

## **Section: Contact Information**

First Name : **Tara**

Last Name : **Henderson**

Institution : **University of Chicago**

Address 1 : **900 East 59th Street**

Address 2 : **KCBD 5124**

City : **Chicago**

State/Province/Region : **IL**

Country : **US**

Zip/Postal Code : **60637**

Phone Number : **7735737690**

Alternate Phone Number : **7737026808**

Email Address : [thenderson@peds.bsd.uchicago.edu](mailto:thenderson@peds.bsd.uchicago.edu)

## **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 : **Colorectal Cancer Screening Intervention in Childhood Cancer Survivors**

Planned research population (eligibility criteria) :

**Childhood cancer survivors exposed to any abdominal or pelvic radiotherapy; no history of colorectal cancer; at least age 35 and no reported colonoscopy in the past 5 years**

Proposed specific aims :

#### **Specific Aims**

**Subsequent cancers represent the most significant risk factor for mortality in adult survivors of childhood cancer. Childhood, adolescent and young adult cancer survivors treated with abdominal or pelvic radiation have a significantly elevated risk of colorectal cancer (CRC) at a young age. In survivors over the age of 40 years, CRC the greatest absolute excess risk of all the SMN. Importantly, recent studies suggest that childhood cancer survivors develop colonoscopy detectable adenomas. Because early detection of colorectal cancer (or precancerous lesions) is strongly associated with survival, colorectal surveillance with colonoscopy is recommended by the Children's Oncology Group, starting at age 35 years in survivors exposed to any radiotherapy to the abdomen or pelvis. Most survivors are unaware of their risk for colorectal cancer and are not followed at a cancer center. Likewise, most primary care physicians**

caring for this population are not aware of this risk or the surveillance guidelines. Thus, over 90% of survivors at high risk for CRC are not adherent to screening colonoscopy in accordance with guidelines.

In order to increase the rates of CRC screening among high risk survivors and to reduce the morbidity and mortality faced by long-term survivors of childhood cancer, the proposed study will bring together a research team with the necessary expertise and experience with the unique resource and infrastructure of the 31-institution Childhood Cancer Survivor Study.

**Primary Aim** To determine the efficacy of a mobile intervention aimed at: 1) patient activation and; 2) PCP plus patient activation, as compared to control participants receiving targeted mailed education materials on completing a screening colonoscopy.

**Hypothesis:** Compared to controls, survivors randomized to the patient or patient plus PCP group will have significantly higher rates of colorectal cancer surveillance.

#### **Secondary Aims**

1. Determine the effectiveness of patient vs patient plus PCP activation on CRC surveillance rates.
2. To conduct a multi-stakeholder mixed-methods process evaluation to understand patient, provider and system factors associated with uptake of our smart-phone based interventions, facilitators and barriers to uptake and recommendations for future adaptation and sustainability.
3. Estimate the replication costs and resultant costs of the proposed interventions.

Will the project require non-CCSS funding to complete? : **Yes**

If yes, what would be the anticipated source(s) and timeline(s) for securing funding? : **NCI R01 Funding - planning February 2019 submission.**

**Group: Does this project require contact of CCSS study subjects for:**

Additional self-reported information : **Yes**

Biological samples : **No**

Medical record data : **Yes**

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

**This will be an ancillary study that requires recontact of participants.**

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

Second Malignancy :

Chronic Disease : **Secondary**

Psychology / Neuropsychology :

Genetics :

Cancer Control : **Primary**

Epidemiology / Biostatistics :

**Section: Outcomes or Correlative Factors**

Late mortality :

Second Malignancy : **Correlative Factors**

**Group: Health Behaviors**

Tobacco : **Correlative Factors**

Alcohol : **Correlative Factors**

Physical activity : **Correlative Factors**

Medical screening : **Primary**

Other :

If other, please specify :

**Group: Psychosocial**

Insurance : **Correlative Factors**

Marriage : **Correlative Factors**

Education : **Correlative Factors**

Employment : **Correlative Factors**

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 :

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 : **Correlative Factors**

Chronic conditions (CTCAE v3) : **Correlative Factors**

Health status : **Correlative Factors**

**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 :

Local institutional statistician : **Yes**

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

**Chaya Moskowitz at Memorial Sloan Kettering Cancer Center will be the co-investigator statistician on this project.**

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**