Section: Contact Information

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Section: Project Requirements and Description

Group: Requirements to submit AOI

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: Psychologic and Cognitive Outcomes in Pediatric Cancer Survivors Diagnosed in Infancy (birth - 1 year of age) Compared to Those Diagnosed in Toddlerhood (1-3 years) and Preschool Age (3-6 years)

Planned research population (eligibility criteria):

All CCSS subjects diagnosed with any cancer at ages: 0-1 years of age compared to survivors diagnosed at ages 1-3 years of age, 3-6 years of age and sibling controls in both the original and expansion CCSS cohorts.

Proposed specific aims:

Primary aims:

- 1. To describe the neurocognitive and psychosocial outcomes in long term cancer survivors diagnosed in infancy (< 12 months) compared to toddlers (1-3 year-olds), preschool age children (3-6 year-olds) and healthy sibling controls.
- 2. To describe the social functioning in long term cancer survivors diagnosed in infancy compared to toddlers, preschool age children and their healthy sibling controls. Secondary aim:
- 1. To identify diagnostic and treatment variables associated with neurocognitive and psychosocial outcomes in infants and young children.

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?:

Group: Does this project require contact of CCSS study subjects for:

Additional self-reported information : No

Biological samples : **No** Medical record data : **No**

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

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

Second Malignancy: Chronic Disease:

Psychology / Neuropsychology: Primary

Genetics:

Cancer Control:

Epidemiology / Biostatistics:

Section: Outcomes or Correlative Factors

Late mortality:

Second Malignancy:

Group: Health Behaviors

Tobacco: Alcohol:

Physical activity:
Medical screening:

Other:

If other, please specify:

Group: Psychosocial

Insurance:

Marriage : Secondary
Education : Secondary
Employment : Secondary

Other:

If other, please specify:

Group: Medical Conditions

Hearing/Vision/Speech : Hormonal systems : Heart and vascular :

Respiratory : Digestive :

Surgical procedures:

Brain and nervous system:

Other:

If other, please specify: **Group: Medications**

Describe medications:

Group: Psychologic/Quality of Life

BSI-18 : **Primary** SF-36 : **Primary**

CCSS-NCQ : Primary

PTS: PTG: Other:

If other, please specify:

Group: Other

Pregnancy and offspring:

Family history:

Chronic conditions (CTCAE v3):

Health status:

Group: Demographic

Age: Correlative Factors

Race: Correlative Factors

Sex: Correlative Factors

Other:

If other, please specify:

Group: Cancer treatment

Chemotherapy : Correlative Factors
Radiation therapy : Correlative Factors

Surgery: Correlative Factors

Section: Anticipated Sources of Statistical Support

CCSS Statistical Center: Yes Local institutional statistician:

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:

Section: Other General Comments

Other General Comments:

The primary focus of this project is to assess the impact of a cancer diagnosis and associated treatment on the youngest and most vulnerable CCSS cohort, which has not been specifically examined.

I agree to share this information with St. Jude: Yes