## *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 Complications from Surgical Asplenia among Survivors of Childhood Cancer**
Planned research population (eligibility criteria) :
**Survivors with surgical asplenia (compared to survivors without asplenia and siblings)**
Proposed specific aims :
**Specific aim 1**
**To describe the incidence of surgical asplenia among childhood cancer survivors.**
**Hypothesis: None.**

**Specific aim 2**
**To describe the incidence of late (≥ 5 years post-diagnosis) infection among childhood cancer survivors with surgical asplenia, compared to siblings and childhood cancer survivors without asplenia.**
**Hypothesis: There is a higher cumulative incidence rate of late infection (including pneumonia, sepsis, meningitis, osteomyelitis, otitis media, sinusitis) among survivors with asplenia, compared to those without asplenia and siblings.**

**Specific aim 3**

**To describe the incidence of late (≥ 5 years post-diagnosis) thromboembolism (e.g. portal vein thrombosis, lower extremity deep venous thrombosis, pulmonary embolism, myocardial infarction) among childhood cancer survivors with surgical asplenia, compared to siblings and childhood cancer survivors without asplenia.**
**Hypothesis: There is a higher cumulative incidence rate of late thromboembolism among survivors with asplenia, compared to those without asplenia and siblings.**

**Specific aim 4**
**To describe the incidence of late (≥ 5 years post-diagnosis) second malignant neoplasm (SMN) among childhood cancer survivors with surgical asplenia, compared to siblings and childhood cancer survivors without asplenia.**
**Hypothesis: There is a higher cumulative incidence rate of late SMN among survivors with asplenia, compared to those without asplenia and siblings.**

**Specific aim 5**
**To describe the incidence of late (≥ 5 years post-diagnosis) mortality among childhood cancer survivors with surgical asplenia who develop the above asplenia-related complications (i.e. infection, thromboembolism, mortality), compared to survivors with asplenia who do not develop asplenia-related complications; siblings; and childhood cancer survivors without asplenia.**
**Hypothesis: There is a higher cumulative incidence rate of late mortality among survivors with asplenia who develop asplenia-related complications, compared to those survivors with asplenia who do not develop asplenia-related complications; siblings; and childhood cancer survivors without asplenia.**

**Specific aim 6**
**To describe the late (≥ 5 years post-diagnosis) use of asplenia prophylaxis (i.e. immunization, antibiotics) among childhood cancer survivors with surgical asplenia.**
**Hypothesis: None.**

**Specific aim 7**
**To characterize and compare the cumulative incidence of late (≥ 5 years post-diagnosis) infection among survivors with surgical asplenia who do and do not use asplenia prophylaxis (i.e. immunizations, antibiotics).**
**Hypothesis: There is a higher cumulative incidence rate of late infection among survivors with asplenia who do not use asplenia prophylaxis, compared to survivors with asplenia who do use asplenia prophylaxis.**

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 : **Secondary**
Chronic Disease : **Primary**
Psychology / Neuropsychology :
Genetics :
Cancer Control :
Epidemiology / Biostatistics : **Secondary**

## ***Section: Outcomes or Correlative Factors***

Late mortality : **Secondary,Correlative Factors**
Second Malignancy : **Primary**

***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 :
Surgical procedures : **Primary,Correlative Factors**
Brain and nervous system :
Other : **Primary**
If other, please specify : **Infection (including meningitis, pneumonia, otitis media, sinusitis, osteomyelitis)**

***Group: Medications***

Describe medications :
**antibiotics (e.g. tmp/smx, penicillins), vaccines, anticoagulants**

### *Group: Psychologic/Quality of Life*

BSI-18 :
SF-36 :
CCSS-NCQ :
PTS :
PTG :
Other : **Secondary**
If other, please specify :

### *Group: Other*

Pregnancy and offspring : **Correlative Factors**
Family history : **Correlative Factors**
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 :