**Section: Contact Information**

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**Section: Project Requirements and Description**

**Group: 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

Project Title: Neurocognitive Functioning in Survivors of Osteosarcoma

Planned research population (eligibility criteria):  
CCSS osteosarcoma survivors diagnosed at any age who have completed the NCQ and BSI instruments

Comparison groups: 1) sibling controls and 2) Ewing sarcoma survivors

Proposed specific aims:

Osteosarcoma patients are exposed to extremely high doses of methotrexate, a chemotherapy associated with significant neurocognitive impairment in ALL populations. Though osteosarcoma patients are treated with methotrexate at more than ten-fold higher cumulative doses than leukemia patients, they have not yet been studied for this important outcome.

1) To determine the prevalence and patterns of neurocognitive impairment in osteosarcoma survivors in the CCSS  
2) To compare the risk of neurocognitive impairment in osteosarcoma to sibling controls and to Ewing sarcoma patients, adjusted for age and gender. Ewing sarcoma patients undergo a similar duration of intense in-patient therapy as osteosarcoma patients, but do not receive methotrexate.

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?

The analysis as presented above would not require additional funding. However, the follow-up plan would be to do an ancillary study of more in-depth neurocognitive assessment with a subset of CCSS osteosarcoma cases in-person. For this project, ancillary funding would be sought from NCI and/or large foundations.

Group: 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.

Group: 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

Section: Outcomes or Correlative Factors

Late mortality
Second Malignancy

Group: Health Behaviors

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

Group: Psychosocial

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

Group: Medical Conditions

Hearing/Vision/Speech: Correlative Factors
Hormonal systems:
Heart and vascular:
Respiratory:
Digestive:
Surgical procedures:
Brain and nervous system:
Other:
If other, please specify:

**Group: Medications**
Describe medications:

**Group: Psychologic/Quality of Life**
BSI-18: *Correlative Factors*
SF-36:
CCSS-NCQ: **Primary**
PTS:
PTG:
Other:
If other, please specify:

**Group: Other**
Pregnancy and offspring:
Family history:
Chronic conditions (CTCAE v3):
Health status:

**Group: Demographic**
Age: *Correlative Factors*
Race: *Correlative Factors*
Sex: *Correlative Factors*
Other:
If other, please specify:

**Group: Cancer treatment**
Chemotherapy: *Correlative Factors*
Radiation therapy: *Correlative Factors*
Surgery: *Correlative Factors*

**Section: 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? :
If other, please explain :

**Section: Other General Comments**

Other General Comments :
I have had a preliminary discussion with Dr. Krull about this project and he is supportive.