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 : **Clinical and Genetic Profiling of Cataract Risk among Long-Term Childhood Cancer Survivors**
Planned research population (eligibility criteria) :
Study participants:
The Discovery cohort will include participants from the Childhood Cancer Survivor Study (CCSS) who i) have survived at least 5 years after diagnosis of leukemia, CNS malignancy, Hodgkin lymphoma, non-Hodgkin lymphoma, Wilms tumor, neuroblastoma, soft tissue sarcoma, or a bone tumor; ii) available genotype data; iii) available phenotype data on study outcome.
The Replication cohort will include participants from the Blood or Marrow Transplant Survivor Study (BMTSS) who i) received BMT following a cancer diagnosis between 1974 and 2014 and survived ≥2y after BMT; ii) available DNA samples; iii) available phenotype data on study outcome.
Outcome:
Self-reported diagnosis of cataract and receipt of cataract surgery will be extracted from the longitudinal CCSS cohort for patients completing the Expansion Baseline Survey, Follow-Up 4 (2007) and Follow-Up 5 (2014) for Discovery; and from the BMTSS questionnaire for Replication. The self-reported outcome is a report of being diagnosed with cataract by a physician and/or receiving cataract surgery.
Proposed specific aims :
Aim 1: Identify single nucleotide polymorphisms (SNPs) associated with cataract risk among long-term survivors of childhood cancer.
Aim 1.1: Identify individual SNP associations using the CCSS cohort (Discovery)
Aim 1.2: Externally replicate the significant SNP associations in an independent cohort of BMTSS survivors (Replication).

Ho: Individual SNPs are associated with increased cataract risk among long-term childhood cancer survivors.
Aim 2: Develop a risk prediction model that integrates clinical and genetic factors to identify cancer survivors at high risk for cataract.
Aim 1.1: Develop a risk prediction model using the CCSS cohort (Discovery)
Aim 1.2: Externally validate the model in an independent cohort of cancer survivors treated with BMT (Replication).
Ho: A combined clinical and genetic model applied to childhood cancer survivors will have a discriminative power as assessed by a C-statistic ≥0.65 to identify individuals at high risk of cataract.

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? :

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 : **Secondary**

Psychology / Neuropsychology :

Genetics : **Primary**

Cancer Control :

Epidemiology / Biostatistics : **Secondary**

Section: Outcomes or Correlative Factors

Late mortality :

Second Malignancy :

Group: Health Behaviors

Tobacco : **Correlative Factors**

Alcohol : **Correlative Factors**

Physical activity :

Medical screening : **Correlative Factors**

Other :

If other, please specify :

Group: Psychosocial

Insurance :

Marriage :

Education :

Employment :

Other :

If other, please specify :

Group: Medical Conditions

Hearing/Vision/Speech : **Primary**
Hormonal systems :
Heart and vascular :
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 :
CCSS-NCQ :
PTS :
PTG :
Other :
If other, please specify :

Group: Other

Pregnancy and offspring :
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 :

Section: Anticipated Sources of Statistical Support

CCSS Statistical Center : **Yes**
Local institutional statistician : **Yes**
If local, please provide the name(s) and contact information of the statistician(s) to be involved. :
Joshua Richman, MD PhD and Lucy Zhou, MS
Institute for Cancer Outcomes and Survivorship
Birmingham, AL 35233
(205) 638-2128 or 638-2120
(205) 638-2121 fax

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 :
I agree to share this information with St. Jude : **Yes**