## Informed Consent Agreement

**Please read this consent agreement carefully before you decide to participate in the study.**

**Purpose of the research study:**

Our research team developed and tested an online insomnia treatment called SHUTi (Sleep Healthy Using the Internet). It was tested and was successful in helping adults under age 65. It was not customized for older adults. The National Institute on Aging (of the NIH) provided funding to make changes to SHUTi to address the special needs of adults age 55 and older. We call this new version of the program SHUTi OASIS (SHUTi for Older Adult Sufferers of Insomnia and Sleeplessness). The purpose of the study is to see if those changes made to SHUTi will bring sleep improvements to older adults with insomnia compared to a patient education website.

**What you will do in the study:** This entire study from this moment to the final thing you do will last slightly more than one year (64 weeks).

**Study Schedule**

| Step | Weeks | Study Phase | What will I do? | Time required? |
|---|---|---|---|---|
| 1 | 0 | Screening | Complete Interest Form<br>Review/Sign Consent Form<br>Phone Interview | <br><br>90 minutes |
| 2 | 2 | Pre Assessment | Complete Questionnaire<br>Enter 10 sleep diaries in 14 days | 60 minutes<br>2 minutes |
| 3 | 3-12 | Intervention | Use assigned website | |
| 4 | 12 | Post-Assessment 9 weeks | Complete Questionnaire<br>Enter 10 sleep diaries in 14 days | 60 minutes<br>2 minutes |
| 5 | 38 | Post-Assessment 6 months | Complete Questionnaire<br>Enter 10 sleep diaries in 14 days | 60 minutes<br>2 minutes |
| 6 | 64 | Post-Assessment 1 year | Complete Questionnaire<br>Enter 10 sleep diaries in 14 days | 60 minutes<br>2 minutes |

You will be asked to complete an Online Interest Form at www.shutioasis.org. You will answer questions about your sleep and willingness to do the study requirements. You will also provide



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contact information. Submitting the Interest Form does not guarantee that you will be able to participate in the study. It will allow us to save this data and contact you soon to determine if you may be eligible for the study. Your interest form data may be used for reporting purposes. For example, race, gender, and age may be used to describe the types of people who were interested in the study. Your name or other identifying information will not be reported.

If you appear to be eligible for the study, the Study Coordinator will contact you to set up a phone interview. Additional details about the study will be provided during the call. This will typically occur within 48 hours of receipt of the online interest form but may take up to 7 days.

**SCREENING PHONE INTERVIEW:**

- The Study Coordinator will call you at your appointment time.
- We will ask you to identify yourself. We will review the study's requirements. You can discuss any questions or concerns you may have about participating in the study.
- If you agree to participate, you will do the following:
    - We will email you a unique website address to access the online consent form.
    - We will walk through the consent form with you to make sure you are fully informed about the study.
    - You will check the box at the bottom of the electronic version of this form to consent to the study. Click submit.
    - The program will email you a copy of the consent form. We will store the document in our database as well. You must submit this form first before we can ask you any questions.
- Next we will ask you some additional questions about your sleep, general health, and health history. You will also be asked questions about your feelings (e.g., whether you feel anxious, depressed, suicidal, irritable) and lifestyle habits (e.g., alcohol and substance use). In cases of suicide risk, a clinical psychologist on the team may follow-up with you to ask some more questions.
- If you are eligible for the study, you will be sent a Welcome email with instructions for setting your password.
- If you are not eligible for the study, you will be told at that time.

**PRE-ASSESSMENT**

- Using your email and password, you will sign in to the study website.



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- **Questionnaire:** You will complete an online Questionnaire asking about your general health, mental health, sleep habits, and daily life activities.
    - If you have any concerns about the questions, please contact the Study Coordinator.
    - You will receive reminder emails from SHUTi to complete the Questionnaire.
    - After you complete it, press Submit to advance to the Sleep Diary phase.
- **Sleep Diaries:** You will record you sleep online by entering Sleep Diaries every day for two weeks.
    - You must enter at least 10 diaries in 14 days to complete this activity with success.
    - You will receive daily reminder emails to complete the Sleep Diaries.
- After you have completed both, the program automatically advances you to the Intervention study phase. For the next nine (9) weeks, you will use your assigned study website. You can start immediately.

**Intervention (9 weeks):**

You will be randomly assigned (like the flip of a coin) to 1 of 3 study groups. You have an equal chance of being assigned to any group. Neither you nor the researchers can choose your group.

**GROUP 1 - Patient Education Website Group:**

You will use a website with information about insomnia. This includes symptoms, causes and diagnosis, and the natural history of insomnia as well as factors that impact insomnia and treatment strategies. The material is like the other 2 groups but presented in a different way. You may sign in and use the website as often as you want. There are no specific time requirements.

**GROUP 2 – SHUTi OASIS Internet Intervention Website Group:**

You will use a website program designed to provide tailored instructions about how to improve your sleep. The program is made up of six Cores which are like chapters in a book. Cores are completed one at a time in order. Each Core is expected to take 45 to 60 minutes to complete.



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Each Core contains information and exercises designed to help change behaviors and thoughts that can contribute to sleep problems. You will receive automated emails encouraging you to complete tasks. You will be asked to complete weekly to dos and enter daily Sleep Diaries to track your sleep.

We expect it may take you up to one week to complete a Core. After you complete a Core, you will have one week to review and practice what you learned in the Core. Seven days later the next Core will unlock so you can open it to start it. To review and follow the Core recommendations may take you another 30 to 45 minutes.

**GROUP 3 - SHUTi OASIS Internet Intervention Website with Contact/Monitoring Group**:

You will use the same SHUTi OASIS website with similar time requirements.

In addition, we will monitor your progress through the Cores. When it looks like you may be stuck in a Core, we will provide additional help through emails or phone calls. It is possible the extra emails or phone calls may add to your time requirements.

**Post-Assessments at 9-Weeks, 6-Months and 1 Year:**

- **Questionnaire:** At the end of the 9-week intervention, you will complete the Post-Assessment Questionnaire. You will log on and answer questions about your sleep, activities, health, and well-being.
- **Sleep Diaries:** Next you will record your sleep by entering Sleep Diaries online every day for two weeks. You must enter at least 10 diaries in 14 days to complete this activity with success.
- Questionnaire and Sleep Diaries will be completed again at the 6 month and 1 year Post-Assessments.
- You will receive two reminder emails for each Post-Assessment. You will also receive daily diary reminders.
- You can continue using your assigned website between each Post-Assessment.

After 1 Year Post-Assessment:

- You have the option of continuing to use your assigned website until the end of grant funding.



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- Or you have the option of using the other version of the website that you did not use during the trial.

**Risks:**

**Potential risks of this study are minimal and include:**

**Breaches of privacy and/or confidentiality**

- The risk of a violation of privacy and confidentiality is minimal. This is due to the requirements of the privacy plan.

**Emotional discomfort due to:**

- **Internet concerns**
  Some adults may not have concerns doing online activities (going to a website, giving information, etc.). Others may feel less comfortable doing this. Some may have concerns about the confidentiality of their digital data.

- **Answering questions of a personal nature**
  Questions of a sensitive and personal nature will be asked during the study. These include questions about medical history, depression, substance use. This may cause some emotional discomfort.

**Increased tiredness due to restricted time in bed:**

- You may contact us if you have significant concerns. We will provide recommendations based on your situation.
- You will be told to avoid operating a car or other heavy machinery when you feel tired.
- We will instruct you to contact your primary care provider or seek professional help at a sleep clinic as needed.

**Other unexpected risks:**

You may have side effects that we do not expect or know to watch for now. Call the Study Coordinator if you have any symptoms or problems.



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**Benefits:**

We cannot promise that you will be helped by being in this study. You may benefit from being in this study, particularly with improvements in your sleep. Information researchers get from this study may help others in the future.

**Confidentiality:**

The information that you give in the study will be handled confidentially. Your information will be assigned a code number. Your code number is not tied to your identity in any way. Our system uses two servers. One private server is configured behind the firewall to store secured data. Here is where the list connecting your name to this code will be stored. The data is password protected. Data access is limited to authorized research personnel. Only individuals who are onsite can connect to this server. A second server maintains the front-end web system so that you can access the system. The only identifying information that is stored in the application is your email address. When the study is completed and the data have been analyzed, the list will be destroyed. Your name will not be used in any published paper.

Banks and shopping websites transfer credit card information online in an encrypted format. This format is called secure hypertext transfer protocol. You may have noticed the 'https' at the beginning of a secure website address. SHUTi OASIS uses https to provide strong security for data transfer to and from our website. The security of your computer may limit data privacy.

The only exceptions to confidentiality are if we learn of possible elder abuse or neglect or danger to self or others. In these cases, confidentiality would be limited due to mandated reporting requirements (e.g., to report the information to the proper authority).

**Voluntary participation:**

Your participation in the study is completely voluntary. You do not have to be in this study to be treated for your condition. You can get the usual treatment even if you choose not to be in this study. The usual treatment would include a visit with your doctor, who may recommend a medication or an appointment with a sleep specialist.



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**Right to withdraw from the study:**

You have the right to withdraw from the study at any time without penalty.

**How to withdraw from the study:**

If you want to withdraw from the study, please let us know right away by contacting one of the Study Coordinators, Jill Glazer at jvg3ab@virginia.edu or Kirsten MacDonnell at kem6e@virginia.edu. There is no penalty for withdrawing. Payment will be prorated based on the number of post-assessments you complete. If you would like to withdraw after your materials have been submitted, please contact Jill or Kirsten.

**Payment:**

**You will be paid up to $200 in gift cards for finishing this study.** The gift cards will be sent about a week after you complete each Post-Assessment. This means you have completed both the questionnaire and 2 weeks of sleep diaries.

- $50 gift card after the 9-week Post-Assessment
- $50 gift card after the Post-Assessment at 6 months
- $100 gift card after the Post-Assessment at 1 year

All payments will be sent via email. We are required to collect your Social Security Number (SSN) before paying you. You will not be paid if decline to provide your SSN. You will not be paid if you decide not to finish this study. However, if the study leader decides you should not continue, but you met full criteria and completed the necessary steps in the timeline presented, you will be paid the full amount for the study.

**If you have questions about the study, contact:**
**Principal Investigator: Karen Ingersoll, PhD**
Psychiatry and Neurobehavioral Sciences, Box 801075
University of Virginia, Charlottesville, VA 22903
Telephone: (434)982-5960
Email: kes7a@virginia.edu



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**Study Coordinators:**


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| **Jill Glazer**<br>Psychiatry and Neurobehavioral Sciences, Box 801075<br>University of Virginia, Charlottesville, VA 22903<br>Telephone: (434) 982-5972<br>Email: jvg3ab@virginia.edu | **Kirsten MacDonnell**<br>Psychiatry and Neurobehavioral Sciences, Box 801075<br>University of Virginia, Charlottesville, VA 22903<br>Telephone: (434) 982-5947<br>Email: kem6e@virginia.edu |


**To obtain more information about the study, ask questions about the research procedures, express concerns about your participation, or report illness, injury, or other problems, please contact:**

Tonya R. Moon, Ph.D.
Chair, Institutional Review Board for the Social and Behavioral Sciences
One Morton Dr Suite 500
University of Virginia, P.O. Box 800392
Charlottesville, VA 22908-0392
Telephone: (434) 924-5999
Email: irbsbshelp@virginia.edu
Website: www.virginia.edu/vpr/irb/sbs

**Agreement:**

I agree to participate in the research study described above.

**Type your name here: <first last name>**

☐ Sign by checking the box

**Date: _____<time/date stamp>**

You will get a copy of this consent form emailed back to you.



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