



Funding Opportunity: Prevention Grants

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Revised 19 July 2022

1 Overview Information

1.1 Funder Overview

The mission of the ALS Association is to discover treatments and a cure for ALS, and to serve, advocate for, and empower people affected by ALS to live their lives to the fullest. Our Research Program contributes to this mission by funding cutting edge research across the translational pipeline from basic science to clinical trials. The Association is the largest philanthropic funder of ALS research worldwide, and our efforts have led to some of the most promising and significant advances in ALS research.

The ALS Association, as a funder in a disease without a cure, believes that the more researchers collaborate and share information, the faster they will arrive at effective treatments and a cure. With

this in mind, the Association encourages open access publications, pre-registered protocols, and open data sharing whenever possible. The Association also values collaboration whenever possible to encourage partnerships to prevent duplication and promote innovation. Both open sharing and collaboration will be positively evaluated in submitted applications.

1.2 Funding Opportunity in Brief

Title: Prevention Grants

Award: \$400,000 in total funding over 2 years

1.3 Key Dates

Request for Application Open: July 21, 2022

Letter of Intent Due Date: August 25, 2022, 5 p.m. US ET

Full Proposal Due Date (by invite only): October 20, 2022, 5 p.m. US ET

Anticipated Award Decision: December 2022

Anticipated Earliest Start Date: December 2022

****Note that start date must be before January 31, 2023**

Our expectation is that contracting is completed within 60 days of award offer. If not, we reserve the right to rescind the award offer and redirect the funds to other projects.

1.4 Grants Policy Statement

For more detail on all policies described in this document, please consult our Grants Policy Statement, available at: <https://www.als.org/Grants-Policy-Statement>

2 Full Text of the Announcement

2.1 Funding Opportunity Description

2.1.1 Overview

One of the ALS Association's goals is to prevent or delay the onset of ALS. Specifically, by 2030, at the latest, when someone is diagnosed with ALS, we would like to be able to offer some advice for their families on how to reduce their risk of developing ALS. Achieving this ambitious goal requires a large body of knowledge, including an understanding of the causes and risk factors for ALS, methods for predicting when the clinical manifestations of ALS will emerge, and viable strategies to intervene either by mitigating risk or by treating the underlying biology of disease before clinically manifest ALS emerges. This 2030 timeframe guides us to emphasize validation and translation rather than exploratory studies. These 2-year awards with a maximum budget of \$400,000 seek to advance the translational science, interventions and tools that could eventually prevent or delay the onset of ALS.

Successful applications will include:

- Strong scientific rationale
 - The logic underlying the scientific hypothesis should be clearly described, along with a clear explanation of why the proposed work is an efficient and effective way to nullify or build support for the hypothesis
 - For infrastructure and tool development efforts, applications should clearly identify a specific gap in the research landscape and describe why the proposed project is an efficient and effective way to address that gap
- A clear path towards significant translational impact in ALS
 - Applications should focus on research that has the potential to ultimately transform the experience of ALS by preventing onset of this devastating disease
 - Projects that will likely lead to human impact by 2030 will be given preference over longer term research

2.1.2 Topics of Interest

For this funding opportunity we will accept applications from all scientific disciplines on topics that have the potential to ultimately prevent ALS. In addition to projects focused on ALS, projects that investigate the continuum of disease spanning ALS and FTD are in scope. We are especially interested in:

- Improved tools for demonstrating a causative role of environmental exposures in a scientifically rigorous manner that is least burdensome to people with ALS
 - Can include direct epidemiological methods, as well as other approaches including Mendelian randomization, epigenetic studies, animal models, etc.
- Development of frameworks for determining the level of evidence required to translate knowledge of an environmental risk factor into a pharmaceutical, behavioral, or ecological intervention
- Preclinical or clinical drug development aimed at prevention of ALS, including efforts to treat prodromal syndromes such as mild motor impairment (MMI)
- Partnerships across FTD and other neurodegenerative and neuropsychiatric disease communities to mitigate ALS risk among different populations at elevated risk for ALS
- New studies leveraging existing population-based cohorts, to study both environmental risk factors for ALS, as well as MMI as a clinical syndrome that is prodromal to ALS
 - Cohorts could include at-risk populations such as military veterans
 - Formal recognition of MMI as a diagnostic entity could facilitate such studies
- Infrastructure to enable study of those at elevated risk for ALS including clinical cohorts and efforts designed to study potential interactions between genetic and environmental risk factors
- Any other proposal with the potential to prevent the onset of ALS

2.1.3 Topics Not Supported Under This Funding Opportunity

Applications focusing on the topics listed below are out of scope for this funding opportunity and may be administratively withdrawn.

- Studies to intended to identify new ALS associated genes

- Studies intended to identify new associations between ALS and environmental exposures

2.2 Award Information

2.2.1 Funding Instrument

- Grant: A support mechanism providing money to an eligible entity to carry out an approved project or activity
- If the funded research contributes to revenue generation, the Association expects to share, proportionally, in that revenue (see [Grants Policy Statement](#) for details)

2.2.2 Funds Available and Anticipated Number of Awards

- The number of awards is contingent upon The ALS Association's budget allocation and the submission of a sufficient number of meritorious applications
- Applications from established investigators, early career investigators and investigators from outside the field of ALS (see [Eligible Individuals](#) section) may be reviewed separately or together depending on the number and quality of applications received

2.2.3 Award Budget

- Budgets for total costs up to \$400,000 (inclusive of both direct and indirect costs) may be requested
- Indirect costs are limited to 10% of total direct costs

2.2.4 Award Period of Performance:

- The maximum period of performance is two (2) years

2.3 Eligibility

2.3.1 Eligible Individuals

- Individuals with the skills, knowledge, and resources necessary to carry out the proposed research may apply as a principal investigator
- Individuals do not need to have a scientific background in ALS research
- Senior post-doctoral fellows, defined as fellows who will have been in their current post-doctoral position for at least three years on the date full proposals are due, may apply as a principal investigator (Letter of Collaboration from mentor will be required at the Full Proposal stage)
 - Junior post-doctoral fellows are not eligible to apply to this opportunity but are invited to consider The ALS Association's Milton Safenowitz Postdoctoral Fellowship instead
- Established investigators, early career investigators and investigators from outside the field of ALS are all eligible to apply as a principal investigator
 - Established investigators are those who currently (at the LOI submission deadline) serve as the principal investigator on an NIH R01 (or similar size grant) focused on ALS

- Early career investigators are not established investigators as defined above but have a significant publication record in ALS and may currently serve as the principal investigator on other grants focused on ALS
- Investigators from outside the field of ALS are those who do not have a significant publication record in ALS and do not serve as the principal investigator on any grants focused on ALS

2.3.2 Eligible Organizations

- U.S. and non-U.S. public and private non-profit entities, such as universities, colleges, hospitals, laboratories, units of state and local governments and eligible agencies of the federal government
- U.S. and non-U.S. biotechnology/pharmaceutical companies, or other publicly or privately held for-profit entities

2.3.3 Collaborations

- Applications are open to investigators participating in synergistic collaborations, though one individual is required to serve as the principal investigator
- If a collaboration is proposed, letters confirming/supporting the collaboration are **required** at the full proposal stage and specific roles and responsibilities for each collaborator need to be clearly articulated

2.4 Content and Review of Applications

The application process has two phases, a Letter of Intent followed, by invitation, by a Full Proposal.

2.4.1 Content of Letter of Intent

By the date listed in [Key Dates](#) above, prospective applicants are required to submit a letter of intent that includes the following information:

- Descriptive title of proposed activity
- Name, address, and telephone number of the Principal Investigator
- Names of other key personnel
- Participating Institution(s)
- Title of this funding opportunity
- A scientific rationale for the proposed study and its relevance to ALS
- A brief description of the study hypothesis and/or objectives and overall experimental plan to meet those objectives
- A brief description of the how the results of the proposed project would ultimately deliver translational impact

2.4.2 Review Criteria for Letter of Intent

- **Fit:** The letter of intent should allow reviewers to assess whether or not there is a good match between The ALS Association's interests and the proposed project
- **Relevance & Rationale:** The letter of intent should provide appropriate scientific rationale for the proposed study and its relevance to ALS

- **Potential Impact:** The letter of intent should describe how results of the proposed study could ultimately contribute to prevention of ALS by 2030

The letter of intent can either be accepted or declined. If the letter of intent is accepted, the applicant will be invited to submit a full proposal. Results from the letter of intent review phase will not be provided to the applicant.

2.4.3 Content of Full Proposal

Application instructions for the full proposal will be provided when/if the applicant is invited to submit the full proposal.

2.4.4 Review Criteria for Full Proposal

- **Translational impact:** Potential for the proposed studies to lead to interventions that would contribute to prevention of ALS by 2030
- **Novelty / Creativity:** New approaches will be required to meet our ambitious goals
- **Research Plan:** Feasibility, timeline and design of experiments and/or milestones
- **Research Team:** Qualifications of the PI, key personnel, and collaborators/consultants

2.4.5 Peer Review and Selection Process

- All applications are peer reviewed by an ad hoc Scientific Review Committee constituted by The ALS Association
- The Scientific Review Committee's priority scores are forwarded only to The ALS Association Board of Trustees, which has the sole authority for approving the funding of research grants
- For applications selected for funding, The ALS Association will send the reviewer comments to the PI. To the extent practical and within the scope of the budget, The ALS Association recommends that the PI integrate any recommendations that the reviewers may have suggested to further optimize the project and outcomes.

2.5 Application and Submission Information

2.5.1 Format of Application Submission

- All applications are to be submitted through our online grants management platform, Proposal Central: <https://proposalcentral.com/>
- To find this funding opportunity on Proposal Central, navigate to the Grant Opportunities tab (<https://proposalcentral.com/GrantOpportunities.asp>) and search for Grant Maker: The ALS Association
- Instructions on how to register as a new user of Proposal Central: <https://docs.proposalcentral.com/RegUser.pdf>
- Applications must be prepared according to Proposal Central's instructions: <https://docs.proposalcentral.com/CreateApp.pdf>
- Upon receipt, applications will be evaluated for completeness and compliance with application instructions. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

2.5.2 Funding Restrictions

The ALS Association awards are subject to the terms and conditions described in The ALS Association Grants Policy Statement (see: [Grants Policy Statement](#)) and the award Agreement.

- Awards will be limited \$400,000 total costs for the entire 2-year period of performance
- Salary and wages and fringe benefits of personnel other than the Principal Investigator are allowed
- Salary and wages and fringe benefits of the Principal Investigator are allowed only when indirect costs are waived
- Direct salary for individuals not to exceed the salary limitation for Executive Level II of the Federal Executive pay scale provided at https://grants.nih.gov/grants/policy/salcap_summary.htm
- Indirect costs are limited to 10% of total direct cost
- Economy travel up to \$2,000 per year to attend scientific conferences is allowed
- Moveable equipment costs not to exceed 20% of the annual budget
- Computer hardware and software costs up to \$2,000
- Recurring annual cost-of-living/inflationary increase up to 3% for personnel and consumable supplies
- All funds must be expended within the approved period of support
- All unexpended funds remaining at the end of the project must be returned to The ALS Association

2.5.3 Administrative and National Policy Requirements

All ALS Association grants include The ALS Association Grants Policy Statement (see: Grants Policy Statement) as part of the Research Grant Agreement. The Grants Policy Statement includes the requirements applicable to animal welfare, human subject protections, data sharing, research resource sharing, publications, etc. All necessary ethical and regulatory approvals must be in place before experiments are initiated.

- **Animal Welfare Requirements:** The ALS Association requires its grantees to establish appropriate policies and procedures to ensure the humane care and use of animals used in research supported by The ALS Association
- **Human Subject Requirements:** The ALS Association requires its grantees to establish appropriate policies and procedures to ensure the protection of human subjects participating in research supported by The ALS Association
 - **Health Insurance Portability and Accountability Act (HIPAA):** Domestic grantees must comply with the requirements of HIPAA
 - **General Data Protection Regulation (E.U. 2016/679):** Foreign grantees must comply with the Regulation E.U. 2016/679, or its amended regulation, of the European Parliament and of the Council of 27 April 2016
- **Intellectual Property:** Grantees shall have the first right, but not the obligation, to prepare, file, prosecute, and maintain all registerable rights in Intellectual Property arising from implementation of the Research Scope of Work at its sole expense

- **Revenue Sharing:** If the funded research contributes to revenue generation, the Association expects to share, proportionally, in that revenue (see [Grants Policy Statement](#) for details)

2.6 Award Administration

2.6.1 Award Agreement and Payment Schedule

- A formal notification in the form of an ALS Association Research Grant Agreement (Agreement) is the authorizing document and will be provided to the applicant organization for successful applicants
- The Agreement, signed by the applicant's authorized organizational representative (AOR), principal investigator and The ALS Association, will include the negotiated terms and conditions of the award between The ALS Association and the Grantee
- Milestone driven award payments will be made to the Grantee on an annual or semi-annual basis as outlined within the Agreement

2.6.2 Administrative Requirements

- The Grantee is expected to utilize The ALS Association funds in direct support of the research project and expend funds in accordance with the established organizational policies and procedures
- Funds charged to The ALS Association award must be for allowable project costs that are determined to be reasonable, allocable, consistently applied and conform to the program guidelines and/or limitations outlined in The ALS Association Funding Opportunity Announcement and the Agreement
- The Grantee is expected to seek The ALS Association's prior approval before making certain types of post-award changes (see [Grants Policy Statement](#))

2.6.3 Reporting Requirements

- The Grantee will be required to submit semi-annual Research Progress Reports and annual Grant Expenditure Reports during the period of an award unless otherwise noted in the Agreement
- Future grant payments are contingent upon the grantee's submission of and The ALS Association's acceptance of the report(s)
- The ALS Association's issuance of the next award payment, when applicable, serves as confirmation that the information provided has been reviewed and approved by The ALS Association
- Final closeout reports (i.e., final research progress and expenditure reports) are due within 90 days following the termination date of the Agreement

2.7 ALS Association Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. Submit all correspondence to researchgrants@alsa-national.org.