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 imapairment 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.