Name	Chaya Moskowitz
Institution	Memorial Sloan Kettering Cancer Center
Address	633 3rd Avenue, 3rd Floor, Memorial Sloan Kettering Cancer Center, Dept of Epidemiology and Biostatistics New York, NY, 10017 United States
Phone Number	646-888-8232
Alternate Phone Number	
Email Address	moskowc1@mskcc.org

Project Requirements and Description

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 Subsequent Malignant Neoplasms in Childhood Cancer Survivors with a History of Cardiovascular Disease

Planned research population (eligibility criteria)

All CCSS participants

Proposed specific aims

1.To evaluate whether major cardiovascular events are risk factors for SMNs in childhood cancer survivors after accounting for childhood cancer treatment. We will evaluate whether self-reported myocardial infarctions, coronary heart disease, congestive heart failure, and stroke are associated with subsequent pan- cancer incidence and different SMNs individually after adjusting for radiation therapy and cardiotoxic chemotherapy.

2. To evaluate whether cancer-specific mortality and SMN recurrence are elevated in childhood cancer survivors who have SMNs and have had major cardiovascular events. In childhood cancer survivors who have an SMN, we will evaluate whether having had a cardiovascular event either prior or subsequent to the SMN is associated with an increased risk of cancer-specific mortality across all SMNS and for different SMNs individually.

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)

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

Outcomes or Correlative Factors

Late Mortality	Secondary
Second Malignancy	Primary

Health Behaviors

Tobacco	

Alcohol	
Physical Activity	
Medical Screening	
Other	

If other, please specify

Psychosocial

Insurance	
Marriage	
Education	
Employment	
Other	

If other, please specify

Medical Conditions

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

If other, please specify

Medications

Describe medications

Psychologic/Quality of Life

BSI-18	
SF-36	
CCSS-NCQ	

PTS	
PTG	
Other	

If other, please specify

Other

Pregnancy and Offspring	
Family History	
Chronic Conditions (CTCAE v3)	
Health Status	

Demographic

Age	Correlative Factors
Race	Correlative Factors
Sex	Correlative Factors
Other	

If other, please specify

Cancer Treatment

Chemotherapy	Correlative Factors
Radiation Therapy	Correlative Factors
Surgery	

Anticipated Sources of Statistical Support

CCSS Statistical Center	No
Local Institutional Statistician	Yes

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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