



# Request for Applications: Prevention Grants

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*Revised 31 March 2023*

## 1 Overview Information

### 1.1 Funder Overview

The ALS Association is the largest philanthropic funder of ALS research worldwide. Our goal is to make ALS livable for everyone, everywhere, until we can cure it. To achieve this goal, our Research Program focuses on finding new treatments and cures, optimizing current treatments and care, and preventing or delaying the harms of ALS. Thanks to the ALS Ice Bucket Challenge and the generous support of our donors, we have been able to dramatically accelerate the fight against ALS by funding cutting-edge

research across the translational pipeline from basic science to clinical trials in addition to research in other important areas, such as assistive technology, natural history, tool development, prevention, fellowship training, and infrastructure. Our efforts have led to the development and approval of new ALS treatments, discovery of new ALS genes, creation of new global research collaborations, and many more promising and significant advances in ALS research.

As a funder in a disease without a cure, we believe that the more researchers collaborate and share information, the faster they will arrive at effective treatments and a cure. With this in mind, we value collaboration as an important tool to increase efficiency, prevent duplication, and promote innovation. We also encourage open access publications, pre-registered protocols, and open data sharing whenever possible. Both collaboration and open sharing will be positively evaluated in submitted applications.

## 1.2 Funding Opportunity in Brief

**Title:** Prevention Grants

**Award:** \$400,000 in total funding over two (2) years to support efforts to prevent or delay the harms of ALS, emphasizing validation and translation over discovery

## 1.3 Key Dates

**Request for Application Open:** April 12, 2023

**Letter of Intent Due:** May 17, 2023, 5 p.m. US EDT

**Full Proposal Due** (by invitation only): July 19, 2023, 5 p.m. US EDT

**Anticipated Award Decision:** September 2023

**Anticipated Earliest Start Date:** October 2023

Our expectation is that contracting will be completed within 60 days of the 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 Association's strategic priorities is to prevent or delay the harms of ALS. Specifically, by 2030, when someone is diagnosed with ALS, we would like to be able to offer advice to their families about how to reduce their risk of developing the disease. 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 ALS symptoms emerge. The 2030 timeframe guides us to emphasize validation and translation over exploratory studies.

These two-year awards with a maximum budget of \$400,000 seek to advance and validate 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 toward significant translational impact in ALS:** Applications should focus on research that has the potential to ultimately transform the experience of ALS by preventing the onset of this devastating disease. Projects that will likely lead to human impact within the next 5–7 years 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 frontotemporal dementia (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 less burdensome to people with ALS
  - Can include direct epidemiological methods in addition to 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 preventing 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 elevated-risk populations
- New studies leveraging existing population-based cohorts to study 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

This funding opportunity emphasizes validation and translation over exploratory studies. As such, applications focused on the topics listed below are out of scope 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 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 ALS field (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 postdoctoral fellows, defined as fellows who will have been in their current postdoctoral position for at least three years on the date full proposals are due, may apply as a principal investigator. A Letter of Collaboration from the fellow's mentor will be required at the full proposal stage.

- Junior postdoctoral fellows are not eligible to apply for this opportunity but are encouraged to consider the Association's [Milton Safenowitz Postdoctoral Fellowship](#) instead.
- Established investigators, early career investigators, and investigators from outside the ALS field are all eligible to apply as a principal investigator.
  - Established investigators are those who, at the letter of intent submission deadline, serve as the principal investigator on an NIH R01 (or similar size grant) focused on ALS.
  - Early career investigators are those who do not meet the definition of an established investigator 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 ALS field 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; however, 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. 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 a full proposal (submitted by invitation only).

### 2.4.1 Content of Letter of Intent

By the date listed in the [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 the funding opportunity
- A scientific rationale for the proposed study and its relevance to ALS and/or FTD

- A brief description of the study hypothesis and/or objectives as well as 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 there is a good match between the Association’s mission, the intent of the funding program, and the proposed project.
- **Relevance and rationale:** The letter of intent should provide appropriate scientific rationale for the proposed study and its relevance to ALS and/or FTD.
- **Potential impact:** The letter of intent should describe how results of the proposed study could ultimately contribute to prevention of ALS in the next 5–7 years.

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. Reviewer comments from the letter of intent review phase will not be provided to the applicant.

#### 2.4.3 Content of Full Proposal

If/when an applicant’s letter of intent is accepted, instructions for submitting a full proposal will be provided.

#### 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 in the next 5–7 years
- **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 principal investigator, key personnel, and collaborators/consultants

#### 2.4.5 Peer Review and Selection Process

- All full proposals are peer reviewed by an ad hoc Scientific Review Committee constituted by the Association.
- The Scientific Review Committee’s priority scores are forwarded only to the Association’s Board of Trustees, which has the sole authority for approving the funding of research grants.
- For applications selected for funding, the Association will send the reviewer comments to the principal investigator. To the extent practical and within the scope of the budget, the Association recommends that the principal investigator integrates 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 application materials (letters of intent and full proposals) 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 are available at <https://docs.proposalcentral.com/RegUser.pdf>.
- Application materials must be prepared according to Proposal Central's instructions, which can be found at <https://docs.proposalcentral.com/CreateApp.pdf>.
- Upon receipt, application materials will be evaluated for completeness and compliance with application instructions. Application materials that are incomplete and/or non-compliant will not be reviewed.

### 2.5.2 Funding Restrictions

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

- Awards will be limited to \$400,000 in total costs for the entire two-year period of performance.
- Salary, wages, and fringe benefits of personnel other than the principal investigator are allowed.
- Salary, wages, and fringe benefits of the principal investigator are allowed only when indirect costs are waived.
- Direct salary for individuals should not exceed the salary limitation for Executive Level II of the Federal Executive pay scale ([https://grants.nih.gov/grants/policy/salcap\\_summary.htm](https://grants.nih.gov/grants/policy/salcap_summary.htm)).
- Indirect costs are limited to 10% of total direct costs.
- Economy travel up to \$2,000 per year to attend scientific conferences is allowed.
- Moveable equipment costs should not exceed 20% of the annual budget.
- Computer hardware and software costs up to \$2,000 are allowed.
- Recurring annual cost-of-living/inflationary increases up to 3% for personnel and consumable supplies are allowed.
- 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 Association.

### 2.5.3 Administrative and National Policy Requirements

All Association grants include the [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 Association requires its grantees to establish appropriate policies and procedures to ensure the humane care and use of animals used in the research it supports.
- **Human subject requirements:** The Association requires its grantees to establish appropriate policies and procedures to ensure the protection of human subjects participating in the research it supports.
  - **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](#)).

## 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 Association, will include the negotiated terms and conditions of the award between the 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 Association's funds in direct support of the research project and expend funds in accordance with the established organizational policies and procedures.
- Funds charged to the Association's 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 Association's Funding Opportunity Announcement and the Agreement.
- The Grantee is expected to seek the Association's approval at least 30 days 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 Association's acceptance of the report(s).
- The Association's issuance of the next award payment, when applicable, serves as confirmation that the information provided has been reviewed and approved by the 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 research program and welcome the opportunity to answer questions from potential applicants. Submit all correspondence to [ResearchGrants@als.org](mailto:ResearchGrants@als.org).