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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: Chronic Health Conditions in Survivors of Childhood Cancer Treated with Abdominal Radiation, a High-Risk CCSS Subpopulation

Planned research population (eligibility criteria): Any patient in the original CCSS cohort treated with abdominal radiation. Siblings and survivors who did not receive radiation therapy will be included as comparators.

Proposed specific aims: Aim 1: Describe the prevalence and cumulative incidence of chronic health conditions in CCSS survivors treated with abdominal radiation. Aim 1b. Assess longitudinal changes in chronic condition risk from the baseline questionnaire to subsequently completed follow-up questionnaires. Aim 2: Determine the relative risk of developing a chronic health condition in CCSS survivors treated with abdominal radiation 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 chronic condition risk in survivors treated with abdominal radiation.

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: Secondary Chronic Disease: Primary Psychology / Neuropsychology: Genetics: Cancer Control: 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: Primary

Health Behaviors

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

Psychosocial

Insurance: Correlative Factors Marriage: Education: Employment: Other: If other, please specify:

Medical conditions

Hearing/Vision/Speech: Hormonal systems: Primary Heart and vascular: Primary Respiratory: Digestive: Primary Surgical procedures: Brain and nervous system: Other: If other, please specify: Infectious complications Medications

Describe medications:

Pregnancy and offspring: Family History:

Psychologic/Quality of Life

BSI-18: SF-36: CCSS-NCQ: PTS: PTG: Other: If other, please specify:

Chronic conditions (CTCAE v3): Primary Health status:

Demographic

Age: Correlative Factors Race: Correlative Factors Sex: Correlative Factors Others: If others, please specify: BMI

Cancer treatment

Chemotherapy: Correlative Factors Radiation therapy: Correlative Factors Surgery: Correlative Factors

Anticipated sources of statistical support

CCSS Statistical Center: Local institutional statistician: Yes If local, please provide the name(s) and contact information of the statistician(s) to be involved.: Chaya Moskowitz, PhD <u>moskowc1@mskcc.org</u> 646-735-8117 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: