

Subject: CCSS Application of Intent - FORM SUBMISSION

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Project Title Late Occurring Secondary Leukemias in Survivors of Childhood Cancers

Planned research population (eligibility criteria) The population of interest will include patients enrolled in the CCSS who have been diagnosed with leukemia as a second malignant neoplasm beyond the five year time point (35 patients). A subset of those patients who were diagnosed with leukemia more than 10 years after their first malignancy will be the particular focus (12 patients).

Proposed specific aims 1. To describe the occurrence of secondary leukemias beyond the standard ten year time-frame when patients are commonly thought to be at risk including the population characteristics, primary malignancy, time from first treatment to development of leukemia, type of leukemia, and current vital statistics of the cohort. 2. To describe pathological findings in this group. 3. To heighten awareness of the medical community that secondary leukemias may occur beyond ten years after initial treatment of a primary malignancy.

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 Yes

Medical record data No

If yes to any of the above, please briefly describe. Attempts will be made to obtain pathology specimens (ie - bone marrow biopsies) on patients who are deceased or on those who have provided consent. these specimens will be confirmed by our institutional hematopathologist.

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

Second Malignancy

Primary - Yes Secondary - No

Chronic Disease

Primary - No Secondary - No

Reproductive

Primary - No Secondary - No

Neurologic

Primary - No Secondary - No

Psychology / Neuropsychology

Primary - No Secondary - No

Genetics

Primary - No Secondary - No

Cancer Control

Primary - No Secondary - No

Epidemiology / Biostatistics

Primary - No Secondary - No

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 - No Secondary - No Correlative Factors - No

Second Malignancy

Primary - Yes Secondary - No Correlative Factors - No

Health Behaviors

Tobacco

Primary - No Secondary - No Correlative Factors - No

Alcohol

Primary - No Secondary - No Correlative Factors - No

Physical activity

Primary - No Secondary - No Correlative Factors - No

Medical screening

Primary - No Secondary - No Correlative Factors - No

Other

Primary - No Secondary - No Correlative Factors - No

If other, please specify

Psychosocial

Insurance

Primary - No Secondary - No Correlative Factors - No

Marriage

Primary - No Secondary - No Correlative Factors - No

Education

Primary - No Secondary - No Correlative Factors - No

Employment

Primary - No Secondary - No Correlative Factors - No

Other

Primary - No Secondary - No Correlative Factors - No

If other, please specify

Medical conditions

Hearing/Vision/Speech

Primary - No Secondary - No Correlative Factors - No

Hormonal systems

Primary - No Secondary - No Correlative Factors - No

Heart and vascular

Primary - No Secondary - No Correlative Factors - No

Respiratory

Primary - No Secondary - No Correlative Factors - No

Digestive

Primary - No Secondary - No Correlative Factors - No

Surgical procedures

Primary - No Secondary - No Correlative Factors - No

Brain and nervous system

Primary - No Secondary - No Correlative Factors - No

Other

Primary - No Secondary - No Correlative Factors - No

If other, please specify

Medications

Describe medications

Pregnancy and offspring

Primary - No Secondary - No Correlative Factors - No

Family History

Primary - No Secondary - No Correlative Factors - No

Psychologic/Quality of Life

BSI-18

Primary - No Secondary - No Correlative Factors - No

SF-36

Primary - No Secondary - No Correlative Factors - No

CCSS-NCQ

Primary - No Secondary - No Correlative Factors - No

PTS

Primary - No Secondary - No Correlative Factors - No

PTG

Primary - No Secondary - No Correlative Factors - No

Other

Primary - No Secondary - No Correlative Factors - No

If other, please specify

Chronic conditions (CTCAE v3)

Primary - No Secondary - No Correlative Factors - No

Health status

Primary - No Secondary - No Correlative Factors - No

Demographic

Age

Primary - No Secondary - No Correlative Factors - Yes

Race

Primary - No Secondary - No Correlative Factors - Yes

Sex

Primary - No Secondary - No Correlative Factors - Yes

Others

Primary - No Secondary - No Correlative Factors - No

If others, please specify

Cancer treatment

Chemotherapy

Correlative Factors - Yes

Radiation therapy

Correlative Factors - Yes

Surgery

Correlative Factors - No

Anticipated sources of statistical support

CCSS Statistical Center

Local institutional statistician Yes

If local, please provide the name(s) and contact information of the statistician(s) to be involved.

Deo Kumar Srivastava

Will this project utilize CCSS biologic samples? Yes

If yes, which of the following?

Buccal cell DNA

Peripheral blood

Lymphoblastoid cell lines

Second malignancy pathology samples Yes

Other requiring collection of samples

If other, please explain

Other general comments

I will be working on this project with Drs. Robison, Bhatia, and Armstrong