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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 Risk of Subsequent Lung Cancer, Thyroid Cancer, and Melanoma among Childhood Cancer Survivors Treated: An International Study of Nearly 50,000 Survivors with Individual Patient Data (IPD)

Planned research population (eligibility criteria)

All survivors diagnosed <21 years and survival ≥5 years from diagnosis from the following cohorts:

- Childhood Cancer Survivor Study (diagnosis 1970-1999).
- St Jude Lifetime Cohort Study
- DCCSS-LATER cohort
- French Childhood Cancer Survivor Study
- National Wilms Tumor Study
- Dutch Hodgkin Lymphoma study
- Swiss Childhood Cancer Survivor Study

Proposed specific aims

Lung Cancer:

1. To determine the long-term relative and absolute risks of subsequent lung cancer in childhood cancer survivors compared to the general population.
2. To determine risk factors for subsequent lung cancer in childhood cancer survivors.

*Chest radiotherapy dose and field

*Chemotherapy agents

*Smoking and possible interaction with chest radiotherapy

3. To determine risks of and risks factors for specific subtypes of lung cancer, in particular mesothelioma

Thyroid cancer:

1. To determine the risks of thyroid cancer associated with chemotherapy among childhood cancer survivors not treated with radiotherapy and to determine chemotherapy-related risks in addition to radiotherapy
2. To determine the prevalence of and risk factors for differentiated thyroid carcinoma in neuroblastoma survivors treated with ¹³¹I-MIBG
3. To determine the risk of thyroid cancer in very long (>30 years after treatment) childhood cancer survivors
4. To evaluate the effect of polygenic risks score developed for thyroid cancer in the general population in childhood cancer survivors

Melanoma:

1. To determine the long-term relative and absolute risks of subsequent melanoma in childhood cancer survivors compared to the general population.
2. To determine risk factors for subsequent melanoma in childhood cancer survivors.
3. To evaluate the effect of polygenic risk scores for melanoma in the general population on melanoma risk in survivors.
4. To compare clinical characteristics and survival of melanoma in survivors compared to melanoma in the general population.

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?

The Foundation KiKA / planned submission: June 1, 2024

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			
	Primary	Secondary	Correlative Factors
PTG			
Other			

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

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

All CCSS investigators involved in the breast cancer IPD project will also be involved in the current project.

Agree

I agree to share this information with St. Jude

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