

Received 4.13.11
First Name: Paul
Last Name: Nathan
Institution: SickKids
Address 1: 555 University Avenue
Address 2:
City: Toronto
State/Province: ON
Country: Canada
Zip: M5G 1X8
Phone: 416-813-7743
Alternate Phone:
Email: paul.nathan@sickkids.ca

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: Gynecological malignancies in female survivors of childhood cancer
Planned research population (eligibility criteria): Female survivors >18 y.o.
Proposed specific aims: 1) To describe the incidence of gynecological second malignant neoplasms in female survivors 2) To examine the risk factors associated with their occurrence 3) To compare the risk of gynecological malignancies with the general population
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: Yes
If yes to any of the above, please briefly describe.: Will use reported/confirmed SMNs as ascertained by the SMN committee. There are 67 reported to date (32 cervical, 18 uterine, 17 ovarian).

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

Second Malignancy: Primary
Chronic Disease:
Psychology / Neuropsychology:
Genetics:
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: Correlative Factors
Alcohol:
Physical activity: Correlative Factors
Medical screening: Correlative Factors
Other:
If other, please specify:

Psychosocial

Insurance: Correlative Factors
Marriage: Correlative Factors
Education:
Employment:
Other:
If other, please specify:

Medical conditions

Hearing/Vision/Speech:
Hormonal systems: Correlative Factors
Heart and vascular:
Respiratory:
Digestive:
Surgical procedures: Correlative Factors
Brain and nervous system:
Other:
If other, please specify:

Medications

Describe medications: Oral contraceptives or other hormone replacement

Pregnancy and offspring: Correlative Factors
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:
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: 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: