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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 OncotypeDX as a Decision-making Tool in Subsequent Breast Cancer

Planned research population (eligibility criteria)

Female CCSS participants with subsequent breast cancer will be included. Further criteria include:
-Stage 0 (in situ) and stage 1 or 2 breast cancer
-For stage 1 or 2 disease, must be ER+, Her2-

Proposed specific aims

Aim 1. Quantify and compare the recurrence and survival benefit associated with OncotypeDX use among women in the general population with primary breast cancer and survivors of childhood cancer with subsequent breast cancer.

- After abstracting OncotypeDX results among females with subsequent breast cancer in CCSS, compare the frequency of OncotypeDX testing and 5- and 10-year EFS and OS between females with primary and subsequent breast cancer diagnosed since 2004.

Aim 2. Assess whether inclusion of childhood cancer treatment factors, chronic health conditions, and genetics/tumor biology to models with OncotypeDX results improves the prediction of breast cancer recurrence and survival among survivors with subsequent breast cancer.

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?

Either CCRF Survivorship Award or NCI R01--summer submission

Does this project require contact of CCSS study subjects for:

Additional self-reported information	No
Biological samples	No
Medical record data	Yes

If yes to any of the above, please briefly describe.

We will need to get permission from females with subsequent breast cancer to get medical records (for OncotypeDX scores, treatment data, toxicity data, etc.)

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

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

Agree I agree to share this information with St. Jude

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