

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 : **Thirty-Five Year Follow-Up of Childhood Wilms Tumor: Impact of Treatment Era on Long-Term Health Outcomes**

Planned research population (eligibility criteria) :

All children diagnosed with Wilms tumor between 1970 and 1999 surviving \geq 5 years after their diagnosis, and their siblings (control group)

Proposed specific aims :

Specific Aim 1: To determine the cumulative incidence of late mortality in 1) the complete cohort and 2) stratified by treatment era (1970-1979, 1980-1989, and 1990-1999).

Specific Aim 2: To determine the cumulative incidence of secondary malignant neoplasms in 1) the complete cohort and 2) stratified by treatment era (1970-1979, 1980-1989, and 1990-1999).

Specific Aim 3: To determine the cumulative incidence of chronic health conditions in 1) the complete cohort and 2) stratified by treatment era (1970-1979, 1980-1989, and 1990-1999).

Specific Aim 4: To determine the influence of treatments rendered (chemotherapy, radiotherapy, surgery) on development of chronic health

conditions, secondary malignant neoplasms, and late mortality.

Specific Aim 5: To evaluate change in treatment over time (stratified by stage if available) and its effect on development of chronic health conditions, secondary malignant neoplasms, and late mortality.

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 : **Secondary**

Chronic Disease : **Primary**

Psychology / Neuropsychology : **Secondary**

Genetics :

Cancer Control :

Epidemiology / Biostatistics : **Secondary**

Section: Outcomes or Correlative Factors

Late mortality : **Primary**

Second Malignancy : **Primary**

Group: Health Behaviors

Tobacco : **Correlative Factors**

Alcohol : **Correlative Factors**

Physical activity : **Primary**

Medical screening : **Correlative Factors**

Other :

If other, please specify :

Group: Psychosocial

Insurance :

Marriage :

Education : **Primary**

Employment : **Primary**

Other :

If other, please specify :

Group: Medical Conditions

Hearing/Vision/Speech :

Hormonal systems :

Heart and vascular : **Primary**

Respiratory :

Digestive :

Surgical procedures : **Correlative Factors**

Brain and nervous system :

Other : **Primary**

If other, please specify : **Renal failurue / Dialysis / Renal transplant**

Group: Medications

Describe medications :

Group: Psychologic/Quality of Life

BSI-18 : **Primary**

SF-36 : **Primary**

CCSS-NCQ :

PTS :

PTG :

Other :

If other, please specify :

Group: Other

Pregnancy and offspring :

Family history :

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

Health status : **Primary**

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 :

Ongoing discussions will be had with active participants in the NWTS and COG renal tumors study group to make sure the aims are in accordance with the most current concerns with respect to late effects in Wilms tumor survivors, particularly as they may pertain to dose reduction strategies and other considerations for future COG studies.