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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

Joint Effect of Physical Activity and Genetics on Cardiovascular Disease and Mortality Risk in Childhood Cancer Survivors

Planned research population (eligibility criteria)

Childhood cancer survivors participating in CCSS, free of cardiovascular disease at baseline, with available data on genetic risk scores and self-reported physical activity.

Proposed specific aims

Aim 1: To evaluate the association between the total volume of moderate-to-vigorous physical activity (MVPA) and the risk of incident cardiovascular disease (CVD) and all-cause mortality, and to determine if this association varies by cardiovascular disease genetic risk strata.
• Hypothesis: Higher levels of MVPA are associated with reduced CVD and mortality risk across genetic risk strata, with potentially stronger effects among those at low or moderate genetic risk.
Aim 2: To assess whether concentrated accumulation of MVPA (1–2 days per week) provides similar protection compared to evenly distributed physical activity, and to determine if this association varies by cardiovascular disease genetic risk strata..
• Hypothesis: The protective effect of concentrated vs. evenly distributed MVPA on CVD and mortality risk will vary cardiovascular disease genetic risk strata.
Aim 3: To determine whether a higher proportion of vigorous physical activity (VPA) within total MVPA confers additional protection against CVD and mortality, and whether this association varies by cardiovascular

disease genetic risk strata.
• Hypothesis: A greater proportion of VPA within MVPA is independently associated with lower risk of CVD and mortality, particularly among individuals at the highest genetic risk.

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			✓
Digestive			✓

	Primary	Secondary	Correlative Factors
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

We have shared and discussed this proposal with Prof kiri Ness to make sure it is feasible and novel.

Agree

I agree to share this information with St. Jude

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