Received 11.24.08
First Name Heather
Last Name Fullerton
Institution University of California, San Francisco
Address 1 Depts of Neurology and Pediatrics
Address 2 Box 0114
City San Francisco
State CA
Zip 94143-0114
Phone 415 353 3681
Email fullertonh@neuropeds.ucsf.edu

Project Title Outcome after Stroke among Long-Term Survivors of Childhood Leukemia and Brain Tumors
Planned research population (eligibility criteria) All CCSS cohort survivors of childhood leukemia or brain tumor would be included in an analysis of how self-reported stroke impacts quality of life and mortality outcomes using existing CCSS data. The subset of children with self-reported first strokes (n=97 among leukemia survivors; n=117 among brain-tumor survivors) would be surveyed regarding recurrent strokes (Bowers, et al; J Clinical Oncology, 2006).
Proposed specific aims 1) To determine whether childhood cancer survivors with stroke have worse quality of life and higher mortality rates than those without stroke. 2) To determine rates of recurrent stroke among childhood cancer survivors reporting first stroke. 3) To determine predictors of stroke recurrence, such as cancer type (leukemia versus brain tumor), timing of first stroke (less than or greater than 5 years from cancer diagnosis), treatment with cranial radiotherapy (CRT), and age at CRT.
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 Yes
Biological Samples No
Medical record data No
If yes to any of the above, please briefly describe. Subjects with self-reported first strokes (n=97 among leukemia survivors; n=117 among brain-tumor survivors) would be asked for additional self-reported information about the first stroke and recurrent strokes. Questions would relate to timing of stroke, stroke type (hemorrhagic or ischemic), treatment, and residual deficits.

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

Second Malignancy
Primary - No Secondary - No

Chronic Disease
Primary - No Secondary - Yes

Reproductive
Primary - No Secondary - No

Neurologic
Primary – No Secondary - Yes

Psychology / Neuropsychology
Primary - Yes 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 - Yes Secondary - No Correlative Factors - No

Second Malignancy
Primary - No 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 - Yes Correlative Factors - No

Education
Primary - No Secondary - Yes Correlative Factors - No

Employment
Primary - No Secondary - Yes 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 - Yes | Secondary - No | Correlative Factors - No

Other
Primary - No | Secondary - No | Correlative Factors - No

If other, please specify

Medications

Describe medications anti-platelets, steroids

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 - Yes | Correlative Factors - No

SF-36
Primary - No | Secondary - Yes | Correlative Factors - No

CCSS-NCQ
Primary - No | Secondary - Yes | Correlative Factors - No

PTS

Primary - No | Secondary - Yes | Correlative Factors - No

PTG
Primary - No | Secondary - Yes | 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 - Yes

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. Dr. Fullerton has a Masters in Clinical Research and is capable of performing the data analyses herself without additional statistical support. However, she also has funding to cover local (UCSF) analytical support if helpful. Specifically, she could involve, Nancy Hills, PhD. Dr. Hills is a biostatistician and epidemiologist within the UCSF Stroke Sciences Group, and provides

support for Dr. Fullerton's more complex analyses. Her email address is: nancy.hills@ucsfmedctr.org. Her phone number is 415-502-2540.
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 Collaborators on this project include CCSS investigators, Dr. Daniel Bowers and Dr. Rob Goldsby. The long-term goal is to use these data as preliminary data to obtain funding for a prospective cohort study of recurrent stroke in children with radiation-induced arteriopathy.