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Project Requirements and Description

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 Chronic Dialysis and Kidney Transplantation in Hematopoietic Stem Cell Transplant Survivors in the Childhood Cancer Survivor Study

Planned research population (eligibility criteria)

- CCSS participants
- Recipient of hematopoietic stem cell transplant (HSCT)
- At least 5 years of follow-up available since the time of HSCT
- The exploratory aim will also include patients listed for kidney transplant with no cancer history from the Organ Procurement & Transplantation Network (OPTN) as a comparison group

Proposed specific aims

Pediatric HSCT recipients are at high risk of developing chronic kidney disease (CKD) from multiple insults occurring prior to, during, and after HSCT including receipt of nephrotoxic therapies, sepsis, critical illness, prior acute kidney injury (AKI), BK viremia, and thrombotic microangiopathy. Most prior investigations of long-term renal outcomes in pediatric HSCT recipients have been limited to single-center studies or have primarily focused on the need for dialysis in patients with a history of AKI. A comprehensive assessment of the risk factors associated with the need for chronic dialysis and kidney transplant is needed in survivors of childhood HSCT. Here, we propose to analyze existing linked data from the CCSS, OPTN, and the Center for International Blood & Marrow Transplant Research to investigate long-term kidney outcomes in survivors of HSCT in a large, multicenter cohort.
Aim 1. Describe the incidence and prevalence of chronic dialysis and kidney transplant in patients who have received HSCT.
Aim 2. Determine risk factors associated with chronic dialysis and kidney transplant in HSCT survivors.
Exploratory Aim: Compare duration of dialysis and waitlist time prior to kidney transplant in HSCT recipients versus age- and sex-matched CKD patients listed for kidney transplant without history of malignancy.

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

primary: chronic dialysis and kidney transplant. correlative: history of receiving continuous renal replacement therapy

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Medications

Describe medications

cyclophosphamide, methotrexate, ifosfamide, platinum-based chemotherapies, calcineurin inhibitors, renal-angiotensin-aldosterone inhibitors, NSAIDs, nephrotoxic antimicrobials

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

Agree

I agree to share this information with St. Jude

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