Are you participating in any other research studies? _____ Yes _____No

CONSENT FORM

FOR QUESTIONS ABOUT THE STUDY, CONTACT: Rachel Manber, 401 Quarry Rd. Stanford, CA 94305; Phone [redacted].

PURPOSE OF RESEARCH

The purpose of the RESTING study is to learn more about ways to provide cognitive behavioral therapy (CBT) for insomnia among middle age and older adults. Cognitive Behavioral Therapy (CBT) is a type of counseling to help you improve your sleep habits and think in a healthy way about your sleep. CBTI is based on the science of sleep regulation. The efficacy of CBTI has been demonstrated in multiple research studies. CBTI consists of multiple treatment components that help patients change thoughts (cognitive components) and behaviors (behavioral components) that interfere with healthy sleep. Patients learn about sleep regulation, factors that influence quantity and quality of sleep, and specific techniques to optimize sleep. You were selected as a possible participant in this study because you are 50 year or older and have an existing diagnosis of insomnia or because you expressed interest in the study. This research study is looking for 240 individuals to participate in the study.

VOLUNTARY PARTICIPATION

Your participation in this study is entirely voluntary. Your decision not to participate will not have any negative effect on you or your medical care. If you can decide to participate now but later decide to stop participation or withdraw your consent there will be no loss of any benefits or medical care to which you are entitled. If you decide to terminate your participation in this study, you should notify the study coordinators at [redacted] or the protocol director, Dr. Rachel Manber at [redacted].

PROCEDURES

If you decide to enroll this study, your participation will begin with a screening visit during, which you will be asked to answer questions that will allow us to determine if you meet study entry criteria. You will be asked general questions about yourself such as age and ethnicity and about your sleep and mood as well as other questions about your general health and the Folstein Mini-Mental status exam (or its phone version). This screening visit will take between 60 and 90 minutes.

If you are determined to be eligible for the study, you will enter the baseline part of the study, during which you will complete daily sleep diary and wear an *Actiwatch*™for two weeks. This is a watch size device to be worn on your wrist. It contains a movement

sensor that records even very slight movements of your wrist. The information is used to derive data on your sleep during the night and your activity level throughout the day.

You will then receive Cognitive Behavioral Therapy for insomnia. You will be assigned by chance to group A or group B. You will have a 50-50 chance of being assigned to either groups.

If you are assigned to group A you will receive the treatment online using a program called Sleepio™. We will provide you a voucher code that will give you access to the program for 12 months.

If you are assigned to group B you will also receive treatment for 12 months but you will begin treatment either with the Sleepio™ program or with a therapist. This will be determined based on a study specific decision checklist. If you are assigned to group B and begin treatment with Sleepio™ but after 8 weeks we determine that you have not received sufficient benefit, then you will continue treatment for the remaining 10 months with a therapist; otherwise you will instead continue to have access to the online program for the next 10 months.

Regardless of which group you are assigned to, you will be asked to:

1. Complete the study screening
2. Complete Study Assessment that will occur at baseline and at 2, 4, 6, 9, & 12 months thereafter. At each assessment you will complete questionnaires (this will take approximately 30-45 minutes on most assessments; but at the initial assessment questionnaire completion will be longer (approximately one hour). You will also have a 20 minute interview at each post-baseline assessment. In addition, for two weeks you will wear an *Actiwatch*™ and complete a sleep diary daily.
3. Engage in treatment. Your therapist or the online program will also ask you to monitor your sleep daily using a sleep diary.
4. If you are one of a quarter of participants selected by chance, you will also participate in two open ended interview with a study research assistant that will ask questions about your experience with insomnia and its treatment. These interviews will take place at baseline, before you start study treatments and approximately a year later. These interviews will be audiotaped for later analysis.

   The recordings will be reviewed only by authorized study staff. The audio recordings will not be shared with anyone outside the study.

   I give consent to be audio-recorded during these study interviews: ☐ Yes ☐ No

DURATION OF STUDY INVOLVEMENT

Your participation in this study will last between about 13 and 14 months. This period includes up to a month of screening and baseline, 12 months of treatment and a final study visit that will take place up to a month after the year of treatment.

MORE ABOUT THE SLEEPIO™ PROGRM

After you gain access to the Sleepio™ program you will be able to follow the program on your computer. If you so choose, you can additionally take advantage of a few optional features, such as downloading a free Sleepio™ app to your mobile device and participating in online discussion groups that are open to all users of the program, including individuals who are not study participants.

MORE ABOUT THE THERAPIST LEAD TREATMENT

When you receive the insomnia therapy with a therapist you will have up to 12 therapy sessions to be completed within 10 to 12 months, depending on whether your first step of treatment was with the Sleepio™ program or with a therapist. You can attend some or all of these sessions by going to a clinician's office or by connecting to a secure videoconference call. These video session will not be recorded.

PARTICIPANT RESPONSIBILITIES

As a participant, your responsibilities include:

- Ask questions as you think of them.
- Follow the instructions of the Protocol Director and study staff.
- Complete your questionnaires and answer interviewer's questions.
- Complete sleep diaries and wear Actiwatch™ daily for two weeks at each Study Assessment time point. You must return the Actiwatch™ unit at the end of the two weeks.
- Engage in study treatment you are assigned (the online program Sleepio™ or therapy sessions)
- Tell the Protocol Director or research study staff
    - If you experience worsening of daytime sleepiness, so that treatment may be altered if necessary.
    - If you are experiencing new symptoms so that your doctor can be notified and/or a referral for treatment can be made, if necessary. You will be financially responsible for this treatment.
    - If you are hospitalized for any reason

  - All medicines that other doctors may have prescribed for you to take, as well as medications you take that do not require prescription.
- Avoid the use of other treatments for insomnia without informing the investigators in this study. This includes psychotherapy, prescription medications as well as over-the-counter (non-prescription) medications (including diphenhydramine, also known as Benadryl and often found in pm cold remedies). This requirement also extends to herbs, such as valerian root and kava kava, and hormones, such as melatonin.
- If you choose to discontinue medications for sleep you should do so gradually under the supervision of the study physician or your personal physician.
- Avoid illegal drugs during your participation in this study.
- Tell research staff if you change your mind about staying in the study.
- While participating in this research study, you should not take part in any other research project without approval from the Protocol Directors of each study. This is to protect you from possible injury from such things as being too sleepy during the day or other similar hazards.

You have the right to refuse to answer particular questions.

WITHDRAWAL FROM STUDY

If you first agree to participate and then you change your mind, you are free to discontinue your participation at any time. You are also free to withdraw (revoke) your consent at any time. Your decision will not affect your ability to receive medical care for your disease and you will not lose any benefits to which you would otherwise be entitled.

If you decide to withdraw your consent to participate in this study, you should notify Dr. Rachel Manber at [redacted].

- If you withdraw from the study
  - You should attend a termination of study visit (in person or by phone) and meet with the treatment provider (in person or by phone) to discuss your continued treatment outside the study.
  - You must return the actiwatch

- The Protocol Director may also withdraw you from the study and the study treatments may be stopped, without your consent, for one or more of the following reasons:
  - Failure to follow the instructions of the Protocol Director and study staff
  - Failure to fulfill study requirements (i.e., if we are unable to reach you to coordinate study visits)

- The Protocol Director decides that continuing your participation could be harmful to you
- You need treatment not allowed in the study
- The study is cancelled
- Other administrative reasons.
- Unanticipated circumstances.

POSSIBLE RISKS, DISCOMFORTS, AND INCONVENIENCES

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. If you have questions, please ask. The risks associated with this study are minimal.

- Some of the questions in the interviews and questionnaires are of a personal nature and could possibly be emotionally upsetting. You have the right to refuse answering any question.
- Occasionally, you may become upset about matters discussed in therapy.
- Some individuals experience increased daytime sleepiness in the early stages of one of the sleep therapies being provided in this study. If you experience this side effect you may need to limit activities that require optimal alertness, including driving a motor vehicle. Typically if sleepiness emerges as a side effect of treatment it lasts only for a few weeks and disappears as treatment progresses. You should alert your treatment provider and/or the study coordinator should you experience an increase in sleepiness.
- Some individuals may experience increase in anxiety and/or insomnia during treatment
- If you choose to discontinue medications for sleep you might experience worsening of sleep. To minimize this, you should do so very gradually.
- Some individuals are not comfortable wearing the Actiwatch™. We can provide a soft gauze that can be used the cover the wrist band to minimize discomfort.
- Travel to attend study visits and study treatment may inconvenience you. We will offer you the opportunity to have some therapy sessions by video conferencing to minimize travel related burden.
- Study treatment or procedures may involve risks that are currently unforeseeable.

POTENTIAL BENEFITS

The benefits which may reasonably be expected to result from this study include improvement in your sleep and associated daytime impairment. Your participation may provide the investigators valuable data, which may lead to advances in the treatment of individual with insomnia. Your participation and your time, therefore, may

ultimately lead to broader benefits for society and for people who experience problems sleeping. **We cannot and do not guarantee or promise that you will receive any benefits from this study. Your decision whether or not to participate in this study will not affect your medical care.**

ALTERNATIVES

The cognitive behavioral therapy that you will be receiving as part of your participation in the study is a standard treatment for insomnia. Another standard treatment for insomnia that is not provided in this study is taking a sleep medication. Your participation does not preclude your engagement in any treatment for insomnia outside the study (but please tell us about it). In addition, you may choose not to participate in this research study.

PARTICIPANT'S RIGHTS

You should not feel obligated to agree to participate. Your questions should be answered clearly and to your satisfaction. If you decide not to participate, tell the Protocol Director or the study coordinator.

You will be told of any important new information that is learned during the course of this research study, which might affect your condition or your willingness to continue participation in this study.

ClinicalTrials.gov

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

CONFIDENTIALITY

In some cases, we will contact the primary care physician you identify in order to obtain clearance for your participation in the study or to notify them about problems we identified that might need their immediate attention. For example, we might want to contact your doctor if you have severe depression or if we suspect you might have an untreated sleep disorder, other than insomnia.

Please select one of the options below:

☐ Yes. I give my permission for the study to contact my doctor. Please provide the name of your doctor _____

☐ No. I do not give my permission for the study to contact my doctor. I understand that this may preclude my participation in this study.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed except as authorized by you or as required by law**.** However, there is always some risk that even de-identified information might be re-identified.

If information is revealed about child abuse or neglect, elder or dependent abuse or neglect, or potentially dangerous future behavior to others or yourself, the law requires that this information be reported to the proper authorities.

Patient information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

You are expected to read and understand privacy policies of the mobile devices you use as well as those of Big Health Inc. (the company producing the Sleepio™ program), since it will independently collect information about you (e.g., name, email). To help maintain your confidentiality, we will not share your name or any other information that can be used to identify you, with the Sleepio™ Company. We will track how you use the Sleepio™ program using only the voucher code that gives you access to the program.

Authorization to Use Your Health Information for Research Purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

What is the purpose of this research study and how will my health information be utilized in the study?
We are interested in learning more about the treatment of insomnia in patients who are 50 years or older using cognitive behavioral therapy (CBT) for insomnia as a web (internet) based program or as a therapist lead treatment. Health information that you provide will be analyzed along with information provided by other study participants and the summary of the analyses, but never your name, will be included in scientific publications and presentations.

Do I have to sign this authorization form?
You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study, including receiving any research-related treatment for insomnia. Signing the form is not a condition for receiving any medical care outside the study.

If I sign, can I revoke it or withdraw from the research later?
If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows us to continue using your information (e.g., necessary to maintain integrity of research). If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you must write to: Dr. Rachel Manber, at 401 Quarry Road, Stanford, CA 94305.

What Personal Information Will Be Obtained, Used or Disclosed?

Your health information related to this study may be used or disclosed in connection with this research study, including, but not limited to, information you provide during the course of the study by responding to questionnaires, forms, sleep diary, and interviews; data from the actiwatch device, and information about your use of the online treatment program (the Sleepio voucher code(s) you receive, and information about your use of the Sleepio program). Data about your insomnia-related care will be drawn from your medical records. These data will be anonymized and pooled to help the researchers understand cost associated with insomnia. The following identifying information will also be used or disclosed: names, telephone numbers, electronic and physical mailing addresses, date of birth, study visit dates, and social security numbers.

Who May Use or Disclose the Information?

The following parties are authorized to use and/or disclose your health information in connection with this research study:

- The Protocol Director (Rachel Manber, PhD)
- BigHealth Inc (which will receive only the sleepio voucher codes)
- The Stanford University Administrative Panel on Human Subjects in Medical Research and any other unit of Stanford University as necessary

Who May Receive or Use the Information?

The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- The Office for Human Research Protections in the U.S. Department of Health and Human Services
- The National Institute of Health
- Members of the study's Data Safety and Monitoring Board

Your information may be re-disclosed by the recipients described above, if they are not required by law to protect the privacy of the information.

When will my authorization expire?
Your authorization for the use and/or disclosure of your health information will end on December 31, 2030 or when the research project ends, whichever is earlier.

Will access to my medical record be limited during the study?
To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it was used to make a medical or billing decision about you (e.g., if included in your official medical record).

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

FINANCIAL CONSIDERATIONS

Payment

The Sleepio™ program will be provided to you at no charge. If you were to purchase the Sleepio™ program on your own outside of this research project it costs $400.00 for 52 weeks (12 months) of unlimited access.

You will receive payment for expenses and inconveniencies associated with study related activities for a total of up to $220. You will receive payment for the expenses associated with the following study-related activities.

Study Procedure	**Estimated time or effort per activity**	**Reimbursement per occasion**	**Total number of occasions**	**Maximum compensation**
Actigraphy (worn 24 hours per day) for a week while also completing a sleep diary	10 minutes per week	$15 per occasion	6	$90
Questionnaires and interviews after screening	30 min.	$20	6	$120
Interviews (applies only to 25% of participants selected by chance)	15 min.	$5	2	$10
Grand total				**$210-220**

Payments will be in the form of gift cards. You can choose to receive a gift card after each qualifying procedure or accumulate them and receive a card at the end of your participation. Each time you receive a gift card, you will need to sign a receipt. We will make arrangements with you to facilitate this process.

It is important to know that any payment for participation in a study is considered taxable income, regardless of the amount or form of payment, including check, cash, gift card, gift certificate, money order, or non-cash items. Stanford University is required by the Internal Revenue Service to report any payments that exceed $600 per person per year.

Do you anticipate receiving any additional funds from Stanford University this year or next that will exceed $600 in total? ☐ Yes ☐ No

If you marked yes above and would like to receive compensation for study related activities, please provide your social security number in a separate form provided by the study staff.

Please be advised that payments may only be made to U.S. citizens, legal resident aliens, and those who have a work eligible visa.

If you wish not to provide your social security number, you may still participate in the study but will not be able to receive any compensation for study related activities.

Costs

If you participate in this study, the study will pay for those services, supplies, procedures, and care associated with the study that are not a part of your routine medical care. However, there may be additional costs to you. These include basic expenses like transportation and the personal time it will take to come to the study visits. You and/or your health insurance must pay for services, supplies, procedures, and care that are required during this study for routine medical care. **You will also be responsible for any co-payments and/or deductibles as required by your insurance.** Participation in this study is not a substitute for health insurance.

Sponsor

The National Institute of Health is providing financial support for this study.

COMPENSATION for Research-Related Injury

All forms of medical diagnosis and treatment – whether routine or experimental – involve some risk of injury. Despite all precautions, you might develop medical complications from participating in this study. If such complications arise, the Protocol Director and the research study staff will assist you in obtaining appropriate medical treatment. In the event that you have an injury or illness that is directly caused by your participation in this study, reimbursement for all related costs of care first will be sought from your insurer, managed care plan, or other benefits program. **You will be responsible for any associated co-payments or deductibles as required by your insurance.** If costs of care related to such an injury are not covered by your insurer, managed care plan or other benefits program, you may be responsible for these costs. If you are unable to pay for such costs, the Protocol Director will assist you in applying for supplemental benefits and explain how to apply for patient financial assistance from the hospital.

You do not waive any liability rights for personal injury by signing this form.

CONTACT INFORMATION

Questions, Concerns, or Complaints: If you have any questions, concerns or complaints about this research study, its procedures, risks and benefits, or alternative courses of treatment, you should ask the Protocol Director, Dr. Rachel Manber at [redacted].

Injury Notification: If you feel you have been hurt by being a part of this study, please contact the Protocol Director, Dr. Rachel Manber at [redacted].

Independent Contact: If you are not satisfied with how this study is being conducted, or if you have any concerns, complaints, or general questions about the research or your rights as a participant, please contact the Stanford Institutional Review Board (IRB) to speak to someone independent of the research team at (650)-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 1705 El Camino Real, Palo Alto, CA 94306.

Appointment Contact: If you need to change your appointment, please contact [redacted] at [redacted].

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

As a research participant you have the following rights. These rights include but are not limited to the participant's right to:

- be informed of the nature and purpose of the experiment;
- be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized;
- be given a description of any attendant discomforts and risks reasonably to be expected;
- be given an explanation of any benefits to the subject reasonably to be expected, if applicable;
- be given a disclosure of any appropriate alternatives, drugs or devices that might be advantageous to the subject, their relative risks and benefits;
- be informed of the avenues of medical treatment, if any available to the subject after the experiment if complications should arise;
- be given an opportunity to ask questions concerning the experiment or the procedures involved;
- be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation without prejudice;
- be given a copy of the signed and dated consent form; and

- be given the opportunity to decide to consent or not to consent to a medical experiment without the intervention of any element of force, fraud, deceit, duress, coercion or undue influence on the subject's decision.

May we contact you about future studies that may be of interest to you? ☐ Yes ☐ No

Signing your name means you agree to be in this study and that you will receive a copy of this signed and dated consent form.

_____ _____
Signature of Adult Participant Date

_____
Print Name of Adult Participant

_____ _____
Signature of Person Obtaining Consent Date

_____
Print Name of Person Obtaining Consent