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

Accelerating Diagnostics Research Award

Announcement Type: Initial

Funding Opportunity Number: W81XWH-22-PRARP-ADRA

**Assistance Listing 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 17, 2022

- **Application Submission Deadline:** 11:59 p.m. ET, July 25, 2022

- **End of Application Verification Period:** 5:00 p.m. ET, July 29, 2022

- **Peer Review:** September 2022

- **Programmatic Review:** December 2022

This program announcement must be read in conjunction with the General Application Instructions, version 702. 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."

II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Year 2022 (FY22) Peer Reviewed Alzheimer's Research Program (PRARP) are being solicited by the U.S. Army Medical Research Acquisition Activity (USAMRAA) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The execution management agent for this program announcement is the Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC). The PRARP was initiated in (FY11 to address the long-term consequences of traumatic brain injury (TBI) as they pertain to Alzheimer's disease (AD) and AD-related dementias (ADRD). Appropriations for the PRARP from FY11 through FY21 totaled $153 million (M). The FY22 appropriation is $15M.

The PRARP prioritizes research that will provide meaningful outcomes to support caregivers and persons with AD and ADRD, with a focus on partnership with those most impacted by these conditions. In addition, the PRARP strongly advocates for study population diversity, including but not limited to ethnic, cultural, socioeconomic, and health access factors.

In addition to a focus on individual and care support, the PRARP seeks to support research focusing on the intersection of TBI-AD/ADRD, including understanding mechanisms, biomarkers, and risk factors associated with Veteran populations. The PRARP is interested in supporting research leading to treatment modalities that have near-term benefit.

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

II.A.1. FY22 PRARP Accelerating Diagnostics Research Award (ADRA) Focus Area

To address the intent of the award mechanism, applications submitted to this program announcement ***must address*** the FY22 PRARP ADRA Focus Area listed below.

Diagnostic, environmental, and prognostic factors: Research to better detect, diagnose, support treatment decisions, and predict long-term outcomes and risk factors associated with AD/ADRD following military service and/or TBI. Research of interest may include, but is not limited to, identification and validation of biomarkers for diagnosis and prognosis of AD and ADRD, including but not limited to, fluid, tissue, and imaging biomarkers, psychosocial indicators, development and validation of devices/technologies, or a combination thereof. In addition, research could address the contribution and identification of risk and resiliency factors for development of AD/ADRD during and after military service, which may include, but are not limited to, life history, genetic, physiological, and psychosocial factors. Epidemiological studies examining TBI and/or military-service-related factors and AD/ADRD development are also included under this Focus Area.

II.A.2. Award History

The PRARP ADRA funding opportunity was first offered in FY20. Since then, 12 ADRA applications have been received, and 3 applications have been recommended for funding.

II.B. Award Information

The intent of the FY22 PRARP ADRA is to support high-impact advancement of robust diagnostic and/or prognostic factors pertaining to AD/ADRD following military service and/or TBI. Applications meeting the intent of this mechanism will accelerate clinically useful factors for rapid transfer to clinical practice to bridge a critical gap between identification of relevant factors and clinical usage. The proposed factors for investigation must correlate with clinical endpoints relevant to AD/ADRD following military service and/or TBI. Inclusion of preliminary data is required.

Applicants should clearly describe the intent, purpose, as well as the clinical and practical utility of the diagnostic and/or prognostic factors being studied. Considerations for how the diagnostic/prognostic factors meaningfully inform care and disease management should be described both at the provider and individual living with AD/ADRD level. As part of the application, the proposed prognostic or diagnostic factors should demonstrate their potential for improved specificity and sensitivity with respect to diagnosis and/or prognosis of AD/ADRD as the study endpoint. Additionally, applications should address the utility of the diagnostic/ prognostic factor(s) in rural or resource-limited environments.

Applications may consider elements of biomarker and risk factor validation as part of the application, particularly if validation is intended to widen the diversity of the population to which the factors/biomarkers will be applicable. Biomarker validation is defined as assessing the biomarker's measurement performance characteristics in terms of reproducibility, accuracy, precision, and limits of sensitivity. Risk factors may include modifiable and non-modifiable factors that influence a person's likelihood to develop AD/ADRD. ***Clinical trials are not allowed;*** however, the FY22 ADRA may use data and/or human anatomical substances from an existing clinical trial to carry out the research.

The FY22 PRARP ADRA ***does not support*** basic discovery of biomarkers or basic epidemiological studies, and *animal research is prohibited*. Investigators with projects that contain such research should consider applying to the FY22 PRARP Investigator-Initiated Research Award (W81XWH-22-PRARP-IIRA) or Translational Research Award (W81XWH-22-PRARP-TRA) funding opportunities, as appropriate.

Due to nature of the FY22 PRARP ADRA, studies are required to prospectively recruit study participants. Applications must provide a plan that demonstrates access to a suitable cohort and a plan for participant accrual. Thus, applications must describe how the anticipated outcome(s) can be attributable to the results of the proposed research (short-term gains), as well as consider the long-term scientific gains from the proposed research project. In addition, applications should describe the diversity of study population and how it is appropriate for the proposed project.

Optimizing Research Impact Through Community Collaboration: Research funded by the FY22 PRARP should be responsive to the needs of persons with AD/ADRD lived experience, family, and care provider communities. Through the establishment and utilization of effective and equitable collaborations and partnerships, the translational and impact potential of the proposed research can be maximized. For the FY22 PRARP ADRA, inclusion of a minimum of one collaborative community partner approach is *required for all applications*.

Clinical trials are not allowed under this mechanism. 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.

Clinical research is defined as: (1) Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are in vitro studies that utilize human tissues that cannot be linked to a living individual. Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies. (2) Epidemiologic and behavioral studies. (3) Outcomes research and health services research. *Note:* Studies that meet the requirements for Institutional Review Board (IRB) Exemption 4 are not considered CDMRP-defined clinical research. IRB Exemption 4 refers to research involving the collection or study of existing de-identified specimens or data, if these sources are publicly available.

Optimizing Research Impact Through Community Collaboration: Research funded by the FY22 PRARP should be responsive to the needs of persons with AD/ADRD lived experience, family, and care provider communities. Through the establishment and utilization of effective and equitable collaborations and partnerships, the translational and impact potential of the proposed research can be maximized. For the FY22 PRARP ADRA, inclusion of collaborative community partner approaches is **required for all projects**.

Collaborative research approaches feature shared responsibility and ownership for the research project to ensure non-tokenistic involvement of community members within the research team. Collaborative research approaches such as community-based participatory research (CBPR), participatory action research, and integrated knowledge transition, generate partnerships between scientific researchers and community members to create knowledge useable by both sets of stakeholders. Recognizing the strengths of each partner, scientific researchers and community members must *collaborate and contribute their expertise equitably* on all aspects of the project, which may include needs assessment, planning, research intervention design, implementation, evaluation, and dissemination. Research results are jointly interpreted, disseminated, fed back to affected communities, and may be translated into interventions or policy. These methods are critically important for community-level interventions and can also augment the potential impact of a research program on people living with dementia, their families, and/or their care partners.

These collaborative relationships are often established through integrating community members into research teams as co-researchers, advisors, and consultants. Some examples for community collaborations include:

- **Lived Experience Consultation:** The research team includes at least one project advisor with AD/ADRD experience who will integrate with the research team to provide consultation throughout the planning, implementation, and dissemination of the research project. Lived experience consultants (LECs) may include individuals with AD/ADRD, their family members, care partners, or others as appropriate.

- **Partnership with a Community-Based Organization:** The research team establishes partnerships with at least one community-based organization that provides consultation throughout the planning, implementation, and dissemination of the research project. Community-based organizations may include advocacy groups, service providers, policymakers, or other formal organizational stakeholders.

- **Community Advisory Board (CAB):** A CAB is composed of multiple community stakeholders and can take many forms, from a board of LECs to a coalition of community-based organizations or any combination thereof. As with LECs and organizational partners, the CAB provides consultation throughout the planning, implementation, and dissemination of the research project.

Additional information on CBPR can be found in:

- Wallerstein N and Duran B. 2010. Community-based participatory research contributions to intervention research: The intersection of science and practice to improve health equity. *American Journal of Public Health* 100(S1):S40-S46. doi: 10.2105/AJPH.2009.184036.

- Jull J, Giles A, and Graham ID. 2017. Community-based participatory research and integrated knowledge translation: Advancing the co-creation of knowledge. *Implementation Science* 12(1):150. doi: 10.1186/s13012-017-0696-3.

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 (direct plus indirect) costs budgeted for the entire period of performance for an FY22 PRARP Accelerated Diagnostics Research Award will not exceed **$2.5M**. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Awards will be made no later than September 30, 2023. For additional information refer to [Section II.F.1, Federal Award Notices](#).

The CDMRP expects to allot approximately $5M to fund approximately two PRARP Accelerating Diagnostics Research Award applications. 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 FY22 funding opportunity will be funded with FY22 funds, which will expire for use on September 30, 2028.

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 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 IRB or Ethics Committee (EC) review. Local IRB/EC approval at the time of submission is *not* required. Allow up to 3 months to complete the HRPO regulatory review and approval process following submission of *all required and complete* documents to the HRPO. Refer to the General Application Instructions, Appendix 1, and the Human Research Protections Office Resources and Overview 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 involves more than one institution, a written plan for single IRB review arrangements must be provided at the time of application submission or 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.

Use of DOD or Department of Veterans Affairs (VA) Resources: If the proposed research involves access to active-duty military or VA 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 detailed information. Refer to the General Application Instructions, Appendix 1, for additional information.

Research Involving Animals: *The FY22 PRARP ADRA prohibits the use of animals in the proposed project.*

Federal Interagency Traumatic Brain Injury Research (FITBIR) Data Sharing: 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 http://fitbir.nih.gov/.

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

1. Updated informed consent language that includes FITBIR data sharing. Sample consent language is included in Appendix 3.

2. Global Unique Identifier (GUID): FITBIR encourages 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 that this PII is never sent to the FITBIR 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.

3. 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 http://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.*

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization: All organizations, including foreign organizations, foreign public entities, and 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 organizations 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:* **An** *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.*

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

II.C.1.b. Principal Investigator

The Principal Investigator (PI) named by the organization on the application must be an independent investigator at or above the level of Assistant Professor (or equivalent).

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

The CDMRP strongly 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).

II.D.1. eBRAP and Grants.gov

eBRAP (https://ebrap.org) is a secure web-based system that allows PIs to submit their pre-applications, view and verify extramural full applications submitted to Grants.gov (https://grants.gov), receive communications from the CDMRP, and submit documentation during award negotiations and throughout the period of performance. eBRAP also allows intramural organizations to submit full applications following pre-application submission.

Grants.gov is a federal system required to be utilized by agencies to receive and process extramural grant applications. Full applications may only be submitted to Grants.gov after submission of a pre-application through eBRAP.

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

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.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 eBRAP 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 eBRAP 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 PI 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 eBRAP 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 and key personnel associated with the application.

  FY22 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 eBRAP 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. ***An invitation to submit a full application is NOT required after LOI submission and applicants should not expect to receive such an invitation in order to proceed to submitting a full application.***

- **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://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-22-PRARP-ADRA from Grants.gov (https://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-22-PRARP-ADRA from eBRAP (https://ebrap.org).

Extramural Submissions	Intramural DOD Submissions
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. **Tab 2 – Application Contacts:** This tab will be pre-populated by eBRAP; add Authorized Organizational Representative.
Descriptions of each required file can be found under Full Application Submission Components: • Attachments • Research & Related Personal Data • Research & Related Senior/Key Person Profile (Expanded) • Research & Related Budget • Project/Performance Site Location(s) Form • Research & Related Subaward Budget Attachment(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: • Attachments • Key Personnel • Budget • Performance Sites **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. **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. *Note:* If either the Project Narrative or the budget fails eBRAP validation or needs to be modified, an updated Grants.gov application package must be submitted via Grants.gov as a "Changed/Corrected Application" with the previous Grants.gov Tracking ID *prior to* the application submission deadline. ***Do not password protect any files of the application package, including the Project Narrative.***	**Submit package components to eBRAP (https://ebrap.org).** **Tab 5 – Submit/Request Approval Full Application:** After all components are uploaded and prior to the full application submission deadline, enter your password in the space provided 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.***

Extramural Submissions	Intramural DOD Submissions
Application Verification Period	
The full application package submitted to Grants.gov may be viewed and modified in eBRAP until the end of the application verification period. During the application verification period, the full application package may be modified *with the exception of the Project Narrative and Research & Related Budget Form*.	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 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. 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 megabytes (MB), and the file size for the entire full application package may not exceed 200 MB.

○ **Attachment 1: Project Narrative (15-page limit): Upload as "ProjectNarrative.pdf".** The page limit of the Project Narrative applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs (uniform resource locators) that provide additional information to expand the Project Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the application.

Describe the proposed project in detail using the outline below.

– **Background:** Present the ideas and scientific rationale behind the proposed clinical research project and endpoints to be measured. Clearly demonstrate that there is sufficient scientific evidence to support the proposed research. Establish the relevance to the FY22 PRARP ADRA intent (refer to Section II.B, Award Information), clearly describing how the project will accelerate the usage of the diagnostic/prognostic/risk factor(s) to near-term clinical utility. Cite relevant literature. Describe previous experience.

– **Hypothesis/Objectives/Specific Aims:** State the hypothesis (or hypotheses) or objectives to be tested. Concisely explain the project's specific aims.

– **Rationale:** Describe the type and intended purpose and utility of diagnostic or prognostic factor(s). Describe the overall plan for access to a suitable cohort and the plan for participant accrual. Describe the suitability and diversity of the cohort or participant population in accelerating to clinical utility.

– **Project Milestones:** Concisely describe expected project milestones relevant to each of the project's technical objectives and specific aims.

– **Preliminary Data:** Provide preliminary data to support the suitability of the biomarker(s) for further testing toward biomarker qualification. Preliminary data may come from the PI's published work or pilot data. Describe the stakeholder engagement performed to support this project.

– **Research Strategy:** Describe the experimental design, methods, outcomes/ endpoints, and analyses, including appropriate controls, in sufficient detail for evaluation of their appropriateness and feasibility. Describe the statistical plan as appropriate for the proposed research. Outline whether researchers, subjects, clinicians, data analysts, and/or others will be blinded during the study. Describe any other measures to be taken to reduce bias. Address potential problem areas and present alternative methods and approaches.

- ▪ ***Full details will be required in the Clinical Research Strategy Statement (*[Attachment 9](#)*).*** This award may not be used to conduct clinical trials.

  - ▪ If prospectively recruited human anatomical samples or data will be used, include a detailed plan for the recruitment of subjects or the acquisition of samples or data. For all human anatomical sample or data projects, describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex/gender, racial, ethnic group, and other diversity measures including measures of health equity. Provide an accompanying rationale for the selection of subjects. Describe the availability of the proposed study population and past successes in recruiting similar populations. If active-duty military, military families, and/or Veteran populations or datasets will be used in the proposed research project, describe the feasibility of accessing the population(s)/dataset(s).

- – Describe the overall strategy for accelerated transfer to clinical practice (refer to [Section II.B, Award Information](#)). If applicable, describe any aspects of biomarker/risk factor validation proposed as part of the application (refer to [Section II.B, Award Information](#) for [validation definition](#)) and show the relevance of the validation to the overall project. Describe how the proposed research will demonstrate the potential of the biomarker, risk factor, or other measure for improved specificity and sensitivity with respect to diagnosis and/or prognosis of AD/ADRD. Describe how the research strategy will correlate with clinical endpoints to relevant to AD/ADRD research.

  - ▪ **Statistical Plan:** Describe the statistical model and data analysis plan with respect to the study objectives. If applicable, specify the approximate number of human subjects to be enrolled. If multiple study sites are involved, state the approximate number to be enrolled at each site. Include a complete power analysis to demonstrate that the sample size is appropriate to meet the objectives of the study and all proposed correlative studies. If a subpopulation of a recruited sample population will be used for analysis, complete a statistical analysis to ensure appropriate power can be achieved within the subpopulation study. Describe plans for the valid analysis of group differences on the basis of sex/gender, race, and/or ethnicity as appropriate for the scientific goals of the study. Ensure sufficient information is provided to allow thorough evaluation of all statistical calculations during review of the application.

  - ▪ Describe the randomization and blinding procedures for the study, and any other measures to be taken to minimize the effects of subjective bias during assessment of results. If randomization and/or blinding will not be utilized, provide justification.

  - ▪ Describe how data will be handled, including rules for stopping data collection, criteria for inclusion and exclusion of data, how outliers will be defined and handled, statistical methods for data analysis, and identification of the primary endpoint(s).

- Describe how data will be reported and how it will be assured that the documentation will support a future regulatory filing with the U.S. Food and Drug Administration (FDA) or international regulatory agency, if applicable.

○ **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.

Quad Chart: Provide a Quad Chart for the proposed project. The format for the quad chart is available on the eBRAP "Funding Opportunities & Forms" web page at https://ebrap.org/eBRAP/public/Program.htm.

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: 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): Provide a signed letter from each collaborating individual or organization that demonstrates that the PI has the support or resources necessary for the proposed work. If an investigator at an intramural organization is named as a collaborator on an application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural organization that authorizes the collaborator's involvement.

Intellectual Property: Information can be found in the 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. Address any impact of intellectual property issues on product development and subsequent government access to products supported by this program announcement."

Data and Research Resources Sharing Plan: Describe how data and resources generated during the performance of the project will be shared with the research community, including the sharing of de-identified data with data repositories. 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.

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.

    Technical abstracts should be written using the outline below. The technical abstract should provide an appropriate description of the project's key aspects; clarity and completeness within the space limits of the technical abstract are highly important. Describe the proposed research project, including the following elements:

- **Background:** Present the ideas and reasoning behind the proposed.

- **Objective/Hypothesis:** State the objective to be reached or the hypothesis to be tested. Provide evidence or rationale that supports the objective/hypothesis.

- **Specific Aims:** State the specific aims of the proposed research project.

- **Research Strategy:** Briefly describe the research strategy and experimental design.

- **Impact:** Briefly describe how the proposed research project will make important contribution(s) to AD/ADRD and/or TBI research fields, patient care, and/or quality of life

- **Relevance to Military Health:** Explain how the project is relevant to the healthcare needs of Service Members, Veterans, and/or military beneficiaries.

○ **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***. ***Do not duplicate the technical abstract.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed.

- Lay abstracts should be written using the outline below. Minimize use of acronyms and abbreviations, where appropriate. The lay abstract is an important component of the application review process because it addresses issues of particular interest to lived experience subject matter experts (consumers).

- State the [FY22 PRARP ADRA Focus Area](#) to be addressed by the proposed research.

- Describe the objectives and rationale for the proposed research in a manner that will be ***readily understood by readers without a background in science or medicine.***

○ Describe the types of patients that will be helped by the research and how it will help them.

○ Describe potential clinical applications, benefits, and risks.

○ Describe the projected timeline to achieve the expected patient-related outcome.

○ Describe the likely contributions of the proposed research project to advance knowledge, treatments, or quality of life of individuals with TBI and/or AD/ADRD/dementia.

○ Describe how the proposed project will impact the health and well-being of Service Members, Veterans, and/or military beneficiaries.

○ **Attachment 5: Statement of Work (no page limit): Upload as "SOW.pdf".** The suggested Statement of Work (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). Recommended strategies for assembling the SOW can be found at https://ebrap.org/eBRAP/public/Program.htm.

For the FY22 PRARP ADRA, refer to either the "*Suggested SOW Strategy Clinical Research*" or "*Suggested SOW Strategy Generic Research*", whichever format is most appropriate for the proposed effort, and use the blank SOW format titled "Suggested SOW Format". The SOW must be in PDF format prior to attaching.

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

– Include the name(s) of the key personnel and contact information for each study site/ subaward site. The contributions of the key personnel and collaborative research partners (e.g., LECs) should be noted for each task.

– Indicate the number (and type, if applicable) of human research subjects and/or human anatomical samples projected or required for each task and at each site.

– Allocate time within the period of performance to obtain local IRB and federal ORP approval. 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.

– Identify cell line(s) and commercial or organizational source(s) to be used.

– If applicable, indicate timelines required for regulatory approvals relevant to human subjects research.

– For FITBIR-eligible research, 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: Community Collaboration Plan (no page limit). Upload as "Collaboration.pdf".**

  – **Collaborative Research Statement (suggested three-page limit):** Include the names of at least one community partner (e.g., LEC, representative of community-based organization) who will provide advice and consultation throughout the planning and implementation of the research project. The individual's role in the project

should be independent of their employment, and they should not be employees of any of the organizations participating in the application.

- ▪ Describe the collaborative research approach that will be used (e.g., Lived Experience Consultation, partnership with community-based organization, CAB, co-researcher model) including a justification for the approach as well as when the approach will be used within the research project.

- ▪ Indicate the input from the partner that has been or will be captured and how this input will be meaningfully integrated and incorporated into the needs assessment, planning, design, execution, analysis, and dissemination of the research.

- ▪ Describe the resource allocation, decision-making, and equitable participation processes to be employed.

- ▪ Describe any training, co-learning, or capacity-building activities that will be provided to both scientific researchers and community members on collaborative research approaches, decision-making, and equitable participation.

- ▪ Describe the process measures used to assess the effectiveness of the chosen collaborative approach.

- – **Letters of Community Collaboration, (suggested two-page limit per letter):** Provide a letter signed by each community partner (e.g., LEC; representative of community-based organization) confirming their role and commitment to participate on the research team. If a community-based organization will be engaged, the letter of commitment should be signed by BOTH the organization point of contact leading the engagement and the organization's leadership endorsing the collaboration. The letter should include the qualifications and background of the individual and describe the relevance of those qualifications to the individual's role within the team and to the proposed research project.

- o **Attachment 7: Impact Statement (three-page limit): Upload as "Impact.pdf".** This attachment should be written in a manner that will be *readily understood by readers without a background in science or medicine.*

  - – *Describe the near-term impact:* Detail the anticipated outcome(s) or knowledge/materiel product(s) that will make important scientific advances and improve the understanding, prevention, and/or treatment of AD, ADRD, and/or TBI health conditions.

  - – *Describe the near-term and long-term community impact:* Explain how the research and/or outcomes will impact the fields of TBI, AD, and ADRD/dementia. Describe how a successful outcome of the proposed research will lead to or impact a practical application in individuals living with TBI and/or AD/ADRD and their communities.

  - – *Describe the long-term impact:* Explain the anticipated long-term benefits from this research in the clinic or field. Discuss how the proposed materiel or knowledge

product represents an improvement to currently available diagnostic/prognostic modalities, devices, or clinical practice guidelines, if applicable.

– *Describe potential issues* that might limit the impact of the proposed research and strategies that may be employed to overcome those issues.

○ **Attachment 8: Relevance to Military Health (three-page limit): Upload as "Military.pdf".**

– Demonstrate how the proposed research project is applicable to the healthcare needs and quality of life of military Service Members, Veterans, and/or their family members and care partners. If active-duty military, Veteran, or military family population(s) will be used in the proposed research project, describe the appropriateness of the population(s) for the proposed research, and the feasibility of using the population. If applicable, describe how the study team composition is able to provide military-relevant subject matter expertise to the proposed research. If a non-military population will be used for the proposed research project, explain how the population simulates the relevant military population.

○ **Attachment 9: Clinical Research Strategy Statement (no page limit): Upload as "Clinical.pdf".**

– Describe the study procedures and outcomes, and detail the clinical research plan. Describe how participants will benefit from the study or knowledge produced by the study, and how participation would impact their daily lives.

– **Study Population and Recruitment:** 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). Provide a table of anticipated enrollment counts at each study site, if applicable. Demonstrate and detail the research team's access and plan to recruit the proposed study population at each site, and describe the efforts that will be made to achieve accrual and retention goals. Describe how the study impacts the daily lives of participants. Explain methods for identification of potential human subjects (e.g., medical record review, obtaining sampling lists, healthcare provider identification). Furthermore, discuss past efforts in recruiting human subjects from the target population for previous clinical research, if applicable. Explain the informed consent process and steps taken to safeguard vulnerable populations (e.g., persons with dementia). Identify any potential barriers to accrual/retention and provide mitigation plans for addressing unanticipated delays (e.g., slow accrual, attrition). Identify ongoing clinical research/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 clinical research proposing to include military personnel or Veterans, refer to the General Application Instructions, Appendix 1, for more information.*

– **Inclusion/Exclusion Criteria:** List the inclusion and exclusion criteria for the proposed clinical research. Describe how the inclusion and exclusion criteria meet the needs of the proposed clinical 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.

– Provide an anticipated enrollment table(s) for the inclusion of women and minorities appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. The Public Health Service (PHS) Inclusion Enrollment Report is a three-page fillable PDF form, which can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm.

o **Attachment 10: Transition Plan (four-page limit): Upload as "Transition.pdf".**

– Applicants are encouraged to work with their organization's Technology Transfer Office (or equivalent) to develop an appropriate transition plan.

– **Describe the steps, methodologies, and strategies** proposed to facilitate the product or knowledge/informational outcomes of the project to the next phases of development and/or clinical use following the successful completion of the proposed effort.

– **Describe how the outcomes** of this translational plan benefit the end-user, how quickly they will be accelerated towards clinical applicability.

– **Describe the funding, collaboration, and resources** required to advance the project to the next logical phase of development along the translational continuum.

– **Provide a schedule with milestones** for the next translational steps.

– **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.

– If applicable, describe the overall regulatory strategy and product development plan that will support the planned product indication or product label change (if applicable). Include a description of the numbers and types of studies proposed to reach approval, licensure, or clearance, the types of FDA meetings that will be held/planned, and the submission filing strategy.

▪ If applicable, provide documentation verifying an Investigational New Drug or Investigational Device Exemption is in place or not needed, as appropriate.

- - A description of the outcomes expected upon completion of the proposed research efforts. Outcomes should be relevant, measurable, and include the intended end-user.

  - A brief schedule and milestones for bringing the outcomes to the next phase of development (e.g., further research, clinical trials, transition to industry, delivery to the market, incorporation into clinical practice, approval by the FDA).

  - **Attachment 11: 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 12: 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 1681[a] 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 (six-page limit): Upload as "Biosketch_LastName.pdf". The suggested biographical sketch format is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP. The

National Institutes of Health (NIH) 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".

  - – For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.

  - – For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.

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

  - – Biographical sketches, or an equivalent document, should also be included for community partners (e.g., LEC, representative of community-based organization), if applicable, to demonstrate background and experience relevant to their role in the proposed research project.

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

  - – For extramural submissions, refer to the General Application Instructions, Section III.A.4, for detailed information.

  - – For intramural submissions, refer to the General Application Instructions, Section IV.A.3, for detailed information.

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 12. (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. Unique Entity Identifier (UEI) and System for Award Management (SAM)

The applicant organization must be registered as an entity in SAM (https://www.sam.gov/SAM/) and receive confirmation of an "Active" status before submitting an application through Grants.gov. As published in the Federal Register, July 10, 2019, (https://www.federalregister.gov/documents/2019/07/10/2019-14665/unique-entity-id-standard-for-awards-management), the UEI for awards management generated through SAM will be used instead of the Data Universal Numbering System (DUNS) number as of April 2022. *All federal awards including, but not limited to, contracts, grants, and cooperative agreements will use the UEI.* USAMRDC will transition to use of the UEI beginning with FY22 announcements and utilize the latest SF424, which includes the UEI. The DUNS will no longer be accepted. Applicant organizations will not go to a third-party website to obtain an identifier. During the transition, your SAM registration will automatically be assigned a new UEI displayed in SAM. (For more information, visit the General Services Administration: https://www.gsa.gov/about-us/organization/federal-acquisition-service/office-of-systems-management/integrated-award-environment-iae/iae-information-kit/unique-entity-identifier-update.) Current SAM.gov registrants are assigned their UEI and can view it within SAM.gov. *Authorized Organizational Representatives with existing eBRAP accounts should update their organizational profile to include the UEI prior to submission of the full application to Grant.gov (see Section II.D.4, Submission Dates and Times below).* Refer to the General Application Instructions, Section III, for further information regarding Grants.gov requirements.

II.D.4. Submission Dates and Times

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

Applicant Verification of Full Application Submission in eBRAP

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 **$2.5M**. 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 **$2.5M** 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 PI to present project information or disseminate project results at one DOD Meeting (such as a PRARP In-Progress Review meeting, Military Health System Research Symposium, or other appropriate DOD-sponsored meeting) during the period of performance. For planning purposes, it should be assumed that the meeting will be held in year 3 of the award in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings.

May be requested for (not all-inclusive):

- Travel in support of multidisciplinary collaborations.

- Costs associated with the collaborative research approach (e.g., consultant costs, equitable participating training, capacity-building exercises).

- Data and research resource sharing costs.

- Travel costs for one investigator to travel to one scientific/technical meeting per year in addition to the required meeting described above. The intent of travel costs to scientific/ technical meetings is to present project information or disseminate project results from the FY22 PRARP ADRA.

Must not be requested for:

- Clinical trial costs

- Equipment

- Mentor salary

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 listed in decreasing order of importance:

- **Research Strategy, Feasibility, and Acceleration**

  - How well the hypothesis, objectives, specific aims, and project milestones are developed.

  - How well the application describes the ideas and scientific rationale behind the proposed clinical research project and endpoints to be measured.

  - How well the preliminary data supports the proposed clinical research and endpoints to be measured.

  - If applicable, how well the stakeholder engagement was described and used to formulate the hypothesis/objective and research strategy.

  - To what extent the experimental design, methods, outcomes/endpoints, and analyses are appropriate and feasible.

  - How well the input from the community partner(s) is meaningfully integrated and incorporated into the planning, design, execution, and dissemination of the research.

  - To what extent the project will accelerate the usage of the diagnostic/prognostic/risk factor(s) to near-term clinical utility.

  - How well the application addresses potential problem areas and presents alternative methods and approaches.

  - Whether the application includes sufficient evidence to support successful recruitment of and access to human subjects, data, and samples.

  - Whether the strategy for the inclusion of women and minorities and distribution of proposed enrollment on the basis of diversity metrics are appropriate for the proposed research.

  - Whether the research can be completed within the proposed period of performance.

- **Impact and Relevance to Military Health**

  - To what extent the anticipated outcome(s) will make important scientific advances and improve the understanding, prevention, and/or treatment of AD, ADRD, and/or TBI health conditions.

- ○ Whether the research and/or outcomes will impact the fields of TBI, AD, and ADRD/dementia.

- ○ If applicable, to what degree the proposed materiel or knowledge product represents an improvement to currently available diagnostic/prognostic modalities, devices, or clinical practice guidelines, if applicable.

- ○ How likely it is that a successful outcome of the proposed research will lead to a practical application in individuals living with TBI and/or AD/ADRD and their communities.

- ○ To what degree the study identifies potential issues that might limit the impact of the proposed research and provides strategies that may be employed to overcome those issues.

- ○ To what degree the proposed research, outcome(s), or product(s) will benefit military health.

- **Translational Potential**

  - ○ How well the application demonstrates the access to all appropriate intellectual property rights necessary for development and/or commercialization of products or technologies supported with this award and the government's ability to access such products or technologies in the future, if applicable.

  - ○ How well the application addresses any impact of intellectual property issues on product development and subsequent government access to products supported by this funding opportunity, if applicable.

  - ○ If applicable, to what extent the data and documentation support a regulatory filing with the FDA or international regulatory agency, or next stage of development.

  - ○ How the data and resources generated during the performance of the project will be shared with the research community, including the sharing of de-identified data with data repositories, are described.

- **Statistical Plan**

  - ○ To what degree the statistical model and data analysis plan are suitable for the planned study.

  - ○ How well the statistical plan, including sample size projections and power analysis, is adequate for the study and all proposed correlative studies.

  - ○ As applicable, how appropriate the randomization and blinding procedures for the study are, and how well any other measures to be taken to minimize the effects of subjective bias during the study and assessment of results are described.

- o Whether the plans for the valid analysis of group differences on the basis of sex/gender, race, and/or ethnicity are appropriate for the proposed research.

- **Research Team**

  - o To what extent the background and experience of the PI and other key personnel are appropriate to accomplish the proposed research project.

  - o To what degree the levels of effort by the PI and other key personnel are appropriate to ensure successful conduct of the proposed work.

  - o If applicable, to what extent the study team composition is able to provide military-relevant subject matter expertise to the proposed research.

  - o How well the collaborative research approach(es) and partners are appropriate and integrated into the study.

- **Ethical Considerations**

  - ○ Whether the population selected to participate in the study stands to benefit from the knowledge to be gained as a result of the proposed research.

  - ○ How well the level of risk to human subjects is minimized and how the safety monitoring and reporting is appropriate for the level of risk.

  - ○ To what degree privacy and confidentiality of study records are appropriately considered.

  - ○ To what degree the process for seeking informed consent is appropriate and whether safeguards are in place for vulnerable populations.

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.

- **Environment**

  - ○ To what degree the scientific environment and the accessibility of institutional/ organizational resources support the proposed research.

  - ○ Whether the quality and extent of institutional support are appropriate for the proposed project.

- **Application Presentation**
  - ○ To what extent the writing, clarity, and presentation of the application components influence the review.

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 Defense Health Program and FY22 PRARP, as evidenced by the following:

  - ○ Adherence to the intent of the award mechanism

  - ○ Relative impact

  - ○ Program portfolio composition

  - ○ Relevance to military health

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. *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 200.1, 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 FY22 funds are anticipated to be made no later than September 30, 2023. 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 the 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 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.A.5.

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.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 [USAMRAA 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.

New Requirement: Certification Regarding Disclosure of Funding Sources. The proposing entity must comply with Section 223(a) of the William M. (Mac) Thornberry National Defense Authorization Act for Fiscal Year 2021, which requires that the PI and all key personnel:

- Certify that the current and pending support provided on the application is current, accurate, and complete;

- Agree to update such disclosure at the request of the agency prior to the award of support and at any subsequent time the agency determines appropriate during the term of the award; and

- Have been made aware of the requirements under Section 223(a)(1) of this Act.

False, fictitious, or fraudulent statements or claims may result in criminal, civil, or administrative penalties (18 USC 1001).

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, including quad charts with each, will be required.

The Award Terms and Conditions will specify if more frequent reporting is required.

Award Expiration Transition Plan: An Award Expiration Transition Plan must be submitted with the final progress report. Use the one-page template "Award Expiration Transition Plan," available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) under the "Progress Report Formats" section. The Award Expiration Transition Plan must outline if and how the research supported by this award will progress and must include source(s) of funding, either known or pending.

PHS Inclusion Enrollment Reporting Requirement *(required for clinical research studies)*: Enrollment reporting on the basis of sex/gender, race, and/or ethnicity will be required with each annual and final progress report. The PHS Inclusion Enrollment Report is available on the "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) in eBRAP.

Awards resulting from this program announcement may entail 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 $10M 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. These 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. eBRAP 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 eBRAP 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 eBRAP 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 702b. The program announcement numeric version code will match the General Application Instructions version code 702.

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.

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 FY22 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 FY22 PRARP Programmatic Panel members can be found at https://cdmrp.army.mil/prarp/pscs/psc22.*

- 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 FY22, 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.

- A clinical trial is proposed.

- Animal research is proposed.

- Community Collaboration Plan ([Attachment 6](#)) is missing.

- The application does not include a minimum of one collaborative community partner.

- Clinical Research Strategy Statement ([Attachment 9](#)) is missing

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"	
	Community Collaboration Plan: Upload as Attachment 6 with file name "Collaboration.pdf"	
	Impact Statement: Upload as Attachment 7 with fila name "Impact.pdf"	
	Relevance to Military Health: Upload as Attachment 8 with file name "Military.pdf"	
	Clinical Research Strategy Statement: Upload as Attachment 9 with the file name "Clinical.pdf" if applicable	
	Transition Plan: Upload as Attachment 10 with the file name "Transition.pdf"	
	Representations (extramural submissions only): Upload as Attachment 11 with file name "RequiredReps.pdf"	
	Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 12 with file name "MFBudget.pdf" if applicable	
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	

Application Components	Action	Completed
	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
ADRA	Accelerating Diagnostics Research Award
ADRD	Alzheimer's Disease-Related Dementias
CAB	Community Advisory Board
CBPR	Community-Based Participatory Research
CDE	Common Data Element
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
DHHS	U.S. Department of Health and Human Services
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
LEC	Lived Experience Consultant
LOI	Letter of Intent
M	Million
MB	Megabytes
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
NINDS	National Institute of Neurological Disorders and Stroke
ORCID	Open Researcher and Contributor ID, Inc.
ORP	Office of Research Protections
PDF	Portable Document Format

PHS	Public Health Service
PI	Principal Investigator
PII	Personally Identifiable Information
PRARP	Peer Reviewed Alzheimer's Research Program
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
TBI	Traumatic Brain Injury
UDE	Unique Data Element
UEI	Unique Entity Identifier
URL	Uniform Resource Locator
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: DOD AND VA WEBSITES

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

Air Force Office of Scientific Research
https://www.wpafb.af.mil/afrl/afosr/

Air Force Research Laboratory
https://www.wpafb.af.mil/afrl

Armed Forces Radiobiology Research Institute
https://afrri.usuhs.edu/home

Combat Casualty Care Research Program
https://ccc.amedd.army.mil

Congressionally Directed Medical Research Programs
https://cdmrp.army.mil

Defense Advanced Research Projects Agency
https://www.darpa.mil/

Defense Health Agency
https://health.mil/dha

Defense Suicide Prevention Office
https://www.dspo.mil/

Defense Technical Information Center
https://www.dtic.mil

Defense Threat Reduction Agency
https://www.dtra.mil/

Military Health System Research Symposium
https://mhsrs.amedd.army.mil/SitePages/Home.aspx

Military Infectious Diseases Research Program
https://midrp.amedd.army.mil

Military Operational Medicine Research Program
https://momrp.amedd.army.mil

Naval Health Research Center
https://www.med.navy.mil/Naval-Medical-Research-Center/Naval-Health-Research-Center/

Navy Bureau of Medicine and Surgery
https://www.med.navy.mil/

Navy and Marine Corps Public Health Center
https://www.med.navy.mil/Navy-Marine-Corps-Public-Health-Center

Naval Medical Research Center
https://www.med.navy.mil/Naval-Medical-Research-Center/

Office of Naval Research
https://www.onr.navy.mil/

Office of the Under Secretary of Defense for Acquisition, Technology and Logistics
https://www.acq.osd.mil/

Psychological Health Center of Excellence
https://health.mil/Military-Health-Topics/Centers-of-Excellence/Psychological-Health-Center-of-Excellence

Telemedicine and Advanced Technology Research Center
https://www.tatrc.org/

Traumatic Brain Injury Center of Excellence
https://health.mil/Military-Health-Topics/Centers-of-Excellence/Traumatic-Brain-Injury-Center-of-Excellence

Uniformed Services University of the Health Sciences
https://www.usuhs.edu/research

U.S. Air Force 59th Medical Wing
https://www.59mdw.af.mil/

U.S. Army Aeromedical Research Laboratory
https://www.usaarl.army.mil/

U.S. Army Combat Capabilities Development Command
https://www.army.mil/ccdc

U.S. Army Institute of Surgical Research
https://usaisr.amedd.army.mil

U.S. Army Medical Materiel Development Activity
https://www.usammda.army.mil/

U.S. Army Medical Research and Development Command
https://mrdc.amedd.army.mil/

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

U.S. Army Research Institute of Environmental Medicine
https://www.usariem.army.mil/

U.S. Army Research Laboratory
https://www.arl.army.mil

U.S. Army Sharp, Ready and Resilient Directorate
https://www.armyresilience.army.mil/sharp/index.html

U.S. Department of Defense Blast Injury Research Program
https://blastinjuryresearch.amedd.army.mil/

U.S. Department of Defense Sexual Assault Prevention and Response Office
https://www.sapr.mil

U.S. Department of Veterans Affairs, Office of Research and Development
https://www.research.va.gov

U.S. Naval Research Laboratory
https://www.nrl.navy.mil

Walter Reed Army Institute of Research
https://www.wrair.army.mil

APPENDIX 3: 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.