

APPLICATION OF INTENT

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

Date May 1, 2008

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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
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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: