**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**: Incidence of Late Anorectal Complications among Childhood Cancer Survivors

Planned research population (eligibility criteria): 

**Planned research population**: Survivors (compared to siblings).  
**Inclusion criteria**: All.  
**Exclusion criteria**: None.  

Proposed specific aims:

**Specific aim 1**  
To describe the cumulative incidence rate of late (≥ 5 years post-diagnosis) anorectal complications (i.e. anorectal stricture, anorectal fistula, proctitis) among childhood cancer survivors.  
Hypothesis: There is a higher cumulative incidence rate of long-term anorectal complications among survivors compared to sibling controls.

**Specific aim 2**  
To characterize and compare the influence of specific demographic and treatment risk factors on late (≥ 5 years post-diagnosis) anorectal complications (i.e. anorectal stricture, anorectal fistula, proctitis) among childhood cancer survivors.  
Hypothesis: There is a higher cumulative incidence rate of late anorectal complications among survivors who have specific demographic (including
underlying diagnosis) and treatment risk factors (including prior radiation, surgery, and/or chemotherapy).

Specific aim 3
To characterize surgical intervention for the treatment of late (≥ 5 years post-diagnosis) anorectal complications (i.e. anorectal stricture, anorectal fistula) among childhood cancer survivors.
Hypothesis: N/A
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 :
Chronic Disease : Primary
Psychology / Neuropsychology :
Genetics :
Cancer Control :
Epidemiology / Biostatistics : Secondary

**Section: Outcomes or Correlative Factors**
Late mortality :
Second Malignancy :

**Group: Health Behaviors**
Tobacco : Correlative Factors
Alcohol : Correlative Factors
Physical activity :
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:
- Heart and vascular:
- Respiratory:
- Digestive: Primary, Correlative Factors
- Surgical procedures: Primary, Correlative Factors
- Brain and nervous system:
- Other: Correlative Factors
If other, please specify:

**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: 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?: No
If yes, which of the following?: 
If other, please explain:

Section: Other General Comments
Other General Comments: 