2016 Application Guidelines for Reach Grants

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- Application Outline and Format: pages 4, 5
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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 toward the clinic. This 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 patients with pediatric cancer and describe how the work performed will allow for the translation to the clinic within a few years of completion. A plan and timeline for clinical testing and implementation is expected, however, this grant does not fund clinical trial infrastructure expenses.

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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 pre-clinical 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 needed to initiate a clinical trial. 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.

Eligibility Criteria
- Primary 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.

Evaluation Criteria
- Proposals must fall within the scope of Alex’s Lemonade Stand Foundation’s mission, focused on childhood cancers, in order to be considered.
- Preliminary data are required and the proposal must be hypothesis driven and demonstrate feasibility.
- Explicit time-based deliverables must be outlined.
- A plan for clinical implementation of the concept and an overall clinical development plan for the therapeutic approach must be included with projected timeline.
- We encourage you to contact ALSF if you have any questions about the appropriateness of your research ideas for this funding mechanism via Grants@AlexsLemonade.org

Budget Guidelines
Maximum of $125,000 in total costs may be requested per year. Principal Investigator(s) salary may be requested up to 10% of grant per principal investigator (PI/co-PIs) per year, for all other 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.

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

Restrictions
- Current Reach Grant recipients are not eligible for funding of related work.
- Clinical trial infrastructure expenses are not fundable under this mechanism.
- Indirect costs are not covered.
- Awards are not renewable.
- 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.
Application Review Process: 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.

Resubmissions: Please use the Resubmission section of the application outline to respond to prior critique. ALSF will score the response to prior critique 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 Grants@AlexsLemonade.org.
Grant Application

All applications must be submitted using ALSF’s online submission process. Applicants must complete the online form and upload the application in one PDF (max 10 MB). Please follow the instructions on page 6.

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 submit contacts for accounts payable, grants management and media or public relations should the project be funded.

B. Project Overview and Layman’s Summary
Specify the project title, request amount, human and animal subject requirements, area of study and type of childhood cancer to be investigated. A 250 word summary of the research project in layman’s terms is required. The Layman’s Summary will be formatted automatically; text 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

INSTRUCTIONS:
- All sections should be combined into one PDF (maximum of 10 MB) and uploaded to the ALSF online form.
- All templates mentioned are available at www.alexslemonade.org/grants/guidelines
- 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 maximum number of pages 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 with ultimate clinical implementation that will 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.
   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 the application 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. Also describe the future plan for clinical implementation.
   
   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, or trial (1/2 page):** Describe plan for clinical implementation of the concept and overall clinical development for the therapeutic approach. A timeline must be included.

4. **Human Subjects (1/2 page):** Include IRB approval letter. Please note if letter is not applicable or if letter is pending. Funds awarded will be held until letter is received. Include IND# or status if applicable.

5. **Vertebrate Animals (1/2 page):** Include IACUC approval letter. Please note if letter is not applicable or if letter 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.

8. **Multiple Investigator Plan (1/2 page):** Designate one investigator as the primary contact. Describe the contribution, role, and responsibility of each investigator.
Important Dates

All Reach Award applications must be received by May 27, 2016 - 11:59 PM ET.

<table>
<thead>
<tr>
<th>Important Dates</th>
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<tbody>
<tr>
<td>Application Due Date</td>
<td>May 27, 2016 (11:59 PM EASTERN TIME)</td>
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<tr>
<td>Award Notification</td>
<td>October/November 2016</td>
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<tr>
<td>Project Start/End</td>
<td>February 1, 2017/January 31, 2019</td>
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<tr>
<td>Progress Report</td>
<td>January 2, 2018</td>
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<tr>
<td>Final Report</td>
<td>March 1, 2019</td>
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Awards are not eligible for renewal.

Application Submission

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

1. Go to ALSFgrants.org 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, under “Get Started/Start a New Application” click the drop down arrow and select the Reach Grant application link.
   - Returning users- login with your email address and password;
   - New users- click New Applicant link to set up an account with email address and password.
4. Complete the online form with contact and project information
   - Upload application as one PDF (maximum of 10 MB) – see format guidelines on previous pages
   - Review & Submit or Save your application and return at a later time to continue working
5. To continue your saved application, go to ALSFgrants.org and click the “Information for grant applicants” button
   - Under “Get Started/Continue a saved application or manage applications,” click the orange LOGIN button.
   - Click the application name link on the “In Progress” list
   - Complete the form and upload the PDF
   - Clicking Review & Submit will send the application to ALSF
6. After your application has been successfully submitted an email confirmation will be sent to your user account login email address. You will not be able to amend the application.

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