First Name: Stefan
Last Name: Essig
Institution: Institute of Social and Preventive Medicine, University of Bern
Address 1: Finkenhubelweg 11
Address 2:
City: Bern
State/Province: BE
Country: Switzerland
Zip: 3012
Phone: +41(0)797552926
Alternate Phone:
Email: sessig@ispm.unibe.ch

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: Estimating long-term risks in children newly diagnosed with ALL based on survivor clusters in the CCSS cohort
Planned research population (eligibility criteria): Acute Lymphoblatic Leukemia survivors
Proposed specific aims: We intend to identify clusters of patients with ALL in the CCSS cohort that were treated in a manner similar to children with ALL treated in the current era. We will document the long-term outcomes in these patient clusters, and use these to infer the anticipated outcomes in newly diagnosed patients. This might allow oncologists treating newly diagnosed children to anticipate the long-term outcomes of their treatment approach in a manner that takes into account the totality of the therapies used (adjusted for patient variables such as age, gender etc.). We intend to define cohorts of patients within the CCSS population that were treated in a manner similar to children treated today. For example, we would define a “low risk” group that received anti-metabolite, corticosteroid and asparaginase therapy. Likewise, we might define a higher risk group that was treated with alkylating agent and anthracycline therapy, but no cranial radiation, etc. Once these groups have been defined, we will examine long-term outcomes in these clusters. Specific aims: 1) To identify clusters of patients in the CCSS survivor cohort who were treaed in a manner analagous to children newly diagnosed with low, intermediate or high risk ALL 2) For each cluster, to document the following long-term outcomes: a. Late mortality b. Second malignant neoplasms c. Other chronic health conditions and overall morbidity d. Health Status e. Psychosocial outcomes (marriage, education, employment, etc.) 3) To identify the patient/demographic modifiers of these

outcomes
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: Secondary
Chronic Disease: Secondary
Psychology / Neuropsychology:
Genetics:
Cancer Control: Secondary
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: Correlative Factors
Alcohol: Correlative Factors
Physical activity: Correlative Factors
Medical screening: Correlative Factors
Other:
If other, please specify:

Psychosocial

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

Medical conditions

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

Medications

Describe medications:

Pregnancy and offspring: Primary
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: Primary

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: 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: Co-Applicant is Paul Nathan, Hospital for Sick Children, Toronto (paul.nathan@sickkids.ca)