Received 10/5/11
First Name: Tara
Last Name: Henderson
Institution: University of Chicago
Address 1: 5841 S. Maryland Ave
Address 2: MC 4060
City: Chicago
State/Province: IL
Country: USA
Zip: 60637
Phone: 773-702-2501
Alternate Phone: 773-573-7690
Email: thenderson@peds.bsd.uchicago.edu

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: 1) Host and demographic factors associated with solid second malignant neoplasms in unirradiated childhood cancer survivors
Planned research population (eligibility criteria): Survivors who have developed SMN in non-irradiated fields.
Proposed specific aims: a. To examine genes associated with risk of solid tumors in unirradiated childhood cancer survivors b. To examine genes associated with heritable breast cancer in unirradiated childhood cancer survivors
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?: R01 funding. Planning to submit grant application in February 2011.

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

Additional self-reported information: Yes
Biological Samples: Yes
Medical record data: No
If yes to any of the above, please briefly describe.: 1. We would propose to recontact survivors for detailed family history and to obtain biologic samples when not available in the CCSS. 2. Biologic samples will be necessary to examine genes associated with their development. Of note, we propose to expand our sample size through collaboration/case

identification at the University of Chicago, Memorial Sloan-Kettering Cancer Center and the Dana-Farber Cancer Institute.

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:

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:
Heart and vascular:
Respiratory:
Digestive:
Surgical procedures:
Brain and nervous system:

Other:
If other, please specify:

Medications

Describe medications:

Pregnancy and offspring:
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: Correlative Factors
Race: Correlative Factors
Sex: Correlative Factors
Others:
If others, please specify:

Cancer treatment

Chemotherapy: Correlative Factors
Radiation therapy:
Surgery:

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?: 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: