



Application Guidelines for the 2021 Reach Grant

*Application Due: March 22, 2021
before 8:00 p.m. (ET)*



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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 improve the lives of children with cancer by funding impactful research, raising awareness, supporting families, and empowering everyone to help cure childhood cancer.

Reach Grant Program Description

The purpose of the Reach Grant is to advance ALSF's mission to find cures and better treatments for childhood cancers by providing support to move hypothesis-driven research into the clinic. 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 preclinical 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 selected late-translational studies. Preference will be given to those research projects which, if funded, will likely result in the initiation of a clinical trial in two to three years from the start of the project, by, for example, completing IND-enabling studies, providing requisite preclinical 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 overseen by ALSF's Scientific Advisory Board.

APPLICATION TIMELINE

PROPOSALS DUE	March 22, 2021 <u>by 8:00 p.m. (ET)</u>
AWARD NOTIFICATION	August 2021
PROJECTED START/END DATE	November 2021 - November 2023
GRANT DURATION	24 months



Applicant Eligibility

- 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.
- Applicant institutions may be based in the United States or Canada, and applicants need not be United States citizens. Funds must be granted to nonprofit institutions or organizations

Evaluation Criteria

- 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 >21 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, but could fit into other ALSF [funding mechanisms](#).
- Preliminary data are required. The proposal must be hypothesis driven and demonstrate feasibility.
- Explicit timeline and time-based deliverables for the proposed studies must be presented.
- A plan for clinical implementation of the concept and an overall clinical development plan for the therapeutic approach must be included with a projected timeline for completing the trial. (Note: This grant does not fund clinical trials.)

Budget

The requested budget should be in proportion to the scope of the proposed project and should be at or under \$250,000 USD in direct costs over two years. ALSF does not pay indirect costs for this grant program. A maximum of \$125,000 in total costs may be requested per year.

- Restrictions:
 - ALSF adheres to the NIH salary cap for principal investigator(s).
 - Indirect costs are not allowed.
 - Other budget items may include fringe, travel, supplies and small pieces of equipment. ALSF funds cannot be used for tuition remission.
- 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. 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 see the [Resource Sharing Form](#).

Resubmissions

One resubmission of an application previously reviewed by ALSF's 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 accept proposals for research utilizing human embryonic stem cells or non-human primates. Research with human induced pluripotent stem cells is permissible.
- Awards are not renewable.
- Clinical trial expenses are not fundable under this mechanism.
- Applications in psychosocial aspects of pediatric cancer and/or cancer control are not eligible for the Reach Grant.

Grant Reporting Requirements

- Annual progress reports, and 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 year one 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; no cost extensions must 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 at ALSF’s [Information 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

- a. **Cover Page (1 page):** Download and complete the [Cover Page Template](#).
- 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):** Describe the unmet clinical need for pediatric cancer patients and how this project will bridge mechanistic-based work with clinical implementation to meet that need.

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.
 - i. The award amount is up to \$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 sub-contractor, you must include their budget. No indirect costs will be paid to the sub-contractor.
 - b. **Budget Justification (1.5 pages)**
 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 this proposal was previously submitted to ALSF and did not receive funding, describe any changes in response to the reviewer's critique (e.g. changes in experimental design, scope, new data).
 - b. **Specific Aims (1 page):** State the unmet clinical need, the hypotheses to be tested, and the relevance to the care of patients with pediatric cancer. Of particular importance, describe how the work performed will allow for the translation of hypothesis-driven research to the clinic.
 - c. **Research Strategy**
 - i. **Significance (1 page):** Describe the relevant clinical and scientific background that supports the current research plan. Explicitly state the scientific finding to be translated to the clinic and what the potential clinical impact will be for pediatric oncology patients.
 - ii. **Innovation (1 page):** Describe how the proposed research allows for an innovative concept to be translated to the clinic. In particular, describe the barriers to clinical translation of the concept, and explain how the proposed work will overcome these barriers.
 - iii. **Approach (4 pages):** Describe the overall strategy to accomplish the aims of the project. Describe methodology, analyses, and how the research aims will be realistically accomplished within the proposed funding period. Provide an account of the investigators' preliminary studies pertinent to the application. Anticipation of potential problems and plans to deal with these is expected. Finally, explicitly state the deliverables that will be generated, and the anticipated time frame for each deliverable.
 - iv. **Plan for clinical implementation, testing, and trial (0.5 page):** Describe the plan for clinical implementation of the concept and overall clinical development for the therapeutic approach. A timeline must be included. Note IND status in this section.



5. **Resource Sharing (1 page):** 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. Use the [Resource Sharing Form](#) to complete this section of the application.
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. Any funds awarded will be held until the letter is received. 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. Any funds awarded will be held until the letter is received. 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 issues of feasibility that can be addressed.
10. **Multiple Investigator Plan (0.5 page):** Designate one investigator as the primary contact. Describe the contribution, role, and responsibility of each investigator.
11. **Appendix:** No appendices are permitted.

Application Submission Instructions

Applicants must not use the IE browser as it is not compatible with the online portal. Chrome and Firefox browsers are recommended.

1. To start an application, navigate to the portal at ALSApps.force.com.
 - a. Returning applicants: login with your username and password.
 - b. First time applicants: click the “New User?” link and complete your one-time registration and then login.
2. After you’ve logged in, follow the directions on the dashboard to submit your application. Complete the online form with applicant contact and project information.
 - a. Enter the Project Title first, even if tentative. Then Save.
 - b. Applicant will be asked for basic contact information for themselves, co-PI(s) if applicable, grant manager and institution. If someone other than the PI is entering information into the portal, the “Contact Person” name entered **must** be the PI’s name.

In the respective sections enter the project title, budget request amount, type of



childhood cancer the project focuses on, as well as a 250-word summary of the research project in lay terms. The applicant will be asked to release this summary for use at ALSF's discretion should the proposal be funded. The applicant may copy and paste information from other documents into these sections.

3. The application document must be uploaded as **one PDF** (maximum of 20 MB).
4. You may save your application to finish later. Go to ALSFapps.force.com and login again. You will land on your dashboard. Click "Applications" to edit your application in progress.
5. Once completed, submit the application by clicking Review & Submit. You will see error messages for any required fields that need to be completed.
6. After your application has been successfully submitted, an email confirmation will be sent. You will not be able to amend the application after submission.

Contact

- If you have any questions regarding the ALSF Reach Grant, please contact Judy Oliver, Sr. Grants Coordinator, at 856-408-3995 or by email at J.Oliver@alexslimonade.org.