

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 : **Overall and Cardiac-Specific Survival Following Serious Cardiovascular Events in Childhood Cancer Survivors**

Planned research population (eligibility criteria) :

CCSS baseline & expanded cohorts, and siblings. Data through FU5.

Proposed specific aims :

AIM 1: Among childhood cancer survivors (CCS) who self-report cardiomyopathy/heart failure (CHF), coronary artery disease (CAD), and stroke, assess the long-term survival following the respective diagnosis of these cardiovascular conditions compared with siblings with similar conditions.

Hypothesis: Overall survival in CCS following the development of one of these serious cardiovascular (CV) conditions will be lower compared with siblings affected by the same condition.

Hypothesis: Even after accounting for competing causes of death, cardiac-specific survival in CCS following the development of one of these serious CV conditions will remain lower in CCS vs. siblings affected by the same condition.

AIM 2: Among CCS affected by one of the serious CV conditions, overall survival and cardiac-specific survival will be differentially influenced by prior cancer

treatment exposures.

Hypothesis: Compared with CCS without a history of radiation (to head, neck, or chest) or anthracycline chemotherapy, those exposed will have lower overall survival and cardiac-specific survival.

Hypothesis: Compared with siblings, CCS without a history of radiation (to head, neck, or chest) or anthracycline chemotherapy will have similar cardiac-specific survival.

Exploratory: Based on the chronic condition CTCAE grading system, describe and compare the latency and timing of CHF (grades 2->5), CAD (grades 3->5), and stroke (grades 4->5) progression from lower to higher grades among CCS and siblings.

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 : **Secondary**

Psychology / Neuropsychology :

Genetics :

Cancer Control :

Epidemiology / Biostatistics : **Primary**

Section: Outcomes or Correlative Factors

Late mortality : **Primary**

Second Malignancy :

Group: Health Behaviors

Tobacco : **Correlative Factors**

Alcohol : **Correlative Factors**

Physical activity : **Correlative Factors**

Medical screening : **Correlative Factors**

Other :

If other, please specify :

Group: Psychosocial

Insurance : **Correlative Factors**

Marriage :

Education :

Employment :

Other :

If other, please specify :

Group: Medical Conditions

Hearing/Vision/Speech :

Hormonal systems :

Heart and vascular : **Primary**

Respiratory :

Digestive :

Surgical procedures :

Brain and nervous system :

Other :

If other, please specify :

Group: Medications

Describe medications :

Group: Psychologic/Quality of Life

BSI-18 :

SF-36 :

CCSS-NCQ :

PTS :

PTG :

Other :

If other, please specify :

Group: Other

Pregnancy and offspring :

Family history :

Chronic conditions (CTCAE v3) : **Primary**

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 :

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 :

It is possible that the number of siblings affected by the target CV conditions will be too few to allow for stable estimates / comparisons. If that is the case, then we can discuss whether the AOI should be withdrawn or wait until FU7 data become available. It is possible that a survivor-only analysis could still be done, but lack of a non-cancer comparison group may dilute its impact.

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