First Name: Kamnesh Last Name: Pradhan

Institution: Indiana University - Riley Hospital for Children

Address 1: 705 Riley Hospital Dr

Address 2: RI-4340 City: Indianapolis State/Province: IN Country: USA Zip: 46202

Phone: 317-944-8784

Alternate Phone: 317-440-7501 Email: pkamnesh@iu.edu

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: The impact of endocrine disorders on physical activity and functional outcomes in the childhood cancer survivor study cohort.

Planned research population (eligibility criteria): Entire CCSS cohort

Proposed specific aims: 1. Assess the impact of endocrine disorders on physical and functional outcomes within the CCSS cohort: After adjusting for co-variates including age, gender, race, socio-economic levels, type of cancer, treatment received, and other non-endocrine medical and psychological health conditions, survivors diagnosed with endocrine disorders at any time point per 1998 (baseline), 2000 (T-1), 2003 (T-2) and 2007 (T-3) self-reported surveys will be compared with survivors without endocrine disorders for physical activity (baseline, T-2, and T-3) and functional outcomes (Fatigue/Sleeping at T-1; SF-36 at T-2 and T-3, FACIT-F for males from 2009 Men's Health Survey). 2. Evaluate specific endocrine disorder with worse physical and functional outcomes within the CCSS cohort: Compare physical activity and functional outcomes after adjusting for co-variates as stated in aim-1, in survivors with thyroid dysfunction, panhypopitutarism (includes more than 1 pituitary hormone deficiency), sex-hormone deficiency, growth hormone deficiency, diabetes mellitus, and osteoporosis. 3. Study the impact of treatment for endocrine disorders on physical and functional outcomes within the CCSS cohort: Compare physical activity and functional outcomes after adjusting for co-variates as stated in aim-1, in survivors treated for thyroid dysfunction, panhypopitutarism (includes more than 1 pituitary hormone dysfunction), sex-hormone deficiency, growth hormone deficiency, diabetes mellitus, and osteoporosis to those survivors who were without treatment.

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:

Chronic Disease: Secondary

Psychology / Neuropsychology: Secondary

Genetics:

Cancer Control: Primary Epidemiology / Biostatistics:

To describe the anticipated scope of the study, please indicate the specific CCSS data to be included as <u>outcome</u> (primary or secondary) or <u>correlative factors</u>. (Check all that apply)

Late mortality:

Second Malignancy:

Health Behaviors

Tobacco: Alcohol:

Physical activity: Primary

Medical screening:

Other:

If other, please specify:

Psychosocial

Insurance: Correlative Factors Marriage: Correlative Factors Education: Correlative Factors Employment: Correlative Factors

Other:

If other, please specify:

Medical conditions

Hearing/Vision/Speech: Correlative Factors

Hormonal systems: Primary

Heart and vascular: Correlative Factors

Respiratory: Correlative Factors
Digestive: Correlative Factors

Surgical procedures: Correlative Factors Brain and nervous system: Correlative Factors

Other:

If other, please specify:

Medications

Describe medications:

Pregnancy and offspring:

Family History:

Psychologic/Quality of Life

BSI-18: Correlative Factors

SF-36: Primary

CCSS-NCQ: Correlative Factors

PTS: PTG:

Other: Primary

If other, please specify: FACIT-F, Fatigue/Sleep, WHQ

Chronic conditions (CTCAE v3): Correlative Factors

Health status: Correlative Factors

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: Correlative Factors

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: The aims have been discussed with Dr.Paul Nathan from cancer Control and Dr.Goli Mostoufi-Moab. Dr.nathan has asked me to move forward with the AOI.