

APPLICATION OF INTENT

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

Date 4/19/08

Investigator Greg Armstrong Institution St. Jude Children's Research Hospital

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Project Title

Analysis of Late Mortality by Treatment Era: Brief Report

Planned research population (eligibility criteria):

ALL Eligible cases from Original Cohort (dx 1970-1986)

Proposed specific aims:

- 1. To compare Cumulative Mortality (all cause, Recurrence only, and non-recurrence, non-external causes) across four treatment eras (1970-73, 1974-77, 1978-81, 1982-86).**
- 2. To report Standardized Mortality Ratios (all cause & cause-specific) by treatment era.**

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Last modified:
04/21/2008 01:14:46 PM

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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 checked="" 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 checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Second malignancy	<input type="checkbox"/>	<input type="checkbox"/>	<input 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 type="checkbox"/>
Marriage	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Education	<input type="checkbox"/>	<input type="checkbox"/>	<input 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 type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
If other, please specify:			

	Outcome(s)		Correlative Factors
	Primary	Secondary	
Medications	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Describe medications:			
Pregnancy and offspring			
Pregnancy and offspring	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Family history			
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)			
Chronic conditions (CTCAE v3)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Health status			
Health status	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Demographic			
Age	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Race	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Sex	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Others	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>
If others, please describe: Treatment era			
Cancer treatment			
Chemotherapy			<input type="checkbox"/>
Radiation therapy			<input type="checkbox"/>
Surgery			<input 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: