Received: 11.11.10
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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: Subsequent breast cancer after childhood cancer: joint effects of treatment and other breast cancer risk factors
Planned research population (eligibility criteria): All females in the Childhood Cancer Survivor Cohort
Proposed specific aims: 1. Quantify breast cancer risk with respect to radiation dose to the breast and ovary 2. Evaluate breast cancer risk with respect to prior treatment with alkylating agents and anthracyclines, including dose as available 3. Assess modification of radiation-related risks with respect to age at irradiation, time since irradiation, attained age, chemotherapy, reproductive and hormonal factors, and family history of breast cancer 4. Evaluate relation between estrogen/progesterone receptor status and effect of irradiation of breast and ovary (recently diagnosed cases)
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?: Intramural NCI funds may be needed to (a) determine breast tumor location, and (b) do hormone receptor assays. The requisite funds would be available.

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.: Will need to obtain information about breast tumor location in order to do the radiation dosimetry

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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:
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:
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: exogneous hormones (as correlative factor)

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:
Race: Correlative Factors
Sex:
Others:
If others, please specify: will match on age

Cancer treatment

Chemotherapy: Correlative Factors
Radiation therapy: Correlative Factors
Surgery: Correlative Factors

Anticipated sources of statistical support

CCSS Statistical Center: Yes
Local institutional statistician: Yes
If local, please provide the name(s) and contact information of the statistician(s) to be

involved.: Peter Inskip phone: 301-594-7515 e-mail:inskippe@mail.nih.gov
Will this project utilize CCSS biologic samples?: Yes

If yes, which of the following?

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

Other general comments: May need to use tumor tissue to determine hormone receptor status (if not available in medical records)