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Requirements to submit AOI:

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

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Project Title: Prediction Model: Breast Cancer in Women Irradiated for a Pediatric Malignancy
Planned research population (eligibility criteria): Women treated with chest radiation.
Proposed specific aims: Aim 1: Derive a breast cancer risk prediction model using chest radiation, additional treatment-related factors, traditional breast cancer risk factors, and other potential risk factors to predict the probability of breast cancer among women who have previously been treated with chest radiation for a childhood malignancy. Aim 2: Validate the model derived in Aim 1 on an independent validation data set. Aim 3: Develop a risk calculator that will predict an individualâ€™s absolute risk of 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?: NIH - currently funded R01

Does this project require contact of CCSS study subjects for . . .

Additional self-reported information: Yes
Biological Samples: No
Medical record data: Yes
If yes to any of the above, please briefly describe.: already completed secondary data collection

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What CCSS Working Group(s) would likely be involved? (Check all that apply)

Second Malignancy: Primary
Chronic Disease:
Psychology / Neuropsychology:
Genetics:
Cancer Control: Secondary
Epidemiology / Biostatistics: Secondary

To describe the anticipated scope of the study, please indicate the specific CCSS data to be included as <u>outcome</u> (primary or secondary) or <u>correlative factors</u>. (Check all that apply)

Late mortality:
Second Malignancy:

Health Behaviors

Tobacco:
Alcohol:
Physical activity:
Medical screening:
Other:
If other, please specify:

Psychosocial

Insurance:
Marriage:
Education:
Employment:
Other:
If other, please specify:

Medical conditions

Hearing/Vision/Speech:
Hormonal systems:
Heart and vascular:
Respiratory:
Digestive:
Surgical procedures:
Brain and nervous system:
Other:
If other, please specify:

Medications

Describe medications:

Pregnancy and offspring:
Family History:

Psychologic/Quality of Life

BSI-18:
SF-36:
CCSS-NCQ:
PTS:
PTG:
Other:
If other, please specify:

Chronic conditions (CTCAE v3):
Health status:

Demographic

Age:
Race:
Sex:
Others:
If others, please specify:

Cancer treatment

Chemotherapy:
Radiation therapy:
Surgery:

Anticipated sources of statistical support

CCSS Statistical Center:
Local institutional statistician: Yes
If local, please provide the name(s) and contact information of the statistician(s) to be involved.:
Chaya Moskowitz
Will this project utilize CCSS biologic samples?: No

If yes, which of the following?

Buccal cell DNA:
Peripheral blood:
Lymphoblastoid cell lines:
Second malignancy pathology samples:
Other requiring collection of samples:
If other, please explain:

Other general comments: