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 : **Improving assessment and treatment of cardiovascular risk factors among childhood cancer survivors**
Planned research population (eligibility criteria) :
The proposal plans to target, using recently developed cardiovascular (CV) risk predictors, a random sample of living high-risk (for heart failure and/or ischemic heart disease) and low-risk participants eligible from both the original and the expansion cohorts. Given the possibility of "contamination" by prior and ongoing CCSS intervention studies, sampling will occur among previously unselected patients if possible. To minimize issues with consent, home-visit scheduling, and return of clinically actionable results, the target population will be restricted to age 18+ years.
Proposed specific aims :
PRIMARY AIM 1. Determine the magnitude of underdiagnosis and undertreatment of conventional CV risk factors (e.g. hypertension, dyslipidemia, and diabetes) among a stratified subset of Childhood Cancer Survivor Study (CCSS) participants free of serious CV disease.

PRIMARY AIM 2. Determine change in rates of underdiagnosis and undertreatment after introduction of a randomized survivorship care plan (SCP) with individualized CV risk assessments supplemented by a remote counseling

intervention.

SECONDARY AIM. Determine whether the intervention also positively influences lifestyle factors thought to be important in influencing overall CV risk (e.g. smoking, physical inactivity, poor diet) among childhood cancer survivors.

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? : **Planned submission as R01 grant for February 2015**

Group: Does this project require contact of CCSS study subjects for:

Additional self-reported information : **Yes**

Biological samples : **Yes**

Medical record data : **Yes**

If yes to any of the above, please briefly describe. :

Using the experience gained from the CCSS EMSI home visit pilot study, participants will be asked to complete a short questionnaire updating select medical outcomes and healthcare use, undergo basic anthropometry and a blood draw via EMSI. As part of the proposed study, participants will also be asked to provide consent to obtain recent clinic records from their primary care provider(s) as a way of further validating certain outcomes over time.

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

Second Malignancy :

Chronic Disease : **Primary**

Psychology / Neuropsychology :

Genetics :

Cancer Control : **Secondary**

Epidemiology / Biostatistics :

Section: Outcomes or Correlative Factors

Late mortality :

Second Malignancy :

Group: Health Behaviors

Tobacco : **Secondary**

Alcohol : **Secondary**

Physical activity : **Secondary**

Medical screening : **Primary**

Other :

If other, please specify :

Group: Psychosocial

Insurance : **Correlative Factors**

Marriage : **Correlative Factors**

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

Group: Medical Conditions

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

Group: Medications

Describe medications :
Updated medication lists will be requested as part of the study.

Group: Psychologic/Quality of Life

BSI-18 :
SF-36 : **Correlative Factors**
CCSS-NCQ :
PTS :
PTG :
Other : **Correlative Factors**
If other, please specify : **We will explore incorporating some measure of general health (possibly SF36 or shorter version), and also the PROMIS short form measures for anxiety and depression, as well as the Multidimensional Health Locus of Control Scale (in order to help classify participants with regards to their attitudes towards healthcare screening).**

Group: Other

Pregnancy and offspring :
Family history : **Correlative Factors**
Chronic conditions (CTCAE v3) :
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. :

Yutaka Yasui's group will provide statistical support for the proposed study.

Will this project utilize CCSS biologic samples? : **No**

If yes, which of the following? :

If other, please explain : **The study will propose to collect new DNA samples.**

Section: Other General Comments

Other General Comments :

Draft proposal has been reviewed by Drs. Kevin Oeffinger, Chuck Sklar, and Yutaka Yasui.