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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 Developing and validating meningioma risk prediction models in long-term survivors of childhood cancer

Planned research population (eligibility criteria)

For clinical model development/training (Aim 1), we will use data from the Childhood Cancer Survivor Study (CCSS), including all 5-year survivors of childhood cancer diagnosed between 1970-1999. For external clinical model validation/testing, we will use data from 5-year survivors participating in the St. Jude Lifetime Cohort (SJLIFE), excluding participants enrolled in CCSS who were also included in the model training data. Novel agnostic genetic association analyses (GWAS and rare variant association analyses) will be conducted

among survivors with whole-genome/-exome sequencing (WGS) in SJLIFE and CCSS survivors with WGS/WES or array-based genotype data (Aim 2). For Aim 3b, CCSS survivors who provided meningioma tumor samples will be evaluated.

Proposed specific aims

Aim 1: Develop and independently validate risk prediction models for subsequent meningiomas among long-term survivors of childhood cancer.

Aim 2: Evaluate whether germline genetic risk variants improve prediction performance, relative to validated meningioma risk prediction models without genetic predictors (from Aim 1).

Aim 3a: Assess validated meningioma risk prediction models (from Aims 1, 2) for their ability to identify survivors at elevated risk for meningioma-related morbidity. Higher-risk meningioma patients are those who have high-grade meningiomas (WHO grades ≥2), multiple meningiomas, meningiomatosis, metachronous meningiomas, or meningiomas with severe symptoms (as defined by Bowers et al., PMID 28339329).

Aim 3b: Among survivors, characterize somatic alterations among frequently mutated genes identified in sporadic meningiomas, and evaluate whether these somatic alterations can support stratification of survivors at risk for meningioma-related morbidity.

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?

Intramural funding (Feb. 2024) followed by extramural funding applications (TBD)

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)

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

Outcomes or Correlative Factors

Late Mortality	

Second Malignancy	Primary

Health Behaviors

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

If other, please specify

Psychosocial

Insurance	
Marriage	
Education	
Employment	
Other	

If other, please specify

Medical Conditions

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

If other, please specify

Medications

Describe medications

Psychologic/Quality of Life

BSI-18	
SF-36	
CCSS-NCQ	
PTS	
PTG	
Other	

If other, please specify

Other

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

Demographic

Age	Correlative Factors
Race	Correlative Factors
Sex	Correlative Factors
Other	Correlative Factors

If other, please specify

Cancer Treatment

Chemotherapy	Correlative Factors
Radiation Therapy	Correlative Factors
Surgery	Correlative Factors

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?	Yes
If yes, which of the following?	Buccal cell DNA Second malignancy pathology samples
If other, please explain	

Other General Comments

Agree	I agree to share this information with St. Jude

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