

FY 2021/22 Kentucky Pediatric Cancer Research Trust Fund Grant Program

Request for Applications

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; 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 taken into consideration:

- Eligible applicants for this RFA are limited to the University of Louisville/Norton Children's Hospital and the University of Kentucky (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;
- Must propose to address the following areas that the Board has identified (Research and/or Treatment);
- If necessary, based on the phase and scope of the project, researchers must have institutional approval (HIPAA waiver granted/IRB approval) by June 30, 2020; 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 (if the scope of the project includes the need for IRB review);
- Must have conflict of interest disclosure submitted and approved by KPRCTF board;
- Must outline how intellectual property will be shared to impact state, national and international childhood cancer mortality and morbidity;
- 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.
- Contracts will be awarded for two fiscal years beginning July 1, 2020 through June 30, 2022.
- Funds will be awarded contingent upon funding approval during the 2020 legislative session.
- 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 will be selected within 90 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 three-month intervals and at the end of the funding period. The 4th quarter report shall also include slides for a power point presentation. 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 NOT-OD-16-149). 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 along with grant cover sheet:

Project Description

Follow standard <u>NIH PHS 398 template outline for National Cancer Institute Program P01 Applications</u> (https://grants.nih.gov/grants/how-to-apply-application-guide/write-application.htm). In addition, applicants should insure that the application addresses the following points:

- 1. State the need for the research or treatment to determine the scientific merit of the proposed project.
- 2. List the primary and secondary objectives of the study including how many children you expect to serve and how your proposed project(s) will directly impact morbidity and mortality of pediatric cancer patients in Kentucky.
- 3. State the method of institutional collaboration and information sharing. Preference will be to applications showing progress in coordination and communication to assure no duplication of effort as well as to encourage collaboration across Kentucky institutions, organizations, and programs.

- 4. Explain your hypothesis and the scientific outcomes directly related to the changes or impact of the research or treatment.
- 5. Provide an implementation plan describing how you will meet your objectives.
- 6. Provide an incremental timeline including an outline of monthly goals with specific tasks as well as a start and end date for the research project that is proposed.
- 7. Include your evaluation plan and describe how you will measure the success of the research or treatment.
- 8. Describe the feasibility of meeting the outlined objectives within the funding period and possible barriers to meeting the objectives.
- 9. Describe how the research findings can be translated into clinical practice.
- 10. Provide documentation of the investigators assigned to meet the research objectives.
- 11. Provide a breakdown of budget activity including a letter from the center director certifying that the principal investigator is an independent researcher who directs his/her own pediatric oncology research and manages his/her own project budget.

The following criteria for screening will be utilized by the objective review committee in determination of awarding funds to grantees.

The Pediatric Cancer Research Trust Fund Screening Criteria

- 1. Project is relevant to the mission of the Pediatric Cancer Research Trust Fund board of research and treatment for pediatric cancer patients.
- 2. Project offers a program or service in the areas of research and/or treatment.
- 3. Primary and secondary objectives are clearly outlined, specific, measurable, achievable, realistic and timely.
- 4. Implementation plans are clearly outlined.
- 5. Timelines are realistic to meet objectives.
- 6. Evaluation plans are clearly defined.
- 7. Program or service is not being duplicated and budget is outlined and appropriate.
- 8. Applications, including budget, NOT to exceed 10 pages for each individual project.
- 9. What type of impact the project will have on the community in serving the mission of the trust fund.

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 \$2,500,000.
- 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: "*Printed with Kentucky Pediatric Cancer Research Trust Funds*".

Financial Reimbursement Process

- 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.
- 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 site reviews on all grantees performed at least twice 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 2021 and 2022 KPCRTF Board meetings. Grantee will also provide a written quarterly report (utilizing a supplied template) by the end of September 2020, January 2021, April 2021, July 2021, September 2021, January 2022, April 2022, and July 2022. 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 http://www.lrc.ky.gov/kar/902/021/030reg.htm
- Kentucky Cancer Consortium, Cancer Action Plan: http://www.kycancerc.org/canceractionplan/canceractionplan.pdf
- American Cancer Society: http://www.cancer.org/
- Centers for Disease Control and Prevention: https://www.cdc.gov/index.htm
- Kentucky Cancer Registry website: www.kcr.uky.edu
- NIH Scoring Guidance: https://grants.nih.gov/grants/policy/review/rev_prep/scoring.htm
- NIH RO1 Application Overview: https://grants.nih.gov/grants/how-to-apply-application-guide/write-application.htm
- The Cure Starts Now Foundation: https://www.thecurestartsnow.org/impact/research-and-grants

Applications can be emailed to janet.luttrell@ky.gov by close of business on July 15, 2019 with an original copy to follow in the mail.

Submissions and approval process:

Mail one original signed copy to:

The Pediatric Cancer Research Trust Fund
Kentucky Department for Public Health
Division of Prevention and Quality Improvement
Chronic Disease Prevention Branch
Janet C. Luttrell
275 East Main Street, HS2WE
Frankfort, Kentucky 40621

As well as one signed copy (via USPS or email) to:

Jamie Ennis Bloyd, MPA
President, Kentucky Pediatric Cancer Research Trust Fund
4781 Firebrook Boulevard
Lexington, Kentucky 40513

- 1. Faxed copies will not be accepted.
- 2. Successful applicants will be notified within 90 days after application deadline, in writing, by certified mail. 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 and will be returned. The Board will provide feedback on all grant applications not approved for funding.
- 3. Contracts will be developed based on successful applications and submitted for final approval. These contracts will be sent via email to successful applicants for signature and must be returned to the Cabinet for Health and Family Services to be fully executed.
- 4. Any grant recipient that is not making satisfactory progress toward meeting grant objectives, as determined by the Board, shall be notified in writing that objectives are not being met. The grant recipient shall submit to the Board within thirty (30) days of receiving the notice a corrective action plan addressing the objectives that are not being met; and reimburse the Board for grant funds received to date if the corrective action plan is not implemented.
- 5. CHFS Institutional Review Board (IRB) approval and organizational/institutional IRB approval, when appropriate, is required prior to project implementation for research projects.
- 6. If you have further questions, please call the Kentucky Department for Public Health, Division of Prevention and Quality Improvement, Chronic Disease Prevention Branch at 502-564-7996 extension 4441.
- 7. 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 the Board of this change within ten (10) business days of the change.