

PROGRAM GUIDELINES

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A. Scientific categories of proposals

Each proposal must be submitted to a specific grant competition. Additionally, proposals must be classified according to the four broad categories of scientific inquiry listed below, along with sample areas of topic within each. The Association recognizes that multiple categories may describe your project; however, we ask that you select the most applicable categorization.

1. Social and behavioral research

Research in diverse populations; assessment of novel approaches to care and support diagnosed individuals and caregivers; special needs of early-stage and early-onset individuals; analysis of the impact of the physical and social environment; evaluation of services and interventions; quality of life; ethical issues; recruitment science; natural language processing and behavioral monitoring for early detection; and health policy.

2. Clinical investigations

Projects in which the majority of data is derived directly from studies involving active participation of human subjects. Examples include pilot studies of new therapies; neuropsychological testing; drug administration; biomarker collection; imaging technology; and risk factors including genetics, cardiovascular issues, diabetes and metabolic factors, lifestyle issues, and emerging technologies such as mobile computing, high-bandwidth sensing, "smart" environments, and robotics. *In vitro* projects conducted in human samples should be categorized as basic biology (the category below) rather than clinical investigations. Projects directed toward fundamental understanding, but meeting the criteria above should still be classified as Clinical Investigations.

3. Basic biology

These are bench science projects involving *in vitro* or animal work pertaining to the causes of dementia; early and accurate detection and diagnosis; animal models; treatments; and prevention. Please note that *in vitro* work involving human samples falls into this category.

4. Cognitive/ functional

Research focusing on identification of cognitive/functional profiles, development of better measures for diagnosis, identification of neural/biological correlates of cognition/function, investigation of how cognitive and functional changes impact on medical, legal, and day-to-day issues; and the use of the cognitive neuroscience approach to better understand and characterize cognitive/functional changes.

5. Computational, Secondary, and Existing Human Data Analyses

Projects in this area will include "big data" datasets, electronic health records, imaging, postmortem, or other pathology samples, and all other already-collected data or samples for use in novel analytic plans. Also included are any use of machine learning, large language models, or other Artificial Intelligence (AI). This could also include secondary data analysis and other similar types of approaches to answering questions.

B. Letter of intent procedures

Please review guidelines details in the RFA of the program you are interested in.

i. Letter of Intent: General Information

- One Letter of Intent per program is allowed
- 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
- First-time users must register and fill out a Professional Profile to begin the LOI/application process and must be submitted by a single Principal Investigator (PI)
- Applicants must submit an LOI for the current active cycle of the program that they are interested in
- An LOI submitted on behalf of another applicant or by an administrator will be rejected
- Hard copies or emails of the LOI will not be accepted.
- 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 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.

NOTE: 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.

AN APPLICANT CANNOT SUBMIT AN LOI TO MORE THAN ONE PROGRAM WITHIN THIS PROGRAM ANNOUNCEMENTS, EVEN IF THE PROJECTS ARE DIFFERENT. APPLICANTS SHOULD APPLY TO ONLY ONE PROGRAM.

• LOIs will not be accepted after the deadline date; no exceptions will be made.

ii. Letter of Intent: Contents

Applicants must complete the required sections and upload any required documents. Some of these required fields are described below:

- Principal Investigator
 - *o* Name & contact information
- Lead Institution
 - *o* Applicant must be a full-time employee at time of submission

o Institution/organization name must be in English

• Current academic rank/position

- o Must be current at the time of submission; *pending promotions are not allowed*
- Proposal title
- Area of focus
 - o Specific options will be available from a dropdown menu

• Brief project description

- *o* Methodology
- o Specific aims of the project
- o Innovation/novelty of the project
- o Impact on Alzheimer's and related dementia field are required.

• Employer Identification Number (EIN) or TIN

o This number must match the non-profit documentation

NOTE: THIS IS INFORMATION SPECIFIC TO THE INSTITUTION NOT THE APPLICANT.

ORCID ID

• Non-profit verification

- *o* W-9 (US entities) signed and dated within the past five years by an authorized institutional signing official and must include the EIN number
- W-8-BEN (non-US entities) signed and dated within the past five years by an authorized institutional signing official and must include the EIN/TIN or VAT number

NOTE: THIS DOCUMENT SHOULD NOT CONTAIN THE APPLICANT'S INFORMATION.

• Biosketch

- *o* For Principal Investigator only (with the exception of the Fellowship program, Mentor bio should be included)
- We highly recommend using the latest NIH biosketch format (excluding Section D. Scholastic Performance), but any format will be accepted. Hyperlinks are allowed in the biosketch only for individual research projects.
- *o* Applicants will be able to provide Biosketches for other members of the project team at the full application stage.

Any additional documents, including budget details, letters of support or recommendation, and additional biosketches, are not allowed at this early LOI stage and will be removed.

iv. Letter of Intent: Evaluation

Each LOI is evaluated by the Alzheimer's Association and a select panel of experts to decide whether to triage or invite to submit 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 on Alzheimer's and related dementia
- Evidence of methodological rigor that address the research question(s) being proposed

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

C. Application procedures

Please review guidelines details in the RFA of the program you are interested in.

i. Application: General Information

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.

- Full applications will not be accepted without an approved LOI from the current cycle of the program
 - *o* If you did not receive an email from an Alzheimer's Association staff member about your approval to submit a full application for the current cycle of the program you should not submit an application, even if one is available in your ProposalCentral Account.
- The full application should not be different than the approved LOI, including title and area of focus
- The PI who submits the application must be the same PI who submitted the approved LOI
- 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.
- 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.
- The application is complete and accurate before submission. Only a single copy of an application will be accepted. **Signatures are not required 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 <u>do not</u> submit the signature page with your application.

ii. Application: Contents

Applicants must complete the required sections and upload required documents as listed. Some fields are identical to the LOI. Some of these required fields are described below:

- Resubmission
 - It is up to the investigator whether or not they wish to declare their application a resubmission. Even if you are submitting a similar application to a prior submission you do not need to declare it a resubmission. Resubmissions are granted a one-page summary addressing comments raised by reviewers in a prior review cycle(s) of the program.
- Principal Investigator, Co-Principal Investigator, and Key Personnel % Effort
 - All % Efforts listed on the application should reflect RESEARCH EFFORT rather than effort as a percentage of salary or % effort to this specific project. It is not required that Co-PI's and Key Personnel accept salary from an Award, but should have some effort listed.
- Institution & Contacts
 - The PI or a first degree relative cannot be listed as the signing official, financial officer or send checks to attention of.
- How the Research Addresses Gaps in knowledge
 - Investigators should describe how their research will impact the advancement of diverse science and in addressing the gap on sex and gender, disability, and racial disparities in AD/ADRD research. This may include, but not limited to, aspects specific to the research project, the samples or to the team conducting the research
 - Facilities and Administration Costs (Indirect Costs) should not exceed 10% of the PERIOD DIRECT COSTS. You may NOT claim more than 10% in one period and then less than 10% in another. Indirect costs should be based on the period direct cost budget, not the total budget of the award.
 - Investigators are not required to have cost share.

iii. Application: Evaluation

Applications will be reviewed by the Alzheimer's Association and a select panel of experts with criteria tailored to each of the programs. Please see Section IV for additional information regarding evaluation of applications within a specific program.

iv. Application: Additional Information

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 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** submitted your application.

• The application is complete and accurate before submission.

Only a single copy of an application will be accepted. Signatures are not required at the time of submission, the signature page provided is for your use should your institution/organization require signatures, and we do not override any institutional policies and/or procedures. **Please** <u>do not</u> submit with your application.

• Applicants may use LLMs and other generative AI tools in the preparation of their LOIs and full applications.

Applicants are fully responsible for the content of their proposal, even those parts produced by an AI tool. Using one of these tools will not affect the review of your application.

D. Multiple and overlapping submissions

Applicants *CANNOT* submit more than one proposal to any of the programs in the current grant competition—even if the proposals cover distinctly different topics (i.e. only one application is allowed regardless of the distinct areas of focus). It is allowed for members of the same team to submit different aspects of a project to different programs. As long as complementary and not the same project.

Applicants may revise and resubmit an application that was previously submitted for an earlier grant cycle; however, a **new** LOI is required each year. A current LOI corresponding to the application year must accompany each application. **Revisions of previous submissions will be treated as new applications.** Efforts will be made to provide some continuity in reviews. A resubmission of an approved LOI *does not* guarantee that you will be invited to resubmit a full application in a future cycle of the program. Resubmissions may be submitted to a different program in this call and still be a resubmission. Resubmissions are reviewed holistically again, and merely responding to reviewer critiques is not enough to be funded on resubmission.

E. Review procedures

All applications are subject to a multiple stage peer-review process carried out with an online system. In the first stage, applications are reviewed and rated by 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/ by the reviewer.
- **2.** Reviewer published with the Applicant in the last four (4) years. This excludes workshop or large consortia (i.e. ADNI, IGAP, etc.)
- **3.** 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 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. Members of the IRGP Council and MSAG are internationally recognized experts with distinguished careers in Alzheimer's and related dementia.

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.

General Reviewer Requirements

- Recognized authority in their respective field.
- Dedicated to conducting high-quality, fair reviews.
- Able to articulate views succinctly while being willing to engage in productive exchanges and active participation in the online discussion of applications.

F. 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. 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. Disparities in peer reviewers' enthusiasm for a proposal and the scores they assign are nearly always considered part of the normal variation in human judgment. The reality is that the Alzheimer's Association International Research Grant Program is 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 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.

Appeals for Letter of Intents are not allowed, only full applications.

G. Ethical/regulatory assurances

Animal welfare and human subject 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 6 months from award notification. However, the Alzheimer's Association encourages investigators to initiate their certification applications on a schedule that recognizes that rDNA certification, IRB/IACUC approval 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. For fellowship grants, if the Ethical certification is on the mentor's name, the Fellow must include the Ethical approval and a signed letter stating that the ethical approval (rDNA certification, IRB/IACUC approval) covers the awarded project with the Fellows name and Award number included.

H. Reporting requirements

i. 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 or Grants & Contracts Office at the recipient's institution. Unobligated funds remaining at the end of the award must be returned to the Alzheimer's Association.

NOTE: FELLOWSHIP AWARDS ALSO HAVE ANNUAL MENTOR EVALUATIONS THAT ARE CONSIDERED PART OF THE ANNUAL PROGRESS REPORTS.

ii. 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 representative 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. The Alzheimer's Association will withhold payments on awards that do achieve diverse recruitment during any period of the award.

iii. Publications, Presentations and Abstracts, and Intellectual Property Disclosures

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. Any intellectual property disclosures resulting from the award must be submitted electronically at the time of publication. The Alzheimer's Association may request any of the research outputs listed here from any awardee up to 7 years following the end of the award.

<u>Please note that reporting timelines and details may be further specified in each RFA for the respective program.</u>

I. Nondiscrimination and harassment statement

The Alzheimer's Association is committed to providing an environment free from harassment and discrimination. 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.