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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 Characterizing Perceived Change in Cognitive Function in Adult Survivors of Childhood Cancer

Planned research population (eligibility criteria)

Survivors and siblings who completed FUP7 from the original cohort (OC) and expansion cohort (EC). For aims 3 and 5, we will include survivors and siblings who completed FUP5 and FUP7. Survivors must be ≥5 years from diagnosis and ≥18 years old at FUP assessment. For aim 6, we will include survivors who completed FUP7 and FUP8.

Proposed specific aims

Aim 1. Estimate the prevalence of perceived change in cognitive function in survivors of childhood cancer compared to sibling controls (FUP7).
Aim 2. Determine demographic, diagnosis-, treatment exposures, treatment era-, and health-related risk factors of perceived cognitive change in childhood cancer survivors.
Aim 3. Examine associations between changes in health from FUP5 to FUP7 and perceived changes in cognitive function at FUP7 in childhood cancer survivors.
Aim 4. Examine associations between changes in health behaviors (e.g., physical activity, risky drinking, smoking) from FUP5 to FUP7 and perceived changes in cognitive function.

Aim 5. Examine associations between changes in neurocognitive function as measured by the NCQ from FUP5 to FUP7 with perceived changes in cognitive function at FUP7 as measured by the PROMIS in childhood cancer survivors and sibling controls.
Aim 6. Explore if perceived changes in cognitive function at FUP7 is associated with performance on CNS-VS at FUP8 in survivors of childhood cancer and siblings.

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

Medications

Describe medications

Psychologic/Quality of Life

	Primary	Secondary	Correlative Factors
BSI-18			
SF-36			
CCSS-NCQ	✓		
PTS			
PTG			
Other	✓		

If other, please specify

CNS-Vital Signs, PROMIS Cognitive Function

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

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

I worked with the Psychology working group Chairs (Drs. Ellen van der Plas and Tara Brinkman) to develop the above aims.

Agree I agree to share this information with St. Jude

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