Annual Report
Fiscal Year 2019

Prepared By:
Kentucky Department for Public Health
Chronic Disease Prevention Branch in collaboration with
Kentucky Pediatric Cancer Research Trust Fund Board

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Kentucky Pediatric Cancer Research Trust Fund
Annual Report

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and
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Report Overview

This report is prepared pursuant to KRS 211.597. This report states that

1) "a report be provided to the Governor and the Legislative Research Commission (LRC) detailing the plan developed for the expenditure of funds for the current and next fiscal year,
2) a summary of the use and impact of prior year funds,
3) a summary of the activities of the board during the prior fiscal year, and
4) any recommendation for future initiatives or action regarding pediatric cancer research funding".

History

In 2015, legislation was enacted creating the Kentucky Pediatric Cancer Research Trust Fund (KPCRTF) under KRS 211.595. The purpose of the fund is to support pediatric cancer research and treatment in Kentucky. The KPCRTF board was created under KRS 211.596 detailing the makeup of the board membership, terms and membership, and meeting details. The board is attached to the Cabinet for Health and Family Services (CHFS). In 2018, funding in the budget was allocated by the legislature to the KPCRTF in the amount of $5,000,000 for FY19/20.

KRS 211.597 authorizes the KPCRTF board to promulgate administrative regulations necessary to carry out the provisions of KRS 211.595 to 211.597, including the establishment of a competitive grant program to provide funding to organizations offering programs or services in the areas of pediatric cancer research and treatment. Accordingly, in March 2017, the Kentucky Department for Public Health (KDPH) filed the KPCRTF regulation, and on June 21, 2017, the administrative regulation, which established the requirements of the KPCRTF Program, went into effect.

Needs Assessment

The Kentucky Cancer Registry (KCR) has developed a population-based childhood cancer incidence report for the Commonwealth of Kentucky. KCR collects uniform, high quality data on approximately 215 new primary cases of childhood cancer occurring in Kentucky residents each year. This report provides detailed information about childhood cancer in Kentucky for the most recent ten-year period of complete, population-based data collected and validated by KCR. The report also provides information about age-adjusted childhood cancer incidence rates. Childhood Cancer in Kentucky 2007-2016 demonstrates the urgent need for the appropriated funds to be utilized for state research and improving outcomes for children diagnosed with cancer in Kentucky. The data also provides insight into which types of childhood cancer diagnoses are being observed beyond what should statistically be expected.

Prioritized List of Programs and Research Projects to be Addressed

Language included in the KPCRTF Request for Applications (RFA) reflects the priorities established by the board and is used to select programs and research projects for grant funding. Special emphasis has been placed on applications demonstrating collaboration and information sharing across institutions.

Plan for Expenditure of Funds and Summary of Use and Impact of Prior Year Funds

During FY19 contracts to the University of Louisville (UL) and the University of Kentucky (UK) took longer to receive approval than originally expected. This delayed the start of all projects. Therefore, projects were not able to spend the total amount awarded to their projects by the end of the fiscal year. FY20 contracts were amended to carry over the unused portion of the FY19 funds to FY20. Below is a summary of each project funded for FY19 and FY20 and progress achieved to date.

The University of Louisville shall:

Primary Objective #1 – Pilot DFMO – FY19 - $14,000 and FY20 – $14,000

1) To evaluate the maximum tolerated dose (MTD) of Eflornithine as a single agent in patients with relapsed or refractory Sonic Hedgehog Molecular Subgroup (SHH) activated, Group 3 or other MYC oncogene (MYC) amplified medulloblastoma.

The project initially has seen several revisions, starting as a conceptualized maintenance strategy for molecular high risk and very high risk medulloblastoma following completion of standard of care therapy. At the request of the initial drug sponsor, Cancer Prevention Pharmaceuticals (CPP), the protocol was revised to a phase I relapse/refractory study with plans to later expand/open a phase II as initially planned. The initial drug sponsor's DFMO product met with several Federal Drug Administration (FDA) issues and the initial investigational new drug (IND) submission in July of 2018 was rejected, which subsequently led to prolonged delays in moving forward with protocol submission to the internal review board (IRB). A written agreement was made that CPP would provide a different drug formulation in powder form that has already met with full FDA approval for another pediatric indication (neuroblastoma). The new formulation was expected to be available in early April 2019.

In mid-March 2019, the project was picked up by Beat Childhood Cancer (BCC) in its initial intended iteration as a maintenance strategy for molecular high risk medulloblastoma. The decision was ultimately made to forego the phase I trial and focus efforts with the initially intended phase II strategy. BCC is a national consortium of research institutions/academic

hospitals dedicated to finding a way to stop childhood cancers. The organization has grown to operate clinical trials in 40 hospitals and research institutions throughout North America. Most recently, they have spearheaded clinical trials of difluoromethylornithine (DFMO) in neuroblastoma. They work closely with Kids Pharmaceuticals, a pharmaceutical company put together by a network of neuroblastoma afflicted families.

The protocol has since been revised and expanded, and is currently being finalized before its expected simultaneous submission to the FDA and BCC's Central IRB in July of 2019. Once finalized, we will also be furnishing a copy of the finalized protocol draft to the KPCRTF IRB. The expected timeline for start of patient enrollment was summer 2019. All funds designated in the contract for FY19 were not utilized and are being carried over to FY20.

<u>Primary Objective #2 – Anti-CD33-CD123 Compound CAR-T Cells – Pediatric Acute Myeloid Leukemia – FY19 - $625,000 and FY20 - $625,000</u>

1) Develop a compound Chimeric Antigen Receptor T Cells (CAR-T cell) approach to combat childhood Acute Myeloid Leukemia (AML).

Working with our project's biotech collaborator, iCell Gene Therapeutics, we have made DNA constructs designed to express on human T cells compound CAR (chimeric antigen receptors) that target both CD33 and CD123 antigens on AML cells. After lentivirus-mediated transfer of the constructs into human T cells, we showed that the two receptors were expressed simultaneously on the surface of the T cells. We demonstrated the ability to eliminate the CAR-T cells by treatment with the monoclonal antibody alemtuzumab as a safety switch to be activated in case of occurrence of undesirable adverse effects.

We are performing essential procedures in our current Good Manufacturing Practice (cGMP) Laboratory to ensure that it is in a condition that can provide the optimal manufacturing environment for production of clinical-grade cellular products. The laboratory is undergoing special triple-cleaning to maintain its "clean room" status. Equipment in the laboratory is being reorganized to generate additional space for full-scale implementation of our projects. Standard operating procedures are being extensively revised and rewritten to generate strict laboratory guidelines that will result in consistently high product quality. Additional training of laboratory personnel is being conducted to maintain an outstanding level of technical expertise required to ensure high product quality.

Preliminary studies are being performed to characterize the cytotoxic activity of compound CAR-T cells targeting AML. Product review is underway to purchase the xCELLigence Real Time Cell Analysis (RTCA) System to set up a platform for real-time, functional characterization of CAR-T cells. Once the RTCA System is available in our laboratory, this platform will undergo validation studies and then be used extensively to test different manufacturing conditions that could produce the best CAR-T cells.

We are preparing the cGMP laboratory to ensure its capacity to produce clinical-grade cellular products necessary for human studies. Once the laboratory preparation work and process optimization studies have been completed, large-scale engineering runs will be performed to produce CAR-T cells for testing of viability, purity, stability, activity and safety.

The funding delay postponed initiation of the project and as a result, UL will be unable to utilize the full first year award amount. However, all unexpended funds designated in the contract for FY19 are requested for carry over to FY20.

Primary Objective #3 – Anti-GD2 CAR-T Cells with Intrinsic PD-1 Checkpoint Blockade for the Treatment of Pediatric Neuroblastoma and Brain Tumors – FY19 – $625,000 and FY20 - $625,000

1) Develop a CAR-T cell approach to combat childhood pediatric neuroblastoma and brain tumors.

We are now making CAR-T-cell constructs that will express a chimeric antigen receptor (CAR) targeting the GD2 antigen present on the surface of neuroblastoma and brain tumor cells. These constructs will include the expression of a modified, activating PD-1 receptor, which will enhance the ability of the anti-GD2 CAR-T cells to kill tumor cells. In a complementary approach, we are developing protocols to expand myeloid-derived suppressor cells, a component of the tumor microenvironment that blocks the cytotoxic function of CAR-T cells. We plan to use the myeloid-derived suppression cells, together with tumor cells and anti-GD2 CAR-T cells, to recreate the tumor microenvironment and evaluate the ability of pharmacological agents that suppress myeloid cells, such as retinoic acid (RA) and DFMO, to enhance the anti-tumor effect of anti-GD2 CAR-T cells. We hypothesize that such an approach could lead to the development of combination immunotherapy that can effectively kill and eliminate neuroblastoma and brain tumor cells.

We are performing essential procedures in our cGMP laboratory to ensure that it is in a condition that can provide the optimal manufacturing environment for production of clinical-grade cellular products. The laboratory is undergoing special triple-cleaning to maintain its "clean room" status. Equipment in the laboratory is being reorganized to generate additional space for full-scale implementation of our projects. Standard operating procedures are being extensively revised and rewritten to generate strict laboratory guidelines that will result in consistently high product quality. Additional training of laboratory personnel is being conducted to maintain an outstanding level of technical expertise required to ensure high product quality.

Preliminary studies are being performed to characterize the cytotoxic activity of anti-GD2 CAR-T Cells targeting neuroblastoma and brain tumors. Product review is underway to purchase the XCELLigence RTCA System to set up a platform for real-time, functional characterization of CAR-T cells.

Once the RTCA System is available in our laboratory, this platform will undergo validation studies and then be used extensively to test different manufacturing conditions that could produce the best CAR-T cells.

We are preparing the cGMP laboratory to ensure its capacity to produce clinical-grade cellular products necessary for human studies. Once the laboratory preparation work and process optimization studies have been completed, large-scale engineering runs will be performed to produce CAR-T cells for testing of viability, purity, stability, activity and safety.

The funding delay postponed initiation of the project and as a result, UL will be unable to utilize the full first year award amount. However, all unexpended funds designated in the contract for FY19 are requested for carry over to FY20.

The University of Kentucky shall:

<u>Primary Objective #1 – Provide Support for Siblings of Pediatric Cancer – FY19 - $8,000 and FY20 - $8,000</u>

1) Estimate the incidence of psychological stress and the potential impact on siblings of pediatric cancer patients using a parent survey.
2) Assess the potential utility of strategies to raise awareness for identification and early intervention for at-risk siblings.

UK did not access any of the funds to date for the sibling project. Currently the study is still under IRB review. As the original IRB review was written, it was felt that consent would need to be obtained from the participants as well as the primary care physicians, and schools. Consenting physicians and the schools would make the study, in effect, impossible to complete. UK is working to rewrite the document eliminating the need for obtaining consent from the physicians and the schools. Once the university IRB approval is achieved, UK will obtain the approval of the state's IRB and proceed with this important work. All of the funds designated for FY19 will be carried over into FY20. These funds will be used as outlined above in order to accomplish the goals of the study.

<u>Primary Objective #2 – Circulating Tumor DNA as a Prognostic Indicator of Minimal Residual Disease and Central Nervous System Relapse in Acute Lymphoblastic Leukemia – FY19 - $220,000 and FY20 - $220,000</u>

1) Develop a new assay that quantifies cell-free, circulating tumor DNA (ctDNA) to sensitively and non-invasively monitor Acute Lymphoblastic Leukemia (ALL) response to conventional chemotherapy and potentially allow for earlier detection of relapse.

UK has purchased or is in process of purchasing all needed equipment for this project, including a liquid nitrogen freezer for patient sample storage (Aim 1), a bioanalyzer to detect isolated cell-free DNA (Aim 2 and 3), low retention pipets for digital polymerase chain reaction (PCR) (Aim 2), and a barcode generator for banking patient samples. This equipment is necessary to begin the project.

Funds were used for salary support for Dr. Blackburn (PhD), Dr. Badgett (MD), and a research technician. Dr. Blackburn designs experiments, Dr. Badgett consents patients and collects patient samples, and the research technician retrieves samples from the clinic and performs experiments under the direction of Dr. Blackburn.

Finally, funds were used to buy the needed consumables for this project, including streck tubes for sample collection and kits to isolate cell-free DNA from samples.

They have been able to create and validate some standard operating procedures in the lab regarding patient sample collection and processing, cell-free DNA isolation, PCR amplification to assess clonality, and have begun to bank some patient samples.

The funding delay postponed initiation of the project and as a result, UK will be unable to utilize the full first year award amount. However, all unexpended funds designated in the contract for FY19 are requested for carry over to FY20.

<u>Primary Objective #3 – Chemotherapy Induced Cognition Impairment (CICI) – Mechanisms and Prevention – FY19 - $230,000 and FY20 - $230,000</u>

1) Develop extracellular vesicles (EVs) as an early and non-invasive biomarker of cancer CICI in children and provide a rapid path to enter clinical trials for therapeutic intervention using the prototype drug MESNA, an FDA approved drug that inhibits oxygen-containing reactive species (ROS) without affecting the efficacy of cancer therapeutics.

This project was approved for the period July 1, 2018, through June 30, 2020. However, funding was not finalized or initiated until March 1, 2019, eight months later than the proposed start date. Despite this significant delay in the availability of the funds, UK rapidly obtained human subject research approval from the University of Kentucky and have begun to recruit children who receive treatment for ALL at the Dance Blue Clinic of the University of Kentucky Children's Hospital. Funds have been used to support the efforts of UK's research team members and to purchase the supplies necessary for the studies. To date, the clinical team has obtained 15 samples from children with ALL. They also have isolated EVs using existing serum samples from children who were treated with doxorubicin. The results are very encouraging, as they have observed a trend toward reduction in the level of brain injury markers in the children who had concurrently received MESNA, an FDA-approved antioxidant drug specifically designed to block oxidative tissue injury without interfering with the effect of anticancer drugs to tumor tissues.

Thus, while the results are very preliminary due to the small sample size, UK plans to accomplish the study as originally proposed by carrying forward into FY20 all funds designated in the contract for FY19. The impact of this funding cannot be understated, as ALL affects mainly children, who can have long, productive lives after cure but may suffer cognition impairment due to the effects of chemotherapy on brain function. Combining FY19 and FY20 funds will allow UK to complete the proposed studies that will develop guidelines for the use of MESNA to prevent therapy-induced cognitive impairments.

Primary Objective #4 – Factors Associated with High Incidence of Pediatric Brain and Central Nervous System Tumors in Kentucky – FY19 - $260,000 and FY20 - $262,371

1) Develop a population-specific study to identify factors associated with the high incidence of pediatric brain and central nervous system tumors (PBCNST) in Kentucky, leveraging the infrastructure provided by the KCR, its Virtual Tissue Repository and the national institutes of health (NIH) Kids First Division of Clinical Research (DCR).

In the first six months of funding, UK has utilized the funds to focus on objectives: 1) initiation of the population-based biospecimen collection; and 2) initiation of the geospatial analysis in exploration of potential environmental exposures. Towards fulfillment of primary objective 1), significant progress has been made towards the development of infrastructures and standard operating procedures for the acquisition, processing and submission of cancer patient biospecimens to the NIH Kids First DCR. IRB approval has been obtained and a biospecimens coordinator position has been recruited. The biospecimen cohort of 379 subjects has been identified, and their associated pathology reports have been reviewed to assess the likelihood of tissue availability. Initial test biospecimens were obtained and shared with the DCR through the Children's Hospital of Philadelphia (CHOP). Evaluation of the initial biospecimens has resulted in the development of a biospecimens protocol acceptable to all parties. A number of necessary agreements between UK and CHOP, such as material transfer agreements, have been established and executed. Cohort specimens are now being requested for processing and shipping to CHOP. IRB approval, staff hire, identification of the biospecimens cohort and establishment of the standard operating procedures and protocols are essential components necessary to ramp up specimen processing and to collect the vast amount of data needed for analyses. This success is the direct result of support from the KPCRTF.

Significant progress has also been made towards the secondary objective to identify potential environmental exposures associated with Kentucky's high rates of PBCNST. The total census of Kentucky PBCNST cases from 2012 forward have been identified. An analytic data file has been extracted by the KCR and shared with the investigators. The geo-spatial analytic team, led by Dr. Jay Christian, have completed an initial analysis. Consistent with previous findings from the KCR, evidence of regionally significantly high rates of PBCNST have been confirmed. Detailed analyses with a variety of tumor types, patient demographics and potential environmental exposures are underway. This initial detailed analyses have revealed additional information

about the PBCNST burden in Kentucky that may not otherwise have been revealed. Support from the KPCRTF has been essential.

It should be noted that actual funding for the project was held up for over 6 months beyond the anticipated start date of July 1, 2018. Work on the project could not begin until the funding was established. The funding delay postponed initiation of the project and as a result, UK will be unable to utilize the full first year award amount. However, all unexpended funds designated in the contract for FY19 (approximately $100K) are requested for carry over to FY20. Work accomplished since funding began on January 15 have set the stage for accelerated progress. We have the capacity to increase staff resources devoted to the project in FY20. Increased effort will be necessary to process a high volume of biospecimens and to complete the extensive analyses proposed for the project. While the funding delay was significant, we are confident that we will be able to complete all of the study objectives through increased efforts in the second funding period.

<u>Primary Objective #5 – IND Enabling Studies of Mithramycin Derivatives for the Treatment of Ewing Sarcoma – FY19 - $540,000 and FY20 - $537,629</u>

1) Advance a compound toward clinical development.

We have developed a new set of chemistries which enables production of the molecules from the parent natural product known as mithramycin (MTM). This is important because the previous synthetic pathway was using a mutated bacterial strain to prepare an intermediate which needed to be isolated from among several similar chemicals produced by the mutant. Furthermore, the production of the natural product, MTM, is already at the commercial level and available from a vendor who has supplied the National Cancer Institute with material to conduct clinical trials. The chemistries vary slightly in the final product but represent a more streamlined approach with a one-step chemistry or a two-step chemistry. We are currently comparing these molecules in vitro and in vivo to assess their respective and relative efficacy and potency. We have initiated negotiations for the purchase of 15 grams of MTM from the commercial vendor. This will allow us to proceed with some of the studies outlined to be conducted at UK.

To be able to measure and understand what the body does to the drug or how the drug appears and disappears in the body following drug administration, we developed a method that uses mass spectroscopy. We validated this method and have a good grasp of how it performs and how to handle, store, and process the experimental samples so that variability is minimized and the conditions are optimal for sample stability during storage, processing, and analysis. This method was published.

For drugs to be effective they must remain in the circulation long enough at concentrations that are high enough to cause an effect. In a recent clinical trial at the NCI with kids suffering from Ewing Sarcoma, it was shown that the original molecule (MTM) does not stay in the circulation

long enough or at high enough concentrations to cure the cancer. In our studies we want to advance molecules that do not have this shortcoming. Here we chose to conduct pharmacokinetic studies in non-human primates, which more closely resemble the circulation and physiology of young children. The graph below demonstrates that in comparison to MTM, two of our molecules have significantly higher concentrations of blood in the circulation over an 8-10 hour period. Note that the scale is logarithmic, and these seemingly small differences are indeed orders of magnitude (10-100-fold) different.

We have tested the efficacy of one of the MTM analogs in Ewing Sarcoma tumors implanted in immunocompromised mice, which allows for the growth of human tumors without the mouse immune system rejecting them. The goal of this study was demonstrate that unlike MTM, the new compound can be effective at doses below the MTD. Our results demonstrate that tumor growth was reversed and suppressed only when using the new analog and at doses that were approximately 2/3 of the maximum tolerated dose. This shows that the new analogs, unlike MTM, have a therapeutic window. Our next step will be to optimize the dosing schedule.

The funding delay postponed initiation of the project and as a result, UK will be unable to utilize the full first year award amount. However, all unexpended funds designated in the contract for FY19 are requested for carry over to FY20.

Summary of Board Activities

The first meeting of the KPCRTF board was conducted on November 28, 2016. During this meeting, members elected Jamie Bloyd as President, and April Wilhoit as Vice President of the board. Members reviewed instruction to the board set forth in the legislation. Quarterly meeting dates were set for 2017 and topics for the next meeting discussed. Subsequently, the KPCRTF board met in January, April, July and October of 2017. These meetings were used to develop a plan of action for the coming fiscal year.

The KPCRTF board developed a grant program to provide funding to not-for-profit entities, academic medical centers, and government agencies offering research funding and treatment for pediatric cancer to Kentucky children impacted by the disease. Meetings were conducted in 2018 in January, May, June, August, and September. Jamie Bloyd was re-elected to serve as board President, and Brad Nunn was elected to serve as board Vice President in 2018 and 2019. During this time, it was determined to refund the FY18 funded UK and UL projects for FY19 and FY20 with donated trust funds. A more elaborate application process was developed to determine the recipients of the appropriated $5,000,000 for FY19 and FY20. The request for applications (RFA) for these funds was distributed in June 2018 and applications for six projects were received. All six projects were funded at the requested amount as shown previously in this document.

Since detailed contracts for these projects took an extended amount of time to approve, it was determined that the RFA for FY21 and FY22 should be distributed in May of 2019 with

applications to be received by July 2019. This RFA provided a caveat that projects will be approved pending legislative funding of the KPCRTF during the 2020 legislative session. Contracts for FY21 and FY22 will be developed during the fall of 2019 and will be ready for submission for approval as soon as funding is approved. It is estimated that following this timeline will allow these contracts to be approved by July of 2020, which will allow the grant recipients a full two years to work on their projects.

On February 15, 2017, the KPCRTF board hosted a pediatric cancer event at the Capitol Rotunda in honor of Childhood Cancer Awareness Day. During this event the new state income tax check off was announced, the new KPCRTF logo was revealed, and conversations were conducted with legislators. Governor Matt Bevin, State Treasurer Allison Ball, Senator Max Wise, and many other state elected officials attended the event. This event was held again on February 15, 2018, and February 13, 2019, as part of International Childhood Cancer Day activities simultaneously conducted on a global scale to increase awareness for childhood cancer as the number one cause of childhood disease-related death in the state, U.S., and internationally.

Recommendations for Future Initiatives

The KPCRTF board plans to continue implementation of goals set forth in the mission statement as well as reflected in the Kentucky Cancer Action Plan with emphasis on scientific advancements in molecularly-targeted treatment and immunotherapy. The board also plans to focus on psychosocial impact of a childhood cancer diagnosis as well as long-term survivorship issues related to toxicity from treatment. Emphasis on information sharing, innovation, and collaboration across institutions will continue to guide decisions on future initiatives.

Program Financial Summary

Revenue for the KPCRTF consists of funds collected from the state income tax check off and any other proceeds from grants, contributions, appropriations, or other money made available for the purposes of the KPCRTF. Citizens may designate donations to the trust fund on their annual Kentucky state income tax form. Donations made through the trust fund check off box are sent to CHFS from the Kentucky Department of Revenue on a monthly basis.

The state income tax check off was first made available to Kentuckians in 2017 on the 2016 tax returns. The amount collected by June 30, 2017, was $21,557. The amount collected between July 1, 2017, and June 30, 2018, was $14,303, and between July 1, 2018, and June 30, 2019, was $16,112. An additional $5,000,000 was allocated by the legislature to the KPCRTF board for FY19 and FY20. Contracts for FY19 and FY20 were approved during the spring of 2019. By June

30, 2019, $987,434.99 was expended for these projects. The contracts will be amended to carry over the unexpended funds to FY20.