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Project Title Long-term outcomes in adult survivors of childhood cancer: a comparison of conventional therapy and hematopoietic cell transplantation (HCT)

Planned research population (eligibility criteria) Bone Marrow Transplant Survivors Study (BMTSS): •Primary diagnoses: Leukemia (Acute Lymphoblastic, Acute Myelogenous), or Lymphoma (Hodgkin, non-Hodgkin) •Underwent HCT ≤ 23 years of age Childhood Cancer Survivors Study (CCSS): •Cancer Survivors o Primary diagnoses: Leukemia (Acute Lymphoblastic, Acute Myelogenous), or Lymphoma (Hodgkin, non-Hodgkin) o Did not undergo HCT as part of treatment of primary disease •CCSS Siblings o Selected from CCSS enrolled cohort

Proposed specific aims Specific Aims: 1) Compare long-term outcomes in adult survivors of childhood cancer who underwent HCT versus healthy controls (CCSS siblings) matched on age, gender, and race. 1.1 Compare the burden of morbidity in the two cohorts with respects to: i. Secondary malignancies ii. Endocrinopathy and reproductive health iii. Cardiovascular complications iv. Psychosocial outcomes 1.2 Identify differences in treatment, disease characteristics, and demographics that may have contributed to a differential morbidity in the two cohorts. 1.3 Describe differences in overall reported health status and screening behavior in the areas of: i. Health care utilization ii. Physical activity iii. Quality of Life (SF-36) iv. Health insurance v. Cancer screening practices vi. Health risk behaviors vii. Impact of HCT on quality of life 2) Evaluate the additional role, if any, conditioning exposures play in the development of long-term complications following HCT using two representative cohorts from BMTSS and CCSS (cancer survivors), matched on age, gender, race, treatment exposures (anthracyclines, alkylating agents, and ionizing radiation). 2.1 Compare the burden of morbidity in the two cohorts with respects to: i. Secondary malignancies ii. Endocrinopathy and reproductive health iii. Cardiovascular complications iv. Psychosocial outcomes 2.2 Identify treatment exposures [HCT conditioning, total body irradiation (TBI), and graft versus host disease (GvHD) treatment or prophylaxis] that may have contributed to a differential morbidity in the two cohorts. 2.3 Describe differences in overall reported health status and screening behavior in the areas of: i. Health care utilization ii. Physical activity iii. Quality of Life (SF-36) iv. Health insurance v. Cancer screening practices vi. Health risk behaviors vii. Impact of HCT on quality of life

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? (Check all that apply)

Second Malignancy

Primary - No Secondary - Yes

Chronic Disease

Primary - Yes Secondary - No

Reproductive

Primary - No Secondary - Yes

Neurologic

Primary - No Secondary - Yes

Psychology / Neuropsychology

Primary - No Secondary - Yes

Genetics

Primary - No Secondary - No

Cancer Control

Primary - No Secondary - Yes

Epidemiology / Biostatistics

Primary - No Secondary - Yes

To describe the anticipated scope of the study, please indicate the specific CCSS data to be included as outcome (primary or secondary) or correlative factors. (Check all that apply)

Late mortality

Primary - No Secondary - No Correlative Factors - No

Second Malignancy

Primary - Yes Secondary - No Correlative Factors - No

Health Behaviors

Tobacco

Primary - Yes Secondary - No Correlative Factors - No

Alcohol

Primary - Yes Secondary - No Correlative Factors - No

Physical activity

Primary - Yes Secondary - No Correlative Factors - No

Medical screening

Primary - Yes Secondary - No Correlative Factors - No

Other

Primary - No Secondary - No Correlative Factors - No

If other, please specify

Psychosocial

Insurance

Primary - Yes	Secondary - No	Correlative Factors - No
Marriage		
Primary - Yes	Secondary - No	Correlative Factors - No
Education		
Primary - No	Secondary - No	Correlative Factors - Yes
Employment		
Primary - Yes	Secondary - No	Correlative Factors - No
Other		
Primary - No	Secondary - No	Correlative Factors - No

If other, please specify

Medical conditions

Hearing/Vision/Speech

Primary - Yes	Secondary - No	Correlative Factors - No
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Hormonal systems

Primary - Yes	Secondary - No	Correlative Factors - No
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Heart and vascular

Primary - Yes	Secondary - No	Correlative Factors - No
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Respiratory

Primary - No	Secondary - No	Correlative Factors - No
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Digestive

Primary - Yes	Secondary - No	Correlative Factors - No
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Surgical procedures

Primary - Yes	Secondary - No	Correlative Factors - No
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Brain and nervous system

Primary - Yes	Secondary - No	Correlative Factors - No
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Other

Primary - No	Secondary - No	Correlative Factors - No
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If other, please specify

Medications

Describe medications To be used as supporting evidence for certain reported comorbidities

Pregnancy and offspring

Primary - Yes	Secondary - No	Correlative Factors - No
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Family History

Primary - No	Secondary - No	Correlative Factors - No
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Psychologic/Quality of Life

BSI-18

Primary - Yes

Secondary - No

Correlative Factors - No

SF-36

Primary - Yes

Secondary - No

Correlative Factors - No

CCSS-NCQ

Primary - No

Secondary - No

Correlative Factors - No

PTS

Primary - No

Secondary - No

Correlative Factors - No

PTG

Primary - No

Secondary - No

Correlative Factors - No

Other

Primary - No

Secondary - No

Correlative Factors - No

If other, please specify

Chronic conditions (CTCAE v3)

Primary - Yes

Secondary - No

Correlative Factors - No

Health status

Primary - Yes

Secondary - No

Correlative Factors - No

Demographic

Age

Primary - No

Secondary - No

Correlative Factors - Yes

Race

Primary - No

Secondary - No

Correlative Factors - Yes

Sex

Primary - No

Secondary - No

Correlative Factors - Yes

Others

Primary - No

Secondary - No

Correlative Factors - No

If others, please specify

Cancer treatment

Chemotherapy

Correlative Factors - Yes

Radiation therapy

Correlative Factors - Yes

Surgery

Correlative Factors - Yes

Anticipated sources of statistical support

CCSS Statistical Center

Local institutional statistician Yes

If local, please provide the name(s) and contact information of the statistician(s) to be involved. F. Lennie Wong, PhD City of Hope National Medical Center Department of Population Sciences Division of Outcomes Research 1500 East Duarte Road Duarte, CA 91010 (626) 256-8631 lwong@coh.org

Will this project utilize CCSS biologic samples? No

If yes, which of the following?

Buccal cell DNA

Peripheral blood

Lymphoblastoid cell lines

Second malignancy pathology samples

Other requiring collection of samples

If other, please explain

Other general comments