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Project Requirements and Description

Requirements to submit AOI

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 Clonal Hematopoiesis and Late Morbidity and Mortality in Childhood Cancer Survivors

Planned research population (eligibility criteria)

Childhood Cancer Survivors enrolled in CCSS with at least one banked peripheral blood specimen

Proposed specific aims

Aim 1: Determine the prevalence of clonal hematopoiesis (CH) in cancer survivors enrolled in CCSS with at least one banked peripheral blood specimen.

Aim 2: Determine the association between demographic factors, primary diagnosis, therapeutic exposures and CH among the cohort described in Aim 1.

Aim 3: Determine the association between CH and subsequent late mortality in childhood cancer survivors.

Aim 4: Determine the association between CH and subsequent adverse health outcomes, including cardiovascular disease (CVD) and secondary malignant neoplasms (SMN), in the cohort described in Aim 1.

Aim 5: Assess associations between CH and measures of accelerated aging, as assessed via the applied cumulative illness rating scale for Geriatrics (CIRS-G), and frailty, as assessed via modified Fried criteria, in childhood cancer survivors.

Will the project require non-CCSS funding to complete?

Yes

If yes, what would be the anticipated source(s) and timeline(s) for securing funding?

Fall 2023 R01 submission

Does this project require contact of CCSS study subjects for:

Additional self-reported information	
Biological samples	Yes
Medical record data	

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

We will collect an additional peripheral blood sample on a subset of survivors to explore time-based clonal dynamics.

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

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

Outcomes or Correlative Factors

Late Mortality	Primary
Second Malignancy	Primary

Health Behaviors

Tobacco	Correlative Factors
Alcohol	Correlative Factors
Physical Activity	Correlative Factors
Medical Screening	
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	Primary
Respiratory	
Digestive	
Surgical Procedures	
Brain and Nervous System	
Other	Primary

If other, please specify

The Cumulative Illness Rating Scale for Geriatrics (CIRS-G) will be used to assess accelerated aging in survivors
Modified Fried Criteria to measure frailty in survivors

Medications

Describe medications

Psychologic/Quality of Life

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

If other, please specify

Other

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

Demographic

Age	
Race	
Sex	
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	
Local Institutional Statistician	Yes

If local, please provide the name(s) and contact information of the statistician(s) to be involved.

Will this project utilize CCSS biologic samples?

Yes

If yes, which of the following?

Peripheral blood

If other, please explain

Other General Comments

This concept will be submitted in collaboration with Dr. Smita Bhatia and Dr. Kelly Bolton

Agree

I agree to share this information with St. Jude

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