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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: Neuropsychological Outcomes in Long Term Survivors of Stem Cell Transplant for Childhood Cancer
Planned research population (eligibility criteria): Patients who have undergone stem cell transplant for childhood malignancy and completed the Neurocognitive Questionnaire (NCQ). Sibling controls of patients who have undergone stem cell transplant and completed the NCQ.
Proposed specific aims: 1. To analyze the neuropsychological outcomes of long-term survivors of stem cell transplant for childhood cancer. 2. To analyze factors predictive of neuropsychological outcome in patients who have undergone stem cell transplant for childhood cancer, specifically examining the effect of total body irradiation as a component of the pre-transplant preparative regimen.
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?: While this project does not necessarily require additional funding, we are applying for funding to cover possible needs such as additional statistical support through a Rally Foundation grant. We also have approximately $3000 of unrestricted funds to devote to this project already.

Does this project require contact of CCSS study subjects for . . .

Additional self-reported information: Yes
Biological Samples: No
Medical record data: Yes
If yes to any of the above, please briefly describe.: If possible, as part of the project we would

request that the patients and siblings in our cohort be contacted for an updated response to the NCQ, in order to obtain longer follow-up. Also, in a preliminary analysis of the feasibility of our study, 324 individuals in the CCSS self-reported a stem cell transplant, but the treating institution was not contacted to provide details of treatment. If possible, we would seek to update this information from the treating institution. However, even if neither of these updates are possible, based on the preliminary analysis, we still feel that there is sufficient available data for a meaningful analysis.

What CCSS Working Group(s) would likely be involved? (Check all that apply)

Second Malignancy:
Chronic Disease:
Psychology / Neuropsychology: Primary
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: Secondary
Second Malignancy: Secondary

Health Behaviors

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

Psychosocial

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

Medical conditions

Hearing/Vision/Speech:
Hormonal systems:
Heart and vascular:

Respiratory:
Digestive:
Surgical procedures:
Brain and nervous system: Secondary
Other:
If other, please specify:

Medications

Describe medications:

Pregnancy and offspring:
Family History:

Psychologic/Quality of Life

BSI-18: Primary
SF-36: Primary
CCSS-NCQ: Primary
PTS: Primary
PTG: Primary
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: 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: