

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 : **Risk of Adverse Cardiometabolic Outcomes in Childhood Cancer Survivors Treated with Total Body Irradiation: A Report from the Childhood Cancer Survivor Study (CCSS)**

Planned research population (eligibility criteria) :

Any patient in the original or expanded CCSS cohort treated with total body irradiation

Proposed specific aims :

Aim 1: Describe the prevalence of diabetes mellitus, hypertension, and dyslipidemia in CCSS survivors treated with total body irradiation

Aim 2: Determine the relative risk of developing: (1) diabetes mellitus, hypertension, or dyslipidemia in CCSS survivors treated with total body irradiation compared to: (a) survivors treated with chemotherapy and/or surgery alone and (b) the sibling comparison group.

Aim 3: Identify additional treatment, primary disease, and demographic-related characteristics that modify diabetes, hypertension, chronic condition risk in survivors treated with total body irradiation.

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? :

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 : **Primary**

Psychology / Neuropsychology :

Genetics :

Cancer Control :

Epidemiology / Biostatistics :

Section: Outcomes or Correlative Factors

Late mortality :

Second Malignancy :

Group: Health Behaviors

Tobacco : **Correlative Factors**

Alcohol : **Correlative Factors**

Physical activity : **Correlative Factors**

Medical screening :

Other :

If other, please specify :

Group: Psychosocial

Insurance : **Correlative Factors**

Marriage :

Education :

Employment :

Other :

If other, please specify :

Group: Medical Conditions

Hearing/Vision/Speech :

Hormonal systems : **Primary**

Heart and vascular : **Primary, Correlative Factors**

Respiratory :

Digestive :

Surgical procedures :

Brain and nervous system :

Other :

If other, please specify :

Group: Medications

Describe medications :

Medications for dyslipidemia

Medications for hypertension

Medications for diabetes (oral or insulin)

Group: Psychologic/Quality of Life

BSI-18 :

SF-36 :

CCSS-NCQ :

PTS :

PTG :

Other :

If other, please specify :

Group: Other

Pregnancy and offspring :

Family history :

Chronic conditions (CTCAE v3) : **Primary**

Health status :

Group: Demographic

Age : **Correlative Factors**

Race : **Correlative Factors**

Sex : **Correlative Factors**

Other :

If other, please specify : **Body mass index**

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 :

AOI discussed with Chuck Sklar, who will be a co-investigator