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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: Estimation of risk ratios in the presence of statistical interactions
Planned research population (eligibility criteria): This project requests the use of data on chest-directed radiation, cardiovascular risk factor, and cardiac outcomes that has been recently analyzed by Armstrong, Oeffinger et al 2012) "Cardiotoxic therapy and modifiable cardiovascular risk factors in the occurrence of major cardiac events among adult survivors of childhood cancer: A report from the childhood cancer survivor study".
Proposed specific aims: This project will examine the concept of "removable statistical interactions" and how to obtain precise estimates of risk ratios when there are removable interactions between the risk factors. To this end, we propose the following aims: (1) to investigate whether the interaction between chest-directed radiotherapy and cardiovascular risk factors is removable under the log link (the canonical link function that is used in Poisson regression models); and (2) to obtain precise estimates of the risk ratios of interest using a novel parsimonious model that will incorporate interactions between the risk factors by using an alternative link function that does not require the inclusion of interaction terms per-se in the model.
Will the project require non-CCSS funding to complete?: Yes
If yes, what would be the anticipated source(s) and timeline(s) for securing funding?: I'm submitting a R01 application to NIH. The submission timeline is December 15th, so that the grant can be reviewed during the February/March review cycle for a possible Summer 2013 or Fall 2013 funding. The requested funding period is 4 years.

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:

Chronic Disease:

Psychology / Neuropsychology:

Genetics:

Cancer Control:

Epidemiology / Biostatistics: Primary

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:

Health Behaviors

Tobacco:

Alcohol:

Physical activity:

Medical screening:

Other: Primary

If other, please specify: The following primary outcomes, analyzed by Armstrong et al (2012), are requested: coronary artery disease, heart failure, valvular disease, and arrhythmia.

Psychosocial

Insurance:

Marriage:

Education: Correlative Factors

Employment:

Other:

If other, please specify:

Medical conditions

Hearing/Vision/Speech:

Hormonal systems:

Heart and vascular:

Respiratory:

Digestive:

Surgical procedures:

Brain and nervous system:

Other:

If other, please specify: The following medical conditions (cardiovascular risk factor), considered by Armstrong et al (2012), are requested: hypertension, dyslipidemia, diabetes, and obesity (BMI scores).

Medications

Describe medications:

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: Correlative Factors

Race: Correlative Factors

Sex: Correlative Factors

Others:

If others, please specify:

Cancer treatment

Chemotherapy: Correlative Factors

Radiation therapy: Correlative Factors

Surgery:

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.:

Jaya Satagopan, Memorial Sloan-Kettering Cancer Center; E-mail: satagopj@mskcc.org; Phone: 646-735-8122.

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: