Name Chantel Cacciotti

Contact Information

Institution London Health Sciences

Address 800 Commissioners Rd East, Rm B1-114
London, Ontario, N6A 5W9
Canada

Phone Number 519-685-8500

Alternate Phone Number

Email Address Chantel.Cacciotti@lhsc.on.ca

Requirements to submit AOI (all answers must be "yes" to proceed)

A comprehensive review of previously published data has been completed	Yes
The specific aims are clear and focused	Yes
The investigator has appropriate experience and expertise to develop the concept proposal; if not, has identified a mentor or senior co-investigator.	Yes
The investigator agrees to develop an initial draft of the concept proposal within 6 weeks of approval of the AOI and to finalize the concept proposal within 6 months	Yes

Project Title Long-term Outcomes of Infant Brain Tumor Survivors

Planned research population (eligibility criteria)

- Infants (<5 years of age) at diagnosis
- Diagnosis of primary CNS tumor- including low and high grade glioma, ependymoma, embryonal tumor, choroid plexus carcinoma

Proposed specific aims

- To review the late effects of treatment on children diagnosed at less than 5 years of age with a CNS tumor.
- To understand how the treatments (surgery, chemotherapy, radiation) were used in infants with various CNS malignancies
- To review whether the presence or absence of hydrocephalus and whether intervention (VP shunt, EVD, ETV) impacts the late effects of these survivors
- To review if the diagnosis of posterior fossa syndrome affects the late effects of these infant survivors
- To review the mortality of these tumors

- To review the chronic health conditions (late effects) of these patients, including neurotoxicity, cardiac toxicity, pulmonary toxicity, endocrine dysfunction, ototoxicity, vision deficits, secondary malignancies, quality of life, ability to complete activities of daily living, and/or live independently.
- To evaluate if aspects of therapy, age at diagnosis (with further breakdowns for age as < than 12 mo, 1- 3 years of age and 4-5 years), presence of hydrocephalus, presence of endocrine dysfunction and tumor type impact the late effects of these survivors

Will the project require non-CCSS funding to complete? No

If yes, what would be the anticipated source(s) and timeline(s) for securing funding?

Does this project require contact of CCSS study subjects for:

Additional self-reported information	No
Biological samples	No
Medical record data	Yes

If yes to any of the above, please briefly describe.

Clinical information such as age at diagnosis, specifics about diagnosis, treatment, outcomes and late effects of therapy are required

What CCSS Working Group(s) would likely be involved? (Select all that apply)

	Primary	Secondary
Second Malignancy		✓
Chronic Disease	✓	
Psychology/Neuropsychology		✓
Genetics		✓
Cancer Control		✓
Epidemiology/Biostatistics		✓

Outcomes or Correlative Factors

	Primary	Secondary	Correlative Factors
Late Mortality	✓		
Second Malignancy		✓	

Health Behaviors

	Primary	Secondary	Correlative Factors
Tobacco			✓
Alcohol			✓
Physical Activity			✓
Medical Screening			✓
Other			

If other, please specify

Psychosocial

	Primary	Secondary	Correlative Factors
Insurance			✓
Marriage			✓
Education			✓
Employment			✓
Other			

If other, please specify

Medical Conditions

	Primary	Secondary	Correlative Factors
Hearing/Vision/Speech		✓	
Hormonal Systems		✓	
Heart and Vascular		✓	
Respiratory		✓	
Digestive		✓	

	Primary	Secondary	Correlative Factors
Surgical Procedures			✓
Brain and Nervous System	✓		
Other			✓

If other, please specify

stroke related problems, fatigue, sleep

Medications

Describe medications

Psychologic/Quality of Life

	Primary	Secondary	Correlative Factors
BSI-18			✓
SF-36			✓
CCSS-NCQ			✓
PTS			
PTG			
Other			

If other, please specify

Other

	Primary	Secondary	Correlative Factors
Pregnancy and Offspring			✓
Family History			✓
Chronic Conditions (CTCAE v3)	✓		
Health Status		✓	

Demographic

	Primary	Secondary	Correlative Factors
Age			✓
Race			✓
Sex			✓
Other			

If other, please specify

Cancer Treatment

	Correlative Factors
Chemotherapy	✓
Radiation Therapy	✓
Surgery	✓

Anticipated Sources of Statistical Support

CCSS Statistical Center	Yes
Local Institutional Statistician	No

If local, please provide the name(s) and contact information of the statistician(s) to be involved.

Will this project utilize CCSS biologic samples?

No

If yes, which of the following?

If other, please explain

Other General Comments

This is a application of intent to conduct research, we have constructed a research team with junior and senior investigators. Our team includes Dr. Chantel Cacciotti, Dr. Natasha Pillay-Smiley, Dr. Peter deBlank and Dr. Nicky Ullrich.
Some of these individuals have been part of prior CCSS studies, whereas others have not.

As this is my first application to CCSS I would value any feedback and suggestions for adjustments to move forward with this project which is aiming at evaluating long term outcomes in infant brain tumor survivors.

Thank you for considering this application.

Agree

I agree to share this information with St. Jude

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