

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 : **Long-term Incidence of Venous Thromboembolism among Survivors of Childhood Cancer**

Planned research population (eligibility criteria) :
Survivors (compared to siblings)

Proposed specific aims :

Specific aim 1

To describe the incidence of late (≥ 5 years post-diagnosis) venous thromboembolism (VTE) among childhood cancer survivors.

Hypothesis: There is a higher cumulative incidence rate of long-term VTE 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) VTE among childhood cancer survivors.

Hypothesis: There is a higher cumulative incidence rate of late VTE among survivors who have specific demographic and treatment risk factors (including surgery, chemotherapy, and radiation).

Specific aim 3

To define the cumulative incidence of late (≥ 5 years post-diagnosis) mortality among survivors who developed VTE, compared to those who did not develop VTE.

Hypothesis: There is a higher cumulative incidence rate of late mortality among survivors who developed VTE, compared to those who did not.

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? : **No funding required.**

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 : **Secondary**

Second Malignancy : **Correlative Factors**

Group: Health Behaviors

Tobacco : **Correlative Factors**

Alcohol : **Correlative Factors**

Physical activity : **Correlative Factors**

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 : **Correlative Factors**

Heart and vascular : **Primary**

Respiratory : **Primary**

Digestive : **Correlative Factors**

Surgical procedures : **Secondary, Correlative Factors**

Brain and nervous system :

Other :

If other, please specify :

Group: Medications

Describe medications :

Exogenous hormone therapy, anticoagulants

Group: Psychologic/Quality of Life

BSI-18 :

SF-36 :

CCSS-NCQ :

PTS :

PTG :

Other :

If other, please specify :

Group: Other

Pregnancy and offspring : **Correlative Factors**

Family history :

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

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 :