

Advancing Research on Care and Outcome Measurement (ARCOM)

In collaboration with LINC-AD (Leveraging an Interdisciplinary Consortium to Improve Care and Outcomes for Persons living with Alzheimer's and Dementia)

BACKGROUND

Leveraging an Interdisciplinary Consortium to Improve Care and Outcomes for Persons living with Alzheimer's and Dementia (LINC-AD) is a five-year consortium funded by the National Institutes of Health (NIH) that is undertaking a series of high-impact activities to usher in the next phase of psychosocial research in Alzheimer's disease and all other dementia.

Recognizing the importance of an interdisciplinary approach, the consortium is composed of researchers as well as stakeholders including individuals with dementia and their care partners, family members and long-term and community-based providers. The consortium has identified a pressing need for process and outcome measures of relevance to stakeholders and sensitive to change in order to generate a set of common and meaningful measurement tools for cross-study comparisons. LINC-AD's overarching goal is to broaden interdisciplinary interest in measuring person-centered outcomes that foster a constructive balance between strengths and deficits assessment; add a new emphasis on evidence-based tools to guide structures and processes of care; and provide a novel conceptual framework to inform measurement related to care.

Through these goals, LINC-AD aims to evaluate existing outcome measures and care tools within each of the nine domains of the Dementia Care Practice Recommendations to (a) establish criteria for evaluating measures and tools; (b) identify measurement priority areas; and (c) review existing measures and tools and identify gaps. As a partner of LINC-AD, the Alzheimer's Association International Research Grant Program is committed to identifying opportunities that address gaps and provide funding for pilot projects. The Advancing Research on Care and Outcome Measurement (ARCOM) funding program, in collaboration with LINC-AD, is the first collaborative program to address these care and outcome measures. More information on LINC-AD: <https://alz.org/linc-ad/overview.asp>

The Alzheimer's Association and Brain Canada Foundation are pleased to partner on any successful application from a Canadian-led team.

PROGRAM OBJECTIVE

The ARCOM funding program aims to address significant gaps in care and outcome measurement, and provide an opportunity to advance research so that care providers can ensure that they are implementing evidence-based practices (using measures to guide care provision) and achieving desired outcomes (using measures to assess outcomes). Work funded through ARCOM must directly advance research projects focused on development of new—and/or validation of previously developed—measures of care and outcomes where measurement gaps exist, and evaluation of the use of such measures in improving care and

outcomes across diverse and underrepresented populations and stages of dementia, and in various settings. Investigators awarded through ACROM will be expected to engage with LINC-AD to share research activities and advances as a part of the overall consortium.

AREAS OF FOCUS

Areas of focus are high-priority research areas in which the Alzheimer's Association actively seeks proposals. **These areas are defined broadly, and the examples cited are not intended to preclude or constrain other projects or proposals.** Potential applicants are encouraged to submit proposals in their own areas of interest or formulate questions different from those presented in this announcement. Innovative and novel ideas to address challenges in research are the core of the Alzheimer's Association's research funding. The Association has identified a number of important focus areas within five broad categories: (1) social and behavioral features, (2) clinical investigations, (3) basic biology, (4) adaptive technology, and (5) cognitive functional studies.

Central to all of our funding programs, the Alzheimer's Association is committed to closing the gap on issues that drive health disparities and to increasing diversity within research and clinical trials. Proposals to develop novel measures, to validate previously developed measures or evaluate measures in diverse and underrepresented populations are highly encouraged, as are studies that focus on the inclusion of minority and underrepresented populations. Projects that address issues related to disparities and diversity are a top funding priority.

Areas of interest include but are not limited to:

- **Outcome measurement**, such as the development of new person-centered outcome measures that foster a constructive balance between strength and deficit assessment (e.g., measures related to engagement, activity involvement, resilience, well-being, and other strengths-based areas)
- **Care measurement**, such as the development of measures to guide care that is known to result in positive outcomes (e.g., checklists of evidence-based care processes to promote independence in activities of daily living or decrease behavioral expressions)
- **Application of measurement**, such as use of measures in new settings, with new populations, or in novel applications (e.g., concurrent use of biomarkers and psychosocial measures; use of new technologies to assist with observational measures)
- **Evaluation of measurement** in intervention research (e.g., examining use and sensitivity of measures in actual practice)

The research plan must address:

- Impact - including the reach of the initiative, the potential of the plan to be scaled and the likelihood of making a positive change for a large number of people);
- Pragmatism with a focus on feasibility and the realistic ability to scale a potential tool and/or measure accordingly without creating burden); and
- Identifying the key stakeholders and how they will be involved.

ARCOM proposals may be supplemental to funded projects from other sources, but may not duplicate the efforts of those projects. More information regarding application details are included later in this program announcement.

FUNDING AND AWARD PERIOD

The Alzheimer’s Association anticipates funding up to 8 ACROM proposals. Each award is limited to \$250,000 total funding (direct and indirect costs) over a period of up to two years (minimum of 1 year). Requests in any given year may not exceed \$250,000 (direct and indirect costs). 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.

KEY DATES

Letter of Intent Launch	By March 30, 2021
Letter of Intent Deadline*	May 5, 2021 at 5:00 pm ET
Application Deadline*	June 29, 2021 at 5:00 pm ET
Application Review	July-August, 2021
Award Notifications	August 30, 2021

***The Letter of Intent and application must be received by 5:00 PM EASTERN 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

- Only established, independent investigators are eligible as evidenced by:
 - Academic appointment (Assistant Professor and above or the equivalent at your institution);
 - Major, peer-reviewed, external multi-year grant support on which the applicant is the principal investigator (PI);
 - Quality and independence of publication record
- **The Alzheimer’s Association recognizes the need to increase the number of scientists from underrepresented groups in the research enterprise. Researchers from these groups are encouraged to apply.**

In general, scientists and clinicians from public, private, domestic and foreign research laboratories, medical centers, hospitals and universities 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 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.

For US 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-US 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 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**. Specifically investigators who currently hold ALZ Research Grant/ Research Grant to Promote Diversity, ALZ Research Fellowship/ Research Fellowship to Promote Diversity or ALZ Clinical Scientist Fellowship / Clinical Scientist Fellowship to Promote Diversity may not be eligible unless they are within the final year of their funding and will close the project by January 2022 (including any applicable No Cost Extensions). Investigators who currently have an active Association grant may apply for ARCOM 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 that have previous Alzheimer's Association awards closed as 'Incomplete' are not eligible to apply without exception. **This policy will be strictly adhered to with no exceptions.**
- Current students and/or postdoctoral fellows are not eligible.
- **Current members of the Association's Medical and Scientific Advisory Group (MSAG) and the International Research Grant Program (IRGP) Council** are ineligible to (a) compete for any research grant and (b) be included as co-investigator or to receive any financial benefit from an application. These individuals may be listed as key personnel/collaborator to 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.**

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, \$250,000 total or up to \$250,000 in any given year. Award can be requested for 1-2 years, and it is required that most of the funds awarded under this program be used for direct research support. **No more than 10% of total direct costs may be included as 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 project proposal budget**)
- 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 \$1,000 in any given year

Not allowable as Direct Costs under this award include:

- Computer hardware or standard software (e.g., Microsoft Office)
- Construction or renovation costs
- Tuition
- Rent for laboratory/office space
- Salary and/or compensation for Alzheimer's Association Staff or current members of the Alzheimer's Association Medical and Scientific Advisory Group (MSAG) and the International Research Grant Program (IRGP) Council. A complete list of MSAG and IRGP Council members can be found on our website.

PROPOSAL SUBMISSION PROCEDURES

1. Letter of Intent Submission

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 – applicant must be a full-time employee at 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 cognitive/functional (options will be available to choose from within the system)
- Brief project description, including methodology, specific aims of the project, innovation/novelty of the project, and the impact on addressing knowledge gaps. Each section is limited to 1,000 characters including spaces, and it is the responsibility of the applicant to ensure space limit is adhered.
- 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.

Budget details are not required at the LOI stage

- Additional attachments not specifically outlined above are not allowed and will be removed

Each LOI is evaluated by the Alzheimer's Association and a select panel of experts from the LINC-AD consortium, and other appropriate experts, will be engaged to decide whether to triage or invite a full proposal, with special attention given to:

- Demonstrable innovation/novelty of the proposed project (especially in the context of the PI's recently funded work)
- Alignment with the research priorities of the Alzheimer's Association
- Impact of project to address knowledge gaps in care and outcome measures
- Evidence of methodological rigor that address the research question(s) being proposed

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

The Alzheimer's Association requires that all applicants be registered as a reviewer with the Association in order to submit a Letter of Intent. If you submit a Letter of Intent/application and are NOT currently registered as a reviewer, you will be automatically added to the Alzheimer's Association reviewer roster. **As a requirement to submitting an LOI/application, you agree to review at least one grant proposal within your area of expertise in one of the other granting mechanisms outside of the specific grant program to which you are applying.**

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:

1. Problem Statement (1 page)
2. Work Plan (5 pages)
3. Recruitment Plan (1 page) – If applicable
4. Available Resources & Budget Justification (2 pages)
5. Biosketch(es) – PI/Co-PI/Key personnel – limited to 4-5 pages each (the new NIH format is acceptable)
6. W9 signed and dated by the signing official for US entities. For non-US entities, a W8 signed and dated by the signing official.
7. Plan for Data Sharing (1 page)
8. 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 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 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 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 Subject Assurances

Human subject 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 Alzheimer's Association encourages investigators to initiate their certification applications on a schedule that recognizes that approvals at many institutions can take more than 90 days. The Association accepts 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; it is not anticipated that applications to the ACROM will use animal models.

Annual Scientific and Financial Reports

Interim 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 subjects 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. 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.

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 is 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 ARCOM if the projects are distinctly different; overlapping funding is not allowed. For an ARCOM project related to an active Association award, the current award must be completed and closed by June 30, 2021.

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 is carried out by the International Research Grant Program (IRGP) Council and invited review committee members, including LINC-AD Research Advisors, Research Steering Committee and Care and Support Advisors, to ensure fairness and equity in the initial review procedures and to make funding recommendations to the Association. Final recommendations from the IRGP Council are shared with the Medical and Scientific Advisory Group (MSAG) and with the Alzheimer's Association for final approval. 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 availability of funds; ACROM is one of the many programs being offered through the IRGP this year. The Association anticipates funding up to 8 ACROM awards.

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 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 alz.org/grants.

For additional information, please send all inquiries to grantsapp@alz.org.

The funding partners for this initiative are the Brain Canada Foundation through the Canada Brain Research Fund, an innovative partnership between the government of Canada (through Health Canada) and Brain Canada, and the Alzheimer's Association.
