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 :