Peach Bowl LegACy Fund

Request for Funding Applications (RFA)

Due date: Tuesday, December 3, 2019 at 12PM (noon)

EST Key Requirements
- The proposal must be focused on one or more pediatric cancers
- One PI of the application must be an Aflac faculty member (may be a multi-PI application)
- Proposals/applications will be routed through Children’s Healthcare of Atlanta

Companion Funding Opportunity
None, however, this funding may supplement a project already funded by another source/s.

Number of Applications
Each individual may only be a PI on one submission each cycle but may be a co-PI or study committee member on other submitted Peach Bowl LegACy proposals/applications.

Funding Opportunity Purpose
The purpose of this RFA is to enhance Children’s Healthcare of Atlanta’s ability to open clinical trials for children, adolescents and young adults with pediatric cancers. This includes the development of novel drugs, devices and treatment strategies. The overall goal is to ensure that high-priority novel agents, devices and treatment strategies can be tested in patients in a more rapid manner. Towards this end, applications are solicited for the Peach Bowl LegACy Fund.

The scope of the application/proposal should cover the design and conduct of a Feasibility, Phase I, Phase II or Phase I/II clinical trial including support for trial development, trial conduct (regulatory), correlative studies (eg. molecular and neurocognitive/quality of life/patient reported outcomes) and personnel (PI, co-PIs and Research team support).

Should an application be selected for funding, the full protocol will be due for review by the Executive Committee within 6-8 weeks after the notice of award receipt (Final award approval will be granted once the full protocol is reviewed and approved).

All applications should include the following in the order described below and save the applications and attachments as individual pdf files. Applications should be in Times New Roman, font 12 point.

Application Requirements
1. Introduction Letter (Attachment A)
a. Applicants should submit a brief (1 page - maximum) letter introducing the project, main goals and importance.

2. **Main Application**
   a. PDF fillable Application

3. **Proposal Description (Attachment B)**
   a. Applicants must submit a proposal describing the Rationale and Background, Objectives, Hypotheses, Abbreviated Eligibility Criteria, Study Design and Treatment Plan. The content page of the form may **not exceed 5 pages (references are not included in 5 page limit)**.
   b. The proposal’s main focus should be a Feasibility, Phase I, Phase II or Phase I/II clinical trial.
      i. Funding to support preclinical testing (for example, for IND, safety etc.) is allowable as a part of the clinical trial proposal. However, a detailed timeline delineating the progression to a clinical trial within 12-24 months is required.

4. **Endpoints and Statistical Considerations (Attachment C)**
   a. Description for the statistical design an analysis plan for both primary and secondary objectives, including correlates. Include information about which statistical test will be applied.

5. **Timeline (Attachment D)**
   a. The proposal must include an anticipated timeline of IRB approvals, contract negotiations timeline, accrual goals and estimated first and last patient enrollment.
      i. Any anticipated accrual period beyond 3 years must be strongly justified.
   b. Accrual numbers must be justified based on the institution or collaborative institutions’ experience and patient numbers

6. **Budget and Budget Justification (Attachment E)**
   a. Applications must include a detailed budget for the years of support requested with appropriate justification.
   b. Funding can include support for outside institutional collaboration start-up fees, personnel and local costs (IRB, pharmacy, tissue handling and shipping, per patient reimbursement cost, etc).
   c. Budgets should not include funding for a protocol writer or statistical support as these areas are funded by the Peach Bowl LegACy Fund’s infrastructure, and these services will be provided to all grant awardees.*The services of the protocol writer will be provided after an LOI is chosen as an awardee.

7. **Collaboration**
   a. If collaborations with outside institutions are part of the trial, letters of support from the main collaborator(s) at these institutions should be included.
   b. If collaboration with a pharmaceutical company is part of the trial, an initial letter of support and approval from the company should be included in the application.
8. **NIH Biosketch**
   a. Applications should include the current NIH biosketch of the PI and co-PIs as well as the NIH biosketch of the main collaborator(s) at each outside institution.

9. **Detailed Other Support**
   a. Please include total amount of each source of support and % effort for each source, including PI(s), Co-PI(s) and major collaborator(s).
   b. Must include the following information:
      i. Title of Project
      ii. Name of Funding Agency
      iii. Period of Support (include start and end date)
      iv. Total Direct Costs
      v. Direct Costs/Year
      vi. PI % Effort