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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

Predicting Pulmonary Dysfunction in Long-term Survivors of Childhood Cancer: A Report from the St. Jude Lifetime Cohort (SJLIFE) and the Childhood Cancer Survivor Study (CCSS)

Planned research population (eligibility criteria)

5-year survivors of childhood cancer in SJLIFE and CCSS.

Proposed specific aims

Aim 1. To develop and validate risk prediction models using sociodemographic-, genetic-, disease-, treatment-specific characteristics, and co-morbidities to discriminate individuals at an elevated risk of pulmonary dysfunction defined by abnormal FEV1, TLC, and DLCO Z-scores ≤-1.65 (individually and all three) among childhood cancer survivors in the SJLIFE cohort

• Aim 1a: To develop risk prediction models using a priori selected variables in the previous SJLIFE-based models such as age, sex, smoking, height, chest radiation, thoracic surgery, and chemotherapy for pulmonary dysfunction in 70% of the SJLIFE cohort (training set)

• Aim 1b: To assess whether the inclusion of important predictors not considered by previous models such as obesity, race/ ethnicity, and polygenic risk score in each model improves the prediction performance in a subset of the training set with available whole genome sequencing data

• Aim 1c: To validate the final risk prediction models for pulmonary dysfunction in the remaining 30% of the SJLIFE cohort (validation set)

Aim 2. To examine associations between Z-scores for FEV1, TLC, and DLCO and self-reported symptoms in entire SJLIFE cohort
Aim 3. To validate the final risk prediction models from Aim 1 using sociodemographic-, genetic-, disease-, treatment-specific characteristics, and co-morbidities to discriminate individuals at an elevated risk of pulmonary dysfunction defined by self-reported symptoms among childhood cancer survivors in the entire SJLIFE cohort

Aim 4. To validate the final risk prediction models to discriminate individuals at an elevated risk of pulmonary dysfunction defined by self-reported symptoms among childhood cancer survivors in the CCSS cohort.

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.

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	✓		

	Primary	Secondary	Correlative Factors
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

	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

Please note that CCSS will be used to validate the model developed in SJLIFE.

Agree

I agree to share this information with St. Jude

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