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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

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Project Title: Long-term morbidity in survivors of childhood CML
Planned research population (eligibility criteria): Survivors of CML (76 patients from the original cohort and 72 patients from the expansion cohort)
Proposed specific aims: 1) Quantify the incidence of late effects in childhood CML survivors 2) Evaluate the risk factors for morbidities in survivors of childhood CML 3) Compare morbidity in childhood CML survivors between the original and expansion cohorts 4) Compare morbidity in childhood CML survivors with the general survivor 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: 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: Primary
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: Primary
Second Malignancy: Primary

Health Behaviors

Tobacco: Secondary
Alcohol: Secondary
Physical activity: Secondary
Medical screening: Secondary
Other:
If other, please specify:

Psychosocial

Insurance: Secondary
Marriage: Secondary
Education: Secondary
Employment: Secondary
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: Secondary

Psychologic/Quality of Life

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

Chronic conditions (CTCAE v3):
Health status:

Demographic

Age: Primary
Race: Primary
Sex: Primary
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: We acknowledge the population is small, but there are very few studies that reported long-term morbidity in children with CML. The proposed study will add valuable information. The plan was discussed with Dr Kiri Ness.