

Received: 4/2/11
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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: Development and validation of an absolute risk prediction model for thyroid cancer in childhood cancer survivors
Planned research population (eligibility criteria): Model development: entire CCSS cohort along with Nordic and LESG study data from PIRATES consortium (both lead investigators have approved their contribute date to build the thyroid cancer prediction model). The French data are proposed as validation set. The lead investigators have not been contacted yet. we'd prefer to first build a model.
Proposed specific aims: build two models to predict risk of any second primary thyroid cancer in individuals who were diagnosed with a childhood cancer and survived at least 5 years past that diagnosis. We also will predict the absolute risk of any second primary cancer other than thyroid. a) Model 1 will investigate the predictive value of risk factors available to the patient, either from recall or the patient's medical record. b) Model 2 will include an estimated radiation dose exposure for the primary cancer treatment (from Marilyn Stovall and Rita Weathers), which is assumed unknown to the patient. Other patient-reported risk factors considered in Model 1 will be included if have predictive value after accounting for dose exposure.
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:
Psychology / Neuropsychology:
Genetics:
Cancer Control:
Epidemiology / Biostatistics: Secondary

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: Secondary
Second Malignancy: Primary

Health Behaviors

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

Psychosocial

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

Medical conditions

Hearing/Vision/Speech:
Hormonal systems: Correlative Factors
Heart and vascular:
Respiratory:
Digestive:

Surgical procedures:
Brain and nervous system:
Other:
If other, please specify:

Medications

Describe medications: Synthroid and other hormones

Pregnancy and offspring:
Family History: Correlative Factors

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: Correlative Factors

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.: Statistical lead: Ruth Pfeiffer, NCI Biostatistics branch. pfeiffer@mail.nih.gov
post-doc who will do the analysis and write the paper: Stephanie Kovalchik, NCI

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: This is an extension of the original thyroid cancer Yard Stick idea, part III in the thyroid cancer cohort study concept proposal (Ronckers et al, 2006). The original idea focused on translating treatment factors into estimated indicators of thyroid gland dose, which could in turn be used to derive a crude estimate of thyroid cancer risk from our own models, whereas current thinking has evolved into the idea of directly estimating absolute risk from available information on prior radiotherapy and other variables/risk factors; secondly, we propose to include data from other studies now to strengthen the model building phase and to incorporate a validation step, which increases the importance and credibility of this work.