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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 Deep phenotyping of subsequent neoplasms in the CCSS cohort

Planned research population (eligibility criteria)

All CCSS participants--we will specifically focus on survivors that develop subsequent neoplasms.

Proposed specific aims

Aim 1: Characterize epidemiologic differences between presenting characteristics of subsequent neoplasms in survivors of childhood cancer and corresponding primary tumors in a population-based sample.

Aim 2: Compare the treatment of SNs and outcomes following SNs among survivors and corresponding primary tumors in the general population.

Aim 3: Building upon new subsequent neoplasm deep phenotyping data, investigate the diversity of biologic and molecular features of SNs and assess their relationships with etiologic risk factors (e.g., host factors, cancer treatment) and outcomes.

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?

Planned R01 submission October 2025

Does this project require contact of CCSS study subjects for:

Additional self-reported information	No
Biological samples	Yes
Medical record data	Yes

If yes to any of the above, please briefly describe.

We will need to obtain additional medical records for SN data and may require additional collection of bio samples for deeper phenotypic characterization

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			✓
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	Yes

If local, please provide the name(s) and contact information of the statistician(s) to be involved.

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Will this project utilize CCSS biologic samples? Yes

If yes, which of the following? Buccal cell DNA; Peripheral blood; Second malignancy pathology samples

If other, please explain

Other General Comments

Agree I agree to share this information with St. Jude

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