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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

Burden Risk and Timing of Neurosensory, Learning/memory, and Neuromotor Impairments among Childhood Cancer Survivors

Planned research population (eligibility criteria)

Childhood cancer survivors and their siblings who were asked whether they had neurosensory , learning/memory, and neuromotor impairment (Set of questions D and K from sections: hearing/vision/speech and brain and nervous system). We will use the original baseline, expansion baseline, and all follow-ups where neurosensory, learning/memory, and neuromotor impairment questions have been addressed (FU1, FU4, FU5, FU7, and FU8)

Proposed specific aims

Aim 1. To quantify the burden of neurosensory, memory/learning, and neuromotor impairments in adult survivors of childhood cancer using Disability-Adjusted Life Years (DALYs).

Aim 2. Estimate the time-varying hazards and the accelerated onset of neurosensory, learning/memory, and neuromotor impairments among childhood cancer survivors using parametric survival models.

Aim 3. Develop a risk calculator to predict the risk and time to onset of neurosensory, learning/memory, and

neuromotor impairments among childhood cancer survivors.

Aim 4 (exploratory). Project the extended impact of childhood cancer on the onset of neurosensory, learning/memory, and neuromotor impairment beyond the observed data using microsimulation modeling.

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.

NA

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			✓
	Primary	**Secondary**	**Correlative Factors**
Second Malignancy			✓

Health Behaviors

	Primary	Secondary	Correlative Factors
Tobacco			✓
Alcohol			✓
Physical Activity			✓
Medical Screening			
Other			

If other, please specify

NA

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

NA

Medications

Describe medications

NA

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			✓

	Primary	Secondary	Correlative Factors
Race			✓
Sex			✓
Other			✓

If other, please specify

Age at cancer diagnosis, country, and state of residence

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?

No

If yes, which of the following?

If other, please explain

Other General Comments

Preliminary discussions of the current application of intent were conducted with the CCSS working group leaders, including Tara Brinkman, Ellen van der Plas, Claire Snyder, Eric Chow, and Greg Armstrong.

Agree

I agree to share this information with St. Jude

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