# Request for Applications:
# Seed Grants

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*Revised February 22, 2024*

# 1 Overview Information

## 1.1 Funder Overview

The ALS Association is working to make ALS a livable disease—by optimizing current treatments and care and preventing or delaying the harms of ALS—while urgently searching for new treatments and a cure. Thanks to the ALS Ice Bucket Challenge and the generous support of our donors, we have dramatically accelerated 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, quality of care, tool development, prevention, workforce development, and research infrastructure. Our efforts have led to the development and approval of new ALS treatments, the discovery of new ALS-linked genes, the creation of new global research collaborations, and many more promising and significant advances in ALS research.

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**: Seed Grants

**Award**: $50,000 in total funding over 1 year to conduct preliminary ALS research that will support funding applications from other sources for larger scale and more impactful research projects. Applications from early career investigators in ALS and investigators from outside the field of ALS are encouraged.

## 1.3 Key Dates

**Request for Application Opens:** March 6, 2024
**Letter of Intent Due Date:** April 9, 2024, 5 p.m. U.S. EDT
**Full Proposal Due Date** (by invitation only): June 20, 2024, 5 p.m. U.S. EDT
**Anticipated Award Decision**: August 2024
**Anticipated Earliest Start Date**: September 2024

Our expectation is that contracting will involve minimal negotiations due to the modest size of these awards and 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 details on the policies described in this document, please consult our Grants Policy Statement, which is available at www.als.org/Grants-Policy-Statement.

# 2 Full Announcement

## 2.1 Funding Opportunity Description

### 2.1.1 Award Overview

Seed Grants provide initial support for projects from across the spectrum of ALS research. These 1-year awards worth up to $50,000 were designed to fund one or two critical experiments intended to gather preliminary data that will serve as the basis for larger grants. As such, Seed Grant applicants do not need to have preliminary data in hand but should instead demonstrate a comprehensive understanding of both why the experiments proposed for funding are the key experiments in the short term and how the results can be leveraged to secure follow-on funding in the longer term.

Applications from early career investigators in ALS and investigators from outside the field of ALS are encouraged. Examples of previous awards can be found on our website.

Successful applications will include:

- **Well-defined path toward follow-on funding**: The Association expects Seed Grant research to be carried forward with support from other funders. To that end, applicants must identify a funding opportunity they intend to apply for based on the results of this award and describe how the results of the proposed work will increase competitiveness for that future funding opportunity.
    - Reviewer comments on a previously unfunded application (e.g., comments received on an NIH R01 application that was not funded) can provide an exceptionally well-defined path toward follow-on funding. If applicants intend to revise a previous application using data collected through a Seed Grant project, then that previous application and summary statements should be submitted as powerful supporting documentation at the full proposal stage of the application process. These documents should be summarized, but not submitted, at the letter of intent stage.
    - While larger ALS Association grants can certainly be a source of follow-on funding, applicants are reminded that the Association does not generally allow concurrent grants to the same grantee on highly related topics.
    - Successful grantees are required to draft a grant application as a final deliverable for this award.
- **Strong scientific rationale**: The logic underlying the scientific hypothesis should be clearly described. Importantly, the applicant should provide an explanation as to why the specific experiments proposed are the most effective way to use the $50,000 budget of the award to nullify or build support for the hypothesis over the course of the 1-year funding period.
    - Evidence supporting the scientific hypothesis and the potential for significant impact in ALS can come from the scientific literature, from studies in other disciplines or disease areas, from clinical observations, or from other sources.
    - Preliminary data generated in the applicant's lab are not required.

- **Potential for significant impact in ALS**: Applications should focus on research that has the potential to ultimately transform the experience of ALS by optimizing the care and treatments we have, finding new treatments and cures, and/or preventing the disease and its harms.

### 2.1.2 Topics of Interest

For this funding opportunity, we are interested in receiving applications from all scientific disciplines on topics that have the potential to ultimately transform the experience of ALS. In addition to projects focused specifically on ALS, projects that investigate the continuum of disease spanning ALS and frontotemporal dementia (FTD) are in scope.

We are especially interested in:

- Studies that document and reduce the harms of ALS on caregivers and families of people living with the disease.
- Studies that advance understanding of delivering state-of-the-art ALS care effectively and consistently, including technologies that address pressing health service delivery issues relevant to the lives of people living with ALS, including telehealth, remote monitoring, and the coordination and provision of home- and community-based health services.
- Clinical tools and techniques
    - Efforts to increase clinical trial participation, reduce burden and risk for participation, and increase clinical trial speed and effectiveness.
    - Efforts to reduce time to diagnosis.
    - Discovery and validation of novel endpoints and outcome measures.
    - Early clinical studies to evaluate feasibility or refine design of future studies.
    - Clinical studies to evaluate impact of potentially low-cost interventions, such as behavioral modifications or social support.
- Novel assistive technologies or the adaptation of existing technologies that can help maintain or improve the health, independence, and/or quality of life of people living with ALS.
- Drug target identification
    - Studies seeking to identify new drug targets.
    - Development of tools for drug target identification, including animal models, cell models, methods for high-throughput screening, etc.
    - Studies that seek to identify rationally designed combination therapies.
    - Studies linking genetic targets to sporadic disease.
- Studies that aim to identify biologically relevant subpopulations within the ALS patient population.
- Prevention research
    - Studies that could ultimately stop ALS progression before impairment, including methods for detecting and identifying potential therapeutic options.
    - Studies to develop interventions for people in the earliest stages of the disease and/or for people who are at risk of developing the disease, or to develop the methodology to test these interventions.

    - Studies that could ultimately reduce the risk of developing ALS for people with genetic risk factors, including studies of epigenetics, gene-environment interactions, and associated methodologies.
    - Studies that seek to understand and/or mitigate the effect of environmental exposures on the risk of developing ALS.
- Big data approaches
    - Analysis of omics or clinical data for purposes such as identification of disease-relevant patient subtypes, new therapeutic targets, or new biomarkers.
    - Data analyzed could come from existing data and specimen repositories, including PRO-ACT, Project MinE, NEALS, the National ALS Registry, and Answer ALS, or from other relevant sources.
- Any other proposal with the potential to significantly improve the lives of those impacted by ALS.

### 2.1.3 Topics Not Supported by This Funding Opportunity

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

- Early drug development studies, including hit-to-lead and lead optimization.
- Preclinical drug development activities, including pharmacokinetics, pharmacodynamics, and safety and toxicology studies. For this type of project, applicants are encouraged to consider funding through our Lawrence and Isabel Barnett Drug Development Program.
- Interventional clinical trials of new and repurposed therapeutics. Applicants are encouraged to consider funding through our Hoffman ALS Clinical Trial Awards Program instead.

Proposals that require significantly more resources than the $50,000 budget and 1-year funding period allocated for this award or those with no identified source of follow-on funding are also out of scope.

## 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 and the submission of a sufficient number of meritorious applications.

### 2.2.3 Award Budget

- Budgets for total costs up to $50,000 (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 1 year.

### 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 (PI).
- Individuals do not need to have a scientific background in ALS research.
- Senior postdoctoral fellows, defined as fellows who have been in their current postdoctoral position for at least 3 years on the date full proposals are due, may apply as a PI.
    - Junior postdoctoral fellows are not eligible to apply as a PI and are encouraged to consider our Milton Safenowitz Postdoctoral Fellowship Program instead.
- Established investigators, early career investigators, and investigators from outside the ALS field are all eligible to apply as a PI.
    - Established investigators are those who currently (as of the letter of intent submission deadline) serve as the PI 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 PI 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 PI on any grants focused on ALS.
    - Applications from established investigators, early career investigators, and investigators from outside the ALS field may be reviewed separately or together depending on the number and quality of applications received.

#### 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, although one individual is required to serve as the PI.
- 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 Letter of Intent

#### *2.4.1.1 Content*

By the date listed in the Key Dates above, applicants are required to submit a letter of intent that includes the following:

- Administrative Information
  - Descriptive Title of Proposed Project
  - PI's Name and Contact Information
  - Names of Other Key Personnel
  - Participating Institution(s)
- Project Information (approximately **2.5 pages total**, see ProposalCentral for character limits for specific sections)
  - Scientific Abstract
  - Scientific Background and Long-Term Project Goals
  - Specific Aims
  - Path to Follow-On Funding
- Attachments
  - PI Biosketch
  - Resubmission Statement (if relevant)

#### *2.4.1.2 Review Criteria*

Review of the letter of intent emphasizes the path to follow-on funding and potential impact, as described in more detail in section 2.4.2.2 Review Criteria for Full Proposal.

### 2.4.2 Full Proposal

#### *2.4.2.1 Content*

If/when an applicant's letter of intent is accepted, further instructions for submitting a full proposal will be provided. In summary, the full proposal will include:

- Webform
  - Administrative Information
  - Lay Abstract
  - Scientific Abstract
- Research Plan (**6 pages total**, not including references)
  - Scientific Abstract (copied from webform)
  - Scientific Background and Long-Term Project Goals
  - Project Roadmap
  - Study Design/Methods
  - Path to Follow-On Funding
  - References

- Budget
    - Planned Expenditures (table)
    - Budget Justification
- Attachments
    - PI Biosketch
    - Resubmission Statement (if relevant)
    - Biosketches for Co-PIs and Collaborators
    - Prior Rejected Application(s) and Summary Reviews (if relevant)
    - Letters of Collaboration (if relevant)
    - W-9 or Other Relevant Tax Information

#### *2.4.2.2 Review Criteria*

- **Fit**: Is there a good match between the Association's mission, the intent of the funding program, and the proposed project?
- **Path to follow-on funding**: What is the likelihood that this project could generate preliminary data that would justify future funding via a larger funding mechanism?
- **Potential impact**: If the project was successful and follow-on funding was obtained, would the results be an important/impactful contribution to ALS research, or would they be incremental? Is this research direction unique within the ALS field?
- **Scientific merit and feasibility**: What are the strengths and weaknesses of the experimental plan? Is the design of the study adequately developed and appropriate to achieve the aims of the study? Are the milestones and timelines feasible given the budget constraints? Are there any additional concerns or feedback related to the study design and methods?
- **Investigator/team/environment**: Are the qualifications of the PI, key personnel, and collaborators/consultants appropriate to perform the proposed research project? Does the scientific environment in which the work will be done contribute to the probability of success?
- **Budget**: Can the proposed work be completed within the scope of this award, or is significant additional funding required to achieve the stated aims? Are there any items in the budget that are inappropriate for funding?

### 2.4.3 Peer Review and Selection Process

- Letters of intent will be either 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 phase are not provided to applicants.
- Full proposals are peer reviewed by an ad hoc Scientific Review Committee of independent external experts. These reviewers are **not** the same individuals as reviewers of the letters of intent.
- Reviewers of full proposals do not have access to the letter of intent. Only information submitted as part of the full proposal will be reviewed.
- For full proposals, the Scientific Review Committee's priority scores will be forwarded only to the Association's Board of Trustees, which has the sole authority for approving

the funding of research grants. Reviewer comments from the full proposal phase will be provided to applicants.

- For applications selected for funding, the Association recommends that the PI integrate any recommendations suggested by the reviewers to the extent practical and within the scope of the budget to further optimize the project and outcomes.
- Application status notifications and other award-related correspondence will come from ResearchGrants@als.org. Applicants are advised to add this address to their safe sender list to ensure notifications are not directed to their spam folder. Applicants can also check the status of their application materials (i.e., letter of intent or full proposal) in ProposalCentral (proposalcentral.com).

## 2.5 Application and Submission Information

### 2.5.1 Format of Application Submissions

- All application materials must be submitted through our online grants management platform, ProposalCentral (proposalcentral.com).
- To find this funding opportunity on ProposalCentral, navigate to the Grant Opportunities tab (proposalcentral.com/GrantOpportunities.asp) and search for Grant Maker: The ALS Association.
- Instructions on how to register as a new user of ProposalCentral are available at docs.proposalcentral.com/RegUser.pdf.
- Application materials must be prepared according to ProposalCentral's instructions, which can be found at 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

All Association awards are subject to the terms and conditions described in the Grants Policy Statement and Research Grant Agreement.

- Awards will be limited to $50,000 total costs for the entire 1-year period of performance.
- Salary, wages, and fringe benefits of personnel other than the PI are allowed.
- Salary, wages, and fringe benefits of the PI 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 (grants.nih.gov/grants/policy/salcap_summary.htm).
- Indirect costs are limited to 10% of total direct costs.
- Economy travel up to $3,000 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 per year 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.

- 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 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), PI, 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 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 Request for Applications 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 the 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. The final closeout report must also include either:
    - A draft of a grant application based on the results of the funded project, or
    - A statement describing why the results of the funded project do not justify seeking follow-on funding (e.g., negative results).

## 2.7 ALS Association Contacts

We encourage inquiries concerning this research program and welcome the opportunity to answer questions from potential applicants. Please direct all correspondence to ResearchGrants@als.org.