# Contact Information


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# Project Requirements and Description

### Requirements to submit AOI (all answers must be "yes" to proceed)

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|---|---|
| **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 outcomes in survivors of pediatric primary solid tumors of the vertebral column and spinal canal

### Planned research population (eligibility criteria)

Survivors of solid tumors of the vertebral column (cervical, thoracic, and lumbar vertebral levels), spinal cord, and associated meninges diagnosed between 1970-1999 who underwent any form of local or systemic control including resection, locally-delivered radiotherapy, and/or chemotherapy. Survivors will be identified based on ICD diagnosis codes for tumors of cervical, thoracic, lumbar spine (ICD dx site C41.2 = vertebral column) or spinal cord (C72.0) and exclude tumors of the sacrum/pelvis (C41.4).

## Proposed specific aims

Specific aim 1: Describe the late health-related quality of life (HRQoL), functional impairment, activity limitations, and psychosocial outcomes of these spine tumor survivors according to tumor and treatment characteristics stratified by local control modality while controlling for systemic (chemotherapy) exposures.

Specific aim 2: Describe late socioeconomic outcomes including education, marriage status, employment/income, and recent healthcare utilization among spine tumor survivors according to tumor characteristics and local control methods.

Specific aim 3: Describe the rate of late-occurring spine surgery as a group and partitioned by tumor characteristics and local control methods.

Specific aim 4: Determine overall late mortality and cause-specific late mortality (heath-related and external cause), late (>5 years from diagnosis) recurrence, and secondary malignancy for spine tumor survivors according to tumor characteristics (tumor type and location) and local control methods (radiotherapy and surgical resection) controlling for systemic exposures.

Specific aim 5: Estimate the cumulative incidence of relevant CTCAE chronic health conditions and scoliosis among spine tumor survivors according to tumor and treatment characteristics and local control methods.

**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)**

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

# Outcomes or Correlative Factors

| | |
|---|---|
| **Late Mortality** | Secondary |
| **Second Malignancy** | Secondary |

## Health Behaviors

| | |
|---|---|
| **Tobacco** | Correlative Factors |
| **Alcohol** | Correlative Factors |
| **Physical Activity** | Secondary |
| **Medical Screening** | Correlative Factors |
| **Other** | |

## If other, please specify

## Psychosocial

| | |
|---|---|
| **Insurance** | Secondary |
| **Marriage** | Secondary |
| **Education** | Primary |
| **Employment** | Primary |
| **Other** | |

## If other, please specify

## Medical Conditions

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

### If other, please specify

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# Medications

### Describe medications

### Psychologic/Quality of Life

| | |
|---|---|
| **BSI-18** | Primary |
| **SF-36** | Primary |
| **CCSS-NCQ** | Primary |
| **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** | |

### If other, please specify

### Cancer Treatment

| | |
|---|---|
| **Chemotherapy** | Correlative Factors |
| **Radiation Therapy** | Correlative Factors |
| **Surgery** | Correlative Factors |

### 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**

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# Other General Comments

This AOI has been discussed and reviewed by all members of the Surgical Working Group plus Dr. Eric Chow. Their input was incorporated into the AOI and their approval was obtained before AOI submission. Additional information related to an analysis plan is below:
Statistical methods
Aim 1: Outcomes will be assessed using CCSS validated surveys, the Short Form (SF)-36, and Brief Symptom Inventory (BSI)-18. Univariate analysis will be used to identify risk factors for SF-36 physical and mental component scores below the population norm. This includes local control modality, demographic variables, and other treatment variables. Similar analysis will identify risk factors for mental and emotional impairment utilizing the BSI threshold T score > 63 to indicate impairment. Multivariate analysis will then be used to describe these outcomes based on previously identified significant factors in univariate analysis while controlling for systemic exposures. Risk ratios will be reported where appropriate.
Other HRQoL and functional outcomes evaluated will include bowel and bladder incontinence, back pain, and neurological symptoms such as deficits of balance, weakness, paralysis, and sensation.

Aim 2: We will evaluate for differences between tumor and treatment groups for socioeconomic outcomes including educational attainment, marriage status, employment status, personal income with respect to poverty level, and health insurance status. Demographic and treatment variables will be controlled for in multivariate analysis. Odds ratios will be reported where appropriate using the CCSS sibling cohort as the reference.

Aim 3: We will tabulate the cumulative incidence and cumulative count of late-occurring spine surgery in all survivors of vertebral column and spinal cord tumors and evaluate for differences due to tumor type and location and local control treatment modalities.

Aim 4: We will tabulate time-dependent rates and cumulative incidence curves for overall survival, cancer-specific and cause-specific mortality, late (>5 years from diagnosis) recurrence, and secondary malignancy according to local control treatment method. Unadjusted risk-ratios for all-cause late mortality, cause-specific mortality, and recurrence will be calculated.

Aim 5: We will tabulate cumulative incidence of relevant CTCAE chronic health conditions, particularly cardiac, GI, MSK, nervous system, and renal/GU conditions.

**Agree**

I agree to share this information with St. Jude

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