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 : **Childhood Surgery and Chronic Pain among Adult Survivors of Childhood Cancer**

Planned research population (eligibility criteria) :
We will include all childhood cancer survivors in the CCSS original cohort (diagnosed 1970-86) who participated in the 2007 (FU4) follow-up survey and all childhood cancer survivors in the CCSS expansion cohort (diagnosed 1987-1999).

Proposed specific aims :
Specific Aim 1: To describe the prevalence of chronic pain among childhood cancer survivors who did and did not undergo surgery as cancer treatment within 5 years of diagnosis.
Hypothesis 1: There is a higher prevalence of chronic pain among survivors who underwent surgery compared to those who did not undergo surgery.
Note: in these estimates and in the aims below, we will carefully consider differences in underlying disease and other risk factors. Siblings will be used only to provide additional baseline estimates (will not have information on exposure/surgery for siblings).

Specific Aim 2:
To compare the prevalence of chronic pain among childhood cancer survivors treated with surgery who did and did not undergo radiotherapy to the operative

site.
Hypothesis 2: There is a higher prevalence of chronic pain among survivors who underwent surgery and radiotherapy, compared to those who were treated with surgery alone.

Specific aim 3:
To define the prevalence of and risk factors for chronic surgical site pain among survivors who underwent surgery as cancer treatment within 5 years of diagnosis.
Hypothesis 3: Certain demographic, diagnosis, and treatment related variables are associated with chronic surgical site pain among survivors who underwent surgery.

Specific aim 4:
To define the use of pain medications among childhood cancer survivors with chronic surgical site pain.
Hypothesis 4: There is a higher cumulative incidence and incidence rate of pain medication utilization among survivors with chronic surgical site pain, compared to those without chronic surgical site pain.

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 :

Psychology / Neuropsychology : **Primary**

Genetics :

Cancer Control :

Epidemiology / Biostatistics : **Secondary**

Section: Outcomes or Correlative Factors

Late mortality :

Second Malignancy : **Correlative Factors**

Group: Health Behaviors

Tobacco : **Correlative Factors**

Alcohol : **Correlative Factors**

Physical activity :

Medical screening :
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 : **Correlative Factors**
Brain and nervous system :
Other :
If other, please specify :

Group: Medications

Describe medications :
Pain medication use (based on free-text responses) as secondary outcome.

Group: Psychologic/Quality of Life

BSI-18 : **Correlative Factors**
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 : **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 : **Yes**
If local, please provide the name(s) and contact information of the statistician(s) to be involved. :
Arin Madenci (in conjunction with CCSS analysts; with the support of Harvard T.H. Chan School of Public Health faculty)
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 :
This proposal has been discussed with Kevin Krull over the past several months.

The above analysis plan is dependent on details of surgical procedures for the Expansion cohort. As such, this project can only begin after the Surgical Coding project for the Expansion cohort has been completed.