental treatment facility, or a DoD activity embedded with a civilian medical center) will be a collaborator in performance of the project, complete the Collaborating DoD Military Facility Budget Form, available for download on the eBRAP “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>), including a budget justification, for each Military Facility as instructed. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section II.C.7., for detailed information.

- 3. Research & Related Senior/Key Person Profile (Expanded):** Refer to the General Application Instructions, Section II.C.4., for detailed information. Biographical Sketch(es) and Previous/Current/Pending Support documents will not be forwarded for peer or programmatic review.

- **PI Biographical Sketch (five-page limit):** Upload as “Biosketch_LastName.pdf.” The suggested biographical sketch format is available on the “Funding Opportunities & Forms” web page (<https://ebrap.org/eBRAP/public/Program.htm>) in eBRAP. The five-page National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in the portable document format (pdf) that is not editable.

Biographical Sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

- **PI Previous/Current/Pending Support (no page limit):** Upload as “Support_LastName.pdf.”
- **Key Personnel Biographical Sketches (five-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 documents will not be forwarded for peer or programmatic review.
 - Budget Justification (no page limit): Upload as “BudgetJustification.pdf.” The budget justification for the entire period of performance must be uploaded to the Research & Related Budget after completion of the budget for Period 1.
 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.

Collaborating DoD Military Facilities Form: A Military Facility collaborating in the performance of the project should be treated as a subaward for budget purposes. However, do not complete the Grants.gov R & R Subaward Budget Attachment Form; instead, complete the Collaborating DoD Military Facility Budget Form (use Attachment 9, Collaborating DoD Military Facility Budget Form) to show all direct and indirect costs. The costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs. Refer to the General Application Instructions, Section II.C.7., for detailed information.

D. Applicant Verification of Grants.gov Submission in eBRAP

Prior to the end of the application verification period, PIs and organizational representatives can review and modify in eBRAP certain components of an application submitted to Grants.gov. Following retrieval and processing of the Grants.gov application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the Grants.gov application submission. eBRAP will validate retrieved files against the specific Program Announcement/Funding Opportunity requirements and discrepancies will be noted in both the email and in the Full Application Files tab in eBRAP. eBRAP does not confirm the accuracy of file content. It is the applicant’s responsibility to review all application components and ensure proper ordering as specified in the Program Announcement/Funding Opportunity. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a “Changed/Corrected Application” with the previous Grants.gov Tracking ID prior to the application submission deadline.*** The Project Narrative and Budget Form cannot be changed after the application submission deadline.

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 submission rejection.

F. Other Submission Requirements

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

All extramural 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, Section II.A., for information on Grants.gov registration requirements.

III. APPLICATION REVIEW INFORMATION

A. Application Review and Selection Process

All applications are evaluated by scientists, clinicians, and consumers in a two-tier review process. The first tier is peer review of applications against established criteria for determining technical merit. Each application is evaluated for its own merit, independent of other applications. The second tier is a programmatic review that makes recommendations for funding to the DHA RDA Directorate and the OASD(HA), based on technical merit, the relevance to the mission of the DHP and PRMRP, the specific intent of the award mechanism, and to other specified evaluation criteria in the Program Announcement/Funding Opportunity. Programmatic review is a comparison-based process in which applications with scientific and technical merit compete in a common pool. ***The highest-scoring applications from the first tier of review are not automatically recommended for funding. Funding recommendations depend on various factors as described in [Section III.B.2., Programmatic Review](#).*** Additional information about the two-tier process used by the CDMRP can be found at <http://cdmrp.army.mil/about/fundingprocess>. ***For this Program Announcement/Funding Opportunity, reviewers at both tiers of review will be blinded to the identity of the PI(s), 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 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, of which Innovation is more significant than the remaining scored criteria, which are of equal importance:

- **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.

- **Research Strategy and Feasibility**

- How well the scientific rationale supports the proposed research project and its feasibility.
- To what degree the hypothesis proposed is clearly defined and testable.
- To what extent the specific aims, experimental design, methods, and analyses are appropriate to test the hypothesis.
- If preliminary data are included, how well they support the proposed research.
- How well the number of research subjects (animal or human) is justified for the proposed research project, if applicable.
- To what degree the model system or human subjects are appropriate to the proposed research project, if applicable.
- How well the PI identifies potential problems and addresses alternative approaches.
- Whether the proposed research project can be completed within an 18-month performance period.

- **Impact/Relevance**

- To what extent the proposed research project impacts an important scientific question relevant to at least one of the FY16 PRMRP Topic Areas.
- To what extent the research has the potential to generate preliminary data that can be used as a foundation for future research projects.
- To what extent the proposed research has potential for short-term and/or long-term impact on the field of study and/or patient care.

In addition, the following unscored criteria 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 and select the application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

a. Ratings and evaluations of the peer reviewers

b. Relevance to the mission of the DHP and FY16 PRMRP, as evidenced by the following:

- Adherence to the intent of the award mechanism
- Military relevance
- Program portfolio composition
- Relative innovation

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.

- The PI(s), collaborator(s), or their organization(s) are identified or referenced in the Project Narrative, Supporting Documentation, Technical and Public Abstracts, Impact Statement, or Military Relevance Statement.
- Use of “I,” “we,” “our,” “this organization,” or similar phrases that refer to the PI(s), collaborator(s), 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(s), collaborator(s), or their organization(s).

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.

C. Withdrawal

The following may result in administrative withdrawal of the application:

- An FY16 PRMRP Programmatic Panel 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 FY16 PRMRP Programmatic Panel members can be found at <http://cdmrp.army.mil/prmrp/panels/panels16>.*
- The application fails to conform to this Program Announcement/Funding Opportunity description to the extent that appropriate review cannot be conducted.
- Inclusion of URLs, with the exception of links in References Cited and Publication and/or Patent Abstract sections.
- Page size is larger than 8.5 inches x 11.0 inches (approximately 21.59 cm x 27.94 cm).
- To preserve the integrity of its peer and programmatic review processes, the CDMRP discourages inclusion of any employee of its review contractors having any role in the preparation, research or other duties for submitted applications. For FY16, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (<http://cdmrp.army.mil/about/2tierRevProcess>). Applications that include names of personnel from either of these companies will be administratively withdrawn unless plans to manage COIs are provided and deemed appropriate by the Government. Refer to the General Application Instructions, Appendix 1, 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 project is not relevant to any of the Congressionally directed FY16 PRMRP Topic Areas.
- If a clinical trial is proposed, the application will be withdrawn.

D. Withhold

Applications that appear to involve research misconduct will be administratively withheld from further consideration pending organizational investigation. The organization 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, 2017. Refer to the General Application Instructions, Appendix 4, for additional award administration information.

Any assistance instrument awarded under this Program Announcement/Funding Opportunity will be governed by the award terms and conditions, which conform to DoD's implementation of the Office of Management and Budget (OMB) circulars applicable to financial assistance. Terms and conditions of new awards made after December 26, 2014 may include revisions to reflect DoD implementation of new OMB guidance in the Code of Federal Regulations, Title 2, Part 200, "Uniform Administrative Requirements, Cost Principles, and Audit Requirements for Federal Awards" (2 CFR part 200).

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 H, for general information on reporting requirements.

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. An organizational transfer of an award will not be allowed in the last year of the (original) period of performance or any extension thereof.

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

VI. VERSION CODES AND AGENCY CONTACTS

A. Program Announcement/Funding Opportunity and General Application Instructions Version

Questions related to this Program Announcement/Funding Opportunity should refer to the Program name, the Program Announcement/Funding Opportunity name, and the Program Announcement/Funding Opportunity version code [20160210i]. The Program Announcement/Funding Opportunity numeric version code will match the General Applications Instructions version code [20160210].

B. 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

C. 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; International 1-606-545-5035

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 Grants.gov application package. If the Grants.gov 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	Upload Order	Action	Completed
SF424 (R&R) Application for Federal Assistance		Complete form as instructed.	
Attachments Form	1	Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf."	
	2	Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf."	
	3	Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf."	
	4	Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf."	
	5	Statement of Work: Upload as Attachment 5 with file name "SOW.pdf."	
	6	Impact Statement: Upload as Attachment 6 with file name "Impact.pdf."	
	7	Military Relevance Statement: Upload as Attachment 7 with file name "MilRel.pdf."	
	8	Letters of Support: Upload as Attachment 8 with file name "Letters.pdf."	
	9	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 9 with file name "MFBudget.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 1 AREAS OF ENCOURAGEMENT

Applications addressing any of FY16 PRMRP Topic Areas are of interest to the program. *Any aspect of research relevant to one or more FY16 PRMRP Topic Areas may be considered for funding.* Areas of encouragement related to the FY16 PRMRP Topic Areas have been identified by the DoD, VA, and other relevant stakeholders. Applicants are urged to read and consider these areas of encouragement before preparing their applications. *The information provided is not exhaustive, and applicants are not restricted to submitting applications that address an area of encouragement in this list.*

Acute Lung Injury

- Research on the etiology and prevention of acute respiratory distress syndrome (ARDS) caused by the immune system's responses to infectious disease.
- Preventive techniques, novel detection technologies, and therapeutics to reduce the incidence and/or severity of ARDS and/or other lung injury secondary to trauma, transfusion, burns, hemorrhagic shock, and/or oxygen exposure.
- Development of clinical laboratory-based device for manufacturing/amplification of stem cells to treat acute lung injury/ARDS due to inhalation injury or due to single or polytrauma.
- Clinical studies to test cellular therapies in the treatment of acute lung injury/ARDS due to inhalation injury or due to single or polytrauma.
- Metrics to associate health outcomes of acute lung injury with physiological and physical performance of military Service members.
- Strategies to support the safe transport of patients with lung injury in order to optimize therapeutic interventions.

Antimicrobial Resistance

- Identification and evaluation of novel antifungals against resistant fungal infections, particularly topical therapies for wounds, surgical, and post-surgical therapies.
- Identification of novel targets for development of antibacterials for resistant strains.
- Development and testing of an aqueous-based multi-spectral antibiotic for immediate flushing of wounds on the battlefield.
- Research on the use of bacteriophages to treat antibiotic-resistant bacteria.
- Development and testing of novel interventions to directly engage patients and families in reducing inappropriate antibiotic use.
- Research on utilizing treatment protocols or diagnostic tests to limit the prescription of antibiotics for conditions that are commonly viral in nature or resolve without antibiotic treatment, such as sinusitis, bronchitis, and viral upper respiratory infections.

Chronic Migraine and 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.
- Epidemiological/natural history studies to characterize specific types of post-traumatic headache, the pathobiology of these headaches (such as the role of cortical spreading depression acutely after injury as a risk factor for chronic headaches of a migrainous type), and 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 effective management of co-occurring psychological health disorders and acute and chronic pain management for chronic migraine and post-traumatic headache, with a focus on assessing and eliminating adverse outcomes and decreasing polypharmacy.
- Research on the utility of the Patient-Centered Medical Home model of care of patients with chronic migraine or post-traumatic headache.
- Research on the treatment and prevention of acute flares of chronic migraine and post-traumatic headaches with an emphasis on non-opioid medications.
- Evaluation of the use of mechanical stimulation and/or other non-pharmaceutical treatments to reduce acute and chronic migraines and headaches.
- Precision medicine research to investigate, develop, and validate biomarkers that are not only useful in diagnosing and monitoring traumatic brain injury patients with chronic migraine or post-traumatic headache, but can also identify individual response to treatment.

Congenital Heart Disease

- Population-based and outcomes-based research projects to assess health outcomes of individuals with congenital heart disease across the lifespan.
- Research on tissue engineering approaches to patches, grafts, and transplantation that provide structural support, restore native activity, allow for tissue growth, and prevent the need for reoperation.
- Research to improve the understanding of the causes of congenital heart defects.
- Research on the transition of care of congenital heart disease patients from pediatric to adult providers.
- Research on the risk of neurologic injury and enhanced neuroprotection before, during, and after surgery for congenital heart disease.
- Research on the ability of patients with congenital heart disease to join or remain on active duty.

Constrictive Bronchiolitis

- Clinical assessments to determine the prevalence and severity of constrictive bronchiolitis and related respiratory diseases in previously deployed military Service members.
- Development and testing of less invasive and non-invasive approaches for diagnosing constrictive bronchiolitis.
- Research to develop novel therapeutics to slow or reverse progression of constrictive bronchiolitis.
- Development and/or validation of animal models of constrictive bronchiolitis, particularly models that reflect inhalation exposure-related constrictive bronchiolitis.
- Research to understand the role of environmental exposures, including mineralized dust and other particulates, in the etiology of constrictive bronchiolitis.

Diabetes

- Development of biomarkers to identify and monitor at-risk individuals and assess treatment response.
- Development and standardization of an electronic medical record (EMR) system for diabetes care to include components such as a comprehensive automated data flow chart, automated health reminders to meet standard of care metrics per the Healthcare Effectiveness Data and Information Set (HEDIS) and National Committee for Quality Assurance (NCQA), automated order entry with decision support algorithms, glycemic management tools to track and monitor glycemic variables, electronic order sets to track, monitor, and adjust insulin usage.
- Development and evaluation of an inpatient glycemic management program with strategies to improve in-hospital dysglycemia, improve short-term and long-term morbidity/mortality, reduce the cost of healthcare, and promote a seamless transition of care between inpatient and outpatient arenas.
- Research on the effectiveness, tolerability, safety, and accessibility of FDA-approved pharmacology for the treatment of obesity and prevention/improvement of obesity-related comorbid diseases in military healthcare beneficiaries, including the active duty population.
- Research on interventions to prevent complications of diabetes including diabetic retinopathy and diabetic neuropathy.
- Research to better understand the heterogeneity of diabetes.
- Research on the transplantation of allogenic or autologous pancreatic islet cells for long term natural insulin production.

Dystonia

- Research on the risk, incidence, etiology, prevention, and/or treatment of generalized dystonia, focal dystonia (including embouchure dystonia), multifocal dystonia, segmental dystonia, and/or hemidystonia.
- Research to improve identification of delayed onset dystonia following traumatic brain injury.

Emerging Infectious Diseases

- Methods to minimize risk from arboviruses among military Service members and families deployed to/living in high-risk areas, including personal protective equipment and environmental controls.
- Development and testing of practical and rapid diagnostics for clinically relevant bacterial pathogens, including biomarkers.
- Targeted vector management of *Aedes aegypti*, including focus areas on novel adult surveillance devices, pathogen identification, spatial repellents, and barrier treatments.
- Research toward understanding the potential influence of dietary intake as a potential repellent to mosquito vectors and vector behavior.
- Evaluation of non-vaccine prophylactics or therapeutics to prevent/treat dengue or Zika virus disease.
- Validation of airborne and droplet precaution recommendations in the medical transport environment.
- Methods for screening and diagnostic detection of emerging bloodborne pathogens, including Zika and others, in blood products.
- Methods for pathogen reduction of emerging bloodborne pathogens, including Zika and others, in blood products.
- Development of rapid diagnostic testing methods for emerging bloodborne pathogens, including Zika virus and others that can be transmitted sexually or by blood transfusion.

Focal Segmental Glomerulosclerosis

- Development of a curative therapy or treatments to delay or halt the progression of focal segmental glomerulosclerosis (FSGS) and/or prevent post-transplantation recurrence.
- Appropriate testing of medications on the market that are being used to treat FSGS without clear evidence of benefit.
- Research to improve understanding of the causes of primary and secondary FSGS, especially genetic mutations.
- Development of non-invasive methods to diagnose FSGS and its variants.

Fragile X Syndrome

- Research to advance the understanding of the pathophysiology of fragile X syndrome.
- Identification and validation of functional measures of the manifestations of fragile X syndrome across the lifespan.
- Identification and testing of novel targets for fragile X syndrome therapeutics.
- Development and evaluation of novel or existing therapeutics for the treatment of fragile X syndrome.

Hepatitis B

- Research on vaccination options for those persons unable to mount immunity to hepatitis B virus (HBV).
- Development of strategies for reliable, non-invasive, early detection of HBV-related liver disease and hepatocellular carcinoma.
- Research on strategies to promote reversal of liver fibrosis and/or assess the associated clinical and pathological outcomes.
- Natural history or other studies to establish risk indicators of progression from asymptomatic or inactive chronic HBV infection to symptomatic disease and parameters for initiation and duration of disease treatment.
- Development and evaluation of strategies to promote vaccination for HBV.
- Research to support development of a curative therapy for HBV infection.
- Clinical studies to evaluate combination therapies for treatment of HBV infection.
- Identification and reduction of HBV in blood products for transfusion.
- Research on strategies to reduce vertical (mother-to-child) transmission of HBV.

Hereditary Angioedema

- Research to improve early diagnosis of hereditary angioedema (HAE).
- Evaluation of existing or novel therapeutics in pediatric HAE patients.
- Research toward the development of a cure for HAE.
- Development and/or validation of novel therapeutic strategies for the treatment and/or prevention of HAE attacks.

Hydrocephalus

- Research on the etiology, prevention, diagnosis, and treatment of post-traumatic hydrocephalus.
- Discovery or validation of novel therapies and therapeutic targets for the treatment of hydrocephalus and its sequelae, including therapies directed at myelin regeneration and repair.
- Research on approaches to lessening the impact of brain damage caused by hydrocephalus.
- Development or validation of biomarkers and imaging techniques, particularly multimodal approaches, to aid in diagnosis, prognosis, and monitoring therapeutic efficacy.
- Research on the prevention of shunt failure.
- Studies to better understand the causes and/or pathogenesis of hydrocephalus.
- Development or validation of improved hydrocephalus model systems.

Inflammatory Bowel Disease

- Clinical studies in human subjects directed toward understanding how acute enteric infections may trigger chronic bowel diseases with acute and sub-acute inflammatory bowel disease (IBD), including systems biology approaches.
- Mechanistic studies in animal models designed to understand how enteric infection may trigger IBD, including genomic, microbiomic, and immune mechanisms.
- Epidemiological studies of post-infectious acute and sub-acute IBD that define risk and provide estimates of illness-associated disability, healthcare costs, and symptom duration from a military health system and societal perspective.
- Studies (epidemiological, clinical, animal model) directed toward understanding the interaction between acute/chronic stress and infection and development of IBD.
- Research to explore whether the travel patterns of active duty personnel increase the risk of developing inflammatory bowel disease by means of exposure to changes in intestinal microflora.
- Research to better characterize the association between the use of drugs, such as isotretinoin and long-term doxycycline, and the development of IBD.
- Research on the role of diet in the development and progression of IBD.
- Research on the influence of the microbiome on IBD.

Influenza

- Research investigating acute and timely diagnostic testing of influenza patients.
- Development and testing of a universal influenza vaccine.
- Development and evaluation of novel and/or combination influenza therapies.
- Research on the underlying mechanisms of influenza drug resistance.
- Research to improve understanding of host responses to influenza infection.
- Research on the factors that contribute to, and/or the risk reduction of, the emergence of zoonotic and pandemic influenza viruses.

Integrative Medicine

- Research on the use of integrative medicine strategies, such as meditation, tai chi, acupuncture, herbal medicine, to improve psychological health and quality of life in cancer patients and survivors.
- Research on the use of integrative medicine in treatment and management of chronic pain disorders, including comparative efficacy studies relative to standard of care.
- Rigorous longitudinal studies of integrative medicine approaches for enhancing resilience and for treating psychological health issues and co-occurring disorders.
- Precision medicine research to investigate, develop, and validate biomarkers that can help determine an individual's response to integrative medicine treatments for pain.

- Development of outcomes tools and measures to evaluate the effectiveness of integrative medicine pain management approaches.
- Definitive studies to determine the effectiveness of self-care meditation-based treatments, courses and training programs in improving resiliency to stress in a military environment, in austere operational platforms such as submarines, small-deck ships, or in combat-fatigued military healthcare providers.

Interstitial Cystitis

- Studies that define the risk and prevalence and assess the impact of interstitial cystitis among active duty personnel.
- Identification biological markers that could be used to make a definitive diagnosis of interstitial cystitis.
- Evaluation and assessment of novel treatment options for interstitial cystitis patients, including intravesical therapy.

Lupus

- Development of early diagnosis technologies and strategies to detect lupus that can be implemented within the Military Health System.
- Studies to elucidate the etiology of lupus and its heterogeneity, with emphasis on gene-environment interactions.
- Studies that seek to identify molecular factors that contribute to the increased incidence and severity of lupus in non-European ancestry populations, such as African-Americans and Hispanic-Americans.
- Research the utility of newer immunosuppressive agents in the treatment of both cutaneous and systemic lupus.
- Research to explore novel sunblocking materials or methods that provide lupus patients, including active duty personnel, more effective and sustained protection from sunlight.
- Epidemiological studies to better elucidate the risk of developing systemic lupus in patients with discoid lupus.

Malaria

- Identification and/or development of novel circulating biomarkers that indicate presence of hepatic hypnozoites in relapsing malarias.
- Identification of novel malaria drug targets for blood and liver stage parasites.
- Development of new, or improvement of existing, strategies for culturing relapsing parasites such as *Plasmodium vivax*, *P. ovale*, and *P. cynomolgi* in vitro.
- Development of rodent models of human/rhesus relapsing malarias.
- Development of methods to induce high levels of long-lived, broadly protective (against multiple strains) immunity against pre-erythrocytic stages of *P. falciparum*.

- Development, testing, and evaluation of spatial repellents to provide protection against Anopheline vectors.
- Development and/or testing of new technologies or rapid diagnostic methods to reduce transfusion-transmitted malaria.

Metals Toxicology

- Identification and development of biomarkers as an assessment tool to evaluate military Service members' acute exposure to toxic metals in an operational environment, and association of health outcomes.
- Retrospective studies to evaluate risk and exposure among workers at DoD industrial facilities.
- Research on the toxicity of metal combinations and the interaction between different metal components.
- Research on the additive effects of multiple exposures to metal(s).

Mitochondrial Disease

- Research on the basic biology and physiology of mitochondria to better understand the pathology of primary mitochondrial diseases.
- Development of improved tools and animal models to study primary mitochondrial disease and evaluate therapeutics.
- Identification and testing of non-invasive techniques and biomarkers to monitor mitochondrial function, aid in diagnosis, and/or evaluate therapeutic efficacy.

Nanomaterials for Bone Regeneration

- Research on nanomaterials-based methods to facilitate recruitment of endogenous cell populations for enhanced bone regeneration and osseointegration.
- Technologies addressing segmental/large bone defects in craniomaxillofacial and/or load-bearing regions.
- Development of controlled release/extended release of growth factors for bone regeneration.
- Technologies that repair the soft tissue envelope to enhance bone regeneration.
- Development and testing of laboratory grown hydroxyapatite crystals for bone regeneration.

Non-Opioid Pain Management

- Research on pain management strategies for patients with limited access to skilled providers and resources, including battlefield and resource-limited environments.
- Development of population-based outcomes tools and measures to evaluate the effectiveness of pain management approaches across time and environment.
- Research on treatments for chronic pain management particularly in complex patients (i.e., chronic, high-utilization polypharmacy patients).

- Research to increase understanding of and preventative treatments for conversion of acute to chronic pain.
- Research that provides evidence of what pain management strategies work for whom and under what conditions.
- Research to identify and address biopsychosocial aspects of pain to reduce or eliminate use of opioid pain medication(s).
- Comparative studies evaluating the efficacy of different pain management strategies, including complementary and alternative medicine approaches.
- Identification and development of non-opioid pain management techniques that promote positive psychological health-related outcomes.
- Research on non-opioid pain management practices appropriate for use in the transport environment (helicopter, aircraft, ambulance, etc.) or in a prolonged field care setting (up to 72 hours).
- Development of non-opioid pain medicine that can be given intramuscularly, inhaled, submucosally, or intravenously on the battlefield to provide adequate relief of pain without affecting the cardiorespiratory systems.
- Research on case management strategies that optimize the effectiveness of pain clinics and use of non-opioid pain therapies.
- Research on standardized approaches for early identification and prevention of chronic musculoskeletal pain.
- Research on the effects of early use of case management to reduce dependence on opioid therapies for pain management.
- Research investigating the use of ketamine for acute flares of chronic, non-cancer painful conditions.

Pancreatitis

- Retrospective studies to determine risk and incidence of pancreatitis among former and current active duty personnel.
- Development and testing of novel therapeutics for acute and/or chronic pancreatitis.
- Research on the basic biology and physiology of the pancreas to better understand the etiology and pathology of pancreatitis.

Pathogen-Inactivated Dried Plasma

- Development of technology to produce pathogen-reduced dried plasma in military/civilian donor centers that is acceptable for FDA licensure in support of contingency/combat operations.
- Development and/or validation of methods for pathogen reduction of emerging bloodborne pathogens, including malaria, Babesi, Ebola, West Nile Virus, dengue, Chikungunya, Zika virus and other pathogens found in blood products.

- Development of a next-generation pathogen reduction device with increased throughput for donor center production of whole blood, platelets and plasma in support of contingency/combat operations.
- Development and/or validation of next generation technologies for the production of pathogen-reduced dried plasma (including emerging pathogens) derived from whole blood that has been pathogen-reduced. Technology should be suitable for military blood bank use in deployed scenarios.

Polycystic Kidney Disease

- Development of improved treatment strategies for polycystic kidney disease (PKD), including approaches to identify and monitor patients at higher risk for progressing to end stage renal disease.
- Research on the underlying pathobiology and molecular mechanisms of PKD, including genetic studies, cyst formation and growth, the role of cilia, and factors that modify disease progression and/or severity.
- Research on the lifestyle factors which may modify the progression of PKD.

Post-Traumatic Osteoarthritis

- Research to establish activity recommendations for maximal joint life following joint repair, particularly in young patient populations.
- Research into cell-based approaches for long-term steroid release.
- Studies to evaluate and develop best practices for multidisciplinary team approaches and treatment algorithms for post-traumatic osteoarthritis.
- Development or validation of novel approaches to restoring joint stability after injury.
- 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.
- Research on therapies that target multiple phases of the cellular response pathways that are implicated in development of post-traumatic osteoarthritis, including cell death, inflammation, matrix changes, and changes in catabolic and anabolic responses.

Psychotropic Medications

- Research on the use of ketamine in patients presenting with suicidal ideations or intent.
- Research on the use of psychotropic medications to increase resilience in military units.
- Identification and/or development of therapies that can completely or selectively reverse the effects of psychotropic medications.
- Research into the use and repurposing of psychotropic medications for the treatment of psychiatric disorders including post-traumatic stress, suicidal ideation, substance abuse, and other comorbidities.

- Research to evaluate the use of psychotropic medications for mental health issues specific to women in the military.
- Research toward increasing the accuracy and effectiveness of prescription practices for mental health medications, including but not limited to development of biomarkers to match patients to medications and measure treatment responsiveness, development of better outcome measures, and/or methods to improve collection of patient data in real time.

Pulmonary Fibrosis

- Retrospective studies to determine risk and incidence of pulmonary fibrosis among current and former military Service members.
- Identification of biomarkers of pulmonary injury or early predictors of lung disease.
- Research into the pathobiology and molecular mechanisms underlying the development of pulmonary fibrosis.
- Development and/or testing of novel treatments to delay or modify the progression of pulmonary fibrosis.
- Development and/or validation of improved tools and animal models to study pulmonary fibrosis and evaluate therapeutics.

Respiratory Health (excludes lung cancer and mesothelioma)

- Research on the cause, treatment, and prevention of respiratory symptoms and ailments possibly associated with deployed and re-deployed military personnel, including acute eosinophilic pneumonia, asthma, allergies, and other chronic lung diseases and breathing problems.
- Research to evaluate the impact of deployment on the prevalence and severity of respiratory disease in military Service members.
- Studies to determine the natural history of deployment-related respiratory disease and to identify factors associated with respiratory disease.
- Identification and development of biomarkers of exposure to military-relevant hazards such as airborne nanomaterials, diesel exhaust, and other combustion products and fuels.
- Development and/or validation of methods to detect volatile organic hydrocarbons from the breath of individuals exposed to toxic chemicals.
- Identification of biochemical, physiological, or combined biomarkers of effect or exposure for evaluating injury from acutely toxic occupational or environmental exposures in military operational environments.
- Identification of biochemical, physiological, or combined biomarkers of effect or exposure for the early assessment of long-term health consequences of military-relevant occupational or environmental toxicant exposures.
- Research investigating the treatment of patients with chronic mild hypoxia.

Rett Syndrome

- Identification and/or validation of novel biological targets for the treatment of Rett syndrome.
- Development and testing of interventions to improve the neurological symptoms of Rett syndrome.
- Research to understand the relationship between genetic mutations, physical traits, and symptoms in individuals with Rett syndrome.
- Research on the pathobiology of the MeCP2 gene and protein.
- Research to understand Rett syndrome's commonalities with and differences from classic autism and regressive autism.

Rheumatoid Arthritis

- Research to better understand the relationship between genetic risk and environmental triggers, such as infection or smoking, in developing rheumatoid arthritis.
- Studies that identify or validate biomarkers or personalized medicine strategies that allow for individualized medication choice based upon the patient's underlying biology or disease state.
- Research on the long-term use of immunosuppressants in patients with rheumatoid arthritis and the likelihood of developing infections.
- Research to establish activity recommendations following joint replacement for maximal joint life.

Scleroderma

- Research on the molecular mechanisms and pathogenesis of scleroderma.
- Development and/or testing of novel therapies and identification of novel therapeutic targets in scleroderma.
- Research on biomarkers and other approaches to diagnose scleroderma, monitor disease progression, and/or assess response to treatment.
- Epidemiologic studies investigating the impact of localized scleroderma (morphea) on duty performance, use of personal protective equipment, and deployability.
- Research on the efficacy of newer immunosuppressive agents in the treatment of morphea and scleroderma.

Sleep Disorders

- Research on how the disruption of normal sleep and circadian biological rhythms adversely affects health, safety, performance, and productivity of military and civilian populations.
- Studies to assess sleep disturbance and clinical sleep disorders in female military personnel.
- Research on the association between sleep disorders and post-traumatic stress disorder (PTSD), traumatic brain injury, depression, and/or anxiety.

- Research to assess clinical algorithms that improve adherence to Continuous Positive Airway Pressure (CPAP).
- Investigations into non-CPAP-based treatment regimens that enhance readiness and deployability in active duty military personnel.
- Studies to determine the efficacy of cognitive behavioral therapy for insomnia (CBTI) in active duty military personnel with insomnia.
- Research focused on investigating how psychiatric disorders (PTSD in particular), combined with the disruption/degradation of sleep quality, impact long-term physical health through changes in glucocorticoid regulation.
- Development and/or testing of non-pharmacological treatments for sleep disorders.
- Research on the impact of sleep deprivation on the efficacy of psychological treatments.
- Research on the prevention and/or mitigation of sleep disorders that are associated with long aeromedical evacuation flights for both clinical team members and patients.

Tinnitus

- Research to understand the mechanisms of tinnitus, its relationship to noise-induced hearing loss, and progression to chronic tinnitus.
- Research to increase the knowledge of the prevalence, incidence, natural history, occupational, and sex-related differences of tinnitus and its possible relation to individual blast/noise exposures.
- Improvement of objective tools to diagnose and characterize tinnitus (e.g., imaging techniques to identify functional and structural changes in the brain, biomarkers of resiliency, and susceptibility to tinnitus).
- Identification of novel therapies for early interventions to prevent and treat tinnitus, including new uses for existing drugs, nutritional and pharmaceutical based strategies, and acoustic, electrical, and other stimulation technologies.

Tuberculosis

- Development of a diagnostic assay that can be used at the point of care to rapidly and accurately diagnose tuberculosis (TB).
- Development of novel TB vaccines, or optimization of current TB vaccines.
- Identification and/or validation of biomarkers that can be used to assess vaccine efficacy and protection against TB disease.
- Research to understand, diagnose, or treat multi-drug resistant TB or extensively drug-resistant TB.
- Research to determine the appropriate precautions to use for the transport of active TB patients.

Vaccine Development for Infectious Disease

- Development of vaccines for Chikungunya virus, dengue virus, and Zika virus.

- Evaluation of passive immunization strategies to use in conjunction with dengue vaccination and Zika vaccination.
- Research leading to a better understanding of the immune mechanisms involved in the clearance of dengue virus and Zika virus and mechanisms of immune enhancement that lead to more severe clinical disease.
- Development of flexible vaccine technologies that can be used to rapidly respond to emerging and re-emerging infectious diseases threats.
- Evaluation of humoral and cellular immune responses after vaccination and natural infection.
- Development of a safe, effective dengue human challenge model for clinical trials.

Vascular Malformations

- Studies into the natural history, genetics, and pathogenesis of vascular malformations.
- Research to discover or develop novel therapeutic targets and treatments to regress or prevent vascular malformations.
- Research to improve methods to diagnose and manage vascular malformations.
- Development of non-invasive or minimally invasive technologies or approaches for the control of internal bleeding associated with vascular malformations.
- Studies to identify risk and/or establish standard practices for the treatment of hemorrhage from brain arteriovenous malformations.
- Research on the prevention or treatment of complications associated with vascular malformations such as pain, infection, seizures, tissue breakdown, tissue overgrowth, or airway obstruction.

Women's Heart Disease

- Retrospective studies to determine risk and incidence of heart disease among former and current female active duty personnel.
- Research focused on elucidating the potential relationship between PTSD and women's heart disease.
- Identification of sex-specific approaches to increase the effectiveness of cardiac rehabilitation programs.
- Research on factors to predict and prevent gestational diabetes, hypertension, preeclampsia, and placental insufficiency.
- Research on trauma-induced cardiac arrest secondary to hemorrhage and polytrauma in the female population.

APPENDIX 2 DOD AND VA WEBSITES

PIs are encouraged to integrate and/or align their research projects with DoD and/or VA research laboratories and programs. Collaboration with DoD or VA investigators is also encouraged. Below is a list of websites that may be useful in identifying additional information about DoD and VA areas of research interest, ongoing research or potential opportunities for collaboration within the FY16 PRMRP Topic Areas.

Air Force Office of Scientific Research
<http://www.wpafb.af.mil/afri/afosr/>

Air Force Research Laboratory
<http://www.wpafb.af.mil/afri/>

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 Technical Information Center
<http://www.dtic.mil>

Defense Threat Reduction Agency
<http://www.dtra.mil/>

Military Health System Research
Symposium
[https://mhsrs.amedd.army.mil/SitePages/Ho
me.aspx](https://mhsrs.amedd.army.mil/SitePages/Home.aspx)

Military Infectious Diseases 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/>

Telemedicine and Advanced Technology
Research Center
<http://www.tatrc.org/>

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

U.S. Army Institute of Surgical Research
<http://www.usaisr.amedd.army.mil/>

U.S. Army Research Institute of
Environmental Medicine
<http://www.usariem.army.mil/>

U.S. Army Medical Research Institute of
Infectious Diseases
<http://www.usamriid.army.mil/>

U.S. Army Medical Research and Materiel
Command
<http://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>