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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

Impact of Total Body Irradiation (TBI) on Late Neurocognitive and Psychosocial Outcomes in Pediatric HSCT Survivors: The Influence of Age at Exposure

Planned research population (eligibility criteria)

Study cohort

- Diagnosis of hematologic malignancy (e.g., ALL, AML, MDS)
- Underwent allogeneic HCT only once
- Did not receive cranial radiation therapy (combined TBI with cranial radiation boost is eligible)
- Survived at least 5 years post-treatment without active disease

Proposed specific aims

This study aims to assess the following outcomes among the same comparison groups as described above (eligibility criteria) as feasible.

Aim 1a: To compare neurocognitive impairment among four groups: survivors of allogeneic HCT who were exposed to total body irradiation (TBI), survivors of allogeneic HCT who were not exposed to TBI, survivors of childhood hematologic malignancy who did not undergo HCT, and sibling controls.

Aim 1b: Explore longitudinal changes in neurocognitive impairment among survivors of allogeneic HCT exposed to TBI and survivors of allogeneic HCT not exposed to TBI.

Aim 1c: To examine whether age at exposure (e.g., <4 years vs. ≥4 years) differentially affects neurocognitive impairment among survivors of allogeneic HCT with TBI, survivors of allogeneic HCT without TBI, and survivors of childhood hematologic malignancy who did not receive HCT.

Aim 2a: To compare social attainment outcomes (e.g., education, employment, income)) among survivors of allogeneic HCT who were exposed to TBI, survivors of allogeneic HCT who were not exposed to TBI, survivors of childhood hematologic malignancy who did not undergo HCT, and sibling controls.

Aim 2b: To examine whether age at exposure (e.g., <4 years vs. ≥4 years) differentially affects social attainment among survivors of allogeneic HCT with TBI, survivors of allogeneic HCT without TBI, and survivors of childhood hematologic malignancy who did not receive HCT.

Aim 3a: To compare mental health, quality of life, and health behaviors, among survivors of allogeneic HCT who were exposed to TBI, survivors of allogeneic HCT who were not exposed to TBI, survivors of childhood hematologic malignancy who did not undergo HCT, and sibling controls.

Aim 3b: To examine whether age at exposure (e.g., <4 years vs. ≥4 years) differentially affects mental health, quality of life, and health behaviors among survivors of allogeneic HCT with TBI, survivors of allogeneic HCT without TBI, and survivors of childhood hematologic malignancy who did not receive HCT.

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

Financial hardship, frailty, physical performance limitation, and participation restrictions, exercise capacity

Medical Conditions

	Primary	Secondary	Correlative Factors
Hearing/Vision/Speech			
Hormonal Systems			
Heart and Vascular			
Respiratory			

	Primary	Secondary	Correlative Factors
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	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

Agree

I agree to share this information with St. Jude

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