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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** Genetic Variants, Treatment Exposures, and their Associations with the Development of Colorectal Cancer as a Subsequent Malignant Neoplasm in Long-term Survivors of Childhood Cancer

### Planned research population (eligibility criteria)

Five-year survivors of childhood cancer participating in the Childhood Cancer Survivor Study (CCSS) and the St. Jude Lifetime Cohort (SJLIFE) with whole exome sequencing data.

## Proposed specific aims

Aim 1: To characterize and compare the prevalence and distribution of pathogenic/likely pathogenic variants, as listed in the American College of Medical Genetics and Genomics (ACMG) Secondary Findings, in survivors diagnosed with a cancer < 21 years of age who subsequently develop colorectal cancer relative to individuals with colorectal cancer and no history of a cancer diagnosed < 21 years.

Aim 2: To characterize the prevalence and distribution of pathogenic/likely pathogenic variants, as listed in the American College of Medical Genetics and Genomics (ACMG) Secondary Findings, in survivors diagnosed with a cancer < 21 years of age who subsequently develop colorectal cancer separately among:  
(a) survivors treated with abdominal/pelvic radiation and no procarbazine or cisplatin for their primary cancer;  
(b) individuals treated with procarbazine or cisplatin and no abdominal/pelvic radiation for their primary cancer; and  
(c) individuals not exposed to abdominal/pelvic radiation, procarbazine, or cisplatin

Aim 3: To estimate the associations of genetic variants with subsequent colorectal cancer in childhood cancer survivors and explore how results differ based on treatment exposures from the primary cancer.

**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			

	Primary	Secondary	Correlative Factors
Brain and Nervous System			
Other			

If other, please specify

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## 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

### 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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