

Received: 10.27.10
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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

Project Title: Prediction of risk of serious health conditions among long-term survivors of childhood cancer

Planned research population (eligibility criteria): All survivors who were alive at baseline

Proposed specific aims: 1. Develop a risk-prediction model to predict the likelihood of a serious chronic health condition among survivors of childhood cancer. 2. Validate the risk-prediction model among childhood cancer survivors.

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: Secondary

Psychology / Neuropsychology:

Genetics:
Cancer Control:
Epidemiology / Biostatistics: Primary

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: 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: Primary
Hormonal systems: Primary
Heart and vascular: Primary
Respiratory: Primary
Digestive: Primary
Surgical procedures: Secondary
Brain and nervous system: Primary
Other:
If other, please specify: Scoring criteria published in NEJM

Medications

Describe medications: Scoring criteria published in NEJM

Pregnancy and offspring:
Family History:

Psychologic/Quality of Life

BSI-18:
SF-36:
CCSS-NCQ:
PTS:
PTG:
Other:
If other, please specify:

Chronic conditions (CTCAE v3): Primary
Health status:

Demographic

Age: Correlative Factors
Race: Correlative Factors
Sex: Correlative Factors
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.: Chaya Moskowitz, PhD
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: Using the published scoring criteria for chronic conditions among CCSS survivors (NEJM 2006), we will develop a risk-stratification model for adult survivors of childhood cancers. Such a model can be used to direct appropriate risk-based post-treatment care for survivors.