Application Guidelines for the 2024 Reach Grant

Full Application Due: March 25, 2024 (by 8:00 p.m. Eastern)
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About Alex's Lemonade Stand Foundation

Alex's Lemonade Stand Foundation (ALSF) emerged from the front yard lemonade stand of 4-year-old Alexandra “Alex” Scott, who was fighting cancer and wanted to raise money to find cures for all children with cancer. Her spirit and determination inspired others to support her cause, and when she passed away at the age of 8, she had raised $1 million. Since then, the Foundation bearing her name has evolved into a national fundraising movement. Today, ALSF is one of the leading funders of pediatric cancer research in the U.S. and Canada, funding more than 1,000 research projects and providing programs to families affected by childhood cancer. ALSF is also the only childhood cancer research organization that has been given the NCI peer-reviewed funder designation for rigorous selection of research grants. The mission of ALSF is to change the lives of children with cancer through funding impactful research, raising awareness, supporting families, and empowering everyone to help cure childhood cancer.

Reach Grant Program Description

Significant barriers exist that impede the translation of innovative and important ideas to the clinic. The Reach Grant seeks to remove one of these barriers by providing support for important pre-clinical hypothesis-driven research projects that are necessary to move a study from the pre-clinical arena into a clinical trial. Thus, the goal of this award is to support translational studies that will result in a phase 1 and/or 2 clinical trial, two to three years from the project end date. Examples of appropriate research projects include but aren’t limited to, completing IND-enabling studies, providing requisite pre-clinical data for clinical trial development, or perhaps through the validation of biomarkers that will enable selection of the correct patients for entry into new clinical trials.

Application Timeline and Review

- A full proposal must be submitted that meets all guideline criteria as well as all eligibility criteria; otherwise, applications will be administratively rejected.
- Proposals will be reviewed by an independent panel of experts according to the NIH recognized peer-review process.

APPLICATION TIMELINE

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<tr>
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<th>March 25, 2024, 8:00p.m. (ET)</th>
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<tbody>
<tr>
<td>FULL PROPOSAL DUE</td>
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<tr>
<td>AWARD NOTIFICATION</td>
<td>August 2024</td>
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<tr>
<td>PROJECTED START/END</td>
<td>November 1, 2024</td>
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Applicant Eligibility: must be met at the time of application

- Applicant institutions must be based in the United States or Canada. Applicants need not be United States citizens. Funds must be granted to nonprofit institutions or organizations.
- Applicants must have an MD, PhD, or MD/PhD or equivalent and be appointed as faculty (or equivalent) at an academic institution.
- Applicants must have a demonstrated track record of pediatric cancer research with experience in translational research.
- Multiple investigator applications that bring together pairs or teams of researchers with complementary expertise are encouraged.

Scope of Proposal

- Proposals must fall within the scope of Alex’s Lemonade Stand Foundation’s mission, focused on childhood cancers. Proposals with a sole/primary focus on patients >19 years of age will not be considered.
- Proposals will be evaluated based on their late-translational potential. Thus, screening projects, discovery projects, and early translational projects are not appropriate for the Reach Grant.
- The proposal must be hypothesis driven and demonstrate feasibility. Preliminary data are required.
- Proposals should be milestone driven; explicit timeline and time-based deliverables for the proposed studies must be presented. A milestone is defined as a scheduled event in the project timeline, signifying the completion of a major project stage or activity.
- **Proposal must include a plan to bring project to a clinical trial. Projects with a clear plan will be prioritized.**

Budget

The requested budget should be in proportion to the scope of the proposed project and should be for direct costs of $250,000 USD or below over 2 years. A maximum of $125,000 in total direct costs may be requested per year.

**Restrictions:**

- ALSF adheres to the NIH Salary Cap for principal investigator(s).
- Indirect costs are not allowed.
- The grant may not be renewed; one no-cost extension request is allowed with the Final Report.
- Other budget items may include fringe, travel, supplies and small pieces of equipment. ALSF funds cannot be used for tuition remission. View ALSF’s complete budget policy.

Alex’s Lemonade Stand Foundation | Grants@AlexsLemonade.org | ALSFgrant.org
If utilizing a subcontract or subaward, you must include this expense in the budget.
- No indirect costs will be paid.
- The PI’s institution is responsible for disbursing funds for subawards and/or subcontracts.

Resource and Data Sharing
Grant recipients are expected to share unique resources developed under this funding award, and as part of the application, applicants are required to submit a Resource Sharing Plan using ALSF’s Resource Sharing Form. Applicants should describe their track record of generating resources that are broadly re-used, the specific resources that will be generated in this proposed project, and the mechanisms by which those resources will be shared. To demonstrate a commitment to sharing that will be actualized, applicants should provide information in their sharing plan that clearly states the type of resource that will be shared, the method, characterization and timing of such sharing, and the anticipated resources (budget, personnel, etc.) required by the applicant and the resource user. Reviewers will consider the extent to which the dissemination of resources produced under the award will enhance or diminish the impact of the proposed work. For a full description and an example, see the Resource Sharing Form. For the full Resource Sharing Policy visit our Resources for Grant Applicants page.

Resubmissions
One resubmission of a full application previously reviewed by ALSF’s Reach Grant Review Board is permitted. Applicants should respond to the prior ALSF critique of the proposal in the Resubmission section of the application. The response to critique will be scored in the review process, and resubmissions compete with new applicants for funding.

Restrictions
- ALSF does not fund proposals for research utilizing human embryonic or fetal stem cells, or non-human primates. Research with human induced pluripotent stem cells is permissible.
- Proposals focused on social determinants of health with an emphasis on oncologic outcomes (rather than psychosocial outcomes) are permitted.

Grant Policies & Reporting Requirements
- Please review ALSF’s Grant Policies, including Budget Expenditures, Resource Sharing and Grant Agreement with IP, found on the Resources for Grant Applicants page.
- Annual progress reports: each year of funding is contingent upon demonstration of satisfactory progress toward the completion of proposed research objectives and appropriate budget expenditures.
• Minor carry-over of funds (25% or less) is permitted each year with justification. Each year’s budget will be approved subsequent to the review of project progress and milestones.
• ALSF may elect to partially fund or to hold new funds if carry-over is excessive.
• A final report is required at the conclusion of funding. Report must state findings, expenditures, as well as publications and presentations which acknowledge ALSF funding.
• The grant may not be renewed; one no-cost extension may be requested in the final report.
• Publications, presentations, and posters featuring results of the experiments funded by this grant mechanism should acknowledge “Alex’s Lemonade Stand Foundation” and include the award number. Copies should be sent via email to Grants@AlexsLemonade.org.

Application Package Instructions
• All sections described below should be combined into one PDF (max 20 MB) and uploaded to the ALSF online application form (see Application Submission instructions).
• All templates mentioned can be found on ALSF’s Resources for Grant Applicants page.

Format Instructions
• PAGE HEADER: All pages of the application should be numbered; the name of the principal investigator should appear in the upper right-hand corner of each page.
• FORMAT: Follow NIH format guidelines: Arial, Helvetica, Palatino Linotype, or Georgia fonts with a font size of 11 points or larger with a minimum of ½ inch margins.
• ORDER & LENGTH: The order of the application should be followed, adhering to the maximum number of pages allowed for each subsection indicated in parentheses.
• Appendices are not allowed.

Section Descriptions
1. Project Information
   b. Table of Contents (1 page): Provide a Table of Contents with page numbers to the corresponding sections.
   c. Scientific Abstract (0.5 page): Summarize the research objectives and rationale.
   d. Impact Statement (0.5 page): How will this project impact childhood cancer?
2. Budget/Justification (3 pages):
   a. Budget Template (1.5 pages): Complete the ALSF budget template. The signature from an institutional representative on the cover page of this grant application
specifically acknowledges and accepts this budget and acknowledges that no indirect costs will be paid.

i. The award amount is $250,000 over 2 years.

ii. ALSF adheres to the NIH Salary Cap for Principal Investigator(s)/Co-Investigator(s).

iii. Indirect costs are not allowed.

iv. If utilizing a subcontractor, you must include their budget. No indirect costs may be paid to the subcontractor.

v. Reasonable travel expenses to national/international research meetings to disseminate findings may be budgeted.

vi. Clinical trial expenses are not fundable under this mechanism.

b. Budget Justification (1.5 pages): Include a narrative for the following. Use N/A in sections as needed:

i. Personnel

ii. Subcontractors/Subawards/Consultants

iii. Equipment (for equipment costs above $5000)

iv. Travel

v. Computer and Software

vi. Other

3. Biographical Sketch(es): Use the NIH five-page biographical sketch (SF424) format for the principal investigator and all key personnel.

4. Research Plan

a. Resubmissions (1 page, if applicable): If this proposal was previously submitted to ALSF and did not receive funding, describe any changes in response to the reviewer critiques (e.g., changes in experimental design, scope, new data)

b. Specific Aims (1 page): List the goals, long-term objectives and what the specific research proposed in this application is intended to accomplish. State the hypothesis to be tested and relevance to childhood cancer research.

c. Significance (1 page): Describe the relevant background that supports the current research plan. State the significance and importance of your proposed project with respect to childhood cancer research. Relate the specific aims to the goals and long-term objectives. Include potential impact in the clinic for children battling cancer.

d. Innovation (1 page): Describe how the proposed research challenges and shifts paradigms, or introduces a novel concept, approach, or technology and how this could potentially translate to the clinic in the near or long term.
e. **Approach (4 pages):** Describe the experimental approach to the research question and how the research will be realistically accomplished within the proposed funding period. This section must include but is not limited to:

   i. Feasibility of the approach to reach project goals; if available, include PI’s preliminary studies pertinent to the project.
   
   ii. Key milestones with expected outcomes, details of potential problems, and plans to address these issues.
   
   iii. A timeline

f. **Clinical Development Plan (1 page):** An overall clinical development plan for the therapeutic approach must be included with a projected timeline (2-3 years from the end date of the project) for initiating the trial. (Note: This grant does not fund clinical trials.) The plan should include the following:

   i. Description of the proposed trial as it relates to the specific aims of the research plan.
   
   ii. Basic trial design such as expected number of subjects, phase 1 dose finding, formulation, safety, tolerability or pharmacokinetics in the target population.
   
   iii. Description of expected/anticipated pharmacodynamic response endpoints/outcome measures such as biomarker activity.
   
   iv. Additionally, when possible, provide proposed trial locations (single institution, multicenter, consortium) and the source for the therapeutic agent for the study.
   
   v. Projected timeline for the study

5. **Resource Sharing (1-2 pages):** Use the Resource Sharing Form to complete this section of the application to describe the outputs from the proposed project and how they will be shared. Reviewers will be asked to consider the manner in which outputs from this project will be shared and the extent to which this plan will increase or decrease the impact of the proposed project.

6. **Literature Cited (no limit):** Use Vancouver or NIH style (numbered citations within text) format.

7. **Human Subjects (1 page):** If approved, include the IRB approval letter or equivalent. If approval is pending, indicate the expected approval date. If IRB approval is not applicable, include a note in this section.

8. **Vertebrate Animals (1 page):** If approved, include the IACUC approval letter or equivalent. If approval is pending indicate the expected approval date. If IACUC approval is not applicable, include a note in this section.
9. **Letters of Support (no limit):** Include any appropriate letters from individuals confirming their roles in the project. Institutional letters of support are not required but can be included, especially if there are feasibility issues that can be addressed.

10. **Appendix:** No appendices are permitted.

**Application Submission Instructions**

**ALSF has migrated to Proposal Central for submitting and accessing awarded research grant applications!**

1. To start an application, navigate to Proposal Central and select I am an: **Applicant or Awardee**
   a. **Returning applicants (with an existing Proposal Central):** log in with your Proposal Central ID.
      i. A password reset request can be sent using the following link: [https://proposalcentral.com/ForgotPassword.asp](https://proposalcentral.com/ForgotPassword.asp)
   b. **First time applicants (using Proposal Central):** click “Need an Account?” under the Login Button or use the following link: [https://proposalcentral.com/register.asp](https://proposalcentral.com/register.asp). Enter all the required fields and click “Submit.”
   c. **ORCID Registrants:** you can login using your ORCID. If you don’t have one, you can obtain one by registering through the link [https://orcid.org/register](https://orcid.org/register).

2. After you’ve logged in to Proposal Central, navigate to the Grant Opportunities tab and you can search **Alex’s Lemonade Stand Foundation** in the search bar to find our active grant application cycles. Click the “Apply Now” button to start an application.

3. The application document must be uploaded as one PDF (maximum of 20 MB), in the Attachments tab. Please see the guidelines for specific format and section instructions.

4. You may save your application to finish later. Just click “Save”.
   a. When you return to Proposal Central, click the “Proposals” tab at the top to navigate to your applications. You can filter your application based on Proposal Status in the upper right-hand corner. Click “In Progress” to return to your existing applications.
   b. Once completed, click “Submit”. Within 10 minutes you will receive a confirmation email. As long as the deadline has not passed, you may unsubmit your application to make changes by clicking the “Unsubmit” button on the “Proposals” tab.

If you have any questions regarding your Proposal Central account, please contact pcsupport@altum.com.
Contact

If you have any questions regarding the ALSF Reach Grant, please contact Katy Estes-Smargiassi, Grant Coordinator, by email at K.ESmargiassi@alexslemonade.org.