# 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

## Leveraging Approaches for Innovation in Care and Support Award

**Announcement Type: Initial**

**Funding Opportunity Number: W81XWH-20-PRARP-LEAPInCASA**

**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), June 22, 2020
- **Application Submission Deadline:** 11:59 p.m. ET, July 21, 2020
- **End of Application Verification Period:** 5:00 p.m. ET, July 24, 2020
- **Peer Review:** September 2020
- **Programmatic Review:** December 2020

***This Program Announcement must be read in conjunction with the General Application Instructions, version 501. The General Application 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 2020 (FY20) 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 dementia, aggression, memory loss, depression, and symptoms similar to those of other neurological diseases. Initiated in 2011, the PRARP addresses the neurodegeneration and symptomatology associated with TBI within the contexts of Alzheimer's disease (AD) and the AD-related dementias (ADRD). This is reflected in the PRARP's vision and mission:

**Vision:** To address the long-term consequences of traumatic brain injury as they pertain to Alzheimer's disease and Alzheimer's disease-related dementias.

**Mission:** The PRARP's mission is devoted to (1) understanding the association between traumatic brain injury and Alzheimer's disease/Alzheimer's disease-related dementias, and (2) reducing the burden on affected individuals and caregivers, especially in the military and Veteran communities.

Appropriations for the PRARP from FY11 through FY19 totaled $123 million (M). The FY20 appropriation is $15M.

***The proposed research must be relevant to active duty Service members, Veterans, military beneficiaries, and/or the American public.***

The FY20 PRARP seeks applications across the program to support its Overarching Challenges and Focus Areas. A full description of the FY20 PRARP Overarching Challenges and Focus Areas are found at the PRARP website. The Overarching Challenges and Focus Areas are award mechanism-specific. Applicants are required to review Section II.B, Award Information, for guidance on which Overarching Challenges an application is required to address for this FY20 PRARP Leveraging Approaches for Innovation in Care and Support Award (LEAP-InCASA). Furthermore, applicants are required to review Section II.B, Award Information, for guidance on which Focus Areas an application should address in support of the FY20 PRARP LEAP-InCASA Overarching Challenges.

### II.A.1. Award History

The PRARP LEAP-InCASA mechanism is being offered for the first time in FY20.

## II.B. Award Information

The intent of the FY20 PRARP LEAP-InCASA is to support innovative and impactful research that improves the quality of life and care for individuals, families and care providers living with the common symptoms of TBI and/or AD/ADRD as related to the PRARP's mission (see Section II.A, Program Description). The proposed work should innovatively challenge existing research paradigms or exhibit high levels of creativity within the contexts of the PRARP's mission and vision. This can include innovations and research for symptom reduction (e.g., cognitive, behavioral, function, mood), resiliency factors, increasing or maintaining independence, and support for families and care providers.

The FY20 PRARP LEAP-InCASA supports multi-institutional, harmonized research initiatives. As such, applications to the FY20 PRARP LEAP-InCASA require a Coordinating Center and a minimum of two Partnering Sites, representing three separate institutions within the application package. While the Coordinating Center provides overall infrastructure and support, each Partnering Site should develop its own unique research initiative that will be part of the overall project. While each Partnering Site will develop its own unique research initiative, the overall project must focus on a single symptomatology category as described later in this section. The application should also demonstrate the study team's experience in both TBI and/or AD/ADRD research, as appropriate. Given the patient-centered intent of the FY20 PRARP LEAP-InCASA, animal research is prohibited.

**Role of the Coordinating Center:** The Coordinating Center is responsible for providing overall leadership and management infrastructure for all research initiatives. In addition, the Coordinating Center will participate as a separate study arm for each Partnering Sites' study, to include participant accrual and participation in the proposed research at the Coordinating Center's performance site. Therefore, it is expected that the Coordinating Center will have the appropriate experience and resources to function as a research performance site for each Partnering Site. The Coordinating Center and all Partnering Sites should work together in order to harmonize research protocols, participant accrual strategies, and analyze data. Plans for interactions between/among the partners should be well-detailed. The plans must include communication, decision-making, allocation of resources, and coordination of research progress and results among all Partnering Sites. The Partnering Site should also provide an intellectual property plan to resolve potential intellectual and material property issues and to remove multi-institutional barriers that might interfere with achieving high levels of cooperation to ensure the successful completion of this award. The Coordinating Center should describe prior experience with administration of multi-institutional research initiatives. ***The Coordinating Center must be from a different institution than the Partnering Sites.***

**Role of the Partnering Sites:** A minimum of two Partnering Sites are required. Each Partnering Site should develop its own unique research initiative as relevant to the overall application design. All Partnering Sites must have appropriate experience, resources, and participant accrual experience toward initiating research activities that will be harmonized with the Coordinating

Center. Each Partnering Site should detail a research initiative that is unique from the other Partnering Sites. ***The Coordinating Center Applicant Organization will submit and be designated as the PI; the other partner(s) will be designated as the Co-PI(s). The Partnering Sites Applicant Organizations must be from different institutions.***

***FY20 PRARP LEAP-InCASA applications must be Innovation- and Impact-based.***

**FY20 PRARP LEAP-InCASA Overarching Challenges:** The Overarching Challenges below are specific to the FY20 PRARP LEAP-InCASA. *Applicants to the FY20 PRARP LEAP-InCASA must address and select one of the Overarching Challenges below:*

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

- **Family and Care Support:** The need for technologies, assessments, interventions, or devices that enhance the lives of those providing care and families of individuals living with the common symptoms of TBI and/or AD/ADRD.

**FY20 PRARP LEAP-InCASA Focus Areas:** The Focus Areas below are specific to the FY20 PRARP LEAP-InCASA. *Applicants to the FY20 PRARP LEAP-InCASA should select one of the Focus Areas below; however*, an application that proposes research outside of these FY20 PRARP LEAP-InCASA Focus Areas is acceptable, as long as the applicant provides a strong justification.

- **Biomarkers:** Development of methods to diagnose, prognose, or characterize neurological changes or risk/resiliency factors associated with TBI and subsequent AD/ADRD.

- **Quality of Life:** Research intended to alleviate, stabilize, or characterize the symptoms, or deficits, common to TBI and AD/ADRD.

- **Family and Caregiver Support:** Research intended to reduce the burden of care on the caregivers or families of individuals living with the common symptoms or deficits of TBI and AD/ADRD.

- **Nonpharmacological Interventions and Devices:** Research into non-pharmaceutical-based interventions and devices to improve quality of life or caregiving for those living with the common symptoms of TBI and AD/ADRD.

- **Bioinformatics:** Tools, including machine learning, to access, annotate, curate, store, and visualize large existing or novel datasets, e.g., multimodal magnetic resonance imaging (MRI), other imaging techniques, surveys, questionnaires, and diagnostics for TBI and subsequent AD/ADRD.

***Each FY20 PRARP LEAP-InCASA application is limited to the choice of one dementia category for the overall application. Applicants must ensure that they have selected the appropriate application category relating to the type of dementia that is the focus of the application:***

- Alzheimer's dementia
- Lewy body dementia
- Frontotemporal dementia
- Mixed dementia
- Vascular dementia

***Note: Mixed dementia research is defined as AD and any of the related dementias described above. Research that focuses exclusively on Chronic Traumatic Encephalopathy is prohibited.***

***Each FY20 PRARP LEAP-InCASA Application is limited to the choice of one symptomatology category for the overall application. Applicants must also ensure that they have selected the appropriate symptomatology category for the application:***

- Cognitive Symptomatology
- Behavioral/Mood Symptomatology (e.g., Stress, Anxiety, Depression, Disinhibition, Aggression, and Poor Judgement)
- Social Isolation
- Autonomy and Activities of Daily Living
- Sleep Challenges and Disorders

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

The types of awards made under the Program Announcement will be assistance agreements. An assistance 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. The level of involvement on the part of the Department of Defense (DoD) during project performance is the key factor in determining whether to award 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), and the award will identify the specific substantial involvement. Substantial involvement may include, but is not limited to, 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.

The anticipated total costs budgeted for the entire period of performance for an FY20 PRARP LEAP-InCASA award will not exceed **$2,800,000**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Awards will be made no later than September 30, 2021. For additional information refer to Section II.F.1, Federal Award Notices.

***The CDMRP expects to allot approximately $2.8M to fund one Leveraging Approaches for Innovation in Care and Support Award application. Funding of applications received is contingent upon the availability of Federal funds for this program as well as the number of applications received, the quality and merit of the applications as evaluated by scientific and programmatic review, and the requirements of the Government. Funds to be obligated on any award resulting from this funding opportunity will be available for use for a limited time period based on the fiscal year of the funds. It is anticipated that awards made from this FY20 funding opportunity will be funded with FY20 funds, which will expire for use on September 30, 2026.***

**Research Involving Human Anatomical Substances, Human Subjects, or Human Cadavers:** All DoD-funded research involving new and ongoing research with human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the U.S. Army Medical Research and Development Command (USAMRDC) 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. ***Allow a minimum of 2 to 3 months for HRPO regulatory review and approval processes***. 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. If the proposed research is cooperative (i.e., involving more than one institution), a written plan for single IRB review arrangements must be provided at the time of award negotiation. The lead institution responsible for developing the master protocol and master consent form should be identified and should be the single point of contact for regulatory submissions and requirements.

***A clinical trial is defined*** as a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

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

**Use of DoD or Department of Veterans Affairs (VA) Resources:** If the proposed research involves access to active duty military or Veteran patient populations and/or DoD or VA resources or databases, the application must describe the access at the time of submission and include a plan for maintaining access as needed throughout the proposed research. Refer to

Section II.D.2.b.ii, Full Application Submission Components, for submission requirements. Refer to the General Application Instructions, Appendix 1, Section C, for additional detailed information.

**Prospective Human Studies and the Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System:** The DoD requires that awardees make TBI research data generated by this award mechanism available to the research community through the FITBIR Informatics System. The FITBIR Informatics System is a free resource designed to accelerate research progress by allowing the storage, re-analysis, integration, and rigorous comparison of multiple datasets. ***Currently, FITBIR-eligible research includes all studies generating prospectively collected human TBI subject data (e.g., clinical, demographic, phenotypic, imaging, and genomic)***. Data reporting to FITBIR is an opportunity for investigators to facilitate their own research and to collaborate with others engaged in 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. FITBIR guidance and policies, as well as the considerable advantages of FITBIR participation to the researcher, are detailed at https://fitbir.nih.gov/. ***Appendix 2 of this Program Announcement contains consent guidance***.

***Note: FITBIR data submission requirement applies only to DHP-funded TBI research projects with 50 or more prospectively recruited human subjects.***

**Use of Common Data Elements (CDEs):** Research data elements must be reported using the National Institute of Neurological Disorders and Stroke (NINDS) TBI CDEs or entered into the FITBIR data dictionary as new, unique data elements (UDEs). For the most current version of the NINDS TBI CDEs, go to https://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. 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. ***Use of UDEs is strongly discouraged and subject to program approval***.

## 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 academic institutions, biotechnology companies, foundations, Federal Government organization other than the DoD, and research institutes.

**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 working within a DoD laboratory or military treatment facility or in a DoD activity embedded within a civilian medical center.***

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

### II.C.1.b. Principal Investigator

The Coordinating Center PI must be **at or above** the level of an assistant professor (or equivalent).

Each named Partnering Site PI must be **at or above** the level of an assistant professor (or equivalent).

Each investigator may be named on only one FY20 PRARP LEAP-InCASA application as a PI.

There are no limitations on the number of applications that a PI can be listed as a Co-PI.

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 https://orcid.org/.

### II.C.2. Cost Sharing

Cost sharing/matching is not an eligibility requirement.

### II.C.3. Other

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.

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:***

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at Grants.gov.

***Intramural DoD Submission:***

- Pre-application content and forms must be accessed and submitted at eBRAP.org.
- Full application packages must be accessed and submitted at eBRAP.org

***Note: Applications from an intramural DoD organization or from an extramural Federal Government organization may be submitted to Grants.gov through a research foundation.***

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

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.

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*** (eBRAP.org) and ***full application*** (eBRAP.org or Grants.gov) as indicated below. The submission process should be started early to avoid missing deadlines. There are no grace periods. Full application submission guidelines differ for extramural (Grants.gov) and intramural (eBRAP.org) organizations (refer to Table 1. Full Application Guidelines).

***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 full 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 submission deadline.

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

***During the pre-application process, eBRAP assigns each submission a unique log number. This unique eBRAP log number is required 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 will delay 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 to request a change in designation.

All pre-application components must be submitted by the applicant organization through eBRAP (https://eBRAP.org/).

The applicant organization and associated PI 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 applicant must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

PIs with an ORCID identifier should enter that information in the appropriate field in the "My Profile" tab in the "Account Information" section of eBRAP.

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**

  Submission of application information includes assignment of primary and secondary research classification codes, which may be found at https://ebrap.org/eBRAP/public/Program.htm. Applicants are strongly encouraged to review and confirm the codes prior to making their selection.

- **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 Research & Related 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 Research & Related 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 applicants 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, Co-PIs and key personnel associated with the application.

  FY20 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.

- **Tab 4 – Conflicts of Interest**

  List all individuals other than collaborators and key personnel who may have a conflict of interest in the review of the application (including those with whom the PI has a personal or professional relationship).

- **Tab 5 – Pre-Application Files**

  **Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted. 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 FY20 PRARP LEAP-InCASA mechanism (see Section II.B, Award Information).
  - A description of how the research initiatives are aligned with one of the FY20 PRARP LEAP-InCASA Overarching Challenges (see Section II.B, Award Information).
  - A description of how the research initiatives are aligned with at least one of the FY20 PRARP LEAP-InCASA Focus Areas (see Section II.B, Award Information). Research initiatives outside of these FY20 PRARP LEAP-InCASA Focus Areas are acceptable, but the justification should be included in the LOI.
  - Describe the type of dementia that will be the overall research focus of the application (see Section II.B, Award Information).

- **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

***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 (https://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 must submit full applications through Grants.gov. Applicants must create a Grants.gov Workspace for submission, which allows the application components to be completed online and routed through the applicant organization for review prior to submission. Applicants may choose to download and save individual PDF forms rather than filling out webforms in Workspace. A compatible version of Adobe Reader **must** be used to view, complete, and submit an application package consisting of PDF forms. If more than one person is entering text into an application package, the ***same version*** of Adobe Reader software should be used by each person. Check the version number of the Adobe software on each user's computer to make sure the versions match. Using different versions of Adobe Reader may cause submission and/or save errors – even if each version is individually compatible with Grants.gov. Refer to the General Application Instructions, Section III, and the "Apply For Grants" page of Grants.gov (https://www.grants.gov/web/grants/applicants/apply-for-grants.html) for further information about the Grants.gov Workspace submission process. Submissions of extramural applications through eBRAP may be withdrawn.

***Do not password protect any files of the application package, including the Project Narrative.***

**Table 1. Full Application Submission Guidelines**

| Extramural Submissions | Intramural DoD Submissions |
|---|---|
| **Application Package Location** | |
| Download application package components for W81XWH-20-PRARP-LEAP-InCASA from Grants.gov (https://www.grants.gov) and create a Grants.gov Workspace. Workspace allows online completion of the application components and routing of the application package through the applicant organization for review prior to submission. | Download application package components for W81XWH-20-PRARP-LEAP-InCASA from eBRAP (https://ebrap.org). |
| **Full Application Package Components** | |
| **SF424 Research & Related 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. |

| Extramural Submissions | Intramural DoD Submissions |
|---|---|
| Descriptions of each required file can be found under Full Application Submission Components:<br>• Attachments<br>• Research & Related Personal Data<br>• Research & Related Senior/Key Person Profile (Expanded)<br>• Research & Related Budget<br>• Project/Performance Site Location(s) Form | **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. |
| **Application Package Submission** | |
| **Create a Grants.gov Workspace.** Add participants (investigators and Business Officials) to Workspace, complete all required forms, and check for errors before submission.<br>**Submit a Grants.gov Workspace Package.** An application may be submitted through Workspace by clicking the "Sign and Submit" button on the "Manage Workspace" page, under the "Forms" tab. Grants.gov recommends submission of the application package **at least 24-48 hours prior to the close date** to allow time to correct any potential technical issues that may disrupt the application submission.<br>**Note:** 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. ***Do not password protect any files of the application package, including the Project Narrative.*** | **Submit package components to eBRAP (https://ebrap.org).**<br>**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 next to "Enter Your Password Here" and press the "Submit Full Application" button. eBRAP will notify your Resource Manager/ Comptroller/Task Area Manager or equivalent Business Official by email. ***Do not password protect any files of the application package, including the Project Narrative.*** |
| **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. | After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/ Task Area Manager or equivalent Business |

| Extramural Submissions | Intramural DoD Submissions |
|---|---|
| During the application verification period, the full application package may be modified ***with the exception of the Project Narrative and Research & Related Budget Form***. | Official and PI will receive 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 may be modified ***with the exception of the Project Narrative and Research & Related Budget Form***. Your Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve prior to the application verification deadline. |
| **Further Information** | |
| **Tracking a Grants.gov Workspace Package.** After successfully submitting a Workspace package, a Grants.gov Tracking Number is automatically assigned to the package. The number will be listed on the "Confirmation" page that is generated after submission.<br><br>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 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 Research & Related 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 have 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. ***It is important to include the attachment name as a header on each page of the attachment files.***

- **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 initiatives for each Partnering Site in detail using the outline below.

  - **Background:** Present the ideas and reasoning behind the proposed research initiatives for each Partnering Site; include relevant literature citations.

  - **Preliminary Data:** Provide preliminary data to support the rationale and feasibility for each study at each Partnering Site. Preliminary data may be derived from a laboratory discovery, clinical observation, or population-based studies.

  - **Hypothesis (or Hypotheses) or Objectives:** State the hypothesis (or hypotheses) or objectives to be tested. The hypotheses or objectives for each Partnering Site should be clearly delineated from the other Partnering Sites.

  - **Specific Aims:** Concisely explain the project's specific aims for each Partnering Site.

  - **Project Milestones:** Concisely provide expected project milestones relevant to each of the project's technical objective and specific aims for each Partnering Site.

  - **Research Initiative Strategies:** For each research initiative at each Partnering Site, describe the experimental designs, methods, and analyses, including appropriate controls in sufficient detail for analysis. Explain how the experimental design addresses the common symptoms of TBI and AD/ADRD. Identify any potential problems. Describe alternative approaches. Research projects may include preclinical studies in human subjects, and human anatomical substances. Clinical research requiring investigational or FDA-approved drugs or medicines is specifically discouraged. Include a detailed plan that discusses recruitment of subjects and/or the acquisition of samples or data (if applicable). State the approximate number to be enrolled at each site. Describe any statistical plans with appropriate power analyses and demonstrate how they support the sample size. Describe how the studies are designed to achieve the objectives, including the endpoints/outcome measures to be used, if applicable.

For both the Partnering Sites and Coordinating Center:

- **Alzheimer's Disease/Related Dementia Description:** Describe the type of dementia that will be the research focus of the application (See Section II.B, Award Information).

- **Symptomatology Description:** Describe the type of common TBI-AD/ADRD symptomatology that will be addressed as part of the application. Briefly describe the suitability of the experimental design. For guidance, refer to Section II.B, Award Information of this Program Announcement.

- **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.

  ***There are no page limits for any of these components unless otherwise noted. Include only those components described below; inclusion of items not requested or viewed as an extension of the Project Narrative 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 articles 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 (three-page limit per letter): 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 (if applicable) (three-page limit per letter): 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. ***Each collaborating individual or organization (e.g. Partnering Sites) should provide a letter of collaboration describing their involvement in 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.

- Use of DoD Resources (if applicable): Provide a letter of support signed by the lowest-ranking person with approval authority confirming access to active duty military populations and/or DoD resources or databases.

- Use of VA Resources (if applicable): Provide a letter of support from the VA Facility Director(s) or individual designated by the VA Facility Director(s), such as the Associate Chief of Staff for Research and Development (ACOS/R&D) or Clinical Service Chief, confirming access to VA patients, resources, and/or VA research space. For VA PIs, if the VA non-profit corporation is not identified as the applicant institution for administering the funds, include a letter from the VA ACOS/R&D confirming this arrangement and identifying the institution that will administer the funds associated with the proposed research.

- **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 overall proposed research project with the following elements for each research initiative that will be performed at each Partnering Site:

- **Background:** Present the ideas and reasoning behind the proposed project.
- **Hypothesis (or Hypotheses) or Objectives:** State the hypothesis (or hypotheses) or objectives to be tested.
- **Specific Aims:** Concisely explain the project's specific aims.
- **Research Strategy:** Briefly describe the research strategy.
- **Innovation and Impact:** Describe how the research innovation and impact can benefit the military, Veteran, and civilian communities.

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.* Furthermore, describe how the research innovation and impact can benefit the military, Veteran, and civilian communities.

  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 (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 LEAP-InCASA mechanism, use the SOW format example titled, "SOW 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 clearly delineate the work of each Partnering Site.*** 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 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.

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

- 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 FDA or other Government agency.

- Briefly state the methods 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.

- Clearly identify the contributions of each PI for each task.

- In addition to the proposed research initiatives, the Coordinating Site should be clearly integrated into the project to include (but not limited to) descriptions of:

    - Which tasks and aims the Coordinating Center will participate in, to include participant accrual and participation in the proposed research for each Partnering Site

    - The work required to harmonize research protocols and analyze data with the Partnering Sites.

- For FITBIR, eligible research (human prospective studies with 50 or more prospectively recruited subjects) should include:

    - FITBIR investigator and study registration within the first 30 days of the award

    - Sharing of draft data collection forms with FITBIR

    - Annual FITBIR data submissions

- **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. ***The Application must include a Human Subject Recruitment and Safety Procedures attachment.***

    - **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(s) (population from whom the sample will be recruited/drawn). Provide a table of anticipated enrollment counts at each study site. Demonstrate that the research team will have access to the

proposed study population at each site, and describe the efforts that will be made to achieve accrual goals. Furthermore, discuss past efforts in recruiting human subjects from the target population (if applicable). Address any potential barriers to accrual and plans for addressing unanticipated delays, including a mitigation plan for slow or low enrollment or poor retention. Identify ongoing clinical trials that may compete for the same patient population and how they may impact enrollment progress. Provide justification related to the scientific goals of the proposed study for limiting inclusion of any group by age, race, ethnicity, or sex/gender. ***For applications proposing to include military personnel, refer to the General Application Instructions, Appendix 1, for more information.***

- **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 USAMRDC. 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.

- **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.

  - If human subjects will be compensated for participation in the study, include a detailed description of and justification for the compensation plan.

  - Describe the recruitment and advertisement materials. The recruitment materials should not be coercive or offer undue inducements and should accurately reflect the study.

- **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 study.

- 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:*** In compliance with 10 USC 980 (https://www.gpo.gov/fdsys/pkg/USCODE-2011-title10/pdf/USCODE-2011-title10-subtitleA-partII-chap49-sec980.pdf), the application must describe a clear intent to benefit for human subjects who cannot give their own consent to participate. If applicable, refer to the General Application Instructions, Appendix 1, for more information.

- ***Assent.*** If minors or other populations that cannot provide informed consent are included in the proposed research, 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.

– **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. ***Note:*** Some screening procedures may require a separate consent or a two-stage consent process.

– **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 exposed to as a result of participation in the research. Consider psychological, legal, social, and economic risks as well as physical risks. If the risks are unknown, this should be stated. Consider how the proposed research might affect the daily lives of the individual human subjects participating in the study. 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:**

  - ❖ Appropriate to the study's level of risk, describe how safety monitoring 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, including 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 study intervention impairing ability to drive) or equipment (e.g., thermometers, telemedicine equipment) needed for human subjects enrolled in the study.

  - ❖ If the IRB determines that a trial presents greater than minimal risk to human subjects, the DoD requires an independent research monitor with expertise consistent with the nature of risk(s) identified within the research protocol. If applicable, refer to the General Application Instructions, Appendix 1, Section B (Research Monitor Requirement), for more information on study reporting authorities and responsibilities of the research monitor.

- **Potential benefits:** Describe known and potential benefits of the study to the human subjects who will participate in the study. Articulate the importance of the knowledge to be gained as a result of the proposed research. Discuss why the potential risks to human subjects are reasonable in relation to the anticipated benefits to the human subjects and others that may be expected to result.

- **Attachment 7: Data Management (no page limit): Upload as "Data_Manage.pdf".** The Data Management attachment should include the components listed below. ***The application must include a Data Management attachment.***

  - **Data Management:** Describe all methods used for data collection, including 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 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 the DoD 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. Describe the database lock process. For FDA-regulated studies, compliance with 21 CFR 11 and appropriate data standards (such as those established by the Clinical Data Interchange Standards Consortium) are required.

- **Data reporting:** Describe how data will be reported and how it will be assured that the documentation will support a regulatory filing with the FDA, if applicable.

- **Sharing study results:** In cases where the human subject could possibly benefit medically or otherwise from the information, explain whether or not the results of screening and/or study participation will be shared with human subjects or their primary care provider, including results from any screening or diagnostic tests performed as part of the study.

– **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, including location of storage, how long specimens will be stored, any special conditions required, labeling, and specimen disposition. Outline the plan to store specimens for future use, including

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, the applicable quality standard, and 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: Innovation and Impact Statement (one-page limit):** Upload as "Impact.pdf". **"InnovationImpact.pdf".** Detail how the research innovatively challenges existing research paradigms or exhibits high levels of creativity within the contexts of the PRARP's mission and vision. Detail how the novel research efforts will benefit researchers and/or practitioners in the health sciences related to the **PRARP's** mission and vision (see Section II.A, Program Description). Furthermore, explain how the innovation and impact can benefit individuals affected by AD/ADRD, their caregivers, and their families. ***The Innovation and Impact Statement is used by all reviewers and must be included in the application.***

- **Attachment 9: Overarching Challenges and Focus Areas Statement (one-page limit): Upload as "OCFAS.pdf".** Describe how the proposed study is responsive and relevant to one of the specific FY20 PRARP LEAP-InCASA Overarching Challenges (see Section II.B, Award Information). In addition, describe how the application addresses at least one of the specific FY20 PRARP LEAP-InCASA Focus Areas (see Section II.B, Award Information). An application that proposes research outside of the FY20 PRARP LEAP-InCASA Focus Areas is acceptable, as long as the applicant provides a strong justification. ***The application must include an Overarching Challenges and Focus Areas Statement.***

- **Attachment 10: Coordinating Center Statement (two-page limit): Upload as "Coord.pdf".** Describe the leadership and management infrastructure for all research initiatives. Describe how the Coordinating Center will participate as a separate study arm, to include participant accrual and participation in the proposed research initiatives at each Partnering Site. Describe how the Coordinating Center will have the appropriate experience and resources to function as a research performance site for each Partnering Site. Describe efforts to harmonize research protocols, participant accrual strategies, and data analysis strategies in conjunction with the Partnering Sites. Clearly state plans for interactions between/among the partners. The plans must include communication, decision-making, allocation of resources, and coordination of research progress and results among all Partnering Sites. Describe the Coordinating Center's prior experience with administering multi-institutional research grants. ***The application must include a Coordinating Center Statement.***

- **Attachment 11: Partnering Site Statement (two-page limit): Upload as "Partners.pdf".** Describe how each Partnering Site has appropriate experience, resources, and participant accrual experience toward initiating independent research

activities. For each Partnering Site, detail how each research initiative is unique from the other Partnering Sites. In addition, each Partnering Site should provide a letter of collaboration describing their involvement in the proposed work as part of the application's Supporting Documentation (Attachment 2). ***The application must include a Partnering Site Statement.***

- **Attachment 12: Data and Research Resources 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 plan is required as part of the application process. Describe the type of data or research resource to be made publicly available as a result of the proposed work. Also, describe the plan for the provision of access to the data or research resources generated from the proposed work to the public and how the data or resource will be made available after award expires. Provide a milestone plan for data dissemination as part of this statement.

  ***Note: Any application that includes human prospective studies of TBI must consider the FITBIR Informatics System as an additional part of the Data and Research Resources Sharing Plan. Animal studies are precluded from the FITBIR Informatics System requirement.***

  ***Note: FITBIR data submission requirement applies only to DHP funded TBI research projects with 50 or more prospectively recruited human subjects.***

  In order to share data with FITBIR, three elements must be included in the proposed research:

  - Updated informed consent language that includes FITBIR data sharing. Sample consent language is included in Appendix 2 of this Program Announcement.

  - Global Unique Identifier (GUID): FITBIR encourage collaboration between laboratories, as well as interconnectivity with other informatics platforms. Such community-wide sharing requires common data definitions and standards. 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 GUID system facilitates repeated and multi-user access to data without the need to personally identify data sources. In order to generate a GUID for a subject, the following personally identifiable information (PII) must be collected in the proposed research

    - Complete legal given (first) name of subject at birth
    - Complete legal additional name of subject at birth (if subject has a middle name)
    - Complete legal family (last) name of subject at birth)
    - Day of birth

- Month of birth
- Year of birth
- Name of city/municipality in which subject was born
- Country of birth

***Note: PII is never sent to the FITBIR Informatics System. PII cannot be extracted from the GUID. Information on GUID compliance with Health Insurance Portability and Accountability Act (HIPAA) regulations can be found at https://fitbir.nih.gov/content/global-unique-identifier.***

- Common Data Elements: Research data elements must be reported using the NINDS TBI CDEs or entered into the FITBIR data dictionary as new UDEs. For the most current versions of the NINDS TBI CDEs, go to https://www.commondataelements.ninds.nih.gov. Assistance will be available to help the researchers map their study variables to specific CDEs and ensure the formats of the CDEs collected are compatible with the FITBIR Informatics System. 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. Use of UDEs is strongly discouraged and subject to program approval.

**For additional guidance regarding sharing of data and research resources, refer to the General Application Instructions, Appendix 2, Section K.**

- **Attachment 13: Representations, if applicable (extramural submissions only): Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the Required Representations template available on eBRAP (https://ebrap.org/eBRAP/public/Program.htm). For more information, see the General Application Instructions, Appendix 5, Section B, Representations.

- **Attachment 14: Suggested Collaborating DoD Military Facility Budget Format, if applicable: Upload as "MFBudget.pdf".** If a military facility (Military Health System facility, research laboratory, medical 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 a separate budget, using "Suggested Collaborating DoD Military Facility Budget Format," 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 & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section III.A.8, for detailed information.

- **Extramural and Intramural Applications**

  To evaluate compliance with Title IX of the Education Amendments of 1972 (20 USC A§1681 et seq.), the DoD is collecting certain demographic and career information to be able to assess the success rates of women who are proposed for key roles in applications in science, technology, engineering, and/or mathematics (STEM) disciplines. To enable this assessment, each application must include the following forms completed as indicated.

  **Research & Related Personal Data:** 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.

  **Research & Related Senior/Key Person Profile (Expanded):** 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.

  - PI Biographical Sketch (five-page limit): Upload as "Biosketch_LastName.pdf". The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The National Institutes of Health Biographical Sketch may also be used. All biographical sketches should be submitted in uneditable PDF format.

  - PI Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf".

  - Key Personnel Biographical Sketches (five-page limit each): Upload as "Biosketch_LastName.pdf".

    - Include Co-PI biographical sketches

  - Key Personnel Previous/Current/Pending Support (no page limit): Upload as "Support_LastName.pdf".

    - Include Co-PI previous/current/pending support

  **Research & Related Budget:** 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.

  **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.6, and for intramural

submissions (via eBRAP), refer to the General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

  **Research & Related Subaward Budget Attachment(s) Form (if applicable):** Refer to the General Application Instructions, Section III.A.7, for detailed information.

  - **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov. (Refer to the General Application Instructions, Section III.A.7, for detailed information.) Verify subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

  - **Intramural DoD Collaborator(s):** Complete the "Suggested Collaborating DoD Military Facility Budget Format" and upload to Grants.gov attachment form as Attachment 13. (Refer to the General Application Instructions, Section IV.A.4, for detailed information.) Each Intramural DoD Collaborator should include costs per year on the Grants.gov Research & Related Budget Form under subaward costs.

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

Applicant organizations and all sub-recipient 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 organization's Entity registration in SAM well in advance of the application submission deadline. Allow several weeks to complete the entire SAM registration process. If an applicant has not fully complied with the requirements at 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.

***Announcement of Transition to SAM-Generated Unique Entity Identifier (UEI):*** Through December 2020, a transition from DUNS to the SAM-generated UEI will occur. Refer to the General Application Instructions, Section III.1, DUNS Number, for more information on the transition and timing.

### 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**

***For Both Extramural and Intramural Applicants:*** eBRAP allows an organization's representatives and PIs to view and modify the full application submissions associated with them. 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 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. eBRAP does not confirm the accuracy of file content. Application viewing, modification, and verification in eBRAP are strongly recommended, but not required. 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 Research & Related Budget Form cannot be changed after the application submission deadline.*** Other application components may be changed until the end of the application verification period. Verify that subaward budget(s) and budget justification forms are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period. After the end of the application verification period, the full application cannot be modified.

***Extramural Submission:*** 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.

***Intramural DoD Submission:*** After eBRAP has processed the full application, the organizational Resource Manager/Comptroller/Task Area Manager or equivalent Business Official and PI will receive email notification of the 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. The Resource Manager/Comptroller/Task Area Manager or equivalent Business Official should log into eBRAP to review and to approve the application package prior to the application verification deadline.

***For All Submissions:*** Verify that subaward budget(s) with budget justification are present in eBRAP during the application verification period. If these components are missing, upload them to eBRAP before the end of the application verification period.

**II.D.5. Funding Restrictions**

The maximum period of performance is **4** years.

The anticipated total costs budgeted for the entire period of performance will not exceed **$2,800,000**. 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 **$2,800,000** 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 **4** years.

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

- Travel costs for the Coordinating Center PI to disseminate project results at the 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 must 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 :

- Data and research resources sharing costs associated with the execution of the Data and Research Resources Sharing Plan

- Costs for the named Coordinating Center and Partnering Site investigators to travel to two scientific/technical meetings per year in addition to the required meeting described above. The intent of travel costs to scientific/technical meeting(s) is to present project information or disseminate project results from the FY20 PRARP LEAP-InCASA.

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 funds 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.5, 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.5*.**

### 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 all equal in importance:

- **Research Strategy and Feasibility**
    - How well the scientific rationale supports the proposed research initiatives for each Partnering Site and its feasibility as demonstrated by relevant preliminary data and logical reasoning.
    - How well the hypothesis (hypotheses) or objectives are developed at each partnering site.
    - How well the aims, experimental design, methods, and analyses are developed at each Partnering Site.
    - How well the experimental designs address the common symptoms of TBI and AD/ADRD at each Partnering Site.
    - How well the applicant acknowledges potential problems and addresses alternative approaches.
    - How well the project's milestones support the accomplishment of the project's objectives and specific aims.
    - How well the application relates to the type of dementia that will be the focus of the application.
    - How well the application relates to common TBI-AD/ADRD symptomatology.
    - How well the statistical plans are appropriately powered for the analyses and support the sample sizes.
- **Recruitment, Accrual, and Feasibility**
    - How well the application describes the target population and the nature, approximate number, and pertinent demographic characteristics of the accessible population at the study site(s).
    - How well the methods for identification of potential human subjects are detailed with respect to performance of the study.
    - The degree to which the recruitment, informed consent, screening, and retention processes for human subjects will meet the needs of the proposed study.

- 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 inclusion/exclusion criteria are justified.

- **Data Management**

  - How well the Data Management plan is suited to the overall goals of the study.

- **Study Personnel and Organization Plan**

  - How well the Study Personnel and Organization Plan are suited to the overall goals of the study.

- **Personnel**

  - How well the applicant shows potential for addressing the PRARP's mission (see Section II.A, Program Description) based on the members' background and experience.

  - How well the study team's background and related experience 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 relevant experience in both TBI and AD/ADRD.

  - To what degree the levels of effort are appropriate for successful conduct of the proposed work.

- **Innovation and Impact**

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

    - The research innovatively challenges existing research paradigms or exhibits high levels of creativity within the contexts of the PRARP's mission and vision.

    - The novel research efforts will benefit researchers and/or practitioners in the health sciences.

    - The research innovation and impact can benefit individuals affected by AD/ADRD, their caregivers and their families.

- **Overarching Challenges and Focus Areas**

  - How well the proposed study addresses one of the FY20 PRARP LEAP-InCASA Overarching Challenges and at least one of the Focus Areas, or provides a strong justification for research outside the FY20 PRARP LEAP-InCASA Focus Areas.

- **Coordinating Center:**
    - How well the leadership and management infrastructure for all research initiatives is detailed and sufficient for the proposed research initiatives.
    - To what extent the plan for how the Coordinating Center will participate as a separate study arm, to include participant accrual and participation in the proposed research initiatives at each Partnering Site is sufficiently detailed.
    - To what extent the Coordinating Center has the appropriate experience and resources to function as a research performance site for each Partnering Site.
    - How well efforts to harmonize research protocols, participant accrual strategies, and data analysis strategies in conjunction with the Partnering Sites are sufficiently detailed and justified.
    - How well the plans for communication, decision-making, allocation of resources, and coordination of research progress and results among all Partnering Sites are developed.
    - To what extent the Coordinating Center's demonstrates prior experience with administering multi-institutional research grants.
- **Partnering Sites:**
    - To what extent each Partnering Site has appropriate experience, resources, and participant accrual experience toward initiating independent research activities.
    - How well detailed each research initiative is in terms of its uniqueness from the other Partnering Sites.
- **Data and Research Resources Sharing Plan**
    - How well the Data and Research Resources Sharing Plan is detailed, including but not limited to:
        - The description of the type of data or research resource(s) to be made publicly available.
        - How well the plan for access to data or research resources is detailed.
        - The appropriateness of plans to ensure the data or research resource(s) is/are accessible after the period of performance expires.
        - The appropriateness of the milestones with respect to making the data or research resource(s) available.
        - The appropriateness of the FITBIR data sharing (if applicable).

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

- **Budget**
    - Whether the **total** costs exceed the allowable 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.
    - If applicable, to what degree the commercialization strategy 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 affected 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 FY20 PRARP, as evidenced by the following:
    - Adherence to the intent of the award mechanism
    - Program portfolio composition
    - Relative impact and innovation

### 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**, the evaluation of applications against established criteria to determine technical merit, where each application is assessed for its own merit, independent of other applications. The second tier is **programmatic review**, a comparison-based process in which applications with high scientific and technical merit are further evaluated for programmatic relevance. Final recommendations for funding are made to the Commanding General, USAMRDC, on behalf of the DHA and the OASD(HA). ***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 https://cdmrp.army.mil/about/2tierRevProcess. An information paper describing the funding recommendations and review process for the award mechanisms for the PRARP will be provided to the PI and posted on the CDMRP website.

All CDMRP review processes are conducted confidentially to maintain the integrity of the merit-based selection process. Panel members sign a statement declaring 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 and approval 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 and approval 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, as defined in 2 CFR 200.88, 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 organization may review FAPIIS, accessible through SAM, and submit comments to FAPIIS on any information about the organization 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 (DoDGARs), 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 supported with FY20 funds are anticipated to be made no later than September 30, 2021. Refer to the General Application Instructions, Appendix 2, for additional award administration information.

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

**Pre-Award Costs:** An institution of higher education, hospital, or other non-profit organization may, at its own risk and without the Government's prior approval, incur obligations and expenditures to cover costs up to 90 days before the beginning date of the initial budget period of a new award. Refer to the General Application Instructions, Section III.B.

***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 document.**

**Federal Government Organizations:** Funding made 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 Manager/Task Area Manager/Comptroller or equivalent Business Official.

### II.F.1.a. PI Changes and 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.1.b. Pre-Award Meeting

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

Applicable requirements in the DoDGARs found in 32 CFR, Chapter I, 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 latest DoD R&D General Terms and Conditions; the General Research Terms and Conditions with Institutions of Higher Education, Hospitals, and Non-Profit Organizations: Addendum to the DoD R&D General Terms and Conditions; 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. ***If there are technical reporting requirement delinquencies for any existing USAMRAA-sponsored awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.***

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

Annual quad charts will be required.

The Award Terms and Conditions will specify if more frequent reporting is 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 Representations (see General Application Instructions, Appendix 5, Section B).

## 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 501e. The Program Announcement numeric version code will match the General Application Instructions version code 501.

### 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 with the same named PI. Only the first application received will be accepted; additional applications will be administratively rejected.
- Human Subject Recruitment and Safety Procedures attachment (Attachment 6) is missing
- Data Management attachment (Attachment 7) is missing
- Innovation and Impact Statement (Attachment 8) is missing
- Overarching Challenges and Focus Areas Statement (Attachment 9) is missing
- Coordinating Center Statement (Attachment 10) is missing.
- Partnering Site Statement (Attachment 11) 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 application:

- An FY20 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 FY20 PRARP Programmatic Panel members can be found at https://cdmrp.army.mil/prarp/pscs/psc20***.
- The application fails to conform to this Program Announcement description.
- 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 FY20, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.army.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies may be administratively withdrawn.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval 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.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The Coordinating Center is from the same institution as the Partnering Sites.
- The Partnering Sites are from the same institutions.
- Coordinating Center PI does not meet the eligibility criteria.
- Partnering Site PIs do not meet the eligibility criteria.
- The application proposes research on more than one symptomatology (see Section II.B, Award Information) category for the overall application.
- The application proposes research on more than one Overarching Challenge (see Section II.B, Award Information) category for the overall application.
- The application proposes research on more than one type of dementia (see Section II.B, Award Information) category for the overall application.
- The application proposes Chronic Traumatic Encephalopathy research.
- An application proposes animal research.

**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 Research & Related Application for Federal Assistance **(extramural submissions only)** | Complete form as instructed | |
| Summary (Tab 1) and Application Contacts (Tab 2) **(intramural submissions only)** | Complete 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" | |
| | Human Subject Recruitment and Safety Procedures: Upload as Attachment 6 with file name "HumSubProc.pdf" | |
| | Data Management: Upload as Attachment 7 "Data_Manage.pdf" | |
| | Innovation and Impact Statement: Upload as Attachment 8 with file name "InnovationImpact.pdf" | |
| | Overarching Challenges and Focus Areas Statement as Attachment 9 with file name "OCFAS.pdf" | |
| | Coordinating Center Statement as Attachment 10 with file name "Coord.pdf" | |
| | Partnering Site Statement as Attachment 11 with file name "Partners.pdf" | |
| | Data and Research Resources Sharing Plan as Attachment 12 with file name "Sharing.pdf" | |
| | Representations (extramural submissions only): Upload as Attachment 13 with file name "RequiredReps.pdf" if applicable | |
| | Suggested Collaborating DoD Military Facility Budget Format: Upload as Attachment 14 with file name "MFBudget.pdf" if applicable | |

| Application Components | Action | Completed |
|---|---|---|
| Research & Related Personal Data | Complete form as instructed | |
| 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 **(extramural submissions only)** | Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field | |
| Budget **(intramural submissions only)** | Suggested DoD Military Budget Format, including justification | |
| Project/Performance Site Location(s) Form | Complete form as instructed | |
| Research & Related Subaward Budget Attachment(s) Form, if applicable | Complete form as instructed | |

## APPENDIX 1: ACRONYM LIST

| | |
|---|---|
| ACOS/R&D | Associate Chief of Staff for Research and Development |
| AD | Alzheimer's Disease |
| ADRD | Alzheimer's Disease-Related Dementias |
| CDE | Common Data Elements |
| CDMRP | Congressionally Directed Medical Research Programs |
| CFR | Code of Federal Regulations |
| DHA | Defense Health Agency |
| DHP | Defense Health Program |
| DoD | Department of Defense |
| DoDGARs | 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 |
| HIPAA | Health Insurance Portability and Accountability Act |
| HRPO | Human Research Protection Office |
| IRB | Institutional Review Board |
| LAR | Legally Authorized Representative |
| LEAP-InCASA | Leveraging Approaches for Innovation in Care and Support Award |
| LOI | Letter of Intent |
| M | Million |
| MIPR | Military Interdepartmental Purchase Request |
| MRI | Magnetic Resonance Imaging |
| NINDS | National Institute of Neurological Disorders and Strokes |
| OASD(HA) | Office of the Assistant Secretary of Defense for Health Affairs |
| ORCID | Open Researcher and Contributor ID, Inc. |
| ORP | Office of Research Protections |
| PI | Principal Investigator |
| PII | Personally Identifiable Information |
| PRARP | Peer Reviewed Alzheimer's Research Program |
| RDT&E | Research, Development, Test, and Evaluation |
| SAM | System for Award Management |

| | |
|---|---|
| SOW | Statement of Work |
| STEM | Science, Technology, Engineering, and/or Mathematics |
| TBI | Traumatic Brain Injury |
| UDE | Unique Data Elements |
| USAMRAA | U.S. Army Medical Research Acquisition Activity |
| USAMRDC | U.S. Army Medical Research and Development Command |
| USC | United States Code |
| VA | Department of Veterans Affairs |

## APPENDIX 2: SAMPLE CONSENT LANGUAGE

### SAMPLE LANGUAGE FOR DISCUSSION OF FITBIR IN INFORMED CONSENT DOCUMENTS

Data from this study may be submitted to the Federal Interagency Traumatic Brain Injury (FITBIR) informatics system. FITBIR is a computer system run by the National Institutes of Health (NIH) that allows researchers studying traumatic brain injury to collect and share information with each other. With an easier way to share, researchers hope to learn new and important things about traumatic brain injury more quickly than before.

During and after the study, the researchers will send information about your or your child's health and behavior, and in some cases your or your child's genetic information, to FITBIR. However, before they send it to FITBIR, they will remove information such as name, date of birth, and city of birth, and replace that information with a code number. Other researchers nationwide can then file an application to obtain access to your study data for research purposes. Experts who know how to protect health and science information will look at every request carefully to minimize risks to your privacy.

You or your child may not benefit directly from allowing your information to be shared with FITBIR. The information provided to FITBIR might help researchers around the world treat future children and adults with traumatic brain injury so that they have better outcomes. FITBIR will report on its website about the different studies that researchers are conducting using FITBIR data; however, FITBIR will not be able to contact you or your child individually about specific studies.

You may decide now or later that you do not want to share your or your child's information using FITBIR. If so, contact the researchers who conducted this study, and they will tell FITBIR, which can stop sharing the research information. However, FITBIR cannot take back information that was shared before you changed your mind. If you would like more information about FITBIR, this is available online at https://fitbir.nih.gov.

### LANGUAGE TO BE USED TO DESCRIBE CERTIFICATES OF CONFIDENTIALITY (THREE VERSIONS)

**1. Language for new studies that will be consenting subjects for the first time or for ongoing studies that will be re-consenting subjects because they are applying for a Certificate of Confidentiality for the study**

To help protect you and/or your child's privacy the investigators of this study [have applied for]/[have obtained] a Certificate of Confidentiality from the National Institutes of Health (NIH), part of the U.S. Department of Health and Human Services (DHHS), an agency of the U.S. Government.

With this Certificate, we, the investigators, cannot be forced (e.g., by court subpoena) to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. Be aware that disclosure of your and/or your child's identity may be found necessary, however, upon request of DHHS for the purpose of audit or evaluation.

You should also understand that a Confidentiality Certificate does not prevent you or a member of your family from **voluntarily** releasing information about your child, yourself, or your involvement in this research. Note, however, that if an insurer or employer learns about your and/or your child's participation and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

We are also asking your consent to provide research data and related findings to the Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system. FITBIR is a biomedical informatics system and data repository, created by the Department of Defense and the National Institutes of Health to assist biomedical researchers working to develop a better understanding of traumatic brain injury and/or to develop more effective methods to diagnose, treat and prevent traumatic brain injuries.

Data entered into FITBIR will be kept confidential, with FITBIR being designed for access by qualified researchers only. Data provided to FITBIR as part of your and/or your child's participation in this research study will be de-identified—i.e., your and/or your child's name will be separated from the data. However, since this institution and others submitting data to FITBIR will retain individually identifying information related to the data they provide, NIH has issued a legislatively authorized "Certificate of Confidentiality" that will help FITBIR and participating institutions avoid being forced to disclose information that may identify you as a FITBIR participant in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

Finally, you should understand that we, the investigators, are not prevented from taking steps, including reporting to authorities, to prevent serious harm to you, your child, or others. With respect to you and/or your child's participation in FITBIR, we do not plan to make voluntary disclosures except if there were severe threats to the public health or safety.

**2. Language for studies that already have a Certificate and will be re-consenting subjects about FITBIR**

With your consent, this study will collect and provide research data and related findings to the Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system. FITBIR is a biomedical informatics system and data repository created by the Department of Defense and National Institutes of Health (NIH)—part of the U.S. Department of Health and Human Services (DHHS), an agency of the U.S. Government—to assist biomedical researchers working to develop a better understanding of traumatic brain injury and/or to develop more effective methods to diagnose, treat and prevent traumatic brain injury.

Data entered into FITBIR will be kept confidential, with FITBIR being designed for access by researchers only. Data provided to FITBIR as part of your and/or your child's participation in this research study will be de-identified—i.e., your and/or your child's name will be separated from the data. However, since this institution and others submitting data to FITBIR will retain individually identifying information related to the data they provide, NIH has issued a legislatively authorized "Certificate of Confidentiality" to help FITBIR and participating institutions avoid being forced (e.g., by court subpoena) to disclose information that may identify you as a FITBIR participant in any federal, state, or local civil, criminal, administrative,

legislative, or other proceedings. Be aware that disclosure of your and/or your child's identity may be found necessary, however, upon request of DHHS for the purpose of audit or evaluation.

As you know, we have obtained a Certificate of Confidentiality from NIH that enables us to keep the individually identifiable information that you provide as a research subject private. With this Certificate, we, the investigators cannot be forced to disclose research information collected in this study that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. This protection will continue to protect your and/or your child's privacy, even though we are providing de-identified data to FITBIR.

You should also understand that a Confidentiality Certificate does not prevent you or a member of your family from **voluntarily** releasing information about your child, yourself, or your involvement in this research. Note, however, that if an insurer or employer learns about you and/or your child's participation, and obtains your consent to receive research information, then the investigator may not use the Certificate of Confidentiality to withhold this information. This means that you and your family must also actively protect your own privacy.

Finally, as we explained when we told you about this privacy protection before, we, the investigators, are not prevented from taking steps, including reporting to authorities, to prevent serious harm to you and/or your child or others based on information they learn during this study. With respect to you and/or your child's participation in FITBIR, we do not plan to make voluntary disclosures except if there were severe threats to the public health or safety.

**3. Language for studies without a Certificate of their own**

With your consent, this study will collect and provide research data and related findings to the Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system. FITBIR is a biomedical informatics system and data repository created by the Department of Defense and the National Institutes of Health (NIH)—part of the U.S. Department of Health and Human Services (DHHS), an agency of the U.S. Government—to assist biomedical researchers working to develop a better understanding of traumatic brain injury and/or to develop more effective methods to diagnose, treat and prevent traumatic brain injury.

Data entered into FITBIR will be kept confidential, with FITBIR being designed for access by researchers only. Data provided to FITBIR as part of your or your child's participation in this research study will be de-identified—i.e., your and/or your child's name(s) will be separated from the data. However, since this institution and others submitting data to FITBIR will still retain individually identifying information related to the data provided, the NIH has issued a legislatively authorized "Certificate of Confidentiality" to help FITBIR and participating institutions avoid being forced (e.g., by court subpoena) to disclose information that may identify you as an FITBIR participant in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings.

Finally, you should understand that we, the investigators, are also permitted to make voluntary disclosures with respect to information that is submitted to FITBIR, but do not plan to do so except in the event of severe threats to public health or safety. If, as part of your participation in this research study itself, we learn about serious harm to you, your child or someone else, we would take steps to prevent that harm including notifying appropriate authorities like the police or child welfare.