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Requirements to submit AOI:

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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: Breast Cancer Following Spinal Irradiation: A Report from the Childhood Cancer Survivorship Study  
Planned research population (eligibility criteria): Female leukemia or CNS tumor survivor treated with spinal radiation, excluding those treated with chest radiation. There are 363 women who fulfill these criteria (195 leukemia, 168 CNS)  
Proposed specific aims: This analysis is part of our work in the breast cancer risk prediction model study (R01CA136783). The aim of this analysis is to estimate the standardized incidence ratio (SIR) for the risk of breast cancer in women treated for leukemia or a CNS-tumor with spinal irradiation to the general US population. We hypothesize that there is NOT an increased risk of early breast cancer (prior to age 40 years) in women treated with therapeutic spinal irradiation during their pediatric years.  
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?:

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

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

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

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

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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)

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Late mortality:  
Second Malignancy:

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Health Behaviors

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

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Psychosocial

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

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Medical conditions

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

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Medications

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Describe medications:

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Pregnancy and offspring:  
Family History:

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Psychologic/Quality of Life

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BSI-18:

SF-36:

CCSS-NCQ:

PTS:

PTG:

Other:

If other, please specify:

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Chronic conditions (CTCAE v3):

Health status:

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Demographic

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Age: Correlative Factors

Race: Correlative Factors

Sex:

Others:

If others, please specify:

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Cancer treatment

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Chemotherapy:

Radiation therapy: Correlative Factors

Surgery:

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Anticipated sources of statistical support

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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, PhD (Wendy Leisenring, PhD as secondary)

Will this project utilize CCSS biologic samples?: No

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If yes, which of the following?

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

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Other general comments: As will be described in more detail in the concept proposal, the COG does not recommend special breast cancer screening for women previously treated with spine radiation who are under age 40 years. However, for men and women treated with  $\geq 30$  Gy, of spine radiation, colon cancer screening is recommended starting age 35. We are interested in adding to the literature a brief report that spine radiation used in the treatment of females with leukemia or a CNS tumor, regardless of radiation dose, is not associated with an increased risk of breast cancer in women under the age of 40 (and thus supporting the current COG breast cancer screening guideline).