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Project Requirements and Description

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 Multi-omics Profiling of Cancer Treatment-related Cardiac Dysfunction Risk in Adult Survivors of Childhood Cancer

Planned research population (eligibility criteria)

Adult survivors of childhood cancer with plasma samples.

Proposed specific aims

Specific Aim 1A: To profile plasma proteins and metabolites in 1,400 asymptomatic SJLIFE survivors and identify cross-sectional associations with echocardiographic parameters of cardiac structure, function, and mechanics.
Specific Aim 1B: To determine longitudinal associations in 600 asymptomatic SJLIFE survivors between changes in plasma proteins and metabolites and changes in cardiac structure, function, and mechanics.

Specific Aim 2A: Using plasma proteins and metabolites at baseline, to develop a risk prediction model in SJLIFE for future incident cardiomyopathy/heart failure development.
Specific Aim 2B: To externally validate a risk prediction model for cardiomyopathy/heart failure in an independent cohort of survivors of childhood cancer from CCSS.

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?

NIH R01 submitted in Feb 2024

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	No
Local Institutional Statistician	Yes

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

Plasma samples will be used.

Agree I agree to share this information with St. Jude

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