

Request for Applications: Milton Safenowitz Postdoctoral Fellowship Program

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1 Overview

1.1 Funder Description

The ALS Association is the largest philanthropic funder of ALS research in the world. We are 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: Milton Safenowitz Postdoctoral Fellowship Program

Award: \$150,000 in total funding over 2 years to support the development of junior postdoctoral fellows who received their terminal research degree (i.e., Ph.D.) and/or reached the end of postgraduate clinical training less than 2 years before the date letters of intent are due

1.3 Key Dates

Request for Applications Open: October 17, 2023 Letter of Intent Due Date: November 21, 2023, 5 p.m. US ET Full Proposal Due Date (by invitation only): February 13, 2024, 5 p.m. US ET Anticipated Award Decision: April 2024 Anticipated Earliest Start Date: May 2024

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 details on the policies described in this document, please consult our Grants Policy Statement, which is available at <u>www.als.org/Grants-Policy-Statement</u>.

2 Full Announcement

2.1 Funding Opportunity Description

2.1.1 Program Overview

The ALS Association believes that attracting bright, young scientists to enter and remain in ALS research is essential for making ALS a livable disease while urgently searching for a cure. That is why the Association supports the development of junior postdoctoral researchers through the Milton Safenowitz Postdoctoral Fellowship Program. Fellows receive up to \$150,000 over 2 years to support research of high scientific merit and relevance to ALS.

The Safenowitz family established this award in 2004 in memory of Milton Safenowitz, who died of ALS in 1998. Safenowitz Fellows work with a senior mentor and receive extensive exposure to the ALS research community through meetings, presentations, and the Association's Postdoctoral Fellowship Consortium. Fellows also develop high-quality papers and collect foundational data to support applications for further funding from the Association, the National Institutes of Health, and other sources.

After completing this fellowship, approximately 75% of awardees stay in ALS research. Many go on to establish their own laboratories and mentor more ALS researchers along the way. Other Safenowitz fellows have moved on to successful careers in industry, medical writing, and non-profit organizations.

2.1.2 Topics of Interest

We are especially interested in supporting fellowships focused on:

- New target validation, including in animal models and human cell models.
- Target or pathway biology in disease-relevant models, including defining upstream / downstream modifiers and convergence of promising target pathways.
- Factors that could ultimately reduce the risk of developing ALS, including studies of genetic risk factors; epigenetics; gene-environment interactions; lifestyle, occupational, or dietary factors; and epidemiology.
- New biomarker identification and the development and/or validation of biomarker assays.
- Managing ALS, including the development and/or validation of novel assistive technologies and the measurement of patient / caregiver / family burden.
- Analysis of -omics data from resources including, but not limited to, PRO-ACT, Project MinE, or Answer ALS to identify disease-relevant patient subtypes, new therapeutic targets, or new biomarkers.

2.1.3 Topics Not Supported by This Funding Opportunity

Proposals with significant overlap to already funded work will likely not be considered. To review the topics of previously funded fellowships, please visit <u>our website</u>.

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 and the submission of a sufficient number of meritorious applications.

2.2.3 Award Budget

- Budgets for direct costs up to \$75,000 per year (for a total of \$150,000) may be requested.
- Indirect costs are not provided for postdoctoral fellowship awards.

2.2.4 Award Period of Performance

• The maximum period of performance is 2 years.

2.3 Eligibility

2.3.1 Eligible Individuals

- Individuals who received their terminal research degree (i.e., Ph.D.) and/or reached the end of postgraduate clinical training less than 2 years before the date letters of intent are due (i.e., on or after November 21, 2021) are eligible to apply.
- Applicants must have the skills, knowledge, and resources necessary to carry out the proposed research and have an existing postdoctoral position, including the support of their mentor.

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.

2.4 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 <u>Key Dates</u> above, applicants are required to submit a letter of intent that includes the following:

- Administrative Information
 - Descriptive Title of Proposed Project
 - Principal Investigator's (PI's) Name and Contact Information
 - Names of Other Key Personnel, including Mentor / Sponsor
 - Participating Institution(s)
- Project Information (approximately **2.5 pages total**, see <u>ProposalCentral</u> for character limits for specific sections)
 - Scientific Abstract
 - Specific Aims
 - Background and Significance
 - Rationale and Goals
- Attachments
 - PI Biosketch
 - Resubmission Statement (if relevant)

2.4.1.2 Review Criteria

Review of the letter of intent emphasizes fit, impact, and investigator / team / environment, 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
 - o Administrative Information
 - Lay Abstract (2,000 characters maximum)
- Research Plan (6 pages total, not including references)
 - Scientific Abstract
 - o Project Roadmap, including Specific Aims and Timeline
 - Background and Significance
 - Preliminary Data
 - Project Design / Methods
 - o References
- Budget
 - Planned Expenditures (table)
 - Budget Justification (5,000 characters maximum)

- Attachments
 - o PI Biosketch
 - Biosketch(es) for Mentor(s) / Sponsor(s)
 - Letter of Recommendation from the Mentor(s)
 - 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?
- Impact: Is the application proposing to pursue a novel approach or an improvement on a previously tested approach? Are the preliminary data relevant to the current proposal, and do they support further funding? If funded, will the results be impactful, open a new avenue of research, or just provide an incremental improvement to our knowledge of ALS?
- Scientific merit: What are the strengths and weaknesses of the experimental plan? Is the design of the study adequately developed and appropriate to address the proposed aims? Are the milestones and timelines feasible?
- Investigator / team / environment: Are the qualifications of the fellow, the mentor, key personnel, and collaborators / consultants appropriate to perform the proposed research project? Does the environment in which the work will be done contribute to the probability of success? Does the applicant propose to employ useful collaborative arrangements to get the work done?
- Budget: Is the budget justified based on the proposed project? 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 <u>not</u> 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 <u>ResearchGrants@als.org</u>. 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 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 <u>docs.proposalcentral.com/RegUser.pdf</u>.
- Application materials must be prepared according to ProposalCentral's instructions, which can be found at <u>docs.proposalcentral.com/CreateApp.pdf</u>.
- 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 ALS Association awards are subject to the terms and conditions described in The ALS Association <u>Grants Policy Statement</u> and the Research Grant Agreement.

- Awards will be limited to \$150,000 total direct costs for the entire 2-year period of performance.
- Indirect costs are not provided for postdoctoral fellowship awards.
- Salary and fringe benefits of the postdoctoral fellow are allowed.
- 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 <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 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 <u>Grants Policy</u> <u>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), 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 semiannual 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 <u>Grants Policy Statement</u>).

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.

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 <u>ResearchGrants@als.org</u>.