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Project Requirements and Description

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 The Relationship between Chronic Pain and Symptoms of

Social Isolation and Loneliness in Long-term Pediatric Cancer

Survivors

Planned research population (eligibility criteria)

We plan to utilize CCSS's retrospective cohort of childhood cancer survivors who are at least five years from diagnosis, ≥18 years of age, diagnosed prior to 21 years of age, who completed measures of pain (migraine, headache, cancer pain, SF-36 bodily pain/pain interference) at Follow-Up 4 and Follow-Up 7, and completed the PROMIS Social Isolation (L20) questionnaire and the loneliness item from the BSI-18 (L6) at Follow-Up 7.

Proposed specific aims

Aim 1. Examine associations between pain and symptoms of social isolation and loneliness (FU7) in adult survivors of childhood cancer.

Hypothesis 1: Survivors with pain will be at greater risk for feelings of social isolation and loneliness compared to survivors without pain.

Aim 2. Examine how pain trajectories are associated with symptoms of social isolation and loneliness in adult survivors of pediatric cancer.

Hypothesis 2: Persistent or worsened pain and pain interference (FU4 to FU7) will be associated with feelings of social isolation and loneliness in survivors (FU7).

Exploratory Aims:

- 1. In survivors with persistent or worsened pain, examine the impact of chronic health conditions on social isolation and loneliness.
- 2. In survivors with persistent or worsened pain, evaluate the mediating effects of social isolation and loneliness on symptoms of depression and anxiety (FU7)

Will the project require non-CCSS funding to complete?



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)

	Secondary
	✓
✓	

Outcomes or Correlative Factors

	Primary	Secondary	Correlative Factors
Late Mortality			
Second Malignancy			

Health Behaviors

	Primary	Secondary	Correlative Factors
Tobacco			✓
Alcohol			✓
Physical Activity			✓
Medical Screening			
Other			

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		✓	
	Primary	Secondary	Correlative Factors
Surgical Procedures		✓	
Brain and Nervous System		✓	
Other			

If other, please specify

Medications

Describe medications

Psychologic/Quality of Life

	Primary	Secondary	Correlative Factors
BSI-18	✓		
SF-36	✓		
CCSS-NCQ			
PTS			
PTG			
Other	✓		

If other, please specify

PROMIS Social Isolation (L20)

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

I am submitting this AOI to develop a concept with Dr. Tara Brinkman for submission to the CCSS Career Development Award.

Agree

I agree to share this information with St. Jude

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