

## **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.**