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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 Deficiency as a Risk Factor for Chronic Health Conditions in Adult Survivors of Childhood Cancer

Planned research population (eligibility criteria)

We plan to use a subset of verified growth hormone deficient (GHD) patients from the CCSS as identified by Charles Sklar (Sklar et al, J Clin Endocrinol Metab 87: 3136-3141, 2002; n=361). We will use the comparison group identified by Sklar in the same publication, consisting of survivors who reported no GHD at the original baseline survey (diagnosis years 1970-1986 only).

Proposed specific aims

Aim 1: To examine the rates and risks of chronic health conditions (CHCs; all as well as grades 3-5) in adult survivors of childhood cancer with verified GHD compared to those without GHD, adjusting for key demographic and clinical characteristics.

Aim 2: To more closely examine the rates and risks of conditions commonly associated with GHD specifically high BMI/obesity, hypertension, dyslipidemia, impaired glucose tolerance/diabetes mellitus and conditions associated with metabolic syndrome including coronary artery disease, cardiomyopathy and cerebrovascular

disease, and lastly osteoporosis and fractures in adult survivors of childhood cancer with verified GHD compared to those without GHD.

Aim 3: To examine differences in quality of life, health status, and frailty (using a modified Fried frailty criteria which was previously defined and applied in the CCSS cohort (Hayek et al, J Clin Oncol, 38: 232-247, 2020)) among adult survivors of childhood cancer who have verified GHD compared to those without GHD.

Exploratory: For all aims, we will also attempt to examine outcomes by whether GHD survivors received growth hormone medications as adults based on CCSS medication data.

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)

Second Malignancy	
Chronic Disease	Primary
Psychology/Neuropsychology	Secondary
Genetics	
Cancer Control	
Epidemiology/Biostatistics	

Outcomes or Correlative Factors

Late Mortality	Secondary
Second Malignancy	

Health Behaviors

Tobacco	
Alcohol	
Physical Activity	Secondary
Medical Screening	
Other	Secondary

If other, please specify

We will be using the physical therapy outcomes to help calculate the frailty score.

Psychosocial

Insurance	
Marriage	
Education	
Employment	
Other	

If other, please specify

Medical Conditions

Hearing/Vision/Speech	
Hormonal Systems	
Heart and Vascular	
Respiratory	
Digestive	
Surgical Procedures	
Brain and Nervous System	
Other	Primary

If other, please specify

We will be using the chronic health conditions dataset and looking at organ specific conditions within the dataset

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Medications

Describe medications

We will be doing a manual search for growth hormone medications within the verified growth hormone deficient patient population.

Psychologic/Quality of Life

BSI-18	
SF-36	Secondary
CCSS-NCQ	
PTS	
PTG	
Other	Secondary

If other, please specify

We will look at the sf-36 for quality of life and to help aid in the calculation of the frailty score.

Other

Pregnancy and Offspring	
Family History	
Chronic Conditions (CTCAE v3)	Primary
Health Status	Secondary

Demographic

Age	Correlative Factors
Race	Correlative Factors
Sex	Correlative Factors
Other	

If other, please specify

Cancer Treatment

Chemotherapy	Correlative Factors
Radiation Therapy	Correlative Factors
Surgery	Correlative Factors

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

If this AOI is approved I plan to submit this project as a career development award.

Agree I agree to share this information with St. Jude

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