



Funding Opportunity: Trial Capacity Awards

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Revised 10 March 2022

1 Overview Information

1.1 Funder Overview

The ALS Association is doing “whatever it takes” to bring us closer to a cure for ALS and to make ALS a livable disease. Our strategic priorities are to find new treatments and cures, optimize current treatments and care, and prevent or delay harms of ALS. Our Research Program supports cutting edge research across the translational pipeline from basic science to clinical trials and funds research in other important areas such as assistive technology, natural history, tool development, fellowship training and infrastructure. The Association is the largest private philanthropic funder of ALS research worldwide, and our efforts have led to some of the most promising and significant advances in ALS research.

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 efforts to 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 25, 2022

Letter of Intent Due Date: June 29, 2022, 5 p.m. US ET

Full Proposal Due Date (by invite only): August 31, 2022, 5 p.m. US ET

Anticipated Award Decision: October 2022

Anticipated Earliest Start Date: November 2022

Our expectation is that contracting is completed within 60 days of 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 [here](#).

2 Full Text of the Announcement

2.1 Funding Opportunity Description

2.1.1 Overview

The ALS Association has established a goal to significantly increase the number of high-quality clinical trials in the ALS ecosystem as part of its strategic priority to find new treatments and cures. There is an urgent need to increase the number and capacity of trial sites to complement this increase in the number of trials. Increases in clinical trial capacity will allow for potential new therapies to be tested faster and will improve trial accessibility for people with ALS in currently underserved areas. The Clinical Trial Capacity Awards will support efforts to increase the number and diversity of people living with ALS who have the opportunity to participate in clinical trials, and efforts to improve the speed and efficiency of clinical trial conduct at both established and emerging clinical trial sites across the US.

Many people living with ALS want to participate in clinical trials but are currently either unaware of opportunities or unable to engage in them due to lack of accessibility to clinical trial sites within their local areas. These awards should help eliminate barriers, especially those impacting currently underserved populations, to trial participation. Similarly, many ALS clinics and drug development companies wish to pursue clinical development in ALS and these awards should help establish infrastructure allowing them to conduct faster and more efficient clinical trials in

ALS. Applications that focus primarily on specific barriers / bottlenecks rather than spreading funding across all trial-related expenses are preferred.

2.1.2 Scope

- 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: lab equipment and space, biosample handling and storage (e.g., freezers, centrifuge) equipment for outcome measures (spirometry, hand held dynamometry, etc.), etc.
- Efforts to increase trial recruitment and retention in 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 costs or travel costs for attendance to 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.
 - 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., coordination with other neurodegenerative diseases, leveraging with other trial sites in the local area to share trial participants or travel funds to support experienced study personnel from established trial sites providing mentorship/training at emerging trial sites).
- Other efforts to improve efficiency and effectiveness of clinical trial recruitment and retention.
- 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 as in scope examples above, 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
- 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 ALS Association's budget allocation and the submission of a sufficient number of meritorious applications

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 that the \$400,000 total budget of the award will be spread roughly evenly across the four-year period of performance, so we expect to make 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 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.

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 and total amount of funding requested
- Contact information of the Principal Investigator and the Organization
- Names of other key personnel
- Project Narrative
 - Scientific abstract
 - Short summary of the proposed project
 - **Current Capabilities:** Please describe the organization and PI's current capabilities relevant to ALS clinical trials (include collaborators if relevant). For example, how many trials were undertaken in the last year and how many patients were enrolled in trials, diversity of 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 describe expertise and resources relevant to ALS clinical trials.
 - **Problem Statement:** Identify barriers or limitations the application intends to address. Briefly describe the strategic, operational, and financial challenges in expanding clinical trials in 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 that this grant funding will 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 the ALS Association staff to assess whether there is a good match between the proposed project and the intent of the funding program.
- **Rationale:** The letter of intent should describe a logical rationale for the proposed project.
- **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. Results from the letter of intent review phase will not be provided to the applicant.

2.4.3 Content of Full Proposal

Application instructions for the full proposal will be provided when/if the applicant is invited to submit the full proposal. Generally, the full proposal covers the same topics covered in 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 both established and emerging clinical trial sites across the US.
- **Project design:** Clarity, feasibility, timelines and methodologies involved.
- **Budget justification:** Are costs outlined in budget necessary and sufficient for conduct 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 perform 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 sustainably into 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 ALS Association
- The Scientific Review Committee's priority scores are forwarded only to The ALS Association Board of Trustees, which has the sole authority for approving the funding of research grants
- For applications selected for funding, The ALS Association will send the reviewer comments to the PI. 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.

2.5 Application and Submission Information

2.5.1 Format of Application Submission

- All applications 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: <https://docs.proposalcentral.com/RegUser.pdf>
- Applications must be prepared according to Proposal Central's instructions: <https://docs.proposalcentral.com/CreateApp.pdf>

- 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.

2.5.2 Funding Restrictions

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

- Awards will be limited \$400,000 total costs for the entire four-year period of performance
- Indirect costs are limited to 10% of total direct cost
- The ALS Association will contract with the lead-PI's organization with all the 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 ALS 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 ALS Association grants include The ALS Association Grants Policy Statement (see: [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.

- **Human Subject Requirements:** The ALS Association requires its grantees to establish appropriate policies and procedures to ensure the protection of human subjects participating in research supported by The ALS Association
 - **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

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 ALS Association, will include the negotiated terms and conditions of the award between The ALS 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 ALS Association funds in direct support of the research 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 (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 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

2.7 ALS Association Contacts

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