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Project Requirements and Description

Requirements to submit AOI

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	Exploring Epidemiologic Aspects of Rare Subsequent Tumors of the Gastro-intestinal Tract
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Planned research population (eligibility criteria)

Study population:
CCSS I and II full cohort

Included outcomes:

Subsequent tumors of the gastro-intestinal tract (topography-based), except colorectal tumors, including malignant and non-malignant tumors

Proposed specific aims

Describe the cumulative incidence and excess risk of specific rare gastro-intestinal (GI-) tract tumors overall and stratified by treatment era, attained age, sex, childhood cancer type, treatment group

Assess the contribution of demographic, cancer-treatment, and classic risk factors for each of the GI tumor types, including potential interactions, including available cohort-based chemotherapy and other radiation exposure

Describe mortality from rare subsequent GI tract tumors
Describe mortality among patients affected by rare GI tract tumors

Characterize patients affected by multiple subsequent tumors including a GI tract tumor

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:

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

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

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			✓
Alcohol			✓
Physical Activity			✓
Medical Screening			✓
Other			✓

If other, please specify

Recreational drug use, nutritional habits

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			

	Primary	Secondary	Correlative Factors
Digestive			✓
Surgical Procedures			✓
Brain and Nervous System			
Other			✓

If other, please specify

other medical conditions that have potential to affect (upward or downward) the risk of GI tract tumors (to be defined in the full proposal)

Medications

Describe medications

heavy NSAID use (as risk factor for stomach disorders); specific, non-general medications used for symptom relief or treatment of GI tract disorders (as indicator of GI tract disorders); viral diseases (risk factor for liver cancer, e.g. hepatitis)

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

diagnosis/treatment era

Cancer Treatment

	Correlative Factors
Chemotherapy	✓
Radiation Therapy	✓
Surgery	✓

Anticipated Sources of Statistical Support

CCSS Statistical Center	Yes
Local Institutional Statistician	No

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

Core Team

Shared PIs: Cécile Ronckers, Lucy Turcotte

Shared Lead: Raoul Reulen, Cindy Im

Statistical analysis: Cindy Im

Methodological and SN expertise Turcotte/Reulen/Ronckers

Close collaboration with Rebecca Howell and the MDA team is envisioned

The project is intended as exploratory analysis of rare GI tract tumors (e.g. esophagus, small intestine, stomach, pancreatic, biliary tract, liver), for which little evidence is published (besides the PanCareSurFup cohort study, that Raoul Reulen led) and Lois Travis' international GI tract SMN study among Hodgkin Lymphoma survivors). RT likely plays a role, the role of chemotherapy and other diseases / exposures is unclear. This proposal is intended to serve as step-up for further work to provide evidence in a clear gap in the late effects literature, that gains relevance in the era of precision RT treatment planning and other modern forms of therapy
