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Project Requirements and Description

Requirements to submit AOI

Requirements to submit AOI (all answers must be "yes" to proceed)

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 Modifiable Risk Factors for Late Cardiovascular Complications in Survivors at Increased Risk

Planned research population (eligibility criteria)

Childhood cancer survivors in the CCSS with at least two surveys at age ≥ 18 .

Proposed specific aims

1. To assess the associations between health behaviors (physical activity, BMI, heavy/risky drinking, smoking, and a combined lifestyle score) and late cardiovascular complications (heart failure, heart attack, cerebrovascular disease, valvular heart disease, or any cardiovascular disease) in childhood cancer survivors exposed to no, low, moderate, and high risk cardiotoxic treatment or to cranial radiation (cerebrovascular disease only).
2. To assess the mediation of the associations between health behaviors and late cardiovascular complications by cardiometabolic risk factors (hypertension, diabetes, and dyslipidemia) in childhood cancer survivors exposed to no, low, moderate, and high risk cardiotoxic treatment or to cranial radiation (cerebrovascular disease only).

3. To assess the absolute excess risk of modifiable risk factors, including health behaviors and cardiometabolic risk factors, for late cardiovascular complications in childhood cancer survivors exposed to no, low, moderate, and high risk cardiotoxic treatment or cranial radiation (cerebrovascular disease only).
4. To estimate the rates of late cardiovascular complications attributable to health behaviors, in childhood cancer survivors exposed to no, low, moderate, and high risk cardiotoxic treatment or to cranial radiation (cerebrovascular disease only). This will be done using both population attributable fractions and attributable relative rate, to compare the rates attributable to these risk factors to the rates in sibling comparators.

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

BMI

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			

	Primary	Secondary	Correlative Factors
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			✓

	Primary	Secondary	Correlative Factors
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

The AOI has been changed by removing the relative rates and population attributable fractions for cardiometabolic risk factors as this is covered in concept 22-05 (assuming analyses are still ongoing). We have also removed the last two aims as these had a different focus.

Agree

I agree to share this information with St. Jude

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