Received: 11.5.2010
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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

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Project Title: Infertility and the use of fertility treatments in female survivors of childhood cancer.
Planned research population (eligibility criteria): Female survivors who completed the baseline questionnaire at > 20 years of age. Female siblings who completed the baseline questionnaire at > 20 years of age. Female survivors and siblings who completed the pregnancy questionnaire.
Proposed specific aims: 1.To describe the prevalence of infertility in female cancer survivors (infertility will be defined by internationally accepted definition of 1 year of pregnancy attempts without success.) 2.To calculate the relative risk of infertility among female survivors compared to siblings. 3.To identify treatment, disease, and demographic characteristics that predict the risk of infertility. 4.To describe the use of infertility treatment including in-vitro fertilization among cancer survivors and compare this utilization to siblings.
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:
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 outcome (primary or secondary) or correlative factors. (Check all that apply)

Late mortality:
Second Malignancy:

Health Behaviors

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

Psychosocial

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

Medical conditions

Hearing/Vision/Speech:
Hormonal systems:
Heart and vascular:
Respiratory:
Digestive:
Surgical procedures:
Brain and nervous system:

Other:
If other, please specify:

Medications

Describe medications: Medication to try and help you get pregnant as listed in baseline questionM.8

Pregnancy and offspring: Primary
Family History:

Psychologic/Quality of Life

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

Chronic conditions (CTCAE v3):
Health status:

Demographic

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

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.: Julie Najita Department of Biostatistics and Computational Biology Dana-Farber Cancer Institute CLS 11007 44 Binney Street Boston, MA 02115 Email: jnajita@jimmy.harvard.edu Phone: 617.582.8377 Fax: 617.632.2444
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: Dr. Lisa Diller will be mentoring me as senior author on this study.