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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

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Project Title: Association between key therapeutic exposures and outcomes - gaps in knowledge
Planned research population (eligibility criteria): Participation in the CCSS study (original and expanded cohort)
Proposed specific aims: COG Guidelines are scored to reflect the strength of evidence for teh association between an exposure and outcome. The score of 2A and 2B reflect a lack of evidence regarding the association between the therapeutic exposure and the outcome. The goal of this project is to identify these gaps in knowledge and address them using the CCSS cohort. A combination of the original and expanded cohort will allow a wider range of exposures (in terms of doses), as well as access to the more contemporary exposures.
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,Secondary
Chronic Disease: Secondary
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: Secondary
Second Malignancy: Primary

Health Behaviors

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

Psychosocial

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

Medical conditions

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

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: Primary
Race: Primary
Sex: Primary
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: Yes
Local institutional statistician: Yes
If local, please provide the name(s) and contact information of the statistician(s) to be involved.:
Canlan Sun, PhD (casun@coh.org) Lennie Wong, PhD (FLwong@coh.org)
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: