Name Rachel Glock

Institution East Carolina University

Address 2195 Hyde Drive

Greenville, NC, 27858

United States

Email Address glockr23@students.ecu.edu

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

Social Determinants, Chronic Comorbidities, and Mental Health as Longitudinal Predictors of Pain Trajectories in Adult Survivors of Childhood ALL: A CCSS Cohort Analysis

Planned research population (eligibility criteria)

Acute Lymphoblastic Leukemia Survivors

Proposed specific aims

Aim 1. Examine whether pediatric ALL survivors with a history of more adverse social determinants of health (SDoH) report higher pain over time compared to those with fewer adverse SDoH, adjusting for comorbid medical conditions.

Aim 1b. Test whether physical activity moderates the longitudinal relationship between adverse SDoH and pain, such that among individuals reporting more adverse SDoH, higher physical activity is associated with lower pain over time, adjusting for comorbid medical conditions. While those with fewer adverse SDoH may also report lower pain with higher physical activity, the magnitude of this association is expected to be smaller.

Aim 2. Determine whether survivors with more adverse SDoH are more likely to report higher psychological distress and cancer-related worry (CRW) across time points, adjusting for comorbid medical conditions.

Aim 3. Evaluate whether CRW and psychological distress interact over time, such that the difference in pain between those reporting elevated psychological distress and those without psychological distress is larger for participants also experiencing CRW, adjusting for comorbid medical conditions.

Aim 4. Test both mediation and moderation pathways linking SDoH, psychological distress, CRW, physical activity, and pain over time, adjusting for comorbid medical conditions, to clarify whether physical activity acts primarily as a moderator or whether psychological distress and CRW explain the SDoH–pain relationship.

Will the	project	require	non-CCSS
funding	to comp	plete?	



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

Area Deprivation Index (ADI), CDC Social Vulnerability Index (SVI), persistent poverty, urbanicity, and redlining

Medical Conditions

	Primary	Secondary	Correlative Factors
Hearing/Vision/Speech			✓
Hormonal Systems			✓
Heart and Vascular			✓
Respiratory			✓
Digestive			✓
Surgical Procedures			
Brain and Nervous System			✓
Other			

Medications

Describe medications

Psychologic/Quality of Life

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

If other, please specify Cancer-Related Worry

Other

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

Demographics

	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	Yes
Local Institutional Statistician	No

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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