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Requirements to submit AOI:

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: Long-term Risk of Small Bowel Obstruction in Pediatric Patients with Primary Abdominal Tumors

Planned research population (eligibility criteria): Inclusion criteria: Diagnosis with primary abdominal tumor.

Proposed specific aims: Specific aim #1. To characterize and compare the long-term rates of bowel obstruction among patients who have and have not been diagnosed with a primary abdominal tumor. Null hypothesis #1: There is no difference in incidence rate of bowel obstruction between patients who have been diagnosed with primary abdominal tumors and those who have not. Specific aim #2: To characterize and compare the long-term rates of bowel obstruction among patients with a primary abdominal tumor who have and have not received cancer therapies such as chemotherapy and radiation. Null hypothesis #2: There is no difference in incidence rate of bowel obstruction between patients with primary abdominal tumors who have and have not received chemotherapy and/or radiation. Specific aim #3: To characterize and describe the long-term rates of bowel obstruction following first and repeat surgical resections of primary abdominal tumors, including modeling risk of obstruction. Null hypothesis #3: There is no association between number of surgical resections and incidence rate of bowel obstruction.

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?: N/A

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.: N/A

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

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

To describe the anticipated scope of the study, please indicate the specific CCSS data to be included as outcome (primary or secondary) or correlative factors. (Check all that apply)

Late mortality:
Second Malignancy: Correlative Factors

Health Behaviors

Tobacco: Correlative Factors
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: Correlative Factors
Surgical procedures: Correlative Factors

Brain and nervous system:

Other: Primary

If other, please specify: "Surgery for intestinal obstruction (blocked intestines)"

Medications

Describe medications:

Pregnancy and offspring:

Family History: Correlative Factors

Psychologic/Quality of Life

BSI-18:

SF-36:

CCSS-NCQ:

PTS:

PTG:

Other:

If other, please specify:

Chronic conditions (CTCAE v3):

Health status:

Demographic

Age: Correlative Factors

Race: Correlative Factors

Sex: Correlative Factors

Others:

If others, please specify:

Cancer treatment

Chemotherapy: Correlative Factors

Radiation therapy: Correlative Factors

Surgery: Correlative Factors

Anticipated sources of statistical support

CCSS Statistical Center:

Local institutional statistician: Yes

If local, please provide the name(s) and contact information of the statistician(s) to be involved.:
Arin Madenci, Arin.Madenci@childrens.harvard.edu
Will this project utilize CCSS biologic samples?: No

If yes, which of the following?

Buccal cell DNA:

Peripheral blood:

Lymphoblastoid cell lines:

Second malignancy pathology samples:

Other requiring collection of samples:

If other, please explain:

Other general comments: