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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 Pilot Validation of Automated Chemotherapy Ascertainment in CCSS

Planned research population (eligibility criteria)

CCSS subjects at Children's Healthcare of Atlanta, Children's Hospital of Philadelphia, Seattle Children's Hospital, St. Jude Children's Research Hospital, and Texas Children's Hospital.

Proposed specific aims

Validate automated binary (yes/no) and cumulative chemotherapy exposure ascertainment in five pediatric institutions participating in CCSS.

Will the project require non-CCSS funding to complete?

Yes

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

Funding is secured.

Does this project require contact of CCSS study subjects for:

Additional self-reported information	No
Biological samples	No
Medical record data	Yes

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

Autoextracted EHR data

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

	Primary	Secondary
Second Malignancy		
Chronic Disease		
Psychology/Neuropsychology		
Genetics		
Cancer Control		✓
Epidemiology/Biostatistics	✓	

Outcomes or Correlative Factors

	Primary	Secondary	Correlative Factors
Late Mortality			
Second Malignancy			

Health Behaviors

	Primary	Secondary	Correlative Factors
Tobacco			
	Primary	Secondary	Correlative Factors
Alcohol			
Physical Activity			
Medical Screening			
Other			

If other, please specify

Psychosocial

	Primary	Secondary	Correlative Factors
Insurance			
Marriage			
Education			
Employment			
Other			

If other, please specify

Medical Conditions

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

If other, please specify

Medications

Describe medications

Chemotherapy medications on MRAF

Psychologic/Quality of Life

	Primary	Secondary	Correlative Factors
BSI-18			
SF-36			
CCSS-NCQ			
PTS			
PTG			
Other			

If other, please specify

Other

	Primary	Secondary	Correlative Factors
Pregnancy and Offspring			
Family History			
Chronic Conditions (CTCAE v3)			
Health Status			

Demographic

	Primary	Secondary	Correlative Factors
Age			
Race			
Sex			
Other			

If other, please specify

Cancer Treatment

	Correlative Factors
Chemotherapy	✓

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.

Will this project utilize CCSS biologic samples?

No

If yes, which of the following?

If other, please explain

Other General Comments

Submitting at Vikki's request to support our upcoming publication.

Agree

I agree to share this information with St. Jude

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