Contact Information

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Project Requirements and Description

Requirements to submit AOI (all answers must be "yes" to proceed)

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 Estimation of and Identification of Significant Risk Factors Related to Late Effects of Childhood Cancer Treatments

Planned research population (eligibility criteria)

On pregnancy and hospitalization of survivors

Proposed Specific Aims

Aim 1: Develop efficient and proper statistical tools for the analysis of mixed event history data or the combination of recurrent event data, panel count data and panel binary data and then apply them to the CCSS to evaluate the cumulative frequency of various adverse events and associated risk factors. We will also compare the analysis results with previous results or reports.
Aim 2: Generalize the methods developed in aim 1 to allow for informative observation processes and reanalyze the CCSS to evaluate the cumulative frequency of various adverse events and associated risk

factors as well as comparing the analysis results with previous results or reports.
Aim 3: Generalize the methods developed in aim 1 to allow for both terminal event and informative observation processes and reanalyze the CCSS to evaluate the cumulative frequency of various adverse events and associated risk factors as well as comparing the analysis results with previous results or reports.

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?

Does this project require contact of CCSS study subjects for:

Biological samples	No

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

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

Chronic Disease	Secondary
Genetics	
Epidemiology/Biostatistics	Primary

Outcomes or Correlative Factors

Late Mortality	Primary
Second Malignancy	Secondary

Health Behaviors

Tobacco	
Alcohol	
Physical Activity	
Medical Screening	
Other	

If other, please specify

Psychosocial

Insurance	
Marriage	
Education	
Employment	
Other	

If other, please specify

Medical Conditions

Hearing/Vision/Speech	
Hormonal Systems	
Heart and Vascular	
Respiratory	
Digestive	
Surgical Procedures	Primary
Brain and Nervous System	
Other	Primary

If other, please specify

hospitalizations

Medications

Describe medications

Psychologic/Quality of Life

SF-36	
PTS	
Other	

If other, please specify

Other

Family History	Secondary
Health Status	

Demographic

Race	Secondary
Other	Secondary

If other, please specify

Cancer Treatment

Radiation Therapy	

Anticipated Sources of Statistical Support

CCSS Statistical Center	No
Local Institutional Statistician	Yes

If local, please provide the name(s) and contact information of the statistician(s) to be involved.
(Tony) Jianguo Sun

Will this project utilize CCSS biologic samples? No

If yes, which of the following?

If other, please explain

Other General Comments

Agree I agree to share this information with St. Jude

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