First Name: Mark
Last Name: Little
Institution: National Cancer Institute
Address 1: Radiation Epidemiology Branch
Address 2: 9609 Medical Center Drive, MSC 9778
City: Bethesda
State/Province: MD
Country: USA
Zip: 20892-9778
Phone: 240 276 7375
Alternate Phone: 301 875 3413
Email: mark.little@nih.gov

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

---

Project Title: Analysis of dose response for circulatory disease in the Childhood Cancer Survivor Study Cohort with a focus on non-cardiac doses
Planned research population (eligibility criteria): Initially all survivors of Hodgkin's lymphoma who have completed a baseline questionnaire in the 1st CCSS cohort, but if that is successful then all survivors with a completed baseline questionnaire in the 1st cohort
Proposed specific aims: In order to test possible non-cardiac etiologically initiating tissues relevant to circulatory disease, we propose to assess all circulatory endpoints, in particular (i) ischemic heart disease (IHD), (ii) heart disease other than IHD, (iii) cerebrovascular disease, (iv) all other circulatory disease in relation to dose to a number of target tissues, in particular doses to the (a) heart, (b) brain, (c) carotid (or thyroid), (d) liver, (e) kidney, (f) aorta, (g) lung, (h) pancreas, (i) red bone marrow. In the first instance approximate surrogate tissues might be used for which radiation dosimetry already exists wihtin the cohort. It would be essential to collect information on all relevant concomitant cardiotoxic therapies, in particular anthracyclines. Lifestyle information, in particular on the major risk factors (diabetes, cigarette smoking, high LDL cholesterol, low HDL cholesterol, high blood pressure) would also be highly desirable (both at baseline and subsequently) although this information may be indirect and based on self-reported medications on the baseline (and subsequent) questionnaires.
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:
Chronic Disease: Primary
Psychology / Neuropsychology:
Genetics:
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: Primary
Second Malignancy:

Health Behaviors

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

Psychosocial

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

Medical conditions

Hearing/Vision/Speech:
Hormonal systems: Primary
Heart and vascular: Primary
Respiratory: Primary
Digestive:
Surgical procedures: Primary

Brain and nervous system:
Other:
If other, please specify:

Medications

Describe medications:

Pregnancy and offspring: Primary
Family History: Primary

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

Cancer treatment

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

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.:
Dr Mark Little
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: