KPCRTF State Funded Projects Reporting Template

University of Kentucky
Germline and Environmental Factors Associated with Pediatric Brain and Central Nervous System Tumors
Program Director: Dr. Eric B. Durbin

Reporting Period: April 1, 2021 – June 30, 2021

Below please provide a brief summary of the status of the Project listed as well as for each Objective listed below. Include any barriers, how and if they were overcome, and successes achieved.

We began active patient contact and recruitment during the first quarter of 2021. From the physician mailings in December, we have received no information about patients who should not be contacted. Honest brokers at the Kentucky Cancer Registry (KCR) validated contact information and mailed the initial patient for 198 patients on January 4. Follow-up letters for non-responders have been sent to at least 41 patients. For the patients who have responded, 63/86 (73.3%) have indicated their willingness to be contacted by the study team. This indicates an extremely high response rate compared to other cancer patient contact studies facilitated by the KCR and suggests the importance of this study to cancer patients and their families in Kentucky. Only 22/86 (25.6%) patients declined contact and we learned that one patient is now deceased. KCR has also attempted to follow-up with telephone calls with 30 patients and is seeking more current telephone information for 83 patients. Dr. Durbin has discussed the study with one family who reached out to him for additional information. The family subsequently decided to participate. Recruitment of the second cohort of 517 patients began in July.

Mr. Scot Mattingly, the study recruiter and survey administrator has received contact information for the 63 patients released from KCR. As of the end of June, he had reached out to all patients and families to request their formal assent/consent to participate in the study. Twenty-six patients have enrolled and 24 have completed the household survey. Twenty-four patients have provided saliva samples for DNA testing. An additional twenty-six patients are in process for scheduling meetings with Mr. Mattingly.

We completed the arrangements for patient reimbursement through the Western Union cash card system at UK. All patients have been reimbursed for their participation.

In addition, the REDCap survey instrument has been revised to accommodate non-responses to certain questions and other refinements that resulted from insights gained from the initial participants. The study IRB has also been revised to reflect improvements made to logistical procedures.

In summary, this patient recruitment study is off to a very good start. The research team is excited about the high response rate. We have improved upon the initial logistical workflows and have tested and improved the survey data collection instrument. We anticipate the pace of recruitments, surveys and sample collections will increase significantly during the following quarters. Planning discussions have also begun regarding the birth certificate linkage and data abstraction component.

Primary Objectives

#1 – Enhance the retrospective population-based molecular and clinical data with germline sequencing and analyses and medical chart review.

We have determined to select two independent patient cohorts to ensure representative data. The first cohort will include 198 survivors from the original cohort. The second cohort will include all 517 patient survivors, representing the entire population of Kentucky pediatric brain and CNS patients. Any patients from the first cohort who are randomly selected in the second cohort will be considered participants in both sub-studies. All participants will be requested to conduct the household survey and submit a saliva sample for sequencing.

The study budget will only support the germline sequencing for 125 consented patients. We therefore intend to bank any additional samples for future sequencing as additional funds become available. In addition, it was determined that the likelihood of patient consent and participation would be greater if we could offer a small cash incentive of up to $50 to compensate families for their time and effort. This amount was not initially budgeted and will be covered by the Kentucky Cancer Registry.

Logistical planning for patient recruitment, survey and specimen collection have been fully implemented and validated.

Cohort 1 (N = 198)

Kentucky Cancer Registry/Virtual Tumor Repository Honest Broker Contact for Patient Assent

Physician Letters	Sent	198
	Contraindication for patient contact	0
Patient Letters	Sent	198
	Returned, Invalid Address/ Seeking alternative contact	46
	Returned, Yes	26
	Returned, No	5
Patient Telephone Contact	Attempted	167
	Succeeded, Yes	37
	Succeeded, No	17
	In Process (9 attempts made)	30
	Invalid number/seeking alternative contact	83
Patient Assent for Study Contact	Yes	63
	No	22
	Deceased	1

	Pending better contact information	113

Study Patient Contact for Referrals (N = 63)

Consented/Completed	Saliva and Survey	22
	Saliva Only	2
	Survey Only	2
	Total	26
Pending Participation	Meeting Scheduled	3
	No Show/Cancellations	15
	Pending Scheduling	18
	Total	36
Declined Participation	No longer interested	1

Cohort 2 (N = 517)

Physician Letters	Sent	94
	Contraindication for patient contact	0
Patient Letters	Sent	94
	Returned, Invalid address/ Seeking alternative contact	2
	Returned, Yes	0
	Returned, No	0
Patient Telephone Contact	Attempted	0
	Succeeded, Yes	0
	Succeeded, No	0
	In Process (9 attempts made)	0
	Invalid number/Seeking alternative contact	0
Patient Assent for Study Contact	Yes	0
	No	0
	Deceased	0
	Pending better contact information	0

#2 – Characterize potential environmental and lifestyle risk factors through patient and family interviews and linkage to birth data.

Data collection is underway with twenty-six patients completing the survey instrument and/or providing saliva samples for DNA testing. Saliva kits will be sent to CHOP for sequencing in batches of 24.

#3 – Incorporate additional data and enhance data sharing infrastructures in collaboration with the Children's Hospital of Philadelphia (CHOP) and the NIH Kids First Data Resource Center (DRC).

CHOP will process and return results in batches of 24. The first shipment to CHOP should occur in July.

Deliverables (check appropriate time period when each deliverable is completed)	**Month 1-3**	**Month 4-6**	**Month 7-9**	**Month 10-12**	**Month 13-15**	**Month 16-18**	**Month 19-21**	**Month 22-24**	√
Obtain and notify DPH when IRB approval is received		√							
Enhance the retrospective population-based molecular and clinical data with germline sequencing and analyses and medical chart review			√ (ongoing)						
Characterize potential environmental and lifestyle risk factors through patient and family interviews and linkage to birth data									
Incorporate additional data and enhance data sharing infrastructures in collaboration with CHOP and the DRC									
Disseminate study results									

Quarterly Reports are due:

- October 15, 2020
- January 15, 2021
- April 15, 2021
- July 15, 2021
- October 15, 2021

- January 15, 2022
- April 15, 2022
- July 15, 2022

Reports should be returned to:
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