

Request for Applications: Hoffman ALS Clinic Development 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 Care Services, Research, and Advocacy Programs focus 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, prevention, fellowship training, and infrastructure. These funds have also supported the expansion of the Association's care programs to increase patient access to ALS specialists.

The ALS Association's Center Program was established in 1989. The strategic objective of the program is to design, implement, and monitor a national standard of best-practice care in the management of ALS. The primary goal of the designation process is to ensure that evidence-based care processes, that are closely linked to positive outcomes, are hard-wired into each individual's clinic experience. The evidence-based guidelines are based on the American Academy of Neurology Practice Parameters and Quality Measures.

ALS Association Certified Treatment Centers of Excellence and Recognized Treatment Centers are acknowledged as offering highly specialized multidisciplinary care that provide measurably higher combinations of expertise and related resources focused on the ALS diagnosis delivered by a comprehensive, interdisciplinary team. Research shows these centers have the ability to dramatically impact outcomes for patients across various communities and have shown this specialized ALS care can extend survival and improve patients' quality of life by using proven clinical pathways to guide treatments, referrals, symptom management, and coordination of care.

1.2 Funding Opportunity in Brief

Title: Hoffman ALS Clinic Development Awards

Award: \$900,000 in total funding over 3 years to establish a brand new ALS Association Certified Treatment Center of Excellence or Recognized Treatment Center; or \$450,000 in total funding for 3 years to uplift/elevate an existing ALS Association affiliated clinic to the level of an ALS Association Certified Treatment Center of Excellence or Recognized Treatment Center.

1.3 Key Dates

Request for Applications Open: July 1, 2024

Letter of Intent Due: August 19, 2024, 5 p.m. U.S. EDT

Full Proposal Due (by invite only): October 21, 2024, 5 p.m. U.S. EDT

Anticipated Award Decision: December 30, 2024 Anticipated Earliest Start Date: Feb 15, 2025 Our expectation is that contracting will be completed within 45 days of the award offer. If not, we reserve the right to rescind the award offer and redirect the funds to other projects.

2 Full Announcement

2.1 Funding Opportunity Description

2.1.1 Award Overview

Multidisciplinary care in ALS encompasses the provision of care to the ALS patient and their family by a range of health care disciplines and support services. In this multidisciplinary care model, professionals who have different skills, knowledge, and experiences work together to achieve optimal care for patients and their families. Given the multitude of physical problems (e.g., loss of mobility, respiratory failure, dysarthria, and dysphagia) and psychosocial problems (e.g., depression, loss, bereavement, and family distress) posed by ALS, people with ALS and their families engage with a team of ALS specialists from a variety of health disciplines.

To comprehensively address ALS patients' broad range of needs, multidisciplinary care optimally includes medical practitioners in neurology, respiratory, gastroenterology, rehabilitation, and/or palliative care; allied health care professionals in physiotherapy, occupational therapy, speech and language pathology, nutrition, and social work; and health professionals in specialist nursing, genetic counseling and psychology, including neuropsychology. Effective delivery of multidisciplinary care in ALS requires seamless collaboration, coordination, and transition between numerous health care professionals within and between disciplines, across a range of health care services and sectors.

Specialized multidisciplinary care in ALS has been shown to extend survival and improve patients' quality of life (Hogden et al., 2017, PMID 28579792) and people with ALS who received care at a multidisciplinary clinic had better prognosis than patients attending a general neurology clinic. However, access and regular utilization of multidisciplinary clinic is estimated to be less than 50% due to barriers such as lack of information on clinics, distance to the clinic, value of such care as assessed by people living with ALS, amongst others. Providing access to more multidisciplinary clinics is one way to increase utilization. Certified Treatment Centers of Excellence and Recognized Treatment Centers implement and monitor a national standard of best-practice multidisciplinary care in the management of ALS and provide certifications if clinics meet care and treatment standards, based on AAN practice parameters.

Applicants must be applying from an affiliated, recognized, or certified center or a new clinic that is willing and able to meet and maintain the requirements of the program.

The Hoffman ALS Clinic Development Program is established to provide support through two areas of clinic development and expansion to include:

- **1.** The establishment of new ALS Certified Treatment Centers of Excellence or Recognized Treatment Centers to address underserved and unserved communities
- **2.** Evolving an existing affiliated clinic to the level of an ALS Association Certified Treatment Center of Excellence or Recognized Treatment Center

2.1.2 Topics of Interest

This funding opportunity is specific to establishing new ALS-specific multidisciplinary clinics or elevating existing affiliated clinics. Examples of items this funding opportunity will support include:

- Salary support for clinic personnel, including but not limited to a medical director, who
 must be a neurologist, an occupational therapist, a physical therapist, a pulmonologist
 or respiratory therapist, a registered dietitian, a nursing professional (LPN, RN, NP), a
 social work professional (LMSW, LCSW), a speech language pathologist, a mental health
 professional, and allied health members of the multidisciplinary team, including certified
 research coordinators (CCRC).
- Equipment required for diagnosing and treating ALS, including but not limited to testing equipment (e.g. spirometer, digital wheelchair scales, dynamometers etc.)
- Efforts to increase recruitment and retention of ALS patients from underserved populations, including but not limited to funding of travel costs for persons with ALS, language translation services, telemedicine utilization, local community partnerships for targeted outreach, etc.
- Training and associated costs specific to establishing a full ALS multidisciplinary team and to maintain competencies.
- Cross-site or cross-disease coordination efforts to improve availability of services to
 people living with ALS (e.g., coordinating across other ALS providers, partnering with
 other sites in the local area to share participants, or having experienced clinic personnel
 from established ALS sites provide mentorship/training at emerging clinic sites).
- Other efforts to improve efficiency and effectiveness of clinics.

2.1.3 Topics Not Supported by this Funding Opportunity

The following are <u>not appropriate</u> for this funding opportunity, and applications focusing on these topics will be administratively withdrawn:

- Support for individual research projects or clinical trials.
- Expenses not directly related to the ALS Clinic.
- General administrative costs, overhead, indirect costs.

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.

2.2.3 Award Budget

- Establishment of new clinics: Budgets for total costs up to \$900,000 may be requested.
- Elevation of existing clinics: Budgets for total costs up to \$450,000 may be requested.
- Indirect costs are not provided for these awards.
- See section 2.5.2 Funding Restrictions below for additional details on allowable costs

2.2.4 Award Period of Performance:

• The maximum period of performance is three (3) years.

2.2.5 Payments Provided

We expect the total budget of the award will be spread roughly evenly across the three-year period of performance, so we anticipate making payments of approximately \$300,000 for new clinics or \$150,000 for elevating existing clinics each year.

2.3 Eligibility

2.3.1 Eligible Clinics/Providers/Organizations

- Applicants must be applying from an affiliated, recognized, or certified center or a new clinic that is willing and able to meet and maintain the requirements of the program.
- Clinics/providers with the skills, knowledge, and resources necessary to carry out the proposed plan may apply.
- Only US based clinics/providers can apply.

2.3.2 Collaborations

- Applications are open to clinics/providers participating in synergistic collaborations, e.g.
 network of clinics partnering to create a solution that meets the requirements of the
 Association's Clinic Program, though one clinic/provider is required to serve as the lead.
- If a collaboration is proposed, letters confirming/supporting the collaboration are
 <u>required</u> 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 Project Lead and the organization
- Names of other key personnel
- Narrative
 - Abstract: A short summary of the proposed plan to increase capacity to serve people living with ALS through establishing a new clinic or elevating a current clinic.
 - Current capabilities: Please describe the organization's and the clinic/provider's current capabilities relevant to the provision of ALS care, including diagnostics, treatment, care coordination (include collaborators if relevant), for example, the number of ALS patients seen in the last year, the diversity of the patients the geographical area served, physical structure, experience with clinical trials, etc. Please also indicate if this clinic is VA Medical Center, Kaiser Permanente clinic private practice, other specialty clinic, or other model of delivery (e.g. telemedicine service providers). Please provide the number of individuals living with ALS and number of other multidisciplinary ALS clinics within a 90-mile radius to the proposed clinic.
 - Problem statement: Identify the specific barriers or limitations to utilization of clinic. Briefly describe the strategic, operational, and financial challenges in expanding clinical care capacity based on the current situation at your organization. Describe any needs assessment completed which justifies establishing a new clinic or elevating an affiliated clinic.
 - 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 serving X number of patients to Y number of
 patients)? Is the proposed clinic development located in an underserved
 geography?
 - Sustainability plan: How would this grant funding help you build clinic capacity that is self-sustaining? What is the timeframe over which you would expect this grant funding to increase clinic capacity?
- Biosketch of the Project Lead
- Signature of the Project Lead

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 people and/or diversity of people living with ALS who have the opportunity to utilize the expertise of a multidisciplinary care team.
- **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 increasing clinic capacity.
- **Team**: Qualifications of the Project Lead, 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 clinic capacity both during the period of award performance and in the years beyond.
- Needs assessment/sustainability: Indicate that a needs assessment was performed to show that there is a need to build a new clinic or expand the current capabilities to serve and provide care for people living with ALS. There should also be a plan submitted to make the clinic self-sustaining beyond the timeframe of this grant funding.
- Collaborations/Information Sharing: Clinic plan for collaborating and sharing of demographic information on patients served and around successes, metrics and challenges with the ALS Association.

2.4.5 Peer Review and Selection Process

- All applications are peer reviewed by an ad hoc Review Committee constituted by the Association.
- Applications for clinic development and expansion may be reviewed separately or together depending on the number and quality of applications received.
- The Review Committee's priority scores are forwarded to the Care Services Committee, which has the sole authority for approving the funding of these grants.

• For applications selected for funding, the Association will send the reviewer comments to the Project Lead. To the extent practical and within the scope of the budget, the Association recommends that the lead physician 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, ProposalCentral: 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 noncompliant will not be reviewed.

2.5.2 Funding Restrictions

The Association's awards are subject to the terms and conditions described in the Award Agreement.

- Awards will be limited to \$900,000 in total costs for establishing a new clinic or \$450,000 in total costs for elevating an existing clinic, for the entire three-year period of performance and will be based on the achievement of explicit milestones.
- The Association will contract with the Project Lead's organization with all funds going to a single organization. The Project Lead will be responsible for budgetary and oversight and management of collaborators.
- The Association generally provides funds in support of the following cost items:
 - Salary, wages, and fringe benefits of Project Lead and other personnel not to exceed the salary limitation for Executive Level II of the Federal Executive pay scale provided on the NIH Salary Cap Summary website:

 grants.nih.gov/grants/policy/salcap_summary.
 - Consumable supplies.
 - Equipment costs, including permanent or fixed equipment and computer costs, are limited to 10% of the annual budget.
 - Economy travel costs up to \$3,000 per year to attend scientific meetings and/or conferences.
 - Per diem rates set by U.S. General Services Administration (GSA).
 - Subawardee and/or consortium costs.

- o Publication costs up to \$2,500 per project.
- NOTE: any recurring annual cost-of-living increase up to 3% only applies to personnel and consumable supplies.
- The Association generally does not provide funds in support of the following cost items:
 - o Indirect costs.
 - Costs of installing and maintaining equipment.
 - Non-economy travel and incidental expenses.
 - Travel costs exceeding \$3,000 per year.
 - o Tuition.
 - Relocation costs.
 - Premiums for insurance of equipment and supplies.
 - o Dues to organizations such as federations or societies.
 - Registration fees for scientific meeting.
 - Purchase of books, journals, or office equipment.
 - o Costs related to "contingency" funds or provision.
 - o Indirect costs for the grantee or any subgrantee in excess of maximum allowance outlined in each funding opportunity's RFA.
 - Over expenditures or cost overruns.
 - Duplication of funding.

2.6 Award Administration

2.6.1 Award Agreement and Payment Schedule

- A formal notification in the form of an ALS Association 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 Signing Official, Project Lead, 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 semiannual 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 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.

2.6.3 Reporting Requirements

- The Grantee will be required to submit semi-annual 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 clinic 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 CareservicesGrants@als.org.