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CONSENT TO ACT AS A PARTICIPANT IN A RESEARCH STUDY

TITLE: Pragmatic Trial of Insomnia Treatment in Primary Care (HUSH)

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We are conducting this research study to understand how adults with insomnia and high blood pressure respond to treatments for their insomnia. Insomnia is a sleep disorder characterized by difficulty falling asleep or staying asleep, despite having enough time in bed. People with insomnia often have daytime difficulties as well, such as fatigue, concentration problems, and irritability. Insomnia is also associated with many common health problems, including high blood pressure (hypertension). We are interested in finding out whether new forms of treatment for insomnia can help sleep problems and blood pressure in people who have both insomnia and hypertension. Our research study will use interviews, questionnaires, home blood pressure monitoring, a home sleep apnea test, and one of three approaches to manage your insomnia.

We are inviting you to participate in this research because you have insomnia and high blood pressure. We plan to include 625 individuals who are 18 years of age or older in our research study. We think that you will be eligible for our study because of the answers you gave during the telephone screening interview.

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As part of this study, you will undergo the following research procedures: 1) initial evaluation; 2) insomnia intervention; and 3) follow-up evaluations at 9 weeks, 6, and 12 months.

1. Initial evaluation:

Evaluation interview: One of our trained study staff will ask you very specific questions about your sleep and daytime functioning. This will be done over the phone and will take approximately 20 minutes.

Online questionnaires: You will complete some online questionnaires about your sleep, physical and emotional health, personal characteristics (age, ethnicity, etc.), and computer and internet use. We will give you instructions for completing the questionnaires online, a secure link, and a study ID number and password. The questionnaires take approximately 30 minutes to complete.

In home screening: You will be mailed a blood pressure monitor (BP785 Omron) to use for one week as well as a device for a one-night in-home apnea screening. You will be given a pre-paid mailer to return the home sleep apnea test. The blood pressure monitor will be yours to keep. During the one week that you are monitoring your blood pressure, you will also keep a sleep diary.

A **sleep diary** is a short questionnaire that you complete once daily, after you wake up in the morning. You will be asked about your sleep on the previous night and, your activities from the previous day. It takes less than 5 minutes to complete the sleep diary each day. You will fill out the sleep diary for 7 days on your computer.

Blood pressure monitoring: During the same time that you keep your sleep diary, you will monitor your blood pressure at home. You will be asked to view online instructions on how to use the monitor. You will take your blood pressure once per day, in the morning soon after awakening, or at night, before going to bed. You will enter your blood pressure values into your on-line sleep diary. It will take approximately 5-10 minutes each time you obtain your readings.

Home Sleep Apnea Test: Finally, you will complete a one-night Home Sleep Apnea Test to see if you have sleep apnea. If you are currently being treated for sleep apnea and/or have had a sleep study within the past 12 months, you may be able to skip this step. You will be mailed a Home Sleep Apnea Test device called an ApneaLink. When you wear the ApneaLink you should go to sleep as you normally would and let the ApneaLink record your breathing during the night and turn the device off when you wake up the following morning.

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If the ApneaLink screening shows severe sleep apnea (periods of shallow breathing and/or pauses in breathing), you will be referred for further evaluation and treatment for your sleep apnea, and you will not participate in remainder of the study. If the screening reveals a lesser degree of apnea, you will be referred for follow- up evaluation but can still participate in our study. If the screening does not indicate the presence of significant sleep apnea, you will continue on through the study, as indicated below.

2. Insomnia intervention: After you have completed the initial evaluation, you will be randomly (like a flip of a coin) assigned by a computer program to receive one of three types of intervention.

Brief Behavioral Treatment for Insomnia (BBTI) Intervention: This part of the study involves a behavioral (non-medication) research intervention. If you receive this intervention you will speak with a research "sleep coach" by way of internet videoconference or phone for an initial session, followed by three brief weekly contacts. The first meeting will last about one hour and subsequent contacts will last approximately 15 minutes. They will take place in your home with the use of the internet and/or phone. These sessions will be audio recorded so we can assure the quality and reliability of these sessions. The recordings will be stored in a protected location and will only be identified with your research ID number.

Based on your sleep diary, you will receive recommendations about sleep hours and time in bed. Throughout the four week treatment phase, we will also ask you to complete a brief online sleep wake diary every day at home that will tell us what your actual sleep patterns are.

Internet Cognitive Behavioral Treatment for Insomnia (CBTI) Intervention (SHUTi): CBTI is another non-medication research intervention for insomnia. Traditionally, it involves meeting with a psychologist or other therapist. In this study you would, if you are assigned to this intervention, receive the treatment by way of the internet, using a self-guided, interactive, and web-based program that is tailored to your specific sleep problems. You will receive information about managing your sleep problem using a variety of behavioral changes and other exercises. Each portion of the program includes: review of previous week's homework and sleep diary information; new material; and assignment of homework (treatment strategies for the coming week). Throughout the six week treatment phase, we will also ask you to complete a brief online sleep wake diary every day at home that will be used to tailor your treatment. You will have continued access to the online program for 8 weeks after you have completed it.

Enhanced Usual Care Intervention: If you are assigned to this intervention, you will be asked to view a 20-30 minute animated online video that includes information about sleep and factors that help to regulate it and habits that help and hurt sleep. You and your physician will receive an individualized report summarizing the results of your sleep diary and other online questionnaires. The report will also contain publically-available educational resources

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(websites, books) and contact information for treatment resources. Participants who complete EUC will be provided with the option of receiving (at no cost to them) the Internet Cognitive Behavioral Treatment for Insomnia (CBTI) Intervention (SHUTi) after they complete their 12-month post-treatment evaluation.

3. Post-treatment evaluations: After you complete one of the three interventions described above, we will ask you to once again complete a series of online questionnaires, sleep diaries, and home blood pressure monitoring. These procedures will be the same as those you completed before treatment (online questionnaires, blood pressure monitoring, and sleep diary, for 7 days). We will ask you to complete these evaluations: at 9 weeks, 6 months, and 12 months following your initial evaluation.

There are a number of possible risks, side effects, and discomforts associated with participation in this Research Study.

Completing questionnaires, sleep diaries, and interviews may make you feel uncomfortable. This is an infrequent risk (occurring in 1-10% of participants). If you feel uncomfortable, you may refuse to answer a question or questions.

Receiving Text Reminders may include the risk of breach of confidentiality because your messages may be stored by your cellular service provider. Also any charges that you would normally occur in the course of sending and receiving texts will apply. So if you are charged for the texts you send and receive, you would be charged by your provider for the texts sent from us to you and those you send to us. This is an infrequent risk (occurring in 1-10% of participants).

Home blood pressure monitoring is considered routine clinical practice, and is available to all individuals without a doctor's prescription. Equipment misuse or malfunction could lead to bruising or soreness of the arm **(occurring in 1-10% of participants).**

There are no known risks associated with the **Home Sleep Apnea Testing.**

Risks **of Brief Behavioral Treatment for Insomnia (BBTI) and Internet Cognitive-Behavioral Intervention for Insomnia (SHUTi).** Risks associated with these two methods of treatment may include daytime sleepiness. This increase in sleepiness could be dangerous if you are operating a motor vehicle or other equipment, and may also cause irritability and difficulty getting along with other people. These risks are infrequent (1-10% of participants). Because of these possible risks, we may ask you to limit your driving or not drive at all during some parts of your treatment.

Additional risks of the **Internet Cognitive-Behavioral Intervention for Insomnia (SHUTi)**. This intervention does not provide human support, meaning that you will not talk with a person about the treatment. As a result you may encounter technical difficulties and experience

frustration (1-10% of participants). You may request technical support if needed, but not additional help with the insomnia treatment itself. Because internet-delivered programs do not have the ability to be as flexible or tailored as a clinician might be, it is possible that you may not follow the treatment as accurately and thoroughly as if you were working with a clinician.

We are also requesting your authorization or permission to obtain specific information from your electronic health record (EHR) to determine whether you meet the conditions for participation in this study, and to characterize your current health. This could result in a **loss of confidentiality**. This is an infrequent risk (1-10% of participants). We will reduce the chances of getting inappropriate information by using a special UPMC service called CARe to get only the information we need from your medical record. This includes a list of your health problems, medications, and most recent height, weight, blood pressure and other measurements. Your medical information will be identified only by your research ID number, not by any other identifying information.

Our study is conducted almost entirely by internet. It is possible that some of your other information could also be made known to people outside of the research study, i.e., **loss of confidentiality**. This is an infrequent risk (1-10% of participants). We will reduce this risk by using computer systems that are protected by the University of Pittsburgh and UPMC; that require passwords; and that are accessible only to members of the research team.

If we learn of any new information about study risks that could cause you to change your mind about continuing to participate, we will notify you promptly.

You may not receive any direct benefit from participation in this research study. Your participation in this study will help us to understand how people with insomnia and high blood pressure respond to different approaches to their sleep.

You may choose other treatments or interventions for your insomnia. A variety of self-help books, CDs, and web-sites are also available to help you treat insomnia without medications. These sources may include many of the same strategies that you would receive in CBTI. Psychologists or other therapists in the community can also provide CBTI to you outside of this research study.

None of the procedures you receive during this research study will be billed to you or your health insurance. If you get a bill or believe your health insurance has been billed for something that is part of the study, notify a member of the research team.

You will receive a payment from us for participating in this program of research. You will be compensated a total of up to $100 for completing follow-up assessments in the form of a WePay card, which looks like a typical debit card, and can be used to get cash or for purchases anywhere MasterCard is accepted. Specifically, you will be paid $25 for 9-week and 6-month follow-up assessments and $50 for the 12-month assessment.

If you believe that research procedures have resulted in an injury to you, immediately contact Dr. Buysse or the Study Coordinator (see first page). Emergency medical treatment for injuries solely and directly related to your participation in this research study will be provided to you by the hospitals of UPMC. Your insurance provider may be billed for the costs of this emergency treatment, but none of those costs will be charged directly to you. If your research-related injury requires medical care beyond this emergency treatment, you will be responsible for the costs of this follow-up care. At this time, there is no plan for any additional financial compensation.

To protect your privacy and maintain the confidentiality of information we obtain from you and from your medical records, we will maintain all information about you in a secure location. All paper records that could identify you will be stored in locked file cabinets, and all electronic records will be stored in password-protected files. All records and data will be kept indefinitely. Your identity on these records will be indicated by a case number rather than by your name, and the code linking your name to this number will be maintained separately with very limited access to research team members. Although we will do everything in our power to protect your privacy and the confidentiality of your records, just as with the use of your medical information for health care purposes, we cannot guarantee the confidentiality of your research records. However, **no third party**, including relatives, personal physicians or insurance companies, or other researchers **will have access to your identifiable research information**, with one exception. Authorized representatives from the University of Pittsburgh Research Conduct and Compliance Office may review your data solely for the purpose of monitoring the conduct of this study.

It is possible that we may use the information obtained from this study in other research studies examining sleep and other symptoms in people with insomnia and in good sleepers. Such studies would be conducted on study information that does not identify you. **This information may also be shared with other researchers** here and at other research centers, but those researchers will never be provided with any personal identifiers that would allow them to learn your identity.

Your participation in this research study is completely voluntary. Whether or not you participate in this research study will have no effect on your current or future relationship with the University of Pittsburgh, UPMC, or its affiliated health care providers or health care insurance providers. **If you decide you no longer wish to continue to participate** after you have signed the consent form, you should contact Dr. Buysse or his research colleagues (412.246.6413). Any information obtained from you up to that point will, however, continue to be used by the research team. Your decision to withdraw from this study will have no effect on your current or future relationship with the University of Pittsburgh or with UPMC or its affiliate health care and insurance operations.

If the investigators feel that you cannot complete the study requirements safely, they may withdraw you from the study. Also, you may be withdrawn from the study if you do not complete the required

questionnaires or sleep diaries. Some study participants may also be withdrawn if their insomnia becomes worse during treatment, as judged by the questionnaires and sleep diaries turned in during weekly visits with study staff.

VOLUNTARY CONSENT

The above information has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions, voice concerns or complaints about any aspect of this research study during the course of this study, and that such future questions, concerns, or complaints will be answered by a qualified member of the research team or by Dr. Buysse, at 412.246.6413. At any time I may also contact the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1.866.212.2668) to discuss problems, concerns, and questions; obtain information; offer input or discuss situations in the event that the research team is unavailable. **To indicate my agreement to participate in this research study, and to allow the use and disclosure of my medical record information for the purposes described above, I consent to participate in the study by clicking the "I agree" box and by completing the fields below.** A copy of this consent form will be given to me.

I agree

Full Name: _____ (first, middle initial, last name)
Birthdate: _____/_____/_____ (mm/dd/year)

Answer ONE of questions from drop down box:

What was the name of your first pet?
What was the name of your first grade teacher?
What is the name of your maternal grandmother?
Where did you go on your honeymoon?
What is the middle name of your oldest sibling?
What was the make/model of your first car?