CCSS Application of Intent Submission

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Project Requirements and Description
Requirements to submit AOI:

	Yes	No
A comprehensive review of previously published data has been completed	✔	-
The specific aims are clear and focused	✔	-
The investigator has appropriate experience and expertise to develop the concept proposal; if not, has identified a mentor or senior co-investigator.	✔	-
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	✔	-

Project Title:
Pharmacogenomic Landscape of Acute Lymphoblastic Leukemia Childhood Cancer Survivors

Planned research population:
1. ALL Childhood cancer survivors with age at diagnosis below 18 years of age
2. Whole genome wide or exome wide genetic data available
3. Consented for using the data to answer other scientific questions

Proposed specific aims:
1. Describe the landscape of Pharmacogenomic variants using whole genome /exome sequences in acute lymphoblastic leukemia CCS
2. To map the prevalent clinically actionable and potentially deleterious pharmacogene variants in acute lymphoblastic leukemia CCS
3. To explore the consequences of the prevalent pharmacogene variants with that of the

Will the project require non-CCSS funding to complete?: Yes
If yes, what would be the anticipated source(s) and timeline(s) for securing funding?:
CANSEARCH Foundation

Does this project require contact of CCSS study subjects for:

	Yes	No
Additional self-reported information	-	✔
Biological samples	-	✔
Medical record data	-	✔

If yes to any of the above, please briefly describe:

What CCSS Working Group(s) would likely be involved?:

	Primary	Secondary
Second Malignancy	-	-
Chronic Disease	-	-
Psychology/Neuropsychology	-	-
Genetics	✔	-
Cancer Control	-	-
Epidemiology/Biostatistics	-	✔

Outcomes or Correlative Factors
Late Mortality and Second Malignancy:

	Primary	Secondary	Correlative Factors
Late Mortality	-	-	✔
Second Malignancy	-	-	-

Health Behaviors: None selected

If other, please specify:

Psychosocial: None selected

If other, please specify:

Medical Conditions: None selected
If other, please specify:

Medications
Describe medications:

Psychologic/Quality of Life:

	Primary	Secondary	Correlative Factors
BSI-18	-	-	-
SF-36	-	-	✔
CCSS-NCQ	-	-	-
PTS	-	-	-
PTG	-	-	-
Other	-	-	-

If other, please specify:

Other:

	Primary	Secondary	Correlative Factors
Pregnancy and Offspring	-	-	-
Family History	-	-	-
Chronic Conditions (CTCAE v3)	-	-	✔
Health Status	-	-	-

Demographic:

	Primary	Secondary	Correlative Factors
Age	✔	-	-
Race	✔	-	-
Sex	✔	-	-
Other	-	-	-

If other, please specify:

Cancer Treatment:

	Correlative Factors
Chemotherapy	✔
Radiation Therapy	-
Surgery	-

Anticipated Sources of Statistical Support:

	Yes	No
CCSS Statistical Center	✔	-
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?:
If other, please explain:

Other General Comments
General comments: This exploration and presentation of the data is essential given the reason of increased survival in pediatric ALL patients, and given the possible morbidness they have to manage using medication.

This exercise will provide insights on the prevalence of the actionable pharmacogene variants in this population, that can optimize medication management by followup survival clinics Or other clinics.

Will also serve as a basis of our future investigations in the project named "MPGxINDALL": clinicaltrials.gov identifier NCT05512169

Agree: I agree to share this information with St. Jude