



Request for Applications: Trial Capacity 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 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: Trial Capacity Awards

Award: \$400,000 in total funding over four years to support efforts to increase participation in ALS clinical trials and/or improve the speed and efficiency of clinical trial conduct at both established and emerging ALS clinical trial sites

1.3 Key Dates

Request for Applications Open: May 4, 2023

Letter of Intent Due: June 8, 2023, 5 p.m. U.S. EDT

Full Proposal Due (by invite only): August 10, 2023, 5 p.m. U.S. 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 <https://www.als.org/Grants-Policy-Statement>.

2 Full Text of the Announcement

2.1 Funding Opportunity Description

2.1.1 Overview

Clinical trials are the most reliable – and ultimately the fastest – way to translate promising laboratory science into new and better ways to treat and care for people living with ALS. Therefore, the Association is working to significantly increase the number of high-quality ALS clinical trials as part of its strategic priority of finding new treatments and cures.

As the number of ALS trials increases, the number of people with ALS participating in research will need to increase as well. Many people living with ALS want to participate in clinical trials but

are unaware of opportunities or lack access to local trial sites. In addition, many trial sites do not have the infrastructure or capacity to accommodate significantly more participants and/or additional trial protocols.

The Association's Trial Capacity Awards support efforts to improve the speed and efficiency of clinical trial conduct at both established and emerging clinical trial sites across the U.S., as well as initiatives to help improve trial accessibility for people with ALS. These awards help eliminate barriers to trial participation, especially those impacting currently underserved populations, to increase the number and diversity of people living with ALS who have the opportunity to participate in clinical trials. Applications that focus primarily on specific barriers or bottlenecks rather than spreading funding across all trial-related expenses are preferred.

2.1.2 Topics of Interest

Examples of items that this funding opportunity will support include:

- Salary support for study personnel, including but not limited to support for clinical trial coordinators, research project or program managers, research assistants, regulatory specialists, physicians and allied health providers, budget/contracting and other administrative support, etc.
- Physical infrastructure, including but not limited to laboratory equipment and space, biosample handling and storage equipment (e.g., freezers, centrifuge) for outcome measures, such as spirometry, handheld dynamometry, etc.
- Efforts to increase recruitment and retention of individuals from underserved populations, including but not limited to funding of patient travel costs, language translation services, telehealth utilization, local community partnerships for targeted outreach, etc.
- Training and associated costs specific to the conduct of ALS trials, such as registration or travel costs to attend NEALS trainings, licensing, professional memberships, and certifications.
- Services specific to the conduct of ALS trials, such as genetic testing and counseling, required hospital services, specialized contract support staff, pharmacy contracting for drug supply, start-up support, etc.
 - Please note that grant support should not be used for services for a specific clinical trial but rather for building capacity that is applicable for multiple trials.
- Cross-site or cross-disease coordination efforts to improve availability of trials and services to patients (e.g., coordinating across other neurodegenerative diseases, partnering with other sites in the local area to share participants, or having experienced study personnel from established trial sites provide mentorship/training at emerging trial sites).
- Other efforts to improve efficiency and effectiveness of clinical trial recruitment and retention.

2.1.3 Topics Not Supported by this Funding Opportunity

The following are **not appropriate** for this funding opportunity:

- Support for individual research projects or clinical trials.
- Support for clinical care.
- Any costs, including those listed above as a Topic of Interest, that are already covered by a clinical trial sponsor.

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.

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 and emerging clinical trial sites 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, if requested, cannot exceed 10% of total direct costs.

2.2.4 Award Period of Performance:

- The maximum period of performance is four (4) years.

2.2.5 Payments Provided

We expect the \$400,000 total budget of the award will be spread roughly evenly across the four-year period of performance, so we anticipate making payments of approximately \$100,000 each year. However, reasonable requests to front load payments (e.g., to support purchase of equipment that will be used throughout the period of performance) or roll some funds over from one year to the next can be accommodated.

2.3 Eligibility

2.3.1 Eligible Individuals

- Individuals with the skills, knowledge, and resources necessary to carry out the proposed plan may apply as a principal investigator (PI).
 - For example, PIs could be clinical directors (medical directors), clinical research coordinators, or other clinically trained personnel.

2.3.2 Eligible Organizations

- Organizations that have the potential or demonstrated ability to carry out clinical research in ALS.

- U.S. public and private non-profit entities, such as ALS clinics, universities, colleges, hospitals, laboratories, units of state and local governments, and eligible agencies of the federal government.

2.3.3 Collaborations

- Applications are open to investigators participating in synergistic collaborations, though one individual is required to serve as the PI.
- 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.

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:

- Title of the project
- Total amount of funding requested
- Contact information of the PI and the organization
- Names of other key personnel
- Project narrative
 - **Scientific abstract:** A short summary of the proposed project
 - **Current capabilities:** Please describe the organization's and the PI's current capabilities relevant to ALS clinical trials (include collaborators if relevant), for example, the number of trials undertaken in the last year, the number of patients enrolled in trials, the diversity of the patients enrolled, and the geographical area served. For clinical sites, describe items including personnel, physical infrastructure, patient population served, experience with clinical trials, etc. For other organization types, please describe expertise and resources relevant to ALS clinical trials.
 - **Problem statement:** Identify the specific barriers or limitations the project intends to address. Briefly describe the strategic, operational, and financial challenges in expanding clinical trials based on the current situation at your organization.
 - **Project plan:** Provide a clear plan for addressing the problem identified above. What will you do with grant funding? What metrics of success do you aim to achieve (e.g., plan to go from running X number of trials to Y number of trials or enrolling X number of patients)? What evidence supports the proposition that the specific tactics proposed are the best way to achieve your objectives?
 - **Sustainability plan:** How would this grant funding help you build trial capacity that is self-sustaining? What is the timeframe over which you would expect this grant funding to increase trial capacity?
- Biosketch of the PI

- Signature of the PI

2.4.2 Review Criteria for Letter of Intent

- **Fit:** The letter of intent should allow reviewers to assess whether there is a good match between the Association’s mission, the intent of the funding program, and the proposed project.
- **Rationale:** The letter of intent should adequately describe the current problem, limitations, and/or barriers and provide a logical rationale for how this project will address them.
- **Team:** The letter of intent should show that the expertise of the team matches the needs of the proposed project.

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 proposal. Reviewer comments from the letter of intent review phase will not be provided to the applicant.

2.4.3 Content of Full Proposal

If/when an applicant’s letter of intent is accepted, instructions for submitting a full proposal will be provided. Generally, the full proposal covers the same topics as the letter of intent but in greater detail.

2.4.4 Review Criteria for Full Proposal

- **Impact/contribution:** Potential for the proposed project to increase the number and/or diversity of people living with ALS who have the opportunity to participate in clinical trials, and/or to improve the speed and efficiency of clinical trial conduct at established or emerging clinical trial sites across the U.S.
- **Project design:** Clarity and feasibility of the timelines and methodologies involved.
- **Budget justification:** Are the costs outlined in the budget necessary and sufficient for the successful completion of the project? Costs must be tightly linked to the goal of improving clinical trial capacity.
- **Team:** Qualifications of the PI, key personnel, and collaborators/consultants are appropriate to conduct the proposed project.
- **Likelihood of success:** Show how the grant funding would complement the applicant’s current capabilities and improve ALS clinical trial capacity both during the period of award performance and in the years beyond.

2.4.5 Peer Review and Selection Process

- All applications are peer reviewed by an ad hoc Scientific Review Committee constituted by the Association.
- The Scientific Review Committee’s priority scores are forwarded only to the Association’s Board of Trustees, which has the sole authority for approving the funding of research grants.
- For applications selected for funding, the Association will send the reviewer comments to the PI. To the extent practical and within the scope of the budget, the Association

recommends that the PI integrate any recommendations 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 application materials (letters of intent and full proposals) 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 are available at <https://docs.proposalcentral.com/RegUser.pdf>.
- Application materials must be prepared according to Proposal Central's instructions, which can be found at <https://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 four-year period of performance.
- Indirect costs are limited to 10% of total direct costs.
- The Association will contract with the lead-PI's organization with all funds going to a single organization. The PI will be responsible for budgetary and scientific oversight and management of collaborators.
- The allowability of costs supported under an Association grant is described in the [Grants Policy Statement](#), but the following exceptions apply to this specific funding opportunity:
 - Permanent or fixed equipment is allowed, and the limit on equipment costs is increased to 50% of the annual budget.
 - Travel costs are allowed, and the limit is increased to 20% of the annual budget.

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.
 - **Health Insurance Portability and Accountability Act (HIPAA):** Domestic grantees must comply with the requirements of HIPAA.

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 program and welcome the opportunity to answer questions from potential applicants. Please submit all correspondence to ResearchGrants@als.org.