



2015 Application Guidelines for Phase I/II Infrastructure Grant

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Alex's Lemonade Stand Foundation evolved from a young cancer patient's front yard lemonade stand to a national foundation for childhood cancer.

Alex's Lemonade Stand Foundation Grant Program is committed to eradicating childhood cancer through basic research, career development and helping to streamline translational clinical research.

Alex's Lemonade Stand Foundation

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Overview

Description:

The Infrastructure Grant is a five year award of up to \$625,000 designed to support pediatric oncology Phase I and II clinical trials by funding infrastructure necessary to conduct these important studies. The aim of the grant is to help institutions build the capacity of their Phase I and II programs over a five year period. To help ensure sustainability of a successful program beyond year five, ALSF offers a year to year grant extension. Funds raised by the institution can be matched by ALSF from \$25,000 up to \$62,500 for an additional five years (see details below).

It is expected that applications will be submitted by seasoned translational/clinical scientists and will stimulate and catalyze early phase clinical trial research efforts at their institution. Unlike traditional granting mechanisms to individuals for their research efforts, these grants will be made to institutions that demonstrate a commitment to conducting early phase clinical trials. Applicants must document a need for clinical research support.

It is expected that proposals will come from outstanding pediatric cancer centers that have a strong track record of participation in Phase I and II clinical trials. The grants are to be used to enhance existing clinical trial infrastructure with the specific aim of increasing patient accrual to early phase trials. Thus, the overall goal of this granting mechanism is to increase accrual of Phase I and II studies that would not otherwise be possible. Applicants must prepare a table of expected trials and enrollment targets. Annual renewal of funding is dependent on progressive, yearly increase in the number of patients screened for/and placed on Phase I and II trials.

These grants will fund personnel who are critical to accomplishing the research mission of delivering new drugs to children with cancer including research nurses, clinical research assistants, data managers or nurse practitioners. Funds may be used for a maximum of \$25,000 for critical equipment with appropriate documentation of the role it will play in the conduct or support of the clinical trial. Funds may be used for a maximum of \$15,000 per year, to cover a physician's salary or fringe.

Eligibility:

- Applications should originate from outstanding pediatric cancer centers with a strong track record of participation in Phase I and II clinical trials.
- The Principal Investigator (PI) or Co-PIs of the grant must demonstrate a track record in conducting early phase clinical research studies.
- Institutions that have completed an ALSF Infrastructure grant prior to 2013 may apply.

Restrictions:

- Phase I/II Infrastructure applications will be limited to one per institution.
- ALSF will not consider applications from institutions that have been awarded an ALSF Center of Excellence Grant or a Phase I/II Infrastructure Grant (2013 or later).
- Established clinical trial consortia are not eligible to apply for this grant, however, institutions participating in such consortia may apply.
- Funds will be granted to institutions or organizations with charitable tax status (501c3 or equivalent) which operate in the United States or Canada. Researchers need not be U.S. citizens.

Budget:

Maximum \$125,000 in total costs will be awarded to applicants annually; up to five years of funding may be requested. A detailed budget and justification is required using the five year budget form provided on the ALSF website (see page 6 for instructions). Funds may not be used for indirect costs.

Extended funding option after the initial five years: ALSF will match funds, to continue the program aims, raised by the institution from \$25,000 to \$62,500 annually for up to an additional five years. The extended

funding is available provided program goals and accrual numbers are being achieved and the institution raises a minimum of \$25,000 annually. The grant extension must be requested each year. If the minimum is not raised by the institution, the grant extension option will end. *A request to match institutional funds raised must be received in Year 4 Progress Report and subsequent reports if applicable.*

Review Process:

- Proposals must fall within the scope of the Alex's Lemonade Stand Foundation mission and purpose for this grant in order to be considered.
- 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.
- Detailed strategy for recruitment to increase enrollment and enumerated accrual targets are critical to a successful application.

Reporting:

- Progress Reports: Annual funding after the first year is contingent upon the review of progress reports which must demonstrate increase in accrual numbers and open trials, as proposed in the application.
 - Budget expenditures must be appropriate.
 - Carry-over will be evaluated in the progress report review. ALSF may elect to partially fund or to hold new funds if carry-over is excessive.
- Final report is required at the conclusion of funding.
- Publications and presentations resulting from funding should be emailed to Grants@AlexsLemonade.org

Application

All applications must be submitted using ALSF's two part online submission process. Applicants must first complete the online form then upload the application in one pdf (max 10 MB).

Part I: Online Form

A. Contact Information: Applicant will be asked for basic contact information for themselves and their institution and other key contacts, should the project be funded.

B. Project Overview and Layman's Summary: The applicant will complete project title, request amount, type of childhood cancer(s) being studied as well as a 250 words summary of the research project in layman's terms. (You will be asked to release this summary for use at ALSF's discretion should proposal be funded.) Text may be copied into these sections.

Part II: Application Outline

- All sections described below should be combined into one pdf (max 10 MB) and uploaded to the ALSF online form.
- All templates mentioned can be found at ALSFgrants.org, [click](#) Information for Applicants. They are also accessible while filling out the online portion of the application by clicking Forms and Guidelines download button at the top right of the page.
- 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 formatting guidelines: Arial, Helvetica, Palatino Linotype, or Georgia fonts with a font size of 11 points or larger and a minimum of ½ inch margins.
- The order of the application should be as follows, adhering to the maximum number of pages allowed for each subsection indicated in parentheses.

A. Cover Page (1 page) Use the document provided on the ALSF website (link above).

B. Table of Contents (1 page) Please provide a Table of Contents with page numbers to the corresponding sections.

C. Project Information

1. **Impact Statement (1/2 page)** How will this grant build the capacity for Phase I and II programs over the five year period and impact pediatric cancer patients?
2. **Scientific Abstract (1/2 page)** Please include a summary of the research objectives and rationale.
3. **Budget & Justification (3 pages)** Use the Five Year Budget template found on the ALSF website. No indirect costs will be paid. The signature from an institutional representative on the cover page of the grant application specifically acknowledges and accepts this provision.
4. **Biographical Sketch (4 pages per biosketch)** Use the NIH five page biographical sketch format for the principal investigator, co-PI and any key personnel.
5. **Project Details**
 - i. **Environment (2 pages):** Describe your institution and, if applicable, collaborating institutions. Please include:
 - Involvement in clinical/translational research for childhood cancer over the last five years and current infrastructure for clinical trials
 - Number of patients enrolled per year for the last five years

- Number of Phase I and Phase II trials open per year for the last five years
- Number of newly diagnosed pediatric cancer patients per year

ii. **Program Details (5 pages)**

Describe the program goals and the infrastructure you are requesting to meet these goals. Provide rationale for the request. Please include:

- Detailed strategy to reach pediatric accrual targets
- Staffing requirements to open/run trial(s)
- Detailed timeline for the trial(s)
- Cost analysis
- IRB & FDA approvals
- Planned Enrollment Table - summarize each trial (and planned trial) with target enrollment completing years one to three. (If funded, annual reports require an updated table with actual data.) Download the template from ALSFgrants.org (see page 6 for instructions). Place the table in the Appendix section. Example:

	Year 1			Year 2			Year 3		
Protocols	Target	Screened	Enrolled	Target	Screened	Enrolled	Target	Screened	Enrolled
Staffing Increases									

Table Instructions:

Protocols: existing and planned consortium and investigator initiated trials to be supported by grant; add rows as needed

Target: pediatric enrollment expected

Screened/Enrolled: update for in-progress or completed pediatric trials

Staffing: name of position(s) add rows for each type of position to be added

- iii. **Long Range Plan (half page)** Describe the long term vision for this program, beyond the five year period of ALSF funding.
- iv. **Resubmission (2 pages – if applicable)** If this proposal was previously submitted and did not receive funding please highlight any changes to the application and respond to the critique.
- v. **Literature Cited** A maximum of 30 references are allowed. Please use Vancouver Format (in text numbered references).
- vi. **Collaborators and/or Consultants** Include appropriate letters from all individuals confirming their roles in the project.

D. Appendix

- Planned Enrollment Table
- Appendices should be included only if essential to the understanding of the application and are limited to one accepted but not yet published manuscript or two pages of additional information and figures.
- Excessive appendices will cause the application to be rejected administratively.

Important Dates

Application Due Date	April 10, 2015 (11:59 PM ET)
Award Notification Date	Late May 2015
Project Start Date	July 1, 2015
Year 1 Progress Report	June 1, 2016 (estimate expenses through year end)
Year 2 Progress Report	June 1, 2017 (estimate expenses through year end)
Year 3 Progress Report	June 1, 2018 (estimate expenses through year end)
Year 4 Progress Report	June 3, 2019 (estimate expenses through year end) Extension Option: Request for matching funds (to start Year 6)
Final Report	August 3, 2020 (depending on the extension option)

Submitting Your Application

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, Forms** section, download the Cover Page, Phase I_II Enrollment Template and Five Year Budget forms.
3. To start an online application, under **Get Started/Start a New Application** click the drop down arrow and select the Phase I/II Infrastructure Grant 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 following 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
 - 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.

Please contact Kay Schaul at 610-649-3034 if you have any questions about your grant application and submission or email questions to Grants@AlexsLemonade.org