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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: A Genome-Wide Association Study of Subsequent Malignancies in Childhood Cancer Survivors
Planned research population (eligibility criteria): Study design: Nested case control Cases: Individuals with subsequent malignancies who have adequate DNA for a genome-wide assay Controls: We will have two sets of controls i) childhood cancer survivors with no subsequent malignancy and ii) cancer-free adults (GWAS data is publicly available) Proposed specific aims: 1. To identify novel genetic regions associated with subsequent malignancies in childhood cancer survivors 2. To identify genetic regions that modify radiation-related risk of subsequent malignancy 3. To identify genetic regions that modify chemotherapy-related risk of second malignancy
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?: We are applying for NIH intramural funding

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

Additional self-reported information: No
Biological Samples: Yes
Medical record data: Yes
If yes to any of the above, please briefly describe.: 1) Biological samples are required for genetic assays. 2) Medical record data may be required to construct treatment variables.

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

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

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: Correlative Factors
Alcohol: Correlative Factors
Physical activity: Correlative Factors
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: Secondary

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

Cancer treatment

Chemotherapy: Correlative Factors
Radiation therapy: Correlative Factors
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.: Preetha Rajaraman rajarama@mail.nih.gov Stephen Chanock chanocks@mail.nih.gov Joshua Sampson sampsonjn@mail.nih.gov
Will this project utilize CCSS biologic samples?: Yes

If yes, which of the following?

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

Other general comments: