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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: Analysis of Late Mortality by Treatment Era
Planned research population (eligibility criteria): All surviviors eligible for the CCSS cohort 1970-1999
Proposed specific aims: 1) To compare cumulative mortality (all cause, recurrence and non-recurrence non-external cause) and standardized mortality ratios (all cause and cause-specific) by treatment era. 2) To compare cumulative mortality (all cause, recurrence and non-recurrence non-external cause) and standardized mortality ratios (all cause and cause-specific) based on changes in therapy within specific cancer diagnoses.
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: Primary
Second Malignancy:

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:
Heart and vascular:
Respiratory:
Digestive:
Surgical procedures:
Brain and nervous system:
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: Correlative Factors
Race: Correlative Factors
Sex: Correlative Factors
Others: Correlative Factors
If others, please specify:

Cancer treatment

Chemotherapy: Correlative Factors
Radiation therapy: Correlative Factors
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: To include survivors who are eligible for, but currently non-participants in CCSS, this will require an amendment to the CCSS protocol at each institution allowing relase of a limited data set of treatment information on non-particpants.
