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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: "Second Malignant Neoplasm in Down syndrome survivors of childhood cancer"

Planned research population (eligibility criteria): 1. CCSS Down syndrome survivors of childhood cancer; 2. CCSS non-Down syndrome survivors of childhood cancer.

Proposed specific aims: 1. To describe the cumulative incidence of second malignant neoplasms in down syndrome survivors of childhood cancer. 2. To determine the risk of second malignant neoplasm in down syndrome survivors of childhood cancer compared with that of the non-down syndrome childhood cancer survivors in the CCSS cohort. 3. To determine specific risk factors associated with the development of second malignant neoplasm in down syndrome children.

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
Chronic Disease:
Psychology / Neuropsychology:
Genetics: Secondary
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: Secondary
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:

Psychologic/Quality of Life

BSI-18:

SF-36:

CCSS-NCQ:

PTS:

PTG:

Other:

If other, please specify:

Chronic conditions (CTCAE v3): Correlative Factors
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:

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: