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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 Prediction of breast cancer risk in childhood cancer survivors

Planned research population (eligibility criteria)

We will use already collected data from the The International Consortium for Pooled Studies on Subsequent Malignancies after Childhood and Adolescent Cancer. We hope to include survivors from the North American CCSS, French CCSS, SJLIFE, DCCSS-LATER, and Dutch HL studies.

In total, we hope to include 17,824 female survivors (9,671 from CCSS), of which 762 have developed a subsequent breast cancer.

Proposed specific aims

Aim 1: Derive a comprehensive breast cancer risk prediction model using childhood cancer treatment-related factors, traditional breast cancer risk factors, and other potential risk factors to predict the probability of breast cancer among women who have previously been treated for a childhood malignancy. To create this model, we will analyze international data from 11,908 female survivors of childhood cancer, of whom 493 have developed breast cancer. The model will account for treatment-related variables, such as chest radiotherapy and chemotherapy details (with a focus on anthracyclines and alkylating agents). It will also include hormonal factors like age at menarche and menopause status, as well as traditional breast cancer risk elements, including reproductive history and family background. Additionally, we will explore potential interactions between these risk factors.

Aim 2: Validate the model derived in Aim 1 on an independent validation data set and develop a risk calculator that will predict an individual’s absolute risk of breast cancer. For the external validation of the model, we will use international data on 5,916 female childhood cancer survivors, among which 269 were diagnosed with breast cancer. We will translate the results of the prediction model into user-friendly software, with the aim to create a tool that provides computer-assisted risk prediction in a format that can be easily used in clinical practice.

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?

R21: <https://grants.nih.gov/grants/guide/pa-files/PAR-23-255.html> timeline: Feb 15 round

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)

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

Outcomes or Correlative Factors

	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

Psychologic/Quality of Life

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

If other, please specify

Other

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

Demographic

If other, please specify

	Primary	Secondary	Correlative Factors
Age			✓
Race			✓
Sex			✓
Other			

Cancer Treatment

	Correlative Factors
Chemotherapy	✓
Radiation Therapy	✓
Surgery	✓

Anticipated Sources of Statistical Support

CCSS Statistical Center	No
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?

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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