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: Association of Radiotherapy Pelvic Dose and Female Sexual Dysfunction Risk in Long-Term Survivors of Childhood Cancer
Planned research population (eligibility criteria): All patients from the original cohort who received treatment for a primary childhood malignancy of any type for whom pelvic dose reconstructions are available as well as those who received no pelvic radiotherapy. All patients must have completed the Women’s Emotional Well Being Intimacy Survey (administered 2001-2003, N=2200 of 3520). The sibling population may be used as well to generate absolute excess risk estimates (N=520 of 880).

Proposed specific aims:
1) Describe the effect of cancer treatment on sexual function and overall sexual outcomes in long term childhood cancer survivors, including chemotherapy, surgery and either a) regional pelvic dose or b) organ dose.

Hypothesis: Treatment-related factors such as chemotherapy type (e.g. platinum, taxane, vinca alkaloid), pelvic surgery, and higher-dose pelvic radiotherapy are associated with worse sexual function and overall sexual outcomes.

2) Describe the dose-response effect of radiotherapy on sexual function and overall sexual outcomes for a) regional pelvic dose or b) organ dose.

Hypothesis: Increasing average dose to the pelvis and pelvic organs is associated with worse erectile function, vaginal function and overall sexual outcomes.

Outcome measures: For each outcome, standardized total average toxicity (STAT) scores
will be determined for each patient. CTCAE >= Grade 2 sexual toxicities will be incorporated into STAT scores, if available. Sensitivity analyses will be performed for those who are sexually active.

Primary Outcome: Sexual Function
Erectile tissue function:
Orgasm: D.12, D.13.e
Arousal: D.13.a/b/d, D.6

Vaginal tissue function:
Vaginal mucosa: D.13.f/g/h/i
Arousal: D.13.a/b/d, D.6

Sexual function (composite):
Orgasm, arousal and vaginal mucosa items

Secondary Outcome: Overall Sexual Outcomes

Overall sexual outcomes (composite):
Frequency (D.7, D.11)
Pleasure (D.10)
Satisfaction (D.17, D.18, D.19, D.23)

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 : Secondary
Genetics :
Cancer Control :
Epidemiology / Biostatistics :

**Section: Outcomes or Correlative Factors**
Late mortality : Correlative Factors
Second Malignancy :

**Group: Health Behaviors**
Tobacco :
Alcohol :
Physical activity :
Medical screening :
Other:
If other, please specify:

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

**Group: Medical Conditions**
Hearing/Vision/Speech:
Hormonal systems: Correlative Factors
Heart and vascular: Correlative Factors
Respiratory:
Digestive:
Surgical procedures: Correlative Factors
Brain and nervous system:
Other:
If other, please specify:

**Group: Medications**
Describe medications:
hormonal/anti-hormonal therapy, antidepressants

**Group: Psychologic/Quality of Life**
BSI-18:
SF-36:
CCSS-NCQ:
PTS:
PTG:
Other: Primary
If other, please specify: Women’s Emotional Well Being Intimacy Survey

**Group: Other**
Pregnancy and offspring:
Family history:
Chronic conditions (CTCAE v3): Primary
Health status: Correlative Factors

**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:
Thank you for your consideration.
I agree to share this information with St. Jude: Yes