Supporting Research in Health Disparities, Policy and Ethics in Alzheimer's Disease and Dementia Research (HPE-ADRD)

The Alzheimer's Association recognizes the importance of supporting research to understand and address diversity, equity, and inclusion in Alzheimer's disease (AD) and related dementias (ADRD). This funding program aims to provide seed or synergistic funding for research with the potential to increase knowledge about Alzheimer's disease and related dementias in populations that have been historically excluded from or are under-represented in research studies. The goal of this funding program is to increase our understanding and develop strategies to address diversity, equity and inclusion in Alzheimer's disease and related dementia research. Projects with community partnerships will be given preference through this funding program and are strongly encouraged. Supplementation of the award with other funding and/or institutional support is also strongly encouraged.

Background:

Neurological diseases are the leading cause of poor health and disability, and the second leading cause of death (Lancet Neurology, 2019). As the global population ages and grows – in part as a result of advances in research, treatment, and the public health initiatives that have followed in cardiovascular disease and cancer – the prevalence of neurological diseases in an aging population will increase. The number of people living with dementia across the world is expected to rise from 55 million in 2019 to 139 million in 2050, according to the World Health Organization.

The purpose of this funding program is to support research to study the incidence, etiology, and underlying pathology, diagnostic and treatment challenges, clinical presentation, healthcare access and behavior, health outcomes, and/or disease burden of AD/ADRD in minoritized and disproportionately affected populations, who are underrepresented in AD/ADRD research. Prioritizing inclusivity in research will broaden our understanding of AD/ADRD, leading to greater awareness, earlier and more accurate diagnosis, and ultimately to equitable treatments and interventions that benefit all communities.

For this Funding Opportunity, minoritized populations include but are not limited to, Black/ African American, Hispanic/ Latino/ Latinx, Asian/ Asian American, Native American/ Indigenous, national or ethnic, religious or linguistic minoritized groups, LGBTQIA+, those in lower socioeconomic groups, persons with disabilities, refugees, internally displaced people, and individuals living in geographies identified as underserved (rural and urban). We welcome applications from international academics researching these areas

Applications should focus on studies in minoritized populations around one or more of the following areas:

- Understand context and history of health-related disparities: Research to advance understanding of the medical history, ethical considerations, and the underpinning of health-related disparities for AD/ADRD within a community (including appropriate community organizations);
- Understand and investigate other understudied or less understood social determinants, such as illiteracy, food access, etc.
- Health Services in Clinical Care: Research to evaluate how systems and structures contribute to racism, discrimination, and other gaps in clinical care in AD/ADRD;
- Disease burden: Research towards robust estimates of AD/ADRD incidence and/or prevalence within communities; this may include specific aspects related to increased awareness or diagnosis within a setting;
- Access to care: Exploration of structural and systematic barriers that prevent access to evaluation of cognition and overall care as related to cognition, and availability and access to/uptake of interventions, therapies, and care-related support. This could include direct access to care, measuring the availability of care, and identifying gaps in resources or could include discussion about workforce-related issues more broadly.

The goal of this RFA is to increase our understanding of and develop strategies to address disparities in AD/ADRD research and clinical care, including projects aimed at identifying and understanding determinants. This could include determinants that are direct or indirect (i.e. could be upstream factors or more proximal, downstream contributions and could be contributors for a community or for the individual). Projects should provide the context for what may be institutional, systemic, and structural determinants of disparities. As we understand these determinants, we will look toward the translation and implementation of strategies to effectively address these disparities in future implementation projects.

Eligibility:

Individuals with expertise to advance research to increase our understanding and develop strategies to address disparities in AD/ADRD research and clinical care are encouraged to apply. We anticipate this to be a highly competitive program and encourage applications to assemble the strongest possible team with the needed expertise to move the work forward. Those working on social determinants of health (i.e. structural and social determinants) and health disparities in underrepresented groups

should also apply, preferably in collaboration with Alzheimer's and other dementia researchers.

Researchers with faculty appointments (e.g. Assistant Professor (entry level) and Associate Professor (mid level)) in a public and private non-profit entity, such as universities, colleges, hospitals, and laboratories are encouraged to apply. Recipients must have completed their Ph.D, MD, MBB, MPH, or their residency within 10 years. Primary applicants must be able to serve as the leading investigator on a grant for their organization/ institution.

Units of state and local governments and eligible agencies of the federal government are not able to be the primary applicant but are able to serve as a subcontractor to the primary applicant. Applications must include appropriate community partnerships (more details below). It is expected that community partners will have operationalized and specific, defined roles in the project. These should be outlined in the letter of intent (as described below).

Alzheimer's Association chapters are eligible community partners; however, no budget that comes from this RFA may support the contribution to this work.

Note: Alzheimer's Association grants are generally open to scientists and researchers across the globe; however, as a U.S.-based charity, the Alzheimer's Association is subject to, and complies with, U.S. law. As a result, the Alzheimer's Association cannot award, and will not award, grants in violation of applicable U.S. statutes and regulations. This means, among other things, that the Alzheimer's Association cannot, and will not, fund any individual or entity (i) that is subject to U.S. comprehensive or targeted sanctions or if awarding funding would result in a violation of such sanctions, (ii) that is on the U.S. List of Specially Designated Nationals or entities owned or controlled by such persons, or (iii) when doing so is otherwise prohibited by U.S. laws related to combating terrorism.

FUNDING AND AWARD PERIOD

The Alzheimer's Association anticipates funding up to 8 proposals. Each award is limited to USD\$240,000 total funding (direct and indirect costs) over a period of up to two years (minimum of 18 months). This is inclusive of USD\$200,000 for the project, including up to 15% for the travel and USD\$50,000 to directly support community partners for effort and no more than 10% indirect of the total award amount. Additional details on allowable costs are outlined in the budget section below. Indirect costs are not to exceed 10 percent (10%) of total direct costs.

Human participation assurances are not required at the time of application. Investigators have until their chosen start date to submit these documents, provided the start date is

within six (6) months from award notification. The Alzheimer's Association encourages investigators to initiate their certification applications on a schedule that recognizes that appropriate ethical (e.g., Institutional Review Board / IRB) approval at many institutions can take more than 90 days.

An extension of the term of a grant without funds (i.e. a no-cost extension) may be approved when requested electronically 45 days prior to the grant expiration. Typically, requests range from six to twelve months; grantees are allowed a 6-month extension for each year of the award (e.g. a two-year award will be eligible for 2 no-cost extensions, up to 6 months each).

KEY DATES

Letter of Intent Launch	November 7, 2023
Letter of Intent Deadline*	January 9, 2024, 5:00 PM EST
Letter of Intent Notifications	Week of February 26, 2024
Application Deadline*	April 2, 2024, 5:00 PM EST
Application Review	April-August 2024
Award Notifications	By August 30, 2024

*The Letter of Intent and application must be received by January 9, 2024, 5:00 PM EASTERN STANDARD TIME on their respective deadlines. They will not be accepted after these dates -- no exceptions will be made. Hard copies or emails will not be accepted.

ELIGIBILITY

Researchers with full-time staff or faculty appointments (Assistant Professor and Associate Professor). In general, scientists and clinicians from public, and private research

laboratories, medical centers, non-profit research institutes, hospitals, and universities from around the world are eligible to apply. State and federal government-appropriated laboratories in the U.S. and abroad and for-profit organizations are prohibited from serving as the lead applicant institution. For U.S. VA-based investigators, please work with your affiliated non-profit organization to apply. In other circumstances, state and federal government scientists can participate as collaborating scientists with research teams from other eligible applicant institutions.

The Alzheimer's Association is committed to excellence through equity. We encourage applicants from representative backgrounds to apply to our funding opportunities, which will promote the expression of diverse perspectives, approaches, and experiences, including those of underrepresented groups.

For U.S. entities, the Letter of Intent (LOI) materials will include proof of your organization's not-for-profit status and a W9 signed and dated by the signing official. Non-U.S. entities must provide a W8-BEN-E signed and dated by the signing official.

Your LOI will not be accepted without these documents (IRS Letter of Determination is no longer accepted). For non-profit organizations (non-academic), additional documentation may be required to confirm your organization has a segregation of duties between transaction execution and transaction utilization.

The Alzheimer's Association reserves the right to request additional documentation and/or materials to verify an applicant's status should any of the eligibility requirements be unconfirmed.

ELIGIBILITY CONSIDERATIONS

- Overlapping funding of more than one Alzheimer's Association grant is not allowed. Investigators who currently have an active Association grant may apply for this program if the projects are distinctly different.
- Investigators delinquent in reporting: The Alzheimer's Association will not accept new grant applications from currently funded investigators who are delinquent in submitting required reports and other deliverables on active grants. Investigators who have previous Alzheimer's Association awards closed as 'Incomplete' are not eligible to apply. This policy will be strictly adhered to with no exceptions.
- Adjunct faculty, current students, and/or postdoctoral fellows are not eligible.
- Current members of the Association's Medical and Scientific Advisory Group (MSAG), the International Research Grant Program (IRGP) Council, and current employees of the Alzheimer's Association are ineligible to (a) compete for any research grant or (b) be included as a co-investigator or to receive any financial benefit from an application. These individuals may be listed as key personnel or collaborators on an application and will be recused from participating in their peer review.

• If you have questions or are unsure of your eligibility, please reach out to the Alzheimer's Association grants team at grantsapp@alz.org.

To avoid disqualification, investigators are encouraged to carefully consider these eligibility and ineligibility requirements before applying. The Alzheimer's Association reserves the right to find an investigator ineligible to submit for a particular program, based on the guidelines below. This section describes general inclusion and exclusion criteria. Specific requirements and additional exclusions to eligibility are noted in some detailed competition descriptions.

BUDGET

A" Budget summary" for the proposed research project is required and must be submitted with the application and within the allowable two-page limit. Your budget must not exceed USD\$160,000 in any given year (direct and indirect costs) nor exceed USD\$240,000 total across all years, including indirect costs. The minimum duration of the award is 18 months, and the maximum duration is up to 2 years – awards cannot be for only one year. This is inclusive of USD\$200,000 for the project, including up to 15% for the travel and USD\$50,000 to directly support community partners for effort. No more than 10% of the total award may be used for indirect costs; this is inclusive of indirect costs for the implementing institution as well as any to subcontracts.

Allowable costs under this award include:

- Small pieces of laboratory equipment and laboratory supplies (purchases over \$10,000 require prior approval, even if included in the proposed budget)
- Computer software is used strictly for data collection
- Salary for the principal investigator, scientific (including postdoctoral fellows), and technical staff (including technicians and modest administrative support)
- Research supplies needed for the proposed studies
- Support for travel to scientific and professional meetings, not to exceed 15% of the total of the award in any given year
- Open access publication fees for journal articles related to the funded research project;
- Membership to ISTAART, the professional society of the Alzheimer's Association; and
- Participant travel for studies involving human volunteers is an allowable cost. Travel that is for participants would not be included in the travel expenses but should be listed as an "other expense" (itemized in the budget).

Not allowable as Direct Costs under this award include:

- Computer hardware or standard software (e.g. Microsoft Office, monitors, computer parts)
- Major pieces of laboratory equipment such as freezers, ultracentrifuges, RT-PCR machines, microscopy/imaging equipment
- Equipment service contract fees
- Construction or renovation costs
- Tuition
- Rent for laboratory/office space
- Expenses such as Data Network Recharges and Computing and communication device support services However, data sharing and/or data storage for imaging, sequencing, and other study data is allowed
- General liability insurance, such as GAEL
- The Alzheimer's Association Medical and Scientific Advisory Group (MSAG), the International Research Grant Program (IRGP) Council members, and current employees of the Alzheimer's Association are allowed to be key personnel or collaborators on projects, however, they are not allowed to receive any salary or compensation. A complete list of MSAG and IRGP Council members can be found on our website alz.org/grants

PROPOSAL SUBMISSION PROCEDURES

1. <u>Letter of Intent Submission</u>

The first step in applying to the Alzheimer's Association for any research grant is to create and submit a Letter of Intent (LOI) through the online application system at http://proposalcentral.com. Applications will not be accepted without an approved LOI. First-time users must register and fill out a Professional Profile to begin the LOI/application process. The LOI and completed application must be submitted by a single Principal Investigator (PI). Applicants must submit an LOI for the current active cycle that they are interested in, NO EXCEPTIONS. All LOIs must be approved or rejected in the current grant cycle. Hard copies or emails of the LOI will not be accepted. The purpose of the LOI is to ensure that all applicants are eligible for the competition they are applying to and to assist Association staff in planning for peer reviews. LOIs will not be accepted after the deadline date. No exceptions will be made. The applicant is responsible for adhering to the space limitations (described below) and any decision regarding moving an LOI forward will be evaluated based on the submitted information.

The Letter of Intent (LOI) is completed through the online interactive system. Applicants must complete the required tabs and upload any required documents. Some of these required fields are described below:

- Name of the principal investigator
- Contact information for the principal investigator
- Lead Institution The applicant must be a full-time employee at the time of submission (*institution/organization name must be in English*)

- List your current academic rank/position at the time of submission, do not list pending promotions
- Proposal title
- Area of focus of the submission, such as diverse populations, social and behavioral, or biological (options will be available to choose from within the system)
- Outline of the proposed work and/or project which should include:
 - Specific question and/or topic to be addressed through the proposed work and why this is an important topic/ question to be investigated
 - While this RFA includes the engagement of community partners, there must be a specific research question being addressed and/or better understood in the proposed work
- Description of institutional/organization environment, including community partner organizations and contributions of each partner for the project; partners are expected to have a clearly defined role and contribution to the overall project. Each section is limited to 8,000 characters including spaces, and it is the responsibility of the applicant to ensure the space limit is adhered to.
- Employer (institution) Identification Number (EIN) -- must match the EIN listed in the non-profit documentation
- All applicants must include an ORCID ID. This is a required field, you will not be able to submit your LOI without this information.
- Provide a W9 signed and dated by the Signing Official for US entities. For non-US entities provide a W8 signed and dated by the signing official. This document should not contain the applicant's information.
- Biosketch is required for the primary applicant only. Additional biosketches can be included at the full application stage. It is highly recommended to use the NIH biosketch format
- Budget details are not required at the LOI stage
- Additional attachments not specifically outlined above are not allowed and will be removed

The LOI will be evaluated in a blinded manner. Applicants should not identify themselves, collaborators, and or/institutions in the project summary of the LOI.

Letters of intent will be reviewed by a program panel, selected by the Alzheimer's Association to include individuals with expertise that are not in conflict with proposals submitted to evaluate LOIs based on the potential impact and feasibility of the proposed work and the qualifications of the proposed team. No feedback will be given following the LOI review. If invited to submit a full proposal, applicants will receive additional information regarding next steps. Should a project be invited for full submission, the project leads will receive additional instructions for a full application.

Note: Due to the high volume of submitted Letters of Intent, specific feedback and reviewer comments are not provided at the LOI stage.

2. Full Application Submission

If you are invited to submit a full application, the required materials including the application format, templates, and instructions, will be available online at

proposalCENTRAL after your LOI has been approved in the system. The full application must consist of the following documents and must not exceed the maximum page limit allowed for each section:

- Background: A description of the environment, research success to date, and identified gaps. Should include an overview of the needs assessment process and results, including how these findings informed the final proposal. (2 pages)
- Workplan: Detailed outline of the proposed work including the specific question and/or topic to be addressed through the proposed work, why this is an important topic/ question to be investigated, what gap this is addressing, how will this understanding impact/ advance future work and build toward increased equity and representation, how the team including the community partners will work together (including roles and responsibilities) to address this proposed work. Work Plan should also include a proposed administration of the project to address any conflicts among partners should they arise. (5 pages).
- Plan for sharing and distribution of findings: A data management and sharing plan should be included, specific to the project; this should include dissemination to the research community but more importantly to the community being engaged in the project. (1 page)
- References: A list of references cited should be provided. There is no required reference style. (1 page)
- Letters of support: Letters of support from community partners should be included (no more than 4 will be allowed) and should detail how these organizations/ individuals will be engaged and describe any financial or in-kind support committed to the project. (no more than 2 pages each)
- CVs/Biosketches: A CV or Biosketch for the Project Lead and each key individual who will participate in the proposed work should be provided. (no more than 5 pages each). Applicants should emphasize any past and or current work with community-based research and/or partnerships and/or future plans to ensure they have the necessary expertise and/or mentorship to accomplish the goals set out in the research plan.
- Budget: A detailed budget broken down by year and aligned with the annual milestones should be provided. (use template)
- Budget Justification: The budget should be accompanied by a justification describing each of the proposed costs, including rationale for proposed level of effort for personnel (2 pages)
- W9 signed and dated by the signing official for US entities. For non-US entities, a
 W8 signed and dated by the signing official.
- Recruitment Plan (1 page) If applicable

Applications will be reviewed by the Alzheimer's Association and a select

panel of experts with special attention to:

- Significance of the question being studied
- Applicant information
- Quality of the work plan
- Quality and adequacy of available resources and budget
- Impact-Risk of the proposal and how it will add to the field's overall knowledge and advancement

The PI who submits the application must be the same PI who submitted the approved LOI. An application submitted on behalf of another applicant or by an administrator will result in a rejected application. Once the applicant enters the application system, on-screen instructions will be provided to complete the application process. The application does not need to be completed in one session; a partially completed application can be saved and completed at any time before the deadline.

It is **imperative** that you proofread your application before submission; you will not be allowed to make any changes to the application after the deadline or once applications are under review.

It is the responsibility of the applicant to ensure and verify that:

- 1. The application is submitted by the receipt date/time deadline. Once submitted, you will receive a confirmation e-mail from proposalCENTRAL that your application was successfully submitted. If you do not receive a confirmation, click the **Proposals** tab and under the "**Status**" column make sure it says **Submitted** and not *In Progress* which indicates you have not yet submitted your application.
- 2. The application is complete and accurate before submission. Only a single copy of an application will be accepted. The Alzheimer's Association does not require signatures at the time of submission, the signature page provided is for use should your institution/organization require signatures; we do not override any institutional policies and/or procedures. Please do not submit the signature page with your application.
- **3.** Revisions, additional materials, letters of collaboration/support and/or reference, manuscripts, appendices, etc., are not allowed and if attached, will be removed from your application.

ETHICAL/REGULATORY APPROVALS & REPORTING REQUIREMENTS

If awarded for funding, the Alzheimer's Association requires that any necessary ethical and/or regulatory approvals are kept current, and may also require specific reporting throughout the lifetime of the award. This includes, but is not limited to, the following:

Human Participants Assurances

Human participants (subject) assurances are not required at the time of application. The

Association accepts only certifications that apply specifically to the funded project and must include the name of the awardee.

Annual Scientific and Financial Reports

Annual Scientific & Financial Reports must be submitted at the end of each reporting period as long as the grant remains active. Final Scientific & Financial Reports must be filed within 90 days of the grant's end date. All reports must be submitted electronically via proposalCENTRAL. The Financial Report must be approved and signed by someone with financial authority in the Office of Research and Sponsored Programs at the recipient's institution.

Publications, Presentations and Abstracts

Electronic copies of publications, presentations and abstracts that report research supported by funds from the Alzheimer's Association must be submitted electronically at the time of publication. These copies will become part of the official file of the grant and will be provided to the Communications Division of the Alzheimer's Association to assist in the efforts to further inform the public about the International Research Grant Program of the Association.

Recruitment Efforts for Clinical Studies

Projects involving human participants must address in their application the appropriate inclusion or exclusion of individuals in the proposed research project and describe recruitment efforts to represent the community in which the study is planned or being conducted. If awarded and prior to distribution of funding, the researcher must also provide a description of their recruitment plan, including an outline describing how their recruitment efforts will ensure diversity in their participants. Recruitment efforts should focus on diversity within key target groups, including a diverse representation of (but not limited to): sex, gender identity, sexual orientation, socioeconomic status, race, and ethnicity. This will be an aspect of required reporting throughout the duration of the grant and continued funding is contingent on applications addressing these goals.

ADDITIONAL INFORMATION

Financial Responsibility

Funding is awarded to the institution, not to the individual principal investigator. The principal investigator or a first degree relative cannot be listed as the signing official or financial officer, or have checks sent to their attention if awarded.

Multiple and Overlapping Submissions

Multiple submissions from one applicant are not permitted. This includes multiple submissions from the same group and/or collaborators. Overlapping submission with an existing Alzheimer's Association award is not allowed. Investigators who currently have an active Association grant may apply for this program if the projects are distinctly different; overlapping funding is not allowed. For a project submitted to this program and related to an active Association award, the current award must be completed and closed by June 30, 2024.

Review Process Overview

All proposals are subject to a multi-stage peer-review process carried out through an online system. In the first stage, applications are reviewed and rated by a minimum of three peer scientists with expertise in the proposed area of research. Applicants may include recommended reviewers and also have the option to exclude specific reviewers from evaluating their application if a conflict of interest exists. Conflicts of interest include (but are not limited to):

- 1. The Applicant trained with/or by the reviewer.
- 2. The Reviewer published with the Applicant in the last four (4) years. This excludes workshops or large consortia (e.g., ADNI, IGAP).
- 3. The Reviewer has been a co-investigator on a grant application or award with the Applicant in the last four (4) years.
- 4. Reviewer has a conceptual difference of opinion with the Applicant that will prevent a fair review.
- 5. Reviewer will receive financial benefit from the Applicant receiving an award.

The second stage includes further review and discussion of the scores and comments resulting from the initial review process. This second review will be carried out by an invited review committee, including representation from the Alzheimer's Association International Research Grant Program (IRGP) Council and reviewers identified by the Alzheimer's Association, to ensure fairness and equity in the initial review procedures and to make funding recommendations to the Association. Final recommendations from the review panel are shared with the Medical and Scientific Advisory Group (MSAG) and with the Alzheimer's Association for final approval in a coordinated manner. This multi-stage process is central to our award decisions and is designed to ensure both scientific rigor and fairness in the review of all submitted applications.

Appeals of Scientific Peer-Review

To maintain a fair and rigorous review system, the Alzheimer's Association has established a process for appeal of funding decisions. There is no appeal accepted for the letter of intent stage. Regarding applications, an appeal is intended to address extraordinary circumstances. Appropriate reasons for initiating an appeal might include:

- Evidence that a reviewer has an undeclared conflict of interest
- An egregious error or misunderstanding in the review process
- Active malfeasance or demonstrable lack of due diligence

The appeal process is not intended to provide a mechanism for routine protest of failure to receive a grant. Funding through the Alzheimer's Association International Research Grant Program (IRGP) is extremely competitive and is limited by the availability of funds.

If an applicant believes an extraordinary circumstance has contributed to failure to receive funding, the principal investigator may send a two-page, double-spaced formal letter of appeal to grantsapp@alz.org. Appeals must be submitted within two weeks from the date your application outcome notification is sent. Notification of action on the appeal will be made via email, usually within 90 days of the appeal deadline.

Nondiscrimination and Harassment Statement

The Alzheimer's Association is committed to providing an environment free from harassment and discrimination. The Alzheimer's Association strictly prohibits harassment and discrimination based on race; creed; color; religion; sex; sexual orientation; national origin; ancestry; age; veteran status; citizenship status; marital status; physical or mental disabilities; pregnancy, gender identity or expression (including transgender status); genetic information; and any other characteristic protected by federal, state or local law.

- - - -

This program announcement is posted on the website of the Alzheimer's Association at <u>alz.org/grants</u>. For additional information, please send all inquiries to grantsapp@alz.org