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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 Pediatric Survivors of Hematopoietic Cell Transplant

Planned research population (eligibility criteria)

Childhood cancer survivors enrolled in the St. Jude Childhood Cancer Survivor Study who were treated with an allogeneic or autologous HCT (including those who received multiple transplants) between the ages of 0 and 20 years of age for any malignant diagnosis

Proposed specific aims

AIM 1: Describe the incidence of SMNs in patients who received either an allogeneic or autologous HCT for a cancer diagnosis. We will further describe the incidence of SMN's stratified by age, race, ethnicity, underlying diagnosis, number of transplants, treatment regimens, use of radiation therapy as part of transplant preparative regimens.

Hypothesis: We hypothesize that patients who have had an HCT, have an increased incidence of SMNs compared to the general population

AIM 2: we will identify groups of patients who are at the highest risk for developing a SMN post HCT
 Hypothesis 1: We hypothesize that patients who received alkylating agents (particularly etoposide and cyclophosphamide, total body irradiation as part of their conditioning regimen, and/or those who received an autologous transplant will be at highest risk for developing subsequent tMNs
 Hypothesis 2: We hypothesize that patients who were transplanted for underlying immunodeficiencies, received serotherapy as part of preparative regimen with significant T cell depletion are at highest risk for developing PTLD
 Hypothesis 3: we hypothesize that patients who receive total body irradiation, local radiation boosts, and develop GVHD (particularly cGVHD) are at greatest risk for developing subsequent solid tumors

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

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	✓		

	Primary	Secondary	Correlative Factors
Sex	✓		
Other	✓		

If other, please specify

ethnicity

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?

If yes, which of the following?

If other, please explain

Other General Comments

Agree

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