**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: Estimating the Clinical Outcomes and Cost-Effectiveness of Preventive Medicines to Reduce Secondary Cancers and Cardiovascular Disease in Childhood Cancer Survivors

Planned research population (eligibility criteria):  
CCSS participants diagnosed between 1970 and 1999

Proposed specific aims:

Aim 1. Assess the clinical benefits, harms and harm-benefit tradeoffs of early initiation of tamoxifen to prevent breast cancer at 5-years from time of recognition of risk.

Aim 2. Evaluate the clinical benefits, harms and harm-benefit tradeoffs associated with aspirin for CRC prevention in at-risk survivors starting at younger ages.

Aim 3. Estimate the clinical benefits and harms associated with early initiation of aspirin for CVD and CRC prevention in at-risk survivors starting at younger ages.

Will the project require non-CCSS funding to complete? : Yes  
If yes, what would be the anticipated source(s) and timeline(s) for securing funding? : I plan to submit a R01 application to NCI.

**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: Secondary
Genetics:
Cancer Control:
Epidemiology / Biostatistics: Secondary

Section: Outcomes or Correlative Factors
Late mortality: Primary
Second Malignancy: Primary

Group: Health Behaviors
Tobacco:
Alcohol:
Physical activity:
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:
Heart and vascular: Primary
Respiratory:
Digestive:
Surgical procedures:
Brain and nervous system:
Other:
If other, please specify:

Group: Medications
Describe medications:

Group: Psychologic/Quality of Life
BSI-18:
SF-36: Secondary
CCSS-NCQ:
PTS:
PTG:
Other:
If other, please specify:

**Group: Other**
Pregnancy and offspring:
Family history:
Chronic conditions (CTCAE v3): **Primary**
Health status:

**Group: Demographic**
Age: **Secondary**
Race: **Secondary**
Sex: **Secondary**
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:
This proposal will use decision modeling to complete the proposed aims. CCSS data will be used to adapt existing simulation models for average-risk individuals to childhood cancer survivors (Aims 1 and 2). CCSS data will also be used to develop a simulation model of CVD and colorectal cancer among childhood cancer survivors (Aim 3).
I agree to share this information with St. Jude: **Yes**