

Name	Emily/Camila Tonorezos/dos Santos
Institution	St. Jude Children's Research Hospital
Address	262 Danny Thomas Place Memphis, TN, 38105 United States
Email Address	emily.tonorezos@stjude.org

Project Requirements and Description

Project Title	Pathologic and Molecular Features of Subsequent Breast Cancer
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Planned research population (eligibility criteria)

CCSS Participants with history of subsequent breast cancer and pathologic specimen for evaluation.

Proposed specific aims

1. Characterize pathologic features of subsequent breast cancer.
 2. Describe differences between pathologic features of subsequent breast cancer and prior research on breast cancer in animal models and in the general population.
- Test for associations between pathologic and clinical features of subsequent breast cancer and cancer treatment variables.

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?

Divisional startup funds, dos Santos and Tonorezos (in hand)

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

Infections, to the extent they are available

Medications

Describe medications

Hormonal medications e.g. tamoxifen and OCP

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

Age at menarche and menopause, if available

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?

Yes

If yes, which of the following?

Peripheral blood

Second malignancy pathology samples

If other, please explain

Other General Comments

Analysis of features of the specimens will be led by Dr. Camila dos Santos in Molecular Oncology, building off her work in breast cancer in animal models and in the general population. Additional work in her lab suggests a mechanistic role in breast cancer carcinogenesis for urinary tract infections and inflammatory factors among females with BRCA mutation and so history of major infections and peripheral blood will be informative, if available.