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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 Health Outcomes and Quality of Life in Childhood Cancer Survivors with Solid Organ Transplants

Planned research population (eligibility criteria)

- CCSS participants who received a solid organ transplant (SOT) after cancer diagnosis, including participants with heart, liver, lung, or kidney transplants (not including multiple-organ transplant recipients)
- CCSS participants without SOT matched by age, sex, primary cancer diagnosis, and year of cancer diagnosis as a comparator group

Proposed specific aims

As a result of the underlying disease and/or treatment-related toxicity, childhood cancer survivors (CCS) may develop organ failure requiring SOT. However, determining candidacy for SOT in CCS with prior history of malignancy requires consideration of multiple factors. These include balancing increased risk of cancer recurrence or subsequent neoplasm (SN) due to transplant immunosuppression versus the potential benefits of improved long-term survival, functionality, or quality of life after SOT. There are few studies investigating survival and graft outcomes in CCS with SOT, and there are no published studies to our knowledge investigating quality of life outcomes in this population. Preliminary analysis of CCSS data through the FU7 survey indicates a cohort size of approximately 250 CCS with SOT.

Aim 1. Describe the overall survival, graft survival, and SN risk of SOT recipients. Overall survival and SN risk will be compared to CCS without SOT. Overall survival, post-transplant malignancy risk, and graft survival will be compared to published estimates of SOT recipients without prior malignancy.
Hypotheses: Mortality and secondary malignancy risk will be elevated in CCS with SOT compared to those without SOT. Mortality may be increased in CCS with SOT compared to published estimates of SOT without prior malignancy, while graft survival and post-transplant malignancy risk will be similar. The majority of CCS with SOT will achieve long-term cancer-free survival.

Aim 2. Compare health-related quality of life and psychosocial outcomes in CCS with SOT versus those without SOT.
Hypothesis: Health-related quality of life and psychosocial outcomes will be similar in CCS with SOT versus CCS without SOT.

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			

	Primary	Secondary	Correlative Factors
Digestive			
Surgical Procedures			
Brain and Nervous System			
Other		✓	✓

If other, please specify

exposure: solid organ transplant recipient (heart, liver, lung, or kidney). secondary outcome: solid organ transplant graft survival

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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

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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