



Grants Policy Statement

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1 Introduction

1.1 Grants Policy Statement

[The ALS Association's](#) Grants Policy Statement (GPS) is intended to make available to the research community the policy requirements that serve as the basis for the terms and conditions of the Association's grant awards. This document also is designed to be useful to others interested in the Association's grantmaking programs and processes.

The 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 Association and the grantee in which:

- 1) The 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 Association will monitor grant progress and assume compliance with applicable standards.
- 2) The principal investigator (PI) 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 Association's prior approval as outlined within this grants policy statement.

1.2 Contact Information

Questions related to the Association's research grant programs can be emailed to researchgrants@als.org.

The Association's mailing address is:

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

1.3 Additional Resources

The Association uses the ProposalCentral grant making portal for application, review, reporting, and other grant administration functions. ProposalCentral maintains several user guides that are available on its website:

- [Guide to registering as a new user](#)
- [Guide on how to create an application](#)

Sample research grant administration documents and answers to frequently asked questions can be found on the Association's website: www.als.org/research/researchers/information-grant-applicants-and-awardees.

2 Application and Award Process

The projects funded by the Association are selected by a panel of independent experts through a rigorous, structured, and deliberative review process. More information about this process is available on the Association's website: www.als.org/research/for-researchers/information-grant-applicants-and-awardees/how-we-fund-research.



This process, from LOI submission through the pre-award process, is considered confidential by the Association. All information related to applicants, applications, reviews, reviewers, contract negotiations, terms and conditions of the Agreement, etc. will be treated as such.

2.1 Request for Applications

The Association solicits grant applications across a wide breadth of focus areas through the issuance of Request for Applications (RFAs). These RFAs are publicly available documents that seek applications related to specific scientific focus areas critical to advancing ALS research. These announcements are posted on the Association's Funding Opportunities webpage: www.als.org/research/funding-opportunities.

Each RFA describes in detail the process, including instructions and deadlines, for applying to that specific opportunity. Most opportunities call for the applicant to propose a research-based project that, if funded, would result in a time-limited, milestone-driven funding agreement. Applications generally consist of a brief letter of intent followed by a full application (submitted by invitation only). Both the letter of intent and full application are subject to scientific review. The Research Committee of the Association's Board of Trustees provides final approval for funding and budget.

2.2 Completing the Pre-Award Process

After an application is selected for funding, the application is 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.

The Association will work with the applicant as part of the pre-award process to negotiate the funding plan and terms of the Agreement and to document administrative, fiscal, and programmatic information. Since grants are made to institutions (referred to as "grantees" throughout this document), not investigators, the information below must be signed and/or submitted by a signing official.

The Association will obtain the following, 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. No Association funds may be used for human subject research without appropriate IRB approval.
- **Verification of Institutional Animal Care and Use Committee (IACUC) Approval:** If the proposed project involves live vertebrate animals, the applicant will be required to provide verification of appropriate legal, regulatory, and ethical oversight and approval (e.g., IACUC approval for domestic grantees). No Association funds may be used for animal research without appropriate approvals.
- **Other Sources of Support and Assurance of No Scientific, Budgetary, or Commitment Overlap:** The applicant will be required to provide information about 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.
 - Association funds shall not be used to duplicate any work supported by other funding sources. It is the responsibility of the PI/grantee to notify the 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 the individual's research endeavors. If any overlap exists, the applicant will be asked to describe the nature of the overlap and provide an explanation as to how the overlap will be resolved and/or mitigated prior to the Association's issuance of an award.
 - In addition, the PI and/or signing official is expected to notify the Association as soon as either party becomes aware of any overlap that may occur during the period of the award.

2.3 The Research Grant Agreement

A formal notification through the issuance of a Research Grant Agreement (Agreement) will be provided to the applicant organization for successful applicants. The terms and conditions of the

Agreement are negotiated between the applicant's signing official and the Association's research team. After the terms and conditions of the Agreement are finalized, the Agreement is sent to the institution for signature by the signing official and PI. The Agreement is fully executed after the Agreement is signed by the Association's signing official. The fully signed and executed Agreement is sent to the signing official and PI via email along with a notification letter.

2.3.1 Overview of Terms and Conditions

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

The Association requires its grantees to:

- Establish and maintain the necessary processes to monitor its compliance and that of its employees, sub-awardee participants, and contractors in accordance with the terms and conditions outlined within this policy statement and the Agreement.
- Take appropriate action to meet the stated objectives.
- Inform the Association of any problems or concerns. The Association may take necessary and appropriate actions to address noncompliance with any applicable requirements.

2.3.2 Timeline for Agreement Signature

The Association expects the Agreement to be signed within 60 days of receipt of the initial draft Agreement for applicant review. If not, the Association reserves the right to rescind the award offer and redirect the funds to other projects.

3 Changes in Project and Budget

Grants issued by the Association require minimal 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.

Rebudgeting between budgetary categories up to 10% of the total cost awarded may be made at the grantee's discretion. If rebudgeting exceeds 10% of the total cost awarded, prior written approval from the Association is required.

3.1 Grantee Authorities

This section describes activities and/or expenditures that do not require the Association's prior approval. Association staff can answer any questions about whether an action requires prior approval or constitutes a change in scope.

3.1.1 Pre-Award Cost Authority

A grantee 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. Pre-award

costs may be incurred without prior approval after the Association notifies the applicant, in writing, that the application has been selected for funding.

3.1.2 Limited Carryover of Funds

Carryover of funds from one year to the next of less than 25% of the total amount received to date is allowed.

3.1.3 Limited Rebudgeting Between Budgetary Categories

Rebudgeting between budgetary categories up to 10% of the total cost awarded is allowed unless the action is considered a change in scope (see section 8 for definition).

3.1.4 Rebudgeting from Indirect Costs to Direct Costs

Rebudgeting from indirect costs to direct costs is allowed.

3.1.5 Limited Transfer of Programmatic Work to a Third Party

Transfer of the performance of programmatic work to a third-party institution within the rebudgeting limitations described in section [3.1.3 Limited Rebudgeting Between Budgetary Categories](#) and within the Description of Research (outlined in Exhibit A of the Agreement) is allowed.

3.2 Prior Approval Requirements

This section describes the activities and/or expenditures that require prior approval by the Association. Requests for prior approval must be submitted in writing at least 30 days before the proposed change.

3.2.1 Carryover of Funds in Excess of 25%

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

3.2.2 No-Cost Extension of the Final Budget Period

The grantee may request a no-cost extension to the period of support for up to six months without additional funds. This time may be used to complete the goals of the project or to provide for an orderly closeout. The fact that funds remain at the completion date of the grant is not sufficient justification for a no-cost extension. A second no-cost extension of an additional six months will be considered on a case-by-case basis. Extensions for more than one year beyond the original contracted period of support are granted only in exceptional circumstances.

If a no-cost extension of the project is desired, the grantee must submit a request through ProposalCentral. The Association will review the request and provide a written response.

3.2.3 Change in Description of Research

A change in the Description of Research is a change in the direction, aims, objectives, or purposes identified in the Description of Research outlined in Exhibit A of the Agreement. PIs are encouraged to contact the Association promptly to discuss any plan for changing the

scope of work. The Association will work with the PI to determine what information is needed for consideration of the request.

3.2.4 Change of Principal Investigator (PI)

A change of PI from one individual to another may be requested unless prohibited by the terms of the award. If the arrangements proposed by the grantee, including the qualifications of any proposed replacement, are not acceptable to the Association, the grant may be terminated. If the grantee decides to terminate the project because suitable alternate arrangements cannot be made, they must notify the Association, in writing, of the decision to terminate the award. In this situation, the grantee should proceed with closeout requirements.

3.2.5 Change of Grantee Institution

A change of grantee institution, which is a 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, may be considered for most Association-funded grants if the original grantee institution agrees to relinquish responsibility for an active award and any remaining funds under the award before the completion date of the project.

Upon the Association's approval of the grant transfer, the original grantee institution must submit a payment to the Association in the amount of the unobligated balance. The Association will provide an Agreement to the new institution.

3.2.6 Change of Grantee Organizational Status

The Association must receive advance notice of the following types of changes 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 Association's grant(s), the procedures for recognizing a success-in-interest will apply. When the action does not involve the transfer of the Association's 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 Association-funded 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 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 Association, and payments are not interrupted. The signing official is encouraged to contact the Association 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 Association as soon as possible so the 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 signing official of the current grantee (transferor) and the successor-in-interest (transferee) must be sent to the Association. The letter must:

- Stipulate that the transfer will be properly affected in accordance with applicable law.
- Indicate that the transferor relinquishes all rights and interests in all affected grants.
- Request that the 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 the EIN is new, include a completed Form W-9 for U.S. organizations and W-8 for foreign organizations.
- Include verification of the transferee's compliance with applicable requirements.

3.2.7 Request to Rebudget Funds

The Association allows its grantees a certain degree of flexibility to rebudget funds between budgetary categories, including between direct and indirect costs, at the discretion of the PI consistent with the terms of the Agreement and institutional policy and procedures. The Association's 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.

4 Research-Related Requirements

The Association requires its grantees to comply with public policy requirements to uphold high ethical, health, and safety standards in the conduct of research and in the expenditure of grant funds. No Association funds may be used until grantees verify they are in compliance with the requirements described in this section.

4.1 Human Subjects Protections

Association-supported 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 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 Association-supported activities.

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

The Association will request verification of IRB approval prior to the issuance of an award. No costs for activities with human subjects may be charged to the Association's 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. The Office for Human Research Protections (OHRP) maintains the International Compilation of Human Subjects Research Standards and a listing of more than 1,000 laws, regulations, and guidelines on human subject protections from 133 countries and many organizations. For more information visit www.hhs.gov/ohrp/international/compilation-human-research-standards.

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

Grantees must notify the Association of an IRB's decision to suspend the involvement of human subjects in the research. 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 Association. Consultation with the Association is encouraged regarding questions concerning allowable costs during a suspension.

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

Foreign grantees must comply with the Regulation E.U. 2016/679, or its amended regulation, of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to processing of personal data and on the free movement of such data.

4.2 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 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. Domestic grantees must verify that they have obtained Institutional Animal Care and Use Committee (IACUC) approval prior to engaging in animal research activities.

Foreign grantees shall comply with applicable laws, regulations, and policies of the jurisdiction in which the research will be conducted. The Association also encourages foreign grantees to commit to following the [International Guiding Principles for Biomedical Research Involving Animals](#) and use the standards found in the [Guide for the Care and Use of Laboratory Animals](#).

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

4.3 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](#).

4.4 Anti-Terrorism and Economic Sanctions

Grants provided by the 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 Association, except as permitted under U.S. law, is strictly prohibited. Funds provided by the 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. Grantees shall fully cooperate with the Association in implementing, monitoring, and maintaining any policies, procedures, and controls that the Association reasonably determines are needed to ensure that the 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.

4.5 Debarment and Suspension

Grantees who accept an award from the Association assume responsibility to ensure that neither the grantee nor any of the individuals or entities that will perform the obligations of the grantee under an Association-funded grant have been debarred by federal agencies, such as the FDA or HHS, 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 Association-funded award, grantees must report to the 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).
- 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 ([sam.gov](#)).

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

4.6 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 Description of Research consistent with and under the licenses, permits, certifications, accreditations, and authorities required under applicable law.

4.7 Insurance

Grantees shall maintain, at their own expense, appropriate insurance against the risks involved in conducting any Association-funded research. Grantees shall provide a certificate of insurance, if applicable, evidencing such coverage to the Association upon written request.

5 Administrative Requirements

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

To increase the speed of ALS research, and to honor the contributions of research participants, the Association supports efforts to ensure that data and resources produced from Association-supported research and data collection projects are as open and transparent as possible and made available to the public. It is expected that PIs and grantee organizations will make the results and accomplishments of their activities available to the research community and to the public at large.

5.1.1 Rights in Data: Publications, Copyrights, and Press Releases

In general, grantees own the rights to data that are conceived and/or reduced to practice resulting from a grant-supported project, although the Agreement may indicate alternative rights. Similarly, any results, publications, data, or other copyrightable works developed under an Association-funded grant may be published without review by the Association and copyrighted without the Association's prior approval unless otherwise stated in the Agreement.

The Association encourages its grantees to exercise diligence in disseminating results and arranging for publication of Association-supported original research in primary scientific journals as soon as practical. As part of the research progress report, the PI is asked to include reference to any publications that resulted from Association-supported research.

The Association encourages research products be as open as possible, specifically by:

- Ensuring publications are available to the reader without charge.
- Using preprints and pre-registering protocols, when possible, to speed dissemination.

- Ensuring other research products are available to the user without charge and with as few usage restrictions as possible.

All grantees must acknowledge the Association's funding when issuing statements, press releases, or other documents describing projects or programs funded in whole or in part with Association money. Written advance notice of press releases should be provided to the Association to allow for coordination and/or review prior to publication.

5.1.2 Sharing Data and Research Resources

All grantees are encouraged to share data and biospecimens that may be developed under an Association grant as a means of enhancing the value of Association-supported research and accelerating the advancement of further ALS research.

5.1.2.1 Data Sharing

The 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 people living with ALS will benefit from the dissemination of research results produced under Association-funded grants. Thus, final research data should be made publicly available as soon as practical.

5.1.2.2 Research Resource Sharing

The Association considers the sharing of biospecimens, research tools, and animal models generated or developed under an Association award to be an important means to enhance the value of the Association-sponsored research. These research resources developed with Association funds should be made available for research purposes to the scientific community, including academia, industry, and medical professionals caring for people living with ALS. Grantees are expected to make research resources publicly available as soon as practical.

5.1.3 Intellectual Property, Patents, Ownership, and Sharing of Net Income

Grantees shall solely own all rights to intellectual property that is either conceived and reduced to practice or further developed by the grantee in performing the funded research and shall have the first right, but not the obligation, to prepare, file, prosecute, and maintain all registerable rights relating to any intellectual property at its sole expense. Grantees shall promptly notify the Association of any newly generated intellectual property relevant to the funded research or any changes in the patent status of intellectual property relevant to the funded research. Grantees shall also notify the Association of the licensing, sale, or transfer of any intellectual property relevant to the funded research and the general terms of any such transaction. If such a transaction generates revenue for the grantee, then the Association expects to share in that revenue according to the terms of the Agreement.

5.2 Management Systems and Procedures

5.2.1 Financial Management System Standards

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

5.2.2 Property Management System Standards

Grantees may use their own property management policies and procedures for property purchased as a direct cost under an Association award. Title to equipment and supplies purchased with Association grant funds shall vest with the grantee.

5.2.3 Procurement System Standards and Subaward Requirements

Grantees may acquire a variety of goods or services in connection with the Association-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 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 Association's 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.

5.3 Monitoring

The Association requires its grantees to manage the day-to-day operations of grant-supported activities using institutional-established controls and policies. The Association monitors its grants to identify problems and areas where technical assistance might be necessary. This active monitoring is accomplished through the Association's review of periodic research progress reports and grant expenditure reports. Monitoring will continue through the end of a project until the Association is no longer providing active grant support in addition to limited post-award reporting. Specific reporting requirements are described in the Agreement.

Research Progress Reports and Grant Expenditure Reports must be completed and submitted through [ProposalCentral](#) as webforms. Webforms can be found under the Deliverable tab.

5.3.1 Reporting

The Association generally requires grantees to submit research progress reports every six months and grant expenditure reports every year during the period of an award (including any no-cost extension period, if relevant) plus a final progress report and a final grant expenditure report at closeout. The schedule for submission of these reports is included in the Agreement. A progress report is also required when a grantee seeks a no-cost extension (see section [3.2.2 No-Cost Extension of the Final Budget Period](#)).

Failure to provide these reports will result in a suspension of all grant payments to the grantee institution, including all awards currently active at the grantee institution, if applicable. Incomplete or inadequate reporting may result in a delay of continued funding. If the Association has concerns about the progress on the grant, the Association will contact the grantee to resolve any concerns or take appropriate action as provided in section [5.4 Remedies for Noncompliance: Additional Terms of Award, Withholding of Support, Suspension and Termination](#).

5.3.1.1 Research Progress Report

Research progress reports generally detail the accomplishments for the reporting period, plans for next reporting period, changes in staffing, impacts of the project (e.g., publications, patents, additional grant funding), and other information relevant to the conduct of the research project. Final research progress reports also include a summary of the overall project.

5.3.1.2 Grant Expenditure Report

Grant expenditure reports should list all values in U.S. dollars and should cover cumulative expenditures from the initiation of the grant through the end of the current reporting period. Grantees will report on the total amount received, total amount expended, any unliquidated and/or unobligated balances, and any anticipated or actual changes to the project budget. Final expenditure reports should also indicate indirect costs expended.

5.3.1.3 Post-Award Reporting

Grantees may be asked to submit reports for up to five years following the termination of the award that list outputs such as papers, patents, and follow-on funding that has resulted from the Association-funded research.

5.3.2 Record Retention and Access

Grantees generally must prepare and retain financial and programmatic records and make these records available to the Association for audit as required by the terms of the Agreement.

5.3.3 Closeout

Timely closeout is a grantee responsibility. Failure to submit timely and accurate closeout documents may affect future funding to the grantee organization.

5.3.3.1 Final Reports

Grantees must submit a final research progress report and a final grant expenditure report as specified in the Agreement following the termination date.

5.3.3.2 Return of Unexpended Funds

Unexpended funds remaining at the termination of the grant must be returned to the Association. However, the Association does not generally require the remittance of unexpended funds remaining at the end of the project totaling less than \$100. See further detail in section [7.2 Payments to The ALS Association](#).

5.4 Remedies for Noncompliance: Additional Terms of Award, Withholding of Support, Suspension, and Termination

A grantee's failure to comply with the terms and conditions of an award may cause the Association to take one or more actions, depending on the severity and duration of the non-compliance. The Association will provide the grantee with the opportunity to develop and implement a corrective action plan, when feasible. However, if that proves inadequate, the Association may take action to impose additional terms of award, withhold future support, suspend funding under the project, or terminate the award to protect its interest in the grant-supported project.

Additional terms that may be imposed to remedy specific deficiencies may include more frequent or detailed financial expenditure reporting. When additional terms are imposed, the Association will notify the grantee in writing of the nature of the terms, the reason why they are being imposed, the type of corrective action needed, the time allowed for completing corrective actions, and the method for requesting reconsideration of the conditions.

Withholding of support is a decision not to make a payment within the period of support of a grant project. Support may be withheld for one or more of the following reasons:

- A PI failed to show satisfactory progress in achieving the objectives of the project.
- A grantee failed to meet the terms and conditions of a separate award, including failure to submit timely and accurate grant expenditure and progress reports.

Note: Because the grantee is the institution, not the PI, status of one award will impact other awards at the same institution.

Reasons for terminating an Agreement may include:

- Breach of contract.
- Unauthorized substitution (or unavailability) of the PI.
- Protection of subjects.
- Failure to submit required reports.

The Agreement will provide the specific terms for and consequences of terminating an Association-funded grant.

6 Cost Considerations

6.1 General Information

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

6.2 Cost Principles

The 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 the Association's 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 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.
- **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 Association's program guidelines and the terms and condition of the award.

6.3 Direct 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.

6.4 Indirect Costs (Facilities and Administrative Costs)

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. Such costs cannot be readily identified with an individual project or program.

Limited indirect costs are awarded and allowed for reimbursement under the Association's grants, generally 10% unless stated otherwise in a grant award opportunity's RFA. 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.

6.5 Allowability of Costs

An allowable cost is a cost incurred by a grantee that is:

- Necessary and reasonable for the performance of the award.
- Allocable to the project.
- Conforms to any limitations or exclusions set forth in the Grants Policy Statement, RFA, or in the Agreement as to the type or amount of cost items.

- Consistent with policies and procedures of the grantee that are applied uniformly to both the Association's grant and other activities of the grantee.
- Accorded consistent treatment as a direct or indirect cost.
- Determined in accordance with generally accepted accounting principles (GAAP).
- Not included as a cost in any other funded award.
- Adequately documented, see 2 CFR 200.403 (Uniform Guidance).

Costs charged to the Association-funded project must be for allowable costs incurred in support of the approved project as described in the Description of Research and comply with institutional policy and procedures, the terms of the Agreement, and the applicable program requirements outlined in the RFA. 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 Association for additional information and/or guidance.

6.5.1 Selected Allowable Costs

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

- Salary, wages, and fringe benefits of personnel other than those costs for the applicant and/or awardee PI.
- Salary, wages, and fringe benefits of the PI only when indirect costs are waived.
- Consumable supplies.
- Computer hardware and software costs up to \$2,000 per year.
- Moveable equipment, not to exceed 20% of the annual budget.
- Economy travel costs up to \$3,000 per year to attend scientific meetings and/or conferences.
- Per diem rates set by U.S. General Services Administration (GSA).
- Subawardee and/or consortium costs.
- Publication costs up to \$2,500 per project.

Notes:

- Direct salary for individuals should not exceed the salary limitation for Executive Level II of the Federal Executive pay scale provided on the NIH Salary Cap Summary website: grants.nih.gov/grants/policy/salcap_summary.
- Indirect costs for the grantee and any subgrantee are generally limited to a maximum of 10% of the total award amount unless stated otherwise in a grant award opportunity's RFA.
- Any recurring annual cost-of-living increase up to 3% only apply to personnel and consumable supplies.

6.5.2 Selected Unallowable Costs

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

- Salary, wages, and fringe benefits of the PI at the grantee 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 \$3,000 per year.
- Tuition.
- 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 for the grantee or any subgrantee in excess of maximum allowance outlined in each funding opportunity’s RFA.
- Over expenditures or cost overruns.
- Duplication of funding.

7 Payment

7.1 General Information

Payment of a grant is generally made in six-month increments following the initial payment in U.S. dollars. The first payment is made following the execution of the Agreement. Subsequent payments are made following the Association’s review and acceptance of the research progress report and/or grant expenditure report, if applicable, as required for submission and outlined in the Agreement. The 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 the Association’s 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.

7.2 Payments to the Association

Any funds sent to the Association must include appropriate identifying information, including the relevant grant number, grantee institution name, and PI 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 request instructions via an email, including the identifying information mentioned above, to the Association at researchgrants@als.org.

8 Glossary of Terms

Term	Definition
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 Association.
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.
Application	A request for grant support of a project or activity submitted to the Association on specified forms and in accordance with the Association's instructions.
Application Number	The application number is a unique identifier for a grant application submitted to the Association.
Assurance	A certification by an applicant, normally included with the application, that indicates the institution complies with, or will abide by, a requirement if awarded a grant by the Association.
Award	The provision of funds issued by the 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 IRB-approved protocol.
Budgetary Overlap	Duplicate or equivalent budgetary items (e.g., equipment, salaries, supplies) are requested in an application that are already provided by another source.

Term	Definition
Change in Scope	An activity whereby the objectives or specific aims identified in the Agreement are significantly changed by the grantee after an award is made. Prior approval is required for a change in scope to be allowable under an Association-funded award. See section 3.2.3 Change in Research Scope of Work 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 Association grantees are subject to when human subjects are involved in an Association-supported project.
Clinical 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
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.
Data	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.
Digital Object Identifier (DOI)	Digital Object Identifiers are globally unique character strings that reference digital, physical, or abstract objects.
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. See section 6.3 Direct Costs for additional information.
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 U.S. laws, and assumes legal and financial accountability for awarded funds and for the performance of grant-supported activities.
Equipment	Tangible personal property, including information technology systems, that have 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).

Term	Definition
Foreign Organization	An entity that is (1) a public or private organization located in a country other than the U.S. 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; (2) a private nongovernmental organization located in a country other than the U.S. that solicits and receives cash contributions from the general public; (3) a charitable organization located in a country other than the U.S. 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 (4) an organization located in a country other than the U.S. not recognized as a Foreign Public Entity.
Grant	A sum of money given by the Association to another eligible institution for the purpose of supporting ALS research.
Grant Number	A unique identifier for a grant created prior to grant payment that is composed of the fiscal year of the first payment, acronym for program name, and serial number. Sample Grant Number: 24-DDC-624.
Grantee	An institution that receives an award from the Association and assumes legal and financial responsibility and accountability both for the awarded funds and the performance of the grant-supported activity.
Grant-Supported Project or Activity	Those activities specific or described in a grant application that are approved by the Association for funding as stated in the Agreement (i.e., 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 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	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. See section 6.4 Indirect Costs (Facilities and Administrative Costs) for additional information.

Term	Definition
Institutional Animal Care and Use Committee	The body that provides oversight and ensures 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 Association-supported activities involving human subjects prior to funding.
Key Personnel	The PI 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 master's or baccalaureate level may be considered key personnel if their involvement meets this definition.
No-Cost Extension	An extension of time to a period of support without additional funds to complete the work during that period. See section 3.2.2 No-Cost Extension of the Final Budget Period for more information.
Notification Letter	A letter accompanying the Agreement that officially notifies the grantee and PI about the issuance of the award. The letter includes the assignment of the grant number, which should be referenced in any future post-award communication with the 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, other grants, cooperative agreements, contracts, or organizational awards. Other support does not include training awards, prizes, or gifts.
Payment	The distribution of funds from the Association to the grantee in support of the approved research project (Statement of Work).
Peer Review	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 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 Association officials responsible for making award decisions.

Term	Definition
Period of Support	The total time period for which support of a project has been programmatically approved by the Association, as shown in the Agreement.
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 award. The PI is the member of the grantee's team responsible for ensuring compliance with the financial and administrative aspects of the award. The PI also serves as the liaison to the Association for issues relating to the development and implementation of the Research Scope of Work under an Association-funded award, leads the implementation of the Description of Research, and performs other responsibilities as set forth in the Agreement.
Prior Approval	Written approval by an authorized Association official evidencing prior consent before a grantee undertakes certain activities or incurs specific costs. See section 3.2 Prior Approval Requirements for additional information.
Research Grant Agreement (Agreement)	The official, legally binding document signed electronically by the signing official, PI, and a member of the Association that contains or references all the terms and conditions of the grant, 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 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.

Term	Definition
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.
Scope of Work	The aims, objectives, and purposes of a grant, as well as the methodology, approach, analysis or other activities, tools, technologies, and time frames needed to meet the grant's objectives. This includes the research plan submitted with the original grant application, along with any approved modifications as stated in the Agreement.
Signing Official	The individual, named by the applicant and/or grantee institution, who is authorized to act for the applicant and/or grantee and assume the obligations imposed by the Association and the terms of the Research Grant Agreement.
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 categorical breakdown of costs, such as personnel, supplies, and other allowable expenses, including indirect costs. The relationship between the grantee and the collaborating organization(s) 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 Association grantee to another institution to carry out part of an Association-funded award activity. It does not include payments to a contractor or payments to an individual that is a beneficiary of an Association program. A subaward may be provided through any form of legal agreement, including an agreement that the grantee considers a contract.
Suspension	An action by the Association that temporarily withholds support of a project pending corrective action by the grantee or a decision by the Association to terminate the grant.
Termination	The ending of an 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 Association, whether based on regulation, policy, or otherwise referenced in the Agreement.

Term	Definition
Total Costs or Total Project Costs	The total allowable costs (both direct and indirect) incurred by the grantee to carry out a grant-supported project or activity.
Unallowable Costs	Charges to an Association award that are determined to be unallowable in accordance with the institution's 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). See section 6.5 Allowability of Costs for additional information.
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 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 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 Association's grant from the cumulative amount of the funds that the Association authorized the grantee to obligate.
Withholding of Support	A decision by the Association not to make a subsequent grant payment.