Contact Information

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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 Emotional Distress, Chronic Health Conditions, and Mortality in Adult Survivors of Childhood Cancer and their Siblings

Planned research population (eligibility criteria)

CCSS survivors and siblings from the original and expansion cohorts who:

- Were at least 18 years old and alive at Baseline/Expansion Baseline assessments
- Have emotional distress data available at Baseline/Expansion Baseline, FU1, and/or FU2 assessments
- Have chronic health condition data at Baseline/Expansion Baseline assessments as well as FU4, FU5, FU6, and/or FU7 assessments

Proposed specific aims

Aim 1: Evaluate associations between emotional distress and development/progression of chronic health conditions in adult survivors of childhood cancer versus sibling controls.
--Hypothesis 1: Higher levels of emotional distress (measured via Baseline/Expansion Baseline, FU1, and/or FU2 assessments) will be associated with subsequent onset or worsening of chronic health conditions (graded as per the CTCAE v3.0) from Baseline/Expansion Baseline to FU4, FU5, FU6, and/or FU7 assessments, and this association will be stronger for survivors compared to siblings.

Aim 2: Evaluate associations between emotional distress and mortality in adult survivors of childhood cancer versus sibling controls.
--Hypothesis 2: Higher levels of emotional distress (measured via Baseline/Expansion Baseline, FU1, and/or FU2 assessments) will be associated with subsequent mortality, and this association will be stronger for survivors compared to siblings

Aim 3: Evaluate the impact of certain treatment exposures on associations between emotional distress and chronic health conditions in adult survivors of childhood cancer.
--Hypothesis 3a: Among adult survivors of childhood cancer who received cardiotoxic therapies, higher levels of emotional distress (measured via Baseline/Expansion Baseline, FU1, and/or FU2 assessments) will be associated with increased risk for subsequent onset or worsening of cardiovascular chronic health conditions (graded as per the CTCAE v3.0) from Baseline/Expansion Baseline to FU4, FU5, FU6, and/or FU7 assessments, compared to survivors without cardiotoxic therapy exposures.
--Hypothesis 3b: Among adult survivors of childhood cancer who received pulmonary-toxic therapies, higher levels of emotional distress (measured via Baseline/Expansion Baseline, FU1, and/or FU2 assessments) will be associated with increased risk for subsequent onset or worsening of pulmonary chronic health conditions (graded as per the CTCAE v3.0) from Baseline/Expansion Baseline to FU4, FU5, FU6, and/or FU7 assessments, compared to survivors without pulmonary-toxic therapy exposures.
--Hypothesis 3c: Among adult survivors of childhood cancer who received therapies associated with obesity and metabolic syndrome, higher levels of emotional distress (measured via Baseline/Expansion Baseline, FU1, and/or FU2 assessments) will be associated with increased risk for subsequent onset or worsening of obesity and/or metabolic syndrome from Baseline/Expansion Baseline to FU4, FU5, FU6, and/or FU7 assessments, compared to survivors without these exposures.

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.

N/A

What CCSS Working Group(s) would likely be involved? (Select all that apply)

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

Outcomes or Correlative Factors

Late Mortality	Primary
Second Malignancy	

Health Behaviors

Tobacco	Correlative Factors
Alcohol	Correlative Factors
Physical Activity	Correlative Factors
Medical Screening	Correlative Factors
Other	

If other, please specify

Psychosocial

Insurance	Correlative Factors
Marriage	Correlative Factors
Education	Correlative Factors
Employment	Correlative Factors
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

Chronic conditions (CTCAE v3) – see below

Medications

Describe medications

Psychologic/Quality of Life

BSI-18	Correlative Factors
SF-36	Correlative Factors
CCSS-NCQ	
PTS	Correlative Factors
PTG	
Other	

If other, please specify

Other

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

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

Agree I agree to share this information with St. Jude

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