

## **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 : **Long-term Renal Complications in Survivors of Childhood Cancer: A Combined Report from the Childhood Cancer Survivor Study (CCSS) and Adult Life after Childhood Cancer in Scandinavia (ALiCCS) Cohorts**

Planned research population (eligibility criteria) :

**Inclusion criteria: All 5-year childhood cancer survivors and siblings within the original and expanded CCSS cohorts; All 5-year childhood cancer survivors and healthy controls within the ALiCCS cohort**

**Exclusion criteria: All survivors and siblings/healthy controls with congenital conditions predisposing to renal failure either in childhood or adulthood (i.e. genetic syndromes, congenital abnormalities of the genitourinary system, etc.). Survivors with cancer predisposition syndromes (Beckwith-Wiedemann, WAGR syndrome, Denys-Drash syndrome, etc) will be included in the analysis.**

Proposed specific aims :

**1. To determine the rate and 35-year cumulative incidence of end stage renal disease and renal transplantation in childhood cancer survivors compared to healthy controls.**

**Hypothesis: As a consequence of cancer therapy in childhood, survivors are at increased risk for renal dysfunction and ultimately, the development of end stage**

renal disease and need for renal transplantation.

2. To determine the risk factors for end stage renal disease in survivors of childhood cancer including: demographic factors, lifestyle factors (smoking), chronic conditions (diabetes, hypertension and other cardiovascular disease, genitourinary disease), treatment factors (treatment era, cancer diagnosis, chemotherapy agents, radiotherapy to the kidneys), type of surgery including nephrectomy (unilateral partial, bilateral partial, unilateral total, bilateral total), and treatment for any second malignant neoplasm.

**Hypothesis:** Chronic conditions developed secondary to childhood cancer therapy, notably cardiovascular and genitourinary diseases, and treatment factors, including renal toxic chemotherapeutic agents, high-dose radiotherapy to the kidney(s), and any nephrectomy are associated with increased risk for end stage renal disease in survivors of childhood cancer.

3. To examine the influence of specific chemotherapy agents and radiotherapy dose to the kidney(s) on the risk for end stage renal disease in survivors of childhood cancer who underwent nephrectomy as treatment of their primary cancer.

**Hypothesis:** Survivors who underwent increasing degrees of kidney resection (i.e. unilateral partial < unilateral total < bilateral partial) are at increasing risk for late development of end stage renal disease. Those who received renal toxic chemotherapeutic agents and/or high-dose radiotherapy to the remaining kidney(s) are at increased risk for development of end stage renal disease.

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 : **Primary**

Psychology / Neuropsychology :

Genetics :

Cancer Control :

Epidemiology / Biostatistics : **Secondary**

**Section: Outcomes or Correlative Factors**

Late mortality : **Correlative Factors**

Second Malignancy : **Correlative Factors**

***Group: Health Behaviors***

Tobacco : **Correlative Factors**

Alcohol : **Correlative Factors**

Physical activity :

Medical screening :

Other :

If other, please specify :

***Group: Psychosocial***

Insurance : **Correlative Factors**

Marriage :

Education : **Correlative Factors**

Employment :

Other :

If other, please specify :

***Group: Medical Conditions***

Hearing/Vision/Speech :

Hormonal systems : **Correlative Factors**

Heart and vascular : **Correlative Factors**

Respiratory :

Digestive :

Surgical procedures : **Correlative Factors**

Brain and nervous system :

Other : **Primary**

If other, please specify : **Renal/Genitourinary system**

***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) : **Correlative Factors**

Health status : **Correlative Factors**

***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 :

**We will plan to combine this data with data from the ALiCCS and individual data points and specific aims may be slightly modified at the time of ACP submission in order to be sure the data between the 2 cohorts are congruent.**