

AOI: Received 6/5/08

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Project Title The risk of osteoporosis and fracture among survivors of childhood cancer
Planned research population (eligibility criteria) -all CCSS cases with FU3 data (the survey that asked specifically about fracture history) -sibling controls with FU3 data
Proposed specific aims - To describe the fracture risk of childhood cancer survivors compared to sibling controls, overall and stratified by cancer diagnosis category -To identify patient, treatment, and health behaviors that are predictive of higher fracture risk. We hypothesize that increased risk will be associated with females, steroid history, cranial radiation, history of hypogonadism, ifosfimide or cisplatin history, lower calcium history, limb sparing surgery, and less physical activity -Describe the distribution and timing of reported fractures.
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

Primary - No Secondary - No

Chronic Disease

Primary - Yes Secondary - No

Reproductive

Primary - No Secondary - No

Neurologic

Primary - No Secondary - No

Psychology / Neuropsychology

Primary - No Secondary - No

Genetics

Primary - No Secondary - No

Cancer Control

Primary - No Secondary - No

Epidemiology / Biostatistics

Primary - No

Secondary - No

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 - No

Secondary - No

Correlative Factors - No

Second Malignancy

Primary - No

Secondary - No

Correlative Factors - No

Health Behaviors

Tobacco

Primary - No

Secondary - No

Correlative Factors - Yes

Alcohol

Primary - No

Secondary - No

Correlative Factors - Yes

Physical activity

Primary - No

Secondary - No

Correlative Factors - Yes

Medical screening

Primary - No

Secondary - No

Correlative Factors - Yes

Other

Primary - No

Secondary - No

Correlative Factors - No

If other, please specify calcium intake

Psychosocial

Insurance

Primary - No

Secondary - No

Correlative Factors - No

Marriage

Primary - No

Secondary - No

Correlative Factors - No

Education

Primary - No

Secondary - No

Correlative Factors - No

Employment

Primary - No

Secondary - No

Correlative Factors - No

Other

Primary - No

Secondary - No

Correlative Factors - No

If other, please specify

Medical conditions

Hearing/Vision/Speech

Primary - No	Secondary - No	Correlative Factors - No
Hormonal systems		
Primary - No	Secondary - No	Correlative Factors - Yes
Heart and vascular		
Primary - No	Secondary - No	Correlative Factors - No
Respiratory		
Primary - No	Secondary - No	Correlative Factors - No
Digestive		
Primary - No	Secondary - No	Correlative Factors - No
Surgical procedures		
Primary - No	Secondary - No	Correlative Factors - Yes
Brain and nervous system		
Primary - No	Secondary - No	Correlative Factors - No
Other		
Primary - No	Secondary - No	Correlative Factors - No

If other, please specify renal disease as correlative factors

Medications

Describe medications calcium supplements, sex hormone replacement, bisphosphonates, vitamin D

Pregnancy and offspring

Primary - No	Secondary - No	Correlative Factors - No
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Family History

Primary - No	Secondary - No	Correlative Factors - No
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Psychologic/Quality of Life

BSI-18

Primary - No	Secondary - No	Correlative Factors - No
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SF-36

Primary - No	Secondary - No	Correlative Factors - No
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CCSS-NCQ

Primary - No	Secondary - No	Correlative Factors - No
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PTS

Primary - No	Secondary - No	Correlative Factors - No
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PTG

Primary - No	Secondary - No	Correlative Factors - No
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Other

Primary - No

Secondary - No

Correlative Factors - No

If other, please specify

Chronic conditions (CTCAE v3)

Primary - No

Secondary - No

Correlative Factors - No

Health status

Primary - No

Secondary - No

Correlative Factors - No

Demographic

Age

Primary - No

Secondary - No

Correlative Factors - Yes

Race

Primary - No

Secondary - No

Correlative Factors - Yes

Sex

Primary - No

Secondary - No

Correlative Factors - Yes

Others

Primary - No

Secondary - No

Correlative Factors - No

If others, please specify

Cancer treatment

Chemotherapy

Correlative Factors - Yes

Radiation therapy

Correlative Factors - Yes

SurgeryCorrelative Factors - Yes

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?** 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 Please also refer to my previous concept proposal based on FU2 data where we had planned to include fracture questions that became accidentally omitted. We plan to also examine self report of osteoporosis and osteopenia as surrogate outcomes. Other investigators that would like to work on this project include Kim Dilley at Northwestern