Section: Contact Information

First Name : Arin Last Name : Madenci Institution : Boston Children's Hospital Address 1 : 300 Longwood Ave Address 2 : City : Boston State/Province/Region : MA Country : US Zip/Postal Code : 02115 Phone Number : 617-355-4503 Alternate Phone Number : Email Address : <u>Arin.Madenci@childrens.harvard.edu</u>

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 Post-Traumatic Stress Disorder Symptoms Among 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 completed the 2003 (FU2) follow-up survey.

Proposed specific aims :

Specific aim 1:

To compare the frequency of post-traumatic stress disorder (PTSD) symptoms among childhood cancer survivors who did and did not undergo surgery as cancer treatment.

Hypothesis 1: Survivors who underwent surgery as cancer treatment have a significantly increased number of PTSD symptoms, compared to survivors who do not undergo surgery.

Specific aim 2:

To define the association between age at surgery and number of PTSD symptoms among childhood cancer survivors.

Hypothesis 2: Among childhood cancer survivors who underwent surgery as cancer treatment, PTSD symptoms are significantly associated with age at surgery. Specific aim 3:

To define the association between sex and number of PTSD symptoms among childhood cancer survivors who undergo surgery.

Hypothesis 3: Among childhood cancer survivors who underwent surgery as cancer treatment, PTSD symptoms are significantly associated with female sex.

Specific aim 4:

To define risk factors for number of PTSD symptoms among childhood cancer survivors who undergo surgery.

Hypothesis 4: Among childhood cancer survivors who undergo surgery as cancer treatment, certain risk factors are significantly associated with PTSD symptoms.

Specific aim 5:

To define the association between surgery and post-traumatic growth among childhood cancer survivors.

Hypothesis 5: Childhood cancer survivors who underwent surgery as cancer treatment are significantly more likely to have post-traumatic growth, compared to survivors who did not undergo surgery as cancer treatment.

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? : N/A

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 : **Correlative Factors** Other : If other, please specify :

Group: Medications

Describe medications :

Group: Psychologic/Quality of Life

BSI-18 : SF-36 : CCSS-NCQ : PTS : **Primary** PTG : **Secondary** 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 and with support from 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 project has been discussed with Kevin Krull over the last several months.