

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 :