



Grants Policy Statement

3-22-2021

INTRODUCTION

The ALS Association is the largest private funder of amyotrophic lateral sclerosis (ALS) disease and entity recognized as not for profit, tax-exempt charitable organization recognized under Section 501(c)(3) of the Internal Revenue Code. The ALS Association's mission is to discover treatments for ALS, and to serve, advocate for, and empower people affected by ALS to live their lives to the fullest. The ALS Association collaborates with the world's experts in ALS, whether in industry, clinics, labs or government, as well as with experts in related disease areas.

The ALS Association provides highly competitive research funding to domestic and foreign institutions, non-profit and for-profit organizations, and government in support of a wide breadth of scientific focus areas including, basic research, therapeutic development, clinical trials (Phases I, II, and III), and managing ALS. Additionally, research funding includes specific fields of study that are critical to advancing ALS research: biomarkers, nanotechnology, disease mechanisms, precision medicine, drug development and more. The ALS Association also supports training through the issuance of postdoctoral and clinical fellowship awards.

The ALS Association's Grants Policy Statement (GPS) is intended to make available to the grantee community the policy requirements that serve as the terms and conditions of The ALS Association grant awards. This document also is designed to be useful to those interested in The ALS Association grants by providing information about The ALS Association, its staff, its grants programs, and its grants process.

The ALS Association requires its grantees to establish and maintain effective internal controls (e.g., policies and procedures) that provide reasonable assurance that the grant award is managed in compliance with the stated requirements and the terms and conditions outlined in The ALS Association Research Grant Agreement.

Grants establish a relationship between The ALS Association and the grantee in which:

- 1) The ALS Association agrees to provide up to a specified amount of financial support for the project to be performed under the conditions and requirements of the grant. The ALS Association will monitor grant progress and assume compliance with applicable standards.
- 2) The grantee agrees to perform the project as proposed, to the prudent management of the funds provided and to carry out the supported activities in accordance with the provisions of the grant and to seek The ALS Association prior approval as outlined within this policy statement.

THE ALS ASSOCIATION GRANTS POLICY STATEMENT ORGANIZATION

The ALS Association's GPS has three parts, which provides general information, including pre and post award information related to the administration of grants awarded by The ALS Association.

- Part 1: The ALS Association General Information
- Part 2: Terms and Conditions of The ALS Association Research Grant Awards
- Part 3: Points of Contact
- Part 4: Resources

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Part 1: The ALS Association General Information

1. Definition of Terms

This part contains a definition of terms used in The ALS Association GPS.

1.1 Definition of Terms:

Administrative Supplement	A request for (or the award of) additional funds during a current award period to provide for an increase in costs due to unforeseen circumstances. All additional costs must be within the scope of the peer reviewed and approved project, unless otherwise approved by The ALS Association.
Animal	Any live, vertebrate animal used or intended for use in research, research training, experimentation, biological testing or related purposes.
Allocation	The process of assigning a cost, or a group of costs, to one or more cost objective(s), in reasonable proportion to the benefit provided or other equitable relationship. The process may entail assigning a cost(s) directly to a final cost objective or through one or more intermediate cost objectives.
Allowable Cost	A cost incurred by a grantee that is: (1) necessary and reasonable for the performance of the award (2) allocable to the project, (3) conform to any limitations or exclusions set forth in The ALS Association Grants Policy Statement, Funding Opportunity Announcement or in the Research Grant Agreement as to the type or amount of cost items; (4) consistent with policies and procedures of the grantee that are applied uniformly to both The ALS Association supported grant and other activities of the grantee; (5) accorded consistent treatment as a direct or indirect cost; (6) determined in accordance with generally accepted accounting principles (GAAP); (7) not included as a cost in any other funded award and (8) adequately documented. See 2 CFR 200.403 (Uniform Guidance)
ALS	Amyotrophic lateral sclerosis
Application	A request for grant support of a project or activity submitted to The ALS Association on specified forms and in accordance with The ALS Association instructions.
Application number	The application number is a unique identifier for a grant application submitted to The ALS Association.
Assurance	A certification by an applicant, normally included with the application indicating that the institution complies with, or that it will abide by, a requirement if awarded an ALS Association grant.

Authorized Organizational Representative	The individual, named by the applicant and/or grantee organization, who is authorized to act for the applicant and/or grantee and to assume the obligations imposed by The ALS Association and the terms of an ALS Association Research Grant Agreement.
Award	The provision of funds issued by The ALS Association, based on an approved application and budget, to an institution to carry out a research project or activity.
Biospecimens	Any tissue, fluid, material or matter derived from a biological source to be collected by the grantee for use in research pursuant to the Institutional Review Board approved protocol.
Budget	The financial plan for the project or program that The ALS Association approves during the award process or in subsequent amendments to The ALS Association award. The approved budget amount in support of the research project is specified in The ALS Association Research Grant Agreement.
Budgetary Overlap	Duplicate or equivalent budgetary items (e.g., equipment, salaries, supplies, etc.) are requested in an application that are already provided by another source.
Change in scope	An activity whereby the objectives or specific aims identified in the Research Grant Agreement are significantly changed by the grantee after an award is made. The ALS Association prior approval is required for a change in scope to be allowable under an ALS Association award. See Administrative Requirements – Changes in Project and Budget – Prior Approval Requirements – Change of Scope section for additional information.
Common Rule	Federal Policy for the Protection of Human Subjects set forth in 45 C.F.R. Part 46 of the Department of Health and Human Services for which The ALS Association grantees are subject to when human subjects are involved in an ALS Association supported project.
Change of Principal Investigator (PI)	A process, usually initiated by the grantee, whereby the approved PI is replaced by another individual, with the approval from The ALS Association. The ALS Association prior approval is required for a change in PI. See Administrative Requirements – Changes in Project and Budget – Prior Approval Requirements – Change of Principal Investigator section for additional information.
Change of Grantee Organization	Transfer of the legal and administrative responsibility for a grant-supported project or activity from one legal entity to another before the expiration of the grant. The ALS Association prior approval is required for a change of grantee institution. See Administrative Requirements – Changes in Project and Budget – Prior Approval Requirements – Change of Grantee Organization section for additional information.

Clinical Research	Human subjects research that is: Patient-oriented research. Research conducted with human subjects (or on material of human origin, such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects
Closeout	The process by which The ALS Association determines that all applicable administrative actions and required work of the grantee have been completed. The grant closeout process which includes the submission of a final research progress report and final expenditure report is initiated as soon as the grant support ends.
Co-Investigator	An individual involved with the PI in the scientific development and execution of a project.
Commitment Overlap	An individual's time commitment exceeds 100% of an individual's research responsibilities, whether or not salary support is requested in the application.
Competitive Supplement	A request for an increase in support during the period of an award to support new or additional activities which are not identified in the current award (Statement of Work) that reflects an expansion of the project's approved scope or research protocol. Competitive supplements require peer review.
Data	Data refers to recorded factual material commonly accepted as necessary to document and support research findings or clinical care. This does not mean summary statistics or tables; rather, it means the data on which summary statistics and tables are based. Data collection does not refer to name collection or mailing lists.
Direct costs	Costs that can be identified specifically with a particular final cost objective or that can be directly assigned to such activities relatively easily with a high degree of accuracy.
Disallowed costs	Those charges to an ALS Association award that is determined to be unallowable, in accordance with the institutions policies and procedures and the terms and conditions of the award. The cost does not meet the general criteria of allowability as stated in 2 CFR Part 200 (Uniform Guidance).
Domestic organization	A public (including a State or other governmental agency) or private non-profit or for-profit organization that is located in the United States or its territories, is subject to the U. S. laws, and assumes legal and financial accountability for awarded funds and for the performance of the grant supported activities.
Equipment	Tangible personal property (including information technology systems) having a useful life of more than one year and a per-unit acquisition cost which equals or exceeds the less of the capitalization level established by

	the institution for financial statement purposes, or \$5,000 consistent with 2 CFR Part 200 (Uniform Guidance).
Financial Officer	The individual responsible for proper accounting of project funds and the submission of payment details.
Foreign organization	<p>An entity that is:</p> <p>A public or private organization located in a country other than the United States and its territories that is subject to the laws of the country in which it is located, irrespective of the citizenship of project staff or place of performance;</p> <p>A private nongovernmental organization located in a country other than the United States that solicits and receives cash contributions from the general public;</p> <p>A charitable organization located in a country other than the United States that is nonprofit and tax exempt under the laws of its country of domicile and operation, and is not a university, college, accredited degree granting institution of education, private foundation, hospital, organization engaged exclusively in research or scientific activities, church, synagogue, mosque or other similar entities organized primarily for religious purposes; or</p> <p>An organization located in a country other than the United States not recognized as a <i>Foreign Public Entity</i>.</p>
Funding Opportunity Announcement	A publicly available document by which The ALS Association makes known its intention to award a grant for various research projects throughout the year as part of its competitive portfolio. Funding opportunity announcements can be known as request for application (RFA) or formerly as “Call for Proposal.”
Grant	A sum of money given by The ALS Association to another eligible institution for the purpose of supporting ALS research.
Grant Expenditure Report	An annual or final expenditure report detailing the costs charged to The ALS Association award for allowable costs incurred in support of the approved Research Scope of Work and comply with institutional policy and procedures, the terms of the Agreement and the applicable ALS Association research program requirements.
Grant Number	A grant number is a unique identifier for a grant that is created prior to grant payment. The grant number is composed of the fiscal year of the first payment, acronym for program name, and serial number. Sample Grant Number: 20-DDC-666.
Grantee	An institution that receives an ALS Association award and assumes legal and financial responsibility and accountability both for the awarded funds and for the performance of the grant-supported activity.

Grants Manager	The ALS Association official responsible for the business management aspects of grants, including the review, negotiation, award and administration of ALS Association awards, and for the interpretation of grants administration policies and procedures.
Grant-supported project or activity	Those activities specific or described in a grant application that are approved by The ALS Association for funding as stated in the Research Grant Agreement (e.g., Research Scope of Work).
Human Subject (a.k.a. Subject)	A living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. The use of human subjects in research extend to the use of human organs, tissues, and body fluids from identifiable individuals as human subjects and to graphic, written, or recorded information derived from such individuals.
Indirect costs/Facilities and Administrative (F&A) Costs	<p>Necessary costs incurred by a grantee for a common or joint purpose benefitting more than one cost objective and not readily assignable to the cost objectives specially benefited, without effort disproportionate to the results achieved. Costs that cannot be readily identified with an individual project or program.</p> <p>The ALS Association limits the award and reimbursement of indirect cost to 10% of total funds awarded for its research grants. Indirect costs are not awarded or allowed under The ALS Association's postdoctoral fellowship award program.</p>
Institutional Animal Care and Use Committee	The body that provides oversight and ensure appropriate review of the use of vertebrate animals in teaching, testing, and research.
Institutional Review Board	An administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the organization with which it is affiliated. The Institutional Review Board (IRB) has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction. IRB review and approval is required for all ALS Association supported activities involving human subjects prior to funding.
Intellectual Property	All tangible and intangible techniques, technology, practices, trade secrets, ideas, inventions or discoveries (whether or not patentable), methods, knowledge, know-how, skill, experience, test data and results (including pharmacological, toxicological and clinical test data and

	results), analytical and quality control data, results or descriptions, software, algorithms, compositions of matter, assays, animal models, physical, biological or chemical material, compounds and any and all improvements thereon developed during the conduct of the Research by the Grantee.
Invention	Means any and all Intellectual Property whether or not patentable that is conceived and/or reduced to practice or further developed by Grantee as a result of performing the activities described in the Research Scope of Work but not limited to the results.
Key Personnel	The Principal Investigator and other individuals who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically, these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered key personnel if their involvement meets this definition.
Name change	An action whereby the name of an organization is changed without otherwise affecting the rights and obligations of that organization as a grantee.
No-cost extension	An extension of time to a period of support without additional funds to complete the work of the grant under that period.
Notification Letter	A letter accompanying the Research Grant Agreement to officially notify the grantee about the issuance of the award. The letter includes the assignment of the grant number that is to be referenced in any future post-award communication with The ALS Association.
Other Support	Includes all financial resources, whether Federal, non-Federal, commercial or organizational, available in direct support of an individual's research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, or organizational awards. Other support does not include training awards, prizes, or gifts.
Patent[s]	Means (a) United States and foreign patents, re-examinations, reissues, renewals, extensions and term restorations, and foreign counterparts thereof, and (b) pending applications for United States and foreign patents, including, without limitation, provisional applications, continuations, continuations-in-part, divisional and substitute applications, including, without limitation inventors' certificates, and foreign counterparts thereof.
Payment	The distribution of funds from The ALS Association to the grantee in support of the approved research project (Statement of Work).
Peer Review	The process that involves the consistent application of standards and procedures to evaluate the scientific merit and relevance to ALS of an

	application submitted to The ALS Association for consideration for funding. The review is performed by experts in the field of ALS and related fields who provide guidance and recommendations to The ALS Association officials responsible for making award decisions.
Period of Support	The total time period for which The ALS Association support of a project has been programmatically approved as shown in the Research Grant Agreement.
Principal Investigator	The individual designated by the applicant and/or grantee to have the appropriate level of authority and responsibility to direct the project or program to be supported by The ALS Association award. The principal investigator is a member of the grantee's team responsible for ensuring compliance with the financial and administrative aspects of the award. The Principal Investigator shall serve as the liaison to The ALS Association for issues relating to the development and implementation of the Research Scope of Work under an ALS Association award, lead the implementation of the Research Scope of Work and have such other responsibilities as set forth in the Research Grant Agreement.
Prior Approval	Written approval by an authorized ALS Association official evidencing prior consent before a grantee undertakes certain activities or incurs specific costs.
Program Director	The ALS Association official responsible for the programmatic, scientific and/or technical aspects of a grant.
Research Grant Agreement	The official, legally binding document signed electronically by the Authorized Organizational Representative, Principal Investigator and a member of The ALS Association that contains or references all the terms and conditions of the grant, The ALS Association funding limits and obligations. The Research Grant Agreement also includes the schedule for submitting research grant progress and expenditure reports and payment information.
Research Progress Report	Periodic, usually semi-annual, report submitted by the grantee and used by The ALS Association staff to assess progress and, except for the final progress report, to determine whether to provide continued funding after that period covered by the report.
Research Resources	Research resources (sometimes called research tools) includes unique research resources developed under an ALS Association award. Categories of these resources include synthetic compounds, organisms, cell lines, viruses, cell products, and closed DNA, as well as DNA sequences, mapping information, crystallographic coordinates, and spectroscopic data. Specific examples include specialized or genetically defined cells, including normal and diseased human cells; monoclonal antibodies; hybridoma cell lines; microbial cells and products, viral products; recombinant nucleic acid molecules; DNA probes; nucleic acid and proteins sequences; certain types of animals, such as transgenic

	mice; and intellectual property, such as computer programs. Research resources also includes biospecimens collected.
Scientific Overlap	The same work is proposed in more than one application and submitted to two or more funding sources for review and funding consideration or a specific research objective and the research design for accomplishing the objective are the same or closely related in two or more applications or awards, regardless of the funding source.
Scientific Review Committee	A peer review committee of experts (peer reviewers), qualified by training or experience in ALS research to evaluate and give expert advice on the scientific and technical merit of the applications. The SRC's priority scores are forwarded only to The ALS Association Board of Trustees for final approval for the funding of research grants for The ALS Association.
Scope of Work	The aims, objectives, and purposes of a grant; as well as the methodology, approach, analysis or other activities; and the tools technologies, and time frames needed to meet the grant's objectives. This includes the research plan included with the original grant application, along with any approved modifications, as stated in the Research Grant Agreement (Statement of Work).
Significant Rebudgeting	A threshold that is reached when expenditures in a single direct cost budget category deviate (increase or decrease) from the categorial commitment level established for the budget period by more than 10 percent of the total costs awarded. Significant rebudgeting is a prior approval action.
Subaward	An award provided by a pass-through entity to a subrecipient for the subrecipient to carry out part of an ALS Association award received by the pass-through entity. A subaward may be provided through any form of legal agreement, including an agreement that the pass-through entity considers a contract.
Subaward agreement	A formalized agreement whereby a research project is carried out by the grantee and one or more other organizations that are separate legal entities. These agreements typically involve a specific level of effort from the consortium organization's PI and a categorial breakdown of costs, such as personnel, supplies, and other allowable expenses, including indirect costs limited to 10% of the total subaward budget. The relationship between the grantee and the collaborating organization is considered a subaward relationship. Under the agreement, the grantee must perform a substantive role in the conduct of the planned research and not merely serve as a conduit of funds to another party or parties.
Subawardee or Subgrantee	An award provided by an ALS Association grantee to another institution (subgrantee) for the subgrantee to carry out part of an ALS Association award activity. It does not include payments to a contractor or payments to an individual that is a beneficiary of an ALS Association program. A

	subaward may be provided through any form of legal agreement, including an agreement that the grantee considers a contract.
Successor-in-Interest	Process whereby the rights to and obligations under an ALS Association grant(s) are acquired incidental to the transfer of all the assets of the grantee or the transfer of that part of the assets involved in the performance of the grant(s). A successor-in-interest may result from legislative or other legal action, such as a merger or other corporate change. The ALS Association prior approval is required for a successor-in interest. See Administrative Requirements – Changes in Project and Budget – Prior Approval Requirements – Successor-in-Interest section for additional information.
Suspension	An action by The ALS Association that temporarily withholds support of a project pending corrective action by the grantee or a decision by The ALS Association to terminate the grant.
Termination	The ending of an ALS Association award, in whole or in part at any time prior to the planned termination date.
Terms and conditions of award	All legal requirements imposed on a grant issued by The ALS Association, whether based on regulation, policy, or otherwise referenced in the Research Grant Agreement.
Total costs	The total allowable costs (both direct and indirect costs) incurred by the grantee to carry out a grant-supported project or activity. Note: When indirect costs are allowed, The ALS Association limits the award and reimbursement of indirect costs up to 10% of the total amount awarded.
Withholding of Support	A decision by The ALS Association not to make a subsequent grant payment.
United States	The 50 States, territories, and possessions of the United States, the Commonwealth of Puerto Rico, the Trust Territory of the Pacific Islands, and the District of Columbia.
Unexpended Funds	Any portion of the grant that has not been spent and is not needed to pay for reasonable, allowable non-cancelable costs properly and actually incurred by the grantee in support of the research project as of the expiration or termination of the Research Grant Agreement.
Unliquidated Obligations	For grantees operating on a cash basis, unliquidated obligations mean obligations incurred by the grantee that have not been paid (liquidated). For grantees operating on an accrual expenditure basis, unliquidated obligations mean obligations incurred by the grantee for which an expenditure has not been recorded.
Unobligated balance	The amount of funds authorized under an ALS Association grant that the grantee has not obligated. The amount is computed by subtracting the cumulative amount of the grantee's unliquidated obligations and expenditures of funds under The ALS Association grant from the

	cumulative amount of the funds that The ALS Association authorized the grantee to obligate.
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PART 2. The ALS Association as a grant making organization

Since 1985, The ALS Association has been at the forefront of ALS research. The ALS Association is the largest private funder of ALS research worldwide. The direct funding of research grants is focused on high impact projects related to ALS anywhere in the world.

The ALS Association Global Research Program mission is to discover new life-extending treatment:

- Drive worldwide research agenda with urgency and boldness to improve outcomes for people with ALS,
- Collaborate with partners in a comprehensive and diverse research model, and
- Facilitate the rapid development of new treatment options to extend and enhance quality of life while seeking a cure.

2.1 Roles and Responsibilities

The ALS Association is responsible for carrying out its mission in a manner that not only facilitates research but utilizes funds effectively and in compliance with its policies and procedures. The ALS Association promotes integrity and accountability of its grants program by relying on a system of checks and balances and separation of responsibilities within its own staff and by establishing a similar set of expectations for its grantee organizations.

2.1.1 The ALS Association staff

The roles and responsibilities of The ALS Association staff are as follows:

Chief Mission Officer, Mission Strategy – The individual leading the advocacy, care services and research program for The ALS Association.

Vice President, Research – The individual reporting to the Executive Vice President, Mission Strategy, to oversee The ALS Association’s research program, by developing and implementing the broader research vision by setting annual priorities and department goals including research funding strategy, research programs, and strategic initiatives. This individual is also responsible for the operational staffing and budgetary oversight of the research program.

Program Director – This individual is responsible for the programmatic, scientific and/or technical aspects of a grant. The individual works with the Manager, Research Operations as a team in the pre and post award administration of The ALS Association grants.

Manager, Research Operations – This individual is responsible for the business management and other non-programmatic aspects of research grant awards. The individual works with the Program Director as a team in the pre and post award administration. The

pre and post award activities include, but are not limited to, evaluating grant applications for administrative content and compliance with regulations, guidelines, and policies; negotiating the terms of the grant; providing consultation and technical assistance to applicants and grantees, including interpretation of grants administration policies and provisions; tracking compliance with funded awards, and administering and closing out grants. This individual is also responsible for the development of new research programs and collaborating on impact measures of the research program and reporting outcomes.

2.1.2 Grantee staff

The roles and responsibilities of the Grantee staff are as follows:

Authorized Organizational Representative (AOR) - The individual, named by the applicant and/or grantee organization, who is authorized to act for the applicant and/or grantee and to assume the obligations imposed by The ALS Association and the terms of an ALS Association Research Grant Agreement. The AOR is responsible for signing the grant application to certify that the statements included within the grant application are true, complete and accurate to the best of one's knowledge. When an application is selected for funding, the AOR is responsible for negotiating the terms of the award and signing the Research Grant Agreement. The AOR certifies that the grantee institution will comply with all financial and administrative aspects of the award, applicable grants administration requirements, including submission of research progress reports and grant expenditure reports outlined in the award. The AOR is accountable both for the appropriate use of awarded funds and for the performance of the grant-supported activities outlined in the Research Grant Agreement (Statement of Work).

Finance Officer – The individual responsible for proper accounting of project funds and the submission of payment details.

Principal Investigator (PI) - The individual designated by the applicant and/or grantee to have the appropriate level of authority and responsibility to direct the project or program to be supported by The ALS Association award. The principal investigator is a member of the grantee's team responsible for ensuring compliance with the financial and administrative aspects of the award. The Principal Investigator will sign the Research Grant Agreement and shall serve as the liaison to The ALS Association for issues relating to the development and implementation of the Research Scope of Work under an ALS Association award, lead the implementation of the Research Scope of Work and have such other responsibilities as set forth in the Research Grant Agreement, including the submission of required research progress reports.

PhD candidates may not serve as principal investigators under The ALS Association fellowship awards. They can apply for the fellowship program only if the individual has already secured a postdoctoral fellowship and are able to provide a letter of support and recommendation of the mentor.

2.2 Application Information and Process

2.2.1 Eligibility

The ALS Association forges partnerships among individuals, non-profits, academic institutions, industry and government to accelerate the pace of ALS research.

In general, The ALS Association awards grants to organizations that are domestic or foreign, public or private, or non-profit or for-profit. In addition, eligible organizations may also include governments, including Federal institutions, institutions of higher education, or other non-profit organizations and hospitals.

2.2.2 Types of Funding Opportunities

The ALS Association solicits grant applications in support of scientific research projects across the research pipeline that supports a wide breadth of scientific focus areas through the issuance of a “Funding Opportunity Announcement” as part of its competitive portfolio.

The ALS Association’s Funding Opportunity Announcement is a publicly available document that seeks applications in support of a particular scientific focus area critical to advancing ALS research. These announcements are posted on The ALS Association’s “Funding OPPORTUNITIES” website at <https://www.als.org/research/funding-opportunities>.

2.2.3 Types of Grants Offered

The following types of grants are currently offered by The ALS Association:

Clinical Development Fellowships – In partnership with the American Brain Foundation (ABF), to support ALS clinical research fellowships focused on projects involving people living with ALS.

- Clinical Research Training Scholarship (CRTS) - Awards are for two years at a maximum budget of \$150,000 total costs for the 2-year period.
- Clinical Scientist Development Award (CSDA) - Awards are for three years at a maximum budget of \$240,000 total costs per year.
- Sheila Essey Award (SEA) – Awards are for one year at a maximum budget of \$50,000 total costs.

The Lawrence and Isabel Barnett Drug Development Program - Funds milestone-driven preclinical drug-development projects to move treatment approaches closer to the clinic. Awards are for two years at a maximum budget of \$250,000 total costs per year.

Managing ALS Awards - Funds research for improving clinical, psychological, and social management of ALS, focusing on both people living with ALS and their caregivers, including development of assistive technology/devices, telemedicine/telehealth, and patient/caretaker burden. Awards are for two years at a maximum budget of \$100,000 total costs per year.

Milton Safenowitz Postdoctoral Fellowship - Fellowships to encourage and facilitate promising new scientists to enter the ALS field. Fellows work with a senior mentor and receive extensive exposure to the ALS research community through meetings and presentations. Awards are for two years at a maximum budget of \$75,000 total costs per year.

Multi-year Investigator-Initiated Grants – Funds research projects to established investigators for up to three years with a maximum budget of \$100,000 total costs per year. Junior postdoctoral fellows are not eligible to apply.

One-year Starter Grants – Funds investigators new to the ALS field or senior postdoctoral fellows establishing their own independent position. A maximum budget of

\$50,000 total costs for one-year. These projects can be pilot studies by established ALS investigators. Senior fellows about to set up independently in their own laboratory are also welcomed to apply. The applications do not require strong preliminary data but must emphasize novelty, feasibility, innovation, and relevance to ALS.

Strategic Challenges - Funds crowdsourcing initiatives such as the ALS Assistive Technology Challenge to help people living with ALS communicate with ease (partnered with Prize4Life) and the TDP43 PET Tracer Grand Challenge to discover a biomarker to track TDP43 in the body (partnered with ALS Finding a Cure®). Budget level and year(s) of support will be determined in the Funding Opportunity Announcement.

Strategic Initiatives - Funds collaborative projects that address research gaps, areas of high risk-high reward, and/or areas that provide novel opportunities. This grant program encompasses large, collaborative research programs. For more information, visit the strategic initiative page and refer to the strategic initiative talking points. Budget level and year(s) of support will be determined in the Funding Opportunity Announcement.

2.2.4 Application Receipt Information and Deadlines

Applicants should carefully read instruction in the Funding Opportunity Announcement and the application guide to determine submission requirements. The Funding Opportunity Announcement will provide unique application deadlines.

The ALS Association expects all applications to be submitted on time.

2.2.5 The Letter of Intent

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 application. Results from the letter of intent review phase are not typically provided to the applicant.

The letter of intent should include the following information:

- a) Descriptive title of proposed activity
- b) Name, address, and telephone number of the PI
- c) Names of other key personnel
- d) Participating institution(s)
- e) A scientific rationale for the proposed study and its relevance to ALS
- f) A brief description of the study hypothesis and/or objectives and overall experimental plan to meet those objectives

The Letter of Intent should be submitted per the application instructions.

2.3 The Peer Review Process

All applications are peer reviewed by outside experts that comprise The ALS Association Scientific Review Committee (SRC). The SRC reviewers are selected ad hoc for their knowledge of the topic proposed.

2.3.1 Scored Review Criteria

The SRC will consider each of the general criteria below for the determination of scientific merit and relevance to ALS, and give a separate score for each, unless otherwise noted in the Funding Opportunity Announcement. The Funding Opportunity

Announcement may include any specific review criteria applicable to the type of application.

- Impact/contribution to ALS
- Justification/rationale for the proposed study
- Research plan
- Research team
- Budget justification (Budgets must be appropriate and justifiable for the work described).

2.3.2 Additional Review Criteria

As applicable for the project proposed and the funding program, reviewers may consider other factors in the determination of scientific and technical merit.

- Protection of Human Subjects and Vertebrate Animals
- Data sharing and resource sharing plans
- Intellectual Property/patent landscape (if developing drugs or assistive technology)
- Future development/commercialization plans

2.3.3 Disposition of Application

The SRC's scores and the reviews are forwarded to and synthesized by The ALS Association scientific staff. The SRC's priority scores and recommendations are forwarded only to The ALS Association Board of Trustees for final approval for the funding of research grants for The ALS Association.

Once the decision is made to fund a particular proposal, The ALS Association will send the combined review results of the grant application to the PI and the authorized organizational representative. 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. Successful applicants will be notified of additional information that may be required or other actions leading to the negotiation and issuance of a Research Grant Agreement. The process leading to an award, including the business management review performed by the Manager, Research Operations, is described in the "Completing the Pre-award Process" below.

Applicants not recommended for funding will also be provided with the combined review critiques. Due to administrative limitations, all review decisions are final; no appeals process is available at this time. Investigators are encouraged to use reviewer comments to improve applications for a subsequent round of funding through The ALS Association or another source.

2.4 Completing the Pre-award Process

After the application is selected for funding, the application will be reviewed for several other considerations. These include, as applicable, assessment of the applicant's management systems, determination of the applicant's eligibility, determination of

scientific, budgetary and/or commitment overlap, allowable costs, and compliance with the protection of vertebrate animals and human subjects, if applicable.

The ALS Association will notify the applicant as part of the pre-award negotiation process to negotiate the funding plan, terms of the Research Grant Agreement and document administrative, fiscal, and programmatic information. Since grants are made to institutions, not investigators, the information below must be signed and/or submitted by an authorized organizational representative.

The ALS Association will obtain the following information, as applicable, prior to the issuance of an award:

Assurance of Institutional Review Board (IRB) Approval: If the proposed project involves human subjects, the applicant will be required to provide a certification of final IRB approval; conditional approval is not sufficient. The IRB approval must be within one year from the budget start date of the award.

Verification of Institutional Animal Care and Use Committee (IACUC) Approval: If the proposed project involves live vertebrate animals, the domestic applicant will be required to provide verification of IACUC approval. The IACUC approval date must be within three years from the budget start date of the award. Foreign institutions will be required to provide a certification of compliance with applicable laws, regulations, policies of the jurisdiction in which the research will be conducted, and a commitment to follow the *International Guiding Principles for Biomedical Research Involving Animals*.

Other Sources of Support and Assurance of No Scientific, Budgetary, or Commitment Overlap: The applicant will be required to provide information on other active and pending support. Other support submission is required for all individuals designated in an application as key personnel. Other support includes all financial resources, whether Federal, non-Federal, commercial, or institutional, available in direct support of an individual's research endeavors.

The ALS Association funds shall not be used to duplicate any work supported by other funding sources. It is the responsibility of the applicant/grantee to notify The ALS Association of any potential scientific, budgetary or commitment overlap.

As part of the other support submission, the applicant must confirm that the pending application does not include any scientific, budgetary or commitment overlap with any other funding sources in direct support of an individual's research endeavors. If any overlap exists, the applicant will be asked to describe the nature of the overlap and provide an explanation how the overlap will be resolved and/or mitigated prior to The ALS Association's issuance of an award.

In addition, the principal investigator and/or authorized organizational official is expected to notify The ALS Association as soon as either party becomes aware of any overlap that may occur during the period of the award.

3. Overview of Terms and Conditions

The ALS Association grants are based on the application submitted to, and approved by, The ALS Association and are subject to the terms and conditions outlined in this Grants Policy Statement, unless otherwise stated in the Research Grant Agreement.

The ALS Association requires its grantees to 1) establish and maintain the necessary processes to monitor its compliance and that of its employees, subawardee participants, and contractors with the terms and conditions outlined within this policy statement and the Research Grant Agreement; 2) take appropriate action to meet the stated objectives; and 3) inform The ALS Association of any problems or concerns. The ALS Association may take any necessary and appropriate action to address noncompliance with any applicable requirements.

4. Research-Related and Other Requirements

The ALS Association requires its grantees to comply with public policy requirements to uphold high ethical, health and safety standards in the conduct of research and the expenditure of its grant funds by its awardees. The signature of the authorized organizational representative on the application and in any awarded Research Grant Agreement, certifies that the organization complies, or intends to comply, with all applicable policies, certifications and assurances referenced in the Funding Opportunity Announcement, application and/or the Research Grant Agreement. The policies and/or requirements may or may not be applicable to the project or program depending the research activity conducted under the award.

4.1 Animal Welfare Requirements

Grantees must establish appropriate policies and procedures to ensure the humane care and use of live vertebrate animals and bear ultimate responsibility for compliance with the noted requirements.

Domestic grantees shall comply with applicable federal, state and local laws, regulations, guidance, standards policies and requirements related to the conduct of research using live vertebrate animals, including the Animal Welfare Act of 1966. The ALS Association requires its grantees to comply with [PHS Policy on Humane Care and Use of Laboratory Animals](#) (PHS Policy) and all other applicable requirements issued by the U.S. National Institutes of Health. Grantees must establish appropriate policies and procedures to ensure the humane care and use of animals and bear ultimate responsibility for compliance with the PHS Policy in all ALS Association grant-supported activities.

Domestic grantees must obtain Institutional Animal Care and Use Committee (IACUC) approval prior to engaging in animal research activities. The ALS Association will request verification of IACUC approval prior to the issuance of an ALS Association award. The IACUC approval must have been granted within three years of the budget start date of the award to be valid. No costs for activities with live vertebrate animals may be charged to The ALS Association award if there is not a valid IACUC approval.

Foreign grantees must comply with applicable laws, regulations, and policies of the jurisdiction in which the research will be conducted, and a commitment to follow the [International Guiding Principles for Biomedical Research Involving Animals](#). IACUC

approval is not required of foreign grantees; however, The ALS Association encourages foreign grantees to use the standards in the [Guide for the Care and Use of Laboratory Animals](#). The ALS Association will require foreign applicant institutions to provide a certification of compliance that the animal activities will be conducted in accordance with all applicable laws, regulations, and policies of the jurisdiction in which the research will be conducted and a commitment to follow the International Guiding Principles for Biomedical Research Involving Animals (see: <http://www.cioms.ch/>).

Grantees must notify The ALS Association within 10 days of an IACUC's (or equivalent committee) decision to suspend the research related to the involvement of animals. The ALS Association may allow expenditure of grant funds for maintenance and care of animals on a case-by-case basis. Consultation with The ALS Association is encouraged regarding questions concerning allowable costs. Contact The ALS Association at researchgrants@alsa-national.org.

4.2 Anti-Terrorism and Economic Sanctions

Grants provided by The ALS Association are subject to U.S. law, including U.S. trade sanctions regulations administered by the U.S. Treasury Department's Office of Foreign Assets Control (“**OFAC**”). The transfer, diversion, or any other transaction involving grant funds provided by The ALS Association, except as permitted under U.S. law, is strictly prohibited. Funds provided by The ALS Association may not be re-granted or otherwise transferred contrary to U.S. law. Grantee warrants that, except as authorized by U.S. law, neither it nor any of its officers, directors, employees, or agents shall, directly or indirectly, engage in any transaction or dealing with any party named on any list maintained by OFAC or any other U.S. government agency that identifies parties subject to U.S. trade sanctions and prohibitions, including without limitation the Specially Designated Nationals List, Denied Persons List, Entities List, Debarred Parties List, Unverified List, and General Order List. Grantee shall fully cooperate with The ALS Association in implementing, monitoring, and maintaining any policies, procedures, and controls that The ALS Association reasonably determines are needed to ensure that Grantee and its affiliated companies (if any) are in compliance with all laws that apply to them, including without limitation the economic sanctions administered and enforced by OFAC and other U.S. agencies.

4.3 Debarment and Suspension

Grantees who accept an award from The ALS Association assume responsibility to assure that neither the grantee nor any of the individuals or entities that will perform the obligations of the grantee under an ALS Association grant, have been debarred by a Federal the government by the Food and Drug Administration (FDA) and the Department of Health and Human Services (HHS) pursuant to pursuant to 21 U.S.C. §335a, as amended, and 2 CFR Part 376. Title 2 CFR 376 implements government-wide debarment and suspension system guidance (2 CFR 180).

Prior to accepting an ALS Association award, grantees must report to The ALS Association if the grantee or any of its principals:

- Are presently excluded or disqualified;

- Have been convicted within the preceding three years of any of the offenses listed in 2 CFR 180.800(a) or had a civil judgement for one of those offenses within that time period;
- Are presently indicted for or otherwise criminally or civilly charged by a government entity (Federal, State, or local) with commission of any of the offenses listed in 2 CFR 180.800(a); or
- Have had one or more public transactions (Federal, State, or local) terminated within the preceding three years for cause or default.

Grantees may utilize The System for Award Management (SAM), an official website of the U.S. government to identify exclusion records (<https://sam.gov>).

Grantees must immediately report to The ALS Association if at any time during the period of an award, including periods of no-cost extension, they discover that they (1) failed to disclose information prior to accepting an award or (b) due to changed circumstances the grantee or any of its principals for the grant now meet the reporting criteria.

4.4 Facility and Other Resources

Grantees must provide safe and healthful working conditions for their employees and foster work environments conducive to high-quality research which includes maintaining and operating laboratories, offices and all other facilities reasonably necessary to carry out the activities to be performed by it pursuant to the Research Scope of Work consistent with and under the licenses, permits, certifications, accreditations, and authorities required under Applicable Law.

4.5 Human Subjects Protections

The ALS Association projects involving human subjects must ensure that subjects are protected from research risks in conformance with the relevant Federal policy known as the Common Rule (*Federal Policy for the Protection of Human Subjects*) provided in the United States (U.S.) Department of Health and Human Services (HHS) regulation at 45 CFR Part 46 (Subpart A). Grantees bear ultimate responsibility for safeguarding the rights and welfare of human subjects in ALS Association-supported activities.

All projects involving human subjects must either have: 1) approval from an Institutional Review Board (IRB) before issuance of an ALS Association award; or, (2) an IRB determination that the project is exempt from review per §46.104(d) of the Commons Rule.

The ALS Association will request verification of IRB approval prior to the issuance of an ALS Association award. The IRB approval provided to The ALS Association must be the date of final IRB approval; conditional IRB approval is not sufficient. No costs for activities with human subjects may be charged to The ALS Association award if there is not a valid IRB approval.

If the project involves human subjects and is to be performed outside of the U.S., evidence of IRB approval also is required. Pursuant to §46.101(g), the Common Rule is not intended to supersede any additional protections that may be afforded to human subjects under foreign laws or regulations. OHRP maintains the International

Compilation of Human Subjects Research Standards and contains a listing of over 1,000 laws, regulations, and guidelines on human subjects protections in 133 countries and from many organizations. For more information see OHRP site <https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html>.

Clinical research involving investigational drugs and devices, or products regulated by the Food and Drug Administration (FDA) of the Department of Health and Human Services, must comply with all FDA requirements in 21 CFR Parts 50, 56, 312 and 812.

Grantees must notify The ALS Association within 10 days of an IRB's decision to suspend the research to the involvement of human subjects. Any IRB suspension or termination of approval must include a statement of the reasons for the IRB's action and must be reported promptly to the investigator, appropriate institutional officials, and The ALS Association. Consultation with The ALS Association is encouraged regarding questions concerning allowable costs during a suspension. Contact The ALS Association at researchgrants@alsa-national.org.

Health Insurance Portability and Accountability Act (HIPAA): The ALS Association requires its domestic grantees to comply with the requirements of HIPAA to ensure the protection of individually identifiable health information for ensuring confidentiality of patient records.

General Data Protection Regulation (E.U. 2016/679): The ALS Association requires its foreign grantees to comply with the Regulation E.U. 2016/679, or its amended regulation, of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to processing of personal data and on the free movement of such data.

4.6. Insurance

Unless the grantee is self-insured against the risks involved, Grantees shall maintain, at its own expense, general and professional liability insurance (including errors and omissions coverage) in an amount consistent with industry standards as shall be necessary to insure itself, its Affiliates and their respective officers, directors, employees, consultants and agents against any claim or claims for damages occasioned directly or indirectly in connection with an ALS Association award. Grantee shall provide a certificate of insurance, if applicable, evidencing such coverage to The ALS Association upon written request.

4.7 Recombinant DNA

Research on recombinant DNA shall be conducted in accordance with Centers for Disease Control/National Institutes of Health (CDC/NIH) Biosafety Guidelines (Biosafety in Microbiological and Biomedical Laboratories) and NIH Guidelines for Research Involving Recombinant DNA.

5. The Research Grant Agreement

A formal notification through the issuance of an ALS Association Research Grant Agreement (Agreement) is the authorizing document. The Agreement will be provided to the applicant organization for successful applicants. The terms and conditions of the

Agreement are negotiated between the applicant's authorized organizational representative (AOR) and the ALS Association research team. After the terms and conditions of the Agreement are finalized, the Agreement is sent to the institution for signature by the AOR and PI. The Agreement is fully executed after the Agreement is signed by The ALS Association's authorized official. The fully signed, executed Agreement is sent to the AOR and PI via electronic mail along with a notification letter.

The Agreement sets forth pertinent information about the grant including, but not limited to the following:

- Name of the Grantee Institution
- Name of the Grantee Institution contact
- Name of the Principal Investigator
- Title of the Project
- Type of Grant
- Total grant amount approved by The ALS Association in United States dollars
- Initial Term of the project (Start date and termination date)
- Number of months of support
- Applicable terms and condition of award, either by reference or inclusion
- Exhibit A – Research Scope of Work (Research Plan)
- Exhibit B - Research Progress Report and Grant Expenditure Report, either by reference or inclusion within the Agreement
- Exhibit C - Payment and Reporting Schedule

6. Payment

6.1 General Information

Payment of a grant is generally made in six-month increments following the initial payment in United States dollars. The first payment is made within ten (10) business days following the execution of an ALS Association Agreement. Subsequent payments are made within ten (10) business days following The ALS Association's review and acceptance of the research progress report and/or grant expenditure report, if applicable, as required for submission and outlined in Exhibit C of the Agreement. The ALS Association reserves the right, upon written notice, to withhold future payments after a specified date if the grantee fails to comply with the terms and conditions of an ALS Association award, including the reporting requirements.

Grant payments to domestic institutions are generally made via a check made payable to the grantee institution. Payments to foreign organizations are made via wire transfer.

Questions regarding grant payments should be sent to researchgrants@alsa-national.org.

6.2 Interest Earned on Advances of Grants Funds

Grantees are expected to maintain advances of grant funds in an interest-bearing account. Interest amounts up to \$500 per year may be retained by the grantee for administrative expense. Any amount in excess of \$500 is to be returned to The ALS Association via check or wire transfer per the instructions in section 8.7.2 below.

7. Cost Considerations

7.1 General Information

Cost considerations are critical throughout the life cycle of a grant. The ALS Association will review budget requests prior to award for compliance with general cost principles and other requirements and policies applicable to the ALS Association grant program. Any resulting award will include a budget amount that is consistent with these requirements. Grantees are ultimately responsible for ensuring that all costs charged to an ALS Association award meet internal policies and procedures and other requirements are met for all charges to an ALS Association award. Otherwise, such costs may be disallowed during by a specific determination of an ALS Association Grants Officer.

7.2 Cost Principles

The ALS Association expects institutions to have in place accounting and internal control systems that provide for appropriate monitoring of grant accounts to ensure that obligations and expenditures are reasonable, allocable, consistently applied, and conform with institutional policy, program guidelines and the terms of award. Grantees should follow the guidance on cost allowability per Federal cost principles, 2 CFR Part 200, Subpart E. Grantees should utilize generally accepted accounting principles (GAAP). In the case of a discrepancy between the special provisions of an ALS Association grant and the standards of the cost principles, the special provisions of the grant will govern.

Grantees should consider the following four tests for determining the allowability of a cost:

- *Reasonableness (including Necessity)*: A cost may be considered reasonable if the nature of the goods or services acquired or applied and the associated dollar amount reflect the action that a prudent person would have taken under the circumstances prevailing when the decision to incur the cost is made.
- *Allocability*: A cost is allocable to a specific grant, if the goods or services involved are chargeable or assignable to that cost objective in accordance with the relative benefits received or other equitable relationship. A cost is allocable to a grant if it is incurred solely in order to advance work under the grant or meets

the criteria for allocating costs for closely related projects based on a reasonable basis and documented methodology for charges such costs.

- *Consistency*: Grantees must be consistent in assigning costs to cost objectives. Costs may be charged as either direct costs or indirect costs, depending on their identifiable benefit to a particular project or program, but all costs must be treated consistently for all work of the organization under similar circumstances, regardless of the source of funding.
- *Conformance*: Costs must conform to The ALS Association's program guidelines and the terms and condition of the award.

7.3 Direct and Indirect Costs

A direct cost is a cost that can be specifically identified with a particular project, program, or activity or that can be directly assigned to such activities relatively easily and with a high degree of accuracy. Direct costs include, but are not limited to, salaries, travel, equipment, and supplies directly benefiting the grant-supported project or activity.

An indirect cost is a cost for a common or joint purpose benefitting more than one cost objective and not readily assignable to the cost objectives specially benefited, without effort disproportionate to the results achieved. Costs that cannot be readily identified with an individual project or program.

The ALS Association generally provides funds in direct support of personnel, consumable supplies, travel and other expenses. The ALS Association generally does not fund salary of the Principal Investigator at the awardee institution, permanent or fixed equipment, costs of installing and maintaining equipment, non-economy travel and incidental expenses, travel costs in excess of \$2,000 per year, duplication of funding, premiums for insurance of equipment and supplies, registration fees for scientific meetings, and costs related to "Contingency" funds or provisions. Limited indirect costs are provided as described in 7.4 below.

7.4 Reimbursement of Indirect Costs (Facilities and Administrative Costs)

Limited indirect costs are awarded and allowed for reimbursement under ALS Association-supported research grants. Grantees and subgrantees may not spend more than 10 percent of the total award amount on indirect costs or overhead allocations. The indirect cost allotment is not an indirect cost rate applied to the total direct costs or modified direct costs but instead it is an overall allotment from the award to be used for the grantee's indirect costs. Therefore, 90 percent of the total project funds must be spent directly on the awarded project.

The indirect cost funds provided may be used to support the costs of compliance with grant requirements (e.g., requirements for the protection of human subjects, animal welfare, and post-award reporting requirements) and for the institution's facilities and administrative costs.

Indirect costs are not allowed under The ALS Association's Post-Doctoral Fellowship Awards program.

7.5 Allowability of Costs

Costs charged to The ALS Association project must be for allowable costs incurred in support of the approved research project as described in the “Research Scope of Work” and comply with institutional policy and procedures, the terms of the Agreement and the applicable ALS Association program requirements outlined in the Funding Opportunity Announcement. Unless otherwise noted, institutions may use the federal Uniform Guidance 2 CFR Part 200 as standard for determining allowability of costs for grantees and subawardees or contact The ALS Association at researchgrants@alsa-national.org for additional information and/or guidance.

7.5.1 Selected Items of Costs

Allowable Costs: The ALS Association generally provides funds in support of the following cost items:

- Salary and wages and fringe benefits of personnel other than the salary of the Principal Investigator
- Salary and wages and fringe benefits of the Principal Investigator only when indirect costs are waived
- Direct salary for individuals not to exceed the salary limitation for Executive Level II of the Federal Executive pay scale provided at the National Institutes of Health “Salary Cap[Summary” website at https://grants.nih.gov/grants/policy/salcap_summary.htm.
- Consumable supplies
- Computer hardware and software costs up to \$2,000
- Moveable equipment not to exceed 20 percent of the annual budget
- Economy travel costs up to \$2,000 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
- Publication costs up to \$2,500
- Other expenses
- Indirect costs up to a maximum of 10 percent of the total amount awarded when permitted under the award
- Any recurring annual cost-of-living increase up to 3 percent applied only to personnel and consumable supplies

Unallowable Costs: The ALS Association generally does not provide funds in support of the following cost items:

- Salary and wages and fringe benefits of the Principal Investigator at the awardee institution when indirect costs are not waived
- Direct salary for individuals in excess of the Executive Level II of the Federal Executive pay scale.
- Permanent or fixed equipment (e.g., sterilizers, casework, fume hoods, cold rooms and glassware/washers)
- Costs of installing and maintaining equipment
- Non-economy travel and incidental expenses
- Travel costs exceeding \$2,000 per year
- Tuition and relocation costs
- Premiums for insurance of equipment and supplies

- Dues to organizations such as federations or societies
- Registration fees for scientific meeting
- Purchase of books, journals or office equipment
- Costs related to “Contingency” funds or provision
- Indirect costs that exceed 10 percent of the total amount awarded
- Over expenditures or cost overruns
- Duplication of funding

8. Administrative and Other Requirements

8.1. Change in Project and Budget

Grants issued by The ALS Association requires minimal ALS Association involvement during the performance of the activities. In general, grantees are allowed a certain degree of flexibility to rebudget funds within and between budget categories to meet unanticipated needs and to make other types of post-award changes.

Some changes may be made at the grantee’s discretion if they are within the limits established by The ALS Association. In other cases, The ALS Association prior written approval may be required before a grantee makes certain budget modifications or starts activities that are considered outside the scope of the approved project.

Requests for prior approval must be submitted in writing (including submission by email) to researchgrants@alsa-national.org, at least 30 days before the proposed change and signed by the authorized organizational representative (AOR) of the grantee institution. Questions related to an award or a post award action should also be directed to this email address.

The ALS Association will review the request and provide a response to the AOR indicating final disposition of the request, with copies to the PI.

8.1.1 Grantee Authorities

This section describes the activities and/or expenditures that do not require The ALS Association prior approval. If you have any questions whether a post award action requires prior approval or constitutes a change in scope, contact The ALS Association at researchgrants@alsa-national.org.

8.1.1.1 Preaward cost authority

An institution may, at its own risk, incur obligations and expenditures to cover costs that are necessary to conduct the project and would be allowable under the grant, if awarded, without The ALS Association prior approval. Preaward costs may be incurred without prior approval after The ALS Association notifies the applicant, in writing, that the application has been selected for funding.

8.1.1.2 Carryover of Funds from one year to the next not to exceed 25 percent of the total amount awarded to date.

8.1.1.3 Rebudgeting between budgetary categories up to 10 percent of the total cost awarded unless the action is considered a change in scope.

8.1.1.4 Rebudgeting from indirect costs into direct costs.

8.1.1.5 Transfer the performance of programmatic work to a third party institution within the rebudgeting limitations described in 8.1.1.3 and within the Research Scope of Work.

8.1.2 Prior Approval Requirements

This section describes the activities and/or expenditures that require The ALS Association prior approval.

8.1.2.1 Carryover of Funds in excess of 25 percent of the total amount received to date (awarded)

As part of the grant expenditure report, grantees will be asked to report on unobligated balances greater than 25% of the total amount received. In addition, the grantee will be asked to explain why the significant balance exists and provide a general description of how it is anticipated that the funds will be spent during the next year.

8.1.2.2. No-Cost Extension of the Final Budget Period

The grantee may request an extension for up to 12 months of a funded project without additional funds to complete the goals of the project or to provide for an orderly closeout. Extensions beyond 12 months are considered on an exceptional basis. The fact that funds remain at the completion date of the grant is not sufficient justification for an extension without additional funds.

If an extension of the project is needed, the grantee must submit a written request to include the following information:

- The start and end date of the no-cost extension.
- The rationale for requesting a no-cost extension.
- A description of the project activities that require support during the extension.
- The estimated unobligated balance remaining at the end of the project.
- A progress report as provided in Exhibit B of the Research Grant Agreement.

The ALS Association will review the request and provide a written response of approval or disapproval to the Principal Investigator and the authorized organizational official. The issuance of a revised Award Agreement is at the

discretion of the ALS Association. Should a revised Award Agreement not be issued, the grantee should retain a copy of The ALS Association's written response in the official grant records for documentation purposes.

Closeout documents (final research progress report and final grant expenditure report) are required for submission within 90 days following the new termination date.

8.1.2.3. Change in Research Scope of Work

A change in the research scope of work is a change in the direction, aims, objectives, or purposes identified in the Research Scope of Work outlined in Exhibit A of the Agreement. The ALS Association encourages Principal Investigators to contact The ALS Association promptly at researchgrants@alsanational.org to arrange a call to describe any plan for changing the scope of work. The ALS Association will work with the grantee to determine what information is needed for consideration of the request.

Some indicators of a change in scope include, but are not limited to, the following:

- Change in the approved specific aims outlined in the Agreement
- Substitution of one animal model for another.
- Change from the approved use of vertebrate animals.
- Change from the approved involvement of human subjects
- Transfer of performance of programmatic work to a third party through a subawardee agreement, by contract, or any other means that results in a rebudgeting action exceeding 10 percent of the total cost awarded.
- Significant rebudgeting from one single direct cost budget category to another that exceeds 10 percent of the total cost awarded (See section 8.1.2.7 below).

8.1.2.4 Change of Principal Investigator (PI)

A change of principal investigator from one individual to another may be requested unless prohibited by the terms of the award.

When a change of PI is permitted, a written request must include the following information:

- The new individual's name, email address, telephone number, and postal address.
- A strong scientific justification related to the scientific project, including any proposed change in scope of the project.
- A Biographical Sketch for the proposed new PI.
- Other Support documentation for the proposed new PI and a certification that there is no budgetary, commitment or scientific overlap.
- Any budgetary changes resulting from the proposed change in PI.

If the arrangements proposed by the grantee, including the qualifications of any proposed replacement, are not acceptable to The ALS Association, the grant may be terminated. If the grantee decides to terminate the project because it

cannot make suitable alternate arrangements, it must notify The ALS Association, in writing, of its decision to terminate the award. In this situation, the grantee should proceed with closeout requirements.

8.1.2.5 Change of Grantee Institution

A change of grantee institution may be considered under most of The ALS Association grants if the original grantees agrees to relinquish responsibility for an active award and any remaining funds under the award before the completion date of the project.

A change of grantee institution request must include the grant-specific information as stated above and the following information:

- A. Original grantee institution must submit a prior approval request to The ALS Association via email at researchgrants@alsa-national.org. The request should include the following information:
 - 1) The grant #, title of project, name of principal investigator and dates of the current award.
 - 2) A written statement signed by an authorized organizational representative relinquishing responsibility and interest for the active ALS Association grant.
 - 3) The reason for the transfer of the grant.
 - 4) The termination date and the proposed start date at the receiving institution.
 - 5) The total amount of the ALS Association award provided within the Agreement.
 - 6) The total amount of ALS Association funds received under the Agreement as of the date of this request.
 - 7) The total amount of any unobligated funds remaining as of the date of this request to be transferred to the receiving institution.
 - 8) Name of the Receiving Institution and authorized organizational representative contact information (i.e., name, title, address, telephone, and email address).

Upon The ALS Association's approval of the grant transfer, the grantee institution must submit a check made payable to "The ALS Association" in the amount of the unobligated balance. The check should be sent to: The ALS Association, Attention: Finance, 1300 Wilson Boulevard, Suite 600, Arlington, VA 22209 with a copy emailed to: researchgrants@alsa-national.org. Wire transfer is also an option by requesting wire transfer instructions from researchgrants@alsa-national.org.

- B. The Receiving Institution must submit a written request via email to The ALS Association's centralized grants office at researchgrants@alsa-national.org to assume responsibility for The ALS Association research project. The request must include the following information:

- 1) The grant #, title of project, name of principal investigator and dates of the current award.
- 2) The proposed start and end date of the research project at the receiving institution.
- 3) The balance of the funds to be transferred from the amount relinquished by the former institution.
- 4) The balance of The ALS Association funds yet to be paid to the original institution that are available for payment at the receiving institution per the Agreement, if applicable.
- 5) A detailed budget by direct cost budget category (e.g., salary, fringe, equipment, consumable supplies, travel, etc.) for the amount of funds remaining per the Agreement. Note indirect costs are generally allowed for award and reimbursement up to 10% of the total ALS Association award, unless indirect costs are not allowed under the specific program (e.g., fellowships).
- 6) Contact person for obtaining payment information.
- 7) Research Scope of Work – Impact Statement, Lay Summary, Specific Aims, Timeline, Goals and Milestones

Upon The ALS Association's review and approval of the change of institution request, The ALS Association will develop an ALS Association Research Grant Agreement (Agreement) for execution. The draft Agreement will be sent to the authorized organizational representative of the receiving institution with a copy to the principal investigator for review and signature.

8.1.2.6 Change of Grantee Organizational Status

The ALS Association must receive advance notice of the following types of change in organizational status:

- *Merger*. Legal action resulting in the unification of two or more legal entities. When such an action involves the transfer of The ALS Association grant(s), the procedures for recognizing a success-in-interest will apply. When the action does not involve the transfer of The ALS Association grant(s), the procedures for recognizing a name change normally will apply.
- *Successor-in-Interest (SII)*. Process whereby the rights to and obligations under an ALS Association grant(s) are acquired incidental to the transfer of all of the assets of the grantee or the transfer of that part of the assets involved in the performance of the grant(s). A SII may result from legislative or other legal action, such as a merger or other corporate change.
- *Name Change*. Action whereby the name of an organization is changed without otherwise affecting the rights and obligations of that organization as a grantee.

Advance notification is required to ensure that the grantee remains able to meet its legal and administrative obligations to The ALS Association, and payments are not interrupted.

The AOR is encouraged to contact The ALS Association at researchgrants@alsa-national.org to explain the nature of the change in organizational status and receive guidance on whether it will be treated as a name change or a SII.

A grantee's formal request for a change in organizational status should be submitted to The ALS Association as soon as possible so that The ALS Association can determine whether the organization will continue to meet the grant program's eligibility requirements and take the necessary action to reflect the change in advance of the change in status.

For a SII, a letter signed by the AORs of the current grantee (transferor) and the successor-in-interest (transferee) must be sent to The ALS Association. The letter must include the following:

- Stipulate that the transfer will be properly affected in accordance with applicable law.
- Indicate that the transferor relinquishes all rights and interests in all of the affected grants.
- Request that The ALS Association modify its records to reflect the transferee as the recipient of record.
- State the effect date of the transfer.
- Provide the transferee's Entity Identification Number (EIN). If EIN is new, include a completed Form W-9.
- Include verification of the transferee's compliance with applicable requirements.

8.1.2.7 Request to Rebudget Funds

The ALS Association allows its grantees some flexibility to rebudget funds between budgetary categories, including direct and indirect costs, at the discretion of the Principal Investigator consistent with the terms of the Agreement and institutional policy and procedures.

The ALS Association prior approval is required if a rebudgeting action results in a single direct cost budget category deviation (increase or decrease) from the amount budgeted by more than 10% of the total costs awarded or when the grantee determines that the rebudgeting action constitutes a change in scope. For example, if the award budget for total costs is \$100,000, any rebudgeting that would result in an increase or decrease of more than \$10,000 in a budget category is considered significant rebudgeting.

Requests for prior approval must include the following information:

- The reason for the rebudgeting.
- The amount of funds being rebudgeted out of and into the specific budget category(ies) involved.
- A scientific justification for the rebudgeting of funds.

8.2 Confidentiality

The ALS Association requires a five-year (5) period following the termination of an ALS Association award for the grantee to maintain in strict confidence all “Confidential Information” disclosed by the receiving and disclosing party.

8.3 Availability of Research Results: Publications, Intellectual Property Rights, and Sharing Research Resources

The ALS Association seeks treatment and a cure for ALS, and advocates for everyone affected by this disease. To increase the speed of ALS research, and to honor the contributions of research participants, The ALS Association supports efforts to ensure that data and resources produced from ALS-supported research and data-collection projects are as open and transparent as possible and made available to the public. It is expected that principal investigators and grantee organizations will make the results and accomplishments of their activities available to the research community and to the public at large.

8.3.1 Rights in Data (Publications, Copyrights and Press Releases)

In general, grantees own the rights in data that is conceived and/or reduced to practice resulting from a grant-supported project. An Agreement may indicate alternative rights as stated in the applicable Funding Opportunity Announcement. Any publications, data, or other copyrightable works developed under an ALS Association grant may be copyrighted without The ALS Association prior approval unless otherwise stated in an Agreement.

The ALS Association encourages its grantees to exercise diligence to disseminate results and arrange for publication of The ALS Association-supported original research in primary scientific journals, as soon as practical.

The results of any work supported by an ALS Association grant may be published without review by The ALS Association. Therefore, responsibility for direction of the work is not to be ascribed to The ALS Association. As part of the research progress report, the grantee is asked to send The ALS Association the reprint of the publication that resulted from the ALS-supported research to researchgrants@alsa-national.org.

The ALS Association encourages research products to be as open as possible. Specifically:

- Ensure publications are available to the reader without charge.
- Use preprints and pre-registering protocols when possible to speed dissemination.
- Ensure other research products are available to the user without charge and with as few usage restrictions as possible.

All grantees must acknowledge The ALS Association funding when issuing statements, press releases, or other documents describing projects or programs funded in whole or in part with The ALS Association money. Each publication, press release, or other document about research supported by an ALS Association grant must include:

Acknowledgement of The ALS Association grant support such as

“The research reported in this [publication/press release/presentation] was supported by The ALS Association grant number [specific ALS Association grant number in this format: 20-DDC-666].”

If the grantee plans to issue a press release about research supported by an ALS Association grant, it should notify The ALS Association at researchgrants@alsanational.org in advance to allow for coordination and review by The ALS Association prior to its release.

When acknowledging The ALS Association, grantees should use the following logo:



8.3.2 Sharing Data and Research Resources

All ALS Association grantees are expected to share data and biospecimens that may be developed under an ALS-supported grant as a means to enhance the value of ALS-supported research and accelerate the advancement of further ALS research. Therefore, when these resources are developed with ALS Association funds and the associated research findings have been accepted for publication, it is important that they be made readily available for research purposes to qualified individuals within the scientific community.

8.3.2.1 Data Sharing

The ALS Association considers data sharing to be essential for expedited translation of research results into knowledge, products, and procedures to improve human health. The ALS research community and medical professionals treating ALS patients will benefit from the dissemination of the research results conducted under ALS Association grants.

Final research data should be made publicly available to achieve important scientific goals. The ALS Association expects and supports the timely release of sharing of final research data from ALS-supported studies for use by other researchers. “Timely release and sharing” is defined as no later than the acceptance for publication of the main findings from the final data set.

Grantees shall make final research data publicly available on the following conditions: (a) data will be provided without charge to end users; (b) data will be used solely for research purposes and consistent with applicable law and ethical obligations, including but not limited to by obtaining all consents, authorizations, and other permissions required under applicable law and by the overseeing IRB(s) to make such data available for such future use. Investigators must exercise great care to ensure that resources involving human cells or tissues do not identify donors or subjects, directly or through identifiers such as codes linked to the donors or subjects. In addition, every effort should be made to acknowledge the source of the data being shared and include a statement that the data was supported by The ALS Association.

Applicants are expected to address data-sharing in their application, when required in the Funding Opportunity Announcement. An example of a data sharing plan would include: 1) What data will be shared 2) Who will have access to the data 3) Where will the data be available 4) When will the data be shared and 5) How will researchers locate and access the data.

The ALS Association will determine the merits of each data sharing plan, when applicable, on a case by case basis, considering the quality of the plan, its openness, and the sponsor's record in sharing data from previous work.

8.3.2.2 Research Resource Sharing

The ALS Association considers the sharing of biospecimens, research tools and animal models generated or developed under an ALS-supported award to be an important means to enhance the value of The ALS Association sponsored research. These research resources developed with The ALS Association funds should be made available for research purposes to the scientific community, including academia and industry, and medical professionals treating ALS patients.

Grantees are expected to make research resources publicly available, on the following conditions: (1) research resources will be provided without charge to end users; (b) research resources will be used solely for research purposes; (c) third parties may be required to pay minimal charges for preparation and transportation of research resources; and (d) consistent with applicable law and with applicable ethical obligations, including but not limited to by obtaining all consents, authorizations, and other permissions required under Applicable Law by the overseeing IRB(s) to make the research resources available for future use. In addition, every effort should be made to acknowledge the source of the resource being shared and include a statement that the resource was supported by The ALS Association.

The Funding Opportunity Announcement may request a plan for sharing research resources or the rationale for why such sharing is restricted or not possible.

8.3.3 Inventions, Patents, Ownership and Sharing of Net Income

Grantee shall promptly notify The ALS Association of any Invention, the nature of such property, and whether the grantee intends to seek Patent protection on such property.

Grantee shall have the first right, but not the obligation, to prepare, file, prosecute and maintain all registerable rights relating to any Invention at its sole expense, except with the respect to any Invention, the rights to which the grantee assigns to The ALS Association per the terms of the Research Grant Agreement.

Grantee shall a) notify The ALS Association of any intent of the grantee: (1) not to seek Patent protection on any Invention, (ii) to abandon any Patent application on any Invention, or (iii) to allow a Patent on any Invention to expire, prior to abandonment or expiration of any such Patent and offer to assign all rights therein to The ALS Association in sufficient time to allow The ALS Association to pursue or maintain the

Patent; and b) notify The ALS Association of the issuance of any patents on any Invention even after the grant termination.

Grantee shall solely own all rights, title and interest to the Invention, subject to the rights of publication of The ALS Association pursuant to the terms of the Research Grant Agreement and any rights assigned to The ALS Association.

Grantee shall promptly notify The ALS Association of the licensing, sale or transfer (collectively "Transfer") of any Invention and the general terms of the Transfer. Net income from a Transfer of any Invention shall be shared with The ALS Association in the same proportion (the "Sharing Proportion") as The ALS Association's financial contribution to the Invention bears to the total direct cost incurred by the grantee in connection with such Invention prior to the Transfer. Net income shall be paid to The ALS Association annually within sixty (60) days following the close of any calendar year in which Net Income is received. Such payment shall be accompanied by a report supporting the calculation of the payments. The Sharing Proportion shall be determined by the parties prior to each Transfer. If, however, the parties disagree as to the sharing of Net Income, the dispute shall be resolved in accordance with the dispute resolution process outlined in the Research Grant Agreement.

8.4 Management Systems and Procedures

8.4.1 Financial Management System Standards

Grantees are expected to have system, policies, and procedures in place by which they manage grant funds and activities to ensure funds awarded by The ALS Association are safeguarded and used solely for authorized purposes. Grantees should maintain records that identify adequately the source and application of funds in support of ALS-supported activities and maintain effective control and accountability for all awarded funds.

8.4.2 Property Management System Standards

Grantees may use their own property management policies and procedures for property purchased as a direct cost under an ALS Association award.

Title to equipment and supplies purchased with ALS Association grant funds shall vest with the Grantee. Generally, The ALS Association limits funding of equipment costs not to exceed 20% of the annual funding.

8.4.3. Procurement System Standards and Subaward Requirements

Grantees may acquire a variety of goods or services in connection with the grant-supported project which may include routine purchases of goods or services and/or those that involve substantive programmatic work.

Grantees should comply with internal policies and procedures to ensure proper use of ALS Association funds when procuring goods or services.

When the grant involves programmatic work to be performed by a third-party, the grantee is expected to develop and implement a written agreement between the grantee and the third-party institution. The agreement should address the scientific, administrative, financial and reporting requirements of the subawardee to ensure the

grantee is able to comply with such requirements. The agreement should incorporate the terms of The ALS Association award that flow to the subawardee (e.g., human, animal, reporting, monitoring, etc.) and the roles and responsibilities of those involved in the research to be performed.

8.5. Monitoring

The ALS Association requires its grantees to manage the day-to-day operations of grant-supported activities using institutional established controls and policies.

The ALS Association monitors its grants to identify problems and areas where technical assistance might be necessary. This active monitoring is accomplished through The ALS Association's review of periodic research progress reports and grant expenditure reports. Monitoring will continue through the end of a project until The ALS Association is no longer providing active grant support. Reporting requirements are outlined in Exhibit C of The Research Grant Agreement.

Research Progress Reports and Grant Expenditure Reports must be submitted to researchgrants@alsa-national.org.

8.5.1 Reporting

The ALS Association requires grantees to submit semi-annual research progress reports during the period of an award and a final progress report at closeout. The semi-annual report is due two weeks prior to the next scheduled payment date, unless otherwise noted in Exhibit C of the Research Grant Agreement. A progress report is also required when the grantee seeks an extension of the project without additional funds (see 8.1.2.2. No-Cost Extension of the Final Budget Period for more information).

8.5.1.1 Research Progress Report

Grantees have an obligation to submit a complete and accurate progress report. Grantees are required to report on the accomplishments for the reporting period, plans for next reporting period, reductions in effort greater than 25 percent for the principal investigator, absence of the principal investigator for more than three consecutive months, inventions, patent applications and/or licenses developed during the reporting period, publications resulting directly from the award, and research projects issued during the reporting period. The ALS Association staff may require additional information to evaluate the project for continued funding and/or to ensure progress is satisfactory. Failure to provide this information will result in a suspension of grant payment for continued funding. Incomplete or inadequate progress reports may result in a delay of continued funding. Future grant payments are contingent upon the grantee's submission of and The ALS Association's acceptance of the report. The ALS Association's issuance of the next award payment, when applicable, serves as confirmation that the Research Progress Report and Grant Expenditure Report, when required and submitted, have been reviewed and approved by The ALS Association. If a subsequent payment is not applicable and the ALS Association has concerns about the progress on the grant, The ALS Association will contact the grantee to resolve any concerns or take appropriate action as provided in Section 8.6 below.

8.5.1.2 Grant Expenditure Report

The ALS Association requires grantees to submit an annual grant expenditure report two weeks prior to the next scheduled payment date as outlined in Exhibit C of the Research Grant Agreement. Grantees will report on the total amount awarded, total amount expended and the unliquidated and/or unobligated balances. In addition, annual expenditure reports will provide the estimated amount expended as of the end of the reporting period (e.g., 4/30/2021 for a due date of 5/15/2021). The annual expenditure report should also include an indication and explanation of any unobligated balance greater than 25% of the total amount awarded and a general description of how it is anticipated that the funds will be spent during the next year. The ALS Association will review the report and upon its acceptance, The ALS Association will initiate the next scheduled payment, if applicable.

8.5.2 Record Retention and Access

Grantees generally must prepare and retain financial (e.g., bills, invoices, cancelled checks and receipts) and programmatic records, supporting documents, statistical records, and all other records that are required by the terms of a grant, or may reasonably be considered pertinent to a grant, for a period of 3 years from the date when the final grant expenditure report is submitted. The grantee is required to make its records available for audit, inspection and copying by The ALS Association when requested.

8.6 Remedies for Noncompliance: Suspension and Termination

A grantee's failure to comply with the terms and conditions of an award, may cause The ALS Association to take one or more actions, depending on the severity and duration of the non-compliance.

The ALS Association will provide the grantee with the opportunity to develop and implement a corrective action plan, when feasible. The ALS Association may take such action to impose additional terms of award, suspend funding under the project, or terminate the award to protect its interest in the grant-supported project.

Reasons for terminating an Agreement may be for cause, unauthorized substitution of the principal investigator, unavailability of the principal investigator, assessment of research, protection of subjects and failure to submit required reports. The Agreement will provide the terms for terminating an ALS Association grant.

8.7 Closeout

Grantees must submit a final research progress report and a final grant expenditure report within 90 days following the termination date and sent electronically to The ALS Association at researchgrants@alsa-national.org unless otherwise instructed.

8.7.1 Final Research Progress Report

Final research progress report will include a summary of progress made toward the achievement of the originally stated aims, a list of significant results (positive or negative) and scientific data inclusive of figures, tables, and images to illustrate and support the results of the grant). The final report will also include a report on any inventions, patent

applications and/or licenses developed including a list of research products issued during the final reporting period.

8.7.2 Final Grant Expenditure Report

Final grant expenditure report that includes the total grant funds expended and unobligated under the award. The final expenditure report may not include any unliquidated obligations (i.e., bill received but not yet paid or commitments of the grantee that have not been paid).

Any unexpended funds remaining at the termination of the grant must be returned to The ALS Association with a note identifying the grant number, grantee name and principal investigator name.

Remittance of funds may be made via a check or wire transfer. Checks must be made payable to “The ALS Association” and mailed to the following address:

The ALS Association
Attn: Finance Department
1300 Wilson Boulevard, Suite 600
Arlington, VA 22209

Grantees choosing to return funds via wire transfer, should send an email to The ALS Association at researchgrants@alsa-national.org to request wire transfer instructions along with the grant information above.

8.7.3 Submission of Closeout Reports

Closeout reports must be countersigned by an authorized organizational representative and sent electronically to The ALS Association’s grants centralized mailbox at researchgrants@alsa-national.org unless otherwise instructed.

Part 3: Points of Contact

The ALS Association’s mailing address is as follows:

The ALS Association
1300 Wilson Boulevard, Suite 600
Arlington, VA 22209

Questions related to The ALS Association’s grant program can be emailed to researchgrants@alsa-national.org.

Part 4: Resources

Sample Research Grant Agreement

Sample Research Progress Report
Sample Grant Expenditure Report
ProposalCentral Guides