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- 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 :
Thyroxine 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 focussing on late effects.