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Part I. Overview Information:

Section 1. Funding Opportunity Title: The ALS Association Research Milton Safenowitz Postdoctoral Program

Section 2. Key Dates:

Request for Applications Open: July 10, 2020

Letter of Intent Due Date, if applicable: August 14, 2020, 5 p.m. US ET

Full Application Due Date (by invite only): October 9, 2020, 5 p.m. US ET

Anticipated Award Decision: December 2020

Anticipated Earliest Start Date: January 2021*

***Note: The stated date of awards is subject to change due to delays associated with COVID-19.**

Part 2. Full Text of the Request for Applications

Section I. Funding Opportunity Description:

The ALS Association Milton Safenowitz Postdoctoral fellowship grant program supports innovative research of high scientific merit and relevance to amyotrophic lateral sclerosis (ALS).

- 1. Overview:** The ALS Association Global Research Program leads the scientific community in finding effective treatments and cure for ALS, and a better life for people with ALS, their caregivers, and families. The ALS 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 ALS Association encourages open access publications, pre-registered protocols, and open data sharing whenever possible. The ALS 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.

The ALS Association is proud to support the development of new scientists through the [Milton Safenowitz Postdoctoral Fellowship](#). The Safenowitz family, through The Greater New York Chapter of The ALS Association, founded the award in memory of Mr. Safenowitz, who died of ALS in 1998. These awards are to encourage and facilitate promising young scientists to enter the ALS field. Fellows work with a senior mentor and receive extensive exposure to the ALS research community through meetings and presentations. After completing this fellowship, approximately 76 percent of the awardees stay in ALS research. They go on to establish their own laboratories to continue studying ALS and mentor more ALS researchers along the way. Other postdoctoral fellows have moved on to successful careers in industry, medical writing, and non-profit.

2. Topics of Interest:

We are especially interested in Fellowships supporting the following:

- Studies for new target validation including in animal models, and human cell models.
- Studies that would elucidate target or pathway biology in disease-relevant models, including defining upstream/downstream modifiers and convergence of promising target pathways.
- Studies of risk 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.
- Studies of new biomarker identification, and development and/or validation of biomarker assays.
- Studies to help people living with ALS, including development and/or validation of novel assistive technology and measurement of caregiver/family burden.

PLEASE NOTE: Priority will be given to specific biological targets and areas of research not previously funded through this program in the last three years. Proposals with significant overlap to already funded work will likely not be considered. To view the previous fellowships awarded through this program, please visit The ALS Association's Milton Safenowitz Postdoctoral Fellowship Program Website (<https://www.als.org/research/research-we-fund/fellowships/milton-safenowitz-postdoc-fellowship-program>).

Section II. Award Information:

- 1. Funding Instrument:**
 - Grant: A support mechanism providing money to an eligible entity to carry out an approved project or activity.
- 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.
- 3. Award Budget:**
 - Budgets for total direct costs up to \$75,000 per year may be requested. Indirect costs are not provided for postdoctoral fellowship awards.
- 4. Award Period of Performance:**
 - The maximum period of performance is two (2) years.

Section III. Eligibility

- 1. Eligible Individuals:**
 - Individuals who have the skills, knowledge, and resources necessary to carry out the proposed research and have an existing postdoctoral fellowship, including the support of their mentor.
 - Applicants who have been fellows for less than three years by the time the award starts are eligible to apply.
- 2. Eligible applicants:**
 - U.S. and non-U.S. biotechnology/pharmaceutical companies, or other publicly or privately held for-profit entities.
 - 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.

Section IV. Application and Submission Information

- 1. Content and Form of Application Submission**
 - It is critical that applicants follow the instruction of the application guide. Applications that are out of compliance with these instructions may be delayed or not accepted for review.
 - **Letter of Intent:** By the date listed in Part I Overview Information, prospective applicants are required to submit a letter of intent that includes the following information:
 - a. Descriptive title of proposed activity
 - b. Name, address, and telephone number of the Principal Investigator
 - c. Names of other key personnel
 - d. Participating Institution(s)
 - e. Number and title of this funding opportunity
 - f. A scientific rationale for the proposed study and its relevance to ALS
 - g. A brief description of the study hypothesis and/or objectives and overall experimental plan to meet those objectives

The Letter of Intent should be submitted per the application instructions at this [link](#). 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. Page Limitations

- All page limitations described in the Research Plan instructions must be followed.

3. Submission Dates and Times

- Part I. Overview Information contains information about Key Dates and times. Applicants are encouraged to submit a letter of intent and an application before the respective due date.
- Organizations must submit applications by accessing the application and instructions [here](#).

4. Funding Restrictions

- The ALS Association awards are subject to the terms and conditions described in The ALS Association Grants Policy Statement (GPS) and the award Agreement. The ALS Association GPS is available at <https://www.als.org/research/funding-opportunities/research-policies>.
- Awards will be limited to \$150,000 total direct costs for two years of support.
- Salary and fringe benefits of the postdoctoral fellow is allowed.
- Economy travel up to \$2,000 per year to attend scientific conferences.
- Equipment costs not to exceed 20 percent of the annual budget.
- Recurring annual cost-of-living/inflationary increases limited to 3 percent for personnel and consumable supplies
- Indirect costs are not provided on postdoctoral fellowship awards.
- 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.

5. Administrative and National Policy Requirements

All ALS Association grants include The ALS Association 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, publications, etc.

- **Animal Welfare Requirements:** The ALS Association requires its grantees to establish appropriate policies and procedures to ensure the humane care and use of animals. Domestic grantees also bear the ultimate responsibility for compliance with The *Public Health Service (PHS) Policy on Human Care and Use of Laboratory Animals* and other applicable requirements issued by the U.S. National Institutes of Health. Foreign grantees also bear the responsibility to applicable laws, regulations, and policies of the jurisdiction in which the research will be conducted, and a commitment to follow the [International Guiding Principles for Biomedical Research Involving Animals developed by](#) the Council for International Organizations of Medical Sciences.
- **Human Subject Requirements:** The ALS Association requires its grantees to establish appropriate policies and procedures to ensure the protection of human subjects used in research supported by The ALS Association. The ALS Association requires its grantees to comply with applicable federal, state, and local laws, regulations, the Department of Health and Human Services (HHS) regulation at Title 45 Code of Federal Regulation (CFR) Part 46. Clinical research involving investigational drugs and devices, or products regulated by the Food and Drug

Administration (FDA), must comply with all FDA requirements in 21 CFR Parts 50, 56, 312 and 812.

- **Health Insurance Portability and Accountability Act (HIPAA):** The ALS Association requires its domestic grantees to comply with the requirements of HIPAA to ensure the protection of individually identifiable health information for ensuring confidentiality of patient records.
- **General Data Protection Regulation (E.U. 2016/279):** The ALS Association requires its foreign grantees to comply with the Regulation E.U. 2016/269, or its amended regulation, of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to processing of personal data and on the free movement of such data.
- **Intellectual Property/Royalty:** The ALS Association expects a royalty from discoveries in proportion to its contribution to the direct activity leading to the discovery, invention, or idea, if applicable. 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. The grantee shall notify The ALS Association if it does not intend to pursue patent protection from any invention, discovery, or idea arising from the implementation of the Research Scope of Work and assign all rights to The ALS Association. Successful applicants will be accountable for providing The ALS Association its portion of the royalty received during and after termination of the award. Remittance of The ALS Association's share of the royalty must be made to The ALS Association per the instructions provided within the Research Grant Agreement.

6. Other Submission Requirements and Information

- Applications must be submitted electronically following the instruction described in the [create application guideline](#). Paper applications will not be accepted.
- 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.

Section V. Application Review Information

1. Review Criteria for Letter of Intent:

- **Fit:** The letter of intent should allow the ALS Association staff to assess whether there is a good match between The ALS Association's interest 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.

2. Review Criteria for Application:

- **Impact/contribution to ALS:** Potential for the proposed studies to make an important contribution to ALS disease management and symptoms and increase our understanding of the causes of ALS.
- **Justification/rationale for the proposed study:** Justification provided for the work proposed and overall goals/hypothesis for the project.
- **Research plan:** Feasibility, timeline and methodology of experiments and whether the research plan will result in concrete results.
- **Research team:** Qualifications of the postdoctoral fellow, senior PI, key personnel, and collaborators/consultants are appropriate to perform the proposed research project.

3. Peer Review and Selection Process:

- All applications are peer reviewed by the Scientific Review Committee constituted by The ALS Association to determine the application's scientific merit and relevance to ALS.
- The Scientific Review Committee's priority scores are forwarded only to The ALS Association Board of Trustees for final approval for the funding of research grants.

4. Anticipated Announcement and Award Dates:

- After the peer review of the application is completed and a selection is made of the application, The ALS Association will send the combined review results of the grant application. 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.
- See Part I, Section II, for dates of peer review, Scientific Review Committee and earliest start date.

Section VI. Award Administration Information

1. Award (Agreement) Notice 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.
- Award payments will be made to the Grantee on an annual or semi-annual basis as outlined within the Agreement.

2. Administrative Requirements.

- The Grantee is expected to utilize The ALS Association funds in direct support of the approved 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.
- Requests for prior approval should be submitted via email to researchgrants@alsa-national.org at least 30 days before the proposed change.

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

Section VII. ALS Association Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants. Submit general questions and other related correspondence to researchgrants@alsa-national.org