ALSF Centers of Excellence
Mission of the Centers of Excellence Award Program

Alex’s Lemonade Stand Foundation’s Centers of Excellence (COE) program will fund selected leading childhood cancer institutions with programs committed to developing and conducting early phase clinical trials for childhood cancer. The purpose of this initiative is to enhance the resources and infrastructure available at these Centers of Excellence sites to more optimally 1) facilitate the evolution of new therapeutic concepts from the pre-clinical arena into fully developed clinical trials, 2) rapidly and efficiently conduct phase I and phase II trials of highly innovative therapies, and 3) train individuals in the field of developmental therapeutics and cancer pharmacology. Although it is understood that ALSF Centers of Excellence will likely be members of existing clinical trial groups or consortia, the COE members agree to collaborate with each other on selected clinical trials.

The ultimate goals of this ALSF Award are to expedite the development of novel therapeutic approaches for pediatric malignancies by establishing more robust Centers of Excellence in pediatric cancer drug development and through training the next generation of leaders in preclinical and clinical drug development.

Background

ALSF recognizes that while a large number of centers throughout the U.S. are capable of participating in phase I and phase II studies, there are a smaller number of centers that have the capacity, resources and commitment to make more significant contributions to the development of novel therapies and to train individuals focused on pediatric cancer developmental therapeutics. These centers have developed relatively substantive developmental therapeutics programs despite a general lack of federal funding in this area. Given the current economic stresses on the healthcare environment, however, these institutions are less able to invest in continuing to build and support their clinical developmental therapeutic programs. These circumstances threaten the ability of investigators in the field of pediatric oncology to develop new treatments aimed at the rapidly increasing number of therapeutic targets that are being identified in childhood cancers. In addition, little money is available to train individuals with expertise in the field of pediatric cancer developmental therapeutics. The intention of this Centers of Excellence Award is to sustain and enhance the infrastructure available in the country’s leading pediatric cancer developmental therapeutics programs to ensure that the development of new agents for pediatric malignancies is enhanced over the coming years and that the next generation of experts in pediatric cancer developmental therapeutics is appropriately trained to effectively and efficiently execute this mission.
ALSF Centers of Excellence
Award Specifics

- A nomination form must be submitted for review to establish eligibility. The form and submission instructions are available through ALSFgrants.org, Guidelines and Submissions.
- An invitation to submit a full application is contingent upon eligibility review.
- COE grant awards will be for $350,000 per year, renewable annually for up to 5 years.
- Funds must be used in the following manner:
  - 50% of the funds must be used to enhance the awardee’s clinical trial infrastructure. These funds can be used to support clinical research assistants, protocol coordinators, nurse practitioners, research nurses, etc.
  - The remaining 50% of funds will be used to support the training of physician scholars in drug development. These individuals should be pediatric oncology fellows in their second or third year of training or board eligible or certified pediatric oncologists within 10 years from completion of their fellowship training, who are committed to and will be participants in a formal developmental therapeutics and/or cancer pharmacology training program.
  - These individuals will be named ALSF Scholars in Developmental Therapeutics and the institutions will be named ALSF Centers of Excellence.
ALSF Centers of Excellence Eligibility

Program/Institution must have:

1. A significant number of new pediatric cancer Phase I diagnoses per year (i.e. minimum 15).

2. A history of conducting Pediatric Oncology Phase I and Phase II trials within cooperative groups or Phase I or Phase II clinical trial consortia; a willingness to collaborate with other institutions by participating in select clinical trials with other ALSF COEs.

3. Formal membership in one or more pediatric oncology consortium.

4. A history of multiple publications in pediatric oncology developmental therapeutics/Phase I/II studies.

5. A Developmental Therapeutics (Phase I /Phase II) Program that includes pre-clinical, translational and clinical components.

6. A formal mechanism for training pediatric oncology fellows and/or Board Eligible or Certified Pediatric Oncologists in Developmental Therapeutics and/or clinical pharmacology. This requires a defined curriculum that includes didactic, laboratory and clinical research elements. The curriculum must include training in design and conduct of Phase I and Phase II trials, bio-statistics, research ethics, principles of clinical pharmacology, and provide experience serving on protocol review committees or participation in IRB activities.

7. Applicants may use Developmental Therapeutics/Clinical Pharmacology curricula that are oriented to train adult oncologist but must show how curriculum will be modified to address specific issues in pediatric oncology.

8. Faculty members with experience in pediatric oncology developmental therapeutics who are able to serve as mentors for ALSF Research Scholars in Developmental Therapeutics.

9. Physician Scholar(s) identified who are candidates for the ALSF Research Scholar in Developmental Therapeutics who meet the following criteria:
   o Pediatric Oncology Fellow in their second or third year of training, or Board eligible or certified pediatric oncologists within 10 years from completion of their fellowship training.
   o Committed to participating and completing a formal developmental therapeutics/or clinical pharmacology training program.
   o Individuals must not have other mentored career development awards, including but not limited to NIH K12 or private foundation.
ALSF Centers of Excellence
Application

I. Cover Sheet (ALSF template)

II. COE Summary Overview (ALSF template)

III. Budget (ALSF template)

IV. Impact Statement (1/2 page)
   How with this funding help impact pediatric cancer patients?

V. Infrastructure Support (5 pages)
   Half of the funds must be used for infrastructure support to stimulate and catalyze early phase clinical trial research efforts. Therefore, funds can be used to support individuals 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 partially used for critical equipment with appropriate documentation of the role it will play in conduct or support of the clinical trial.

   Provide a description of the infrastructure you are requesting and rationale for the request.

VI. Physician Scholars Training
   Half of the funds must be used to support the training of one or more physician scholars in drug development. These individuals will be designated Alex's Lemonade Stand Foundation Research Scholars in Developmental Therapeutics. The potential scholar(s) must be identified, and their CVs submitted, at the time of application. Scholar(s) must be:
   - Pediatric oncology fellows in their second or third year of training or board eligible or certified pediatric oncologists within 10 years from completion of their fellowship training.
   - Committed to and participants in a formal developmental therapeutics/ or cancer pharmacology training program.

   a. BioSketches
      Include the NIH 4 page BioSketches for the Scholar(s) and Mentor(s).

   b. Scholar(s) Training Plan (2 pages each)
      Please include a detailed plan of how the scholar(s) will be mentored during this program. Describe career development strategies, continued education, and plans for obtaining future research funding. Include a letter of recommendation from their
mentor(s). Include a separate plan and letter for each scholar this grant would support.

c. Outline of Scholar Training Curriculum (2-3 pages)
   Please describe the training curriculum and timeline for the Research Scholar. If your program has an accredited clinical pharmacology program, please indicate.

Restrictions:
- Centers of Excellence (COE) applications will be limited to one per institution per cycle. If an institution is funded via a COE grant they are not eligible to apply for another COE until the first is finished.
- Established clinical trial consortia are not eligible to apply for a Centers of Excellence Grant.
- Funds will be granted to non-profit institutions or organizations operating in the United States or Canada. Researchers need not be U.S. citizens.
- ALSF does not pay indirect costs.

Budget:
Maximum $350,000 in total costs will be awarded to successful applicants annually. A detailed budget and justification is required using the form provided. Five years of funding may be requested. As noted above, funds may not be used for indirect costs.

Review Process:
- Proposals must fall within the scope of Alex’s Lemonade Stand Foundation in order to be considered.
- Application and report review process will be overseen by ALSF’s Scientific Advisory Board.

2013 Grant Cycle Dates
- Nomination Form Submission Due Date September 6, 2013
- Eligibility Notification mid September
- Full Application Due Date November 4, 2013 (11:59 PM ET)
- Award Notification Date late November 2013
- Project Start Date December 2013
- Progress Reports will be due December of each year starting in 2014

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