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 Care Award

Announcement Type: Initial

Funding Opportunity Number: HT942524PRARPTrCA

Assistance Listing Number: 12.420 Military Medical Research and Development

SUBMISSION AND REVIEW DATES AND TIMES

- **Pre-Application (Letter of Intent) Submission Deadline:** 5:00 p.m. Eastern time (ET), May 22, 2024
- **Application Submission Deadline:** 11:59 p.m. ET, June 20, 2024
- **End of Application Verification Period:** 5:00 p.m. ET, June 26, 2024
- **Peer Review:** August 2024
- **Programmatic Review:** October 2024

This program announcement must be read in conjunction with the General Application Instructions, version 901. 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

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to the fiscal year 2024 (FY24) Peer Reviewed Alzheimer's Research Program (PRARP) using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The Congressionally Directed Medical Research Programs (CDMRP) at the U.S. Army Medical Research and Development Command (USAMRDC) is the program management agent for this funding opportunity. Congress initiated the PRARP in 2011 to provide support for research of high potential impact and exceptional scientific merit. Appropriations for the PRARP from FY11 through FY23 totaled $183 million (M). The FY24 appropriation is $15M.

Consistent with the PRARP's mission and vision, the program seeks to support transformative research on the intersection of traumatic brain injury (TBI) and Alzheimer's disease (AD) and related dementias (ADRD). The PRARP prioritizes efforts aimed at improving care for those living with and AD/ADRD diagnosis and their care partners and families.

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.

II.B. Award Information

The intent of the FY24 Transforming Care Award (TrCA) is to support research that provides answers and solutions in critical areas to improve quality of life, reduce caregiver burden and stress, reduce health disparities, and increase support for the individual with a diagnosis of Alzheimer's disease and related dementias (AD/ADRD), their care partner/caregiver, and/or both, as well as the impact on families and/or communities. For this mechanism, "family" is broadly defined as the family of choice and/or the family of origin. Additionally, the TrCA definition of "care" does not include medical care (such as medical interventions administered by a physician), as the care landscape extends beyond that of medical interventions to be inclusive of research into integration, education, and support.

The PRARP requires projects to ensure strategies maintain the dignity of the individual living with a dementia diagnosis and their family/care/social communities.

All applications submitted to this funding opportunity must clearly indicate how the project addresses a critical unmet need, explain how the research will be representative of the population it intends to benefit, and demonstrate cultural competence. Culturally competent research factors the cultural background and diversity of the intended beneficiaries of the research outcomes when developing research ideas, conducting research, and implementing the research findings. Cultural competency in research is critical in reducing health disparities and enhancing the quality and impact of research by ensuring inclusivity, understanding, and responsiveness to the needs of diverse populations.

The TrCA targets research that includes, but is not limited to, improvements in long-term care, quality of life, psychosocial wellness, and supporting aging-in-place, belonging, and community living for individuals, care partners, and families living with a dementia diagnosis. Studies may include, but are not limited to, topics such as considerations for dementia care that are specific to military Service Members and/or Veterans and their Families, navigating the AD/ADRD diagnosis and care path, and overcoming care partner/caregiver stress.

Projects may address knowledge gaps, interventions, strategies, technologies, and/or tools. Clinical research and clinical trials are allowed, however, clinical trials solely testing or evaluating pharmacological interventions do not meet the intent of this funding opportunity.

Key elements of this award mechanism are:

- **Person-centered research:** All applications to the FY24 PRARP TrCA should be person-centered. This mechanism is intended to provide answers and solutions in critical areas to improve quality of life, reduce burden and stress, and increase support for individuals living with a diagnosis, their families, and their care partners (hereafter referred to as Community(ies) in this Funding Opportunity). The research should have near-immediate impact on the intended beneficiaries. To facilitate success, the TrCA ***requires Community collaboration for all projects***.

- **Focus on outcomes:** The intent of the TrCA is to advance knowledge and capacity in the AD/ADRD care field. As such, applicants should clearly articulate outcomes, clearly demonstrate a pathway of feasibility, and identify realistic approaches to scaling and Community level implementation for widespread use. Additionally, applications should plan for and describe how the research will be manualized (i.e., compiled in a manual) and fed back into the research, lived experience, and care communities. See Attachment 6, Research Manual and Progression Plan.

- **Representation:** Awards supported by the PRARP are expected to address gaps in representative AD/ADRD data sets. Applicants must prioritize diversity and equity in clinical study populations including, but not limited to, social and structural determinants of health such as sex, gender, ethnicity, culture, socioeconomic status, geography, and health care access, are expected.

    - Projects supported by this mechanism must represent a non-incremental advance in the care field. Preliminary data are required. ***For this mechanism, studies utilizing animal models do not meet the intent of the mechanism and are not allowed.***

- **Milestone meeting:** The Principal Investigator (PI) will be required to present an update on progress toward accomplishing the goals of the award at a Milestone Meeting to be held in the National Capital Area during years 2-4 of the period of performance. The PI may bring up to three additional members of the research team, including their Community partner, to the meeting. The Milestone Meeting will be attended by members of the PRARP Programmatic Panel, CDMRP staff, the USAMRAA Grants/Contracts Officer, and other stakeholders.

- **Optimizing research impact through Community collaboration:** Research funded by the FY24 PRARP should be responsive to the needs of Communities in the remainder of the Funding Opportunity, maximizes the translational and impact potential of the proposed research. Establishing and utilizing effective and equitable collaborations and partnerships with members of the AD/ADRD lived experience Communities is essential to maximize the translational and impact potential of the proposed research.

  Collaborative research approaches feature shared responsibility and ownership for the research project to ensure fully integrated involvement of Community members within the research team. Collaborative research approaches such as Community-based participatory research, 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 lived 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 an AD/ADRD diagnosis, their family members, care partners, or others as appropriate.

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

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

Career Initiation or Transition (CIT) Partnership Option: The FY24 PRARP encourages applications that include meaningful and productive collaborations between two principal investigators. To promote enhanced research capacity within the AD/ADRD field, the FY24

TrCA includes an option for a CIT Principal Investigator (PI) to partner with an experienced investigator to jointly address a research question.

The CIT PI must have nominal, if any, research support in the field and may be either one of the following:

1. The **Career Initiation** PI must be an early-career researcher, at least 3 years post their terminal degree but no more than 7 years into their independent position. Both PIs may have similar or disparate expertise, but each PI is expected to bring distinct and complimentary contributions to the application.

2. The **Career Transition** PI must be an investigator (at any stage) who is new to the military health, TBI, or AD/ADRD field(s). "New to the field" is defined as having only nominal, if any, publications in the field. The other partnering investigator must have complimentary experience (as evidenced by publications) in military health, TBI, and/or AD/ADRD field(s).

The CIT 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 CIT 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 and complimentary contributions to the application. If recommended for funding, each PI will be named to an individual award within the recipient organization(s). For individual submission requirements for the Initiating and Partnering PI, refer to Section II.D.2, Content and Form of the Application Submission.

Additional Considerations:

The CDMRP encourages research on health areas and conditions that affect women uniquely, disproportionately, or differently from men, including studies analyzing sex as a biological variable. Such research should relate anticipated project findings to improvements in women's health outcomes and/or advancing knowledge for women's health.

A clinical trial is defined in the Code of Federal Regulations, Title 45, Part 46.102 (45 CFR 46.102) 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.

For the purposes of this funding opportunity, research that meets the definition of a clinical trial is distinct from clinical research. Clinical research encompasses research with human data, human specimens, and/or interaction with human subjects. Clinical research is observational in nature and includes:

(1) Research conducted with human subjects and/or material of human origin such as data, specimens, and cognitive phenomena for which an investigator (or co-investigator) does ***not*** seek to assess the safety, effectiveness, and/or efficacy outcomes of an intervention. Research meeting this definition 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 assess 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 data or specimens that cannot be linked to a living individual and meet the requirements for exemption under §46.104(d)(4) of the Common Rule.

The types of awards made under the program announcement will be cooperative agreements (31 USC 6305) based on anticipated "substantial involvement" on the part of CDMRP. Substantial involvement includes assistance, guidance, coordination, and/or participation by CDMRP staff in project activities, including but not limited to, Milestone Meetings wherein recommendations for continued funding will be made based on overall study progress.

The anticipated total costs budgeted for the entire period of performance for an FY24 PRARP TrCA should not exceed **$1.4M** for the option without the CIT and **$1.6M** for the CIT. Refer to Section II.D.5, Funding Restrictions, for detailed funding information.

Awards supported with FY24 funds will be made no later than September 30, 2025.

The CDMRP expects to allot approximately $4.4M to fund approximately three Transforming Care Award applications. Funding of applications received is contingent upon the availability of federal funds for this program, the number of applications received, the quality and merit of the applications as evaluated by peer 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 FY24 funding opportunity will be funded with FY24 funds, which will expire for use on September 30, 2030.

II.C. Eligibility Information

II.C.1. Eligible Applicants

II.C.1.a. Organization

Extramural and Intramural organizations are eligible to apply, including foreign or domestic organizations, for-profit and non-profit organizations, and public entities.

Extramural Organization: An eligible non-Department of Defense (DOD) organization. Examples of extramural organizations include academic institutions, biotechnology companies, foundations, federal government organizations other than the DOD (i.e., intragovernmental organizations), and research institutes.

Intramural DOD Organization: Refers specifically to DOD organizations including DOD laboratories, DOD military treatment facilities, and/or DOD activities embedded within a civilian medical center.

Awards are made to eligible ***organizations***, not to individuals. Refer to the General Application Instructions, Appendix 1, for additional recipient qualification requirements.

II.C.1.b. Principal Investigator

Independent investigators at all career levels may be named by the organization as the PI on the application.

Career Initiation or Transition Partnering PI Option: At least one investigator must meet the CIT eligibility requirements to be eligible for this 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 with only nominal, if any, research support or publications in the field. Lapses in research time or appointments as denoted in the biographical sketch should be explained in the application. **Career transition** investigators may be any level, but new to military health, TBI, and/or AD/ADRD fields, with nominal, if any, publications/research support for their intended field.

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

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 to fulfill the financial and technical deliverable requirements of the award and submit invoices for payment.

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

II.D. Application and Submission Information

II.D.1. Location of Application Package

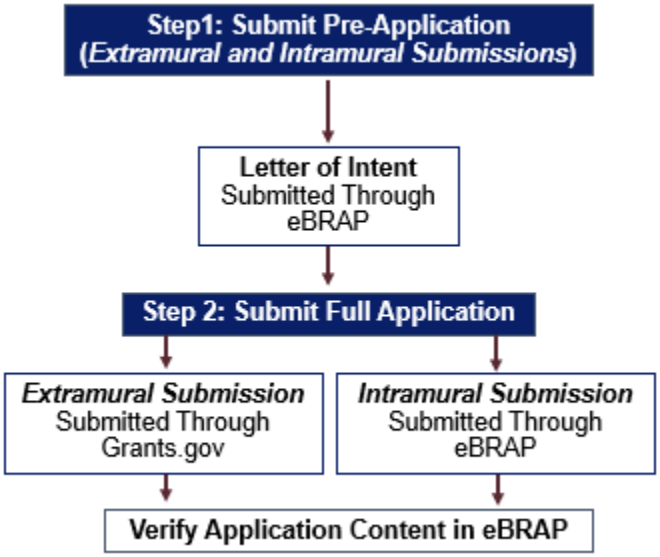
Submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP.org) and a ***full application*** (eBRAP.org or

Grants.gov). Depending on the type of submission (i.e., extramural vs. intramural), certain aspects of the submission process will differ.

The CDMRP uses two portal systems to accept pre- and full application submissions.

eBRAP (https://ebrap.org) is a secure web-based system that allows PIs and/or organizational representatives from both extra- and intramural organizations to receive communications from the CDMRP and submit their pre-applications. Additionally, eBRAP allows extramural applicants to view and verify full applications submitted to Grants.gov and allows intramural DOD applicants to submit and verify full applications following their pre-application submission.

Grants.gov (https://grants.gov) is a federal system that must be used by funding agencies to announce extramural grant applications. Full applications for CDMRP funding opportunities can only be submitted to Grants.gov after submission of a pre-application through eBRAP.



Extramural Submission: An application submitted by an extramural organization for an extramural or intramural PI working within an extramural or intramural organization. For example, a research foundation submitting an application for a DOD employee working within a DOD organization would be considered an extramural submission and should follow instructions specific to extramural submissions.) Download application package components for HT942524PRARPTrCA from Grants.gov (https://grants.gov). Full applications from extramural organizations ***must*** be submitted through Grants.gov.

Intramural Submission: An application submitted by an intramural DOD organization for an investigator employed by that organization. Intramural DOD organizations may submit full applications to either eBRAP or Grants.gov. Download application package components for HT942524PRARPTrCA from the anticipated submission portal eBRAP (https://ebrap.org) or Grants.gov.

The submission process should be started early to avoid missing deadlines. Regardless of submission type or portal used, all pre- and full application components must be submitted by the deadlines stipulated on the first page of this program announcement. There are no grace periods for deadlines; failure to meet submission deadlines will result in application rejection. ***The USAMRAA cannot make allowances/exceptions for submission problems encountered by the applicant organization using system-to-system interfaces with Grants.gov.***

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

Submitting applications that 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).

Unnecessary duplication of funding or accepting funding from more than one source for the same research, is prohibited. See CDMRP's full position on research duplication at https://cdmrp.health.mil/funding/researchDup.

Including classified research data within the application and/or proposing research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns, may result in application withdrawal. Refer to the General Application Instructions, Appendix 7, Section B.

FY24 PRARP Programmatic Panel members should not be involved in any pre-application or full application. For questions related to panel members and pre-applications or applications, refer to Section II.H.2.c, Withdrawal, or contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507.

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

All pre-application components must be submitted by the PI or Initiating PI through eBRAP (https://eBRAP.org/), including the submission of contact information for the Partnering PI if exercising the **Career Initiation or Transition Partnering PI Option**.

During the pre-application process, eBRAP assigns each submission a unique log number. This unique log number is required during the full application submission process. The eBRAP log number, application title, and all information for each PI, the Business Official(s), performing organization(s), and contracting organization(s) 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: After the Initiating PI confirms submission of the pre-application, the Partnering PI will be notified of the pre-application submission via an email from eBRAP. ***The Partnering PI must follow the link in the notification email to associate the partnering pre-application with their eBRAP account.*** If not previously registered, the Partnering PI must register in eBRAP.

After associating the pre-application with their eBRAP account, the Partnering PI should email the eBRAP Help Desk (help@ebrap.org) to have the desired contact information associated with 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).

Partnering PIs should not initiate a new pre-application based on the same research project submitted by the Initiating PI. Partnering PIs 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 full application during the verification period in eBRAP.
- Any intramural Partnering PI will not be able to submit their full application package components to eBRAP.

When starting the pre-application, applicants will be asked to select a "Mechanism Option". Please be sure to select the correct option appropriate to your pre-application:

Application Includes:	Select Option:
Single PI	No Option
Initiating PI (Career Initiation or Transition Partnering PI Option)	Partnering PI

II.D.2.a.i. Pre-Application Components

Pre-application submissions must include the following components (refer to the General Application Instructions, Section III.B, for detailed instructions regarding pre-application submission):

- **Letter of Intent (LOI) (one-page limit):** Provide a brief description of the research to be conducted, including the topic and approach. Indicate if human study participants, biospecimens, or data will be included. If the study is a clinical trial, provide a brief description of the intervention. **Briefly describe the Community collaboration including names of individuals participating.**

  LOIs are used for program planning purposes only (e.g., reviewer recruitment) and will not be reviewed during either the peer or programmatic review. ***An invitation to submit a full application is NOT provided after LOI submission. Applicants are encouraged to develop pre-application and full application components concurrently and submit a full application AFTER successful submission of the pre-application.***

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

II.D.2.b.i. Full Application Submission Type

Extramural Submissions: Full applications from extramural organizations ***must*** be submitted through Grants.gov Workspace. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application Instructions, Section IV, for considerations and detailed instructions regarding extramural full application submission.

Intramural Submissions: Intramural DOD organizations may submit full applications through either eBRAP or Grants.gov. There is no preference from the CDMRP for which submission portal is utilized; submission through one portal or the other does not provide the application any advantage during the review process. Intramural DOD organizations that choose to submit through Grants.gov should follow Extramural Submission instructions. Intramural DOD organizations that are unable to submit through Grants.gov should submit through eBRAP. For the remainder of this program announcement, it will be assumed intramural DOD submissions will proceed through eBRAP. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding intramural DOD full application submission.

II.D.2.b.ii. Full Application Submission Components for the PI or Initiating PI

Career Initiation or Transition Partnership Option: The CDMRP requires separate full application package submissions for the Initiating PI and Partnering PI, even if the PIs are located within the same organization. Each full application package must be submitted using the unique eBRAP log number received by the Initiating and Partnering PIs during pre-application submission. ***All associated applications (the Initiating PI's and the Partnering PI's) must be submitted by the full application submission deadline.***

Each application submission must include the completed full application package for this program announcement. See Section II.H.3, Full Application Submission Checklist, of this program announcement for a checklist of the required application components.

(a) SF424 Research & Related Application for Federal Assistance Form *(Extramural Submissions Only)*: Refer to the General Application Instructions, Section IV.B, for detailed information.

(b) 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 2.

- **Attachment 1: Project Narrative (12-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 that expands 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/Rationale:** Present the ideas and scientific rationale behind the proposed research project. Cite relevant literature and demonstrate how this research leverages existing knowledge. Indicate the health disparity(ies) the project addresses, if applicable. Demonstrate how this research represents a non-incremental advance upon the existing knowledge.

- **Specific Aims/Objectives:** Clearly and concisely explain the project's specific aims and objectives. If the proposed research project is part of a larger study, *present only tasks that this PRARP award would fund*.

- **Preliminary Data:** Clearly demonstrate that there is sufficient evidence to support the proposed stage of research. 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 and Feasibility:** Describe the research strategy, study design, methods, 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 capacity to transform care for individuals living with dementia, their families care partners/caregivers, and communities.

    - As applicable, describe the person-centric intervention that provides answers and solutions in critical areas to improve quality of life, care, reduce burden and stress, and increase support for individuals living with a diagnosis and their care partners.

    - 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.

    - Detail measures to ensure enrollment of an appropriate, representative, and inclusive study population, including the equitable distribution of women and minorities. Explain how the study team will address health inequity in study populations including, but not limited to, social and structural determinants of health such as sex, gender, ethnicity, culture, socioeconomic status, geography, and health care access.

    - Include a detailed plan for any prospective recruitment for human biospecimens and/or data, as applicable.

    - If applicable, specify the approximate number of study participants 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 and/or clinical trial(s) might affect the daily lives of the individual participants during their time in the study.

- Describe accessibility, decentralization strategies including virtual elements/tools for participant recruitment/enrollment, intervention administration/delivery, and/or outcome data acquisition, and/or other measures taken to reduce burden and increase participation.

- Outline the process for seeking informed consent and describe what safeguards 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 any required data sharing, memorandum of understanding, or other agreements required to access and publish data. A letter confirming support or access is required in Attachment 2, Supporting Documentation.

- Describe the ethical implications and considerations of the clinical research and/or clinical trial 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 study participants is minimized, what safety monitoring and reporting measures are taken for the level of risk.

- Describe potential problem areas and provide alternative methods and approaches.

- **Statistical Plan and Data Analysis:** Describe the statistical model and data analysis plan with respect to the study objectives. 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.

  - Describe plans for the valid analysis of group differences 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.

- **Attachment 2: Supporting Documentation: Combine and upload as a single file named "Support.pdf".** Start each document on a new page. 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.

- **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols.

- **Facilities, Existing Equipment, and Other Resources (two-page limit is recommended):** 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.

- **Inclusion Enrollment Plan:** Provide an anticipated enrollment table(s) for the inclusion of women and minorities using the Public Health Service (PHS) Inclusion Enrollment Report, a three-page fillable PDF form, that can be downloaded from eBRAP at https://ebrap.org/eBRAP/public/Program.htm. The enrollment table(s) should be appropriate to the objectives of the study with the proposed enrollment distributed on the basis of sex/gender, race, and ethnicity. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, gender, ethnicity, or race (typically classified as exempt from Institutional Review Board [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.

- **DOD Data Management Plan (two-page limit is recommended):** Describe the data management plan in accordance with Section 3.c, Enclosure 3, DoD Instructions 3200.12. ***Do not duplicate the Data and Research Resources Sharing Plan.*** Refer to General Application Instructions, Section IV.B, Attachments Form, Attachment: Supporting Documentation, for detailed information regarding Data Management Plan content. Include details on 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).

- **Data and Research Resources Sharing Plan (one-page limit is recommended):** Describe the type of data or research resource to be made publicly available as a result of the proposed work. Describe how data and resources generated during the performance of the project will be shared with the research Community. Include the name of the repository(ies) where scientific data and resources arising from the

project will be archived, if applicable. If a public repository will not be used for data or resource sharing, provide justification. Provide a milestone plan for data/results dissemination including when data and resources will be made available to other users, including dissemination activities with a particular focus on feeding back the data to affected communities and/or research participants. Refer to CDMRP's Policy on Data & Resource Sharing located on the eBRAP "Funding Opportunities & Forms" web page https://ebrap.org/eBRAP/public/Program.htm for more information about CDMRP's expectations for making data and research resources publicly.

- **Letters of Organizational Support (one-page limit per letter is recommended):** 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) (one-page limit per letter is recommended):** Provide a signed letter from each collaborating individual and/or organization demonstrating that the PI has the support and resources necessary for the proposed work. If an investigator at an intramural DOD organization is named as a collaborator on a full application submitted through an extramural organization, the application must include a letter from the collaborator's Commander or Commanding Officer at the intramural DOD organization authorizing the collaborator's involvement.

- **Use of DOD/U.S. Department of Veterans Affairs (VA) Resources *(if applicable)*:** Provide a signed letter of support confirming access for the entire period of performance to active-duty military population, VA patients, and/or VA/DOD resources, databases, or research space. Provide any additional details regarding data sharing or other agreements needed here.

- **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.*** 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. Clarity and completeness within the space limits are highly important.

  - **Background:** Concisely state the evidence and rationale behind the proposed research project.

  - **Objective(s):** State the objective(s) of the study.

  - **Specific Aims:** State the specific aims of the study.

- **Study Design:** Describe the person-centered study design, including appropriate controls.

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

- **Attachment 4: Lay Abstract (one-page limit): Upload as "LayAbs.pdf".** The lay abstract is used by all reviewers, and addresses issues of particular interest to the affected Community. ***Abstracts of all funded research projects will be posted publicly.*** Use only characters available on a standard QWERTY keyboard. Spell out all Greek letters, other non-English letters, and symbols. Graphics are not allowed. ***Do not duplicate the technical abstract.***

  Lay abstracts should address the points outlined below. 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). It is important that the abstract be written in a manner that will be ***readily understood by the general public, especially those without a background in science or medicine.***

  - Summarize the objectives and rationale for the proposed research.

  - What population will the research help, and how will it help them? Include details on accessibility and access.

  - What are the potential applications, benefits, and risks of the anticipated outcomes?

  - What are the likely contributions of the proposed research project to advancing AD/ADRD/TBI research, dementia care, and/or quality of life?

- **Attachment 5: Statement of Work (five-page limit): Upload as "SOW.pdf".** Refer to the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm) for the suggested SOW format and recommended strategies for assembling the SOW.

  Use the "Suggested SOW Format" to develop the SOW for the proposed research. Submit as a PDF.

  - 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. The contributions of the Initiating PI and the Partnering PI should be noted for each task.***

- **Attachment 6: Research Manual and Progression Plan (five-page limit is recommended). Upload as "Manual.pdf".**

- Describe the framework to *manualize,* i.e., compile a manual of the steps taken during the research project that will be completed **during the period of performance**. This should contain information to enable another party to adapt and expand the research with fidelity.

- Explain what resources are needed to *initiate* the research for the proposed project, and the timelines involved to ramp up.

- Describe, briefly, how the Community collaboration approach used within the research project will be adjusted to ensure meaningful incorporation into the research design, execution, and dissemination at any scale. Explain how this serves the Community/intended user base.

- Describe how the outcomes, resources and/or data generated during the performance of the project will build knowledge, increase capacity, and be shared the research, patient, and participating Community.

- Describe the approaches that will be utilized to scale and implement at the Community level, to facilitate widespread use, by the end of the period of performance. If another step is required, identify *the next immediate logical steps following the period of performance and describe the* ***research progression***.

    a. For the next immediate logical steps following the period of performance, describe the timeline needed, with defined milestones, for that next step to progress toward application and implementation of the research. If another research project is required, describe why this additional study is needed and whether that will produce outcomes ready to execute and implement.

    b. Describe how the bidirectional feedback and dissemination from the AD/ADRD/TBI Community will be integrated into the progression of this research.

    c. Describe the scientific, technical, and/or regulatory requirements needed to advance the research findings. Include steps necessary for regulatory approval, as applicable.

    d. Describe collaborations and other resources that will be used to help progress the continuity of 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). Include considerations of intellectual property and commercialization plans, as applicable here.

- **Attachment 7: Community Collaboration Plan *(required)*: Combine and upload as a single file named "Collaboration.pdf".** Refer to Section II.B, Award Information, for more details regarding the Community collaboration requirement. This attachment must be written in a manner that will be ***readily understood by the general public, especially those without a background in science or medicine.***

- **Collaborative Research Statement (three-page limit is recommended):** Describe the collaborative research approach that will be used (e.g., LECs, partnership with Community-based organization, CAB, co-researcher model). Detail when and how the approach will be used within the research project, how input will be meaningfully incorporated into the research design, execution, and dissemination, and explain how this best serves the Community/intended user base.

  - Name the individuals(s) participating and describe how the Community collaborator(s) are connected to the study population(s).

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

- **Letters of Community Collaboration (suggested two-page limit per letter):** Provide a letter signed by each Community partner 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 mention why the qualifications and background of the individual will benefit the proposed research project.

- **Attachment 8: Representative, Inclusive Research Plan (two-page limit). Upload as "Inclusion.pdf."** Detail measures the study team will undertake to ensure enrollment of an appropriate, representative, and inclusive study population, including the equitable distribution of women and minorities. Explain how the study team will address current health inequities in their study populations including, but not limited to, social and structural determinants of health such as sex, gender, ethnicity, culture, socioeconomic status, geography, and health care access. Discuss how the project could, whether in the short term or long term, lead to significant reduction or elimination of the disproportionate effects of AD/ADRD on specific populations, such as women and minority groups. Provide an anticipated enrollment table(s) with the proposed enrollment distributed on the basis of sex/gender, race, and/or ethnicity in Attachment 2, Supporting Documentation, using the Inclusion Enrollment Report form.

- **Attachment 9: Impact Statement (two-page limit): Upload as "Impact.pdf".** The Impact Statement is considered by all reviewers on both the peer and programmatic review panels and therefore must be written in a manner that will be ***readily understood by the general public, especially those 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 **as though the proposed project is successful in all its aims**. Applications should include the following:

- How does the project address an impactful advance to critical barriers to care? How does this result in change?

- How and when will scientific knowledge, technical capability, clinical practice, and/or dementia care be improved and communicated to the research and lived experience communities?

- What are the immediate and potential long-term benefits of successful completion of this project? What benefits does the project yield for persons living with TBI and/or AD/ADRD diagnosis(es), their families and care partners? How are these benefits measurable, realistic, and of ultimate value overall?

- What are the potential issues that might limit or lessen the impact of the proposed research, and what strategies could overcome those issues?

- **Attachment 10: 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 11: 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 8, Section B, Representations.

- **Attachment 12: Suggested Intragovernmental/Intramural Budget Form *(if applicable)*: Upload as "IGBudget.pdf".** If an intramural DOD organization will be a collaborator in performance of the project, complete a separate budget using the "Suggested Intragovernmental/Intramural Budget Form", available for download on the eBRAP "Funding Opportunities & Forms" web page (https://ebrap.org/eBRAP/public/Program.htm). The budget should cover the entire period of performance for each intramural DOD site and include a budget justification as instructed. The ***total*** costs per year for each subaward (direct and indirect costs) should be included on the Grants.gov Research & Related Budget Form under subaward costs. Refer to the General Application Instructions, Section V.A.(e), for additional information and considerations.

(c) Research & Related Personal Data: For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed instructions.

(d) Research & Related Senior/Key Person Profile (Expanded): For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural

submissions, refer to the General Application Instructions, Section V.A.(d), for detailed instructions.

- **PI Biographical Sketch (five-page limit):** Upload as "Biosketch_LastName.pdf".
- **PI Previous/Current/Pending Support (no page limit):** Upload as "Support_LastName.pdf".
- **Career Initiation or Transition Partnering PI:** If the CIT PI is the *Initiating PI*, explain how their level of research support and/or publications supports their eligibility.
- **Key Personnel Biographical Sketches (five-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".

(e) Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed instructions.

- **Budget Justification (no page limit):** For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Section L, for instructions. For intramural submissions, refer to General Application Instructions, Section V.A.(e), Budget Justification Instructions.

Initiating and Partnering PIs must have a separate budget and justification specific to their distinct portions of the effort that the applicant organization(s) 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.***

(f) Project/Performance Site Location(s) Form: For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to the General Application Instructions, Section V.A.(f), for detailed instructions.

(g) Research & Related Subaward Budget Attachment(s) Form *(if applicable, Extramural Submissions Only)*: Refer to the General Application Instructions, Section IV.B.(g), for detailed instructions.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload through Grants.gov.

- **Intramural DOD Subaward:** Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled **IGBudget.pdf** to Grants.gov as Attachment 11.

II.D.2.b.iii. Full Application Submission Components for the Partnering PI

The application submission process for the Partnering PI uses an abbreviated full application package. Refer to the equivalent attachment above for details specific to each of the following application components.

(a) SF424 Research & Related Application for Federal Assistance Form *(Extramural Submissions Only)*: Refer to the General Application Instructions, Section IV.B.(a), for detailed information.

(b) Attachments:

- **Attachment 5: Statement of Work (three-page limit): Upload as "SOW.pdf".** Each PI must submit an identical copy of a jointly created SOW.

- **Attachment 11: Representations *(Extramural submissions only)*: Upload as "RequiredReps.pdf".**

- **Attachment 12: Suggested Intragovernmental/Intramural Budget Form: Upload as "IGBudget.pdf".**

(c) Research & Related Personal Data: For extramural submissions, refer to the General Application Instructions, Section IV.B.(c), and for intramural submissions, refer to the General Application Instructions, Section V.A.(c), for detailed information.

(d) Research & Related Senior/Key Person Profile (Expanded): For extramural submissions, refer to the General Application Instructions, Section IV.B.(d), and for intramural submissions, refer to the General Application Instructions, Section V.A.(d), for detailed information.

- **PI Biographical Sketch (five-page limit):** Upload as "Biosketch_LastName.pdf".

- **Career Initiation or Transition Partnering PI:** If the CIT PI is the *Partnering PI*, explain how their level of research support and/or number of publications supports their eligibility.

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

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

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

(e) Research & Related Budget: For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), for detailed information.

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

The Initiating and Partnering PI(s) 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.

(f) Project/Performance Site Location(s) Form: For extramural submissions, refer to the General Application Instructions, Section IV.B.(f), and for intramural submissions, refer to General Application Instructions, Section V.A.(f), for detailed information.

(g) Research & Related Subaward Budget Attachment(s) Form *(if applicable, Extramural Submissions Only)*: Refer to the General Application Instructions, Section IV.B.(g), for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form through Grants.gov.

- **Intramural DOD Subaward:** Complete the "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward and upload as a single document titled IGBudget.pdf to Grants.gov as Attachment 14.

II.D.2.c. Applicant Verification of Full Application Submission in eBRAP

Independent of submission type, once the full application is submitted it is transmitted to and processed in eBRAP. At this stage, the PI and organizational representatives will receive an email from eBRAP instructing them to log into eBRAP to review, modify, and verify the full application submission. Verification is strongly recommended but not required. eBRAP will validate full application files against the specific program announcement requirements, and discrepancies will be noted in the "Full Application Files" tab in eBRAP. However, eBRAP does not confirm the accuracy of file content. It is the applicant's responsibility to review all application components and ensure proper ordering as specified in the program announcement. ***The Project Narrative and Research & Related Budget Form cannot be changed after the application submission deadline. 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 full application submission deadline.*** Other application components, including subaward budget(s) and subaward budget justification(s), may be changed until the end of the application verification period. The full application cannot be modified once the application verification period ends.

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/content/home) and receive confirmation of an "Active" status before submitting an application through Grants.gov. Organizations must include the UEI generated by SAM in applications to this funding opportunity.

II.D.4. Submission Dates and Times

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.

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

II.D.5. Funding Restrictions

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

The application's total costs budgeted for the entire period of performance should not exceed **$1.4M** (Single PI). 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.

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

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 **$1.6M**. 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.

- 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.
- Any application that requests the higher level of funding and that does not include a Partnering PI will have its budget reduced as appropriate.

The applicant(s) 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) and up to three members of their team to travel to an annual PRARP milestone meeting or DOD meeting. Travel costs for a Community partner must be

included. For planning purposes, it should be assumed that the meeting will be held in years 2, 3, and 4 of the period of performance in the National Capital Area. These travel costs are in addition to those allowed for annual scientific/technical meetings and the DOD meeting.

May be requested for (not all-inclusive):

- Travel in support of multi-institutional collaborations.
- Costs associated with data and research resource sharing.
- Costs associated with the Community collaborative research approach (e.g., consultant costs, equitable participating training, capacity-building exercises).
- Costs associated with participation in the study.
- Costs for one investigator to travel to one scientific/technical meeting per year in addition to the required meetings described above. The intent of travel costs to scientific/technical meetings is to present project information or disseminate project results from the FY24 PRARP TrCA.
- Clinical trial costs

Must not be requested for:

- Costs for travel to scientific/technical meeting(s) beyond the limits stated above.
- Animal costs

II.D.6. Other Submission Requirements

Refer to the General Application Instructions, Appendix 2, 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 individually evaluated according to the following **scored criteria**, which are listed in *decreasing order of importance*:

- **Impact**
    - Does this project address an impactful advance to critical barriers to care?
    - If the aims of the project are achieved, to what extent will scientific knowledge, technical capability, clinical practice, and dementia care be improved?

- If the aims of the project are achieved, to what extent are the scientific knowledge, technical capability, clinical practice, and dementia care improved and communicated in a timely manner?

- To what extent are the immediate and long-term benefits of successful completion of this project impactful for persons living with TBI and/or AD/ADRD diagnosis(es), their families, and their care partners/caregivers? How realistic and valuable are these benefits overall?

- **Research Strategy and Feasibility**

  - To what extent the research strategy, methods, and analyses are appropriate and feasible, and whether the application includes sufficient evidence to support successful access to and recruitment of study participants, data, and/or samples.

  - To what extent the research strategy provides a person-centered, culturally competent and representative approach to non-incremental research.

  - Whether the representation, inclusivity, diversity and distribution of the proposed enrollment, including distribution of women and minorities is appropriate for the proposed research.

  - 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 accessibility, de-centralization strategies, and/or other measures taken to reduce burden and increase participation are appropriate.

  - How well the scientific rationale, relevant literature, preliminary and/or published data support the feasibility of the research project.

  - How well the application acknowledges potential problem areas and provides alternative methods and approaches.

  - To what extent the statistical plan, including sample size projections and power analysis, is appropriate to meet the objectives of the study and all proposed correlative studies.

  - Whether the plans for the valid analysis of group differences on the basis of demographics are appropriate for the proposed research.

- **Research Manual**

  - Whether the resources needed to initiate the research and timelines 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 Communities.

- Whether the Community collaboration approach used within the research project is appropriate and adjustable. How well Community input is meaningfully incorporated into the research design, execution, and dissemination to allow for scaling, and how well it serves the Community/intended user base.

- To what extent anticipated outcomes to be completed during the period of performance build capacity to transform care for individuals living with dementia, their families, care partners/caregivers, and communities.

- Whether the described approaches to manualize (i.e., compile a manual), scale, and implement at the Community level during the period of performance are sufficient to facilitate widespread use.

- **Research Progression**

  - Whether the progression plan realistically details the plan required for the immediate next logical step of the research.

  - How well the progression plan realistically details timelines for the next step and integrates feedback from the AD/ADRD/TBI Community.

  - Whether the scientific, technical, and regulatory (as applicable) requirements described are appropriate and achievable.

  - How well the progression plan incorporates collaboration, intellectual property, and commercialization needs, and resources, as applicable, that will be used to provide continuity of research to the next stage of development.

- **Ethical Considerations**

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

  - How the level of risk to study participants is minimized and how the safety monitoring and reporting are appropriate for the level of risk.

  - To what extent the proposed clinical research might affect the daily lives of the individuals participating in the study.

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

- **Research Team**

  - To what extent the background, experience, and effort of the Community collaborative research partner(s) are appropriate to support the proposed research study.

  - How well the Community partner is integrated into the study.

- To what extent the background, experience, and levels of effort of the PI, Partnering PI (if applicable), and other key personnel are appropriate to accomplish the proposed research project.

- **Career Initiation or Transition Partnering PI Option:** How well the partners' combined experience and expertise will better address the research question than could be achieved through separate efforts, and how the partnership will build research capacity in the field by developing new or transitioning PIs.

In addition, the following criteria will also contribute to the overall evaluation of the application, but will not be individually scored and are therefore termed **unscored criteria**:

- **Budget**

  - Whether the **total** costs exceed the allowable total costs as published in the program announcement.

  - Whether the budget is appropriate for the proposed research.

  - **Career Initiation or Transition Partnering PI Option:** 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 and accessibility to facilities and resources.

  - To what extent the quality and level of institutional support are appropriate for the proposed research project.

- **Application Presentation**

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

II.E.1.b. Programmatic Review

To make funding recommendations and select the application(s) that, individually or collectively, will best achieve the program objectives, the following criteria are used by programmatic reviewers:

- Ratings and evaluations of the peer reviewers

- Relevance to the priorities of the Defense Health Program and FY24 PRARP, as evidenced by the following:

  - Relative impact

- Program portfolio balance
- Adherence to the intent of the funding opportunity
- Benefit to end users, including military. 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.

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 review panel. Violations of confidentiality can result in the dissolution 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 a 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 SAM.

An applicant organization may review SAM and submit comments on any information currently available about the organization that a federal awarding agency previously entered. 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.F. Federal Award Administration Information

II.F.1. Federal Award Notices

Each applicant organization and PI will receive email notification when the funding recommendations are posted to eBRAP. At this time, each PI will receive a peer review summary statement on the strengths and weaknesses of the application and an information paper describing the funding recommendation and review process for the PRARP award mechanisms. The information papers and a list of organizations and PIs recommended for funding are also posted on the program's page within the CDMRP website.

If an application is recommended for funding, after the email notification is posted to eBRAP, a government representative will contact the person authorized to negotiate on behalf of the recipient organization.

Only an appointed USAMRAA Grants Officer may obligate the government to the expenditure of funds to an extramural organization. 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 (i.e., assistance agreement).***

Intra-DOD obligations of funding will be made according to the terms of a negotiated Inter-Agency Agreement and managed by a CDMRP Science Officer.

Funding obligated to ***intragovernmental and intramural DOD organizations*** will be sent through the Military Interdepartmental Purchase Request (MIPR), Funding Authorization Document (FAD), or Direct Charge Work Breakdown Structure processes. Transfer of funds is contingent upon appropriate safety and administrative approvals. Intragovernmental and intramural DOD investigators and collaborators must coordinate receipt and commitment of funds through their respective Resource Manager/Task Area Manager/Comptroller or equivalent Business Official.

An 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. For extramural submissions, refer to the General Application Instructions, Section IV.B.(e), Pre-Award Costs section, and for intramural submissions, refer to the General Application Instructions, Section V.A.(e), Pre-Award Costs section, for additional information about pre-award costs.

If there are technical reporting requirement delinquencies for any existing CDMRP awards at the applicant organization, no new awards will be issued to the applicant organization until all delinquent reports have been submitted.

II.F.2. PI Changes and Award Transfers

Unless otherwise restricted, changes in PI or organization will be allowed on a case-by-case basis, provided the intent of the award mechanism is met. The organizational transfer of an award supporting a clinical trial is strongly discouraged and in most cases will not be allowed. Approval of a transfer request will be on a case-by-case basis 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 7, Section F, for general information on organization or PI changes.

II.F.3. 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 7, for general information regarding administrative requirements.

Refer to the General Application Instructions, Appendix 8, for general information regarding national policy requirements.

Refer to full text of the latest DoD R&D Terms and Conditions and the USAMRAA Research Terms and Conditions: Addendum to the DoD R&D Terms and Conditions for further information.

Funded trials are required to post a copy of the IRB-approved informed consent form used to enroll subjects on a publicly available federal website in accordance with federal requirements described in the Code of Federal Regulations, Title 32, Part 219 (32 CFR 219). Funded studies are required to register the study in the National Institutes of Health (NIH) clinical trial registry, www.clinicaltrials.gov, prior to initiation of the study. Refer to the General Application Instructions, Appendix 6, Section F, for further details.

Applications recommended for funding that involve animals, human data, human specimens, human subjects, or human cadavers must be reviewed for compliance with federal and DOD animal and/or human subjects protection requirements and approved by the USAMRDC Office of Human and Animal Research Oversight, prior to implementation. This administrative review requirement is in addition to the local Institutional Animal Care and Use Committee, IRB, or Ethics Committee review. Refer to the General Application Instructions, Appendix 6, for additional information.

The PRARP requires that all TBI-related clinical research and/or clinical trials funded by this program be shared through the jointly supported DOD-NIH Federal Interagency TBI Research Information System (FITBIR) for FY24. Recipients will be required to upload study data

annually, at minimum, and in accordance with the FITBIR data submission policies. There is no fee to use FITBIR, and detailed guidance and policies, including a cost estimator tool for budgeting considerations, can be found at https://fitbir.nih.gov.

II.F.4. Reporting

Quarterly and annual technical progress reports as well as a final technical progress report will be required. Annual and final quad charts will be required. Annual and final technical reports must be prepared in accordance with the Research Performance Progress Report (RPPR).

The Award Terms and Conditions will specify whether 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 *(required for clinical research 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 SAM 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 8, Section B).

II.G. Federal Awarding Agency Contacts

II.G.1. eBRAP Help Desk

Questions regarding program announcement content or submission requirements as well as technical assistance related to pre-application or intramural application submission:

Phone: 301-682-5507

Email: help@eBRAP.org

II.G.2. Grants.gov Contact Center

Questions regarding Grants.gov registration and Workspace:

Phone: 800-518-4726; International 1-606-545-5035

Email: support@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 901a. The program announcement numeric version code will match the General Application Instructions version code 901.

II.H.2. Administrative Actions

After receipt of full applications, the following administrative actions may occur.

II.H.2.a. Rejection

The following will result in administrative rejection of the full application:

- Pre-application was not submitted.
- Project Narrative exceeds page limit.
- Community Collaboration Plan (Attachment 7) is missing.
- 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 full application:

- An FY24 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, including letters of support/recommendation. ***A list of the FY24 PRARP Programmatic Panel members can be found at https://cdmrp.health.mil/prarp/panels/panels24***.

- 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.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies. For FY24, 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).
- 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.
- Applications submitted by a federal government organization (including an intramural DOD organization) may be withdrawn if (a) the organization cannot accept and execute the entirety of the requested budget in current fiscal year (FY24) funds and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- Application includes research data that are classified and/or proposes research that may produce classified outcomes, or outcomes deemed sensitive to national security concerns.
- Submission of the same research project to different funding opportunities within the same program and fiscal year.
- The PI and/or Partnering PI, if applicable, does not meet the eligibility criteria.
- The application contains animal work.
- The clinical trial solely tests or evaluates pharmacological interventions.
- Research Manual and Progression Plan (Attachment 6) is missing.
- Community Collaboration Plan (Attachment 7) is missing.
- The application does not include a minimum of one collaborative Community partner.
- 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.2.e. Other Funding Opportunities

The PRARP is committed to leveraging efforts with other funding organizations to accelerate progress in AD/ADRD research. At the time of funding notifications, the PRARP may inform highly rated, unfunded applicants about opportunities to provide their PRARP applications and peer review summary statements to non-governmental funders, who will determine the specific criteria for funding consideration.

II.H.3. Full Application Submission Checklist

Full Application Components	Uploaded	
	PI/Initiating PI	Partnering PI
SF424 Research & Related Application for Federal Assistance *(Extramural submissions only)*	☐	☐
Summary (Tab 1) and Application Contacts (Tab 2) *(Intramural submissions only)*	☐	
Attachments		
Project Narrative – Attachment 1, upload as "ProjectNarrative.pdf"	☐	
Supporting Documentation – Attachment 2, upload as "Support.pdf"	☐	
Technical Abstract – Attachment 3, upload as "TechAbs.pdf"	☐	
Lay Abstract – Attachment 4, upload as "LayAbs.pdf"	☐	
Statement of Work – Attachment 5, upload as "SOW.pdf"	☐	☐
Research Manual and Progression Plan – Attachment 6, upload as "Manual.pdf"	☐	
Community Collaboration Plan – Attachment 7, upload as "Collaboration.pdf"	☐	
Representative, Inclusive Research Plan – Attachment 8, upload as "Inclusion.pdf"	☐	
Impact Statement – Attachment 9, upload as "Impact.pdf"	☐	
Partnership Statement – Attachment 10, upload as "Partnership.pdf" *(if applicable)*	☐	
Representations *(Extramural submissions only)* – Attachment 11, upload as "RequiredReps.pdf"	☐	☐
Suggested Intragovernmental Budget Form – Attachment 12, upload as "IGBudget.pdf" *(if applicable)*	☐	☐
Research & Related Personal Data	☐	☐
Research & Related Senior/Key Person Profile (Expanded)	☐	☐
Attach PI Biographical Sketch (Biosketch_LastName.pdf)	☐	☐
Career Initiation or Transition Partnering PI	☐	☐
Attach PI Previous/Current/Pending Support (Support_LastName.pdf)	☐	☐
Attach Biographical Sketch (Biosketch_LastName.pdf) for each senior/key person	☐	☐

Attach Previous/Current/Pending (Support_LastName.pdf) for each senior/key person	☐	☐
Research & Related Budget *(Extramural submissions only)* Include budget justification	☐	☐
Budget *(Intramural submissions only)* Include budget justification	☐	☐
Project/Performance Site Location(s) Form	☐	☐
Research & Related Subaward Budget Attachment(s) Form *(if applicable)*	☐	☐

APPENDIX 1: ACRONYM LIST

ACURO	Animal Care and Use Review Office
AD/ADRD	Alzheimer's Disease and Related Dementias
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CIT	Career Initiation or Transition Partnering Option
DOD	Department of Defense
DoDGARs	Department of Defense Grant and Agreement Regulations
eBRAP	Electronic Biomedical Research Application Portal
ET	Eastern Time
FAD	Funding Authorization Document
FY	Fiscal Year
IRB	Institutional Review Board
LOI	Letter of Intent
M	Million
MIPR	Military Interdepartmental Purchase Request
NIH	National Institutes of Health
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
PRARP	Peer Reviewed Alzheimer's Research Program
RPPR	Research Performance Progress Report
SAM	System for Award Management
SOW	Statement of Work
STEM	Science, Technology, Engineering, and/or Mathematics
TrCA	Transforming Care 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	U.S. Department of Veterans Affairs