

Received: 11.9.10
First Name: Tiffany
Last Name: Chang
Institution: University of California, San Francisco
Address 1: 505 Parnassus Ave
Address 2: Box 0106
City: San Francisco
State/Province: CA
Country: USA
Zip: 94143
Phone: 415-476-3831
Alternate Phone: 650-814-3491
Email: changt@peds.ucsf.edu

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: Risk of second malignant neoplasms in long-term survivors of childhood cancer with diabetes mellitus
Planned research population (eligibility criteria): Participants will include the Childhood Cancer Survivor Study (CCSS) cohort diagnosed between January 1, 1970 and December 31, 1986. A nested case control study will be conducted to compare the risk of second malignant neoplasms in survivors who reported using medications for diabetes to matched controls not taking diabetes medications.
Proposed specific aims: Aim 1: Determine the standardized incidence ratio of second malignant neoplasms (SMN) in survivors with diabetes mellitus compared to matched controls Aim 2: Assess influence of SMN risk based on diabetes therapy (glucophage vs. insulin vs. other) Aim 3: Determine the cumulative risk of SMN in survivors with diabetes compared to those without diabetes
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: No
Medical record data: No
If yes to any of the above, please briefly describe.:

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

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

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:
Second Malignancy: Primary

Health Behaviors

Tobacco:
Alcohol:
Physical activity:
Medical screening:
Other:
If other, please specify:

Psychosocial

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

Medical conditions

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

Medications

Describe medications: Medicines in treatment of Diabetes Mellitus

Pregnancy and offspring:
Family History:

Psychologic/Quality of Life

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

Chronic conditions (CTCAE v3):
Health status:

Demographic

Age:
Race:
Sex:
Others:
If others, please specify:

Cancer treatment

Chemotherapy:
Radiation therapy:
Surgery:

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?

Buccal cell DNA:

Peripheral blood:

Lymphoblastoid cell lines:

Second malignancy pathology samples:

Other requiring collection of samples:

If other, please explain:

Other general comments: I am a second year pediatric hematology/oncology fellow at UCSF with a strong interest in late effects. I plan to work closely with Dr. Robert Goldsby on this project. We have had preliminary discussions regarding this project with Dr. Charles Sklar and Dr. Greg Anderson. If this AOI is approved, we will certainly incorporate input from other appropriate CCSS investigators.