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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: Fertility following Contemporary Chemotherapy in Childhood Cancer Survivors
Planned research population (eligibility criteria): All survivors (ages 15 to 44) from baseline and expansion cohorts who are not surgically sterile and were not exposed to gonadal or cranial radiation. Siblings of the same age range and who are not surgically sterile will be used as a comparison group. Analyses will be performed for each sex separately.
Proposed specific aims: Primary: Determine if more contemporary chemotherapy agents and treatment combinations, specifically those that include ifosfamide and platinum-containing agents, are associated with a differential likelihood of male and female fertility compared with regimens that do not contain these agents. Secondary: Apply classification and regression tree (CART) methods to determine which agents and agent-dose combinations will be most strongly associated with a lower likelihood of fertility.
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: Primary
Psychology / Neuropsychology:
Genetics:
Cancer Control:
Epidemiology / Biostatistics:

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

Psychosocial

Insurance: Correlative Factors
Marriage: Correlative Factors
Education: Correlative Factors
Employment: Correlative Factors
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:

Pregnancy and offspring: Primary
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:
Surgery: Correlative Factors

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: This is the 2nd planned AOI from the Chronic Disease WG based on anticipated data from the expansion cohort. We specifically are going to avoid evaluating XRT exposures given the limited availability of that data from the expansion cohort. Proposal has been reviewed by Drs. Oeffinger, Sklar, and Green.