Study Application (Version 1.5)

1.0 General Information

*Please enter the official title of your study:		
Reducing Health Disparities for Black Women in the Treatment of Insomnia		
***Please enter the Study Nickname you would like to use to reference the study:**		
PCORI * This field allows you to enter an abbreviated version of the Study Title to quickly identify this study.		

2.0 Add Department(s)

2.1 List departments associated with this study (Note: The primary department should accurately reflect the primary Department or Section of the PI. Please verify that the primary department listed is correct (in some cases the "default" department of BU/BMC Medicine has been selected). For large departments, the PI's appropriate "section" should be listed as the primary department (e.g. if the PI is from Neurology or Infectious Disease). If the PI is from the SPH - select the appropriate department within SPH (e.g. Epidemiology) as primary.):

Primary Dept?	Department Name
◉	**BMC/BUMC** - *MED* - Slone Epidemiology Center

3.0 List of Internal (BMC/BUMC) Study Personnel. All personnel listed in this section will have access to this study (limited or full access).

3.1 * Please add a Principal Investigator for the study:
(Note: Only faculty members can serve as Principal Investigators on IRB protocols for studies at the School of Dental Medicine)

Rosenberg, Lynn, ScD

Select if applicable

☐ Student ☐ Resident

☐ Fellow

If the Principal Investigator is a Student, Resident, or Fellow, the name of the Supervising Principal Investigator (formerly known as Faculty Sponsor) must be supplied BOTH in Section 3.3 (Study Contact) AND in Section 3.4 (Supervising Principal Investigator) below.

3.2 If applicable, please select the Research Staff personnel. Individuals must be listed if they will have contact with research subjects or their identifiable data in the performance of any research related activities, including enrollment, consenting, collection of study data, interventions, long-term follow-up or data analysis, either as Co-Investigators in A) or as Research Support Staff in B).

A) Additional Investigators

Auerbach, Sanford, M.D.
Co-Investigator
Bethea, Traci N, PhD, MPA
Co-Investigator

B) Research Support Staff

Al-Mahdi, Somaliyah
Research Assistant
Simmons, Patricia Dorothea, MS
Study Coordinator

3.3 *Please add a Study Contact:

Russell, Cordelia, MPH

The Study Contact(s) will receive all important system notifications along with the Principal Investigator. The study contact(s) are typically either the Study Coordinator or the Principal Investigator. A Study Contact must also be listed in Section 3.1, 3.2, 3.4, or 3.6. If the PI is a student, resident, or fellow, the Supervising Principal Investigator MUST be entered here.

3.4 If the PI is a student, resident, or fellow, you MUST add the Supervising Principal Investigator here:

3.5 Please ONLY list the PI's Department Chair/Section Chief below. The system will automatically route for signoff to any additional "Special Routing" approvals, so please do not list those here.

Kaufman, David W., ScD
Department Chair/Section Chief

Add the name of the individual authorized to approve and sign off on this study from your Department (e.g. the Department Chair or Dean). This should be someone other than the Principal Investigator. For more information, **click here.

3.6 If applicable, please select the Administrative Assistant(s):

☐ Vezina, Richard M, MPH

List here anyone performing administrative tasks only (not engaged in research and having no contact with subjects or identifiable data; where training and COI disclosure are not required) An Administrative Assistant can also be a Study Contact.

4.0 Review Path Determination

4.1 Review Path Determination

○ This project meets the definition of Not Human Subject Research (NHSR). Examples are non-research Quality Improvement/Quality Assurance projects; studies that involve obtaining anonymous data /tissues or coded data; or BMC/BU Medical Campus is not 'engaged' in human subjects research.

○ BMC/BU Medical Campus (the Relying Institution) cedes IRB review to another institution (the Reviewing Institution) under an Authorization Agreement.

- ○ The only research activities in this study involve chart reviews.
- ○ This study fits into one or more of the federal Exempt categories or the study does not have external funding and fits into one or more of the Equivalent Protections Exempt categories.
- ◉ None of the above. This study requires Expedited review or the review of the Full Board.

4.2 Emergency Use Report

Is this a report of an Emergency Use of an Investigational Drug or Device that has already occurred? For more information, click **here**.

○ Yes ◉ No

4.3 Individual Patient IND

Is this application for an FDA approved Individual patient (single use) IND under **21 CFR 312.310**?

○ Yes ◉ No

4.4 Humanitarian Use Device

Is this application for an FDA approved Humanitarian Use Device under **21 CFR 814**?

○ Yes ◉ No

5.0 Required Training and Conflict of Interest

5.1 BMC/BU Medical Campus Institutional Requirements for training

☑ The PI confirms the following:

- All individuals at Boston Medical Center or Boston University Medical Campus who will have contact with subjects or their identifiable data have been listed on this application in Section 3.0 (including those who will obtain informed consent, analyze identifiable data, perform study interventions, recruit subjects, etc.)
- All individuals listed in Section 3.0 have completed their INSPIR profile or have been asked to do so.
- All individuals listed in Sections 3.1, 3.2, and 3.4 are up to date with human subjects training and with GCP training if required. For more information, click **here**.

5.2 Conflict of Interest Disclosure

I confirm that **all** those responsible for the design, conduct, or reporting of the proposed program, including at minimum, all Senior/key personnel in the grant application, will, before this application is submitted, have completed the required financial interest disclosure through **COI Smart** for **Boston Medical Center** or through the **Financial Interest Disclosure form** for **Boston University**. NOTE: The IRB considers any missing financial interest disclosures to be noncompliance by the Principal Investigator.

☑ I confirm

Of the financial interest disclosure forms that will be completed, will any significant financial interests that are related to the research be disclosed?

○ Yes ◉ No

6.0 Funding Source

6.1 Funding Source

What is the source of your research funding? If you have multiple sources of funding (including sub-awards), check all that apply.

- [ ] Student/Resident/Fellow Research with no External Funding (choose if the PI is a student/resident/Fellow and the study is student/resident/Fellow research)
- [ ] Department/Internally Funded (choose if the PI is not a student/resident/Fellow and the study has no specific funding)
- [ ] Government
- [ ] Industry
- [x] Foundation/Other
- [ ] Training Grant (e.g. T32, K-award)

6.2 Study Type

This study is:

- (•) Initiated by the BMC/BU Medical Campus PI
- ( ) Other

Does this study meet the definition of a clinical trial as defined by the International Committee of Medical Journal Editors? (See help for definition)

(•) Yes ( ) No

NOTES:

- Studies that meet the ICMJE definition will **not** receive final IRB approval until the IRB is provided with the NCT number from **clinicaltrials.gov**. The responsibility for registering falls to the PI or Sponsor of the trial. For more information, click **here**.
- Clinical trials that are also initiated by the BMC/BU Medical Campus PI are **required** to consult with the **CRRO** prior to submission. Note that this pre-review consultation requirement is not satisfied by a consultation about registering with clinicaltrials.gov.
- All **BMC** and **BU Medical Campus** investigators or research team members that need assistance with **ClinicalTrials.gov** should contact ***Karla Damus*** *in the CRRO (**damusk@bu.edu**, (617) 358-7382)* . Examples of help include: registration of a clinical study to obtain the **NCT identifier** required by the IRB for all clinical trials, accessing/becoming a ClinicalTrials.gov user, resetting a forgotten password, and updating or reporting results for registered studies.

Date of pre-review consultation with the CRRO:

12/11/2017 and 11/26/2018

If this trial has been registered, please enter the 8 digit NCT number in the box, below:

NCT03613519

6.3 Funding Details

For instructions on how to complete this section, click on the Help icon.

View Details	Sponsor Name	Sponsor Type	Contract Type:	BU SAP Grant Number or BMC AU Number	Award Number
⊟	Patient-Centered Outcomes Research Institute	Private - Non-profit	Contract		AD-2017C1-6314

Sponsor Name:	Patient-Centered Outcomes Research Institute
Sponsor Type:	Private - Non-profit
Sponsor Role:	Payor;
Grant/Contract Number:	
Project Period:	From:03/01/2018 to:03/31/2022
Is Institution the Primary Grant Holder:	Yes
Contract Type:	Contract
BU SAP Grant Number or BMC AU Number:	
Award Number:	AD-2017C1-6314
Grant Title:	
PI Name: (If PI is not the same as identified on the study.)	

6.4 Grants Office

In the check boxes below, please indicate which grants office is handling your award/ sub-award.

- [x] BU Office of Sponsored Programs (OSP-med)
- [ ] BMC Research Finance (RF)
- [ ] BMC Clinical Trial Office (CTO)
- [ ] Charles River Campus Office of Sponsored Programs (OSP-CRC)
- [ ] Other (must list below)

Funding Notifications:

- [x] I have received a Notification of Award (NoA)
- [ ] I have received a Just In Time notice (JIT)

☐ I have received a fundable score for this study.

7.0 Study Summary

7.1 Provide a brief summary of the project in terms understandable to a non scientist (in 500 words or less). Do NOT copy from a grant application.

Black women are at a higher risk of developing insomnia and insomnia has profound physical and psychological health consequences especially for Black women. There is an internet-based self-administered treatment for insomnia called SHUTi (Sleep Healthy Using the Internet) which seeks to change behaviors around sleep that has been proven effective for the general population but there is little evidence of the effectiveness of this treatment among Black women. The goal of this study is to conduct a randomized trial to determine which of three web-based treatments is most effective in Black women: SHUTi, a modification of SHUTi (SHUTi-Black Women) that we will develop with the specific sleep problems of Black women in mind, and standard treatment (web-based information about habits and life-style practices that promote or inhibit healthy sleep, also called Sleep Hygiene). This study aims to provide the much needed evidence to help Black women make informed decisions regarding treatment for their insomnia. The subjects in this study will be women with insomnia in the Black Women's Health Study (BWHS) (H-31535) who choose to participate. The participants in the BWHS enrolled in 1995 and have been completing biennial questionnaires since then; they have also answered special questionnaires and provided biological samples. We will enroll 303 women: they will be randomized to one of the three treatments. Participants will complete questionnaires and sleep diaries in addition to using the education /information/tools from the assigned treatment group.

8.0 Navigation Menu

Please note: Questions in the Navigation Menu section determine which subsequent sections will be displayed and which ones will be hidden. If later you make any change to the Navigation Menu section, you will need to click on the "Save and Continue to Next Section" button throughout the whole application to display any new required section or hide any sections that are no longer required.

8.1 Separate Protocol

Is this a new submission with a separate protocol? This protocol must be from the sponsor or cooperative group or be based on the **protocol template** found on the IRB website, and must include the purpose, inclusion/exclusion criteria, design/procedure, and data safety and monitoring plan. A separate protocol is REQUIRED for all initial submissions of medical or surgical clinical trials. A GRANT APPLICATION IS NOT A PROTOCOL.

- ○ Yes
- ◉ No
- ○ Not applicable, this is not a new submission

8.2 International Research

Are any BU/BMC investigators involved in any way in research activities at non-US sites, including oversight of international research activities?

- ○ Yes ◉ No

8.3 Subjects Recruitment

Is the PI/study staff recruiting subjects for this study?

- ◉ Yes
- ○ No

8.4 Subjects Consent

Will informed consent be obtained from any of the subjects?

- (•) Yes
- ( ) No

8.5 Genetics

Does this research involve genetic testing, gene therapy, or collection of genetic information?

- ( ) Yes
- (•) No

8.6 Biological Samples Collection

Does this study involve collecting biological samples for research purposes?

- ( ) Yes
- (•) No

8.7 Drugs/Biological Agents

Does this study involve administering drugs or biological agents?

- ( ) Yes
- (•) No

8.8 Devices

Does this study involve the use of one or more device (as **defined** by the FDA) other than for routine measurements or monitoring (e.g., an EKG machine)?

- ( ) Yes
- (•) No

8.9 Radiation

As part of this study, will subjects be exposed to any procedures involving ionizing radiation for research purposes only?

- ( ) Yes
- (•) No

8.10 Samples or Data Retained for Extra Use

Will you be collecting samples or data that will be retained for extra use by yourself or other investigators? Extra use means any analysis that is in addition to that required for the study endpoints. Please also answer Yes if this study has been submitted solely to establish a repository.

- (•) Yes
- ( ) No

8.11 StudyFinder Listing

Do you agree to have the study title, summary, and PI name and e-mail address listed on StudyFinder, a publicly viewable medical campus website for general publicity and collaboration purposes? (If you also want to use StudyFinder to recruit subjects, there is another question to answer in the Recruitment section.)

○ Yes ◉ No

9.0 Study Site Information

9.1 Select one:

○ Single site research - conducted by BMC/BU Medical Campus investigator(s)
○ Multi-site research project - BMC/BU Medical Campus is a research site but is NOT the main study site
◉ Multi-site research - BMC/BU Medical Campus is the main research site and/or the BMC/BU Medical Campus Principal Investigator is the overall PI of the entire study or the FDA sponsor

9.2 IRB Authorization Agreement – BMC/BU Medical Campus is the Reviewing Institution

Does this study have or require an Authorization Agreement for External (non-BMC/BU Medical Campus) investigators who will rely on BMC/BU Medical Campus IRB review? ***

◉ Yes ○ No

***If this study has or will require an IRB Authorization Agreement where BMC/BU Medical Campus investigators will rely on IRB review by another institution, do not check YES here, but instead, go to Section 4.1 and check the 2nd option, "BMC/BU Medical Campus (the Relying Institution) cedes IRB review to another institution (the Reviewing Institution) under an Authorization Agreement.".

9.3 Provide details of all other research sites involved in this study. PREAMBLE – ALL INDIVIDUALS ENGAGED IN THE RESEARCH MUST HAVE IRB APPROVAL, EITHER FROM THEIR OWN INSTITUTION OR UNDER THE BMC/BU Medical Campus IRB BY AN APPROPRIATE AUTHORIZATION AGREEMENT..

Institution & PI Information	IRB approval for site
PI Name: Dr. Eric Zhou **Institution Name:** Dana Farber Cancer Institute	○ IRB approval will be obtained at this site ◉ Requesting an appropriate Authorization Agreement for this Relying Institution
PI Name: Dr. Karen Ingersoll **Institution Name:** University of Virginia	○ IRB approval will be obtained at this site ◉ Requesting an appropriate Authorization Agreement for this Relying Institution

9.4 Management of Information

Describe the processes for communication among sites concerning information relevant to the protection of participants, such as Unanticipated Problems, interim results, and protocol modifications.

We are the primary site. Participants' email addresses will be the only identifiable data stored in the SHUTi program. The only personal information that University of Virginia will have is the participants' email addresses. They will have no other identifying information. Their only function is to maintain the websites on which the treatments are offered. All data collected on these websites will be transferred to us at the end of the study. Once the study is completed, they will have no access to the data, which will be stored in protected computers at the Slone Epidemiology Center at Boston University. Emails or phone calls for help with the SHUTi program will be handled by staff at the Black Women's Health Study at Boston University. If there is any other problem, such as wishing to stop being in the study, that will be handled by us at Boston University.

Dr. Zhou is Co-PI for this study and as such co-leads this study with Dr. Rosenberg. Dr. Zhou will not have access to identifiable data and will not interact with subjects for research purposes. Dr. Zhou, will have contact with participants only if they ask to speak to him. If a subject finds that her participation in this study has resulted in a psychological problem that is upsetting, and she contacts Black Women's Health Study, she will be given the option to contact Dr. Zhou, a psychologist who treats people with sleep problems. In that case, the participant will be given a telephone number at which to contact Dr. Zhou or, if she desires, she can leave her telephone number for him to call.

9.5 Study Attachments

Please attach any study site related documents. If you are requesting an Authorization Agreement(s) for external sites that will cede to the BMC/BUMC IRB, you must attach the CV(s) for the external Site PI(s).

Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
No Document(s) have been attached to this form.							

10.0 IRB Authorization Agreement – BMC or BU Medical Campus is the Reviewing Institution

10.1 Identify the category which best describes the Relying Institution(s) and/or External Investigators. The BMC/BU Medical Campus IRB will be the IRB of Record (the Reviewing Institution) through an appropriate Authorization Agreement.

☑ A. Relying Institution(s) with an FWA Number

(The IRB requires the name(s) of the Relying Site Principal Investigator(s) to be listed in Study Site Information 9.3)

Please list the relying institution's information in the table below:

Institution Information	Contact for IRB Authorization Agreement
Institution Name: (if the institution is not listed, please send a request to **medirb@bu.edu** to add the institution) IAA List: Dana Farber Cancer Institute Is this Institution a participating Smart IRB member (see list of Participating Institutions at **www.smartirb.org**): ◉ Yes ○ No FWA Number: FWA00001121	Contact Name: Emily Eldh Contact Phone: (617) 632-4229 Contact Email: emily_eldh@dfci.harvard.edu

Institution Name: (if the institution is not listed, please send a request to **medirb@bu.edu** to add the institution)

IAA List: University of Virginia

Is this Institution a participating Smart IRB member (see list of Participating Institutions at **www.smartirb.org**):

(•) Yes ( ) No

FWA Number:

FWA00006183

Contact Name:

Joanna Faulconer

Contact Phone:

434-982-1855

Contact Email:

jld6p@virginia.edu

☐ B. External Investigators who fall into any of these Special Categories:

SPECIAL CATEGORIES

- BU-CRC faculty/staff (Institution: Enter "BU-CRC")
- BU-CRC students who are obtaining academic credit for their research activities (Institution: Enter "BU-CRC")
- Students from an outside institution (non-BU) who are obtaining academic credit for their research activities, including a Supervising Principal Investigator from their home institution (if required and listed in Section 9.3). (Institution: Enter name of institution)
- Physicians and staff from any of the Boston HealthNet Community Health Centers who will be engaged in research for the study (Institution: Enter name of Health Center)
- External Investigators who are working on the study independent of and/or not affiliated with any employer, institution, or organization (Institution: Enter "IIA")
- External Investigators who are affiliated with an institution that does not have an FWA (Institution: Enter "CIIA")

10.3 Funding

If external site has a grant attach here:

Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
No Document(s) have been attached to this form.							

10.4 Conflicts of Interest

Do any of the External Investigators have a COI or potential COI? Please state Yes or No. If yes, please describe the nature of the COI and whether the Relying Institution has a COI program.

Dr. Lee Ritterband is part of a small commercial program that uses SHUTi. The University of Virginia has stipulated that an individual unaffiliated with that entity must be part of any study in which Dr, Ritterband is involved in order to assure that independence is maintained. In addition, University of Virginia IRB must approve any study using SHUTi in which he takes part. Thus, his potential conflict of interest is acknowledged and taken into account. Attached is a Conflict of Interest Management Plan 2018-12 for Dr. Lee Ritterband.

10.5 **PI agreement to the terms of the IAA - PI must agree to these terms. I understand that, if this request is approved, the BMC/BU Medical Campus IRB ("the IRB") will be the IRB of record responsible for conducting the initial and continuing review of this protocol. I understand that the decision to cede IRB review is made jointly with the IRBs of the Relying Institution (or the Independent External investigator) and will not be the decision of the PI. The IRB, as the IRB of record, will have full responsibility for oversight of all aspects of the protocol EXCEPT for the following: The PI will have full responsibility for ensuring that the engaged research staff of the Relying Site Principal Investigator(s) in OPTION A have met all their home institutional requirements for ceded research. I will comply with the applicable policies of the IRB. I understand that this agreement is NOT considered approved until a formal Authorization Agreement is signed by the Institutional Officials of both institutions (or with each Independent External Investigator), and the fully signed Agreement is attached to this protocol. I understand that as PI for this study I am responsible the ethical conduct of this study. Oversight responsibilities include:**

- **Ensuring that all OPTION B External Investigators are listed in the Table of External Investigators of this application**
- **Ensuring that all the investigators follow the IRB protocol as approved and make no changes to the protocol without the approval of the IRB (except to eliminate immediate harm to subjects)**
- **Reporting to the IRB (per policy) any adverse events, protocol deviations, or unanticipated problems related to the research activities conducted by the External Investigators**
- **Reporting to the IRB any changes related to the status of the External Investigators**
- **Following all applicable HIPAA rules and using appropriate safeguards to prevent the unauthorized use or disclosure of PHI (Protected Health Information)**
- **Ensuring that External Investigators follow any determinations related to conflict of interest from BMC/BU Medical Campus or from their own Relying Institution.**

(●) Yes, as PI, I agree to the above terms.

( ) No, I do not agree to these terms (at which case BUMC will not agree to serve as the IRB of record for the External Investigators.)

11.0 Purpose

11.1 Background/Rationale/Purpose

Provide background information, study rationale, and purpose / study objective(s) and/or hypotheses for this study.

Black women are at a higher risk of developing insomnia and insomnia has profound adverse physical and psychological health consequences, including cardiovascular disease, diabetes, and anxiety. There is a non-pharmacological internet-based self-administered treatment for insomnia called SHUTi (Sleep Healthy Using the Internet) that has been shown to be effective in multiple randomized trials among populations that were predominantly white. There were few Black participants and there is little evidence of the effectiveness of this treatment among Black women; specifically, the few Black women in the trials were less likely to finish the treatment program than other participants. The goal of this study is to conduct a comparative effectiveness trail of three internet-based intervention approaches to insomnia treatment:

1) usual care (website providing sleep hygiene information)
2) standard SHUTi six-module program
3) modified SHUTi six-module program tailored for Black women, i.e., SHUTi-BW.

This study aims to provide the much needed evidence to help Black women make informed decisions regarding treatment for their insomnia.

12.0 Subjects

12.1 Inclusion Criteria

Include age ranges and sex. If study involves different criteria for different cohorts, please list separately.

Order Number	Criteria
1	Participants in the Black Women's Health Study (H-31535)
1	BWHS participants with clinically elevated symptoms of insomnia previously reported on a BWHS questionnaire
1	Internet access
1	Access to computer or tablet

12.2 Exclusion Criteria

Include age ranges and sex. If study involves different criteria for different cohorts, please list separately. Do NOT duplicate inclusion criteria; if no additional criteria, indicate "None."

Order Number	Criteria
1	Self-reported unstable or acute medical condition, or condition requiring surgery in the next two months
1	Self-reported untreated, current, and/or severe psychiatric condition
1	Self-reported night shift work or alternating shift work employment
1	Employed in a position where sleep restriction may endanger others' lives
1	Self-reported 1 or more sleep disorders other than insomnia, such as sleep apnea, that are not being managed by a medically prescribed method.
1	Intention to change use pattern of prescribed or over-the-counter sleep aid
1	Consume 14 or more alcoholic drinks/week

12.3 Race / Ethnicity

Will the expected demographic breakdown of the study population reflect either the Boston population or BMC population?

- ○ Yes
- ◉ No

If you answered "No", please explain why below:

This is a study of Black women from across the U.S. who are enrolled in the Black Women's Health Study.

12.4 Limited- and non-readers

NOTE: This question is new. If this submission is an amendment and your study is still consenting subjects, as a separate step, you must check the signature page of your active consent form(s). If any do

not comply with the below requirements, you MUST submit edited consent form(s) meeting these requirements with this submission. See **Editing-Signature-Page** for more detailed instructions.

1. Limited- and non-readers excluded:

- No witness signature line AND
- Subject statement does not say "(or has been read to me)"

2. Limited and non-readers not excluded:

- Subject statement says "(or has been read to me)"
- If the study is greater than minimal risk, either a witness signature line appears or another method to assure and document subject comprehension is described in the Consent section

Are limited- and non-readers EXCLUDED from the study?

- (•) Yes
- ( ) No
- ( ) Not Applicable - No subjects are to be consented for this study (consent will be waived or enrollment is complete)

Explain why it is not appropriate to include limited- and non-readers in this study:

Subjects for this study will be recruited from the Black Women's Health Study whose participants fill out questionnaires. None are limited or non-readers.

12.5 Special Populations (for more information, click on the (?) Help icon)

Please indicate if ANY (even one) of the following populations will be recruited (Note: Enrollment from any of these categories requires prior IRB approval):

- [ ] Minors who are wards of the State**
- [ ] Cognitively impaired subjects (will require use of an LAR, and assessment of ability to consent)**
- [ ] Employees, students, or trainees under the direct supervision of the PI**
- [ ] Minors**
- [ ] Minors independently making their own healthcare decisions**
- [ ] Non-English speaking subjects**
- [ ] Pregnant Women**
- [ ] Prisoners**
- [x] Women of child-bearing potential
- [ ] Individuals whose HIV testing status is provided to the study team prior to consent being obtained (e. g., for recruitment)
- [ ] Individuals identified as a patient of a federally-assisted substance use disorder clinic (Project RESPECT, Office-Based Addiction Clinic, CATALYST Clinic, or others - see (?) Help Icon for full list)

Please indicate if any of the following populations will be targeted by your research:

- [ ] BMC Residents or Fellows
- [ ] BU Dental Students
- [ ] BU Medical Students and/or Graduate Medical Sciences Students
- [ ] BU School of Public Health Students
- [ ] Homeless**
- [ ] Individuals with psychiatric disorders**
- [ ] Terminally ill patients**

**designated as vulnerable

13.0 Design/Procedure

13.1 Design and Procedure

Describe in detail the experimental design, including all materials and all procedures to be performed. Do NOT copy from a grant application – your application will be returned to you for revision if you do so.

Please include a clear timeline of the procedures to be performed. Clarify which procedures /test articles are investigational and which are part of standard clinical care. This description may include:

1. methods
2. specific information concerning experimental interventions, such as dose and frequency of drug (and placebo) administration, or deception/debriefing process for social behavioral studies
3. number, frequency and duration of subject contacts (visits, telephone calls, mail outs, emails)
4. entire duration of participation for a single subject
5. any additional requirements of the subject (post treatment follow-up, diary cards, questionnaires, etc.)
6. If any nursing staff (other than research nurses) are expected to interact with subjects, include a brief description of the plan for inservice training of nursing staff.

   (Note: For multiple sites, indicate which of the procedures will be done at any other sites other than BMC/BU Medical Campus (see Study Site Information). Attach, in the Study Attachments section, copies of any surveys, questionnaires, and other data collection instruments.)

Eligible subjects will be BWHS participants who completed a 7-question questionnaire about sleep, called the Insomnia Severity Index (ISI), which was included in the 2015 BWHS biennial follow-up questionnaire. The ISI was scored, with a score of 15 or more indicating symptoms of clinical insomnia. Women with scores of 15 or more will be sent a brochure and email that will inform them of the opportunity to participate in a free program designed to test which of three insomnia treatments works best in Black women. Women will be selected at random since there are many more potentially eligible women (4000+) than women who can participate in the trial (n=303). We will start with a group of 300 women. The women will be directed to a special BWHS insomnia study website that contains the information in the brochure as well as an online screening questionnaire. Up to 6 reminders will be sent to the women to encourage participation. Once this group has been contacted and received a reminder, we will proceed to select a second group of 300 women at random. This procedure will be followed until the final group of 303 participants has been entered into the study.

After a woman submits her screening questionnaire (attached to this IRB application as "Eligibility Questionnaire"), an assessment will be made by the project coordinator to determine if she is eligible (e. g., does not have sleep apnea). Those determined to be ineligible will be sent a thank you email and informed that they were not eligible for this trial. Those who meet the qualifications for the study will be contacted by the project coordinator to set up a telephone call to discuss the study and the informed consent. The coordinator will then call the woman; during the call the coordinator will review each section of the consent form. The consent form will contain a description of the study and describe all aspects of the study. Subjects will have ample time to consider whether or not they want to participate in the study. A verbal acknowledgement of consent, or non-consent, will be recorded in our database and a copy of the consent sent to the participant. A waiver of documentation of consent is requested below in the consent section.

At this point, the BWHS Project Coordinator will enroll participants by entering their email and study ID into the SHUTi Administrative site. The BWHS Project Coordinator will be responsible for SHUTi program administration during the clinical trial. The SHUTi program will maintain contact with the woman through regular emails until the end of the woman's participation, as described below. Participants needing help will contact BWHS via email (bwhs@bu.edu) or the BWHS toll free number (800-786-0814) posted on the SHUTi website. At the end of each woman's participation, the data she has supplied (ISI scores, etc.) will be transferred from the SHUTi database to BWHS. None of the data collected will have identifiers such as names and addresses.

Once a participant is enrolled, she will be sent a Welcome email with instructions for setting her password. Enrolled participants will login and complete an online Questionnaire (attached to this IRB application as "Pre-Assignment Questionnaire") asking about her health, sleep habits, and daily life activities (approximately 30 minutes). Participants will receive reminder emails to complete the Questionnaire.

After completing the Pre-Assignment questionnaire, participants will advance to the Sleep Diary phase. Participants will record their sleep online by entering Sleep Diaries (2 minutes to complete each) during the next two weeks. Participants must complete at least 10 diaries in those two weeks to complete this phase with success. Participants will receive daily email reminders to complete the Sleep Diaries. A sample Sleep Diary is attached to this IRB application as "SHUTi Sleep Diary".

After a participant has completed both (the Pre-Assignment Questionnaire and 10 Sleep Diaries in a two week time period), the program automatically advances the participant to the treatment phase. Via email, participants will be directed to 1 of the 3 study programs to which they have been randomly assigned. For the next nine (9) weeks, each participant will use her assigned study website.

Sleep Education/Sleep Hygiene

One program will be a commonly used treatment for insomnia, called sleep information or sleep hygiene. Participants assigned to this treatment program will use a website that discusses ways to improve behaviors and environments that can affect sleep. This material is also included in the other 2 treatments but is presented in a different way. Participants may log in as often as they like and there are no time requirements. An example of this program is attached to this IRB application as "Draft - Sleep Education Website".

SHUTi (Sleep Healthy Using the Internet)

The other 2 treatment programs, Sleep Healthy Using the Internet (SHUTi), and a modification of SHUTi designed for Black women called SHUTi-BW, will involve participation in online treatment programs that have six modules called Cores. Each participant will log in to the six modules of her assigned treatment program over a 6 to 8-week period. Participants will use a website program designed to provide tailored instructions about how to improve their sleep. Cores are completed one at a time in order. Each Core is expected to take 45 to 60 minutes to complete. Each Core contains information and exercises designed to help change behaviors and thoughts that can contribute to sleep problems. Participants will receive automated emails encouraging them to complete tasks. Participants will be asked to complete weekly to dos and enter daily Sleep Diaries to track their sleep. After each module, participants will need to complete 5 sleep diaries to proceed to the next module (2 minutes to complete each).

Nine weeks after she completes the initial (Pre-Assignment) questionnaire, regardless of which treatment program she is assigned to, the participant will be asked to complete a Post-Assignment questionnaire about her sleep and health (45 minutes) and she will be asked again to complete 10 sleep diaries. The Post-Assignment Questionnaire will include the same questions asked at the beginning and additional evaluation questions. Six months later, participants will be asked again to complete a questionnaire, including evaluation questions, (45 minutes) and 10 sleep diaries. These three questionnaires are attached to this IRB application as Pre-Assignment Questionnaire, Post-Assignment Questionnaire and 6 Month Follow-up Questionnaire.

Participants can continue to use their assigned website between the two post treatment questionnaires.

After participants have finished their assigned program for the research, they may choose to take one of the other insomnia treatment programs. It will be offered free of charge but it will not be counted as part of this research.

This table summarizes what will happen in this randomized trial.

Step	Week	Study Phase	What happens during this phase	Time required
1	1-2	Pre assignment	Complete Pre- Assignment Questionnaire	30 minutes
			Enter 10 sleep diaries in 14 days	2 minutes each
2	3-12	Treatment 9 weeks	Use assigned website	
3	12	Post treatment	Complete Post-Assignment Questionnaire	45 minutes
			Enter 10 sleep diaries in 14 days	2 minutes each

4	38	6 months after post treatment	Complete 6 Month Follow-up Questionnaire	45 minutes
			Enter 10 sleep diaries in 14 days	2 minutes each

Participants will receive $25 for completing the pre-assignment questionnaire and 10 sleep diaries, $50 for completing the post-assignment questionnaire and ten sleep diaries, and $75 for completing the 6-month follow-up questionnaire and 10 sleep diaries (total=$150). This incremental reimbursement strategy is designed to help maximize follow-up data collection.

The SHUTi program has 6 cores that include behavioral, educational, and cognitive components. Most cores contain "vignettes" or stories about the sleep problems of specific (fictional) individuals, that may be presented in videos or written material with the names and faces of a variety of (fictional) men and women, of whom one is a black woman. Some of the cores contain advice from sleep experts (mostly actors playing those roles).

Core 1 provides an overview and rationale for the treatment.

Cores 2 and 3 are behavioral cores that provide rules for sleep restriction and stimulus control. Rules are provided to regulate the sleep-wake schedule and strengthen the connection between the bedroom and sleep. Stimulus control means going to bed only when sleepy, getting out of bed when unable to sleep and returning to bed when sleepy, and curtailing other activities in the bedroom (e.g., reading, television). Sleep restriction means limiting the time spent in bed to increase sleep efficiency (amount of time in bed spent sleeping).

Core 4 focuses on improving sleep hygiene practices (e.g., avoiding alcohol before bedtime).

Core 5, the cognitive core, addresses unhelpful beliefs about sleep (e.g., the belief that a certain number of hours of sleep are required).

Core 6, the last core, integrates the various elements and presents strategies to prevent relapse.

SHUTi-BW will have the same structure and elements as SHUTi. The vignettes will be changed, so that Black women will be the characters of interest. The vignettes will also contain material that was not covered in SHUTi, such as sleep problems resulting from housing that is not quiet or that may require room sharing. The "experts" will be Black men or women. The changes will be made with the advice of a Leadership Team that includes Black women from the community who have sleep problems, a Black community advocate, a sleep expert, a physician who treats individuals with sleep problems, and the co-PIs of this study.

13.2 Outcomes

Describe anticipated primary outcome and any secondary outcomes and how they will be measured:

The outcomes of interest are:
Change in sleep patterns
Mood and quality of life
Sleep intervention acceptability, utilization and preference

13.3 Data Analysis

Provide a description of your plan for data analysis. State the types of comparisons you plan (e.g. comparison of means, comparison of proportions, regressions, analysis of variance). Which is the PRIMARY comparison/analysis? How will the analyses proposed relate to the primary purposes of your study? If you are doing qualitative research please state how comparisons will be made.

The chief outcome of interest will be improvement in the ISI score. An ISI score reduction of 8 is considered to be a clinically significant improvement in insomnia symptoms. Other outcomes of interest will be WASO (wake after sleep onset, i.e., amount of time awake after first falling asleep) and SOL (sleep onset latency, i.e., time awake before first falling asleep).
We will analyze the data on an intention to treat basis.
For the primary outcome, ISI, a factorial 2 (groups) x 3 (times) mixed model analysis will compare improvement in the treatment groups to the usual care group, and to one another. Using a General Linear Mixed Model (GLMM) analysis will allow us to include dropouts in the analysis and to model the appropriate temporal dependencies in the dataset. We will also use GLMM to test whether 2 hypothesized mediators -- dysfunctional beliefs about sleep and sleep incompatible behaviors – mediate intervention efficacy.

Analyses for WASO and SOL will be similar.
Finally, an important variable will be the proportion of women who complete each of the treatment arms.

13.4 Sample Size/Specimens

How many subjects (or records, or specimens, or charts) will be enrolled in this study? Be sure to include all subjects who will be consented - even those who will be disqualified following consent because they did not meet the enrollment criteria.

Subjects under BMC/BU Medical Center PI (click on the Help icon for instructions)
303

For multi-center studies only - Total worldwide subjects, including subjects under BMC/BU Medical Center PI
303

Sample Size Justification

Describe how you will have access to a population that will allow recruitment of the necessary number of subjects. Indicate why you chose the sample size proposed. Provide your sample size calculations. If this is a pilot study, this justification does not necessarily require a formal sample size calculation, but should provide a rationale for choosing the sample size proposed (e.g. to estimate a mean to a certain accuracy, to determine if the response rate is above a certain percentage, etc.) Note: Once the IRB approves a certain study sample size then you may not enroll beyond that sample size without first obtaining approval from the IRB. Explain how many evaluable subjects you will need to end up with to answer your study question and how many subjects you will need to enroll and consent to achieve this number. The IRB counts study subjects starting when they are consented.

The 2015 BWHS biennial health questionnaire contained the Insomnia Severity Index. A total of 26,175 participants completed the questions, of whom 4,159 experienced clinically elevated levels of insomnia symptoms (i.e., scores of 15 or greater). For the present study, in addition to an ISI score indicating insomnia, participants must have access to the internet and to a laptop or tablet, and not have any of the conditions (e.g., sleep apnea) that would be disqualifying. Data collected in the BWHS suggest that >75% have computers or tablets, and almost all have email (i.e., access to the internet). Based on previous efforts in the BWHS, we estimate that to recruit 303 women with insomnia would require screening as many as 1400 subjects. Thus, we have a substantial sample from which to recruit the total of 303 participants need for this study (n=101 in each treatment arm).

13.5 Study Attachments

You must attach to this application all surveys, interviews, questionnaires, focus group outlines, etc. that will be used in this study. The IRB must review these materials. If these items are included as part of the attached protocol they do not have to be submitted again. Failure to provide this information could result in a delay in IRB review. If some of the materials are not finalized- submit the DRAFT versions. The final versions will need to be approved by the IRB via an amendment PRIOR to use.

Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
No Document(s) have been attached to this form.							

14.0 Risks & Benefits & Justification for Approval

14.1 Potential Risk/Discomforts

List the reasonably foreseeable risks or discomforts to subjects as a result of their participation in the research. Be sure to include physical harms, discomforts, hazards, inconveniences as well as the potential for any social harms (e.g. loss of job or insurability due to breach in confidentiality). For each risk listed be sure to describe the magnitude (seriousness) of the risk, the probability of occurrence, and the potential duration.

There are several potential risks to participants, which are minimal:

There is a risk of loss of confidentiality.
Some women may have concerns about going to a website and doing on-line activities.
Some women may have concerns about answering questions of a personal nature.
Some may have increased tiredness due to the restricted time in bed introduced after the first module.
Women who have an undiagnosed sleep problem may not benefit from the program.

Provide a description of how risks will be minimized including, if appropriate, the availability of medical or psychosocial resources that subjects might need as a consequence of the research.

We will minimize the potential risks to participants by:

We will train staff to maintain a sensitive and responsive approach to speaking with participants.

Confidentiality concerns: In order to minimize any risks of loss of confidentiality, participants will be identified by coded study number. The file linking this coded study number to patient identifiers will be stored in a password protected database available only to relevant members of the study team involved in direct contact with participants. The data collected via the Internet will be obtained through secured means and stored on secure servers at the University of Virginia. All data on the servers are password protected and limited to authorized research personnel. The University of Virginia study team has previously worked out a system with their prior Internet intervention studies in which two servers have been set up with one private server configured behind the HIPAA compliant firewall where secured data resides and only individuals who have onsite or VPN access are able to connect to this server. A second server maintains the front-end web system so that individuals (the participants) offsite can access the program. Data submitted by these users are captured and transferred to the secure server. Analyses will be conducted without identifiers.

Concerns about using an internet program: participants will be instructed to contact study staff if they have any concerns or questions about the on-line program. They are invited to contact study staff through either email or phone calls.

Concerns about answering personal questions: BWHS participants have provided personal data for 24 years in the BWHS. If they have concerns, they can call the project coordinator who will explain the safeguards for the data.

Initial tiredness: Participants who follow recommendations to restrict sleep could initially feel more tired. To minimize the risk associated with sleep restriction, the SHUTi system does not recommend that participants restrict sleep beyond the total amount of sleep the participant is already getting (based on diary data). We will instruct participants that they may contact us if they have significant concerns. As needed, we will instruct participants to contact their primary care provider or seek professional help at a sleep clinic.

14.2 Potential Benefits

Describe potential benefit(s) to be gained by the individual subject as a result of participating in the research. (Payments to subjects should not be included in this section.) If there are no direct benefits to individual subjects, you must include a societal benefit that may result from this study.

There are two major potential benefits. Women taking part in the study may well improve their sleep, which in turn can improve their emotional and physical health. Those randomized to a program they don't like will be able to take the program, at no cost, that they think they will prefer after completing their assigned treatment.

The second benefit is to black women in general who have insomnia. The effectiveness of SHUTi has not been established in black women. This study will establish whether SHUTi, or SHUTi-BW (which are cognitive behavioral treatments for insomnia (CBTi), or both, are better at treating insomnia in black women than standard care, which is giving the person sleep information. Since there are very few trained practitioners in CBTi, very few individuals get this most effective treatment for insomnia. Demonstration that SHUT or SHUTi-BW is effective will provide an opportunity for any black woman with access to the internet and a computer to address her insomnia effectively.

14.3 Risk to Benefit Ratio

Describe how risks to subjects are reasonable in relation to anticipated benefits:

The risk/benefit ratio is highly favorable. Confidentiality is protected by the use of numbers to identify data; the protection of computer files by firewalls and limiting access to study personnel; the storage of consents in locked files; the statistical analysis of de-identified data; and the presentation of results of aggregate data. The benefit to scientific knowledge is large and far outweighs any risk.

15.0 Data & Safety Monitoring

A data and safety monitoring plan (DSMP) is meant to assure that each clinical investigation has a system for oversight and monitoring of the conduct of the clinical investigation. This oversight is intended to ensure the safety of the participants and the validity and integrity of the data. A DSMP should be commensurate with the risks.

A DSMP can be as simple as the investigator reporting Unanticipated Problems, Adverse Events, and Protocol Deviations to the IRB. A DSMP can be as complex as having a Data and Safety Monitoring Board.

A DSMP can include clinical trial monitoring. Clinical trial monitoring refers to the methods used to oversee the conduct of, and reporting of data from, clinical investigations including appropriate clinical investigator supervision of study site staff. Monitoring activities include communication with the investigator and the study site staff; review of the study site's processes, procedures, and records; and verification of the accuracy of the data.

15.1 For more than minimal risk research, your application needs to include a separate Data and Safety Monitoring Plan. For more information, click here. Please check-off one of the options below:

- [x] This study is not greater than minimal risk. Unanticipated Problems, Adverse Events, and protocol deviations will be reported to the IRB as required by IRB policies.
- [ ] A DSMP is attached in a detailed protocol (provide page number in textbox below).
- [ ] A DSMP is attached in the Study Attachments section below.

15.2 Who will monitor the research for safety of the participants? (check all that apply)

- [x] The Principal Investigator at Boston Medical Center or BU Medical Campus who will report all adverse events and Unanticipated Problems to the IRB in compliance with IRB policy, Federal/State regulations,

and sponsor requirements (as applicable).

- ☐ An independent Data Safety Monitoring Board/Data Monitoring Committee
- ☐ The Sponsor or Funding Agency
- ☐ Other:

15.3 DSMP Attachments

Here you can attach any Data and Safety Monitoring Plan documents including your DSMP, Data Safety Monitoring Board charter, and any other related documents.

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No Document(s) have been attached to this form.							

16.0 Recruitment Procedures/Materials

16.1 Recruitment Procedures

Describe in detail how the research population will be identified and your methods for contacting potential subjects and providing them with information about the study.

Note: The IRB has approved informational brochures that you may provide to potential subjects covering topics such as general participation in research and specific research procedures. These brochures do not have to be listed or uploaded in this submission. For access to these approved brochures, click **here**.

We will identify Black women from the BWHS cohort with clinically elevated levels of insomnia on the 2015 questionnaire (a score of ≥15 on the ISI). Recruitment letters that contain a toll-free telephone number, along with a brochure explaining the study, will be sent to participants with insomnia. A reminder email will be sent to encourage participation. Women who express interest in participation will be screened for eligibility with an online questionnaire. Those found to be potentially elibible will be called to clarify any unclear responses and review the full consent.

The Principal Investigator confirms the following:

- No direct or indirect remuneration that constitutes an inducement for recruiting or enrolling subjects will be accepted by any member of the research team; and
- No bonus payments based on the rate or timing of subject recruitment or enrollment will be accepted by any member of the research team; and
- Research involving medical services will comply with federal and state anti-kickback laws and applicable anti-kickback polices of Boston Medical Center and Boston University; and
- No payment or financial incentives (finder's fees) will be offered to any healthcare providers for referring patients to research studies.

☑ I Confirm

16.2 Recruitment Material

Attach all study related recruitment documents including, but not limited to, materials such as: posters, flyers, newspaper ads, script for in-person or telephone recruitment (if any). You may download a recruitment script template **here**. Final versions of all materials should be attached. If a video, submit the tape. If a website, provide the URL and attach screenshots for every page. Note that approved brochures downloaded from **here** are IRB-approved and do not need to be attached.

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1.0		Email for Ineligible women	Letter		Approved		80.08 KB
1.1		Recruitment Email and Letter	Recruitment /Advertising		Approved and Stamped		49.44 KB
1.1		Brochure for Recruitment	Recruitment /Advertising		Approved		380.58 KB

16.3 Recruitment using the StudyFinder website

The BMC/BU Medical Campus Study Finder is a medical campus website that lists research studies for public view. If you are using Study Finder to recruit subjects, you should complete the Study Finder Form in the Submission Forms section of INSPIR.

Will you be listing your study in Study Finder to recruit subjects? If "yes," select "yes" below and complete the Study Finder Form (located in the Submissions Forms section of the Study Management view of INSPIR II - for more information, click **here**).

- ○ Yes
- ◉ No

16.4 Will you be recruiting using one or more Boston HealthNet Community Health Centers (CHC)?

- ○ Yes
- ◉ No

16.5 Screening

Will any sensitive information or protected health information (PHI) collected during the screening without obtaining consent be retained that can be linked to the potential subjects OR does the study require any clinical screening procedures (blood draw, fasting, etc) performed solely for the purpose of determining eligibility in this research?

○ Yes ◉ No

Will any potential subjects be directly contacted to obtain screening information?

- ◉ Yes
- ○ No
- ○ Not Applicable - all screening activities have been completed for this already-approved study

17.0 Screening Procedures

17.1 Describe the procedures that will be used for screening to determine subject eligibility. If screening procedures are described in a separate protocol, indicate the protocol section here.

A web-based screening questionnaire on a secure website maintained by Boston University will include the ISI test and questions about disqualifying conditions:
lack of access to internet on a daily or almost daily basis and lack of access to a computer or tablet; ISI score <15; sleep apnea; consumption of 14+ alcoholic drinks a week; planned major surgery in the coming 2 months; planned major change in sleep medications in the coming 2 months, diagnosis of bipolar disorder.

17.2 Describe what eligibility data will be stored and how it will be stored, who will have access, and when these data will be destroyed. For screening failures, please detail how and what data will be retained, if any, along with when these data will be destroyed. Please describe whether identifiers are being retained from those who screen out. Please note if contact information is being retained for future research.

The screening data will be stored in protected data files and identified by ID number only. These data will be stored separately from identifying data needed to follow BWHS participants. Only selected study staff have access to the identifiers, and all have been trained in human subject's research. The data will be destroyed after the end of the BWHS follow-up study. Contact information is routinely kept in the BWHS for follow-up purposes and will be kept for the purposes of the main BWHS study. (H-31535)

17.3 Describe the screening consent process. Full consent for screening is required if either of the following is true:

- **identifiable sensitive information or PHI will be retained (retained as opposed to destroyed after being used to determine eligibility), or**
- **the screening involves clinical procedures**

A Brief Screening Agreement may be used for all other screening involving direct contact with subjects. For full consent form templates and the Brief Screening Agreement Template, click here.

There will be a Full Screening Consent (version 1.2) form preceding the screening questionnaire (Eligibility Questionnaire). That Full Screening Consent and the Eligibility Questionnaire are attached.

17.4 Screening Related Documents

Here you can attach any screening scripts, surveys, or forms and other screening related documents. Do NOT attach screening consent forms here; instead, attach them to the Initial Review Form after completing this Study Application.

Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
No Document(s) have been attached to this form.							

18.0 Consent Procedures

18.1 Consent Procedures

You indicated in the "Navigation Menu" section that informed consent will be obtained from subjects. Describe in detail the informed consent process. Include:

1. How and where potential subjects will be provided with an opportunity to discuss the information provided to them
2. The individual(s) (identified by role) who will be involved in obtaining consent. If the study involves a drug, device, or surgical procedure, there are **new requirements** for studies submitted for initial approval on or after September 1, 2019: You must either (A) Confirm that a member of the study team who is a Licensed Independent Practitioner (for example, Physician, Dentist, Physician Assistant, Nurse Practitioner) will discuss the purpose, risks, benefits, and alternatives with potential subjects (either by conducting the entire consent discussion or by participating along with another study team member) or (B) Provide a justification for a different process; and
3. How long subjects will have to decide if they want to participate.
4. If the study includes limited- and non-readers and is greater than minimal risk, how you will use an impartial witness or another method to assure and document subject comprehension (such as a quiz or "teach back"), for limited- and non-readers only or for all subjects.

As explained above, a brochure explaining the trial as well an email inviting the participant to view a BWHS insomnia study website with the same information will be sent to eligible BWHS participants explaining this trial. The participant can then link to the website and read a Full Screening Consent (version 1.2) for the screening questionnaire. After filling out the screening questionnaire, if she is eligible and wants to participate in the study, she will be asked to supply a telephone number and time at which she can be called by the project coordinator to lead her through the informed consent document, which will describe all study procedures. Subjects will have ample time to consider whether or not they want to participate in the study, and will be sent a copy of the consent form. An 800 number will also be provided for potential subjects to call and have questions answered that they might have about the study.

18.2 Verbal Consent/Assent - Waiver of Documentation of Informed Consent

Will this research include an informed consent process, but require a Waiver of Documentation of Consent? For more information, click **here**.

- ○ No
- ◉ Yes, because the research presents no more than minimal risk of harm to the subjects and involves no procedures for which written consent would normally be required outside of the research.
- ○ Yes, because the only record linking the subjects to the research would be the consent document and the main risk in the research would be the potential harm because of a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.
- ○ Yes, because the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, the research presents no more than minimal risk of harm to the subjects, and there is an appropriate alternative mechanism for documenting that informed consent was obtained

18.3 Waiver or Alteration of Informed Consent Process

Does the study meet the criteria for a Waiver or Alteration of Consent Process?

- ◉ No
- ○ Yes

18.5 Consent by Substituted Judgment

Do you intend to obtain consent from a Legally Authorized Representative (LAR) for cognitively impaired/decisionally impaired adult subjects?? For more information, click **here**.

- ○ Yes
- ◉ No

18.6 Non-English Language Consent Forms:

Will you obtain consent from subjects who are not fluent in English? For more information, click **here**.

○ Yes ◉ No

19.0 Privacy and Confidentiality

19.1 Privacy (Privacy refers to an individual's control over who has access to him/herself)

Please check one:

☑ The following measures will be used to protect the privacy of subjects and potential subjects:

- The information that will be obtained from and/or about subjects and potential subjects is the minimum necessary to conduct the study; and
- If any interventions and interactions occur with subjects and potential subjects, they will take place in private settings.

☐ Other appropriate measures will be used to protect the privacy of subjects and potential subjects (describe):

19.2 Confidentiality of the Data

In the section below indicate how the study will ensure subject confidentiality and privacy on all study data/results, documents, CRFs, and other documents/files:

☑ Study data/results, documents, CRFs, and other documents/files will be identified with a unique study ID #. The study ID # will be linked to a master-code list that contains all study ID #s and direct subject identifiers (i.e. name, address, DOB, MRN, etc). The master-code list will be maintained separately from study files and access limited to the researchers.

☐ All study data, documents, CRFs, and other documents/files will be recorded as anonymous. There is NO master-code. There will be no reasonable way to link study data and documents to individual subjects, even temporarily AND subject identities cannot be reasonable ascertained via deductive disclosure.

☐ There is an alternate plan for how subject will be identified in study data, documents, CRFs, and other documents/files. Please specify in text box below.

You have indicated above that Study data/results, documents, CRFs, and other documents /files will be identified with a unique study ID #. Please select one of the options below:

○ Study data/results, CRFs, and other documents/files for subjects who have been assigned a study ID # may also contain subject identifiers that by themselves or when combined with other identifiers, could result in identifying a subject (ex. maintaining paper medical records that contains a subject's name and MRN in a participant's research file.)

◉ Study data, documents, CRFs, and other documents/files for subjects who have been assigned a study ID # will NOT contain any subject identifiers that by themselves or when combined with others identifiers, could result in identifying a subject.

- **Please describe in the text box below how you will secure the data (e.g. how the master-code will be stored relative to the study data).**
- **If the dataset contains protected health information (PHI) or Personal Information (as defined under Massachusetts law) and is being stored electronically, please provide explicit confirmation that it will be stored according to BMC and/or BU policy for secure storage of such data. Please see the (?) Help Icon to the right for the definitions of PHI and Personal Information and for the appropriate storage options for BMC and BU and specify which will be used.**

All research data is in an encrypted database that will identify all subjects with a study number. These filing systems are separate from the name-address file of subjects in the study, which resides on a separate computer. The analytic datasets to be used by investigators in this study will not include the name of the subject (or other personal identifying information), and all analyses and reports will be based on aggregate data, so that study subjects cannot be identified.

19.3 Release of identifiable data.

Is identifiable data being released outside of BMC/BU Medical Campus? (e.g. to sponsors, because of mandated reporting, etc).

- (•) Yes
- ( ) No

If identifiable data is being transmitted outside of BMC/BU Medical Campus, please describe what information will be released and under what circumstances, to whom the information will be released, and how confidentiality will be maintained during data transmission. (e.g. encrypted email, encrypted flash drive, sponsor-provided data capture system).

The only identifiable data stored in the SHUTi program will be the participant's email. The assignment into the treatment group in this randomized trial will be done by the BU study coordinator. The email address will be entered into the program by the BU study coordinator. The email will be used to send reminders to the participant of the various phases of the trial; messages will be sent by the SHUTi program at the University of Virginia in an automated fashion. The only identifying information stored in the SHUTi application is the email address. No other identifiable data will be shared or input into the SHUTi program. No identifiable data will be shared with Dr. Eric Zhou.

Pertinent findings (related to the aims of the study) and incidental findings (unrelated to the aims of the study): Does the research (including screening) involve any test or procedure done for research purposes only that may yield findings that are of potential health or reproductive importance to the individual subjects (e.g., disease risk, abnormal lab values, imaging abnormalities, genetic results)?

- ( ) Yes
- (•) No
- ( ) Not Applicable - no additional research results will be collected for this study.

Do you plan to share data with a third-party vendor or software application or program? Note: sponsors are not considered third parties.

- ( ) Yes
- (•) No

19.4 Destruction of Identifiers

If the data are identifiable and/or if a master-code exists, when and how will the data be de-identified or the master-code be destroyed?

The identifiers are maintained by the parent BWHS (H-31535). They will be maintained until seven years post completion of this insomnia treatment study. University of Virginia will destroy emails at the end of the trial.

19.5 Certificate of Confidentiality from the NIH

Please check one option below. For more information, click **here**.

- ( ) This study IS funded by the NIH or CDC; therefore, the study automatically has a Certificate of Confidentiality
- (•) This study is NOT funded by the NIH or CDC

Please select one of the following options:

- (•) A Certificate of Confidentiality is NOT needed, because the identifiable study data does not include

potentially damaging information that needs protection from compelled disclosure

- ○ A Certificate of Confidentiality IS needed to protect identifiable study information from compelled disclosure - the PI is responsible for applying to NIH for the Certificate of Confidentiality after IRB conditional approval

Note: Consent forms must be consistent with the above information. For consent form templates that show confidentiality language, click **here**.

20.0 HIPAA Compliance

20.1 Do you need access to protected health information (PHI) without signed authorization from the individual whose information you need?

- ○ Yes
- ◉ No

21.0 Cost/Payment

21.1 Cost

Please describe the costs of research visits and procedures and who (the sponsor, the subject's insurance, or the subject) will be responsible for these costs. If any research costs will be billable to insurance, the costs to the subjects will include deductibles and co-payments. Costs of travel and/or parking should be included if the study requires additional visits beyond what would be required for standard clinical care.

There will be no cost to the subject for participation in this project.

21.2 Payment

Will the subject be reimbursed for participating in this study? (e.g. money, gift certificates, coupons, etc.)

- ◉ Yes
- ○ No

Describe the frequency, method, timing, and amount of payment. Please include the total amount paid to subjects and the plan to prorate payment for subjects who withdraw early from the study.

Participants will receive $25 for completing their pre-intervention questionnaires, $50 for completing their post-intervention questionnaires, and $75 for completing their 6-month follow-up questionnaires (total=$150).

22.0 Retention of Samples or Data

22.1 Introduction

The purpose of this section is to obtain information about studies where investigators will be

- Including a plan for retaining samples/data in an initial submission
- Adding a plan for retaining samples/data to an existing approved study
- At the completion of a research project, changing the study to a repository so that the samples /data obtained for the research can be stored for future use
- Collecting samples/data as part of this study to be added to a repository elsewhere (e.g. another research site, a national database, another investigator's repository, etc.)

Do not complete this section if you will ONLY be using data OBTAINED from another source such as a repository to answer the study question in this submission. If that's the case, please change your selection on the "Navigation Menu" for "Samples or Data Retained for Extra Use" to "No".

22.2 Purpose

Provide an overall description of the purpose of retaining the samples/data and how retained samples/data will be used. *For consent form templates that contain language about retention of samples or data, click **here**.*

The overall purpose of this study is to assess two web based insomnia treatments. During the study data will be collected from Black Women's Health Study participants. After the trial has been completed, the data obtained throughout this study may be used for future analyses in the main BWHS study (H-31535). In addition, the funder, PCORI, encourages use of the data by other qualified investigators, in order to check the results and to conduct further analyses of deidentified data.

22.3 Please indicate the source of the samples/data to be retained (check all that apply)

- [x] Samples/data obtained directly from subjects
- [ ] Samples/data from other sources

22.5 Provide the specific data points that will be retained (or attach it as a separate document). If samples will be retained, specify which data elements will be attached to the samples.

Data points will be coded answers from questions asked during the trial: sleep diaries, ISI test scores, questionnaire responses (e.g., sleep attitudes).

22.6 Will data that contain genetic information be retained?

- ( ) Yes (if yes, must complete the Genetics section of this application)
- (•) No

22.7 Stewardship

Indicate who (individual or organization) is responsible for maintaining the retained samples /data. If a repository is being established by the PI of this protocol, please indicate if he/she is delegating the task of management of the repository to another staff member or entity (e.g. BU Data Coordinating Center).

The PI of the Black Women's Health Study will be responsible for maintaining the repository. The PI will be assisted by other BWHS investigators and staff at the Slone Epidemiology Center. Under the direction of the BWHS PIs, IT staff maintain repositories of data supplied by participants through questionnaires and from medical records, cancer registries, and other sources. The study also maintains repositories of samples that participants have provided, such as blood samples.

22.8 Release of samples/data

Please indicate the plans for releasing of samples/data

- [x] Data/specimens will/may be released to other investigators for their own separate study activities
- [ ] Data /specimens will be released to national databases for use by multiple investigators (e.g. dbGAP)
- [ ] Data/specimens will/may be released to commercial entities

(Note: The uses or potential uses of the data/specimens must be included in the consent form and the HIPAA Authorization (if applicable))

Please describe what information will be required to request a release, and how and by whom release requests will be reviewed to ensure that the use is consistent with the consent provided by the subjects and that confidentiality protections are adequate.

Outside investigators may apply to the BWHS for use of data collected by the BWHS. These requests are reviewed by the BWHS PIs and the BWHS investigators closest to the subject matter of the request. The NCI, which supports the infrastructure of the BWHS, encourages data sharing with responsible outside investigators. If the study proposed by the outside investigator is judged to be of scientific merit, and if the data needed can be supplied only by the BWHS, then anonymous data will be provided to the outside investigator with data use agreements that protect the integrity of the data and require return of the data or destroying it when the project is completed.

22.9 Confidentiality

Indicate the protections that will be put into place to protect subjects' privacy and confidentiality of their data

- ○ All samples/data will be de-identified at the time they are retained
- ◉ All subject identifiers will remain at BMC/BU Medical Campus. Only coded samples/data will be given to other investigators/entities - BMC/BU Medical Campus investigators will maintain the master-code/key and will never release it to outsiders
- ○ Subject identifiers will be released to outside entities (e.g. NCI repositories) with subjects specific consent to do so
- ○ Access to subject identifiers will be limited to certain people (specify below)
- ○ Other (specify below)

23.0 Study Attachments

23.1 Attach here any remaining study documents that you have not attached in previous sections.

Version	Sponsor Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
1.0		Draft - Sleep Education Website	Manual		Approved		43.58 KB
1.0		Instructions to Link to SHUTi Demo	Data Collection Form		Reviewed		1.38 MB
1.0		SHUTi Program overview	Manual		Reviewed		3.85 MB
1.0		PCORI Grant	Grant				1.20 MB
1.1		Sample Email Communication for Insomnia Study	Letter		Approved		16.75 KB
2.1		SHUTi Program - Vignette	Manual		Reviewed		175.18 KB
1.2		2015 BWHS Q with ISI sleep questions (Qs 2-5)	Not Defined		Reviewed		53.19 KB
1.1		Sleep Hygiene Brochure	Materials handed out to subjects		Approved and Stamped		197.55 KB

1.1		SHUTi Sleep Diary	Survey		Approved and Stamped		362.80 KB