Section: Contact Information

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Section: Project Requirements and Description

Group: 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 : **Long-term outcomes among survivors of childhood acute myeloid leukemia**

Planned research population (eligibility criteria) :
Survivors with a history of AML; will use siblings and non-AML survivors for comparison

Proposed specific aims :
1. Quantify mortality rates in long-term survivors of AML.
a. Estimate cumulative incidence of mortality by decade of diagnosis and HCT status (yes/no) and calculate standardized mortality ratios, using US population data, to compare changes over time.
b. Compare cumulative incidence of mortality to other CCSS survivors by attained age and to the U.S. population.
c. Describe causes of death, by decade of diagnosis, and estimate cumulative incidence of cause-specific death by decade of diagnosis.
d. Use piecewise exponential models to estimate the impact of temporal changes in therapeutic exposures on mortality rates.

2. Describe late health consequences in long-term survivors of AML, including overall chronic conditions, cardiac and endocrine complications and subsequent neoplasms.

a. Estimate the cumulative incidence and cumulative burden of overall chronic health conditions (grades 1-5 and 3-5) by decade of diagnosis and HCT status and compare changes over time and compare with siblings.
b. Examine cumulative incidence and cumulative burden of individual conditions (grades 1-5 and 3-5) by decade of diagnosis and compare changes over time.
c. Perform regression analyses to assess associations between treatment exposures and cumulative burden.

3. Compare health status outcomes among long-term survivors of AML, including general health, mental health, functional impairments, activity limitations, pain related to cancer or treatment, and fears/anxiety related to cancer or treatment.
a. Quantify the proportion of AML survivors, by decade of diagnosis and/or attained age, experiencing the outcomes above. Compare differences based on decade of diagnosis, attained age and HCT status and compare to siblings.
b. Use piecewise exponential models to estimate the impact of temporal changes in therapeutic exposures on health status 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? :

Group: 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. :

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

Second Malignancy : **Secondary**

Chronic Disease : **Primary**

Psychology / Neuropsychology : **Secondary**

Genetics :

Cancer Control :

Epidemiology / Biostatistics : **Secondary**

Section: Outcomes or Correlative Factors

Late mortality : **Secondary**

Second Malignancy : **Secondary**

Group: Health Behaviors

Tobacco : **Correlative Factors**

Alcohol :

Physical activity :

Medical screening :

Other :

If other, please specify :

Group: Psychosocial

Insurance :
Marriage :
Education :
Employment :
Other :
If other, please specify :

Group: Medical Conditions

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

Group: Medications

Describe medications :

Group: Psychologic/Quality of Life

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

Group: Other

Pregnancy and offspring :
Family history :
Chronic conditions (CTCAE v3) : **Primary**
Health status : **Primary**

Group: Demographic

Age : **Secondary**
Race : **Secondary**
Sex : **Secondary**
Other :

If other, please specify :

Group: Cancer treatment

Chemotherapy : **Correlative Factors**

Radiation therapy : **Correlative Factors**

Surgery :

Section: 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? :

If other, please explain :

Section: Other General Comments

Other General Comments :

This AOI was invited by Drs. Armstrong and Oeffinger as part of a series of manuscripts based on primary cancers. Senior author will be Eric Chow.