



**LEGACY
FUND**

Peach Bowl LegACy Fund: Request for Proposal

The Aflac Cancer and Blood Disorders Center at Children's Healthcare of Atlanta and Emory University is releasing the Cycle 5A Request for Proposal (RFP) supported by the Peach Bowl LegACy Fund. We are pleased to continue this peer-reviewed program to provide funding 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.

Letter of Intent

LOIs will be evaluated to determine if projects can move forward with the application process. Notifications will be sent to the PI by EOD Friday, September 13, 2024.

The LOI should include the following and should be no longer than two pages, and in Arial, 11-point font with 1-inch margins.

- Name of Trial/Protocol
- PI and all potential co-investigators and/or collaborators on the project
- Disease area of focus (must be pediatrics)
- A brief description of the proposed research project and objective(s)
- Timeline estimation for enrollment and completion
- It is expected that the first patient will be enrolled within 18 months of the notice of award

The PI's current Biosketch should also be included and is not part of the page limit. LOIs should be submitted as a single document to peach.bowl@emory.edu, no later than **5:00 PM on Monday, September 9, 2024.**

Eligibility Criteria

1. The project must be focused on one or more pediatric cancers.
2. 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 for pediatric/adolescent and young adult patients. Funding will include support for trial development, trial conduct (regulatory), correlative studies (e.g., molecular and neurocognitive/quality of life/patient reported outcomes) and personnel (PI, co-PIs and Research team support).
3. The PI of the application **must** have a primary or secondary appointment with the Aflac Cancer and Blood Disorders Center.

Application Requirements (NOTE: Full applications will be invited following LOI review)

1. All applications should be completed and include the following in the order described below. Applications must be submitted in Arial, 11-point with 1-inch margins and saved as one PDF file.

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

Main Application: PDF fillable Application

Proposal

- a. Applicants must submit a proposal describing the Rationale and Background, Objectives, Hypotheses, Abbreviated Eligibility Criteria, Study Design and Treatment Plan and Written Protocol (if applicable). 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 18 months is required.

Endpoints and Statistical Considerations

- a. Description for the statistical design and analysis plan for both primary and secondary objectives, including correlates. Include information about which statistical test will be applied.

Timeline

- 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.

Budget and Budget Justification

- 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.*
- d. Requests should not exceed \$1 million, however, additional funding beyond \$1 million will be considered for specific projects with a detailed explanation and budget.
- e. Indirect costs are not allowable.
- f. This is a non-sponsored award and should not be routed through RAS.

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

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.

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.

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

Protocol

- a. Please include the current version of the proposed clinical trial protocol if available. Ideally, this would be a complete protocol for the Scientific Review Committee to make a full assessment.
- 2. Should your 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).
 - 3. Members receiving funding are expected to submit progress reports to the Peach Bowl LegACy Fund Executive Committee. Specific instructions on due dates of reports will be provided at the time of funding.

Key Dates and Schedule

RFP Announcement	08/06/2024
Letter of Intent Due	09/09/2024
Application Released	09/13/2024
Application Due	12/09/2024
Notification of Award	February 2025

Please direct any questions you have regarding this funding opportunity to the Peach Bowl team at peach.bowl@emory.edu.