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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 Internet-delivered Cognitive Behavioral Therapy to Improve Pain and Frailty in Adult survivors of Childhood Cancer

Planned research population (eligibility criteria)

Adult survivors (>18 years of age) of childhood cancer who have chronic pain and are pre-frail or frail.

Proposed specific aims

Aim 1: Evaluate the efficacy of Internet-delivered cognitive behavior therapy (ICBT) vs. attention control (online pain education) in improving chronic pain (pain severity and pain-related disability) among adult survivors of childhood cancer who are pre-frail or frail.

Aim 2: Examine the impact of ICBT on components of frailty.

Aim 3: Determine whether ICBT impacts symptom multimorbidities (depression, anxiety, sleep, fatigue), functional outcomes (neurocognitive function, physical activity, social participation), and opioid use among

prefrail and frail adult survivors of childhood cancer with chronic pain.

Exploratory Aim 1: Examine associations between biomarkers of physiologic activity (heart rate variability, respiratory rate, electrodermal activity), inflammation (high sensitivity c-reactive protein, fibrinogen, interleukin-1, tumor necrosis factor-alpha, interleukin-6), and DNA methylation and changes in pain and frailty post-intervention and at 6-month follow-up.

Exploratory Aim 2: Determine whether baseline clinical characteristics including mood, anxiety related factors [anxiety, pain catastrophizing, fear of cancer recurrence, intolerance of uncertainty, anxiety sensitivity], and sleep moderate the effect of ICBT on pain severity, pain-related disability, and frailty.

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?

R01 application to be submitted June 2025

Does this project require contact of CCSS study subjects for:

Additional self-reported information	Yes
Biological samples	Yes
Medical record data	No

If yes to any of the above, please briefly describe.

collection of serum to assess biomarkers of inflammation and DNA methylation

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			
Second Malignancy			

Health Behaviors

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

If other, please specify

sleep

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			
Brain and Nervous System			
Other	✓		

If other, please specify

frailty status

Medications

Describe medications

Psychologic/Quality of Life

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

If other, please specify

chronic pain - primary; fatigue - secondary; depression/anxiety - secondary; social participation - secondary

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

We are proposing a two-arm RCT of internet delivered CBT for chronic pain vs. attention control [patient education] for survivors who have chronic pain and are pre-frail or frail. Survivors will complete a baseline assessment (including self-report of symptoms; in home frailty assessment, biomarker collection), 8-week iCBT intervention, and post-intervention and 6-month follow-up assessments that parallel the baseline assessment.

Agree

I agree to share this information with St. Jude

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