Name Emily Tonorezos

Institution National Cancer Institute

Address 9609 Medical Center Drive
Rockville, MD, 20850
United States

Phone Number 6466516815

Alternate Phone Number

Email Address emily.tonorezos@nih.gov

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 Chronic Conditions of the Hepatobiliary System

Planned research population (eligibility criteria)

CCSS participants from the original and expanded cohorts who were asked questions about fatty liver and other hepatobiliary conditions.

Proposed specific aims

1. Describe the prevalence of hepatobiliary chronic conditions, including fatty liver and cirrhosis, among participants in the CCSS.

2. Identify treatment-related risk factors for hepatobiliary chronic conditions. Candidate risk factors include history of treatment with radiation therapy fields that included the liver, bone marrow transplant, and chemotherapeutic agents 6-mercaptopurine, 6-thioguanine, and methotrexate.

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			✓

	Primary	Secondary	Correlative Factors
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

hepatitis B and C, cholelithiasis, liver transplant, cholecystectomy

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Medications

Describe medications

metformin, statins, niacin, ezetimibe, fibrates, estrogen, antivirals

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	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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