Program Announcement for the Department of Defense
Defense Health Program

Alzheimer's Research Program Transforming Research Award

Funding Opportunity Number: HT942525AZRPTrRA

Pre-Application Due: June 12, 2025

Application Due: August 29, 2025

This program announcement must be read in conjunction with the General Application Instructions, version CD25_01.

Content

Before You Begin

- **Active SAM.gov, eBRAP.org, and Grants.gov registrations are required for application submission.** User registration for each of these websites can take several weeks or longer. Each applicant must ensure their registrations are active and up to date prior to application preparation.
- **Read the funding opportunity announcement in the order it is written before beginning to prepare application materials**. It is the responsibility of the applicant to determine whether the proposed research meets the intent of the funding opportunity and that all parties meet eligibility requirements.

Who to Contact for Support

eBRAP Help Desk

301-682-5507
help@eBRAP.org

Questions regarding funding opportunity submission requirements, as well as technical assistance related to pre-application or intramural application submission.

Grants.gov Contact Center

800-518-4726
International: 1-606-545-5035
support@grants.gov

Questions regarding Grants.gov registration and Workspace.

This document uses internal links; you can go back to where you were by pressing Alt + left arrow key (Windows) or command + left arrow key (Macintosh) on your keyboard.

1. Basic Information About the Funding Opportunity

Summary: Supports non-incremental research designed to reduce risk of or prevent the development of Alzheimer's disease and/or Alzheimer's disease related dementias (AD/ADRD). Allowable research includes projects utilizing animal models as well as clinical research projects.

Distinctive Features: This funding opportunity allows for multiple principal investigators (PIs) under the Career Initiation or Transition (CIT) Partnership Option. If utilizing this option, only the initiating PI will submit a pre-application, but each PI will need to submit a full application. Be advised, all associated applications for a research project may be withdrawn if the initiating or partnering application is rejected or administratively withdrawn.

Community collaboration is required for projects proposing clinical research.

Leveraging existing resources and cohorts, particularly those that address critical health challenges and facilitate applicability to military health, is strongly encouraged.

Funding Details: The Congressionally Directed Medical Research Programs (CDMRP) expects to allot approximately $4 million (M) to fund approximately 4 Transforming Research Award applications with total cost caps of $1M for the single PI option, and $1M for the CIT Partnership Option. The maximum period of performance is 3 years. It is anticipated that awards made from this fiscal year 2025 (FY25) funding opportunity will be funded with FY25 funds, which will expire for use on September 30, 2031. Awards supported with FY25 funds will be made no later than September 30, 2026.

Submission and Review Dates and Times

- **Pre-Application (Preproposal) Submission Deadline:** 5:00 p.m. Eastern Time (ET), June 12, 2025
- **Invitation to Submit an Application:** July 12, 2025
- **Application Submission Deadline:** 11:59 p.m. ET, August 29, 2025
- **End of Application Verification Period:** 5:00 p.m. ET, September 1, 2025
- **Peer Review:** October 2025
- **Programmatic Review:** December 2025

Announcement Type: Initial

Funding Opportunity Number: HT942525AZRPTrRA

Assistance Listing Number: 12.420

2. Eligibility Information

2.1. Eligible Applicants

2.1.1. Organization

Extramural and intramural organizations are eligible to apply***, including foreign and domestic organizations, for-profit and non-profit organizations, and public or private 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.

2.1.2. Principal Investigator

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

Career Initiation or Transition Partnership Option: At least one investigator must meet the CIT Partnership Option eligibility requirements to be eligible for this option.

- Career Initiation investigators must have at least three years research experience beyond a terminal degree but no more than seven 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, traumatic brain injury (TBI), and/or AD/ADRD fields, with nominal, if any, publications and/or research support for their intended field.

Individuals affiliated with an eligible organization are eligible to be named as PI regardless of ethnicity, nationality, or citizenship status.

2.2. Cost Sharing

Cost sharing is not an eligibility requirement.

2.3. Other

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

3. Program Description

The U.S. Army Medical Research Acquisition Activity (USAMRAA) is soliciting applications to this funding opportunity using delegated authority provided by United States Code, Title 10, Section 4001 (10 USC 4001). The CDMRP at the U.S. Army Medical Research and Development Command (USAMRDC) is the program office managing this FY25 funding opportunity as part of the Alzheimer's Research Program (AZRP). Congress initiated the AZRP in 2011 to provide support for research of high potential impact and exceptional scientific merit. Appropriations for the AZRP from FY11 through FY24 totaled $198M. The FY25 appropriation is $15M.

AZRP Vision Statement: Mitigate the impact of Alzheimer's and related dementias associated with TBI, military, and diverse risks.

AZRP Mission Statement: Fund impactful, solution-oriented research to address critical needs and improve quality of life for Service Members, Veterans, their Families, and the public who are living with Alzheimer's disease and related dementias.

3.1. Award History

The AZRP Transforming Research Award mechanism was first offered in FY23. Since then, 212 Transforming Research Award applications were received, and 14 were recommended for funding.

3.2. Intent of the Transforming Research Award

The FY25 AZRP Transforming Research Award (TrRA) is geared toward supporting robust, well-designed research projects that provide significant impact on the AD/ADRD field, Community, and military health. For the purposes of this funding opportunity, the following terms are defined:

- *Community* encompasses the network of individuals living with an AD/ADRD diagnosis, their care partner(s), families, advocates, and/or other close connections. The CDMRP refers to these individuals as consumers.
- *Military or military health* refers to not only members of all components of the Armed Forces, but Veterans, their Families, and other U.S. Department of Defense (DOD) beneficiaries.

The FY25 AZRP TrRA is intended to support studies that will make transformative contributions to risk reduction and prevention of the development of AD/ADRD. The AZRP challenges investigators to appreciably accelerate efforts in AD/ADRD risk and prevention research and demonstrate tangible impact toward improving patient care and/or quality of life.

To meet the intent of the funding opportunity, applications must robustly address an important problem or a critical challenge in risk reduction and/or prevention for AD/ADRD. Risk reduction considering TBI, similar brain health exposures, and/or military service is of particular interest to the program. *Projects focused primarily on basic and/or mechanistic research, disease-modifying treatments, and/or pharmacological therapeutic development research do not meet the intent of this mechanism*.

3.2.1. Focus Areas for the TrRA

For the FY25 TrRA, all projects must respond to one of the following focus areas:

- Risk factor knowledge: Projects responsive to this focus area must advance understanding, identification, and/or validation of risk and/or protective factors, with research outcomes/products focused on accelerating solutions. Projects may include but not limited to research on environmental, epigenetic, genetic, lifestyle, occupational, or other risks not listed here.
- Risk reduction solutions: Projects responsive to the focus area include research that describes methods, technologies, and strategies that contribute to reducing risk and preventing AD/ADRD.

3.2.2. Key Elements for the TrRA

Key elements of this award mechanism are:

- **Research Should be Robust:** Characteristics of robust research include transparency, adequate sample size, strong methodology, replicability, and control for biases. *Use of animal models must be fully justified for relevance to human health.*
- **Non-Incremental Advancement:** Research projects should leverage existing knowledge to accelerate ideas, strengthen evidence, and move the field forward. Projects proposing incremental improvements to the existing body of knowledge and do not significantly propel the field do not meet the intent of this award mechanism. *Preliminary data are required*.
- **Feedback to the Community:** Applicants are expected to articulate *a plan for relaying the results and outcomes of the research* supported by this mechanism back to the research and lived experience Community(ies) to allow for continued knowledge building.
- **Community-Informed Research:** Research funded by the FY25 AZRP should be responsive to the needs of people living with AD/ADRD and their Communities. Applicants are encouraged to leverage the lived experience community and/or patient perspectives research to inform the proposed research question and study design.

  For the FY25 AZRP TrRA, *Community collaboration* is required for applications proposing clinical research. Research teams are expected to establish and utilize effective and equitable collaborations and partnerships with members of the AD/ADRD lived experience Community to maximize the translational and impact potential of the proposed research.
- **Career Initiation or Transition (CIT) Partnership Option:** The TrRA includes the CIT Partnership Option to include meaningful and productive collaborations between two PIs. One PI will be identified as the Initiating PI and will be responsible for the majority of the administrative tasks associated with application submission. The other PI will be identified as a Partnering PI. All PIs should contribute significantly to the development and execution of the proposed research project. If recommended for funding, each PI will be named on separate awards to the recipient organization(s). Each award will be subject to separate reporting, regulatory, and administrative requirements. For individual submission requirements for the Initiating and Partnering PIs, refer to Section 5.3, Submission Instructions.

3.2.3. Other Important Considerations for the TrRA

Community collaboration in research is defined by the AZRP as research that incorporates shared responsibility and ownership of a research project between the scientific investigators and Community members.

Community collaboration supports strengths-based approaches where scientific researchers and Community members work in partnership 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 and/or organizations into research teams as co-researchers, advisory board members, and consultants. It is up to each applicant to choose the appropriate approach that is best suited for the unique needs of the research project.

Clinical trials are not allowed; however, projects may include prospectively enrolled participants, data, and/or human anatomical substances from an existing clinical trial or study to carry out the research.

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. An ***intervention*** includes both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.

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.

3.3. CDMRP-wide Encouragements

The following encouragement is broadly applicable across many CDMRP programs, including the AZRP. Investigators are encouraged to consider addressing this area in their applications if doing so is appropriate for their line of research and meets the intent of this funding opportunity.

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

3.4. Funding Instrument

The funding instrument for awards made under the program announcement will be grants (31 USC 6304).

3.5. Funding Details

Period of Performance: The maximum period of performance is **3** years.

3.5.1. Application Submission With a Single PI

Cost Cap: The application's total costs budgeted for the entire period of performance should not exceed **$1M** (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.

3.5.2. Application Submission With the Career Initiation or Transition Partnership Option

Cost Cap: The combined total costs budgeted for the entire period of performance in the applications of the Initiating PI and the Partnering PI should not exceed **$1M**. 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.

3.5.3. Applies to Both Options Within This Funding Opportunity

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

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

The appropriateness of the budget for the proposed research will be assessed during peer review

Direct Cost Restrictions: For this award mechanism, direct costs:

May be requested for (not all-inclusive):

- Travel in support of multi-institutional collaborations.
- Costs for one investigator to travel to one scientific/technical meeting per year. The intent of travel to scientific/technical meetings should be to present project information or disseminate project results from the AZRP TrRA.
- 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.
- Animal costs.

Must not be requested for:

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

4. Application Contents and Format

4.1. Application Overview

Application submission is a two-step process requiring both a ***pre-application*** submitted via the Electronic Biomedical Research Application Portal (eBRAP) and a ***full application*** submitted through eBRAP or Grants.gov. Depending on the submission portal, certain aspects of the application will differ.

Intramural DOD organizations submitting a full application should follow instructions for submission through eBRAP.

Extramural organizations submitting a full application must follow instructions for submission through Grants.gov.

4.2. Step 1: Pre-Application Components

Pre-application submissions must include the following components.

Note: Upload documents as individual PDF files unless otherwise noted.

- **Preproposal Narrative (two-page limit):** The Preproposal Narrative page limit applies to text and non-text elements (e.g., figures, tables, graphs, photographs, diagrams, chemical structures, drawings) used to describe the project. Inclusion of URLs that provide additional information to expand the Preproposal Narrative and could confer an unfair competitive advantage is prohibited and may result in administrative withdrawal of the pre-application.

  The Preproposal Narrative should include the following:

  - **Background, rationale, and adherence to intent of the mechanism:** Briefly describe the research question and FY25 focus area the project aligns to. Clearly demonstrate that there is sufficient rationale, background data, and readiness to support the stage of research. Indicate how the research question or study design is informed by Community and/or patient perspectives research. Describe how this is responsive to the intent of the FY25 TrRA.
  - **Specific Aims and Strategy:** Concisely state the hypothesis and specific aims and provide a brief overview of the research strategy for the study.
  - **Impact:** Describe the potential impact to people living with dementia, their families, or care partners using lay language. Guidelines for writing in lay language, known also as plain language, can be found online.
- **Pre-Application Supporting Documentation:** The items to be included as supporting documentation for the pre-application ***must be uploaded as individual files*** and are limited to the following:
  - **References Cited (one-page limit):** List the references cited (including URLs if available) in the Preproposal Narrative using a standard reference format that includes the full citation (i.e., author[s], year published, reference title, and reference source, including volume, chapter, page numbers, and publisher, as appropriate).
  - **List of Abbreviations, Acronyms, and Symbols:** Provide a list of abbreviations, acronyms, and symbols used in the Preproposal Narrative.

- **Key Personnel (one-page limit):** Provide a list of key personnel, including community collaborators, identifying their role in the project.

4.3. Step 2: Full Application Components

Applicants must receive an invitation to submit a full application. Uninvited full application submissions will be rejected.

4.3.1. Full Application 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 each Partnering PI, even if the PIs are located within the same organization. The application submission process for the Partnering PI uses an abbreviated full application package.

Each application submission must include the completed full application package for this program announcement. See Appendix 1 for a checklist of the full application components.

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

IMPORTANT: When completing the SF424 R&R, enter the eBRAP log number assigned during pre-application submission into Block 4a – Federal Identifier.

(b) Attachments:

Each attachment of 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. Studies prospectively recruiting human patients must append an inclusion enrollment report (see Attachment 2, Supporting Documentation). If animal subjects are to be used, Attachment 9, Animal Research Plan, is required.

  - **Background/Rationale:** Present the ideas and scientific rationale behind the proposed research project, indicating how this responds to a FY25 TrRA focus area. Provide a review and analysis of relevant literature and completed/ongoing studies, including preliminary studies, preclinical data, and community/patient perspectives research as appropriate. Demonstrate how this proposed 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 AZRP 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 robust approach to non-incremental research.
  - 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.
  - Identify potential problem areas, and present alternative methods and approaches.
  - For clinical studies, describe measures to ensure the research study is representative of the population(s) intended to benefit from the research.
    - If applicable, indicate the access to the study population, recruitment plans, and inclusion/exclusion criteria.
    - Describe the strategy for the inclusion of women and minorities appropriate to the objectives of the study, including a description of the composition of the proposed study population in terms of sex, racial, and ethnic group, and an accompanying rationale for the selection of subjects.
    - Outline the process for seeking informed consent and describe the safeguards that are in place for vulnerable populations.
    - Explain how the proposed clinical research might affect the daily lives of the individuals participating in the study.
    - Include a detailed plan for any prospective recruitment for human biospecimens and/or data, as applicable.
    - If applicable, 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, and what safety monitoring and reporting measures are taken for the level of risk.
- **Statistical Plan and Data Analysis:** Detail the statistical model and data analysis plan with respect to the study objectives in sufficient detail to allow a thorough evaluation of the information. Include power analysis calculations, and demonstrate the analytical plan is sufficient to meet study objectives, including valid analyses of group differences. Further information describing the strategy for how sex will be considered as a biological variable will be requested in Attachment 2.

- **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.
- **Letters of Support (one-page limit per letter *is recommended*):** Provide individual letters signed by collaborating individuals and/or organizational officials demonstrating that the PI has the support and resources necessary for the proposed work. Letters from the PI's Department Chair, or appropriate organization official, should also confirm that the PI(s) meet eligibility criteria. If applicable, provide a letter of support, signed by the lowest-ranking person with approval authority, confirming participation of intramural DOD collaborator(s) and/or access to military populations, databases, or DOD resources. If applicable, provide a letter of support signed by the U.S. Department of Veterans Affairs (VA) Facility Director(s), or individual designated by the VA Facility Director(s), confirming access to VA patients, resources, and/or VA research space.
- **Sex as a Biological Variable Strategy (two-page limit is recommended)**: Describe the strategy for how sex will be considered as a biological variable. This strategy should include a brief discussion of what is currently known regarding sex differences in the applicable research area. Clearly articulate how sex as a biological variable will be factored into the data analysis plan and how data will be collected and disaggregated by sex. If needed, provide a strong rationale for proposing a single-sex study, based on justification from scientific literature, preliminary data, or other relevant considerations. Refer to the CDMRP Directive on Sex as a Biological Variable in Research for additional information.
- **Data and Research Resources Sharing Plan (one-page limit is recommended):** It is expected that data and/or or research resources (e.g., bio-specimen, analysis tool/software, training material) will be made publicly available as a result of the proposed work. Provide a plan describing how data and resources will be shared with the research community and other affected communities, including clinical trial participants. Refer to CDMRP's Policy on Data & Resources Sharing for more information about CDMRP's expectations for making data and research resources publicly available.

- **Inclusion Enrollment Report *(only required if clinical research is proposed):*** 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, race, and ethnicity. The "Public Health Service (PHS) Inclusion Enrollment Report" is a three-page fillable PDF form that can be downloaded from eBRAP. Studies utilizing human biospecimens or datasets that cannot be linked to a specific individual, ethnicity, or race (typically classified as exempt from Institutional Review Board [IRB] review) are exempt from this requirement.

- **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:** Present the scientific rationale behind the proposed research project, and explain the responsiveness to the FY25 TrRA focus area.
  - **Hypothesis/Objective(s):** State the hypothesis to be tested and/or objective(s) to be reached. Indicate how this research is a non-incremental advance.
  - **Specific Aims:** State the specific aims of the study.
  - **Study Design:** Describe the study design, including appropriate controls.
  - **Experimental Design:** Briefly describe the experimental design, including appropriate controls.
  - **Impact:** Briefly describe how the proposed research project, if successful, will make transformative and impactful 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 readers without a background in science or medicine***. Avoid scientific jargon, acronyms, and abbreviations.

  - Summarize the objectives and rationale for the proposed research.
  - What population will the research help, and how will it help them?
  - What are the potential applications, benefits, and risks of the anticipated outcomes?
  - How does the proposed research project advance AD/ADRD/TBI research, dementia care, and/or quality of life? Applicants should be realistic when describing timelines stated to direct clinical impact.

- **Attachment 5: Statement of Work (two-page limit): Upload as "SOW.pdf".** Refer to eBRAP for the "Suggested SOW Format".

  For the Transforming Research Award, refer to "Example: Assembling a Generic Statement of Work" for guidance on preparing the SOW.

  - For Federal Interagency TBI Research (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, and (c) annual FITBIR data submissions.
  - **Career Initiation or Transition Partnership 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: Impact Statement (two-page limit): Upload as "Impact.pdf".** The Impact Statement is considered by all reviewers on the both the peer and programmatic review panels, and it is important that this attachment be written in a manner that will be ***readily understood by the general public, especially those without a background in science or medicine.*** Avoid scientific jargon, acronyms, and abbreviations.

  Clearly detail the short- and long-term impact of the proposed research outcomes **as though the proposed project is successful in all its aims**.

  - How will this project provide a solution to an important problem or a critical barrier to prevention and risk reduction?
  - Explain why this solution is a non-incremental advance that results in impactful change.
  - How would the results from this project transfer from a civilian to military population, or vice versa?
  - If the aims of the project are successful, 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 immediate and potential long-term benefit(s) does successful completion of this project yield for persons living with TBI and/or AD/ADRD, their families, and care partners/caregivers?
  - What potential issues that might limit or lessen the impact of the proposed research, and what strategies could overcome those issues?

- **Attachment 7: Progression Plan (two-page limit): Upload as "Progression.pdf".** For FY25, the AZRP requires all applicants to contemplate and provide a plan outlining a practical trajectory to implementation for the research they are proposing, and how this will ultimately translate to benefit the intended recipients.

  Assuming the project is successful in all its aims:

  - Outline the next immediate and subsequent logical steps to be taken following the period of performance to progress the research to clinical application. Describe the timeline needed with defined milestones. Should another research project be required, describe why this additional study is needed and how those outcomes would contribute to progressing the research toward clinical utility. Include steps necessary for regulatory approval, if applicable.
  - Describe how the bidirectional feedback and dissemination from the AD/ADRD/TBI Community will be integrated into the progression of this research.

- Describe collaborations and other resources (e.g., clinical partners, commercial partners, manufacturing partners, clinical practice guideline development/execution committees, training providers/resources) that are necessary to help progress the continuity of research to the next stage of development or clinical implementation. Indicate which of these are already in place or will be established.

- **Attachment 8: Community Collaboration Plan *(if applicable; required for all applications proposing clinical research)*: Combine and upload as a single file named "Collaboration.pdf".** Refer to Section 3.2.3. Other Important Considerations for the TrRA 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.*** Avoid scientific jargon, acronyms, and abbreviations.
  - **Collaborative Research Statement (three-page limit is recommended):** 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.
    - 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. Detail how this best serves your Community/intended user base.
    - Describe how the Community collaborator(s) are connected to your study population(s).
    - Indicate the input from the partner that has been or will be captured and how this input will be meaningfully integrated and incorporated into the needs assessment, planning, design, execution, analysis, and dissemination of the research.
    - Describe the resource allocation, decision-making, and equitable participation processes to be employed.
    - Describe any training, co-learning, or capacity-building activities that will be provided to both scientific researchers and Community members on collaborative research approaches, decision-making, and equitable participation.
    - Describe the process measures used to assess the effectiveness of the chosen collaborative approach.
  - **Letters of Community Collaboration (two-page limit per letter is recommended):** 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 include a mention of why the qualifications and background of the individual will benefit the proposed research project.
- **Attachment 9: Animal Research Plan (four-page limit): Upload as "Animal.pdf". *(Attachment 9 is only applicable and required for applications that are using animal models.)*** When the proposed study involves animals, the applicant is required to submit a plan describing the animal research that will be conducted. Applicants should

not submit a verbatim replica of the protocol(s) to be submitted to the Institutional Animal Care and Use Committee (IACUC) as the Animal Research Plan, nor should this replicate the Project Narrative. The Animal Research Plan should address additional information needed to fully explain the models and procedures for the proposed animal study:

- Briefly describe the research objective(s) of the animal study.
- Explain how and why the animal species, strain, and model(s) being used can and are necessary and appropriate to address the scientific objectives of the proposed research project.
- Explain why the specific animal AD/ADRD and/or TBI model was chosen over other models and how it is the optimal model for addressing the study aims.
- Provide clear and strong justification for the specific animal model's relevance to human TBI and/or AD/ADRD. Explain how the chosen animal model(s) is validated and well-justified in the literature.
- Summarize the procedures to be conducted, including methods to enhance research rigor, and how the study will be statistically controlled.
- Describe approaches that will be undertaken to validate or corroborate findings from animal studies to relevant human data sources/populations. This could include, but is not limited to, validation of animal transcriptomic data using publicly available human transcriptomic datasets, confirmation of histological findings in a human postmortem case series, and validation against fluid-based or imaging biomarkers.
- Describe what approach(es) will be used to de-risk the possibility the animal findings may not translate to human populations.

- **Attachment 10: Partnership Statement (one-page limit): Upload as "Partnership.pdf".** ***(Attachment 10 is only applicable and required for applications submitted under the Career Initiation or Transition Partnership 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** ***(Grants.gov submissions only)*****: Upload as "RequiredReps.pdf".** All extramural applicants must complete and submit the "Required Representations" document that is available on eBRAP. 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 the performance of the project, complete a separate budget for that organization using the "Suggested Intragovernmental/Intramural Budget" form that is available for download on eBRAP. Refer to the General Application Instructions, Section V.B.(c), for instructions and considerations.

(c) Research & Related Personal Data: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(a); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(a).

(d) Research & Related Senior/Key Person Profile (Expanded): Complete a Profile for each person who will contribute in a substantive, meaningful way to the scientific development or execution of the proposed research project. A biographical sketch and full description of each PI and senior/key person's current/pending support information must be attached to the individual's profile in the Attach Biographical Sketch and Attach Current & Pending Support fields, respectively.

- **Biographical Sketch:** Upload as "Biosketch_LastName.pdf".

  The CDMRP staff and reviewers use biosketches to evaluate whether research teams are equipped with the expertise necessary to carry out the proposed research.

  Biosketches must conform to the federal-wide Biographical Sketch Common Form. To prepare their biosketch attachments, applicants may use the instructions provided in the General Application Instructions, Section IV.C.(b), for Grants.gov submissions; or General Application Instructions, Section V.B.(b), for eBRAP submissions; or may use a pdf form created in SciENcv for the National Institutes of Health (NIH) or the U.S. National Science Foundation (NSF).

- **Current/Pending Support:** Upload as "Support_LastName.pdf".

  Current and pending (other) support information are used to assess the capacity or any conflicts of commitment that may impact the ability of the individual to carry out the research effort as proposed. The information also helps to assess any potential scientific and budgetary overlap/duplication with the project being proposed.

  Current and pending support documentation must conform to the federal wide format. To prepare their Current and Pending Support form, applicants may use the instructions provided in the General Application Instructions, Section IV.C.(b), for Grants.gov submissions; or General Application Instructions, Section V.B.(b), for eBRAP submissions; or may use a pdf form created in SciENcv for NIH or NSF.

(e) Research & Related Budget: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(c).

- **Budget Justification (no page limit):** For instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c), Section L; for eBRAP submissions, refer to General Application Instructions, Section V.B.(c), Budget Justification Instructions.
- For the CIT Partnership Option only, 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 Partnering PIs even if they are located within the same organization. Refer to Section 3.5, Funding Details, for detailed information.

(f) Project/Performance Site Location(s) Form: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(d); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(d).

(g) Research & Related Subaward Budget Attachment(s) Form *(if applicable, Grants.gov Submissions only)*: Refer to the General Application Instructions, Section IV.C.(e), for detailed information.

- **Extramural Subaward:** Complete the Research & Related Subaward Budget Form and upload it through Grants.gov.
- **Intramural DOD Subaward:** Complete a separate "Suggested Intragovernmental/Intramural Budget Form" for each intramural DOD subaward. Combine them into a single document, then upload the file to Grants.gov as an attachment named "IGBudget.pdf". Refer to Attachment 12.

4.3.2. Full Application Components for the CIT Partnership Option Partnering PI

Refer to the equivalent attachment above for details specific to each of the following application components. See Appendix 1 for a checklist of the full application components required for the Partnering PI.

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

NOTE: Enter the eBRAP log number assigned during pre-application submission into Block 4a – Federal Identifier Box

(b) Attachments:

- **Attachment 5: Statement of Work (two-page limit): Upload as "SOW.pdf".** Each PI must submit an identical copy of a jointly created SOW.
- **Attachment 11: Representations *(Grants.gov submissions only)*: Upload as "RequiredReps.pdf".**
- **Attachment 12: Suggested Intragovernmental/Intramural Budget Form: Upload as "IGBudget.pdf".**

(c) Research & Related Personal Data: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(a); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(a).

(d) Research & Related Senior/Key Person Profile (Expanded): Complete a Profile for each person who will contribute in a substantive, meaningful way to the scientific development or execution of the proposed research project. A biographical sketch and full description of each PI and Senior/Key Person's current/pending support information must be attached to the individual's Profile in the Attach Biographical Sketch and Attach Current & Pending Support fields, respectively.

(e) Research & Related Budget: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(c); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(c).

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

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 Partnering PIs should not include budget information for the Initiating PI, even if they are located within the same organization. Refer to Section 3.5, Funding Details, for detailed information.

(f) Project/Performance Site Location(s) Form: For detailed instructions for Grants.gov submissions, refer to the General Application Instructions, Section IV.C.(d); and for eBRAP submissions, refer to the General Application Instructions, Section V.B.(d).

(g) Research & Related Subaward Budget Attachment(s) Form *(if applicable, Grants.gov Submissions Only)*: Refer to the General Application Instructions, Section IV.C.(e), 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.

4.4. Other Application Elements

- If recommended for funding, a Quad Chart will be requested. The format for the quad chart is available on the eBRAP website.
- If recommended for funding, a data management plan compliant with Section 3.c, Enclosure 3, DoD Instructions 3200.12 will be requested.
- The government reserves the right to request a revised budget, budget justification and/or additional information for applications recommended for funding.

5. Submission Requirements

5.1. Location of Application Package

Download the application package components for HT942525AZRPTrRA from Grants.gov or eBRAP, depending on which submission portal will be used.

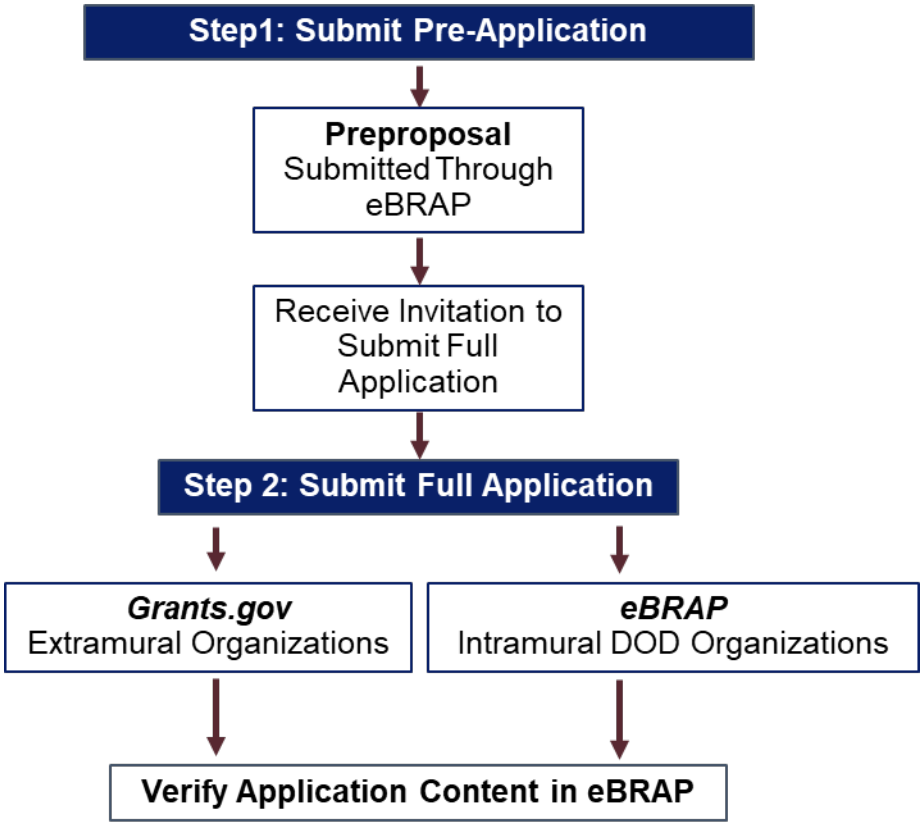
5.2. Unique Entity Identifier and System for Award Management

The applicant organization must be registered as an entity in the System for Award Management (SAM), SAM.gov, and receive confirmation of an "Active" status before submitting an application through Grants.gov. Organizations must include the unique entity identifier generated by the SAM in applications to this funding opportunity and maintain an active registration in the SAM at all times during which it has an active Federal award or an application under consideration. More information regarding SAM registration can be found in the General Application Instructions, Section IV.A.

5.3. Submission Instructions

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

Application Submission Workflow



5.3.1. 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 each Partnering PI if exercising the Career Initiation or Transition Partnership 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 the PI, Business Official(s), performing organization, and contracting organization must be consistent throughout the entire pre-application and full application submission process. Inconsistencies may delay application processing and limit or negate the ability to view, modify, and verify the application in eBRAP. If any changes need to be made, the applicant should contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507 prior to the application submission deadline.

Career Initiation or Transition Partnership Option: After the Initiating PI confirms submission of the pre-application, the Partnering PI(s) will be notified of the pre-application submission via an email from eBRAP. ***The Partnering PI(s) must follow the link in the notification email to associate the partnering pre-application with their eBRAP account and confirm their organization and Business Official information.*** If not previously registered, the Partnering PI must register in eBRAP.

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 associate the partnering pre-application with their eBRAP account as soon as possible. If this is not completed by the full application deadline:

- 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”. 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 Partnership Option)	Partnering PI

A change in PI or organization after submission of the pre-application may be allowed after review of a submitted written appeal (contact the eBRAP Help Desk at help@eBRAP.org or 301-682-5507) and at the discretion of the USAMRAA Grants Officer.

Refer to the General Application Instructions, Section III.A, for considerations and detailed instructions regarding pre-application submission.

5.3.2. Full Application Submission

Grants.gov Submissions: Full applications from extramural organizations *must* be submitted through the Grants.gov Workspace. Refer to the General Application Instructions, Section IV, for considerations and detailed instructions regarding Grants.gov submissions.

eBRAP Submissions: Only intramural DOD organizations may submit full applications through eBRAP. Full applications from extramural organizations, including non-DOD federal organizations, received through eBRAP will be withdrawn. Refer to the General Application Instructions, Section V, for considerations and detailed instructions regarding eBRAP submissions.

5.3.3. Applicant Verification of Full Application Submission in eBRAP

Independent of submission portal, once the full application is submitted, it is transmitted to and processed in eBRAP; the transmission to eBRAP may take up to 48 hours. 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 the 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 through the appropriate portal 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.

5.4. Submission Dates and Times

The pre-application and full application submission process should be started early to avoid missing deadlines. Regardless of submission portal used, all pre- and full application components must be submitted by the deadlines stipulated in 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.***

All submission dates and times are indicated in Section 1, Basic Information above.

5.5. Intergovernmental Review

Not applicable for this funding opportunity.

6. Application Review Information

6.1. Application Compliance Review

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).

While it is allowable to propose similar research projects to different programs within CDMRP or to other organizations, duplication of funding or accepting funding from more than one source for the same research is prohibited. See the CDMRP's full position on research duplication.

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.

Members of the FY25 AZRP Programmatic Panel should not be involved in any pre-application or full application including, but not limited to, concept design, application development, budget preparation, and the development of any supporting documentation, including personal letters of support/recommendation for the research and/or PI. Programmatic panel members ***may*** provide letters to confirm PI eligibility and access to laboratory space, equipment, and other resources necessary for the project if that is part of their regular roles and responsibilities (e.g., as Department Chair). ***A list of the FY25 AZRP Programmatic Panel members can be found on the CDMRP website.***

Additional restrictions and associated administrative responses are outlined in Section 9.2, Administrative Actions.

6.2. Review Criteria

6.2.1. Pre-Application Screening Criteria

To determine the technical merits of the pre-application and the relevance to the mission of the AZRP, pre-applications will be screened based on the following criteria:

- **Background and Rationale:** How well the project is described and justified by the background and rationale. To what extent the research question or study design is informed by the lived experience community and/or patient perspectives research.
- **Specific Aims and Strategy:** How well the specific aims are stated.
- **Impact:** How likely the proposed research will impact people living with dementia, their families, or care partners.
- **Adherence to the Intent of the Funding Opportunity:** How well the project adheres to the focus area and intent of the funding opportunity.

6.2.2. Peer Review Criteria

To determine technical merit, all applications will be individually evaluated according to the following **scored criteria**, which are of equal importance:

- **Impact**
  - If the aims of the project are achieved, to what extent does the project address an important problem or a critical barrier for risk reduction and prevention?
  - To what extent does this project represent a non-incremental advance compared to the current status of the field?
  - If the aims of the project are achieved, to what extent are scientific knowledge, technical capability, clinical practice, and dementia care improved and communicated to the research and lived experience communities in a timely manner?
  - To what extent the immediate and long-term benefits of successful completion of this project yield for persons living with TBI and/or AD/ADRD, their families, and their care partners/caregivers? Are these benefits realistic and valuable overall?
- **Research Strategy and Feasibility**
  - To what extent the research strategy, methods, and analyses are robust, appropriate, and feasible. Whether sample size, control for biases, transparency. and replicability are sufficient.
  - To what degree the research question or study design is informed by the lived experience community and/or patient perspectives research.
  - How well the data analysis plan, including sample size projections and power analysis, is appropriate to meet the objectives of the study and all proposed correlative studies.
  - Applicable for projects with *proposed clinical research only*:
    - Whether the application includes sufficient evidence to support successful recruitment of and/or access to study populations, data, and samples.
    - Whether the strategy for the inclusion of women and minorities and the distribution of proposed enrollment are appropriate for the proposed research, including a description of the composition of the proposed study population in terms of sex, racial, and ethnic group, and an accompanying rationale for the selection of subjects.
    - How well the study population represents the beneficiaries of the research.
  - Applicable for projects with *proposed animal studies only*:
    - To what extent the animal study describes how and why the animal species, strain, and model(s) being used are necessary and appropriate to address the scientific objectives of the proposed research project.
    - Whether the animal model is sufficiently relevant to human TBI and/or AD/ADRD to facilitate translation to clinical research.
    - Whether the approaches that will be undertaken to validate or corroborate findings from animal studies are relevant to human data sources/populations.
    - Whether these approaches sufficiently de-risk the possibility that the animal findings may not translate to human populations.
  - Whether the strategy for considering sex as a biological variable is appropriate to the objectives of the study, or whether the justification for a single-sex study is sufficiently strong.
  - How well the application acknowledges potential problem areas and provides alternative methods and approaches.

- **Research Implementation**
  - Whether the progression plan realistically outlines the next immediate and subsequent logical steps of the research, or clinical application, as appropriate. How well the progression plan realistically details timelines and milestones for the next steps, including regulatory interactions, if applicable.
  - Whether the established or planned collaborations and resources are appropriate for the progression plan.
  - How well the progression plan incorporates feedback from and dissemination to the AD/ADRD/TBI Community.
- **Research Team**
  - As applicable, 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 background, experience, and levels of effort of the PI, Partnering PI (if applicable), and other personnel are appropriate to accomplish the proposed research project.
  - **Career Initiation or Transition Partnership 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**:

- **Ethical Considerations (for research involving human subjects)**
  - 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, 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 individual human subjects participating in the study.
  - To what degree the process for seeking informed consent is appropriate, and whether safeguards are in place for vulnerable populations.
- **Budget**
  - Whether the budget is appropriate for the proposed research.
  - For the CIT Partnership 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 of 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.

6.2.3. 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 FY25 AZRP, as evidenced by the following:
  - Adherence to the intent of the funding opportunity.
  - Program portfolio balance.
  - Relative impact.
  - Benefit to end users including transferability between populations, including military, as applicable.

6.3. Application Review and Selection Process

6.3.1. Pre-Application

Following the pre-application screening, Initiating PIs will be notified as to whether they are invited to submit full applications. The estimated date when PIs can expect to receive notification of an invitation to submit a full application is indicated in Section 1, Basic Information about the Funding Opportunity. No feedback (e.g., a critique of the pre-application's strengths and weaknesses) is provided at this stage. Because the invitation to submit a full application is based on the contents of the pre-application, investigators should not change the title or research objectives after the pre-application is submitted.

6.3.2. Full Application

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 6.2.3, Programmatic Review.*** Additional information about the two-tier process used by the CDMRP can be found on the CDMRP website.

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.

6.4. Risk, 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.

In accordance with National Security Presidential Memorandum and all associated laws, all fundamental research funded by the DoD must be evaluated for affiliations with foreign entities. All applicant organizations must disclose foreign affiliations of all key personnel named on applications. Failure to disclose foreign affiliations of key personnel shall lead to withdrawal of recommendations to fund applications. Applicant organizations may be presented with an opportunity to mitigate identified risks, particularly those pertaining to influence from foreign entities specified in law. Implementation of mitigation discussions and utilization of the OUSD R&E Decision Matrix must decrease risk of foreign influence in accordance with the above-mentioned laws and guidance prior to award.

7. Federal Award Notices

For each full application received, the organizational representative(s) and PI will receive email notification when the funding recommendations are posted to eBRAP, typically within 6 weeks after programmatic review. 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 application receipt and review process for the AZRP 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 additional information about pre-award costs for Grants.gov submissions, refer to the General Application Instructions, Section I.D, Pre-Award Costs section; and for eBRAP submissions, refer to the General Application Instructions, Section 1.D, Pre-Award Costs section.

8. Post-Award Requirements

8.1. 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.

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.

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 (OHARO), prior to implementation. This administrative review requirement is in addition to the local IACUC, IRB, or Ethics Committee (EC) review. Refer to the General Application Instructions, Appendix 6, for additional information.

The AZRP requires that TBI-related clinical research funded by this program be shared through the jointly supported DOD-FITBIR. Recipients will be required to upload study data annually 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.

8.2. Reporting

Annual technical progress reports as well as a final technical progress report 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.

PHS Inclusion Enrollment Reporting ***(Required for research proposing clinical research and/or 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 eBRAP.

Award Expiration Transition Plan: An Award Expiration Transition Plan, using the template available on eBRAP, must be submitted with the final progress report.

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).

8.3. Additional Requirements

The PI or Initiating PI is expected to participate in at least one In-Progress Review (IPR) for the funded project. For planning purposes, PIs can expect that the IPR will last no longer than one day and will be hosted virtually by the AZRP. The invitation and format for the IPR will be provided by the Grants Officer's Representative at least 90 days prior to the scheduled IPR date.

Unless otherwise restricted, changes in the PI or organization are not allowed, except under extenuating circumstances on a case-by-case basis, provided the intent of the award mechanism is met.

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 H, for general information on organization or PI changes.

9. Other Information

9.1. 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 CD25_01c. The program announcement numeric version code will match the General Application Instructions version code CD25_01.

9.2. Administrative Actions

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

9.2.1. Rejection

The following will result in administrative rejection of the pre-application:

- Preproposal Narrative is missing.

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

- Project Narrative is missing.
- Budget is missing.
- Submission of an application for which a letter of invitation was not issued.

9.2.2. Modification

- Pages exceeding the specified limits will be removed prior to review for all documents.
- Documents not requested will be removed.

9.2.3. Withdrawal

The following may result in administrative withdrawal of the full application:

- A member of the FY25 AZRP Programmatic Panel is named as being involved in the development or execution of the research proposed or is found to have assisted in the pre-application or application processes.
- Applications that include names of personnel from either of the CDMRP peer or programmatic review companies for which conflicts cannot be adequately mitigated. For FY25, the identities of the peer review contractor and the programmatic review contractor may be found on the CDMRP website.
- 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) if: (a) the organization cannot accept and execute the entirety of the requested budget in FY25 funds; and/or (b) the federal government organization cannot coordinate the use of contractual, assistance, or other appropriate agreements to provide funds to collaborators.
- 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.
- 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 invited application proposes a different research project than that described in the pre-application.
- The project fails to address at least one of the FY25 TrRA Focus Areas.
- Failure to submit all associated (Initiating and Partnering PI) applications by the deadline.
- A clinical trial is proposed.
- ***If applicable, for applications proposing clinical research:***
    - The Community Collaboration Plan (Attachment 8) is missing.
    - The application does not include a minimum of one collaborative Community partner.
- ***If applicable, for applications proposing animal research:***
    - The Animal Research Plan (Attachment 9) is missing.

9.2.4. 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.

Appendix 1. Full Application Submission Checklist

Full Application Components	Uploaded	
	Initiating PI	Partnering PI
SF424 Research & Related Application for Federal Assistance *(Grants.gov submissions only)*	☐	☐
Summary (Tab 1) and Application Contacts (Tab 2) *(eBRAP 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"	☐	☐
Impact Statement – Attachment 6, upload as "Impact.pdf"	☐	
Progression Plan – Attachment 7, upload as "Progression.pdf"	☐	
Community Collaboration Plan – Attachment 8, upload as "Collaboration.pdf"	☐	
Animal Research Plan – Attachment 9, upload as "Animal.pdf" (*if applicable*)	☐	
Partnership Statement – Attachment 10, upload as "Partnership.pdf" (*if applicable*)	☐	
Representations *(Grants.gov submissions only)* – Attachment 11, upload as "RequiredReps.pdf"	☐	☐
Suggested Intragovernmental/Intramural Budget Form *(if applicable)* – Attachment 12, upload as "IGBudget.pdf"	☐	☐
Research & Related Personal Data	☐	☐
Research & Related Senior/Key Person Profile (Expanded)	☐	☐
Attach Biographical Sketch for PI and Senior/Key Persons ("Biosketch_LastName.pdf")	☐	☐
Attach Current/Pending Support for PI and Senior/Key Persons ("Support_LastName.pdf")	☐	☐
Research & Related Budget Include Budget Justification	☐	☐
Project/Performance Site Location(s) Form	☐	☐
Research & Related Subaward Budget Attachment(s) Form (*if applicable*)	☐	☐
Additional Application Components		
Confidential Letters of Recommendation	☐	☐

Appendix 2. Acronym List

AD	Alzheimer's Disease
ADRD	Alzheimer's Disease Related Dementias
AD/ADRD	Alzheimer's Disease and Alzheimer's Disease Related Dementias
AZRP	Alzheimer’s Research Program
CDMRP	Congressionally Directed Medical Research Programs
CFR	Code of Federal Regulations
CIT	Career Initiation or Transition Partnership Option
DOD	U.S. 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
FITBIR	Federal Interagency Traumatic Brain Injury Research
FY	Fiscal Year
IACUC	Institutional Animal Care and Use Committee
IPR	In-Progress Review
IRB	Institutional Review Board
LEC	Lived Experience Consultant
NIH	National Institutes of Health
NSF	U.S. National Science Foundation
M	Million
MIPR	Military Interdepartmental Purchase Request
OHARO	Office of Human and Animal Research Oversight (previously Office of Research Protections)
OUSD	Office of the Under Secretary of Defense
PDF	Portable Document Format
PHS	Public Health Service
PI	Principal Investigator
QWERTY	First six letters of the second row of a standard English-language keyboard
RPPR	Research Performance Progress Report
R&D	Research and Development
SAM	System for Award Management
SciENcv	Science Experts Network Curriculum Vitae
SF424	Standard Form 424 (Application for Federal Assistance, Research & Related)

SOW	Statement of Work
TBI	Traumatic Brain Injury
TrRA	Transforming Research Award
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