

FY 2024/25 Kentucky Pediatric Cancer Research Trust Fund Grant Program

Request for New Applications

The Kentucky Pediatric Cancer Research Trust Fund has been approved by the Kentucky legislature for additional one-time funding for the FY 23/24 biennium. Due to this additional funding, this request for applications is being distributed to solicit applications for pediatric cancer research and treatment projects for FY 24 and FY 25 (July 1, 2023 through June 30, 2025). Questions should be addressed to the Cabinet for Health and Family Services, Department for Public Health at <u>pediatric.cancer@ky.gov</u> or by calling Janet Luttrell at 502-321-9011.

OUR MISSION

To make childhood cancer a state health priority and give all Kentucky children access to new and innovative cancer research, development, and precision treatment — with less toxicity while encouraging psychosocial support and focus on the complicated issues of long-term survivorship. These efforts target the needs and challenges specific to Kentucky childhood cancer epidemiology and treatments but hope to serve as a national model for how other states approach childhood cancer research.

OUR VISION

To serve as an umbrella organization to organize all pediatric cancer work across the state. It is not designed to compete with other organizations but to augment and elevate collaborative efforts; and, to serve as a reservoir of collaboration and information so that all efforts are amplified through an organized channel eliminating silos and fostering innovation with compassion and collaboration.

HISTORY

The Kentucky Pediatric Cancer Research Trust Fund (KPCRTF) was established in 2015 by passage of Senate Bill 82 in the Kentucky General Assembly and funded in the amount of \$2.5 million each year of the biennium as part of the budget bill in 2018. The KPCRTF is an independent board administered by the Kentucky Cabinet for Health and Family Services, as described in KRS 211.596 and KRS 211.597. Eligible grant applicants include non-profit entities, educational institutions, and government agencies in the Commonwealth of Kentucky. Each applicant must offer research or treatment that seeks to address the needs of the Commonwealth.

The following program/service criteria to be considered:

• Eligible applicants for this Request for Applications (RFA) are limited to the University of Louisville/Norton Children's Hospital and the University of Kentucky/Kentucky Children's Hospital (as described in HB 200) as well as non-profit entities, educational institutions and government agencies in the Commonwealth of Kentucky.

- Must be relevant to the mission of the Pediatric Cancer Research Trust Fund Board;
- Must offer a program or service in the areas of pediatric cancer research and/or treatment;
- If necessary, based on the phase and scope of the project, researchers must have institutional approval (HIPAA waiver granted/internal review board (IRB) approval) by June 15, 2023; receipt of funds are contingent on IRB approval if IRB approval is determined to be necessary;
- Must have Cabinet for Health and Family Services IRB approval by June 30, 2023 (if the scope of the project includes the need for IRB review);
- Must have conflict of interest disclosure submitted by April 1, 2023 and approved by KPCRTF Board;
- First preference will be to emerging, novel, and innovative high risk/high impact proposals with scientific research that can be quickly translated into new treatments for Kentucky children;
- Investigators must commit to providing testimony and information as requested by the KPCRTF Board and Kentucky General Assembly to include legislative hearings as well as content for the KPCRTF Annual Report;
- Investigators agree to attend, as requested and necessary, meetings of the KPCRTF Board;
- Individual applications shall be submitted for each proposed project;
- Each individual research project, when appropriate, must receive IRB approval, both at the university and CHFS levels by June 30, 2023;
- Contracts will be awarded for two fiscal years beginning July 1, 2023 through June 30, 2025. Since these two years are in two separate bienniums, a new contract for each fiscal year will be required.
- Modifications to the original project proposal will be considered by the Board if research is failing to produce expected outcomes. Researchers will be allowed to propose a different project to the Board for consideration for continued use of funds.

Grant recipients are selected within 120 days of the application deadline. It is the intent of the KPCRTF to support novel research and avoid a duplication of funding for the same work due to limited resources for childhood cancer research nationwide. Funding is for the direct costs related to the implementation of the proposed and approved research project. Direct costs include personnel, salary/fringe benefits, supplies, and equipment exclusive to work in the pediatric oncology field. Support for salary must not exceed percentage related to the research proposed. Travel costs and indirect costs are excluded from funding.

Progress reports must be submitted on an approved KPCRTF template on six-month intervals and at the end of the funding period. Failure to submit reports on a timely basis will disqualify the investigator from any future funding. Funding by the KPCRTF Board must be acknowledged in all presentations and publications that involve research funded by the KPCRTF Board.

Clinical research result sharing should adhere to the guidelines of the National Institutes of Health (NIH) Policy on Dissemination of NIH-funded Clinical Trial Information (NIH Guide Notice <u>NOT-OD-16-149</u>). Our goal is to share information and research so that all children have hope for a cure, no matter where they may live. All study results must be shared promptly with the scientific community and not be kept strictly for proprietary purposes. Failure to share study results may result in disqualification from future funding opportunities and/or a discontinuation of any funding yet to be disbursed under the current grant.

Institutions that receive funding shall submit an official letter certifying that receipt of KPCRTF Board support will not result in loss of funding, supplanting, or redirection of funds previously received by the pediatric oncology program and instead should be viewed as supplemental or new money in addition to existing resources.

Submissions to the KPCRTF Board for grant approval should not be considered confidential information and the submitting institution or organization agrees to release the KPCRTF Board and its' officers from any and all liability from the discussions, internet posting or consideration of all documents submitted.

Include the following information (limit of 10 pages):

- Cover Letter
 - Name of Principal investigator (must be the same as the PI for the parent grant)
 - PI's phone number, mailing address, and email address
 - KPCRTF Grant Title
 - Request up to two (2) years of support up to \$250,000 a year. The Board may consider proposals whose scope of work justify more than \$250,000 a year but requires that the PI clearly makes a compelling case for a larger budget.
 - Name and title of the institutional official including the phone number, mailing address and email address
 - Cover letter should be signed by the PI and an appropriate institutional official documenting specific institutional commitment for this award.
- Project Summary/Abstract
 - Provide a summary of the proposed grant. This summary should list the project goals and provide rationale how the project will impact childhood cancer.
- Budget and Justification
 - All requests must include a detailed budget and budget justification (using attached format)
 - Allowable costs include:
 - Salary support for investigators commensurate with the percent level of effort and research costs
 - o Indirect costs are not permitted
- Proposal Describing the Grant Activities
 - Specific Aims
 - Research Strategy
 - This section should contain sufficient detail to allow assessment of the scientific merit of the proposed plans and activities, and the appropriateness of the request for supplemental funds.
- Bio-sketches of PI and key personnel in current NIH bio-sketch format (bio-sketches of coinvestigators can be included in a separate document for reference as needed).
- Literature Citation

The following information provides detail on regulations of funding received by the Pediatric Cancer Research Trust Fund.

Financial Information

- 1. Detailed budget of requested funds not exceeding \$250,000 per year.
- 2. Purchase of food or travel are not approved expenses covered in the reimbursement process.
- 3. Other funding sources for this program or service including in-kind participation.
- 4. Grantees are required to include the following statement on <u>all</u> promotional materials: "*This work was supported by Kentucky Pediatric Cancer Research Trust Funds"*.

Financial Reimbursement Process

- 1. Monthly invoice on activity performed by grantee shall be submitted to the Kentucky Department for Public Health Division of Prevention and Quality Improvement, Chronic Disease Prevention Branch at <u>Pediatric.cancer@ky.gov</u>.
- 2. Invoice is reviewed by the Chronic Disease Prevention Branch for appropriate spending in accordance with the budget submitted.
- 3. Once invoice is approved for payment, a check will be processed within 30 days.
- 4. There will be financial reviews on all grantees performed as needed during the fiscal year grant period. This will include a review of purchases made with grant funds, proof of receipt for line items included on approved budget, and the progress in which the project has provided.
- 5. The Board has the right to request proof of receipt at any time an audit is required/necessary. While receipts are not required with invoices for reimbursement, it is strongly recommended that grantees keep proof of receipt for all transactions.
- 6. Grantee will provide a summation of progress and achievement of outcomes at the January and July 2024 and 2025 KPCRTF Board meetings. Grantee will also provide a written progress report (utilizing a supplied template) by the 15th of January 2024, July 2024, January 2025, and July 2025. Grantee will also provide power point slides in August of each year in anticipation of a legislative update at the September interim joint Health and Welfare and Family Services committee meeting.

The KPCRTF Board will utilize an enhanced NIH scoring system and peer reviewed by leading pediatric oncologists representing multiple institutions ranked by the U.S. News and World Report review of pediatric oncology programs. The KPCRTF administrative staff will first review applications to ensure guidelines/formatting requirements are met. The Scientific Peer Review Panel will then review applications for scientific merit and score them based on adherence to program mission/vision and the NIH scoring system. Grant applications may also be sent to physicians or investigators in the particular field of interest for review of the scientific merit. Final decisions will be made by the voting members of the KPCRTF Board as defined by legislative statute.

References/Data Resources:

- KRS 211.595 211.597 Pediatric Cancer Research Trust Fund http://www.lrc.ky.gov/statutes/chapter.aspx?id=38167
- 902 KAR 21:030 Pediatric Cancer Research and Treatment Grant Program <u>http://www.lrc.ky.gov/kar/902/021/030reg.htm</u>
- Kentucky Cancer Consortium, Cancer Action Plan: <u>http://www.kycancerc.org/canceractionplan/canceractionplan.pdf</u>
- American Cancer Society: <u>http://www.cancer.org/</u>
- Centers for Disease Control and Prevention: <u>https://www.cdc.gov/index.htm</u>
- Kentucky Cancer Registry website: <u>www.kcr.uky.edu</u>

- NIH Scoring Guidance: <u>https://grants.nih.gov/grants/policy/review/rev_prep/scoring.htm</u>
- NIH RO1 Application Overview: <u>https://grants.nih.gov/grants/how-to-apply-application-guide/write-application.htm</u>
- The Cure Starts Now Foundation: <u>https://www.thecurestartsnow.org/impact/research-and-grants</u>

Each proposed grant application should submit a letter of intent (LOI) which should include the following items and should arrive on requesting agencies letterhead no later than July 15, 2022 and be no more than two pages in length.

- Name of investigator
- Qualifications of investigative team
- Summary paragraph (describe the proposed new project)
- Discuss the significance of the work and how it relates to childhood cancer
- Brief description of the specific aims containing information about what systems and methods will be proposed in the application
- <u>A statement as to whether the budget will be no more than the recommended</u> \$250,000 per year for two years or whether additional funding will be requested with a brief justification for the additional funding.

Letters of intent should be sent electronically to: Janet Luttrell at janet.luttrell@ky.gov No later than July 15, 2022.

LOI's will be reviewed by a scientific peer review panel and those chosen to submit full applications will be notified by September 20, 2022.

Applications should be emailed to janet.luttrell@ky.gov by close of business on November 15, 2022. An email confirming receipt will follow. If you do not receive this email by November 22, 2022, please contact Janet Luttrell at 502-321-9011.

Submissions and approval process:

- 1. Faxed copies will not be accepted.
- 2. Successful applicants will be notified within 120 days after application deadline, in writing, by email. A modified proposal may be requested. Grant agreements will also be distributed for signature by successful applicants and must be signed, submitted back to the Chronic Disease Prevention Branch and postmarked within two (2) weeks of receipt. Incomplete applications will not be considered. Feedback will be provide on all grant applications not approved for funding.
- 3. Institutions that receive funding shall submit an official letter certifying that receipt of KPCRTF Board support will not result in loss of funding, supplanting or redirection of funds previously received by the pediatric oncology program and instead should be viewed as supplemental or new money in addition to existing resources.
- 4. Contracts will be developed based on successful applications and submitted for final approval. These contracts will be sent via Docusign to successful agencies for signature and must be returned to the Cabinet for Health and Family Services to be fully executed.
- 5. CHFS Institutional Review Board (IRB) approval and organizational/institutional IRB approval, when appropriate, is required prior to project implementation for research

projects. All pertinent IRB approvals should be received and KDPH staff notified by June 30, 2023. Successful applicants should begin the IRB approval process as soon as grant approval notification has been received.

- 6. A conflict of interest disclosure shall be submitted by successful applicants and approved by the KPCRTF Board by May 1, 2023;
- 7. Any grant recipient that is not making satisfactory progress toward meeting grant objectives shall be notified in writing that objectives are not being met. The grant recipient shall submit within thirty (30) days of receiving the notice a corrective action plan addressing the objectives that are not being met; and reimburse CHFS for grant funds received to date if the corrective action plan is not implemented.
- 8. Grantees are responsible for notifying the Chronic Disease Prevention Branch with changes in grantee information including contact information. If any changes occur to address, email, phone number, contact name, etc...it is the grantees responsibility to inform CHFS of this change within ten (10) business days of the change.