Section: Contact Information

First Name: Kathy
Last Name: Ruble
Institution: Johns Hopkins University
Address 1: 1800 Orleans Street, Bloomberg Children's Center
City: Baltimore
State/Province/Region: MD
Country: US
Zip/Postal Code: 21287
Phone Number: 410 614 5062
Email Address: rubleka@jhmi.edu

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.