Section: Contact Information

First Name: Danielle Novetsky
Last Name: Friedman
Institution: Memorial Sloan Kettering Cancer Center
Address 1: 1275 York Avenue
City: New York
State/Province/Region: NY
Country: US
Zip/Postal Code: 10065
Phone Number: 212-639-7376
Alternate Phone Number:
Email Address: friedmad@mskcc.org

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: Risk of Adverse Cardiometabolic Outcomes in Childhood Cancer Survivors Treated with Total Body Irradiation: A Report from the Childhood Cancer Survivor Study (CCSS)
Planned research population (eligibility criteria):
Any patient in the original or expanded CCSS cohort treated with total body irradiation
Proposed specific aims:
Aim 1: Describe the prevalence of diabetes mellitus, hypertension, and dyslipidemia in CCSS survivors treated with total body irradiation

Aim 2: Determine the relative risk of developing: (1) diabetes mellitus, hypertension, or dyslipidemia in CCSS survivors treated with total body irradiation 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 diabetes, hypertension, chronic condition risk in survivors treated with total body irradiation.
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: 
- Genetics: 
- Cancer Control: 
- Epidemiology / Biostatistics: 

**Section: Outcomes or Correlative Factors**

- Late mortality: 
- Second Malignancy: 

**Group: Health Behaviors**

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

**Group: Psychosocial**

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

**Group: Medical Conditions**

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

**Group: Medications**
Describe medications:
Medications for dyslipidemia
Medications for hypertension
Medications for diabetes (oral or insulin)

**Group: Psychologic/Quality of Life**
BSI-18:
SF-36:
CCSS-NCQ:
PTS:
PTG:
Other:
If other, please specify:

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

**Group: Demographic**
Age: **Correlative Factors**
Race: **Correlative Factors**
Sex: **Correlative Factors**
Other:
If other, please specify: **Body mass index**

**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:
AOI discussed with Chuck Sklar, who will be a co-investigator