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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: Differences in participant characteristics and changes in treatment characteristics from the original to the expanded cohorts
Planned research population (eligibility criteria): The original CCSS cohort has been well described. As we begin to examine outcomes in the expanded cohort, it will be important to identify similarities/differences between the two cohorts. In addition, treatment factors in the original CCSS cohort have been well described. Identical medical record abstraction in the expanded cohort will allow treatment factors in this cohort to be well described as well. As we begin to examine outcomes in the expanded cohort, it will be important to note similarities/differences in treatment between the two cohorts.
Proposed specific aims: This proposed analysis will look at demographic and socioeconomic information to determine differences and similarities between the two CCSS cohorts. We propose the following objectives: â€¢Objective 1: Determine the characteristics that are similar/different between cohorts, overall and by primary diagnosis. â€¢Objective 2: Identify characteristics that may impact outcomes This proposed analysis will also compare specific treatment factors between the two CCSS cohorts. We propose the following objectives: â€¢Objective 1: Determine treatment factors that are similar/different between cohorts, overall and by diagnosis group. â€¢Objective 2: Identify differences in treatment factors that may impact outcomes
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:
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: Secondary
Second Malignancy: Secondary

Health Behaviors

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

Psychosocial

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

Medical conditions

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

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

Medications

Describe medications:

Pregnancy and offspring:
Family History:

Psychologic/Quality of Life

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

Chronic conditions (CTCAE v3): Secondary
Health status:

Demographic

Age: Secondary
Race: Secondary
Sex: Secondary
Others: Primary
If others, please specify: Diagnosis factors, alive/dead status, HIPAA consent, treatment type, specific chemotherapy (anthracyclines, alkylating agents, epipodophyllotoxins, bleomycin); specific radiation sites (brain, chest, gonads); specific surgeries (amputations, transplant)

Cancer treatment

Chemotherapy:
Radiation therapy:
Surgery:

Anticipated sources of statistical support

CCSS Statistical Center:
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: Mertens and Leisenring will be co-leads for this AOI. This AOI is for consideration as a high priority analysis from the Epi/Biostats Working Group