

APPLICATION OF INTENT

To conduct research in the Childhood Cancer Survivor Study (CCSS)

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Project Title

STUDY TITLE **Genitourinary complications in survivors of childhood cancer**

Planned research population (eligibility criteria):

Inclusion criteria:

- 1) CCSS survivors-all disease
- 2) Sibling cohort

Proposed specific aims:

Aim 1. Describe late genitourinary (GU) effects within the Childhood Cancer Survivor Study (CCSS) cohort.

- 1a) Calculate incidence rates of GU outcomes
- 1b) Compare the risk of developing adverse GU outcomes among survivors relative to sibling controls
- 1c) Assess the disease, treatment and demographic factors for adverse GU outcomes.

Return completed form to: Greg Armstrong, MD, MSCE
St. Jude Children's Research Hospital
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Memphis, TN 38105-2794
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Will this project require non-CCSS funding to complete? Yes No

If yes What would be the anticipated source(s) and timeline(s) for securing the funding?

Does this project require contact of CCSS study subjects for:

	Yes	No
Additional self-reported information	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Biological samples	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Medical record data	<input type="checkbox"/>	<input checked="" type="checkbox"/>

If yes, briefly describe

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

	Primary	Secondary
Second Malignancy	<input type="checkbox"/>	<input type="checkbox"/>
Chronic Disease	<input type="checkbox"/>	<input type="checkbox"/>
Reproductive	<input type="checkbox"/>	<input type="checkbox"/>
Neurologic	<input type="checkbox"/>	<input type="checkbox"/>
Psychology/Neuropsychology	<input type="checkbox"/>	<input type="checkbox"/>
Genetics	<input type="checkbox"/>	<input type="checkbox"/>
Cancer Control	<input type="checkbox"/>	<input type="checkbox"/>
Epidemiology/Biostatistics	<input type="checkbox"/>	<input type="checkbox"/>

To describe the anticipated scope of the study, please indicate the specific CCSS data to be included as outcome or correlative factors. **(Check all that apply)**

	Outcome(s)		Correlative Factors
	Primary	Secondary	
Late mortality	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Second malignancy	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Health behaviors			
Tobacco	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Alcohol	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Physical activity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Medical screening	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If other, please specify:			
Psychosocial			
Insurance	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Marriage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Education	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Employment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If other, please specify:			
Medical conditions			
Hearing/Vision/Speech	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Hormonal systems	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Heart and vascular	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Respiratory	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Digestive	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Surgical procedures	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Brain and nervous system	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If other, please specify:			
Genitourinary			

	Outcome(s)		Correlative Factors
	Primary	Secondary	
Medications	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Describe medications:			
Pregnancy and offspring	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Family history	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Psychologic/Quality of life			
BSI-18	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SF-36	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
CCSS-NCQ	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PTS	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PTG	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If other, please specify:			
Chronic conditions (CTCAE v3)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Health status	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Demographic			
Age	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Race	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Sex	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
Others	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If others, please describe:			
Cancer treatment			
Chemotherapy			<input checked="" type="checkbox"/>
Radiation therapy			<input checked="" type="checkbox"/>
Surgery			<input checked="" type="checkbox"/>

Anticipated sources of statistical support:

CCSS Statistical Center

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?

Yes

No

If yes, which of the following:

Buccal cell DNA

Peripheral blood

Lymphoblastoid cell lines

Second malignancy pathology samples

Other requiring collection of samples - Please explain:

Comments: