2014 Application Guidelines for BIO-THERAPEUTICS IMPACT AWARD

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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.

Bio-Therapeutics Impact Awards fund investigator initiated biological clinical trials and are designed to fill a high impact funding niche by providing support to implement effective clinical trials of biologics developed to treat childhood cancers.

Alex’s Lemonade Stand Foundation
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ALSFgrants.org

Contact:
Grants Specialist, Kay Schaul
Grants@AlexsLemonade.org
Overview

Description:
The ALSF Bio-Therapeutics Impact award provides funding to support investigator-initiated clinical trials using biologic therapies, including but not limited to immunotherapy, gene therapy and small molecules. This grant category was initiated to accelerate the development of clinical trials for promising biologic approaches to treat childhood cancers through clinical trials.

ALSF’s Travel Fund is available to patients enrolled in the clinical trials supported by the Bio-Therapeutics Impact Award. Transportation, lodging, and meal accommodations are available to eligible families who meet our criteria as listed in the Travel Fund guidelines. A medical representative can apply on behalf of the family using our online form; you must specify the clinical trial and that it is funded by ALSF’s Bio-Therapeutics Impact Award.

This funding opportunity includes support for the following:

1.) Clinical trials in which all pre-clinical studies have been completed, an IND has been approved and funding is needed to conduct and complete the clinical trial.

Researcher Eligibility:
1. Completed pre–clinical study for childhood cancer and are holding an approved IND.
2. A demonstrated track record of implementing novel biologic therapies.
3. Experience with executing and completing clinical trials with a history of meeting projected accrual targets in a timely manner.
4. A well-defined plan that will complete trial enrollment within 2 years of initiation.
5. Individual Investigator may be working within a consortium.

2.) Pre-clinical funding available for investigators who need to perform IND enabling studies. Subsequent funding of the trial will be contingent upon first obtaining all necessary regulatory approvals.

Researcher Eligibility:
1. Completing pre–clinical study for childhood cancer or have submitted an IND and are awaiting approval. Please include in your budget justifications how you will spend $100,000 (Year 1); once IND is approved the remainder of funds will be released (see budget section).
2. A demonstrated track record of implementing biologic therapies.
3. Experience executing and completing clinical trials that meet projected accrual targets in a timely manner.
4. A well-defined plan that will complete IND submission and approval within 1 year and trial enrollment within two years of initiation. Second year of funding will be contingent on Food and Drug Administration (FDA) approval of the IND.
5. Individual Investigator may be working within a consortium.
**Restrictions:**
- Industry sponsored clinical trials are not eligible.
- Funds will be granted to non-profit institutions or organizations operating in the United States or Canada. Principal Investigators need not be U.S. citizens.

**Budget:**
Maximum of $1.5 million in total costs will be awarded over three years ($500K per year for three years).

If applying for pre-clinical funding to perform IND enabling studies or have submitted an IND and are awaiting approval, funding will be capped at $100K (Year 1) and the balance for the clinical trial initiation will be released after the IND is approved.

A detailed budget and justification is required using the downloadable Standard Budget form provided on the ALSF website (ALSFgrants.org). Funds may not be used for indirect costs.

Budget items may include:
- Personnel salary; ALSF follows the NIH salary cap restrictions
- Clinical trial operations including per patient billing for research costs
- Coorelative research laboratory studies
- Equipment: must justify why this is essential to the project (maximum of $250K over three years)
- Travel for research personnel; must justify travel costs for protocol management/oversight and/or presenting results at scientific meetings

**Review Process:**
- Proposals must fall within the scope of ALSF’s mission for this grant to be considered.
- Applications will be reviewed by a panel of experts in pediatric cancer drug development with an emphasis on biologic therapies according to the NIH recognized peer-review process. The review process will be overseen by ALSF’s Scientific Advisory Board.

**Progress Reporting:**
- Annual funding after the first year is contingent upon the review of progress reports which must demonstrate satisfactory progress toward proposed objectives particularly targets for patient accrual goals. Budget expenditures must be appropriate.
- Must submit a letter of confirmation from your institution along with a copy of the IND approval from the FDA for clinical trial to ALSF before funding is released.
- A final report is required at the conclusion of funding.
**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, their institution and other key personnel.

**B. Project Overview and Layman’s Summary**
Applicants must fill in their project title, requested amount, type of childhood cancer(s) being studied as well as provide a 250 word 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 on the Guidelines and Submission page of the ALSF website: ALSFgrants.org. 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 project 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 Standard 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 PHS 398 four page biographical sketch format for the principal investigator and any key personnel.

5. Project Details
   i. Research Plan (5 pages)
      Describe the project’s research goals and the infrastructure you are requesting to meet these goals. Provide rationale for the request. Please include:
      • Background and Rationale
      • Preliminary Data
      • Experimental Design - describe the clinical trial and you must include:
        o Target enrollment for trial (per year)
        o Staffing requirements to open/run trial
        o Cost analysis
        o IRB & IND approval plans (please include IND confirmation if already approved)
        o Detailed statistical plan
      • Potential Problems and Alternative Methods
   ii. Environment (2 pages): Describe your institution and, if applicable, collaborating institutions. Please include:
      • An explanation that documents your institutions infrastructure and how it will provide support to perform clinical trials using biologic therapies.
      • Institutions involvement in clinical/translational research for childhood cancer over the last 5 years and current infrastructure for clinical trials.
      • # of patients enrolled per year for the last 5 years on Phase I and II Trials.
      • # of Phase I and # of Phase II trials open per year for the last 5 years.
      • # of newly diagnosed pediatric cancer patients per year at your institution
   iii. Long Range Plan (half page)
      Describe the long term vision for this trial, beyond the 3 year period of ALSF funding.
   iv. Literature Cited
      Please use Vancouver Format (in text numbered references).
   v. Collaborators and/or Consultants
      Include appropriate letters here from all individuals confirming their roles in the project.

D. Appendix
   • Include the most current copy of the clinical trial documentation, e.g.; Full protocol, protocol draft, concept or letter of intent, etc.
• Additional 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

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<thead>
<tr>
<th>Important Dates</th>
<th>Dates</th>
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<tbody>
<tr>
<td>Application Due Date</td>
<td>June 12, 2014 (11:59 PM ET)</td>
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<tr>
<td>Award Notification Date</td>
<td>September 2014</td>
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<tr>
<td>Project Start Date</td>
<td>October 1, 2014</td>
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<tr>
<td>Year 1 Progress Report</td>
<td>October 1, 2015</td>
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<tr>
<td>Year 2 Progress Report</td>
<td>October 1, 2016</td>
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<tr>
<td>Final Report</td>
<td>December 1, 2017</td>
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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”, 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 Bio-Therapeutics Impact Award 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 name of the application 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