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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	Growth hormone treatment for growth impairment after total body irradiation: A CCSS study
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Planned research population (eligibility criteria)

Inclusion criteria:

- Childhood cancer survivors in the CCSS initial and expansion cohorts

Exclusion criteria:

- 1) HCT at ≥ 5 years from diagnosis
- 2) Relapse of the primary disease at ≥ 5 years from diagnosis
- 3) Received more than one HCT
- 4) Genetic syndrome diagnosis (eg, Down syndrome)

Study arms

- 1) TBI-HCT: Patients received HCT (either allogeneic or autologous) with TBI
- 2) Non-TBI-HCT: Patients received HCT (either allogeneic or autologous) without TBI
- 3) Matched non-HCT: Patients who received neither HCT (either allogeneic or autologous) nor TBI. Subjects are matched with the HCT cohorts on sex, age of diagnosis, and diagnosis.

Proposed specific aims

Aim 1: To describe the impact of TBI and HCT on the growth of survivors, with respect to the age of HCT and GH deficiency diagnosis

Aim 2: To analyze the efficacy of GH therapy for growth impairment in survivors with and without GH deficiency after TBI with 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

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

Final adult height (ie, height at 18 years old or older), history of GH therapy, GH deficiency diagnosis

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

HCT, TBI, cranial radiation therapy

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
