**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: The impact of thyroid hormone replacement therapy on the cardiovascular health burden in childhood cancer survivors

Planned research population (eligibility criteria):
Childhood cancer survivors (who have survived >5 years from cancer diagnosis) that have been diagnosed with cancer from 1970-1986. All childhood cancer survivors with thyroid hormone replacement therapy (that have been diagnosed with hypothyreosis or whose thyroids have been removed after cancer survival) will be the research population. The control population are childhood cancer survivors with a possibly similar/same cancer diagnosis at a similar age at diagnosis (and the same gender would be optimal as control, if possible) without thyroid hormone replacement therapy.
The siblings serve as an additional reference cohort.

Proposed specific aims:
To investigate the cardiovascular late conditions (e.g. myocardial infarction, cardiac insufficiency, cerebrovascular outcomes (stroke),) and possible cardiovascular mortality in childhood cancer survivors with thyroid replacement therapy and compare their outcomes with those from childhood cancer survivors with thyroid hormone replacement and to siblings (one could subdivide siblings into those with thyroid hormone replacement versus those without as well).

Will the project require non-CCSS funding to complete? Yes
If yes, what would be the anticipated source(s) and timeline(s) for securing funding?:

The funding depends on the additional information. Ideally, one would obtain the thyroid values (T4, T3, TSH) for childhood cancer survivors (and siblings, if possible) on thyroid replacement therapy.

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

Additional self-reported information: **Yes**

Biological samples: **Yes**

Medical record data: **Yes**

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

- Self-reported information would include: physical activity, alcohol intake and smoking (weight, BMI?), diabetes mellitus, hypercholesterolism, cardiovascular medication.

- Biological samples: Blood samples to evaluate T4, T3, and TSH—those values should be available by access to a databank, since these lab values are usually continuously monitored during thyroid hormone replacement therapy.

Medical record data: Radiation to the neck or brain area Y/N, total body irradiation Y/N (information on possible, but rare congenital hypothyroidism to hypothyroidism prior to cancer diagnosis).

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

- Second Malignancy:
- Chronic Disease: **Primary, Secondary**
- Psychology / Neuropsychology:
- Genetics:
- Cancer Control:
- Epidemiology / Biostatistics: **Primary**

**Section: Outcomes or Correlative Factors**

Late mortality: **Primary**

Second Malignancy: **Correlative Factors**

**Group: Health Behaviors**

- Tobacco: **Correlative Factors**
- Alcohol: **Correlative Factors**
- Physical activity: **Correlative Factors**
- Medical screening:
- Other:
  - If other, please specify:

**Group: Psychosocial**
Insurance:
Marriage:
Education:
Employment:
Other:
If other, please specify:

**Group: Medical Conditions**
Hearing/Vision/Speech:
Hormonal systems: Secondary, Correlative Factors
Heart and vascular: Primary
Respiratory:
Digestive:
Surgical procedures: Correlative Factors
Brain and nervous system: Correlative Factors
Other:
If other, please specify:

**Group: Medications**
Describe medications:
**Thyrooxine medications**

**Group: Psychologic/Quality of Life**
BSI-18:
SF-36:
CCSS-NCQ:
PTS:
PTG:
Other:
If other, please specify:

**Group: Other**
Pregnancy and offspring: Correlative Factors
Family history: Correlative Factors
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?: Yes
If yes, which of the following?: Peripheral blood
If other, please explain: The T3, T4, TSH results should be already available in a database.

Section: Other General Comments
Other General Comments:
It would be great to receive support/advice on this project from an experienced senior researcher focusing on late effects.