Received: 5/9/11
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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: Risk of Breast Cancer in Childhood Cancer Survivors Not Exposed to Chest Radiation
Planned research population (eligibility criteria): All women in the cohort who have not been exposed to chest or spinal radiation.
Proposed specific aims: With updated SMN data, 1. Determine the cumulative incidence of breast cancer in female childhood cancer survivors not exposed to chest radiation. 2. Determine the relative risk and absolute excess risk of developing breast cancer in females survivors not exposed to chest/spinal radiation compared to the general population. 3. To describe the risk factors associated with the development of breast cancer in women not previously exposed to chest/spinal irradiation (including but not limited to, previous chemotherapy exposure, exposure to pelvic radiation, family history).

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? (Check all that apply)

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

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

Late mortality: Secondary
Second Malignancy: Primary

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: Correlative Factors
Heart and vascular:
Respiratory:
Digestive:
Surgical procedures:
Brain and nervous system:
Other:
If other, please specify:

Medications

Describe medications: Estrogen replacement

Pregnancy and offspring: Correlative Factors
Family History: Correlative Factors

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: Primary
Race: Secondary
Sex:
Others:
If others, please specify:

Cancer treatment

Chemotherapy: Correlative Factors
Radiation therapy:
Surgery: Correlative Factors

Anticipated sources of statistical support

CCSS Statistical Center: Yes
Local institutional statistician:
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?

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

Other general comments: