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The Alzheimer's Association &

The Foundation of the American Society of Neuroradiology (ASNR) Funding Opportunity

Imaging Research in Alzheimer's and other Neurodegenerative diseases

Background:

The Alzheimer's Association's mission is to end Alzheimer's and all other dementia — by accelerating global research, driving risk reduction and early detection, and maximizing quality care and support. The American Society of Neuroradiology (ASNR) has a mission to promote education and research in the field of neuroradiology and the development of new ideas for clinical practice. The Association and ASNR are partnering to offer this unique funding program to leverage their respective expertise, their communities, *Imaging Research in Alzheimer's and other Neurodegenerative diseases*. The goal of this program is to support the development of new novel imaging tools, to advance imaging-based research and to provide funding for novel and innovative imaging data analysis as relates to Alzheimer's and related dementia.

Purpose:

Imaging is an important tool to better understand brain related changes in Alzheimer's and other neurodegenerative diseases and to develop opportunities for early and accurate diagnosis. With ongoing and planned clinical studies to advance our understanding as well as to evaluate potential future treatments, it is important to incorporate imaging biomarkers into these trials as well as continuing to improve the diagnostic and prognostic power of these techniques.

The purpose of this partnership between the Alzheimer's Association and the American Society of Neuroradiology is to provide support for the advancement of the field of imaging of Alzheimer's disease and other neurodegenerative diseases by providing support for early stage pilot projects that will advance research to support the development of new novel imaging tools, to advance imaging-based research and to provide funding for novel and innovative imaging data analysis.

This mechanism highly encourages investigators to include within an explicit plan for overcoming barriers to the enrollment of individuals from health disparity populations in their study.

The evaluation of causative factors including environmental and genetic factors contributing to disease development and progression, identifying potential new treatment strategies and information to improve care for people with dementia, and advancing our knowledge of risk reduction and disease prevention are long-term goals. The goal of this program is to translate research into strategies to increase our understanding of the pathogenesis of Alzheimer's and other neurodegenerative diseases, and to help stratify populations and possible treatments.





Three awards, each having a maximum budget of \$200,000 (including no more than 10% indirect costs), are available for one-year award.

Funding and award period

ASNR and the Alzheimer's Association anticipates funding up to 3 proposals through this joint initiative. Each award is limited to \$200,000 total funding (direct and indirect costs, indirect costs are restricted to no more than 10% including subcontracts) over a period of 1 year. Additional details on allowable costs are outlined in the budget section.

Key Dates:

- Letter of Intent Launch May 1, 2023
- Letter of Intent Deadline June 5, 2023
- Letter of Intent Notifications week of July 31. 2023
- Application Deadline September 7, 2023
- Application Review September December 2023
- Award Notifications by December 20, 2023

The Letter of Intent and application must be received by 5:00 PM Eastern Time on their respective deadlines via ProposalCentral (instructions below). They will not be accepted after these dates – no exceptions will be made. Hard copies or emails will not be accepted.

Eligibility Requirements

- Awards made through this joining initiative support investigators at every professional stage and are also designed to help talented scientists establish careers in Alzheimer's and other neurodegenerative imaging research.
- Submissions from collaborative research that have experience across aging and neurodegenerative diseases are strongly encouraged. Novel and creative ideas are sought, and proposals should also demonstrate feasibility.
- Neuroradiologists (MD, MD/PhD, DO) and scientists (PhD) with faculty appointments are encouraged to apply, including instructor, assistant, associate and full professor levels.
- Clinical neuroradiology fellows and post-doctoral fellows are eligible to apply as a principal investigator (PI) but must collaborate with an administrative PI who serves as the director of the laboratory in which the research will be conducted, who should have oversight of reporting requirements, if funded.
- Training or mentoring-only proposals will not be considered.
- Multidisciplinary teams are encourage to apply

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Letter of Intent (LOI) Submission

The first step in applying 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).** 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; it is not a letter but rather specific fields in the online system for the applicant to complete. Applicants must complete the required tabs and upload any required documents.

The LOI should include the following information:

- Descriptive title of proposed research
- Name, physical address, email address, and telephone number of the principal investigator(s)
- Names of other key personnel
- Name of participating institution(s)
- Include a concise description of your proposed project, including methodology (1,000 characters)
- Specific aims, including a description of how your project addresses this specific RFA (1,000 characters) (1,000 characters)
- Include your plan for overcoming barriers to the enrollment of individuals from health disparity populations in the project; including name(s) any established community partnerships/collaborations that will facilitate recruitment (1,000 characters)

Full Application Submission

If you are invited to the *Imaging Research in Alzheimer's and other Neurodegenerative diseases* to submit a full application, the required materials including the application format, templates, and instructions, will be available online at <u>proposalcentral.com</u> 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:

- Problem Statement (1 page).
- Work Plan (5 pages).
- Recruitment Plan (1 page).
- Available Resources & Budget Justification (2 pages).



- Up to 3 letters of support (no more than 2 pages each) highlighting the community support and/or partnerships of applicable organizations.
- Biosketch(es) PI/Co-PI/Key personnel limited to 4-5 pages each (the new NIH format is acceptable).
- W9 signed and dated by the signing official for U.S. entities. For non-U.S. entities, a W8 signed and dated by the signing official.
- Plan for Data Sharing (1 page).
- References (1 page) use the reference style that is most common in the major journal(s) for your discipline, specialty, or sub-specialty.

Applications will be reviewed by ASNR and 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 overall knowledge and advancement.
- Applications that emphasize collaborative approaches will be given preference.

The PI who submits the application must be the same PI who submitted the approved LOI. An LOI submitted on behalf of another applicant or by an administrator will result in a rejected LOI. 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 <u>not</u> 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:

- The application is submitted by the receipt date/time deadline. Once submitted, you will receive a confirmation email from proposalcentral.com 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.
- The application is complete and accurate before submission. Only a single copy of an application will be accepted. We do 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.



• Revisions, additional materials, and/or reference, manuscripts, appendices, etc., are not allowed and, if attached, will be removed from your application. Up to 3 letters of support (no more than 2 pages each) are allowed. Additional letters will be removed.

Full Applications must be submitted no later than 5 pm (EST) on September 7, 2023

Multiple and Overlapping Submissions

Multiple submissions from one applicant is not permitted. This includes multiple submissions from the same group and/or collaborators. No more than one LOI is allowed per applicant.

Review Process Overview

Letter of intent (LOI):

LOI are subject to a peer-review process carried out through an online system. LOIs are reviewed and rated by up to three peer scientists with expertise in the proposed area of research.

Full Applications:

All Full proposals are subject to a multistage peer-review process carried out through an online system. In the first stage, applications are reviewed and rated by up to 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. The Foundation of the ASNR and the Alzheimer's Association will carefully select reviewers to avoid any conflict of interest. Conflict of interest may be as follows.

- The Applicant trained with/or by the reviewer.
- The Reviewer published with the Applicant in the last 4 years. This excludes workshops or large consortia (e.g., ADNI, IGAP).
- The Reviewer has been a co-investigator on a grant application or award with the Applicant in the last 4 years.
- Reviewer has a conceptual difference of opinion with the Applicant that will prevent a fair review.
- Reviewer will receive financial benefit from the Applicant receiving an award.
- There might be other instances that may constitute a Conflict of Interest and the organizations reserve the right to identify or note as a conflict of interest beyond those listed.

The second stage includes further review and discussion of the scores and comments resulting from the initial review process. This second review is carried out by ASNR and the Alzheimer's Association with an identified committee of experts to ensure fairness and equity in the initial review procedures and to make funding recommendations to the funding partners. This multistage process is central to the award decisions and is designed to ensure both scientific rigor and fairness in the review of all submitted applications. Following review, ASNR and Alzheimer's Association will jointly finalize funding decisions based on available funding.



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. However, if the application is to be awarded, a more detailed budget will be required and must be approved before the disbursement of funds. Your budget must not exceed the maximum amount of the award of \$200,000 in total. Award is for one-year duration, and it is required that most of the funds awarded under this program be used for direct research support. No more than 10% of budget may be included as indirect costs, including subcontracts; 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 project proposal budget).
- Computer equipment required to perform advanced analyses such as those involving artificial intelligence
- Computer software if used strictly for data collection and/or analysis.
- Salary for the principal investigator, scientific (including postdoctoral fellows) and technical staff (including modest administrative support).
- Research supplies needed for the proposed studies.
- Support for travel to scientific and professional meetings, not to exceed \$2,500.
- 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 insurances, such as GAEL
- Wire and currency exchange fees
- The Alzheimer's Association <u>Medical and Scientific Advisory Group (MSAG)</u>, the <u>International</u> <u>Research Grant Program (IRGP) Council members</u> and current employees of the Alzheimer's Association and ASNR employees 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





Additional Information

Ethical/regulatory approvals and reporting requirements

If awarded for funding, ASNR and the Alzheimer's Association require 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 Participant Assurances

Human participant assurances are not required at the time of application. Investigators have up to 90 days after receipt of their award notification to submit these documents. However, the ASNR and the Alzheimer's Association encourage investigators to initiate their certification applications on a schedule that recognizes that approvals at many institutions can take more than 90 days. We will accept only certifications that apply specifically to the funded project and must include the name of the awardee. An award letter will not be issued unless the appropriate certifications are in place and include the name of the awardee within the 90 days from award notification. The same applies for animal ethical approvals, if applicable. Clinical trials should be registered at an appropriate trial registry within the first year of the award. Appropriate registries can be found here:

https://www.who.int/clinical-trials-registry-platform/network/primary-registries. The trial ID must be included in all publications resulting from the funded research.

Annual Scientific and Financial Reports

Interim Scientific and Financial Reports must be submitted at the end of each reporting period as long as the grant remains active. Final Scientific and Financial Reports must be filed within 90 days of the grant's end date. All reports must be submitted electronically via <u>proposalcentral.com</u>. 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. All reports submitted will be evaluated by the Alzheimer's Association and ASNR.

Publications, Presentations and Abstracts

Electronic copies of publications, presentations, and abstracts that report research supported by funds from the "Alzheimer's Association & American Society of Neuroradiology Imaging Research in Alzheimer's and other Neurodegenerative Diseases Program" should acknowledge that support and must be submitted electronically at the time of publication to grantsapp@alz.org

Recruitment Efforts for Clinical Studies

Projects involving human participants must address 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. Prior to distribution of funding, the researcher must provide a description of their recruitment plan, including an outline describing how their recruitment efforts will ensure diversity in their participants (see https://www.nimhd.nih.gov/about/overview/ for NIH operationalization). 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 tracked throughout the duration of the grant and continued funding is contingent on applications addressing these goals.

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 is not permitted. This includes multiple submissions from the same group and/or collaborators.

Appeals of Scientific Peer Review

To maintain a fair and rigorous review system, ASNR and the Alzheimer's Association have 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. It is anticipated that funding through this program will be extremely competitive and is limited by 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 (Word document) to grantsappeals@alz.org. Any supporting documents included must be submitted as a PDF. **Appeals must be submitted within 2 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

ASNR and the Alzheimer's Association are committed to providing an environment free from harassment and discrimination. ASNR and 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.