

### **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 : **Development and Validation of a Prediction Model for End-stage Renal Disease in Childhood Cancer Survivors**

Planned research population (eligibility criteria) :

**All patients from the CCSS baseline and expanded cohorts.**

Proposed specific aims :

- 1. Identify the demographic, disease, and treatment-specific characteristics that predict the risk of dialysis and end-stage renal disease (ESRD) per the chronic disease matrix CTCAE grades 4 and 5 classifications.**
- 2. Develop a prediction algorithm utilizing demographic factors and treatment characteristics to predict individual risk of serious renal outcomes.**
- 3. Validate the prediction algorithm using the National Wilms Tumor Study Group and St. Jude LIFE study.**

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 : **Correlative Factors**  
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 :  
Surgical procedures :  
Brain and nervous system :  
Other : **Correlative Factors**

If other, please specify : **Would consider examining hypertension and diabetes as potential predictors.**

**Group: Medications**

Describe medications :

**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 : **Correlative Factors**

Chronic conditions (CTCAE v3) : **Primary**

Health status :

**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. :

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 :

**This project was previously discussed with Eric Chow and Wendy Leisenring (CCSS and NWTs). Yutaka Yasui and Melissa Hudson are also aware from St. Jude LIFE study.**

I agree to share this information with St. Jude : **Yes**