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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	Long-Term Outcomes of Late Cardiothoracic Surgery in Survivors of Childhood Cancer: A Linkage Study Between the Childhood Cancer Survivor Study (CCSS) and the Society of Thoracic Surgeons (STS) Databases
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Planned research population (eligibility criteria)

This would be a linkage study between subject in the CCSS cohort and patients undergoing cardiothoracic operations in the Society for Thoracic Surgeons (STS) database. Eligibility criteria is as follows:

- Participants in the CCSS cohort diagnosed with a first primary malignancy before age 21.
- Survived ≥ 5 years from initial cancer diagnosis.
- Underwent a cardiac or thoracic surgical procedure captured in the STS Adult Cardiac or General Thoracic Surgery Database after completion of initial cancer therapy.
- Surgery performed ≥ 5 years post–cancer diagnosis (classified as “late surgery”).

Proposed specific aims

Aim 1: Characterize the incidence, indications, and timing of cardiothoracic surgery among this cohort of childhood cancer survivors.

Aim 2: Evaluate perioperative outcomes and late survival following cardiac surgery in childhood cancer survivors compared with non-cancer controls.

Aim 3: Evaluate perioperative outcomes and late survival following major non-cardiac thoracic surgery in childhood cancer survivors compared with non-cancer controls.

Aim 4: Identify treatment-related and patient-specific risk factors associated with adverse surgical outcomes and reduced long-term survival in childhood cancer survivors.

Will the project require non-CCSS funding to complete?

Yes

If yes, what would be the anticipated source(s) and timeline(s) for securing funding?

Dr. Cameron has institutional funding and is eligible for certain career development awards as well as foundational grants as early career faculty.

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			

	Primary	Secondary	Correlative Factors
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	✓		

	Primary	Secondary	Correlative Factors
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

There have already been coordinated meetings with CCSS Leadership and STS Research team and study collaborators to discuss logistics of a proposed linkage study and there is support and interest from both study groups.