

## **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 : **Analysis of Non Alcoholic Fatty Liver Disease (NAFLD) as a Modifier of Cardiometabolic Disease Risk in the Cancer Survivor**

Planned research population (eligibility criteria) :

**All CCSS survivors and siblings in the original cohort who completed the FU4 (2007) CCSS Survey and survivors in the expansion cohort who completed the Baseline CCSS Survey (and siblings in the expansion cohort when available).**

Proposed specific aims :

**Background: Worldwide prevalence of non-alcoholic fatty liver disease (NAFLD) is reported to be 20-30% in the general population and reaches 57-74% in obese patients. Prevalence of NAFLD in the childhood cancer survivor is less clear. Studies report abnormal liver functions tests in 7.9-52.8% of patients but the etiology is unknown. Additionally studies show that transaminases (liver enzymes) can be normal in up to 79% of patients with imaging-confirmed hepatic steatosis (fatty liver).**

**NAFLD is associated with a two-fold increased risk of cardiac-specific mortality in the general population. It is unclear how NALFD (fatty liver) modifies cardiovascular disease risk among childhood cancer survivors. Further, how NALFD influences the risk of other traditional risk factors, such as diabetes and dyslipidemia, in this population is not well studied. Thus, our aims are to:**

1. Estimate the prevalence of self-reported fatty liver in CCSS survivors and estimating the odds of having a fatty liver in comparison with non-cancer individuals (siblings);
2. Determine if there is an association between fatty liver and cardiometabolic disease (including, diabetes, dyslipidemia, hypertension, obesity and coronary artery disease);
3. Identify treatment exposures and other factors associated with fatty liver;
4. Compare all-cause and cardiac-specific mortality in survivors with and without fatty liver in adjusted models.

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 : **Secondary**

**Section: Outcomes or Correlative Factors**

Late mortality : **Primary**

Second Malignancy :

**Group: Health Behaviors**

Tobacco :

Alcohol :

Physical activity :

Medical screening :

Other :

If other, please specify :

**Group: Psychosocial**

Insurance :

Marriage :

Education :

Employment :

Other :

If other, please specify :

**Group: Medical Conditions**

Hearing/Vision/Speech :

Hormonal systems : **Correlative Factors**

Heart and vascular : **Correlative Factors**

Respiratory :

Digestive : **Primary**

Surgical procedures :

Brain and nervous system :

Other :

If other, please specify :

**Group: Medications**

Describe medications :

**All medications for diabetes, hypertension and dyslipidemia**

**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) :

Health status :

**Group: Demographic**

Age :

Race :

Sex :

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 :