

## **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 : **Internet-delivered cognitive behavioral pain management for pediatric cancer survivors with chronic pain: A randomized controlled trial**

Planned research population (eligibility criteria) :

**Participants will be recruited from the CCSS cohort. All participants must be ≥ 18 years of age, endorse experiencing pain for ≥ 3 months, speak and read English, have access to a computer and the internet, not currently participating in cognitive behavioral therapy, not currently experiencing a psychotic illness or severe symptoms of depression.**

Proposed specific aims :

#### **Primary Aim:**

**Determine if integrating wearable respiration technology (Spire device) with an internet-delivered cognitive behavioral pain management program (Pain Course) is more effective than both the Pain Course alone, and an attention-control in reducing pain severity and pain-related disability among adult survivors of childhood cancer.**

#### **Secondary Aims:**

**1.Examine the impact of the Pain Course and Spire on symptoms of anxiety as measured by the GAD-7, depression as measured by the PHQ-8, quality of life as measured by the SF-12, and functional status as measured by the BPI Pain Interference Subscale.**

**2.Identify baseline characteristics of survivors (e.g., anxiety) that may moderate/mediate treatment outcomes.**

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? :

**Anticipate applying for R01 funding in Spring 2019.**

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

Additional self-reported information : **Yes**

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 :

Psychology / Neuropsychology : **Secondary**

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 : **Correlative Factors**

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 : **Correlative Factors**

Hormonal systems : **Correlative Factors**

Heart and vascular : **Correlative Factors**

Respiratory : **Correlative Factors**

Digestive : **Correlative Factors**

Surgical procedures : **Correlative Factors**

Brain and nervous system : **Correlative Factors**

Other :

If other, please specify :

**Group: Medications**

Describe medications :

**psychotropics; analgesics**

***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) : **Correlative Factors**

Health status : **Correlative Factors**

***Group: Demographic***

Age :

Race :

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 :

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