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

Transforming Diagnosis Award

Announcement Type: Initial

Funding Opportunity Number: HT9425-23-PRARP-TDA

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), May 31, 2023
- **Application Submission Deadline:** 11:59 p.m. ET, July 10, 2023
- **End of Application Verification Period:** 5:00 p.m. ET, July 14, 2023
- **Peer Review:** September 2023
- **Programmatic Review:** December 2023

This program announcement must be read in conjunction with the General Application Instructions, version 801. The General Application Instructions document is available for downloading from the Grants.gov funding opportunity announcement by selecting the "Package" tab, clicking "Preview," and then selecting "Download Instructions."

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II. DETAILED INFORMATION ABOUT THE FUNDING OPPORTUNITY

II.A. Program Description

Applications to the Fiscal Year 2023 (FY23) 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 and mitigate the long-term consequences of traumatic brain injury (TBI) and military service as they pertain to Alzheimer's disease (AD) and AD-related dementias (ADRD). To do so, the PRARP executes a mission to support research to (1) understand the association between TBI and other military service-related risk factors and AD/ADRD, and (2) improve quality of life and reduce the burden on affected individuals and caregivers for the military, Veterans, and the public. Appropriations for the PRARP from FY11 through FY22 totaled $168 million (M). The FY23 appropriation is $15M.

Consistent with the PRARP's mission and vision, the program seeks to support transformative research on the intersection of TBI-AD/ADRD. The PRARP prioritizes efforts aimed to improve diagnosis and prognosis *now* –including methods, technologies, patient access and education, and accuracy.

There is an urgent need to prevent and reduce the risk of developing AD/ADRD, particularly following TBI and other deleterious exposures. Active-duty and former military personnel are at increased risk of developing dementia following their service. The PRARP encourages culturally competent innovation to accelerate research and interventions in the risk reduction and prevention space.

The PRARP supports research which improves the lives of people living with dementia *now*. PRARP-supported research should, with a sense of urgency, provide meaningful outcomes to support caregivers and persons with AD and ADRD. Additionally, the PRARP prioritizes a focus on partnership between those performing the research with those most impacted by these conditions.

Like millions of Americans and others around the globe, active-duty Service Members and Veterans often shoulder the additional responsibility of caring for a loved one with dementia. Unique pressures and challenges exist for active-duty Service Members as care and support partners in situations such as deployment and re-assignment, which can significantly impact a Service Member's readiness and a Veteran's health. The program prioritizes support for more research in this critical area. Much more work is needed to effectively support quality of life for both the individual living with the diagnosis and their families/care communities.

The PRARP emphasizes that the outcomes of PRARP-funded research should be applicable to all and are representative of the populations they aim to benefit. Therefore, awards supported by

the program are expected to address diversity and equity in investigator teams and study populations, including but not limited to social and structural determinants of health such as, sex, gender, ethnicity, culture, socioeconomic status, geography, and healthcare access.

The proposed research should be transformative, strive for near-term benefit and must be relevant to active-duty Service Members, Veterans, military beneficiaries, and/or the American public.

II.A.1. FY23 PRARP Transforming Diagnosis Award (TDA) Focus Area

To address the intent of the award mechanism, applications submitted to this program announcement ***must address*** the FY23 PRARP TDA **Diagnostic, Environmental, and Prognostic Factors** Focus Area. The proposed research may explore questions which include, but are not limited to, the following areas:

- Understanding how types of family recognized social behavioral changes factor into biomarkers and diagnosis of disease (e.g., biobehavioral makers)
- Accelerating technologies and methods for early and premortem diagnosis
- Validation and implementation of diagnostic and prognostic tests
- Diagnosis access challenges (such as availability, timing, low-cost options)
- Diagnostic/prognostic tests that can be administered at home to reduce patient burden
- Implementation of diagnostic/prognostic tests into the clinic and community

These areas are defined broadly, and the examples cited above are not intended to preclude or constrain other types of projects related to the TDA Focus Area. All projects submitted to this Focus Area must clearly demonstrate how the research will be culturally competent and inclusive.

II.A.2. Award History

The PRARP TDA funding opportunity is being offered for the first time in FY23.

II.B. Award Information

The TDA is intended to improve diagnosis *now*. Proposed projects must build knowledge, capacity, and research to reduce important barriers to obtaining a diagnosis, meaningful disease monitoring, and accurate prognosis. Barriers could include but are not limited to cost, patient access and education, clinical implementation, relationship to clinical outcome measures, biomarker validation, diagnosis technologies, lack of longitudinal data to inform prediction/prognosis, health equity barriers including structural and social determinants of health, and more. The investigator must clearly attune their project to provide true benefit to the intended end user – the person with dementia and their families.

Key elements of this mechanism are:

- **Near term applicability**: To meet the intent of this mechanism, applications should be focused on addressing diagnosis now. Near term, for the FY23 PRARP TDA, means acceleration within three to five years, focusing on implementation to the community as soon as possible.

- **Person-focused research**: For diagnostic/prognostic outcomes proposed by the research to be successful, those impacted by AD/ADRD need to buy into the approach. This means researchers should design their projects to focus on the people who need the outcomes most, and the best way to do this is to partner with those stakeholders. Therefore, the FY23 PRARP TDA ***requires all projects to include collaborative community partner approaches.***

  For this mechanism, there is an expectation that the investigator will host a community meeting with a facilitated discussion, to occur within the first three quarters of the period of performance that will help inform the execution of the research. This meeting should involve the intended research population and their community. The intent of this meeting is to gather feedback and input that will inform the execution of the research, optimize and refine research questions and execution therefore as well as help inform the dissemination strategy of the research outcomes.

- Prospective recruitment of study participants: To meet the intent of the mechanism, the TDA requires an element of prospective human subjects' data collection. The proposed project should leverage existing resources where possible; however, the study must ensure the advances proposed by the project aims are representative and applicable to a diverse population. Consideration of equitable, diverse inclusion of the study populations and team is essential to ensuring AD/ADRD diagnostic or prognostic solutions are of benefit to all and is a high priority for the program.

Clinical trials are not allowed; however, the FY23 TDA may use data and/or human anatomical substances from an existing clinical trial to carry out the research. Projects may include elements of biomarker discovery, but projects where the primary goal is basic biomarker discovery are ***not supported*** and ***animal research is prohibited***. Investigators with projects that contain such research should consider applying to the FY23 PRARP Transforming Research Award (HT9425-23-PRARP-TRA).

Optimizing Research Impact Through Community Collaboration: Research funded by the FY23 PRARP should be responsive to the needs of persons with AD/ADRD lived experience, family, and care provider communities. Establishment and utilization of effective and equitable collaborations and partnerships, maximizes the near-term translational and impact potential of the proposed research. For the FY23 PRARP TDA, 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/caregivers, 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.

Federal Interagency Traumatic Brain Injury Research (FITBIR) Data Sharing: The Department of Defense (DOD) requires that awardees make TBI research data generated by this award mechanism available to the research community through the FITBIR Informatics System. FITBIR guidance and policies are detailed at http://fitbir.nih.gov/.

Career Initiation and Transition PI Option (CITPO): To promote enhanced research capacity within the diagnostic/prognostic areas of the AD/ADRD field, the FY23 TDA includes an option for a CITPO Principal Investigator (PI) to partner with another investigator to jointly address a research question. The CITPO PI may be (1) an early-career researcher, at least 3 years post their terminal degree but no more than 7 years into their independent position or (2) an investigator (at any stage) who is new to the TBI/AD/ADRD field. "New to the field" is defined as having only nominal, if any, support or publications in the field. The CITPO is structured to accommodate two PIs. One PI will be identified as the Initiating PI and will be responsible for most of the administrative tasks associated with application submission. The other will be identified as a Partnering PI. Either PI can be the CITPO PI. Both PIs should contribute significantly to the development of the proposed research project, including the Project Narrative, Statement of Work (SOW), and other required components. Both PIs may have experience in similar or disparate scientific disciplines, but each PI is expected to bring distinct contributions to the application. The PIs do not need to be at the same organization. If recommended for funding, each PI will be named to an individual award to each recipient organization. For individual submission requirements for the Initiating and Partnering PI, refer to Section II.D.2, Content and Form of the Application Submission.

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 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 FY23 PRARP TDA should 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, 2024. For additional information refer to Section II.F.1, Federal Award Notices.

The CDMRP expects to allot approximately $5M to fund approximately two FY23 PRARP TDA 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 FY23 funding opportunity will be funded with FY23 funds, which will expire for use on September 30, 2029.

Research Involving Human Data, Human Anatomical Substances, Human Subjects, or Human Cadavers: All DOD-funded research involving new and ongoing research with human data, human anatomical substances, human subjects, or human cadavers must be reviewed and approved by the USAMRDC Office of Human and Animal Research Oversight (OHARO), Office of Human Research Oversight (OHRO), prior to research implementation. This administrative review requirement is in addition to the local Institutional Review Board (IRB) or Ethics Committee (EC) review. Local IRB/EC approval at the time of application submission is ***not*** required; however, local IRB/EC approval is necessary prior to OHRO review. Allow up to 3 months to complete the OHRO regulatory review and approval process following submission of ***all required and complete*** documents to the OHRO. Refer to the General Application Instructions, Appendix 1, and the OHARO web page https://mrdc.health.mil/index.cfm/collaborate/research_protections/hrpo for additional information.

As of January 20, 2020, U.S. institutions engaged in non-exempt cooperative research ***must*** rely on a single IRB to review and approve the portion of the research conducted at domestic sites in accordance with Code of Federal Regulations, Title 45, Part 46.114(b) (45 CFR 46.114[b]). If the proposed, non-exempt research involves more than one U.S.-based 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.

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 a placebo or another control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.

Studies that do not seek to measure safety, effectiveness, and/or efficacy outcome(s) of an intervention are not considered clinical trials.

Clinical research encompasses research with patient samples, data, and interaction with patients that may or may not be considered a clinical trial. ***For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research.*** Clinical research is observational in nature and includes: (1) Research that does not seek to evaluate the effects of interventions. Research conducted with human subjects (or on material of human origin such as data, tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects, but does not seek to assess the effects of an intervention, qualifies as clinical research. Patient-oriented research may include but is not limited to: (a) mechanisms of human disease, (b) diagnostic or detection studies (e.g., biomarker or imaging), (c) health disparity studies, and (d) development of new technologies.
(2) Epidemiologic and behavioral studies that do not seek to study the safety, effectiveness, and/or efficacy outcomes of an intervention. (3) Outcomes research and health services research that do not fit under the definition of clinical trial. Excluded from the definition of clinical

research are in vitro studies that utilize human tissues that cannot be linked to a living individual. ***Note:*** Studies that meet the requirements for exemption under §46.104(d)(4) of the Common Rule are not considered clinical research as defined by CDMRP. Exemption category 4 refers to secondary research for which consent is not required.

Use of DOD or Department of Veterans Affairs (VA) Resources: If the proposed research involves access to active-duty military and/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.

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 PI named by the organization on the application must be an independent investigator at any career level.

Career Initiation or Transition Partnering PI Option: Career initiation investigators must have at least 3 years research experience beyond a terminal degree but no more than 7 years within their first independent research position. Career transition investigators may be at any

level, but new to either the TBI and/or AD/ADRD fields, with nominal, if any, publications and/or support. Lapses in research time or appointments as denoted in the biographical sketch should be explained in the application.

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

The electronic Biomedical Research Application Portal (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(s), 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.

Career Initiation or Transition Partnering PI Option: The Initiating PI must complete the pre-application submission process and submit the contact information for the Partnering PI. The Partnering PI will then be notified of the pre-application submission separately by email. ***The Partnering PI must follow the link in the notification email to associate the partnering pre-application with their eBRAP account. After associating the pre-application to their eBRAP account, the Partnering PI should email the eBRAP Help Desk (help@ebrap.org) to have the desired contact information associated to their pre-application. The email should include the pre-application log number, the name of the Business Official, the name(s) of the Performing/Contracting Organization(s), and the submission-type for the pre-application (extramural or intramural).*** If not previously registered, the Partnering PI must register in eBRAP. A new pre-application based on this research project should not be initiated by the Partnering PI. Applicants are urged to complete these steps as soon as possible. If they are not completed, the Partnering PI will not be able to view and modify their application during the verification period in eBRAP. If these steps are not completed, an intramural partner will not be able to submit the Partnering PI's required full application package components to eBRAP.

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(s) or Business Official(s) 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 (for single PI applicants) or Initiating PI (for applicants submitting under the CITCO) through eBRAP (https://eBRAP.org/).

The applicant organization and associated PI(s) identified in the pre-application should be the same as those intended for the subsequent application submission. If any changes are necessary after submission of the pre-application, the applicant must contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

When starting the pre-application, applicants will be asked to select a "Mechanism Option." Applicants are responsible for selecting the appropriate option for the pre-application:

Applicant	eBRAP Mechanism Option
Single PI	No Option
Initiating PI (Career Initiation or Transition Partnering PI Option)	Partnering PI

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, including any LECs or representatives of community-based organizations involved in this project. Community collaborators should be entered under "Consumer."

  FY23 PRARP Programmatic Panel members should not be involved in any pre-application or application. For questions related to panel members and pre-applications or applications, refer to Section II.H.2.c, Withdrawal, or contact the CDMRP Help Desk at help@eBRAP.org or 301-682-5507.

  CITPO: The Initiating PI must enter the contact information for the Partnering PI in the Partnering PI section.

- **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[s] 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. Identify the FY23 PRARP TDA Focus Area under which the application will be submitted. Describe whether human subjects, human anatomical substances/data, or cadaveric tissues will be used. 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 HT9425-23-PRARP-TDA 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 HT9425-23-PRARP-TDA from eBRAP (https://ebrap.org).
Full Application Package Components	
SF424 Research & Related Application for Federal Assistance Form: Refer to the General	**Tab 1 – Summary:** Provide a summary of the application information.

Extramural Submissions	Intramural DOD Submissions
Application Instructions, Section III.A.1, for detailed 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(s) 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.

Career Initiation or Transition Partnering PI Option: In order to make separate awards to each PI, the USAMRAA requires separate full application package submissions for the Initiating PI and Partnering PI, even if the PIs are located within the same organization. Initiating and Partnering PIs will each be assigned a unique eBRAP log number. Each full application package must be submitted using the unique eBRAP log number. ***Note: All associated applications (the Initiating PI's and Partnering PI's) must be submitted by the full application submission deadline.***

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. Cite relevant literature. Establish the relevance and applicability of the proposed research and findings to the FY23 PRARP TDA intent (refer to Section II.B, Award Information), clearly describing how the project addresses the FY23 PRARP TDA Focus Area.

    - **Hypothesis/Objectives/Specific Aims:** State the hypothesis (or hypotheses) and/or objectives to be tested. Concisely explain the project's specific aims. If the proposed research project is part of a larger study, *present only tasks that this PRARP award would fund*.

    - **Rationale:** Describe how the project will ultimately improve diagnosis and accelerate understanding. Describe the suitability and representation of the cohort and how that will reduce barriers to diagnosis. Detail how this approach is person-focused, culturally competent, and appropriate for the study population.

    - **Project Milestones:** Concisely describe expected project milestones relevant to each of the project's technical objectives and specific aims and how they align to near-term applicability.

- **Preliminary Data:** Provide preliminary data to support the proposed research and endpoints to be measured. Preliminary data may come from the PI's published work or pilot data.

- **Research Strategy:** Describe the experimental design, methods, outcomes/ endpoints, and analyses, including appropriate controls, in sufficient detail for evaluation of their appropriateness and feasibility. Detail how the research strategy provides a person-centered, culturally competent approach and how the research builds to near-term implementation and utility for individuals living with dementia, their families care partners/caregivers, and communities.

    - Describe how outcomes and feedback from the community input meeting will influence the research strategy and design.

    - Describe how the research strategy and experimental design will produce outcomes ready for near-term applicability.

    - Describe all measures to reduce bias, such as descriptions of how researchers, subjects, clinicians, data analysts, and/or others will be blinded during the study and other measures.

    - Describe measures to ensure enrollment of a representative, inclusive, and diverse study population, including the distribution of women and minorities. Detail how the study population represents the beneficiaries of the research.

    - 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.

    - 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. Describe the availability of the proposed study population and past successes in recruiting similar populations. Explain how proposed clinical research might affect the daily lives of the individual human subjects participating in the study.

    - Describe accessibility, decentralization strategies, and/or other measures taken to reduce burden and increase participation.

    - Outline the process for seeking informed consent is appropriate and describe the safeguards that are in place for vulnerable populations.

    - If active-duty military, military families, and/or Veteran populations or datasets will be used in the proposed research project, detail the strategy and feasibility of accessing the population(s)/dataset(s).

    - Describe the ethical implications and considerations of the clinical research strategy, including 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 the level of risk to human subjects is minimized, what safety monitoring and reporting measures are taken for the level of risk.

- Described potential problem areas and proposed alternative approaches/methodologies.

– **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.

- **Inclusion Enrollment Report:** 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. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from IRB review) are exempt from this requirement.

- **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 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 demonstrating that the PI(s) 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 2 CFR 200.315, "Intangible Property."

  - **Intellectual and Material Property Plan (if applicable):** Provide a plan for resolving intellectual and material property issues among participating organizations.

  - **Commercialization Strategy (if applicable):** Describe the commercialization plan. The plan should include intellectual property, market size, financial analysis, strengths and weaknesses, barriers to the market, competitors, and management team. Discuss the significance of this development effort, when it can be anticipated, and the potential commercial use for the technology being developed.

  - 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.

- **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. 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.

- **Data Management Plan (two-page limit):** Describe the data management plan in accordance with Section 3.c, Enclosure 3, DoD Instruction 3200.12.

  - For Extramural Applications: Refer to General Application Instructions, Section III.A.2, Attachments Form, Attachment 2, Supporting Documentation, for more detailed information.

  - For Intramural Applications: Refer to General Application Instructions, Section IV.A.1, Application Component – Attachments, Attachment 2, Supporting Documentation, for more detailed information.

- **Relevance to Military Health (one-page limit):** Describe how the proposed project is applicable and relevant to the health, quality of life, and well-being of the military. Military is used broadly by the FY23 PRARP to include not only active-duty Service Members, but Veterans, their families, care partners, and/or other DOD beneficiaries. If applicable, describe how the study team composition provides military-relevant subject matter expertise to the proposed research. If a non-military population will be used for the proposed research project, explain how insight from this population will

help reduce the impact of TBI/AD/ADRD on the Service Member and/or their families, to protect overall mission readiness.

- **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 limit 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 and impact the addressed FY23 PRARP TDA Focus Area.

- **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). Therefore, the abstract should be written in a manner that will be ***readily understood by readers without a background in science or medicine, at or about the eighth-grade biology level.***

- State the FY23 PRARP TDA 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 at or about the eighth-grade biology level.***

- 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 (five-page limit): Upload as "SOW.pdf".** The suggested SOW format and examples specific to different types of research projects are available on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). Recommended strategies for assembling the SOW can be found at https://ebrap.org/eBRAP/public/Program.htm.

  For the FY23 PRARP TDA, refer to the "***Suggested SOW Strategy Clinical Research***" 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. Indicate quarterly enrollment targets, if prospectively enrolling human subjects.

- Allocate time within the period of performance to obtain local IRB and USAMRDC OHRO approval, and other regulatory approvals as applicable. Refer to the General Application Instructions, Appendix 1, for additional information regarding regulatory requirements.

- For FITBIR-eligible research include (a) FITBIR investigator and study registration within the first 30 days of the award, (b) sharing of draft data collection forms with FITBIR, (c) annual FITBIR data submissions

Career Initiation or Transition Partnering PI Option: ***Each PI must submit an identical copy of a jointly created SOW.***

- **Attachment 6: Community Collaboration Plan (no page limit). Upload as "Collaboration.pdf".** Refer to Section II.B for more details regarding the community collaboration requirement. This attachment should be written in a manner that will be ***readily understood by readers without a background in science or medicine.***

  - **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. Clearly detail how the community collaboration has and will continue to serve as partner(s) during the period of performance.

    - 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. Clearly detail how this best serves your community/intended user base.

    - Describe the community collaborator(s)'s connection to your study population(s) and how they are connected in that community/population.

    - Outline what and how have you integrated community collaboration in your research question/approach, needs assessment, and planning phases.

    - Describe the goals, audience, and how feedback from discussions at the required community meeting will be incorporated into the study. Describe how the conclusions and summaries will be shared with the community involved and the research community at large.

    - Indicate how the input from the community collaborator(s) will continue to be captured and how this input will be meaningfully integrated and incorporated into the 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 actives 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 describe how the qualifications and background of the individual are relevant to the individual's role within the team and to the proposed research project.

○ **Attachment 7: Impact Statement (three-page limit): Upload as "Impact.pdf".** The impact statement is considered by all reviewers on the both the peer review and programmatic review panels, and therefore should be written in a manner that will be ***readily understood by readers without a background in science or medicine at or around the eighth-grade level.*** Do not use jargon. Applications should clearly detail the short- and long-term impact of the proposed research outcomes on the intersectional TBI, and/or AD/ADRD research fields. Additionally, the application should describe the steps the research needs to progress to provide near-term impact as well as persons with dementia and/or their support network. Applications should include the following:

– How will the project address an important problem or a critical barrier to progress in the field?

– If the aims of the project are successful, how will scientific knowledge, technical capability, clinical practice, and dementia care be improved?

– If the aims of the project are successful, describe the feasibility of the timeline to meaningful implementation for the outcomes of the research?

– What immediate, near-term benefit does successful completion of this project yield for persons living with TBI and/or AD/ADRD, their families and care partners/ caregivers?

– How will near-term impact be communicated to the research and patient/care communities?

– How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

- **Attachment 8: Progression Plan (four-page limit): Upload as "Progression.pdf".** For FY23, the PRARP is requiring all applicants to prove a plan demonstrating the trajectory of the science they are proposing. Applicants should consider and identify the next logical steps to progress this research and reach the intended beneficiaries following the end of the period of performance, assuming the proposed project is successful.

  - Describe the immediate next logical step. If this step is immediately executable on diagnosis/prognosis, describe what is needed next to implement. If another research project is required, describe why this additional study is needed and whether that will bring the outcomes to stage ready to execute and implement.

  - Describe the community engagement that would be required for the next logical step.

  - Describe the timeline, with defined milestones and deliverables, needed for that next step to progress toward application and implementation of the research.

  - Describe how stakeholder input will be solicited and integrated during the progression to end user benefit. Specifically, address how you plan to integrate feedback from the AD/ADRD/TBI community in the progression of this research.

  - Describe of the scientific or technical requirements needed to advance the research findings. Include steps necessary for FDA regulatory approval, as applicable.

  - Include a description of collaborations and other resources that will be used to help progress the research to the next stage of development or clinical implementation (e.g., clinical partners, commercial partners, manufacturing partners, clinical practice guideline development/execution committees, training providers/resources).

- **Attachment 9: Partnership Statement (one-page limit): Upload as "Partnership.pdf".** ***(Attachment 9 is only applicable and required for applications submitted under the Career Initiation or Transition Partnering PI Option.)*** Describe the experience of the Initiating and Partnering PIs. Describe the contribution and the time commitment of each PI toward the proposed research project and indicate how the award will help to enhance research capacity in the TBI and/or AD/ADRD fields. Describe how the partners' combined experience will better address the research question and explain why the work should be done together rather than through separate efforts.

- **Attachment 10: 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 11: 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.

Career Initiation or Transition Partnering PI Option: Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization will submit as separate Grants.gov or eBRAP application packages. The Initiating PI should not include budget information for the Partnering PI even if they are located within the same organization. Refer to Section II.D.5, Funding Restrictions, for detailed information.

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 11. (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.

Suggested DOD Military Budget Format: A military facility collaborating in the performance of the project (but not participating as a Partnering PI) should be treated as a subaward for budget purposes. ***Note:*** Applicants should complete a separate military 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]) (Attachment 11) to show all direct and indirect costs. 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.

Application Components for the Partnering PI if applying under the Career Initiation or Transition Partnering PI Option

The Partnering PI must follow the link in the email from eBRAP and, if not registered in eBRAP, complete the registration process prior to the application submission deadline in order to associate their full application package with that of the Initiating PI.

For the Partnering PI, the Initiating PI must identify if the Partnering PI will be named on an extramural or intramural application (in accordance with the guidelines in Section II.C.1.a, Organization) and the appropriate mode of submission (Grants.gov for extramural and eBRAP for intramural). The Partnering PI must verify their contact information and mode of submission within eBRAP to ensure proper submission of their application.

The application submission process for the Partnering PI uses an abbreviated full application package that includes:

- **Extramural and Intramural Applications**

  Attachments:

  - **Attachment 5: Statement of Work (five-page limit): Upload as "SOW.pdf".** Refer to the General Application Instructions, Section III.A.2, for detailed information on completing the SOW. Each PI must submit an identical copy of a jointly created SOW. The contributions of the Initiating PI and the Partnering PI should be noted for each task.

  - **Attachment 10: Representations (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 11: Suggested Collaborating DOD Military Facility Budget Format: Upload as "MFBudget.pdf".** Refer to the General Application Instructions, Section IV.A.4, for detailed information. The costs per year should be included on the Grants.gov Research & Related Budget Form under subaward costs.

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 NIH Biographical Sketch may also be used. All biographical sketches should be submitted in the PDF format that is not editable.

- 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, refer to the General Application Instructions, Section III.A.5, and for intramural submissions, refer to the General Application Instructions, Section IV.A.4, for detailed information.

Budget Justification (no page limit): Upload as "BudgetJustification.pdf".

Initiating and Partnering PIs must each submit a budget and justification specific to their own portion of the efforts as part of their separate Grants.gov or eBRAP application packages. The Research & Related Budget for the Partnering PI should not include budget information for the Initiating PI, even if they are located within the same organization. Refer to Section II.D.5, Funding Restrictions, for detailed information.

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 General Application Instructions, Section IV.A.5, for detailed information.

- **Extramural Applications Only**

  Research & Related Subaward Budget Attachment(s) Form:

  - **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.)

  - **Intramural DOD Collaborator(s):** Complete a separate DOD military 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]), and upload to Grants.gov attachment form as Attachment 11. (Refer to the General Application Instructions, Section III.A.8, for detailed information.)

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 of April 2022, all federal awards including, but not limited to, contracts, grants, and cooperative agreements will use the UEI generated through SAM.gov.*** 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(s) 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(s) 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 (or PIs, if the application involves Partnering PIs) 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.

Single PI Option: The application's total costs (direct costs plus indirect costs) budgeted for the entire period of performance should 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.

Career Initiation or Transition Partnering PI Option: The applications' total costs budgeted for the entire period of performance in the applications of the Initiating PI and the Partnering PI should 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. Collaborating organizations

should budget associated indirect costs in accordance with each organization's negotiated rate. The combined budgeted direct costs approved by the government will not exceed **$2.5M** or use an indirect cost rate exceeding each organization's negotiated rate.

- A separate award will be made to each PI's organization.
- The PIs are expected to be partners in the research, and direct cost funding should be divided accordingly unless otherwise warranted and clearly justified.

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(s) 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.
- Costs to hold one community input meeting with facilitated discussion, to provide feedback to the research team from the community to refine the research design and strategy.

May be requested for (not all-inclusive):

- Travel in support of multidisciplinary collaborations.
- Costs associated with data and research resource sharing.
- Costs associated with the collaborative research approach (e.g., consultant costs, equitable participating training, capacity-building exercises).
- 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 FY23 PRARP TDA.
- Equipment costs may be requested but may not exceed 5% of the total budget.

Must not be requested for:

- Clinical trial costs
- Animal costs

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 and Feasibility**
    - To what extent the rationale supports a person-focused, culturally competent approach that will accelerate understanding and improve diagnosis. To what extent the rationale describes a feasible, suitable, and representative cohort that reduces barriers to diagnosis.
    - How well the preliminary data supports the proposed research and endpoints to be measured.
    - To what extent the expected project milestones are realistic and relevant to each of the project's technical objectives and specific aims and how they align to near-term applicability.
    - To what extent the experimental design, methods, outcomes/endpoints, and analyses are appropriate and feasible.
    - How well the application acknowledges potential problem areas and provides alternative methods and approaches.
    - To what extent anticipated outcomes are feasibly ready for near-term applicability.
    - How well the application plans to incorporate outcomes and feedback from the community input meeting regarding the research strategy and design.

- How well the research strategy describes measures to reduce bias.
- Whether the application includes sufficient evidence to support successful recruitment of and access to human subjects, data, and samples.
- Whether the measures to ensure enrollment of a representative, inclusive, and diverse study population, including the distribution of women and minorities are appropriate. The extent to which the study population represents the beneficiaries of the research.
- Whether the distribution of the proposed enrollment is appropriate for the proposed research.
- Whether accessibility, de-centralization strategies, and/or other measures taken to reduce burden and increase participation are appropriate.
- How well the resources and/or data generated during the performance of the project will be shared with the research, patient, and participating community.

- **Impact**
  - 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 addresses an important problem or a critical barrier to progress in the field.
  - If the aims of the project are achieved, the extent to which scientific knowledge, technical capability, clinical practice, and dementia care are improved.
  - To what extent, should the aims of the project be achieved, the timeline to implement outcomes of the research is meaningful, feasible, and realistic.
  - Whether the immediate benefits of successful completion of this project are impactful for persons living with TBI and/or AD/ADRD, their families, and their care partners/ caregivers.
  - To what extent the stated plans to communicate the impact to the research and patient/care communities is meaningful and appropriate.
- **Progression Plan**
  - The extent to which the next steps outlined in the plan realistically result in a ready to execute and implement state.
  - How well the progression plan details realistic and appropriate community engagement to support the immediate next step.
  - How well the progression plan details timelines, milestones, and deliverables of post-award progression.

- Whether the scientific and technical requirements and, regulatory steps (as applicable) are appropriate and realistic.
- How well the progression plan addresses and integrates stakeholder/community/patient input.
- Whether the description of collaboration and resources needed to provide continuity of development is realistic and appropriate for the described plan.

- **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.
  - 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**
  - To what extent the background and experience of the PI, Partnering PI (if applicable), and other key personnel are appropriate to accomplish the proposed research project.
  - To what extent the collaborative research approach(es) and partners are realistic, appropriate, and well-integrated into the study.
  - To what degree the levels of effort by the PI, Partnering PI (if applicable), and other key personnel are appropriate to ensure successful conduct of the proposed work.
  - If applicable, to what extent the study team composition provides military-relevant subject matter expertise to the proposed research.
  - **Career Initiation or Transition Partnering PI Option:** How well the partners' combined experience will better address the research question than could be achieved through separate efforts.

- **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.
  - Whether planned dissemination of the research back to the participants is described and appropriate.

- 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** (direct plus indirect) costs exceed the allowable total (direct plus indirect) costs as published in the program announcement.
  - Whether the budget is appropriate for the proposed research.
  - For the CITPO, whether the funding is equitably distributed proportional to the project and each individual's effort.
- **Environment**
  - To what extent the environment is appropriate for the proposed research project.
  - How well the research requirements are supported by the availability of and accessibility to facilities and resources.
  - To what extent the quality and level of institutional support are appropriate for the proposed research project.

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 FY23 PRARP, as evidenced by the following:
- Relative impact
- Program portfolio composition
- Adherence to the intent of the award mechanism

- Programmatic relevance to military health. Note that military is used broadly to include not only active-duty Service Members, but Veterans, their families, and other DOD beneficiaries.

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.health.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(s) 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 FY23 funds are anticipated to be made no later than September 30, 2024. 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(s) authorized to negotiate on behalf of the PI's organization(s).

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 will be evaluated on a case-by-case basis and at the discretion of the Grants Officer.

An organizational transfer of an award supporting the Initiating PI or Partnering PI will be evaluated on a case-by-case basis and only allowed 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 and the USAMRAA General Research Terms and Conditions: Addendum to the DoD R&D General Terms and Conditions for further information.

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, Partnering PI (if applicable), 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 additional and/or 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 whether 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 ***(only required for clinical research studies and clinical trials)***: 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 (closed on most U.S. federal holidays). 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 801b. The program announcement numeric version code will match the General Application Instructions version code 801.

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 FY23 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 FY23 PRARP Programmatic Panel members can be found at https://cdmrp.health.mil/prarp/panels/panels23***.

- 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 FY23, the identities of the peer review contractor and the programmatic review contractor may be found at the CDMRP website (https://cdmrp.health.mil/about/2tierRevProcess). Applications that include names of personnel from either of these companies may be administratively withdrawn.
- Personnel from applicant or collaborating organizations are found to have contacted persons involved in the review or approval process to gain protected evaluation information or to influence the evaluation process.
- Applications from extramural organizations, including non-DOD federal agencies, received through eBRAP may be withdrawn.
- Applications submitted by an intramural DOD organization may be withdrawn if the intramural organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to extramural collaborators.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The application does not address the FY23 PRARP TDA **Diagnostic, Environmental, and Prognostic Factors** Focus Area.
- 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.
- The CITPO PI(s) does not meet the eligibility criteria, if applicable.
- **CITPO:** Failure to submit all associated (Initiating and Partnering PI) applications by the deadline.

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	Single or Initiating PI Completed	Partnering PI 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 file name "Impact.pdf"		
	Progression Plan: Upload as Attachment 8 with the file name "Progression.pdf"		
	Partnership Statement: Upload as Attachment 9 with file name "Partnership.pdf" if applicable		
	Representations (extramural submissions only): Upload as Attachment 10 with file name "RequiredReps.pdf"		
	Suggested Collaborating DOD Military Facility Budget Format: Upload as Attachment 11 with		

Application Components	Action	Single or Initiating PI Completed	Partnering PI Completed
	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		
	Attach PI Previous/Current/Pending Support (Support_LastName.pdf) to the appropriate field		
	Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person to the appropriate field		
	Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person to the appropriate field		
Research & Related Budget **(extramural submissions only)**	Complete as instructed. Attach Budget Justification (BudgetJustification.pdf) to the appropriate field		
Budget **(intramural submissions only)**	Suggested DOD Military Budget Format, including justification		
Project/Performance Site Location(s) Form	Complete form as instructed		
Research & Related Subaward Budget Attachment(s) Form, if applicable	Complete form as instructed		

APPENDIX 1: ACRONYM LIST

ACOS/R&D	Associate Chief of Staff for Research and Development
AD	Alzheimer's Disease
ADRD	Alzheimer's Disease-Related Dementias
CAB	Community Advisory Board
CBPR	Community-Based Participatory Research
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CITPO	Career Initiation and Transition PI Option
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
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
IRB	Institutional Review Board
LEC	Lived Experience Consultants
LOI	Letter of Intent
M	Million
MB	Megabytes
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
OHARO	Office of Human and Animal Research Oversight (previously Office of Research Protections)
OHRO	Office of Human Research Oversight (previously Human Research Protection Office)
ORCID	Open Researcher and Contributor ID, Inc.
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
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
TDA	Transforming Diagnosis Award
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