CCSS Application of Intent Submission

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Project Requirements and Description
Requirements to submit AOI:

	Yes	No
A comprehensive review of previously published data has been completed	✔	-
The specific aims are clear and focused	✔	-
The investigator has appropriate experience and expertise to develop the concept proposal; if not, has identified a mentor or senior co-investigator.	✔	-
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	✔	-

Project Title:
Impact of Radiotherapy Breast Dose and Dose-Volume Metrics on Subsequent Breast Cancers in Female Childhood Cancer Survivors

Planned research population:
All female survivors in CCSS

Proposed specific aims:
1. Develop and integrate a representative pediatric/adolescent breast model into an age-scalable computational phantom used for dose reconstruction.
2. Estimate breast and nipple doses for all females in CCSS that received RT (nipple doses will be calculated for females < age 11 years at RT and breast doses will be calculated for females ≥ 11 years at RT).
3. Establish dose-response relationships correlating novel radiation factors (i.e., dose and dose-volume metrics) with subsequent breast malignancies. We aim to define breast dose and dose-volume metrics above which RT-related risk increases.

These data could guide pre-treatment planning decisions by defining breast dose and dose-volume constraints for future pediatric and adolescent RT patients

Will the project require non-CCSS funding to complete?: Yes
If yes, what would be the anticipated source(s) and timeline(s) for securing funding?:
A medical physics doctorate student, Taylor Meyers in Rebecca Howell's lab will be funded through

graduate school funds. Additionally, Rebecca Howell will apply for a trainee diversity supplement for R01CA261750 (MPI: Howell, Yasui, Mulrooney).

Does this project require contact of CCSS study subjects for:

	Yes	No
Additional self-reported information	-	✔
Biological samples	-	✔
Medical record data	-	✔

If yes to any of the above, please briefly describe:

What CCSS Working Group(s) would likely be involved?:

	Primary	Secondary
Second Malignancy	✔	-
Chronic Disease	-	-
Psychology/Neuropsychology	-	-
Genetics	-	-
Cancer Control	-	-
Epidemiology/Biostatistics	-	✔

Outcomes or Correlative Factors

Late Mortality and Second Malignancy:

	Primary	Secondary	Correlative Factors
Late Mortality	-	✔	-
Second Malignancy	✔	-	-

Health Behaviors:

	Primary	Secondary	Correlative Factors
Tobacco	-	-	✔
Alcohol	-	-	✔
Physical Activity	-	-	-
Medical Screening	-	-	✔
Other	-	-	-

If other, please specify:

Psychosocial: None selected

If other, please specify:

Medical Conditions: None Selected
If other, please specify:

Medications
Describe medications:

Psychologic/Quality of Life: None selected

If other, please specify:

Other:

	Primary	Secondary	Correlative Factors
Pregnancy and Offspring	-	-	-
Family History	-	-	✔
Chronic Conditions (CTCAE v3)	-	-	-
Health Status	-	-	-

Demographic:

	Primary	Secondary	Correlative Factors
Age	-	-	✔
Race	-	-	✔
Sex	-	-	✔
Other	-	-	-

If other, please specify:

Cancer Treatment:

	Correlative Factors
Chemotherapy	✔
Radiation Therapy	✔
Surgery	✔

Anticipated Sources of Statistical Support:

	Yes	No
CCSS Statistical Center	✔	-
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:

Other General Comments
General comments: Co-PIs: Rebecca Howell and James Bates (will mentor Taylor Meyers)