



Request for Applications: Assistive Technology

Table of Contents

| | | |
|-----|---|----|
| 1 | Overview Information..... | 1 |
| 1.1 | Funder Overview..... | 1 |
| 1.2 | Funding Opportunity in Brief..... | 2 |
| 1.3 | Key Dates..... | 2 |
| 1.4 | Grants Policy Statement..... | 2 |
| 2 | Full Text of the Announcement..... | 2 |
| 2.1 | Funding Opportunity Description..... | 2 |
| 2.2 | Award Information..... | 5 |
| 2.3 | Eligibility..... | 5 |
| 2.4 | Content and Review of Applications..... | 7 |
| 2.5 | Application and Submission Information..... | 9 |
| 2.6 | Award Administration..... | 10 |
| 2.7 | ALS Association Contacts..... | 11 |

Revised 25 May 2023

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 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: Assistive Technology

Award: \$400,000 in total funding over two (2) years to support efforts to develop or adapt assistive technologies for people living with ALS

1.3 Key Dates

Request for Application Open: June 1, 2023

Letter of Intent Due: July 6, 2023, 5 p.m. US EDT

Full Proposal Due (by invitation only): September 7, 2023, 5 p.m. US EDT

Anticipated Award Decision: October 2023

Anticipated Earliest Start Date: November 2023

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

Our goal is to make ALS livable for everyone, everywhere, until we are able to find a cure. This means not only searching for new ways to treat the disease but also finding ways to empower people with ALS to live their lives to the fullest. The needs of people living with ALS can vary from person to person and throughout the course of the disease. As ALS progresses, diverse assistive technologies play a crucial role in helping manage symptoms and maintain independence. These devices can make it easier for people with ALS to communicate, move,

breathe, and perform daily activities, making life better for both the person living with the disease and their caregivers.

These two-year awards with a maximum budget of \$400,000 seek to accelerate the development of innovative technologies or the adaptation of existing technologies that can help maintain or improve the health, independence, and/or quality of life of people living with ALS (see section [2.1.2 Topics of Interest](#) below). **This funding opportunity is intended to support work after the exploration and discovery phase** (see section [2.1.3 Stages of Development Supported](#) below).

Successful applications will demonstrate:

- **High potential for impact:** The proposed assistive technology should seek to provide a unique or highly differentiated solution to a problem that matters to people living with ALS. (See results of our ALS Focus survey on the topic at www.als.org/research/als-focus/survey-results/survey-2-results.)
- **Strong scientific rationale:** The proposed project should have a high likelihood of technical success, and successful completion of the project's aims should significantly advance the development of the technology.
- **Well-defined commercialization path:** The applicant should articulate a clear plan for funding and executing the steps beyond the proposed project needed to bring the proposed assistive technology to market and make it broadly accessible to people living with ALS.

See section [2.4 Content and Review of Applications](#) for more detail about the criteria that will be used to select applications for funding.

Given that technologies at different stages of development could receive funding through this opportunity, successful project outcomes could include advancement of the technology, adaptation of existing finished products to the particular needs or requirements of the ALS community, or deployment of the technology to a meaningful number of end users. For most recipients, this award will constitute a minority of the funding needed to reach commercial launch, but the Association's support should catalyze follow-on funding that will enable further development or commercialization activities.

2.1.2 Topics of Interest

For this funding opportunity, we will accept applications from all scientific disciplines that are focused on developing novel assistive technologies or integrating or repurposing existing technologies to create new solutions for people living with ALS. Types of assistive technologies supported could include, but are not limited to:

- Technologies to assist with activities of daily living, such as call bells and other devices that enable calling for help, transfer devices (i.e., devices to more easily and safely move people with mobility challenges to and from a wheelchair, chair, bed, car, bathtub, toilet, etc.), home monitoring systems or automation that allow an individual to control appliances, electronics, or other aspects of their environment.

- Devices that can help individuals with ALS communicate more effectively (i.e., augmentative and alternative communication devices), such as eye-tracking technology, customized speech-generating devices, or brain-computer interfaces.
- Mobility aids and assistive devices that can help individuals with ALS move around and perform daily tasks more independently, such as powered wheelchairs, wheelchair-mounted robotic arms, or bathroom mobility aids.
- Innovative technologies that can improve breathing, such as more effective tools for non-invasive ventilation.
- Technologies that can increase access to and participation in recreational activities and environments.
- Technologies that address pressing health service delivery issues relevant to the lives of people living with ALS, including telehealth, remote monitoring, and the coordination and provision of home- and community-based health services.

Both technologies that are designed specifically for people living with ALS and technologies that cater to a wider customer base (but still have important benefits for people living with ALS) are suitable topics for this funding opportunity.

2.1.3 Stages of Development Supported

This funding opportunity will support projects focused on technology development, efficacy testing, or scale-up evaluation. For the purposes of this funding opportunity, we define the stages of assistive technology development as:

1. **Exploration and discovery:** This stage of research generates hypotheses or theories through new and refined analyses of data, producing observational findings and creating other sources of research-based information. This research stage may include identifying or describing the barriers to and facilitators of improved outcomes for individuals with ALS, as well as identifying or describing existing practices, programs, or policies that are associated with important aspects of the lives of individuals with disabilities. Results achieved during this stage of research may inform the development of interventions or lead to evaluations of technologies or policies.
2. **Technology development:** This stage of research focuses on generating and testing technologies that have the potential to improve outcomes for individuals with disabilities. Technology development involves determining the active components of possible technologies, developing measures that would be required to illustrate outcomes, specifying target populations, conducting field tests, and assessing the feasibility of conducting a well-designed efficacy study. Results from this stage of research may be used to inform the design of a study to test the efficacy of a technology.
3. **Efficacy testing:** This stage of research evaluates and tests whether a technology is feasible, practical, and has the potential to yield positive outcomes for individuals with ALS. Efficacy research may assess the strength of the relationships between the technology and specified outcomes and may identify factors or individual characteristics that affect the relationship between the technology and these outcomes. Efficacy research can inform decisions about whether there is sufficient evidence to support “scaling-up” a technology to other sites and contexts. This stage of research may include assessing the training needed for wide-scale

implementation of the technology and approaches to evaluation of the technology in real-world settings.

4. **Scale-up evaluation:** This stage of research analyzes whether a technology is effective at producing improved outcomes for individuals with ALS when implemented in a real-world setting. During this stage of research, a project tests the outcomes of an evidence-based technology in different settings. The project examines the challenges to successful use of the technology and the circumstances and activities that contribute to successful adoption of the technology in real-world settings. This stage of research may also include well-designed studies of a technology that has been widely adopted in other settings but lacks sufficient evidence to demonstrate its effectiveness for people living with ALS.

2.1.4 Topics Not Supported Under This Funding Opportunity

This funding opportunity emphasizes development, validation, and translation over exploratory studies. As such, applications focused on exploration and discovery work, as defined above, are out of scope and may be administratively withdrawn.

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 \$400,000 (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 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 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 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 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. technology, medical device, biotechnology, or other publicly or privately held for-profit entities.
- The applicant organization must be the organization that controls the intellectual property under development. For example, if an academic lab has out-licensed the relevant intellectual property to a commercial partner, then the commercial partner must be the applicant organization even if the work will be completed by the academic lab. Please consult ALS Association staff if you need clarification.

2.3.3 Collaborations

- Given the variety of skills necessary to successfully bring an assistive technology to market (e.g., scientific, engineering, product development, marketing, business development, commercialization, legal, etc.), applications are open to investigators participating in synergistic collaborations; however, one individual is required to serve as the principal investigator.
- 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.
- Collaborative applications must identify a lead organization, which must be the entity that controls the intellectual property under development.

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
 - Specific Aims
 - Scientific Rationale and Potential Impact
 - Commercialization Plan
- 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
 - Technology Summary
 - Preliminary Data / Published Results
 - Experimental Plan / Methods / Statistics
 - For clinical studies, this must include plans for participant recruitment, retention, and long-term follow-up.
 - Commercialization Plan
 - 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 commercialization 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 assistive technology solve a problem that matters to people living with ALS? How common is the problem to be solved, how do people living with ALS currently solve it, and what impact does it have on quality of life? Is the proposed assistive technology a novel intervention, or are there similar technologies already available? If similar technologies are available, the applicant must show how the proposed technology is differentiated from and superior to existing technologies.
- **Scientific merit:** What are the technical strengths and weaknesses of the proposed project? Do the preliminary data justify the choice of proposed project as a logical next step in development of the technology? 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 clear and used to inform further development of the technology?
- **Investigator / team / environment:** Are the qualifications of the principal investigator, key personnel, and collaborators/consultants appropriate to perform the proposed project and downstream product development and product launch tasks? 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?
- **Commercialization plan:** Does the commercialization plan describe product development and launch activities beyond the scope of the project proposed for funding? Is this plan sufficiently logical and detailed? Is the balance between the potential market size (including but not limited to ALS) and the estimated development cost sufficient to attract the amount of follow-on funding that will be necessary to complete development and launch activities? Are the descriptions of current funding and plans for obtaining future funding sufficiently detailed, and would the projected total funding meet current and future needs? Are there any IP/patent issues that could impede development? What is the regulatory path to be pursued, and what is the timeline for bringing a product to market? What is the likelihood of the product receiving Medicare reimbursement (e.g., relevant precedents that have received coverage)?

- **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 \$400,000 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 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 [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 this research program and welcome the opportunity to answer questions from potential applicants. Submit all correspondence to ResearchGrants@als.org.