Alzheimer's Association and NACC's New Investigator Award Program (NIAP) – RFA 2024-25 Funding Cycle

Overview:

National Alzheimer's Coordinating Center (NACC) is home to one of the largest, oldest, and most powerful Alzheimer's disease and related dementias (ADRD) datasets, built in collaboration with more than 42 Alzheimer's Disease Research Centers (ADRCs) throughout the US over the past 20+ years. The Alzheimer's Association is the world's largest non-profit funder of Alzheimer's and all dementia science, with over $360 million in funding committed today to over 1,000 projects in 53 countries.

This year, these two organizations are partnering together to offer the Alzheimer's Association and NACC New Investigators Awards Program (NIAP).

Up to ten (10) NIAP awards will be granted in the spring of 2024 based on the scientific merit, through peer-review as described below, of submitted applications. Eligible candidates include new and early-career investigators from across the 37 ADRCs programs. These awards aim to support career development and advance scientific research on ADRD.

Funding early career investigators is a core tenant of the missions of the Alzheimer's Association, NACC and the ADRCs.

Features of a Successful New Investigator Project:

Successful NIAPs must demonstrate scientific rigor. This will be determined through peer review; the peer-review process will evaluate the scientific merit and potential impact on the field of ADRD. Areas of study are open across the entire spectrum of proposed research on-going within the ADRC network, including but not limited to data-driven and methodological studies, if they rely on credible data sources. The research studies may be discovery science, translational, clinical or care related, and may include a range of methodologies including genomic studies and data science.

Research proposals should advance ADRD science through new approaches that have the potential to identify and characterize important gaps in knowledge related to environmental exposures, social and structural determinants of health, biomarkers, disease mechanisms, or novel therapeutic approaches. Research questions may be rooted in multiple disciplines, such as neuropathology, epidemiology, neurology, psychiatry, gerontology/aging, psychology, imaging/radiology, pharmacology, informatics, and data science/biostatistics.

Importantly, the research should aim to provide novel insights and bring new insights to our understanding, rather than replicating previous studies.

Data Sources:

New Investigator projects may leverage any data source or study base but must defend its scientific rigor to address the research questions at hand. NACC data are NOT required to be used to NIAP proposals that allow the investigator to visit and/or collaborate across ADRCs to meet with experts (internal or external Mentors) or obtain study-specific data are encouraged.

Funding and Award Period:

The partners will fund up to ten (10) awards, totaling $135,000 in direct costs for one to two years total for the 2024-2025 award cycle, with funds to be distributed June 2024 through May 2026. For awards funded by the Alzheimer's Association, the indirect rate will be restricted to 10% on top of the direct costs. Details regarding the budget and timeline are addressed in the Application section below.

Applications will be funded based on the decision of the NACC Steering Committee, based on the scientific merit and potential impact as determined by peer review.

New investigators will have up to two years to complete their project.

The ADRC Director is expected to provide oversight of the NIAP award for the distribution of funds and/or the expenditures. The partners will work with the ADRC institutional Grants Office on the appropriate reporting.

KEY DATES

Letter of Intent and Request a Mentor from the ADRC RECs Deadline*	**November 30, 2023, 5 pm EST**
Application Deadline*	**February 16, 2024, 5 pm EST**
Application Review	**February – April 2024**
Award Notifications	**May 2024** - **Award winners announced at 2024 Spring ADRC Meeting, Austin, TX**

*The Request for a Mentor, Letter of Intent and Application must be received by 5:00 EST Time on their respective deadlines.

Eligibility:

- **You must be a new investigator**, defined as post-doctoral fellows, residents, or junior faculty that have not yet been promoted to associate professor rank (MD or PhD), within 10 years of rank, and not already having had an R01 grant at the time of applying for a NIAP. Researchers and investigators with a higher or lower academic rank are not eligible to apply.
- **New investigators must be affiliated with an ADRC.** ADRC Directors must provide a letter to confirm that the new investigator is affiliated with their ADRC. A template for the letter is provided in the online application materials.

Apply for a New Investigator Award

How to Apply

Step No. 1: Submit a Letter of Intent (LOI) and Optional Request a Mentor

How to Request a Mentor:

All applicants will have the opportunity to be connected with a mentor who can provide guidance during the NIAP application process. These mentors will be provided through a partnership with the ADRC Program's Research Education Component (REC) Steering Committee.

To request a mentor, applicants must complete a letter of intent (LOI) and indicate on the LOI form if they would like to be matched with a mentor by the REC Steering Committee.

Mentor and Mentee expectations:

- REC will match mentees with a mentor who is knowledgeable about the areas of research indicated by the keywords on the LOI.
- Mentors are expected to review applicants' specific aims and proposal draft, which can be accomplished asynchronously, between December 28, 2023, and February 15, 2024

How to Submit a Letter of Intent:

The first step in applying for a NIAP is to submit a Letter of Intent (LOI) through the proposalCENTRAL online application system at proposalcentral.com. Applications will not be accepted without an approved LOI submitted within that grant cycle/program. First-time users must register and fill out a Professional Profile in proposalCENTRAL to begin the LOI and application process.

Key Requirements:

- The LOI, mentor request, and completed application must all come from the same new/ early career investigator.
- You must submit an LOI for the current active grant cycle you're interested in; **no exceptions** will be allowed.
- Hard copies or emails of the LOI will **not** be accepted.

Purpose and Deadline:

- The LOI ensures your eligibility for the competition and assists in the planning of peer reviews.
- **No LOIs will be accepted after the deadline; no exceptions.**

Submission Guidelines:

- Applicants are responsible for adhering to space limitations and other submission requirements.
- Decisions on progressing an LOI will be based on the information submitted.
- Complete the LOI through the online interactive system, making sure to fill in all required tabs.

Required fields you'll need to complete for your LOI:

- Name of the new investigator, academic rank, position title, and contact information; this should not include pending promotions and should be specific to your academic rank and position title at time of application.
- Name of Alzheimer's Disease Research Center – and the ADRC Director (applicant must be affiliated with an ADRC at the time of submission)
- Proposal Project Title, keywords, and 1-2 sentence brief description of the topic area
- Each LOI is reviewed by NACC and Alzheimer's Association teams to verify eligibility.
- When an applicant requests a mentor by indicating it on the LOI form on ProposalCENTRAL Central, the partners will work with the REC Steering Committee to help match NIAP applicants with appropriate mentors.
  - Mentors and mentees are expected to arrange an initial contact and plan for at least two review and feedback sessions during the application process.

Step 2: Write the Research Plan:

Prepare a research plan that emphasizes methods and uses the following outline format. DO NOT SKIP ANY SECTIONS. *Applications missing any of the following will be returned to the new investigator with <u>no further review</u> taking place. The completed research plan should be inserted <u>at the end</u> of your application packet.*

Specific Aims (one page).

State the goals of the proposed research and summarize the rationale and expected outcome(s), including the impact that the results of the proposed research will exert on the research field(s) involved.

List succinctly the specific objectives of the research proposed (e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology). These may be stated as specific "research questions" or as testable hypotheses.

Research Plan (6 pages total for #1, 2, 3 below)

Organize the research strategy in the specified order and using the instructions provided below or as stated in the RFA. Start each section with the appropriate section heading—**Significance, Innovation, Approach.** Cite published experimental details in the research plan section text, in order of occurrence, consistent with AMA or similar numbered style, and provide the full reference in the bibliography and references cited section: #4 below.

Do not include hyperlinks in your Specific Aims or Research Strategy.

1. **Significance**
   a. Explain the importance of the problem or critical barrier to progress that the proposed project addresses.
   b. Describe the scientific premise for the proposed project, including consideration of the strengths and weaknesses of published research or preliminary data crucial to the support of your application.
      i. Describe the "rigor of prior research" in your topic area in that it identifies weaknesses or gaps in knowledge. See NIH "Rigor and reproducibility" Rigor and reproducibility links below
      ii. https://grants.nih.gov/policy/reproducibility/resources.htm
      iii. https://grants.nih.gov/policy/reproducibility/guidance.htm
   c. Explain how the proposed project will improve, impact, drive scientific knowledge, technical capability, and/or clinical practice in some manner for Alzheimer's disease and/or related dementias.
2. **Innovation**
   a. Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
   b. Describe any novel theoretical concepts, approaches or methodologies, instrumentation or intervention(s) to be developed or used, and any advantage over existing methodologies, instrumentation, or intervention(s).

c. Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

3. **Approach**
    a. Describe the overall scientific strategy, methodology, and analyses to be used to accomplish the Specific Aims of the project. Depending on your specific aims you may wish to describe each Specific Aim individually or you may treat them as a group.
        i. Describe the experimental design and methods proposed and how they will achieve robust and unbiased results. Include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
        ii. Describe how your methods for analysis and sample size are appropriate for your plans.
        iii. If applicable, describe your strategy to establish feasibility, and address the management of any high-risk aspects of the proposed work.
        iv. Explain how relevant biological variables, such as sex, are factored into research designs and analyses for studies in vertebrate animals and humans. Refer to the NIH Guide Notice on Sex as a Biological Variable in NIH-funded Research for additional information.
        v. Include a timeline and milestones for your study.

4. **Bibliography and References Cited (No page limit)**
    a. Provide a bibliography of any references cited in the Research Strategy or Specific Aims sections. Reference citations should be provided in AMA or similar style, in order of their occurrence in the text. (hint: Use a reference manager tool such as EndNote or numerous others to do this easily). There are no page limits of references to be included.

Step 3: Prepare the institutional description and budget pages.

All applications must be prepared and submitted as a single PDF file via online submission. All forms packets should include the following PHS 398 form pages.

- **Page 1** - Cover (Face page)- The Center Director must be listed as the PI on the face page, with the New Investigator and any mentor(s) listed in the multiple PI section on the continuation page. *The initial proposal does not have to be signed*, but if the project is awarded funding, then a face page signed by a grants official will be required. Funding will be awarded to the Center Director, not the New Investigator *(see section titled "Budget considerations" on page 3.)* PHS 398 Cover Page Template
- **Page 2** – Project Summary, Relevance, Performance Sites - PHS 398 Template
- **Page 3** - Key Personnel, Other Significant Contributors.

- **Page 4** - Detailed budget for initial budget period *(project can span one to two years)* The Center Director and mentor are asked not to request FTE on the application. PHS 398 Template.
- **Page 5**- Budget Justification - PHS 398 Template
  - Your budget must not exceed the maximum amount of the award, $135,000 in direct costs.
  - Applicants should not include indirect costs in your budget.
    - Note: For awards funded by the Alzheimer's Association, the indirect rate will be restricted to 10% of the direct costs.
  - The budget justification should clearly detail how effort or other budgeted items are necessary to support the proposed project (the budget pages must follow the required NIH format). Allowable costs under this award:
    - Salary for the principal investigator, scientific (including postdoctoral fellows) and technical staff (including modest administrative support)
    - Computer software if used strictly for data collection and/or analysis
    - Research supplies needed for the proposed studies
    - Open access publication fees for journal articles related to the funded research project
    - Support for travel to scientific and professional meetings not to exceed $5,000 in any given year, this may include site visits. A total of $5,000 over a two-year period may be requested for travel purposes and is not to exceed $5,000 in any given year
  - Not allowable as direct costs under this award:
    - Salary and/or compensation for REC Mentors, NACC or Alzheimer's Association staff or current members of the Alzheimer's Association Medical and Scientific Advisory Group (MSAG) or NACC's Scientific Review Committee (SRC).
    - Computer, laptop, hardware or standard software (e.g. Microsoft Office, mouse monitor, computer parts)
    - Laboratory equipment such as freezers, ultracentrifuges, RT-PCR, Microscopy/imaging equipment
    - Service contract fees of equipment
    - Tuition
    - Rent for laboratory/office space
  - Expenses such as data network recharges are not allowable as direct costs under this award:
- **Page 6**- Resources Format page - PHS 398 Template

- **Page 7**- Checklist Form page - <u>PHS 398 Template</u>
- **Page 8**- Project Timeline
- **Page 9-** Signed letter of support from the Center Director *(including all of the following)*:
    - Verification that the New Investigator has received appropriate training in the responsible conduct of research, as mandated by DHHS
    - Confirmation that the Director accepts responsibility for disbursing awarded funds to the New Investigator and tracking project costs
    - See example Letter of Support

Page 9+- Biographical Sketch(s)- NIH Format *(for the New Investigator and research project mentor(s) only.)* Biosketch(s) are restricted to no more than 5 pages.

Step No. 4: Submit the New Investigator Award Program (NIAP) Application

Applications must be submitted using the proposalCENTRAL online application platform. The applicant submitting the application must be the same individual who submitted the approved LOI. Applications submitted on behalf of another applicant or by an administrator will be rejected.

Applicants will find on-screen instructions upon entering the application system. The application can be saved at any stage and completed later, as long as it's before the deadline.

Proofreading is crucial; no changes will be permitted post-deadline or during the review process. It's the applicant's responsibility to:

- Ensure the application is submitted before the deadline. A confirmation email from ProposalCENTRAL Central will confirm a successful submission. If no confirmation is received, check the 'Status' column in the 'Proposals' tab to ensure it says 'Submitted.'
- Verify the application is complete and accurate. Only one application copy is accepted. Neither NACC nor the Alzheimer's Association require signatures at submission time. Comply with your ADRC's policy if it requires a signature page.
- Note that revisions, additional materials, and appendices are not allowed and will be removed from your application if included.
- Submit applications online via the proposalCENTRAL platform. Log in to the platform with the profile you used to submit the LOI.
- For more information, contact grantsapp@alz.org

Review Process Overview

Applications undergo a thorough, multi-stage review to assess scientific and technical merit. This process is facilitated by the online system proposalCENTRAL and involves multiple organizations and committees including NACC, the Alzheimer's Association, and NACC's Scientific Review Committee (SRC).

Review Criteria

- Overall Impact: The potential for the project to significantly influence relevant research fields.
- Significance: The importance of the project.
- Investigator(s): The qualifications of the research team.
- Innovation Approach: The novelty of the research methods.
- Environment: The adequacy of the research setting.
- Budget & Resources: Quality and suitability of the proposed budget and resources.

Additional Criteria

- Protections for Human Subjects
- Inclusion of Women, Minorities, and Children
- Vertebrate Animals
- Biohazards

Review Stages (For Full Applications)

First Stage: NACC and the Alzheimer Association review applications for eligibility and completeness and assign them for peer review.

Second Stage: Review by the NACC Scientific Review Committee (SRC) through proposalCENTRAL and will include a panel of at least three peer scientists with relevant expertise. These reviewers will provide written commentary, scores (using NIH scale), and will engage in a thorough discussion of each application. The committee's evaluation centers on the criteria noted above.

Overall Impact: Each committee member, who has no conflict of interest, will assign an overall impact score after discussion in the SRC meeting. This score will reflect their assessment of the project's potential to significantly influence the research fields involved.

The score will take into account various review criteria as well as any additional criteria relevant to the specific project.

Note: Applications that initially score below the median may not be discussed during the committee meeting and will be marked 'unscored.' However, written reviews for these applications will still be returned to the applicant.

Final Approval

Final Impact scoring and review summaries from the SRC are forwarded to the NACC Steering Committee and the Alzheimer's Association for final selection. This rigorous, multi-level review ensures fair and scientifically sound award decisions.

Once finalists are identified, NACC and the Alzheimer's Association will contact both the ADRC and the New Investigator to finalize the award details, including award amounts. At that time, NACC and the Alzheimer's Association will also provide a list of any further required documents—such as "Just in Time" information, including but not limited to: Other Support.

Post Award Information

ETHICAL/REGULATORY APPROVALS & REPORTING REQUIREMENTS

If awarded funding, NACC and the Alzheimer's Association require any necessary ethical and/or regulatory approvals to be 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. NACC and the Alzheimer's Association accept 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 end date. All reports must be submitted electronically via ProposalCENTRAL Central. 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 NACC and 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 and the National Alzheimer's Coordinating Center (NACC) to assist in the efforts to further inform the public about the Research Grant Program of the Alzheimer's Association, NACC's New Investigator Award Program, and the Alzheimer's Disease Research Center Program.

Recruitment Efforts for Clinical Studies

If your project involves human participants, your application must clearly describe your inclusion and exclusion criteria, as well as your efforts to recruit a diverse participant pool from the community where the study takes place.

Upon awarding, and before fund disbursement, you will need to submit a detailed recruitment plan. This should outline how you'll ensure diversity across various key demographic variables, such as sex, gender identity, sexual orientation, socioeconomic status, race, and ethnicity.

These diversity and inclusion goals will be a key focus in the grant's ongoing reporting requirements. Continued funding depends on your success in meeting these objectives.

ADDITIONAL INFORMATION

Financial Responsibility

Funding is awarded to the institution of the ADRC, 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.

Nondiscrimination and Harassment Statement

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