

Received: 4/27/11  
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Requirements to submit AOI:

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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: Testicular cancer following pediatric cancer  
Planned research population (eligibility criteria): All men in the CCSS cohort, including deceased.  
Proposed specific aims: 1. Estimate the standardized incidence ratio (SIR) for the risk of testicular germ cell tumors in men treated for a childhood cancer relative to the general US population. Hypothesis: Male survivors in the CCSS will not have an increased risk of testicular germ cell tumors than males in the general US population. 1a. Determine if men treated with radiation therapy to the testicles have an increased risk of testicular germ cell tumors relative to men in the general US population. Hypothesis: Radiation involving the testicles will not be associated with an increased risk of testicular germ cell tumors in men. 2. Describe the clinical and pathologic characteristics of the germ cell tumors in men treated for childhood cancer.  
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?:

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

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Additional self-reported information: No  
Biological Samples: No  
Medical record data: No  
If yes to any of the above, please briefly describe.:

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

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Second Malignancy: Primary

Chronic Disease: Secondary

Psychology / Neuropsychology:

Genetics:

Cancer Control:

Epidemiology / Biostatistics:

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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)

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Late mortality: Secondary

Second Malignancy: Primary

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Health Behaviors

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Tobacco:

Alcohol:

Physical activity:

Medical screening:

Other:

If other, please specify:

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Psychosocial

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Insurance:

Marriage:

Education:

Employment:

Other:

If other, please specify:

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Medical conditions

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Hearing/Vision/Speech:

Hormonal systems:

Heart and vascular:

Respiratory:

Digestive:

Surgical procedures: Correlative Factors

Brain and nervous system:

Other:

If other, please specify:

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Medications

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Describe medications:

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Pregnancy and offspring: Correlative Factors  
Family History: Correlative Factors

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Psychologic/Quality of Life

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BSI-18:

SF-36:

CCSS-NCQ:

PTS:

PTG:

Other:

If other, please specify:

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Chronic conditions (CTCAE v3):

Health status:

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Demographic

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Age: Correlative Factors

Race: Correlative Factors

Sex:

Others:

If others, please specify:

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Cancer treatment

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Chemotherapy: Correlative Factors

Radiation therapy: Correlative Factors

Surgery: Correlative Factors

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Anticipated sources of statistical support

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CCSS Statistical Center:

Local institutional statistician: Yes

If local, please provide the name(s) and contact information of the statistician(s) to be involved.: Chaya Moskowitz, PhD

Will this project utilize CCSS biologic samples?: No

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If yes, which of the following?

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Buccal cell DNA:

Peripheral blood:

Lymphoblastoid cell lines:

Second malignancy pathology samples:

Other requiring collection of samples:

If other, please explain:

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Other general comments: In the current SMN dataset, there are only 5 men in the cohort with testicular germ cell tumors, none had testicular radiation.