Received 4.20.10
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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: Scoring Alkylating Agent Exposure: Evaluation of the Cyclophosphamide Equivalent Dose Score
Planned research population (eligibility criteria): A. Outcome of Interest Relative risk of pregnancy B. Eligibility Cases 1. Male participant in the CCSS who completed the Baseline Questionnaire and for whom a Medical Record Abstract Form was completed by the participating institution 2. Any diagnosis 3. Testicular radiation dose < 10 cGy
Proposed specific aims: The specific aims of this concept are: 1. Determine the distribution of cumulative drug doses for each alkylating agent using cyclophosphamide equivalent drug doses among the males 15 years of age or older in the CCSS cohort; 2. Determine the distribution of total cumulative alkylating agent doses for each patient using cyclophosphamide equivalent doses for each agent; 3. Evaluate the utility of the cyclophosphamide equivalent dose (CED) score using cyclophosphamide dose groupings of 1000 mg/m2, 2000 mg/m2 and 3000 mg/m2 (i.e. CED = 0 for no alkylating agent exposure, CED = 1 for 1000 mg/m2 , 2 for 2000 mg/m2, 3 for 3000 mg/m2, 4 for 4000 mg/m2, etc. for 1000 mg/m2 equivalents; CED = 1 for 2000 mg/m2, 2 for 4000 mg/m2, 3 for 6000 mg/m2, 4 for 8000 mg/m2, etc. for 2000 mg/m2 equivalents; CED = 1 for 3000 mg/m2,2 for 6000 mg/m2, 3 for 9000 mg/m2 , 4 for 12000 mg/m2, etc. for 3000 mg/m2 equivalents). Each possible grouping for CED will be evaluated for its correlation with male fertility, using the methods published previously. We will examine the results to see if any of the three dose groupings provides clearer evidence of a fertility threshold and/or stronger evidence of a dose-response relationship than the currently employed AAD.

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: Secondary
Chronic Disease: Primary
Reproductive:
Neurologic:
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:
Second Malignancy:

Health Behaviors

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

Psychosocial

Insurance:
Marriage: Correlative Factors
Education: Correlative Factors
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: 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:
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.: Vikki G. Nolan, D. Sc. Department of Epidemiology and Cancer Control St. Jude Children's Research Hospital 262 Danny Thomas Place Mail Stop 735 Memphis, Tennessee 38105
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: