

## **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 : **Individual prediction of premature ovarian insufficiency (POI) in childhood cancer survivors**

Planned research population (eligibility criteria) :

**Female childhood cancer survivors**

Proposed specific aims :

- 1. Quantify the complex relationship between age at diagnosis, cancer type and cancer treatment and the risk of POI using stratified analysis and survival trees. We will utilize standard and modern statistical models to model the data;**
- 2. Select the best risk prediction model and validate its properties on external cohorts using time-specific and comprehensive performance measures, such as AUC(t), AP(t), Brier score, calibration plots, and integrated Brier score;**
- 3. With input from knowledge users and KT experts, develop simplified risk scores for clinical use;**
- 4. Create a web-based risk prediction calculator and mobile app for knowledge dissemination.**

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? : **Canadian Institutes of Health Research. Funding will be applied for in March 2016. Funding decision is made in July 2016.**

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

Additional self-reported information : **No**

Biological samples : **No**

Medical record data : **Yes**

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

**We request comprehensive cancer treatment information that includes treatment modality, cumulative radiation dose and targeted body parts, specific chemotherapy agents and dosage, survivor cyclophosphamide equivalent dose exposure (CED), and history of treatment with stem cell transplantation.**

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

Second Malignancy :

Chronic Disease :

Psychology / Neuropsychology :

Genetics :

Cancer Control :

Epidemiology / Biostatistics : **Primary**

**Section: Outcomes or Correlative Factors**

Late mortality :

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 : **Primary**

Heart and vascular :

Respiratory :

Digestive :

Surgical procedures :

Brain and nervous system :

Other : **Primary**

If other, please specify : **premature ovarian insufficiency -- cessation of menses before age 40.**

### ***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 :

Chronic conditions (CTCAE v3) :

Health status :

### ***Group: Demographic***

Age : **Correlative Factors**

Race : **Correlative Factors**

Sex :

Other : **Primary**

If other, please specify : **menarche status at diagnosis**

### ***Group: Cancer treatment***

Chemotherapy : **Correlative Factors**

Radiation therapy : **Correlative Factors**

Surgery :

## **Section: 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. :

**Yan Yuan & Yutaka Yasui**

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 :