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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

Psychological Symptom Profiles and Their Impact on Health and Quality of Life of Childhood Musculoskeletal Tumor Survivors

Planned research population (eligibility criteria)

Survivors of primary musculoskeletal tumors and sibling controls who completed FUP5 and FUP7 in the expanded cohort (1987-1999).

Proposed specific aims

Aim 1. To identify psychological symptom profiles (cognition, pain, distress [FU5]) in adult survivors of childhood musculoskeletal tumors.

Aim 2. To identify treatment-related and survivorship-related risk factors (i.e. reconstruction type, chemotherapy, and radiation cumulative doses, chronic health conditions, etc) associated with increased risk of adverse psychological symptom profiles.

Aim 3. To identify the impact of psychological symptom profiles on concurrent and future health behaviors (substance use, physical activity [FU5 & FU7]; sleep [FU6]) and psychoactive medication use.

Aim 4. To identify the impact of psychological symptom profiles on health-related quality of life [FU 5].

Aim 5. To identify the impact of psychological symptom profiles on activities of daily living [FU8].

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			
	Primary	Secondary	Correlative Factors
Second Malignancy			✓

Health Behaviors

St.

	Primary	Secondary	Correlative Factors
Tobacco		✓	
Alcohol		✓	
Physical Activity		✓	

If other, please specify

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			
Digestive			
Surgical Procedures			✓

	Primary	Secondary	Correlative Factors
Brain and Nervous System			✓
Other			

If other, please specify

Medications

Describe medications

Psychoactive medications will be gathered as part of Aim 3. Chemotherapy medications will be recorded as part of Aim 2 to investigate treatment related risk factors for adverse psychological profiles.

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

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

Agree

I agree to share this information with St. Jude

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