

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 : **Burden of Morbidity after Basal Cell Carcinoma in Childhood Cancer Survivors**

Planned research population (eligibility criteria) :

Subject population: Eligibility criteria for our study will mirror the eligibility for the CCSS cohort.

Outcome of interest: The primary outcomes of interest are:

i) Subsequent malignant neoplasms developing after the diagnosis of BCC

ii) All CTCAE grades ≥ 3 chronic health conditions

iii) Key chronic health conditions such as cognitive impairment, congestive heart failure, coronary artery disease and diabetes mellitus

Proposed specific aims :

Aim 1. Determine the risk of subsequent non-BCC SMNs among childhood cancer survivors with BCC, when compared with childhood cancer survivors without BCC

Hypothesis 1. Childhood cancer survivors with BCC will be at increased risk for developing SMNs when compared with those without BCC, after adjusting for radiation, chemotherapy and demographic risk factors.

Aim 2. Determine the risk of subsequent chronic health conditions among

childhood cancer survivors with BCC, when compared with childhood cancer survivors without BCC

Hypothesis 2. Childhood cancer survivors with BCC will be at increased risk for developing chronic health conditions when compared with those without BCC, after adjusting for radiation, chemotherapy and demographic risk factors.

Aim 3. Develop a risk prediction model that includes the diagnosis of BCC and other relevant clinical and demographic predictors to optimize identification of survivors at higher risk for developing invasive SMNs or key non-malignant conditions

Hypothesis 3. A parsimonious set of clinical variables will allow identification of childhood cancer survivors at increased risk of SMNs or key non-malignant conditions

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 : **Yes**

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

The following information will be requested from CCSS questionnaire data:

- o Primary cancer diagnosis
- o Subsequent malignant neoplasms
- o Chronic health conditions \geq grade 3
- o Age at primary cancer diagnosis
- o Age at diagnosis of BCC
- o Age at diagnosis of SMN
- o Age at diagnosis of chronic health conditions
- o Age at most current questionnaire completion
- o Date of death (and cause)
- o Gender
- o Race/ethnicity
- o Treatment history, including:
 - o Radiation yes/ no
 - o Radiation field
 - o Chemotherapy: yes/ no
 - o Anthracycline cumulative dose
 - o Sun exposure
 - o Sun burn history

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

Second Malignancy : **Secondary**

Chronic Disease : **Secondary**

Psychology / Neuropsychology :

Genetics : **Secondary**

Cancer Control :

Epidemiology / Biostatistics : **Primary**

Section: Outcomes or Correlative Factors

Late mortality :

Second Malignancy : **Primary**

Group: Health Behaviors

Tobacco : **Primary**

Alcohol : **Primary**

Physical activity : **Secondary**

Medical screening : **Secondary**

Other : **Primary**

If other, please specify : **Chronic health conditions**

Group: Psychosocial

Insurance :

Marriage :

Education :

Employment :

Other :

If other, please specify :

Group: Medical Conditions

Hearing/Vision/Speech : **Secondary**

Hormonal systems : **Secondary**

Heart and vascular : **Primary**

Respiratory : **Primary**

Digestive : **Primary**

Surgical procedures :

Brain and nervous system : **Primary**

Other : **Primary**

If other, please specify : **All Chronic Health Conditions - graded by CTCAE**

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) :

Health status :

Group: Demographic

Age : **Primary**

Race : **Primary**

Sex : **Primary**

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 : **Yes**

If local, please provide the name(s) and contact information of the statistician(s) to be involved. :

Lennie Wong, PhD (City of Hope)

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 :