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Requirements to submit AOI:

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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: Tiled study design: using temporal overlap as a method to extend longitudinal follow-up among carefully selected time-limited cohorts  
Planned research population (eligibility criteria): Original cohort, acute lymphoblastic leukemia (ALL) patients without relapse or SMN prior the baseline CCSS survey. Exclude those who received spinal radiotherapy as part of initial treatment.  
Proposed specific aims: Use the CCSS dataset to empirically determine the utility and possible analytic constraints related to the use of the proposed “tiled” study design as a time and resource-efficient way to study the association and correlation of biomarkers over time with outcomes of interest. Specifically, as a demonstration analysis, we propose to use acute lymphoblastic leukemia (ALL) patients free of relapse or SMNs at the time of the baseline survey, stratified by cranial radiotherapy exposures (none, 15-19 Gy, 20-29 Gy), in order to examine the established relationship of BMI (a continuous “biomarker”) with the development of selected cardiometabolic conditions (e.g. diabetes, hypertension). Results from this “tiled” study design will be compared against those estimated from a conventional cohort analysis.  
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?:

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Does this project require contact of CCSS study subjects for . . .

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Additional self-reported information: No  
Biological Samples: No

Medical record data: No

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

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

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Second Malignancy:

Chronic Disease: Secondary

Psychology / Neuropsychology:

Genetics:

Cancer Control:

Epidemiology / Biostatistics: Primary

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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)

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Late mortality: Correlative Factors

Second Malignancy: Correlative Factors

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Health Behaviors

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Tobacco:

Alcohol:

Physical activity: Correlative Factors

Medical screening:

Other:

If other, please specify:

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Psychosocial

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Insurance:

Marriage:

Education: Correlative Factors

Employment: Correlative Factors

Other:

If other, please specify:

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Medical conditions

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Hearing/Vision/Speech:

Hormonal systems: Correlative Factors

Heart and vascular: Primary

Respiratory:

Digestive:

Surgical procedures:

Brain and nervous system:

Other:

If other, please specify:

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Medications

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Describe medications:

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Pregnancy and offspring:

Family History:

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Psychologic/Quality of Life

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BSI-18:

SF-36:

CCSS-NCQ:

PTS:

PTG:

Other:

If other, please specify:

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Chronic conditions (CTCAE v3):

Health status:

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Demographic

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Age: Correlative Factors

Race: Correlative Factors

Sex: Correlative Factors

Others:

If others, please specify:

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Cancer treatment

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Chemotherapy: Correlative Factors

Radiation therapy: Correlative Factors

Surgery:

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Anticipated sources of statistical support

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CCSS Statistical Center: Yes

Local institutional statistician:

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

Yutaka Yasui and Qi Liu will directly oversee the analysis with additional input from Wendy Leisenring.

Will this project utilize CCSS biologic samples?: No

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If yes, which of the following?

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Buccal cell DNA:

Peripheral blood:

Lymphoblastoid cell lines:

Second malignancy pathology samples:

Other requiring collection of samples:

If other, please explain:

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Other general comments: