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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 Impact of the COVID-19 Pandemic on Major Health Events and Death Among Survivors of Childhood Cancer

Planned research population (eligibility criteria)

For health outcomes aims: Participants in CCSS who completed at least one survey between 2010 and 2025
For mortality aims: Potentially eligible for CCSS (mortality)

Proposed specific aims

1. Describe the change in rate (or prevalence) of self-reported major adverse cardiovascular events (including death due to heart disease or stroke) in the 10 years prior to the COVID 19 pandemic and after March 1, 2020 among CCSS survivors and then compared to sibling controls.
2. Describe the cumulative incidence of SMN in the 10 years prior to the COVID 19 pandemic and after March 1, 2020 (post-COVID) among CCSS survivors. Compare the relative rate of SMN pre- and post-COVID among survivors. Compare the rate of SMN among survivors to the general population using SIR pre- and post-COVID pandemic.
3. Describe the mortality rate among survivors overall and by specific cause in the 10 years prior to the COVID 19 pandemic and after March 1, 2020 among CCSS survivors. Compare the rate of deaths among survivors pre- and post-COVID to those in the general population using SMR.
4. Exploratory: Describe changes in the pattern of modifiable lifestyle risk factors (overweight/obesity, smoking status, physical activity and heavy or risky drinking) among survivors pre and post-COVID pandemic. If there are significant differences, we will consider exploring the degree to which lifestyle change accounts for differences in cardiovascular disease or mortality pre- and post-COVID pandemic.

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

None

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

Will need release of FU8 data freeze and updated NDI data to complete.

Agree

I agree to share this information with St. Jude

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