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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: Subsequent Neoplasms in Survivors of Medulloblastoma at St. Jude Children's Research Hospital

Planned research population (eligibility criteria): The research population will include 5 year survivors enrolled on medulloblastoma treatment protocol SJMB96, SJMB03 (surgery, radiation therapy, adjuvant chemotherapy) to be compared with 140 patients from the CCSS cohort with medulloblastoma treated with radiation therapy and surgery alone.

Proposed specific aim: Determine whether historical changes in primary therapy for medulloblastoma (i.e. addition of adjuvant chemotherapy) have resulted in an increase in the cumulative incidence of subsequent neoplasms.

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: Yes

If yes to any of the above, please briefly describe.: In patients diagnosed with a subsequent neoplasm, specific histopathology of the reported second neoplasm will be reported and compared to the distribution of subsequent neoplasms in the St. Jude cohort.

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

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

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: Primary

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:
Brain and nervous system: Correlative Factors
Other:
If other, please specify:

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: Correlative Factors
If others, please specify: Location of tumor, treatment era, follow up duration, recurrence status, latency from diagnosis to development of second neoplasm,

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.:
Deo Kumar Srivastava PhD St. Jude Children's Research Hospital Room 6010 (Longinotti Building) Mail Stop 768 Memphis, TN 38103 Phone 901-595-3372 901-595-5501 Fax 901-595-8843 Email kumar.srivastava@stjude.org
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: We acknowledge the potential for overlap with the currently approved analysis of the medulloblastoma population by Dr. Allison King. We emphasize that this will not be a primary report of the CCSS population, but a primary report of the St. Jude population using a subset 140 of 300 medulloblastoma survivors as comparison population for cumulative incidence of subsequent neoplasms. Dr. Greg Armstrong will be Dr. Tsui's (St. Jude Neuro-oncology fellow) mentor for this study.