

2018 Application Guidelines for Reach Grants Due May 21, 2018

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Alex's Lemonade Stand Foundation (ALSF) evolved from the front yard lemonade stand of cancer patient Alexandra "Alex" Scott (1996-2004) into a national fundraising movement to raise awareness and find cures for all childhood cancers.

Reach Grants are designed to move hypothesis-driven research into the clinic. The \$250,000, two year grant is intended to fund developmental therapeutic studies in the late stage of preclinical testing. A successful application will identify an unmet clinical need relevant to the care of pediatric patients with cancer and describe how the work performed will allow for the translation to the clinic within two years of completion. A plan and timeline for clinical testing and trial implementation is expected. This grant does not fund clinical trial expenses.

Contact: Kay Schaul 111 Presidential Blvd. Suite 203 ◊ Bala Cynwyd, PA 19096 (866) 333-1213 ALSFgrants.org Grants@AlexsLemonade.org

Revised 2018

Reach Grants

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 two to three years from the start of the project.

Applicant Eligibility Criteria

- Applicants may be Assistant, Associate or Professor level investigators who demonstrate a track record of discovery, investigation and external funding.
- Applicants must be M.D., D.O., Ph.D, or M.D./Ph.D.
- 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.

Proposal 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 more appropriate for 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.)
- We encourage you to contact ALSF if you have any questions about the appropriateness of your research ideas for this funding mechanism via <u>Grants@AlexsLemonade.org</u>

Budget Guidelines

A maximum of \$125,000 in total costs may be requested per year.

- Principal Investigator/Co-Investigator(s) salary may be requested up to 10% of grant per principal investigator (PI/co-PIs) per year (or \$12,500).
- For other key personnel, please adhere to the NIH salary cap. Other budget items may include fringe, travel, supplies and small pieces of equipment (less than \$5000).
- A detailed budget and justification is required using the form provided on the ALSF website (see Instruction box pg. 4).
- A maximum of two years of funding may be requested.
- ALSF does not pay indirect costs this includes budgets for subcontracts or consultants.
- Principal Investigator's institution is responsible to disburse funds for subcontracts or consultants.

Funds will be granted to non-profit institutions or organizations operating in the United States or Canada. Primary Investigator(s) need not be U.S. citizens.

<u>Restrictions</u>: Please contact us at <u>Grants@AlexsLemonade.org</u> if you have questions about these restrictions.

- Current Reach Grant recipients are not eligible for funding of related work.
- Clinical trial expenses are not fundable under this mechanism.

- ALSF funds cannot be used for research utilizing human embryonic stem cells or non-human primates.
- Indirect costs are not allowed.
- Awards are not renewable.
- One resubmission of an application previously reviewed by ALSF's Review Board is permitted.
- Applications in psychosocial aspects of pediatric cancer and/or cancer control are not eligible for the Reach Grant.
- Applications not following the guidelines will be administratively rejected.
- No appendices are permitted.

<u>Application Review Process</u>: Grants will be reviewed by an independent panel of experts according to the NIH recognized peer-review process and overseen by ALSF's Scientific Advisory Board. Applicants will receive comments from the review after decision notification.

<u>Resubmissions</u>: Please use the Resubmission section of the application outline to respond to the prior ALSF critique of the proposal. The response will be scored in the review process in addition to the criteria used for new applications. Resubmissions compete with new applicants for funding.

Required Reports

- Progress Report: A second year of funding is contingent upon a non-competitive review of a report which demonstrates satisfactory progress toward proposed research objectives and appropriate budget expenditures.
 - Carryover of unused funding may be requested in the progress report with appropriate progress and justification.
 - ALSF may elect to partially fund or to hold new funds if year one carry-over is excessive.
- Final Report: At the conclusion of funding the PI will submit a report of results and expenditures. No cost extensions may be requested in the report.
- Publications: Please acknowledge "Alex's Lemonade Stand Foundation" in publications and presentations based on the funded project. PDFs of the publications should be emailed to <u>Grants@AlexsLemonade.org</u>.

Important Dates

All Reach Award applications must be received by May 21, 2018 - 11:59 PM ET.

Application Due Date	May 21, 2018 (11:59 PM EASTERN TIME)
Award Notification	October/November 2018
Project Start/End	February 1, 2019/January 31, 2021
Progress Report	January 15, 2020
Final Report	March 1, 2021

Reach Grants are not eligible for renewal.

Application

Submission

All applications must be submitted using ALSF's online portal (ALSFapps.force.com). A one-time registration is required to create a user account. Please use a browser other than IE if possible, for the best result! Thereafter, you will login to submit an application form and upload the required PDF. Please see page 6 for details.

Part I: Online Form

A. Contact Information

Provide contact details for the Principal Investigator, Co-Principal Investigator (if applicable) and institution. In addition, applicants are asked to add a contact for the grant management.

B. Project Details and Lay Summary

Specify the project title, request amount, human and animal subject requirements, area of study and type(s) of childhood cancer to be investigated. A 250 word summary of the research project in <u>everyday terms</u> is required. The Lay Summary may be copied and pasted into this section. ALSF requests release of the summary for use, at ALSF's discretion, should the proposal be funded.

Part II: Application Outline

FORMAT INSTRUCTIONS:

- o All sections should be combined into one PDF (maximum of 10 MB) and uploaded to the ALSF online form.
- o All templates mentioned are available at <u>www.alexslemonade.org/grants/guidelines</u>
- 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.
- Please follow NIH font guidelines: Arial, Helvetica, Palatino Linotype or Georgia fonts with a font size of 11 points or larger with a minimum of half inch margins.
- Please adhere to the order of the application and the page maximums indicated for each subsection.
- Appendices are not allowed.
- A. Cover Page (1 page): Use the document provided on the ALSF website noted above.
- **B.** Table of Contents (1 page): Please provide a Table of Contents with page numbers to the corresponding sections.

C. Project Information

- 1. Scientific Abstract (1/2 page): Please summarize the research objectives and rationale.
- 2. Overall Impact Statement (1/2 page): Describe the unmet clinical need for pediatric cancer patients and how this project will bridge mechanistic-based work will bridge with clinical implementation to meet that need.
- **3. Budget/Justification:** Use ALSF's Standard Budget template. The signature from an institutional representative on the cover page of the grant application accepts the provision that no indirect costs will be paid. Justification may be added to the template or here. Incorporate the template in the document.
- **4. Biographical Sketch(es):** Use the NIH five page biographical sketch format for the principal investigator and co-investigator(s) or collaborators.

D. Research Plan

1. **Resubmissions (1 page):** If this proposal was previously submitted to ALSF and did not receive funding, please describe any changes in response to the reviewer's critique (e.g. changes in experimental design, scope, new data)

- 2. Specific Aims (1 page): State the unmet clinical need, the hypotheses to be tested, and its 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.
- 3. 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 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 (1/2 page):** Describe plan for clinical implementation of the concept and overall clinical development for the therapeutic approach. A timeline <u>must</u> be included. If applicable, note IND status.
- **4. Human Subjects:** Include IRB approval letter. Please note if IRB is not applicable or if letter is pending. Funds awarded will be held until letter is received.
- 5. Vertebrate Animals: Include IACUC approval letter. Please note if letter is not applicable or if approval is pending. Funding will be held until approval letter is received.
- 6. Literature Cited: A maximum of 30 references are allowed. Please use Vancouver format (numbered consecutively in order of appearance in the text).
- 7. Collaborators and/or Consultants: Include letters from any appropriate individuals confirming their roles in the project. Include expenses in your budget.
- 8. Multiple Investigator Plan (1/2 page): Designate one investigator as the primary contact. Describe the contribution, role, and responsibility of each investigator.

Application Submission

All requests must be submitted using ALSF's online application.

- 1. Go to <u>ALSFgrants.org</u> and click the "Information for grant applicants" button.
- 2. Under "Resources for Applicants," download the Cover Page and Budget forms.
- 3. To start an online application, Click "Get Started" to access the portal. If you are new to ALSF's portal, here is a <u>step-by-step guide</u> with screen shots!
 - Returning users- login with your username and password.
 - First time applicants: click the "New User?" link and complete your one-time registration and then log in.

4. After you've logged in at <u>ALSFapps.force.com</u>, select the grant you wish to submit. Complete the online form with contact and project information.

- <u>Upload</u> the application document as <u>one PDF</u> (maximum of 20 MB) see format guidelines on previous pages
- <u>Review & Submit</u> or <u>Save</u> your application and return at a later time to continue working.

5. To continue a saved application, return to <u>ALSFapps.force.com</u> and log in.

- You will land on your dashboard. Click "Applications" to edit your application in progress.
- Complete the form and upload the PDF

6. To submit, click <u>Review & Submit</u>. Once you have looked over the form, click Submit. You will see error messages for any required fields that need to be completed.

- 7. After your application has been successfully submitted an *email confirmation will be sent*. You will not be able to amend the application after submission.
- 8. Make sure your Profile contact information is correct while on your dashboard!

Questions? Please contact Kay Schaul at 866-333-1213 or Grants@AlexsLemonade.org