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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 X-chromosome based PheWAS of late effects in long-term survivors of childhood cancer

Planned research population (eligibility criteria)

Five-year survivors of childhood cancer in the St. Jude Lifetime Cohort (SJLIFE) and Childhood Cancer Survivor Study (CCSS) with whole genome/exome sequencing or SNP array data for common variant analysis.

Proposed specific aims

Aim 1a: To perform ancestry-specific XWAS to identify associations of common variants on the X-chromosome with risks of late effects (e.g., cardiomyopathy, neurocognitive outcomes, etc.) and continuous traits (e.g., BMI, lipid levels, blood pressure, etc.) in survivors of European and African ancestry in SJLIFE. To replicate XWAS findings in European ancestry childhood cancer survivors in CCSS. All XWAS analyses in this and following aims will be conducted in males and females separately and joint via meta-analysis.
Aim 1b: To analyze the potential gene by environment interaction (e.g., cancer therapies) among top variants from Aim 1a, using stratified analysis and test for interactions.
Aim 2a: To describe the prevalence of rare X-chromosome variants in five-year survivors of childhood cancer and compare prevalence between survivors of European and African ancestry.
Aim 2b: To compare prevalence of rare X-chromosome variants between five-year survivors of childhood cancer and healthy controls from the general population (TOPMed, gnomAD, etc.).
Aim 2c: To analyze the association between rare X-chromosome variants and late effects in 5-year survivors of childhood cancer.

Results from these analyses will provide insight into X-chromosome risk factors for multiple late effects, providing guidelines for identifying individuals at risk for improved long-term follow-up and care among childhood cancer survivors.

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	✓		
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	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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