

# Request for Applications: Seed Grants

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## 1 Overview Information

#### 1.1 Funder Overview

The ALS Association is doing "whatever it takes" to make ALS livable for everyone, everywhere, until we can cure it. Our strategic priorities are to find new treatments and cures, optimize current treatments and care, and prevent or delay harms of ALS. To support these priorities, our Research Program funds 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. 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.

As a funder in a disease without a cure, the Association believes that the more researchers collaborate and share information, the faster they will arrive at effective treatments and a cure. With this in mind, we encourage open access publications, pre-registered protocols, and open data sharing whenever possible. We also value 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: Seed Grants

**Award**: \$50,000 in total funding over one year for the generation of preliminary data that will ultimately serve as the basis for larger grants that fund impactful research in ALS. Applications from early career investigators in ALS and investigators from outside the field of ALS are encouraged.

## 1.3 Key Dates

Request for Application Open: March 21, 2023

Letter of Intent Due Date: April 25, 2023, 5 p.m. U.S. EDT

Full Proposal Due Date (by invitation only): June 27, 2023, 5 p.m. U.S. EDT

**Anticipated Award Decision**: September 2023 **Anticipated Earliest Start Date**: October 2023

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

## 2 Full Text of the Announcement

#### 2.1 Funding Opportunity Description

#### 2.1.1 Overview

The ALS Association's Seed Grant program seeks to fund research with a strong scientific rationale and potential for significant impact in ALS but limited preliminary data. These one-year awards with a maximum budget of \$50,000 should be used to gather preliminary data that will support future applications to larger grant award programs. 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.

- **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 ALS.
- **Limited preclinical data**: Evidence contributing to the scientific hypothesis and supporting 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 for the purpose of exploring the specific scientific hypothesis proposed is not required, and reviewers will be reminded of this.
- Path to build support for future applications: The Association expects Seed Grant
  research to be carried forward with support from other funders. To that end, applicants
  will identify a funding opportunity that they are aiming to apply for based on the results
  of this award.
  - If applicants are collecting data to support an application revision, the prior application and summary statements should be submitted with the full Seed Grant proposal. (Note: These documents are not required to be submitted with the Letter of Intent.)
  - Successful grantees are required to draft a grant application as a final deliverable for this award.

#### 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 transform the experience of ALS by optimizing the care and treatments we have, finding new treatments and cures, and/or preventing 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:

- 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
- Biomarkers
  - Studies to discover and validate ALS biomarkers that can facilitate clinical trials, demonstrate biological effect of promising therapeutics, and speed diagnosis
  - 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 detection and identification of potential therapeutic options

- 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
- Clinical tools and techniques
  - Efforts to increase clinical trial participation, reduce burden and risk for participation, and increase clinical trial speed and effectiveness
  - o Efforts to reduce time to diagnosis
  - o Discovery and validation of novel endpoints and outcome measures
- Big data approaches
  - Analysis of omics or clinical data for purposes such as identification of diseaserelevant patient subtypes, new therapeutic targets, or new biomarkers
  - Data analyzed could come from resources including, but not limited to, PRO-ACT, Project MinE, or Answer ALS
- Assistive technology
- Studies that document and reduce the harms of ALS on caregivers and families of people living with the disease
- Any other proposal with the potential to significantly improve the lives of those impacted by 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.

- Clinical trials
- Preclinical drug development activities, including pharmacokinetics, pharmacodynamics, and safety and toxicology studies
- Early drug development studies, including hit-to-lead and lead optimization

#### 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 <u>Grants Policy Statement</u> 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 <u>Eligible Individuals</u> 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 \$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 one (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.
- 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 three years on the date full proposals are due, may apply as a principal investigator.
  - Junior postdoctoral fellows are not eligible to apply to this opportunity but are invited to consider The ALS Association's <u>Milton Safenowitz Postdoctoral</u> <u>Fellowship Program</u> 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 currently (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, though one individual is required to serve as the principal investigator.

 If a collaboration is proposed, letters confirming/supporting the collaboration are required, and specific roles and responsibilities for each collaborator need to be clearly articulated.

## 2.4 Content and Review of Applications

#### 2.4.1 Content of Letter of Intent

By the date listed in <u>Key Dates</u> 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
- A brief description of the study hypothesis and/or objectives and an overall experimental plan to meet those objectives
- Path to follow-on funding
  - Applicants should identify a specific funding opportunity that they are aiming to apply (or reapply) for and describe how the results of this Seed Grant will enable a successful application.
  - If relevant, applicants should consider briefly summarizing reviews from rejected grant applications (e.g., an NIH R01 application) as evidence of how the proposed work could bolster a future resubmission.
  - Submission of prior rejected application(s) and summary statements is allowed / encouraged but only as part of the full proposal.

#### 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 Association's interests and the project.
- **Relevance and rationale**: The Letter of Intent should provide appropriate scientific rationale for the proposed study and its relevance to ALS.
- Overall experimental objectives: The Letter of Intent should describe the study hypothesis and/or objectives and an overall experimental plan to meet those objectives.
- **Path to follow-on funding**: The Letter of Intent should describe how results of the proposed study would fit into an application for further funding.
  - Submission of a grant application for follow-on funding is the final milestone for all funded projects.

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

- Impact/contribution to ALS: Potential for the proposed studies to make an important contribution to ALS research
- Research plan: Feasibility, timeline, and design of experiments
- Research team: Qualifications of the principal investigator, key personnel, and collaborators/consultants
- Path to follow-on funding: Likelihood that successful project execution will lead to follow-on funding

#### 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 ALS
   Association 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 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 Submissions

- All application materials (i.e., 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 in Proposal Central, navigate to the Grant Opportunities tab (<a href="https://proposalcentral.com/GrantOpportunities.asp">https://proposalcentral.com/GrantOpportunities.asp</a>) 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 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 <u>Grants Policy Statement</u> and the award Agreement.

- Awards will be limited to \$50,000 total costs for the entire one-year period of performance.
- Salary, wages, and fringe benefits of personnel other than the salary of 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).
- 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 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 increase 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 ALS Association <u>Grants Policy Statement</u> 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 research supported by the Association.
- **Human subject requirements**: The Association requires its grantees to establish appropriate policies and procedures to ensure the protection of human subjects participating in research supported by the 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 <u>Grants Policy Statement</u> 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 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 semiannual basis as outlined within the Agreement.

#### 2.6.2 Administrative Requirements

- The Grantee is expected to utilize 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 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 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. The final closeout report must 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 further 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. Submit all correspondence to <a href="mailto:ResearchGrants@als.org">ResearchGrants@als.org</a>.