

# **Program Announcement**

**for the**

**Department of Defense**

**Defense Health Program**

**Congressionally Directed Medical Research Programs**

## **Peer Reviewed Alzheimer's Research Program Epidemiology of Military Risk Factors Research Award**

**Funding Opportunity Number: W81XWH-16-PRARP-EMRF**

**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), August 17, 2016
- **Invitation to Submit an Application:** October 5, 2016
- **Application Submission Deadline:** 11:59 p.m. ET, November 9, 2016
- **End of Application Verification Period:** 5:00 p.m. ET, November 15, 2016
- **Peer Review:** January 2017
- **Programmatic Review:** April 2017

*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 Alzheimer's Research Program (PRARP) 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).

Military personnel and other individuals living with traumatic brain injury (TBI) face an increased risk for developing several long-term health problems. These include Alzheimer's-like dementia, aggression, memory loss, depression, and symptoms similar to those of other neurological diseases. The PRARP (formerly the Militarily Relevant Peer Reviewed Alzheimer's Disease Research Program) was initiated in 2011 to address the long-term consequences of TBI as they pertain to Alzheimer's disease (AD) and AD-related dementias (ADRD). The PRARP's mission is devoted to (1) understanding the association between TBI and AD/ADRD, and (2) reducing the burden on affected individuals and caregivers, especially in the military and Veteran communities. Support for the PRARP's mission is anticipated to be delivered by the research community through a combination of mechanistic and preclinical studies.

Appropriations for the PRARP from FY11 through FY15 totaled \$63 million (M). The FY16 appropriation is \$15M.

### **B. Award Information**

The PRARP Epidemiology of Military Risk Factors Research Award (EMRFA) mechanism is being offered for the first time in FY16.

The intent of the FY16 PRARP EMRFA is to investigate the etiology and epidemiology of military-related TBI and AD/ADRD. The research impact will benefit the military, Veteran, and civilian communities. To this end, the PRARP has identified FY16 EMRFA Overarching Challenges and Focus Areas by which the intent of this mechanism can be facilitated (see [Section I.B., FY16 PRARP EMRFA Overarching Challenges and Focus Areas](#)). These should be carefully considered as part of the application process.

Applications should describe how the association of TBI and subsequent AD/ADRD will be characterized. Applications should carefully consider how their studies will characterize the cognitive and behavioral symptoms that result in functional impairments in the proposed identified cohort. Studies that use combinations of measures (e.g., neuropsychological assessments, imaging, genomics, and cerebral spinal fluid biomarkers) are encouraged. Applications that develop interdisciplinary teams or consortia as part of the support plan for executing the research are encouraged.

The FY16 PRARP EMRFA is open to Principal Investigators (PIs) at or above the level of Assistant Professor (or equivalent) from any field or discipline who seek to bring their expertise to address the PRARP's mission (see [Section I.A., Program Description](#)). However, as part of the application, the PI should demonstrate that the study team has experience in both TBI and AD/ADRD research. Preliminary data, while not required, are encouraged. Preliminary data may come from the PI's published work, pilot data, or from peer-reviewed literature.

**Important Note:** Applications must detail and demonstrate expedited access to a well-defined, already identified study cohort. Applications must detail how the cohort will be used in the study in support of the proposed research hypothesis (or hypotheses). Refer to the Review Criteria in [Section III](#) of this Program Announcement/Funding Opportunity for details.

**FY16 PRARP EMRFA Overarching Challenges:** This FY16 PRARP EMRFA funding opportunity requires applications to address one or more of the following FY16 PRARP EMRFA Overarching Challenges:

- **Paucity of Research Resources:** The paucity of research resources to examine the interrelationship between TBI and subsequent AD/ADRD for the military, Veteran, and civilian communities.
- **Paucity of Clinical Studies:** The paucity of clinical studies to examine the interrelationship between TBI and subsequent AD/ADRD for the military, Veteran, and civilian communities.
- **Diagnostic Technologies, Tests, Biomarkers, or Devices:** The need for technologies, tests, or devices to detect the progression to AD/ADRD subsequent to TBI.
- **Epidemiology:** The paucity of epidemiological research to examine the interrelationship between TBI and subsequent AD/ADRD for the military, Veteran, and civilian communities.

**FY16 PRARP EMRFA Focus Areas:** In addition to addressing one or more of the specified FY16 PRARP EMRFA Overarching Challenges, applications should address at least one of the following FY16 PRARP EMRFA Focus Areas in support of the FY16 PRARP EMRFA Overarching Challenges. An application that proposes research outside of these FY16 PRARP EMRFA Focus Areas is acceptable, as long as the applicant provides a strong rationale.

- **Genomics/Proteomics:** Studies or technologies (e.g., genetic, proteomic, and epigenetic strategies) intended to characterize neurological change(s) associated with TBI and subsequent AD/ADRD. In addition, relevant technologies or tests may be considered under this focus area.
- **Diagnostics and Biomarkers:** Development of strategies to characterize neurological changes associated with TBI and subsequent AD/ADRD (e.g., fluid-based, imaging, physiological, and clinical approaches).
- **Epidemiological Research:** Research focusing on the incidence, distribution, outcomes, and other factors relating to the health of individuals affected by TBI and subsequent AD/ADRD.

**The following is specifically discouraged under the FY16 PRARP:**

**Pharmacologic Interventions:** Clinical research requiring investigational or U.S. Food and Drug Administration (FDA)-approved drugs or medicines.

**C. Information Regarding Human Research**

**Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers:** All Department of Defense (DoD)-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Materiel Command (USAMRMC) Office of Research Protections (ORP), Human Research Protection Office (HRPO) 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.

**D. Information Regarding Common Data Elements and Data Sharing**

**Use of TBI Common Data Elements:** Data elements must be reported using the National Institute of Neurological Disorders and Stroke (NINDS) TBI Common Data Elements (CDEs) or entered into the Federal Interagency TBI Research (FITBIR) data dictionary as new, unique data elements. For the most current version of the NINDS TBI CDEs, go to <http://www.commondataelements.ninds.nih.gov>. Assistance will be available to help researchers map their study variables to specific CDEs and ensure the formats of the CDEs collected are compatible with the FITBIR Informatics System. If the proposed research data cannot be entered in CDE format, the investigators must supply a proposal for an alternative data submission or data sharing vehicle and justification for its use. Use of the TBI CDEs is required wherever possible in an effort to create standardized definitions and guidelines about the kinds of data to collect and the data collection methods that should be used in clinical studies of TBI.

**FITBIR Reporting Requirement for Projects Producing TBI Datasets:** The DoD requires that awardees make available to the TBI research community all data generated via this award mechanism by depositing de-identified research data into the FITBIR Informatics System on a quarterly basis. The FITBIR Informatics System is a free resource to the TBI community and is designed to accelerate comparative effectiveness research on brain injury diagnosis and treatment. Data reporting to FITBIR is an opportunity for investigators to facilitate their own research and to collaborate with others doing similar research. While there is no direct charge to users of the FITBIR Informatics System, a project estimation tool (<https://fitbir.nih.gov/jsp/contribute/fitbir-costs.jsp>) is available to help estimate costs and manpower needs that may be associated with data submission. To contribute to FITBIR, researchers should contact the

FITBIR Operations Center ahead of time to arrange for data entry support and to ensure all data has been made compatible with the system. FITBIR guidance and policies, as well as the considerable advantages of FITBIR use to the researcher, are detailed at FITBIR: Federal Interagency Traumatic Brain Injury Research Informatics System (<http://fitbir.nih.gov/>).

FITBIR allows for de-identification and storage of data (medical imaging, clinical assessment, environmental and behavioral history, etc.) of various types (text, numeric, image, time series, etc.). Use of FITBIR's Global Unique Identifier (GUID) system facilitates repeated and multi-user access to data without the need to personally identify data sources. FITBIR encourages collaboration between laboratories, as well as interconnectivity with other informatics platforms. Such community-wide sharing requires common data definitions and standards.

*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.*

#### **E. Eligibility Information**

- The PI must be an independent investigator **at or above** the level of Assistant Professor (or equivalent).
- 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 military 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.

#### **F. Funding**

- The maximum period of performance is **4** years.
- The anticipated **total costs (direct and indirect)** budgeted for the entire period of performance will not exceed **\$2.5M**. Indirect costs are to be budgeted in accordance

with the organization's negotiated rate. No budget will be approved by the Government exceeding **\$2.5M** total costs or using an indirect rate exceeding the organization's negotiated rate.

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

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

- Travel costs for the PI to disseminate project results at one annual DoD PRARP In-Progress Review meeting starting in year 2 and throughout the remaining period of performance. Annual costs associated with travel to this meeting should be included in the budget. For planning purposes, it should be assumed that the meeting will be held in the National Capital Area for a single day. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Salary
- Research-related supplies and subject costs
- Preclinical research costs
- Subject reimbursement and compensation
- Support for multidisciplinary collaborations
- Travel between collaborating organizations
- Data sharing costs associated with the execution of the data sharing plan
- Travel costs for up to two investigators to travel to two scientific/technical meetings per year. This is in addition to the aforementioned In-Progress Review meeting.

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 \$2.5M of the \$15M FY16 PRARP appropriation to fund approximately one Epidemiology of Military Risk Factors Award application, 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 or different funding levels within the same program and fiscal year is prohibited and will result in administrative withdrawal of the duplicative application(s).***

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](mailto: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-PRARP-EMRF 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/>). Because the invitation to submit an application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

PIs and organizations identified in the pre-application should be the same as those intended for the subsequent application submission. A change in PI or organization after submission of the pre-application may be allowed after review of a submitted written appeal (contact the CDMRP Help Desk at [help@eBRAP.org](mailto: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**
- **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 PRARP Programmatic Panel members should not be involved in any pre-application or application.** For questions related to Programmatic Panel members and pre-applications or applications, see [Section IV.C., Withdrawal](#), or contact the CDMRP Help Desk at [help@eBRAP.org](mailto: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**

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

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

The Preproposal Narrative should include the following:

- A description of how the pre-application meets the intent of the EMRFA mechanism (see [Section I.B., Award Information](#)).
- A description of how the research is aligned with the FY16 PRARP EMRFA Overarching Challenges (see [Section I.B., Award Information](#)).
- A description of how the research is aligned with at least one of the FY16 PRARP EMRFA Focus Areas (see [Section I.B., Award Information](#)). Research outside of

these FY16 PRARP EMRFA Focus Areas is acceptable, but a strong rationale is required and must be included in the Preproposal Narrative.

- A description of the proposed scientific hypothesis (or hypotheses) and rationale.
- Relevant preliminary data (if available). Preliminary data may come from PI's published work, pilot data, or from peer-reviewed literature.
- Evidence of expedited access to an already identified, suitable study cohort that will support the proposed hypothesis (or hypotheses).

**Note: Pharmacological interventions are discouraged. This is defined as clinical research requiring investigational or FDA-approved drugs or medicines.**

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

- References Cited (one-page limit): List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
- List of Abbreviations, Acronyms, and Symbols: Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.
- Key Personnel Biographical Sketches (six-page limit per individual). *All biographical sketches should be uploaded as a single combined file.* Biographical sketches should be used to demonstrate background and expertise through education, positions, publications, and previous work accomplished.

- **Tab 6 – Submit Pre-Application**

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

## **Pre-Application Screening**

- **Pre-Application Screening Criteria**

To determine the technical merits of the pre-application and the relevance to the mission of the DHP and the PRARP (see [Section I.A., Program Description](#)), pre-applications will be screened based on the following criteria:

- Does the pre-application meet the intent of the FY16 PRARP EMRFA mechanism?
- Does the pre-application identify and align with one or more of the FY16 PRARP EMRFA Overarching Challenges?
- Does the pre-application identify and align with one or more of the FY16 PRARP EMRFA Focus Areas? If the proposed research does not align with any of the FY16 PRARP EMRFA Focus Areas, is the rationale clear and reasonable?
- What are the merits of the scientific hypothesis (or hypotheses) and rationale as they pertain to the mission (see [Section I.A., Program Description](#)) of the PRARP?

- Are the preliminary data, if available, supportive of the proposed hypothesis (or hypotheses) and rationale?
- Are the qualifications of the PI and key personnel appropriate?
- Does the study team demonstrate expertise in both TBI and AD/ADRD?
- Does the pre-application demonstrate expedited access to an already identified, suitable study cohort that will support the proposed hypothesis (or hypotheses)?
- **Notification of Pre-Application Screening Results**

Following the pre-application screening, PIs will be notified as to whether or not they are invited to submit applications; however, they will not receive feedback (e.g., a critique of strengths and weaknesses) on their pre-application. The estimated timeframe for notification of invitation to submit an application is indicated on the [title page](#) of this Program Announcement/Funding Opportunity. Invitations to submit a full application are based on the Pre-Application Screening Criteria as published above.

### **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 System for Award Management (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.

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

*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.***

The Grants.gov application package must be submitted using the unique eBRAP log number to avoid delays in application processing.

**Grants.gov application package components:** For the Epidemiology of Military Risk Factors Research 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 (20-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) 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.

- **Background:** Present the ideas and reasoning behind the proposed research; include relevant literature citations. Describe previous experience most pertinent to this application.
- **Preliminary Data:** Provide preliminary data (if available) to support the rationale and feasibility of the study. Preliminary data may come from PI’s published work, pilot data, or from peer-reviewed literature.
- **Hypothesis (or Hypotheses):** State the hypothesis (or hypotheses) to be tested.
- **Specific Aims:** Concisely explain the project’s specific aims.
- **Project Milestones:** Concisely provide expected project milestones relevant to each of the project’s technical objectives and specific aims.
- **Expedited Cohort:** Detail and demonstrate expedited access to a well-defined, already identified study cohort. Furthermore, detail how the cohort will be used in the study in support of the proposed research hypothesis (or hypotheses).

- **Research Strategy and Data Analysis:** Describe the experimental design, methods, and analyses including appropriate controls in sufficient detail for analysis. Specify the approximate number of human subjects to be enrolled, if applicable. If multiple study sites are involved, state the approximate number to be enrolled at each site. Clearly describe the statistical plan and the rationale for the statistical methodology as well as an appropriate power analysis, if applicable. Address potential problem areas and present alternative methods and approaches. Include a detailed plan for the recruitment of subjects and the acquisition of samples. **Note that pharmacologic interventions are specifically discouraged.**
- **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:** List the references cited (including URLs, if available) in the Project Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, title of reference, source of reference, volume, chapter, page numbers, and publisher, as appropriate).
  - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.
  - **Facilities, Existing Equipment, and Other Resources:** Describe the facilities and equipment available for performance of the proposed project and any additional facilities or equipment proposed for acquisition at no cost to the award. Indicate whether or not Government-furnished facilities or equipment are proposed for use. If so, reference should be made to the original or present Government award under which the facilities or equipment items are now accountable. There is no form for this information.
  - **Publications and/or Patents:** Include a list of relevant publication URLs and/or patent abstracts. If publications are not publicly available, then copies of up to five published manuscripts may be included in Attachment 2. Extra items will not be reviewed.
  - **Letters of Organizational Support:** Provide a letter (or letters, if applicable), signed by the Department Chair or appropriate organization official, confirming the laboratory space, equipment, and other resources available for the project. Letters of support not requested in the Program Announcement/Funding Opportunity, such as those from members of Congress, do not impact application review or funding decisions.
  - **Letters of Collaboration:** Provide a signed letter from each collaborating individual or organization that will demonstrate that the PI has the support or resources necessary for the proposed work.

- **Intellectual Property:**
  - Intangible property acquired, created or developed under this award will be subject to all rights and responsibilities established at 2 CFR 200.315. Should the applicant intend to use, in the performance of this program, pre-existing, legally protected and perfected intangible property and for which no Federal funds had been used in the development of said property, the applicant must:
    - Clearly identify all such property;
    - Identify the cost to the Federal Government for use or license of such property, if applicable; or
    - Provide a statement that no property meeting this definition will be used on this project.
  - **Intellectual and Material Property Plan (if applicable):** Provide a plan for resolving intellectual and material property issues among participating organizations.
  - **Commercialization Strategy (if applicable):** Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.
- **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 publicly. ***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.

Describe the proposed research project including the following elements:

- **Background:** Present the ideas and reasoning behind the proposed project.
- **Hypothesis (or Hypotheses):** State the hypothesis (or hypotheses) to be tested.
- **Specific Aims:** Concisely explain the project’s specific aims.
- **Research Strategy:** Briefly describe the research strategy.

Of particular importance, programmatic reviewers typically do not have access to the full application and therefore rely on the technical abstract for appropriate description of the project’s key aspects. Therefore, clarity and completeness within the space limits of the technical abstract are highly important.

- **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 publicly. ***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.

Describe the scientific objective and rationale for the proposed project in a manner that will be *readily understood by readers without a background in science or medicine*.

Of particular importance, programmatic reviewers typically do not have access to the full application and therefore rely on the lay abstract for appropriate description of the project's key aspects. Therefore, clarity and completeness within the space limits of the lay abstract are highly important.

- **Attachment 5: Statement of Work (SOW) (three-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 Epidemiology of Military Risk Factors Award mechanism, use the SOW format example titled “SOW for Clinical Research (Including Trials, Special Populations.” 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: Human Subject Recruitment and Safety Procedures (no page limit): Upload as “HumSubProc.pdf.”** The Human Subject Recruitment and Safety Procedures attachment should include the components listed below.
  - a. **Study Population:** Describe the target population (to whom the study findings will be generalized) and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site (population from whom the sample will be recruited/drawn). Demonstrate that the study team has access to the proposed study population. Furthermore, discuss past efforts in recruiting human subjects from the target population. Address any potential barriers to accrual and plans for addressing unanticipated delays. Include justification of any age, race, ethnicity, or sex limitations provided.
  - b. **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed research. Inclusion/exclusion criteria should take into consideration the specific risk profile of the studies to be conducted and the standard of care for that patient population. Provide detailed justification for exclusions.

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

- c. **Description of the Recruitment Process:** Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, healthcare provider identification).
- Describe the recruitment process in detail. Address who will identify potential human subjects, who will recruit them, and what methods will be used to recruit them.
  - Include a detailed description of and justification for the compensation plan if the human subjects will be compensated for participation in the study.
  - Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study.
- d. **Description of the Informed Consent Process:** Specifically describe the plan for obtaining informed consent from human subjects.
- ***For the proposed study, provide a draft, in English, of the Informed Consent Form.***
  - Identify who is responsible for explaining the study, answering questions, and obtaining informed consent. Include a plan for ensuring that human subjects' questions will be addressed during the consent process and throughout the trial.
  - Include information regarding the timing and location of the consent process.
  - Address issues relevant to the mental capacity of the potential human subject (e.g., altered capacity due to administration of any mind-altering substances such as tranquilizers, conscious sedation or anesthesia, brain injury, stress/life situations, or human subject age), if applicable.
  - Address how privacy and time for decision making will be provided and whether or not the potential human subject will be allowed to discuss the study with anyone before making a decision.
  - Consider the need for obtaining ongoing consent or for re-assessing capacity over the course of a long-term study and describe any relevant procedures to assure continued consent.
  - Describe the plan for the consent of the individual's Legally Authorized Representative (LAR) to be obtained prior to the human subject's participation in the study. State law defines who may act as the LAR. The local IRB of record should be consulted for guidance regarding who can serve as LAR for research at the study site. **Note: The PI must describe a clear intent to benefit for human subjects who cannot give their own consent to participate in the proposed study to be in compliance with Title 10 United States Code Section 980 (10 USC 980)** (<http://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf>). If applicable, please refer to the General Application Instructions, Appendix 6, for more information.

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

- a. **Data Management:** Describe all methods used for data collection to include the following:
- **Identifiers:** Describe the unique identifiers or specific code system to be used to identify human subjects, if applicable.
  - **Confidentiality:**
    - Explain measures taken to protect the privacy of study human subjects and maintain confidentiality of study data. Strategies to protect the privacy and confidentiality of study records, particularly those containing identifying information, should be addressed.
    - Address who will have access to study records, data, and specimens, including an acknowledgment that representatives of USAMRMC are eligible to review study records.
    - Address requirements for reporting sensitive information to state or local authorities.
  - **Data capture, verification, and disposition:** Describe how data will be captured and verified. Describe where data (both electronic and hard copy) will be stored, who will keep the data, how the data will be stored, the process for locking the database at study completion, and the length of time data will be stored. Describe the proposed database, how it will be developed and validated, and its capability to safeguard and maintain the integrity of the data. For FDA-regulated studies, compliance with 21 CFR 11 is required.
- b. **Laboratory Evaluations:**
- **Specimens to be collected, schedule, and amount:** All specimens that will be collected for study purposes must be clearly stated. The collection schedule and amount of material collected must also be clearly described.
  - **Evaluations to be made:** Describe all evaluations that will be made for study purposes. Explain how the results of laboratory evaluations will be used to meet the objectives of the study (or to monitor safety of human subjects).
  - **Storage:** Describe specimen storage, to include location of storage, how long specimens will be stored, any special conditions required, labeling, and disposition. Outline the plan to store specimens for future use to include considerations for informed consent and providing human subjects with an opportunity to decline participation in the study.
  - **Labs performing evaluations and special precautions:** Identify the laboratory performing each evaluation, as well as any special precautions that should be taken in handling the samples. Special precautions that should be taken by the human subject before, during, or after the laboratory procedure should be clearly defined. If transport of samples is required, describe provisions for ensuring proper storage during transport.

- **Attachment 8: Study Personnel and Organization (no page limit): Start each document on a new page. Combine into one document and upload as “Personnel.pdf.”** The Study Personnel and Organization attachment should include the components listed below.
  - a. **Organizational Chart:** Provide an organizational chart identifying key members of the study team including institution/center/department and name each person’s position on the project. A research monitor (external to the study) should be included. If applicable, include any external consultants or other experts who will assist with FDA applications. While there is no specified format for this information, a table(s) or diagram is recommended.
  - b. **Study Personnel Description:** Briefly describe the roles of the individuals listed in the organizational chart on the project. Describe relevant experience and qualifications that demonstrate appropriate expertise for the given role.
  - c. **Study Management Plan:** Provide a plan for ensuring the standardization of procedures among staff and across sites (if applicable). If the proposed study is multi-institutional, plans for communication and data transfer between the collaborating institutions, as well as how data, specimens, and/or imaging products obtained during the study will be handled, should be included. Provide a plan for real-time communication among collaborating institutions (if applicable).
  
- **Attachment 9: Surveys, Questionnaires, and Other Data Collection Instruments, if applicable (no page limit): Upload as “Surveys.pdf.”** The Surveys, Questionnaires, and Other Data Collection Instruments attachment should include a copy of the most recent version of surveys, questionnaires, data collection forms, rating scales, interview guides, or other instruments. For each instrument, describe how the information collected is related to the objectives of the study.
  
- **Attachment 10: Overarching Challenge and Focus Areas Statement (one-page limit): Upload as “OCFAS.pdf.”** Describe how the proposed study is responsive to the specified FY16 PRARP EMRFA Overarching Challenges (see [Section I.B., Award Information](#)). In addition, describe how the application addresses at least one of the FY16 PRARP EMRFA Focus Areas (see [Section I.B., Award Information](#)). An application that proposes research outside of these FY16 PRARP EMRFA Focus Areas is acceptable, as long as the applicant provides a strong rationale. **The application must include the Overarching Challenges and Focus Areas Statement.**
  
- **Attachment 11: Impact Statement (one-page limit): Upload as “Impact.pdf.”** Detail the anticipated outcome(s) that will be directly attributed to the results of the proposed research (short-term gains). Explain the anticipated long-term gains from the proposed research project. Furthermore, detail how the research efforts will benefit researchers and/or practitioners in the health sciences related to the PRARP’s mission (see [Section I.A., Program Description](#)), and ultimately affected individuals and families. **The application must include the Impact Statement.**

- **Attachment 12: Data Sharing Plan (two-page limit): Upload as “Sharing.pdf.”** A robust data sharing plan is required as part of the application process. Describe the type of data or resource to be made available as a result of the proposed work. Also, describe the plan for the provision of access to the data or resource generated from the proposed work to the public, and how the data or resource will be made available after the award expires. Provide a milestone plan for data dissemination as part of this statement.
  - **Applications that include studies of TBI must consider the following as part of their Data Sharing Plan:**
    - **Use of Common Data Elements:** If an applicant’s study involves the generation of TBI datasets, the applicant must describe how (s)he will use the NINDS TBI CDEs (see <http://www.commondataelements.ninds.nih.gov>). If the proposed research is not compatible with the required CDEs, the applicant should supply justification why these measures will not be incorporated into the research.
    - **FITBIR Reporting Requirement:** A plan for reporting to the FITBIR (<https://fitbir.nih.gov/content/contribute-data>) data repository must also be described in the data sharing plan, if applicable. If the proposed study is not compatible with the database, the applicant should supply a justification for not using the database. Applicants should review the FITBIR guidance regarding the inclusion of costs in the proposed budget associated with reporting to FITBIR.

**For additional guidance regarding Sharing of Data and Research Resources, refer to the General Application Instructions, Appendix 4, Section K.**

- **Attachment 13: 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.
- **PI Biographical Sketch (six-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 six-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 (six-page limit each): Upload as “Biosketch\_LastName.pdf.”
  - Key Personnel Previous/Current/Pending Support (no page limit): Upload as “Support\_LastName.pdf.”
- 4. Research & Related Budget:** Refer to the General Application Instructions, Section II.C.4., for detailed information.
- Budget Justification (no page limit): Upload as “BudgetJustification.pdf.” 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 13 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 PRARP, 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>.

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, which are listed in decreasing order of importance:

- **Research Strategy and Feasibility**

- How well the scientific rationale supports the project and its feasibility as demonstrated by a critical review and analysis of the literature, relevant preliminary data (if available), and/or logical reasoning.
- How well the hypothesis (or hypotheses), aims, experimental design, methods, and analyses are developed.
- How well the inclusion and randomization criteria meet the needs of the proposed study (if applicable).
- How well plans to collect specimens and conduct laboratory evaluations are addressed, if applicable.
- How well the PI acknowledges potential problems and addresses alternative approaches.
- How well the logistical aspects of the proposed study (e.g., communication plan, data transfer and management, standardization of procedures) meet the needs of the proposed study.
- How well the cohort supports the proposed research hypothesis (or hypotheses).

- **Impact Statement**

Assuming the objectives/goals of the proposed research project are realized, to what extent:

- The anticipated outcomes (short-term) will be used as the foundation for future research projects.
- The anticipated long-term scientific gains will contribute to the goal of achieving the PRARP's mission (see [Section I.A., Program Description](#)).
- The efforts will benefit researchers and/or practitioners in the health sciences related to the PRARP's mission (see [Section I.A., Program Description](#)) and ultimately affected individuals and families.

- **Personnel**

- How well the PI shows potential for addressing the PRARP's mission (see [Section I.A., Program Description](#)) based on his/her background and experience.
- How well the study team's background and related expertise are appropriate with respect to its ability to perform the proposed work (e.g., statistical expertise, expertise in the disease, and clinical studies).

- To what extent the composition of the study team (e.g., study coordinator, statistician), to include the PI, is appropriate and includes expertise in both TBI and AD/ADRD.
- To what degree the levels of effort are appropriate for successful conduct of the proposed work.
- **Overarching Challenges and Focus Area Statement**
  - How well the proposed study addresses the FY16 PRARP EMRFA Overarching Challenge(s) and Focus Area(s), or provides a rationale for research outside the FY16 PRARP EMRFA Focus Areas.
- **Statistical Plan**
  - To what degree the statistical model and data analysis plan are suitable for the planned study.
  - To what degree the statistical plan, including sample size projections and power analysis, is adequate for the study and all proposed correlative studies.
  - To what degree the statistical plan compensates for the use of a subpopulation of a recruited sample population to ensure appropriate power can be achieved within the subpopulation study.
- **Recruitment, Accrual, and Feasibility**
  - How well the PI addresses the availability of human subjects for the proposed study and the prospect of their participation.
  - How well expedited access to a well-defined, already identified study cohort is demonstrated.
  - The degree to which the recruitment, informed consent, screening, and retention processes for human subjects will meet the needs of the proposed study.
  - How well the application identifies possible delays (e.g., slow accrual, attrition) and presents adequate contingency plans to resolve them.
  - To what extent the proposed study might affect the daily lives of the individual human subjects participating in the study (e.g., will human subjects still be able to take their regular medications while participating in the study? Are human subjects required to stay overnight in a hospital?)
  - How well the exclusion criteria are justified.
- **Data Sharing Plan**
  - To what degree the proposed plan for data sharing is appropriate, including but not limited to:
    - The description of the type of data or resource to be made available.
    - Ease of access for other researchers to the data or resource.
    - The appropriateness of plans to ensure continued access to the data or resource after the period of performance expires.

- The appropriateness of the milestones with respect to making the data or resource available.
- (If applicable) The appropriateness of the FITBIR data sharing plan.

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

- **Environment**

- To what degree the scientific environment is appropriate for the proposed research.
- To what degree the quality and extent of organizational support are appropriate.

- **Budget**

- Whether the **total** maximum costs are equal to or less than the allowable total maximum costs as published in the Program Announcement/Funding Opportunity.
- Whether the budget is appropriate for the proposed research and within the limitations of this Program Announcement/Funding Opportunity.
- Whether there may be significant overlap with existing or pending awards of the PI.

- **Intellectual Property:**

- If applicable, to what degree the intellectual and material property plan is appropriate.

- **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 PRARP, as evidenced by the following:**

- Adherence to the intent of the award mechanism
- Program portfolio composition
- Programmatic relevance
- Relative impact

### **C. Recipient Qualification**

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

### **D. Application Review Dates**

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

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

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

## **IV. ADMINISTRATIVE ACTIONS**

After receipt of pre-applications from eBRAP or applications from Grants.gov, the following administrative actions may occur:

### **A. Rejection**

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

- Preproposal Narrative exceeds page limit.
- Preproposal Narrative is missing.

The following will result in administrative rejection of the application:

- Submission of an application for which a letter of invitation was not received.
- Project Narrative ([Attachment 1](#)) exceeds page limit.
- Project Narrative ([Attachment 1](#)) is missing.
- Overarching Challenges and Focus Areas Statement ([Attachment 10](#)) is missing.
- Impact Statement ([Attachment 11](#)) is missing.
- Budget is missing.
- Submission of the same research project to different funding opportunities or different funding levels within the same program and fiscal year.

### **B. Modification**

- Pages exceeding the specific limits will be removed prior to review for all documents other than the Preproposal Narrative and Project Narrative.
- Documents not requested will be removed.

## C. Withdrawal

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

- An FY16 PRARP 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 PRARP Programmatic Panel members can be found at <http://cdmrp.army.mil/prarp/pscs/psc16>.*
- 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 invited application does not propose the same research project described in the pre-application.
- An application is submitted by a PI who does not meet the eligibility criteria.

## 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.

Quarterly technical progress reports will be required.

In addition to written progress reports, in-person presentations may be requested.

Copies of all scientific publications and presentations as a result of this funding are required.

Quad charts are required.

## **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 20160210j. 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](mailto: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](mailto: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	Human Subject Recruitment and Safety Procedures: Upload as Attachment 6 with file name "HumSubProc.pdf."	
	7	Data Management: Upload as Attachment 7 with file name "Data_Manage.pdf."	
	8	Study Personnel and Organization: Upload as Attachment 8 with file name "Personnel.pdf."	
	9	Surveys, Questionnaires, and Other Data Collection: Upload as Attachment 9 with file name "Surveys.pdf," if applicable.	
	10	Overarching Challenge and Focus Areas Statement: Upload as Attachment 10 with file name "OCFAS.pdf."	
	11	Impact Statement: Upload as Attachment 11 with file name "Impact.pdf."	
	12	Data Sharing Plan: Upload as Attachment 12 with file name "Sharing.pdf."	
	13	Collaborating DoD Military Facility Budget Form(s): Upload as Attachment 13 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.	