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
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**