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: immunosuppressive medication use

**Group: Medications**
Describe medications:
immunosuppressive 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