# I. OVERVIEW OF THE FUNDING OPPORTUNITY

**Program Announcement for the Department of Defense**

**Defense Health Program**

**Congressionally Directed Medical Research Programs**

## Peer Reviewed Alzheimer's Research Program

## Research Partnership Award

**Announcement Type: Initial**

**Funding Opportunity Number: W81XWH-17-PRARP-RPA**

**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), September 21, 2017
- **Application Submission Deadline:** 11:59 p.m. ET, October 5, 2017
- **End of Application Verification Period:** 5:00 p.m. ET, October 10, 2017
- **Peer Review:** November 2017
- **Programmatic Review:** February 2018

***This Program Announcement must be read in conjunction with the General Application Instructions, version 20170516. The General Applications Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."***

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# II. Detailed Information About the Funding Opportunity

## II.A. Program Description

Applications to the Fiscal Year 2017 (FY17) Peer Reviewed Alzheimer's Research Program (PRARP) are being solicited for the Defense Health Agency (DHA) J9, Research and Development Directorate, by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 2358 (10 USC 2358). As directed by the Office of the Assistant Secretary of Defense for Health Affairs (OASD[HA]), the DHA manages the Defense Health Program (DHP) Research, Development, Test, and Evaluation (RDT&E) appropriation. The execution management agent for this Program Announcement 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 FY16 totaled $78 million (M). The FY17 appropriation is $15M.

## II.B. Award Information

The PRARP Research Partnership Award (RPA) mechanism is being offered for the first time in FY17.

The intent of the RPA is to create an avenue for collaborative research partnerships between investigators to address a research problem or question in a manner that would be unachievable through separate efforts. In addition to supporting basic research, applications proposing preclinical research are acceptable under this mechanism.

The FY17 PRARP RPA is open to Principal Investigators (PIs) at or above the level of Assistant Professor (or equivalent) from any field or discipline. The FY17 PRARP RPA requires that two investigators (i.e., partners) jointly design a single research project. ***It should be clear that each partner had equal intellectual input into the design of the research project***. ***Either partner may submit as the PI; the other partner will be designated as the Co-PI.*** Multi-institutional research is encouraged but not required.

The success of the project must be supported by the unique skills and contributions of each partner. The proposed studies must demonstrate how they will accelerate research that addresses the PRARP's mission (see Section II.A, Program Description) into clinical applications. Applications must include a Collaboration Statement (Attachment 9).

The proposed study must include clearly stated plans for interactions between the partners. The plans must include communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data among all investigators and organizations participating in the project. Additionally, multi-institutional applications must provide an intellectual property plan to resolve potential intellectual and material property issues and to remove institutional barriers that might interfere with achieving high levels of cooperation to ensure the successful completion of this award.

***Preliminary data to support the feasibility of the research hypothesis (or hypotheses) and research approaches are required.*** Preliminary data may be derived from a laboratory discovery, clinical observation, or population-based studies.

The anticipated total costs budgeted for the entire period of performance for an FY17 PRARP RPA will not exceed **$1,300,000**. The maximum period of performance is **3** years. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

The research impact is expected to benefit the military, Veteran, and civilian communities. To this end, the PRARP has identified RPA Overarching Challenges and Focus Areas by which the intent of this mechanism can be facilitated. These should be carefully considered as part of the application process.

**FY17 PRARP RPA Overarching Challenges:** This FY17 PRARP RPA funding opportunity requires applications to address one or more of the following FY17 PRARP RPA 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. This includes research into risk factors that may predispose individuals to AD/ADRD subsequent to TBI.

- **Diagnostic Technologies, Tests, Biomarkers, or Devices:** The need for technologies, tests, or devices to detect or prognose the progression to AD/ADRD subsequent to TBI. This includes research into risk factors that may predispose individuals to AD/ADRD subsequent to TBI.

- **Quality of Life:** The need for technologies, assessments, interventions, or devices to benefit individuals living with the common symptoms or deficits of TBI and AD/ADRD.

- **Caregiver Burden:** The need for technologies, assessments, interventions, or devices with the goal of reducing burden for caregivers of individuals living with the common symptoms or deficits of TBI and AD/ADRD.

- **Epidemiology:** The paucity of epidemiological research to examine the interrelationship between TBI and subsequent AD/ADRD for the military, Veteran, and civilian communities. This includes research into risk factors that may predispose individuals to AD/ADRD subsequent to TBI.

**FY17 PRARP RPA Focus Areas:** In addition to addressing one or more of the specified FY17 PRARP RPA Overarching Challenges, applications should address at least one of the following FY17 PRARP RPA Focus Areas in support of the FY17 PRARP RPA Overarching Challenges. An application that proposes research outside of the FY17 PRARP RPA Focus Areas is acceptable, as long as the applicant provides a strong rationale.

- **Genomics/Proteomics:** Studies or technologies (e.g., genetic, proteomic, bioinformatics, 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.

- **Mechanisms of Pathogenesis:** Identification of contributing mechanisms (e.g., pathology of Tau, non-neuronal cells, inflammatory factors, and vascular contributions) associated with TBI and subsequent AD/ADRD pathogenesis.

- **Quality of Life:** Research intended to alleviate, stabilize, or characterize the symptoms or deficits common to TBI and AD/ADRD. Examples of research in this Focus Area include identification and management of comorbidities and modifiable risk factors (e.g., sleep apnea, obesity), cognitive training interventions, studies of health and wellness, and behavioral interventions.

- **Caregiver Support:** Research intended to reduce the burden of care on the caregiver for individuals living with the common symptoms or deficits of TBI and AD/ADRD. Examples of research in this Focus Area include caregiver training, home-based support, behavioral interventions, and relationship interventions.

- **Biomarkers:** Development of strategies to diagnose, prognose, or characterize neurological changes or risk factors associated with TBI and subsequent AD/ADRD (e.g., fluid-based, imaging, physiological, and clinical approaches).

- **Novel Target Identification:** Basic research (non-human) directly leading to the identification of new targets for the development of existing or new investigational medicines, drugs, or agents.

- **Epidemiological Research:** Research focusing on the incidence, distribution, and other factors relating to the health of individuals affected by TBI and subsequent AD/ADRD.

***The following is specifically discouraged under the FY17 PRARP:***

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

**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***. When possible, protocols should be written for research with human subjects and/or human anatomical substances that are specific to the DoD-supported effort outlined in the submitted application. Submission to HRPO of protocols covering more than the scope of work in the DoD-funded award will require HRPO review of the entire protocol as DoD-supported research and may include extensive modifications to meet DoD human subjects protection requirements. Refer to the General Application Instructions, Appendix 1, and the Human Subject Resource Document available on the electronic Biomedical Research Application Portal (eBRAP) "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for additional information.

A clinical trial is defined as a prospective accrual of patients (human subjects) in whom an intervention (e.g., device, drug, biologic, surgical procedure, rehabilitative modality, behavioral intervention, or other) is tested for a measurable outcome with respect to safety, effectiveness, and/or efficacy. This outcome represents a direct effect on the subject of that intervention or interaction.

**Research Involving Animals:** 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 the General Application Instructions, Appendix 1, for additional information.

**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 have 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 (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 among 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 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 2, Section K.

Awards will be made no later than September 30, 2018. For additional information refer to Section II.F.1, Federal Award Notices.

## II.C. Eligibility Information

### II.C.1. Eligible Applicants

**II.C.1.a. Organization: All organizations, including international organizations, are eligible to apply.**

**Government Agencies within the United States:** Local, state, and Federal Government agencies are eligible to the extent that applications do not overlap with their fully funded internal programs. Such agencies are required to explain how their applications do not overlap with their internal programs.

As applications for this Program Announcement may be submitted by extramural and intramural organizations, these terms are defined below.

**Extramural Organization:** An eligible non-DoD organization. Examples of extramural organizations include academia, biotechnology companies, foundations, Government, and research institutes. *Extramural Submission: Application submitted by a non-DoD organization to Grants.gov.*

**Intramural DoD Organization:** A DoD laboratory, DoD military treatment facility, and/or DoD activity embedded within a civilian medical center. *Intramural Submission: Application submitted by a DoD organization for an intramural investigator who is a DoD military or civilian employee working within a DoD laboratory or military treatment facility or in a DoD activity embedded within a civilian medical center*.

***Note:*** Applications from an intramural organization or from an extramural non-DoD Federal organization may be submitted through a research foundation.

The USAMRAA makes awards to eligible organizations, not to individuals.

**II.C.1.b. Principal Investigator and Co-Investigator:**

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

An eligible PI, regardless of ethnicity, nationality, or citizenship status, must be employed by, or affiliated with, an eligible organization.

The CDMRP encourages all PIs to participate in a digital identifier initiative through Open Researcher and Contributor ID, Inc. (ORCID). Registration for a unique ORCID identifier can be done online at http://orcid.org/.

### II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

### II.C.3. Other

Extramural organizations must be able to access **.gov** and **.mil** websites in order to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

Each investigator may submit only one FY17 PRARP RPA application as a PI.

For general information on required qualifications for award recipients, refer to the General Application Instructions, Appendix 3.

Refer to Section II.H.2, Administrative Actions, for a list of administrative actions that may be taken if a pre-application or application does not meet the administrative, eligibility, or ethical requirements defined in this Program Announcement.

## II.D. Application and 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).***

***Extramural Submission*** is defined as an application submitted by a non-DoD organization to Grants.gov.

***Intramural Submission*** is defined as an application submitted by a DoD organization for an intramural investigator, who is 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.

### II.D.1. Address to Request Application Package

***Submitting Extramural and Intramural Organizations:*** Pre-application content and forms can be accessed at eBRAP (https://eBRAP.org).

***Submitting Extramural Organizations:*** Full application packages can be accessed at Grants.gov.

***Submitting Intramural DoD Organizations:*** Full application packages can be accessed at eBRAP.org.

Contact information for the CDMRP Help Desk and the Grants.gov Contact Center can be found in Section II.G, Federal Awarding Agency Contacts.

### II.D.2. Content and Form of the Application Submission

Submission is a two-step process requiring both ***pre-application*** and ***full application*** as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods.

**Pre-Application Submission:** All pre-applications for both extramural and intramural organizations must be submitted through eBRAP (https://eBRAP.org/).

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.

**Full Application Submission:** Full applications must be submitted through the online portals as described below.

***Submitting Extramural Organizations:*** Full applications from extramural organizations must be submitted through Grants.gov. Applications submitted by extramural organizations (e.g., research foundations) on behalf of intramural DoD or other Federal organizations or investigators will be considered extramural submissions.

***Submitting Intramural DoD Organizations:*** Intramural DoD organizations may submit full applications to either eBRAP or Grants.gov. Intramural DoD organizations that are unable to submit to Grants.gov should submit through eBRAP. Intramural DoD organizations with the capability to submit through Grants.gov may submit following the instructions for extramural submissions through Grants.gov or may submit to eBRAP. Applications from extramural organizations, including non-DoD Federal organizations, received through eBRAP will be withdrawn. See definitions in Section II.C.1, Eligible Applicants.

eBRAP allows intramural organizations to submit full applications following pre-application submission.

***For both Extramural and Intramural applicants:*** A key feature of eBRAP is the ability of an organization's representatives and PIs to view and modify the full application submissions associated with them. eBRAP will validate full application files against the specific Program Announcement 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.

The application title, eBRAP log number, and all information for the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and application submission process. Inconsistencies may delay application processing and limit or negate 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.

### II.D.2.a. Step 1: Pre-Application Submission Content

**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 full application submission process.**

To begin the pre-application process, first select whether the submitting organization is extramural or intramural, then confirm your selection or cancel. **Incorrect selection of extramural or intramural submission type may result in delays in processing.**

If an error has been made in the selection of extramural versus intramural and the pre-application submission deadline has passed, the PI or Business Official must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

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**
- **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 be either 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 be either 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.

FY17 PRARP 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 II.H.2.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 pre-application or application preparation, research, or other duties for submitted pre-applications or applications. For FY17, 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). Pre-applications or 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 Grants Officer. Refer to the General Application Instructions, Appendix 3, 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 the General Application Instructions, Appendix 3, Section C, for further information regarding COIs.

- **Tab 5 – Pre-Application Files**

  **Note:** Upload documents 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.

  - **Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. Include the FY17 PRARP RPA Overarching Challenge(s) and Focus 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. The LOI should include the following:

    - A description of how the pre-application meets the intent of the FY17 PRARP RPA mechanism (see Section II.B, Award Information).

    - A description of how the research is aligned with one or more of the FY17 PRARP RPA Overarching Challenges (see Section II.B, Award Information).

    - A description of how the research is aligned with at least one of the FY17 PRARP RPA Focus Areas (see Section II.B, Award Information). Research outside of these FY17 PRARP RPA Focus Areas is acceptable, but the rationale should be included in the LOI.

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

- **Tab 6 – Submit Pre-Application**

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

### II.D.2.b. Step 2: Full Application Submission Content

***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. Refer to the General Application Instructions, Section III, 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 full application package for this Program Announcement. The full application package is submitted by the Authorized Organizational Representative through Grants.gov (http://www.grants.gov/) for extramural organizations or through eBRAP (https://ebrap.org/) for intramural organizations. See Table 1 below for more specific guidelines.

### II.D.2.b.i. Full Application Guidelines

Extramural organizations, including non-DoD Federal agencies, must submit full applications through Grants.gov. Submissions of extramural applications through eBRAP may be withdrawn.

**Table 1. Full Application Submission Guidelines**

| Extramural Submissions | Intramural DoD Submissions |
|---|---|
| **Application Package Location** | |
| Download application package components for W81XWH-17-PRARP-RPA from Grants.gov (https://www.grants.gov). | Download application package components for W81XWH-17-PRARP-RPA from eBRAP (https://ebrap.org). |
| **Full Application Package Components** | |
| **SF424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section III.A.1, for detailed information. | **Tab 1 – Summary:** Provide a summary of the application information.<br>**Tab 2 – Application Contacts:** This tab will be pre-populated by eBRAP; add Authorized Organizational Representative. |
| Descriptions of each required file can be found under Full Application Submission Components:<br>• Attachments<br>• Research & Related Senior/Key Person Profile (Expanded)<br>• Research & Related Budget<br>• Project/Performance Site Location(s) Form<br>• R&R Subaward Budget Attachment(s) Form (if applicable) | **Tab 3 – Full Application Files:** Upload files under each Application Component in eBRAP. Descriptions of each required file can be found under Full Application Submission Components:<br>• Attachments<br>• Key Personnel<br>• Budget<br>• Performance Sites<br>**Tab 4 – Application and Budget Data:** Review and edit proposed project start date, proposed end date, and budget data pre-populated from the Budget Form. |

| Extramural Submissions | Intramural DoD Submissions |
|---|---|
| **Application Package Submission** | |
| **Submit package components to Grants.gov (https://www.grants.gov).** If either the Project Narrative or the budget fails eBRAP validation or if the Project Narrative or the budget 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. | **Submit package components to eBRAP (https://ebrap.org).** **Tab 5 – Submit/Request Approval Full Application:** After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided "Enter Your Password Here" and press the "Submit Full Application" button. eBRAP will notify your Resource Manager/Comptroller or equivalent Business Official by email to log into eBRAP to review and to approve prior to the application submission deadline. |
| **Application Verification Period** | |
| The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form,*** may be modified. | After eBRAP has processed the full application, the organizational Resource Manager/Comptroller or equivalent Business Official and PI will receive an email notification of this status and will be able to view and modify application components in eBRAP. During the application verification period, the full application package, ***with the exception of the Project Narrative and Budget Form,*** may be modified. |
| **Further Information** | |
| Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements. | Refer to the General Application Instructions, Section IV, for further information regarding eBRAP requirements. |

***The organization's Business Official or Authorized Organization Representative (or Resource Manager/Comptroller) should approve/verify the full application submission prior to the application verification deadline.***

Application viewing, modification, and verification in eBRAP are 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.

***Material submitted after the end of the application verification period, unless specifically requested by the Government, will not be forwarded for processing.***

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

**II.D.2.b.ii. Full Application Submission Components:**

- **Extramural Applications Only –**

  **SF424 (R&R) Application for Federal Assistance Form:** Refer to the General Application Instructions, Section III.A.1, for detailed information.

- **Extramural and Intramural Applications –**

  **Attachments:**

  ***Each attachment to the full application components must be uploaded as an individual file in the format specified and in accordance with the formatting guidelines listed in the General Application Instructions, Appendix 4.***

  For all attachments, ensure that the file names are consistent with the guidance. Attachments will be rejected if the file names are 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, there are file size limits that may apply in some circumstances. Individual attachments may not exceed 20 MB and the file size for the entire full application package may not exceed 200 MB.

  - **Attachment 1: Project Narrative (15-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 to support the rationale and feasibility of the study. Preliminary data may be derived from a laboratory discovery, clinical observation, or population-based studies.

    - **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.

- **Research Strategy:** Describe the experimental design, methods, and analyses, including appropriate controls, in sufficient detail for evaluation. Applications should also identify any potential pitfalls and delays. Applications should describe possible solutions to the pitfalls and delays. Research projects may include preclinical studies in animal models, human subjects, and human anatomical substances. If human subjects or human anatomical samples will be used, include a plan for the recruitment of subjects or the acquisition of samples and document the experience of the PI, Co-PI, and/or key collaborators in recruiting human subjects for similar projects. Describe any statistical plans with appropriate power analyses and demonstrate how it supports the sample size. Describe how the studies are designed to achieve the objectives, including the choice of model and endpoints/outcome measures to be used, if applicable.

- **Project Coordination and Communication:** Describe plans for communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data between/among the PI, Co-PI, and institutions participating in the project.

***Note that pharmacological interventions are specifically discouraged for this mechanism.***

- **Attachment 2: Supporting Documentation:** Combine and upload as a single file named "Support.pdf." Start each document on a new page. If documents are scanned to PDF, the lowest resolution (100 to 150 dpi) should be used. The Supporting Documentation attachment should not include additional information such as figures, tables, graphs, photographs, diagrams, chemical structures, or drawings. These items should be included in the Project Narrative. Any additional material viewed as an extension of the Project Narrative will be removed or may result in administrative withdrawal of the application.

  ***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, 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 and Co-PI each has the support or resources necessary for the proposed work. 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.

- Intellectual Property: Information can be found in Code of Federal Regulations, Title 2, Part 200.315 (2 CFR 200.315), "Intangible Property."

    - 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 RPA mechanism, use the SOW format example titled "SOW (Statement of Work) Generic Format." The SOW must be in PDF format prior to attaching.

  The SOW should include a list of major tasks that support the proposed specific aims, followed by a series of subtasks outlined related to the major tasks and milestones within the period of performance. The SOW should describe only the work for which funding is being requested by this application and, as applicable, should also:

  Include the name(s) of the key personnel and contact information for each study site/ subaward site.

  Indicate the number (and type, if applicable) of research subjects (animal or human) and/or human anatomical samples projected or required for each task and at each site. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.

  Briefly state the methods to be used.

  For studies with prospective accrual of human subjects, indicate quarterly enrollment targets.

Identify cell line(s) and commercial or organizational source(s) to be used. If human anatomical substances (including cell lines) will be used, specify whether or not identifiable information is accessible to the research team by any means.

If applicable, indicate timelines required for regulatory approvals relevant to human subjects research (e.g., Investigational New Drug and Investigational Device Exemption applications) by the U.S. Food and Drug Administration or other Government agency.

- **Attachment 6: Overarching Challenges and Focus Areas Statement (one-page limit):** Upload as "OCFAS.pdf." Describe how the proposed study is responsive to one or more of the specified FY17 PRARP RPA Overarching Challenges (see Section II.B, Award Information). In addition, describe how the application addresses at least one of the FY17 PRARP RPA Focus Areas (see Section II.B, Award Information). An application that proposes research outside of these FY17 PRARP RPA 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 7: 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 II.A, Program Description), and ultimately benefit individuals affected by AD/ADRD, their caregivers, and their families. **The application must include an Impact Statement.**

- **Attachment 8: Data Sharing Plan (two-page limit):** Upload as "Sharing.pdf." Refer to the General Application Instructions, Appendix 2, Section K, for more information about the CDMRP expectations for making data and research resources publicly available. ***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 the Data Sharing Plan:**

  - **Use of TBI 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) 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 2, Section K.**

- **Attachment 9: Collaboration Statement (two-page limit):** Upload as "Collab.pdf." Clearly describe the proposed collaboration. Delineate the specific contributions of each partner and discuss how successful completion of the project depends on their unique skills and contributions. Each partner should demonstrate how he/she will contribute to the project such that the proposed work could not be accomplished without his/her involvement. This is expected to include both intellectual input and research resources (e.g., supplies, reagents, equipment, personnel, services, tissue samples, or access to patients or populations). In addition, each partner should provide a letter of collaboration describing his/her involvement in the proposed work as part of the application's Supporting Documentation (Attachment 2). The application must include a Collaboration Statement.

- **Attachment 10: DoD Military 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 DoD Military 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 III.A.7, for detailed information.

- **Extramural and Intramural Applications –**

  **Research & Related Senior/Key Person Profile (Expanded):** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.3, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.2, 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 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.

  - 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."

**Research & Related Budget:** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.4, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.3, 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.

**Project/Performance Site Location(s) Form:** For extramural submissions (via Grants.gov), refer to the General Application Instructions, Section III.A.5, and for intramural submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.4, for detailed information.

- **Extramural Applications Only –**

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

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.6, for detailed information.)

**Intramural DoD Collaborator(s):** Complete the DoD Military Budget Form and upload to Grants.gov as Attachment 10. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Intramural DoD Collaborator(s) costs per year should be included on the Grants.gov Research and Related Budget form under subaward costs.

### II.D.3. Dun and Bradstreet Universal Numbering System (DUNS) Number and System for Award Management (SAM)

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. Verify the status of the applicant's organization's Entity registration in SAM well in advance of the application submission deadline. Allow 3 to 4 weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements by the time the Federal awarding agency is ready to make a Federal award, the Federal awarding agency may determine that the applicant is not qualified to receive a Federal award and use that determination as a basis for making a Federal award to another applicant. Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

### II.D.4. Submission Dates and Times

All submission dates and times are indicated in Section I, Overview of the Funding Opportunity. Pre-application and application submissions are required. The pre-application and application submission process should be started early to avoid missing deadlines. There are no grace periods. Failure to meet either of these deadlines will result in submission rejection.

**Applicant Verification of Full Application 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 a submitted application. Following retrieval and processing of the full application, eBRAP will notify the organizational representatives and PI by email to log into eBRAP to review, modify, and verify the full application submission. eBRAP will validate retrieved files against the specific Program Announcement 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. ***If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated full application package must be submitted prior to the application submission deadline.*** The Project Narrative and Budget Form cannot be changed after the application submission deadline.

### II.D.5. Funding Restrictions

The maximum period of performance is **3** years.

The anticipated total costs budgeted for the entire period of performance will not exceed **$1,300,000**. If indirect cost rates have been negotiated, indirect costs are to be budgeted in accordance with the organization's negotiated rate. No budget will be approved by the Government exceeding **$1,300,000** total costs or using an indirect cost rate exceeding the organization's negotiated rate.

All direct and indirect costs of any subaward or contract must be included in the total direct costs of the primary award.

The applicant may request the entire maximum funding amount for a project that may have a period of performance less than the maximum **3** years.

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 (IPR) 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 four investigators to travel to two scientific/technical meetings per year in addition to the required IPR meeting described above

Extramural (non-Federal) awards will consist solely of assistance agreements (Cooperative Agreements and Grants). For extramural awards with an intragovernmental component, direct transfer of funds from an extramural award recipient to a DoD or other Federal agency is not allowed except under very limited circumstances. Funding to intramural DoD and other Federal agencies will be managed through a direct fund transfer. Intragovernmental only funding to intramural DoD and other Federal agencies will be managed through a direct fund transfer. Intramural applicants are responsible for coordinating through their agency's procedures the use of contractual or assistance funding awards or other appropriate agreements to support extramural collaborators.

Refer to the General Application Instructions, Section III.A.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 the General Application Instructions, Section III.A.4***.

***The CDMRP expects to allot approximately $3.9M of the $15M FY17 PRARP appropriation to fund approximately three Research Partnership Award applications, depending on the quality and number of applications received. Funding of applications received in response to this Program Announcement is contingent upon the availability of Federal funds for this program.***

### II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 4, for detailed formatting guidelines.

## II.E. Application Review Information

### II.E.1. Criteria

#### II.E.1.a. 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, and/or logical reasoning.
    - To what degree the preliminary data support the foundation of the research.
    - How well the hypothesis (or hypotheses), aims, experimental design, methods, and analyses, including statistical plans and analyses, are developed.
    - How well the applicant acknowledges potential problems and addresses alternative approaches.
    - How well the plans for communication, decision-making, allocation of resources, coordination of research progress and results, and sharing of data between/among the PI, Co-PI, and institutions participating in the project are likely to lead to success.
- **Personnel**
    - How well the study team shows potential for addressing the PRARP's mission (see Section II.A, Program Description) based on their 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.
    - To what extent the composition of the study team 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.
- **Collaboration Statement**
    - How well the partners demonstrate the use of their unique skills to successfully complete the project.
    - How well the partners demonstrate that their involvement will lead to the successful completion of the project.

- **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 II.A, Program Description).
  - The efforts will ultimately benefit individuals affected by AD/ADRD, their caregivers, and their families.

- **Overarching Challenges and Focus Area Statement**

  - How well the proposed study addresses the FY17 PRARP RPA Overarching Challenge(s) and Focus Area(s) or provides a strong rationale for research outside the FY17 PRARP RPA Focus Areas.

- **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.
    - The appropriateness of the FITBIR Data Sharing Plan (if applicable).

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

- **Budget**

  - Whether the maximum **total** costs are equal to or less than the allowable maximum total costs as published in the Program Announcement.
  - Whether the budget is appropriate for the proposed research.

- **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.
    - How well the application reflects knowledge and respect for the needs of individuals, caregivers, and their families.
- **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.

### II.E.1.b. 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:

- Ratings and evaluations of the peer reviewers
- Relevance to the mission of the DHP and FY17 PRARP, as evidenced by the following:
    - Adherence to the intent of the award mechanism
    - Program portfolio composition
    - Relative impact

### II.E.2. 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 Commanding General, USAMRMC, on behalf of the DHA 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. 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 II.E.1.b, 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 18 USC 1905.

### II.E.3. Integrity and Performance Information

Prior to making an assistance agreement award where the Federal share is expected to exceed the simplified acquisition threshold (currently $150,000) over the period of performance, the Federal awarding agency is required to review and consider any information about the applicant that is available in the Federal Awardee Performance and Integrity Information System (FAPIIS).

An applicant, at its option, may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about itself that a Federal awarding agency previously entered and is currently available in FAPIIS.

The Federal awarding agency will consider any comments by the applicant, in addition to other information in the designated integrity and performance system, in making a judgment about the applicant's integrity, business ethics and record of performance under Federal awards when determining a recipient's qualification prior to award, according to the qualification standards of the Department of Defense Grant and Agreement Regulations (DoDGAR), Section 22.415.

### II.E.4. Anticipated Announcement and Federal Award Dates

All application review dates and times are indicated in Section I, Overview of the Funding Opportunity.

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.

## II.F. Federal Award Administration Information

### II.F.1. Federal Award Notices

Awards will be made no later than September 30, 2018. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

Awards are made to organizations, not to individual PIs. The types of awards made under the Program Announcement will be assistance agreements (grants or cooperative agreements). The level of involvement on the part of DoD during project performance is the key factor in determining whether to award a grant or cooperative agreement.

***Extramural Organizations:*** An assistance agreement (grant or cooperative agreement) is appropriate when the Federal Government transfers a "thing of value," to a "state, local government," or "other recipient," to carry out a public purpose of support or stimulation authorized by a law of the United States, instead of acquiring property or service for the direct benefit and use of the U.S. Government. An assistance agreement can take the form of a grant or cooperative agreement. If "no substantial involvement" on the part of the funding agency is anticipated, a grant award will be made (31 USC 6304). Conversely, if substantial involvement on the part of the funding agency is anticipated, a cooperative agreement will be made (31 USC 6305). Substantial involvement may include collaboration, participation, or intervention in the research to be performed under the award. The award type, along with the start date, will be determined during the negotiation process.

After email notification of application review results through the eBRAP, and if selected for funding, a representative from the USAMRAA will contact the business official authorized to negotiate on behalf of the PI's organization.

Only an appointed USAMRAA Grants Officer may obligate the Government to the expenditure of funds. No commitment on the part of the Government should be inferred from discussions with any other individual. The award document signed by the Grants Officer is the official authorizing documents.

***Intramural Organizations:*** Awards to Federal Government organizations (to include intramural DoD organizations) will be executed through the Military Interdepartmental Purchase Request (MIPR) or Funding Authorization Document (FAD) process. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intramural applicants and collaborators are reminded to coordinate receipt and commitment of funds through their respective resource managers (RM).

After email notification of application review results through the eBRAP, and if selected for funding, a representative from the CDMRP will contact the business official authorized to negotiate on behalf of the PI's organization.

### II.F.1.a. 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 2, Section B, for general information on organization or PI changes.

### II.F.2. Administrative and National Policy Requirements

Applicable requirements in the DoDGAR found in 32 CFR, Chapter 1, Subchapter C, and 2 CFR, Chapter XI, apply to grants and cooperative agreements resulting from this Program Announcement.

Refer to the General Application Instructions, Appendix 2, for general information regarding administrative requirements.

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

Refer to full text of the USAMRAA General Research Terms and Conditions for Institutions of Higher Education, Hospitals, and Non-Profit Organizations and the USAMRAA General Research Terms and Conditions with For-Profit Organizations for further information.

### II.F.3. Reporting

Refer to the General Application Instructions, Appendix 2, Section A, for general information on reporting requirements.

Quarterly technical progress reports will be required.

Annul quad charts 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.

Annual progress reports as well as a final progress report will be required.

Awards resulting from this Program Announcement will incorporate additional reporting requirements related to recipient integrity and performance matters. Recipient organizations that have Federal contract, grant, and cooperative agreement awards with a cumulative total value greater than $10,000,000 are required to provide information to FAPIIS about certain civil, criminal, and administrative proceedings that reached final disposition within the most recent 5-year period and that were connected with performance of a Federal award. Recipients are required to disclose semiannually information about criminal, civil, and administrative proceedings as specified in the applicable Terms and Conditions. The applicable Terms and Conditions for institutions of higher education, hospitals, and nonprofit organizations are available in OAR Article I, Section B, in the July 2016 R&D General Terms and Conditions. The applicable Terms and Conditions for for-profit organizations are available in Section 34 of the February 2017 USAMRAA General Research Terms and Conditions with For-Profit Organizations.

## II.G. Federal Awarding Agency Contacts

### II.G.1. CDMRP Help Desk

Questions related to Program Announcement content or submission requirements as well as questions related to the pre-application or intramural application submission 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

### II.G.2. Grants.gov Contact Center

Questions related to extramural 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 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.

## II.H. Other Information

### II.H.1. Program Announcement and General Application Instructions Versions

Questions related to this Program Announcement should refer to the Program name, the Program Announcement name, and the Program Announcement version code 20170516c. The Program Announcement numeric version code will match the General Applications Instructions version code 20170516.

### II.H.2. Administrative Actions

After receipt of applications, the following administrative actions may occur:

### II.H.2.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.
- More than one application is received from the same PI. Only the first application received will be accepted; additional applications will be administratively rejected.
- Overarching Challenges and Focus Areas Statement (Attachment 6) is missing.
- Impact Statement (Attachment 7) is missing.
- Collaboration Statement (Attachment 9) is missing.

### II.H.2.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.

### II.H.2.c. Withdrawal

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

- An FY17 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 FY17 PRARP Programmatic Panel members can be found at http://cdmrp.army.mil/prarp/pscs/psc17***.
- The application fails to conform to this Program Announcement 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 FY17, 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 Grants Officer. Refer to the General Application Instructions, Appendix 3, 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.

- Applications from extramural organizations, including non-DoD Federal agencies, received through eBRAP may be withdrawn.

- Applications submitted by an intramural DoD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.

- An application for which the PI does not meet the eligibility criteria will be withdrawn.

- Submission of the same research project to different Funding Opportunities within the same program and fiscal year.

- Applications submitted by an intramural DoD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.

**II.H.2.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.

### II.H.3. Application Submission Checklist

| Application Components | Action | Completed |
|---|---|---|
| SF424 (R&R) Application for Federal Assistance **(Extramural submissions only)** | Complete form as instructed. | |
| Summary (Tab 1) and Application Contacts (Tab 2) **(Intramural submissions only)** | Complete these tabs as instructed. | |
| Attachments | Project Narrative: Upload as Attachment 1 with file name "ProjectNarrative.pdf." | |
| | Supporting Documentation: Upload as Attachment 2 with file name "Support.pdf." | |
| | Technical Abstract: Upload as Attachment 3 with file name "TechAbs.pdf." | |
| | Lay Abstract: Upload as Attachment 4 with file name "LayAbs.pdf." | |
| | Statement of Work: Upload as Attachment 5 with file name "SOW.pdf." | |
| | Overarching Challenges and Focus Areas Statement: Upload as Attachment 6 with file name "OCFAS.pdf." | |
| | Impact Statement: Upload as Attachment 7 with file name "Impact.pdf." | |
| | Data Sharing Plan: Upload as Attachment 8 with file name "Sharing.pdf." | |
| | Collaboration Statement: Upload as Attachment 9 with file name "Collab.pdf." | |
| | DoD Military Budget Form(s): Upload as Attachment 10 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. | |

| Application Components | Action | Completed |
|---|---|---|
| Research & Related Budget **(Extramural submissions only)** | Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field. | |
| Budget **(Intramural submissions only)** | Complete the DoD Military Budget Form and Justification. | |
| Project/Performance Site Location(s) Form | Complete form as instructed. | |
| R&R Subaward Budget Attachment(s) Form | Complete form as instructed. | |

## APPENDIX 1: ACRONYM LIST

| | |
|---|---|
| ACURO | Animal Care and Use Review Office |
| AD | Alzheimer's Disease |
| ADRD | Alzheimer's Disease-Related Dementias |
| CDEs | Common Data Elements |
| CDMRP | Congressionally Directed Medical Research Programs |
| CFR | Code of Federal Regulations |
| COI | Conflict of Interest |
| DHA | Defense Health Agency |
| DHP | Defense Health Program |
| DoD | Department of Defense |
| DoDGAR | Department of Defense Grant and Agreement Regulations |
| DUNS | Data Universal Numbering System |
| eBRAP | Electronic Biomedical Research Application Portal |
| EC | Ethics Committee |
| ET | Eastern Time |
| FAD | Funding Authorization Document |
| FAPIIS | Federal Awardee Performance and Integrity Information System |
| FDA | U.S. Food and Drug Administration |
| FITBIR | Federal Interagency Traumatic Brain Injury Research |
| FY | Fiscal Year |
| GUID | Global Unique Identifier |
| HRPO | Human Research Protection Office |
| IACUC | Institutional Animal Care and Use Committee |
| IPR | In-Progress Review |
| IRB | Institutional Review Board |
| LOI | Letter of Intent |
| M | Million |
| MIPR | Military Interdepartmental Purchase Request |
| NINDS | National Institute of Neurological Disorders and Stroke |
| OASD(HA) | Office of the Assistant Secretary of Defense for Health Affairs |
| OMB | Office of Management and Budget |

| | |
|---|---|
| ORP | Office of Research Protections |
| PI | Principal Investigator |
| PRARP | Peer Reviewed Research Program |
| RDT&E | Research, Development, Test, and Evaluation |
| RM | Resource Manager |
| RPA | Research Partnership Award |
| SAM | System for Award Management |
| SOW | Statement of Work |
| TBI | Traumatic Brain Injury |
| USAMRAA | U.S. Army Medical Research Acquisition Activity |
| USAMRMC | U.S. Army Medical Research and Materiel Command |
| USC | United States Code |