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Project Requirements and Description

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	Attributable Fraction of Mortality in Childhood Cancer Survivors

Planned research population (eligibility criteria)

All eligible 5-year survivors of childhood cancer from the Childhood Cancer Survivor Study.

Proposed specific aims

Aim 1: Estimate attributable fraction (AF) of all-cause and cause-specific mortality in survivors of childhood cancer in the CCSS due to cancer treatment exposure, disease specific genetic variants, modifiable lifestyle and cardiovascular risk factors and social determinants of health (SDOH).

a. The analysis for cancer treatment exposures will include all eligible survivors from the CCSS. All other analyses will include CCSS participants.
b. Genetic factors will include rare pathogenic/likely pathogenic (P/LP) variants in cancer susceptibility genes and those listed by the American College of Medical Genetics (ACMG) and disease-specific (eg., cardiovascular disease, cancer) polygenic risk scores (PRSs) and the PRSs for mortality/longevity from the general population.
c. Because of the complex and often bidirectional relationship between certain lifestyle factors, cardiovascular risk factors and SDOH we will explore the change in AF when each of these components are added to the estimates to better understand their relationship to late mortality.

Aim 2: Assess whether the AFs for all-cause and cause-specific mortality differ among males and females, follow-up age periods (or treatment era) and race/ethnicity. Given the high correlation between age and treatment era, we will attempt stratified analyses based on either follow-up age periods or treatment era, if possible. Analyses based on race/ethnicity will be attempted only if sufficient sample sizes are available. Aim 3: Compare the AF of all-cause and cause-specific mortality in survivors with those from the general population (eg., NHANES). This comparison will focus on AFs due to modifiable cardiovascular/lifestyle factors and SDOH that are available in NHANES.

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?

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.

What CCSS Working Group(s) would likely be involved? (Select all that apply)

	Primary	Secondary
Second Malignancy		
Chronic Disease		
Psychology/Neuropsychology		
Genetics		✓
Cancer Control		
Epidemiology/Biostatistics	✓	

Outcomes or Correlative Factors

	Primary	Secondary	Correlative Factors
Late Mortality	✓		
Second Malignancy			✓

Health Behaviors

	Primary	Secondary	Correlative Factors
Tobacco			✓
Alcohol			✓
Physical Activity			✓
Medical Screening			✓
Other			

If other, please specify

Psychosocial

	Primary	Secondary	Correlative Factors
Insurance			✓
Marriage			
Education			
Employment			✓
Other			

If other, please specify

Medical Conditions

	Primary	Secondary	Correlative Factors
Hearing/Vision/Speech			
Hormonal Systems			
Heart and Vascular			
Respiratory			
Digestive			
Surgical Procedures			
Brain and Nervous System			
Other			

If other, please specify

Medications

Describe medications

Psychologic/Quality of Life

	Primary	Secondary	Correlative Factors
BSI-18			
SF-36			
CCSS-NCQ			
PTS			
PTG			
Other			

If other, please specify

Other

	Primary	Secondary	Correlative Factors
Pregnancy and Offspring			
Family History			
Chronic Conditions (CTCAE v3)			✓
Health Status			

Demographic

	Primary	Secondary	Correlative Factors
Age			✓
Race			✓
Sex			✓
Other			

If other, please specify

Cancer Treatment

	Correlative Factors
Chemotherapy	✓
Radiation Therapy	✓
Surgery	✓

Anticipated Sources of Statistical Support

CCSS Statistical Center	Yes
Local Institutional Statistician	No

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

Other General Comments

Agree   I agree to share this information with St. Jude

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