Funding Opportunity: Seed Grants

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 private 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:** 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: April 12, 2022
Letter of Intent Due Date: May 17, 2022, 5 p.m. US ET
Full Application Due Date (by invite only): July 19, 2022, 5 p.m. US ET
Anticipated Award Decision: September 2022
Anticipated Earliest Start Date: October 2022

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](https://www.als.org/Grants-Policy-Statement)

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 1-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 potential for significant impact in ALS can come from the scientific literature, from studies in other disciplines or disease areas, from clinical observations or other sources
  o 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 ALS Association expects research from these awards to be carried forward by support from other funders. To that end, applicants will identify a funding opportunity that the applicant is aiming to apply for based on the results of this seed grant.
  o If applicants are collecting data to support an application revision, they should include their prior application and summary statements in their full application (note that these documents are not required at the Letter of Intent stage)
  o Successful grantees are encouraged 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 FTD are in scope. We are especially interested in:
• Drug target identification
  o Studies of or methods for drug target identification including animal models, cell models, methods for high throughput screening, etc
  o Studies that seek to identify rationally designed combination therapies
  o Studies linking genetic targets to sporadic disease
• Biomarkers
  o Studies to discover and validate ALS biomarkers that can facilitate clinical trials, demonstrate biological effect of promising therapeutics, and speed diagnosis
  o Studies that aim to identify biologically relevant sub-populations within the ALS patient population
• Prevention research
  o Studies that could ultimately stop ALS progression before impairment, including methods for detection and identification of potential therapeutic options
  o 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
  o Studies that seek to understand and or mitigate the effect of environmental exposures on the risk of developing ALS
• Clinical tools and techniques
  o 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

- 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 resources including, but not limited to, PRO-ACT, Project MinE or Answer ALS

- Assistive technology
- Studies to document and reduce the harms of ALS on caregivers and families of people with ALS
- Any other proposal with the potential to significantly improve the lives of those impacted by this disease

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 PK/PD or safety and toxicology studies
- Early drug discovery studies including high-throughput screening, hit-to-lead, and lead optimization
- Research infrastructure

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 $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 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 applications are due, may apply as a principal investigator
  - 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 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 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
• Path to follow-on funding
  o Applicant should identify a specific funding opportunity that the applicant is aiming to apply (or reapply) for and describe how the results of this seed grant will enable a successful application
  o 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

2.4.2 Submission of prior (rejected) application and summary statements is allowed / encouraged only during the full application 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 project.
• **Relevance & 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 provide study hypothesis and/or objectives and 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
  o 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 application. Results from the letter of intent review phase will not be provided to the applicant.

2.4.3 Content of Full Application

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

2.4.4 Review Criteria for Full Application

• **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 PI, 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 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 $50,000 total costs for the entire 1-year period of performance
- Salary and wages and fringe benefits of personnel other than the salary of 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
  o Health Insurance Portability and Accountability Act (HIPAA): Domestic grantees must comply with the requirements of HIPAA

• 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.
  - Final closeout report must include either:
    - A draft of a grant application based on the results of the funded project.
    - 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 funding opportunity and welcome the opportunity to answer questions from potential applicants. Submit all correspondence to researchgrants@alsa-national.org.