

Section: Contact Information

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Section: Project Requirements and Description

Group: Requirements to submit AOI

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 : **eHealth Intervention for Insomnia in Acute Lymphoid Leukemia Survivors**

Planned research population (eligibility criteria) :

- 1. History of acute lymphoid leukemia(ALL)**
- 2. Screen positive for insomnia**
- 3. Not currently receiving cognitive therapy for insomnia**

Proposed specific aims :

1. Evaluate the effectiveness of an eHealth cognitive behavioral therapy intervention to treat ALL survivors with insomnia.

2. To assess the impact of insomnia treatment on anxiety, depression and fatigue in ALL survivors.

3. To assess the impact of insomnia treatment on indices of cardiovascular health in ALL survivors.

4. To assess the impact of insomnia treatment on neurocognitive function in ALL survivors

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 submission planned June 2016

Group: Does this project require contact of CCSS study subjects for:

Additional self-reported information : **Yes**

Biological samples : **Yes**

Medical record data : **Yes**

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

-additional self-reports- Insomnia Severity Index, online sleep diary, BSI-18, SF-36, Facit-F, neurocognitive questionnaires

-biological samples pre and post study hs-CRP, cortisol

-Medical record data- pre and post blood pressure

Group: What CCSS Working Group(s) would likely be involved? (Check all that apply)

Second Malignancy :

Chronic Disease :

Psychology / Neuropsychology : **Primary**

Genetics :

Cancer Control : **Secondary**

Epidemiology / Biostatistics :

Section: Outcomes or Correlative Factors

Late mortality :

Second Malignancy :

Group: Health Behaviors

Tobacco :

Alcohol :

Physical activity :

Medical screening :

Other :

If other, please specify :

Group: Psychosocial

Insurance :

Marriage : **Correlative Factors**

Education : **Correlative Factors**

Employment : **Correlative Factors**

Other :

If other, please specify :

Group: Medical Conditions

Hearing/Vision/Speech :

Hormonal systems :

Heart and vascular : **Secondary**

Respiratory :

Digestive :

Surgical procedures :

Brain and nervous system :

Other :

If other, please specify :

Group: Medications

Describe medications :

prescription and non-prescription medications used to treat insomnia

Group: Psychologic/Quality of Life

BSI-18 : **Secondary**

SF-36 : **Secondary**

CCSS-NCQ : **Secondary**

PTS :

PTG :

Other : **Primary**

If other, please specify : **Pittsburgh sleep, sleep diary, insomnia severity index,**

Facit-F

Group: Other

Pregnancy and offspring :

Family history :

Chronic conditions (CTCAE v3) : **Correlative Factors**

Health status : **Correlative Factors**

Group: Demographic

Age : **Correlative Factors**

Race : **Correlative Factors**

Sex : **Correlative Factors**

Other :

If other, please specify :

Group: Cancer treatment

Chemotherapy : **Correlative Factors**

Radiation therapy : **Correlative Factors**

Surgery :

Section: Anticipated Sources of Statistical Support

CCSS Statistical Center : **Yes**

Local institutional statistician :

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 :

Section: Other General Comments

Other General Comments :

Mentor- Kevin Krull, PhD

The platform we are proposing to use is the SHUTi program developed by Lee Ritterband (U Virginia). Lee is an expert in eHealth and will be a co-investigator on the grant. The SHUTi program is already operational and has been used in the general population. Paul Jacobsen is also exploring the potential of using it in breast cancer survivors, but this is still in development.