

CCSS Application of Intent Submission

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Project Requirements and Description

Requirements to submit AOI:

	Yes	No
A comprehensive review of previously published data has been completed	✓	-
The specific aims are clear and focused	✓	-
The investigator has appropriate experience and expertise to develop the concept proposal; if not, has identified a mentor or senior co-investigator.	✓	-
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	✓	-

Project Title: Racial and ethnic disparities in chronic health conditions among childhood cancer survivors in the St. Jude Lifetime Cohort (SJLIFE) and Childhood Cancer Survivor Study (CCSS)

Planned research population: The study populations for these analyses will include all Non-Hispanic White (NHW) and Non-Hispanic Black (NHB) five-year survivors participating in SJLIFE or CCSS with evaluable CTCAE-graded chronic health conditions (CHCs) or mortality data.

Proposed specific aims: Our primary analysis will be conducted in the St. Jude Lifetime Cohort (SJLIFE). We aim to:

Aim 1: Estimate the cumulative burden of evaluable individual CHCs in NHW and NHB survivors and grouped by organ system, with additional stratified analyses by diagnosis and age.

Aim 2: Compare the relative rate of developing individual CHCs or any of the CHCs classified into the pre-specified organ systems between NHW and NHB survivors, adjusting for potential confounders including demographic characteristics, cancer treatment exposures, and baseline socioeconomic status (SES) and lifestyle risk factors.

Aim 3: Compare all-cause and cause-specific mortality between NHW and NHB survivors, including an assessment of the association of race/ethnicity with all-cause and cause-specific mortality rates adjusting for potential confounders including demographic characteristics, cancer treatment exposures, and baseline SES and lifestyle risk factors.

Secondary analyses consistent with these aims will be conducted in CCSS, prioritizing subsequent neoplasms and mortality outcomes. Given that some chronic health conditions cannot be assessed as multiple/recurrent events in CCSS due to the design of questionnaires used to ascertain outcomes, we will examine evaluable chronic health conditions grouped by organ system in CCSS acknowledging these limitations. For such endpoints, results of the primary SJLIFE analysis will be reviewed with members of relevant CCSS and SJLIFE working groups before secondary analyses in CCSS begin to discuss the validity and limitations of comparisons between these cohorts.

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:

	Yes	No
Additional self-reported information	-	✓
Biological samples	-	✓
Medical record data	-	✓

If yes to any of the above, please briefly describe:

What CCSS Working Group(s) would likely be involved?:

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

Outcomes or Correlative Factors

Late Mortality and Second Malignancy:

	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	-	-	-
Brain and Nervous System	-	✓	-
Other	-	-	-

If other, please specify:

Medications

Describe medications: None listed

Psychologic/Quality of Life: None selected

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:

	Yes	No
CCSS Statistical Center	-	✓
Local Institutional Statistician	✓	-

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: