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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

Project Title: Diet and insulin resistance in survivors of childhood leukemia
Planned research population (eligibility criteria): We propose an investigation of diet, activity, eating behaviors, and insulin resistance in a random sample of 230 ALL survivors and 115 non-cancer controls, stratified by gender and, among ALL survivors, history of treatment with cranial radiotherapy.
Proposed specific aims: Specific Aim 1: Compare intake of dietary fat, added sugar, and whole grain intake among ALL survivors to non-cancer participants 1a. Estimate saturated fat, added sugar, and other dietary variables 1b. Determine if ALL survivors have a higher saturated fat or added sugar, or lower whole grain intake, compared to non-cancer subjects. Hypothesis 1: ALL survivors will have higher saturated fat and added sugar intake and lower whole grain intake compared to non-cancer subjects from the CCSS. Specific Aim 2: Identify dietary features that contribute to insulin resistance among ALL survivors. 2a. Estimate insulin sensitivity using fasting insulin and glucose levels. 2b. Use multivariate models to determine the strength of the relationship, if any, between dietary factors and insulin sensitivity. Hypothesis 2a: Higher saturated fat or added sugar intake correlates with worsened insulin resistance. Hypothesis 2b: Lower whole grain intake correlates with worsened insulin resistance. Specific Aim 3: Measure other food-related behaviors, such as eating for comfort and nighttime eating. Hypothesis 3: ALL survivors are more likely to have maladaptive behaviors, such as eating for comfort, than non-cancer controls.
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?:

Ongoing application for funds from the American Institute for Cancer Research, plus existing support from the Lauri Strauss Leukemia Founding.

Does this project require contact of CCSS study subjects for . . .

Additional self-reported information: Yes

Biological Samples: No

Medical record data: No

If yes to any of the above, please briefly describe.: The study will include a diet, dietary behaviors, and physical activity questionnaire.

What CCSS Working Group(s) would likely be involved? (Check all that apply)

Second Malignancy:

Chronic Disease: Secondary

Psychology / Neuropsychology:

Genetics:

Cancer Control: Primary

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:

Alcohol:

Physical activity: Secondary, Correlative Factors

Medical screening:

Other:

If other, please specify:

Psychosocial

Insurance:

Marriage:

Education:

Employment:

Other:

If other, please specify:

Medical conditions

Hearing/Vision/Speech:
Hormonal systems: Primary
Heart and vascular:
Respiratory:
Digestive:
Surgical procedures:
Brain and nervous system:
Other:
If other, please specify: Obesity and insulin resistance

Medications

Describe medications:

Pregnancy and offspring:
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:

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.: Dr. Chaya Moskowitz, PhD in the Department of Epidemiology and Biostatistics at MSKCC.

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: