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 : **Melanoma among Adult Survivors of Childhood Cancer: A Report from the Childhood Cancer Survivor Study**
Planned research population (eligibility criteria) :
This proposal would encompass all CCSS participants in both the initial and expansion cohort. This proposal would not utilize the sibling cohort. Further detail would be required for those patients who developed in situ or invasive melanoma.
Proposed specific aims :
Primary aim:
Describe the incidence and risk factors for melanoma among survivors of childhood cancer

Previously Pappo, et al. published data using the initial CCSS cohort and found a 2.5x risk of melanoma among childhood cancer survivors. Since this time, many additional melanomas have been detected with additional follow- up as well as the expansion cohort (previously n= 57, now at least 163) which will increase power available for this analysis.

Secondary aim 1:
Determine if radiation therapy is a risk factor for the development of melanoma as a second malignant neoplasm

Previous publications (Pappo, et al. Pediatric Blood & Cancer. 2013) did not detect such a relationship in the initial cohort. Since this time, many additional melanomas have been detected which will increase power available for this analysis. Additionally, more granular data from the CCSS Radiation Physics Center may increase the ability to detect

a relationship

Secondary aim 2:
Determine if the survival of invasive melanoma has improved in more recent eras.

In 2011, the FDA approved Ipilimumab for the treatment of melanoma. Since that time other immunotherapy drugs targeting the PD-1 pathway have also been approved, which has led to better treatment outcomes for melanoma patients in the general population. Whether these benefits also carry over to childhood cancer survivors is not known.

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 : **Primary**

Chronic Disease :

Psychology / Neuropsychology :

Genetics :

Cancer Control :

Epidemiology / Biostatistics :

Section: Outcomes or Correlative Factors

Late mortality : **Secondary**

Second Malignancy : **Primary, Correlative Factors**

Group: Health Behaviors

Tobacco :

Alcohol :

Physical activity :

Medical screening :

Other : **Correlative Factors**

If other, please specify : **SUN SENSITIVITY- part of LTFU 2, but unclear if sufficient data to warrant inclusion; other non-melanoma skin cancers would also be analyzed as a risk factor for melanoma**

Group: Psychosocial

Insurance :

Marriage :

Education :

Employment :

Other :

If other, please specify :

Group: Medical Conditions

Hearing/Vision/Speech :
Hormonal systems :
Heart and vascular :
Respiratory :
Digestive :
Surgical procedures :
Brain and nervous system :
Other : **Correlative Factors**
If other, please specify : **immunosuppresive medication use**

Group: Medications

Describe medications :
immunosuppresive 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 : **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 :

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. :
We have local masters level statistical support who is familiar with the CCSS and could work on this. However, i would expect a quicker turnaround time if we are able to work with the CCSS statistical center.

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