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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

Exploring the Prognostic Impact of Mutational Signatures Induced by Childhood Cancer Treatment in the Development of Subsequent Neoplasms

Planned research population (eligibility criteria)

Patients who developed subsequent neoplasms, and similarly treated controls who did not.

Proposed specific aims

Aim 1: Determine the extent of therapy-induced mutational signatures in major leukocyte lineages in peripheral blood of childhood cancer survivors.
Aim 2: Determine the prognostic impact of therapy-induced mutational signatures in blood in the development of subsequent neoplasms.

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?

An R21 is being submitted February 2025.

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			✓
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? Yes

If yes, which of the following? Peripheral blood

If other, please explain

Other General Comments

This is an Ancillary Study to our prior CCSS Concept "The Genomic Landscape of Subsequent Malignant Neoplasms in Childhood Cancer Survivors." It builds on our findings of therapy-induced mutational signatures in subsequent neoplasms; we now propose to test whether these signatures can also be identified in normal blood, and whether they are enriched in patients who developed subsequent neoplasms. We will use a novel single-cell whole-genome sequencing technology, primary template-directed amplification (PTA) to ascertain mutational signatures in peripheral blood.

Agree I agree to share this information with St. Jude

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