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**