



Request for Applications: Quality of Care Research Awards

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1 Overview Information

1.1 Funder Overview

The ALS Association is the largest philanthropic funder of ALS research worldwide. Our goal is to make ALS livable for everyone, everywhere, until we can cure it. To achieve this goal, our Research Program focuses on finding new treatments and cures, optimizing current treatments and care, and preventing or delaying the harms of ALS. Thanks to the ALS Ice Bucket Challenge and the generous support of our donors, we have been able to dramatically accelerate 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, natural history, tool development, prevention, fellowship training, and infrastructure. Our efforts have led to the development and approval of new ALS treatments, discovery of new ALS genes, creation of new global research collaborations, and many more promising and significant advances in ALS research.

As a funder in a disease without a cure, 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 coordination. 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: Quality of Care Research Awards

Award: \$500,000 in total funding over two (2) years to support studies focused on improving quality of care or increasing implementation of evidence-based care for people living with ALS

1.3 Key Dates

Request for Application Open: June 21, 2023

Letter of Intent Due: August 9, 2023, 5 p.m. U.S. EDT

Full Proposal Due (by invitation only): October 11, 2023, 5 p.m. U.S. EDT

Anticipated Award Decision: December 2023

Anticipated Earliest Start Date: January 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 detail on all policies described in this document, please consult our Grants Policy Statement, available at www.als.org/Grants-Policy-Statement.

2 Full Text of the Announcement

2.1 Funding Opportunity Description

2.1.1 Overview

ALS is a devastating disease that causes motor neurons to degenerate over time until they eventually die. When motor neurons die, the brain can no longer initiate and control muscle movement, causing people with ALS to progressively lose the ability to speak, eat, move, and/or breathe. There is no cure, and people with ALS live, on average, about 2–5 years after diagnosis.

Specialized multidisciplinary care and symptom management are vital components of ALS care, helping to extend survival and improve quality of life ([Hogden et al., 2017](#); [Miller et al., 2009](#)). With two new disease-modifying drugs approved by the FDA in the past year, along with rapid technological changes in the practice of medicine, the landscape of ALS treatment and care is changing at a pace never before seen by the ALS community. However, transforming these advances into meaningful improvements in outcomes for everyone, everywhere, will require greater insight into the best ways to optimize the efficacy, efficiency, and accessibility of ALS care.

These two-year awards with a maximum budget of \$500,000 seek to support the development and/or testing of interventions intended to improve quality of life; make ALS care safer, of higher quality, more accessible, more equitable, and more affordable; reduce complications; and enhance service delivery at the point of care.

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 improve the health and quality of life of people with ALS and/or reduce the burdens or complications of the disease.

Topics supported could include, but are not limited to:

- Improving existing therapies
 - Developing and/or testing interventions to improve quality at the point of care.
 - Optimizing combinations of FDA-approved disease-modifying drug treatments (e.g., Riluzole, Radicava, Relyvrio, Qalsody) or non-pharmacological approaches to improve care.
 - Developing and/or testing protocols to improve the efficiency of intrathecal medication administration and/or reduce side effects.
- Reducing complications
 - Developing and/or testing care interventions intended to reduce complications of the disease, such as falls, pneumonia, emergency room visits, respiratory failure, and sialorrhea, amongst others.
 - Developing and/or testing care interventions intended to address nutritional needs, respiratory management, coping, isolation, medication alignment, or palliative care.
 - Developing and/or testing strategies to reduce caregiver burden.
 - Developing and/or testing protocols for symptom management and end-of-life care.
- Improving systems and services
 - Developing and/or testing interventions intended to reduce racial, ethnic, geographic, gender, or other disparities in diagnosis, access to care, and treatment outcomes.
 - Developing and/or testing strategies to reduce time to diagnosis.
 - Developing and/or testing interventions to increase utilization of evidence-based practices, such as multidisciplinary ALS clinics, high-quality respiratory care, and genetic counseling and testing.
 - Developing and/or testing telehealth or telemedicine approaches to reduce burden on ALS specialty clinics and improve quality of care for people with ALS.

- Developing and/or testing strategies to improve quality of care for people with ALS being managed in their community, such as improving links between primary care services, general neurology, and specialized ALS clinics or connecting clinical services at multidisciplinary clinics and non-multidisciplinary clinics.
- Developing and/or testing support systems, education, or programs for health care professionals to manage fatigue and the emotional distress they encounter in ALS practice.

2.1.3 Topics Not Supported Under This Funding Opportunity

The following are considered out of scope for this funding opportunity and will be administratively withdrawn:

- Development and testing of assistive technologies
- Development and testing of new pharmacological interventions
- Studies conducted outside the United States (due to the unique context of the American health care system)

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 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 section [2.3.1 Eligible Individuals](#)) 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 \$500,000 (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 two (2) years.

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 the principal investigator.

- Applicants do not need to have a scientific background in ALS research.
- Senior postdoctoral fellows, defined as fellows who will have been in their current postdoctoral position for at least three years on the date full proposals are due, may apply as the principal investigator. A Letter of Collaboration from the fellow’s mentor will be required at the full proposal stage.
 - Junior postdoctoral fellows are not eligible to apply for this opportunity but are encouraged to consider the Association’s [Milton Safenowitz Postdoctoral Fellowship](#) instead.
- Established investigators, early career investigators, and investigators from outside the ALS field are all eligible to apply as the principal investigator.
 - Established investigators are those who, 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 public and private non-profit entities, such as clinics, universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government.
- U.S. biopharmaceutical industry, technology, medical device, health care consulting, or other publicly or privately held for-profit entities.

2.3.3 Collaborations

- For this funding opportunity, we encourage collaboration between implementation science, quality improvement, and health services researchers and ALS clinician-scientists.
- 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.
 - One individual is required to serve as the principal investigator.
- Collaborative applications must identify a lead organization.

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 Content of Letter of Intent

By the date listed in the [Key Dates](#) above, prospective applicants are required to submit a letter of intent that includes the following information:

- Administrative Information
 - Descriptive Title of Proposed Project
 - Principal Investigator's Name and Contact Information
 - Names of Other Key Personnel
 - Participating Institution(s)
- Project Information (**2.5 pages total**, see [Proposal Central](#) for character limits for specific sections)
 - Scientific Abstract
 - Project Goal and Specific Aims
 - Scientific Rationale and Potential Impact
- Attachments
 - Principal Investigator Biosketch
 - Resubmission Statement (if relevant)

2.4.2 Content of Full Proposal

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:

- Administrative Information
 - See [Proposal Central](#) webform for details.
- Research Plan (**10 pages total**, not including references)
 - Scientific Abstract
 - Project Roadmap, including Specific Aims and Timeline
 - Potential Impact
 - Preliminary Data / Published Results
 - Plan / Methods / Statistics
 - If studies involving people with ALS are needed, proposals must include plans for recruitment, retention, and long-term follow-up.
 - Team / Environment
 - References
- Budget
 - Planned Expenditures (table)
 - Budget Justification (5,000 characters maximum)
- Attachments
 - Principal Investigator Biosketch
 - Biosketches for Co-Principal Investigators and Collaborators
 - Letters of Collaboration (if relevant)
 - W-9 or Other Relevant Tax Information

2.4.3 Review Criteria for Letter of Intent

Review of the letter of intent emphasizes fit, potential impact, and the research plan, as described in more detail in section [2.4.4 Review Criteria for Full Proposal](#).

2.4.4 Review Criteria for Full Proposal

- **Fit:** Is there a good match between the Association’s mission, the intent of the funding program, and the proposed project?
- **Potential impact:** Does the proposed intervention or strategy have the potential to improve quality of life or quality of care for people living with ALS? What is the current clinical practice, and how will the proposal significantly improve upon this practice?
- **Scientific merit:** What are the technical strengths and weaknesses of the proposed project? Is the design of the project adequately developed and appropriate for the purpose of the project? Have potential problem areas been acknowledged and alternative tactics been considered? Are the milestones and timelines feasible? Are the go/no-go decision points (if any required) clear?
- **Investigator / team / environment:** Are the qualifications of the principal investigator, key personnel, and collaborators/consultants appropriate to perform the proposed project? Does the environment in which the work will be done contribute to the probability of success? Will the proposed collaborative arrangements help 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?

2.4.5 Peer Review and Selection Process

- All applications (i.e., letters of intent and full proposals) are peer reviewed by an ad hoc Scientific Review Committee constituted by the Association.
- Letters of intent will 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 applicants.
- 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 review phase will be provided to applicants.
- For applications selected for funding, the Association recommends that the principal investigator integrate any recommendations that the reviewers may have suggested, to the extent practical and within the scope of the budget, to further optimize the project and outcomes.

2.5 Application and Submission Information

2.5.1 Format of Application Submission

- All application materials are to be submitted through our online grants management platform, Proposal Central: proposalcentral.com.

- To find this funding opportunity on Proposal Central, 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 Proposal Central are available at docs.proposalcentral.com/RegUser.pdf.
- Application materials must be prepared according to Proposal Central'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

The Association's awards are subject to the terms and conditions described in the [Grants Policy Statement](#) and the award Agreement.

- Awards will be limited to \$500,000 in total costs for the entire two-year period of performance.
- Salary, wages, and fringe benefits of personnel other than 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 (grants.nih.gov/grants/policy/salcap_summary.htm).
- Indirect costs are limited to 10% of total direct costs.
- 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 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 ALS 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 human subject protections, data sharing, research resource sharing, publications, etc. All necessary ethical and regulatory approvals must be in place before experiments are initiated.

- **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. Grantees must comply with the requirements the Health Insurance Portability and Accountability Act (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](#)).

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 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 the 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 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.

2.7 ALS Association Contacts

We encourage inquiries concerning these research awards and welcome the opportunity to answer questions from potential applicants. Please submit all correspondence to ResearchGrants@als.org.