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**