DUKE UNIVERSITY HEALTH SYSTEM

Consent To Participate In A Research Study

Hypertension and Insomnia
IRB #: 00102036

CONCISE SUMMARY

The purpose of this study is to further our understanding of how poor sleep quality contributes to hypertension and increases cardiovascular disease risk.

Participants will undergo 2 blood pressure screenings and complete sleep surveys. Once screening is complete, eligible participants will complete a series of baseline assessments and repeat these assessments 6 weeks later. Next, all participants will receive Cognitive Behavioral Therapy for Insomnia (CBT-I) that will be delivered by a trained therapist at weekly 1-hour sessions, for a total of 6 sessions over 6 weeks. Assessments will then be repeated immediately following the CBT-I treatment intervention, and again 6 months later. Total study duration time is about 9 months.

All 4 assessments include questionnaires, sleep quality monitoring with a small device worn on the wrist, 24-hour ambulatory blood pressure monitoring, ultrasound imaging of blood vessels, and a blood draw. Two assessments will also include ultrasound imaging of the heart and a 24-hour urine collection. Completion of these assessments will take about 2.5 hours at our research facility, followed by 24 hours of wearing the automated monitoring devices.

Benefits include 24-hour monitoring of blood pressure, which is the gold standard of blood pressure measurement, assessments of sleep quality, and CBT-I treatment to improve sleep quality.

This study involves minimal risks with the possibility of minor discomfort and bruising following the blood draw by a trained phlebotomist, and minor discomfort associated with upper-arm cuff inflations during 24-hour ambulatory blood pressure monitoring.

If you are interested in learning more about this study, please continue reading below.

You are being asked to take part in this research study because you have hypertension and insomnia. Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

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A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of Dr. Andrew Sherwood and his research team's salaries will be paid by this grant.

WHO WILL BE MY DOCTOR ON THIS STUDY?
If you decide to participate, Andrew Sherwood, PhD will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

WHY IS THIS STUDY BEING DONE?
The purpose of this study is to further our understanding of how poor sleep quality contributes to hypertension and increases cardiovascular disease risk.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?
Approximately 150 people will take part in this study at Duke. Since not all participants who enroll will qualify, we expect more than 150 people will enroll.

WHAT IS INVOLVED IN THE STUDY?
If you agree to be in this study, you will be asked to sign and date this consent form. You will then be asked to complete a brief physical exam, which includes measuring your height, weight and blood pressure. You will also be asked about your sleep habits and snoring. If your score on this test warrants, you will be asked to wear a device while you sleep in your own home to test for sleep apnea; this device uses a smartphone, either your own or loaned by Duke. Women of child-bearing potential will also undergo a urine pregnancy test, which must be negative for study participation.

If you meet the study eligibility criteria, you will then proceed to the other study assessments. You will have the following tests and procedures:

- Baseline assessment
- 6-week assessment
- Cognitive Behavioral Therapy (6 weekly 1-hour sessions)
- 12-week assessment
- 6-month assessment

All Assessment Testing
The following assessments will be conducted in our research facility in Duke Hospital South on 4 different days (baseline, 6-week, 12-week, 6-month). Each session will last approximately 2.5 hours and include wearing automated monitoring devices for 24 hours. After the 6-week assessment, you will receive the Cognitive Behavioral Therapy intervention. All of these procedures are described below. You will be asked to arrive in the morning, before you have eaten breakfast.

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Blood Pressure Screenings
Your blood pressure will be taken by a staff member at each visit, including the screening visits. After having an automated blood pressure cuff attached to your arm, you will rest quietly in a room for 5 minutes. The blood pressure monitor will automatically take 3 blood pressure readings 2 minutes apart.

Ultrasound and Blood Vessel Elasticity
We will measure the function of your blood vessels by taking ultrasound pictures of the artery in your arm while you lie quietly for about ten minutes. We will also take pictures after a cuff has been inflated on your arm for 5 minutes. The cuff is similar to the kind used while taking your blood pressure, and since it will be inflated for 5 minutes, your arm may feel uncomfortable and may tingle or feel "asleep." This procedure will take about 30 minutes to complete.

At two visits, the elastic properties of your arteries will be assessed by measuring the time it takes for your pulse to reach various points on your body. Your pulse will be recorded by placing sensors comfortably on the skin over the arteries in your neck and upper thigh. This procedure will be performed while you are lying on a bed and will take a total of 15 minutes to complete.

Ultrasound pictures of your heart will be taken at two visits. This procedure takes 15 minutes to complete and involves placement of a sensor against your left chest area.

Blood Work
You will be asked to have blood samples (about 9 teaspoons) drawn to measure your cholesterol and other substances in your blood. Blood sampling will involve the insertion of a small needle into an arm vein. You will be offered a snack after the blood draw.

Movement and Sleep Quality
You will be asked to wear a small watch-like device on your wrist for 8 days. The device will collect information about the amount of movement you are performing each day, as well as how efficiently you are sleeping at night. You will be encouraged to engage in your normal activities while wearing the device.

24-Hour Ambulatory Blood Pressure Monitoring
Your blood pressure will be measured over a 24-hour period with a small portable blood pressure monitor that you will wear as you take part in your normal activities.

24-Hour Urine Collection
You will be asked to collect your urine over a 24-hour period. The full volume of urine will be collected in two separate containers, one for daytime urine and one for nighttime urine. A cooler will be provided

to keep the urine samples cold. These samples are used to collect information about the levels of stress hormones in your body and sodium (salt).

Questionnaires
You will be asked to complete several questionnaires about your feelings and activities. Some of the questions are personal (for example, how do you feel?). You may refuse to answer any question that makes you feel uncomfortable. This information will be kept strictly confidential and you will be identified only by a special code number. The questions should take less than one hour to complete.

Cognitive Behavioral Therapy for Insomnia
After your 6-week assessment, you will receive six 1-hour weekly cognitive behavioral therapy sessions with a trained therapist to help improve your sleep quality. Some of these sessions will be audio-recorded and reviewed by Dr. Sherwood and his staff for quality control.

Session 1: Sleep Education and Introductions to CBT-I and Sleep Diaries. Participants will receive an overview of CBT-I treatment concepts and approach. They will be instructed in establishing realistic treatment goals and the process for keeping weekly sleep diaries.

Session 2: Introduction to Sleep Restriction Therapy and Stimulus Control. Sleep hygiene education will be provided for topics that are relevant to the participant (e.g., the effects of alcohol on sleep). The therapist will introduce the rationale for behavior changes and review the participant's sleep diaries to tailor specific recommendations. An initial "sleep prescription" will be established and participants will be asked to follow this sleep schedule during the upcoming week.

Session 3: Introduction to Relaxation Therapy. Participants will be introduced to Relaxation Therapy. Participants will be asked to practice relaxation strategies, follow their sleep prescription, and continue to track their sleep on diary during the upcoming week.

Sessions 4 and 5: Sleep Prescription Titration. The therapist will review the sleep diary with the participant and modify the sleep prescription, as needed. Participants will be asked to continue using relaxation strategies, follow their sleep prescription, and track their sleep on diary during the upcoming week.

Session 6: Relapse Prevention. The therapist will review the sleep diary with the participant and provide instruction on adjusting their sleep schedule after treatment, as needed. Treatment gains will be reviewed, and the therapist and participant will jointly develop a plan for ensuring that treatment gains are maintained.

Photo
We will obtain information about your health from your medical records. We will also ask your permission to take your photograph. Your photograph will be stored like other confidential medical information. You may decline having your photograph taken and still continue to participate in other parts of the study. The photograph will help research staff remember you and will only be stored in a

password-protected database on a Duke-maintained secure directory with access limited to study personnel.
_____ Yes, I agree to have my photograph taken
_____ No, I do not agree to have my photograph taken

HOW LONG WILL I BE IN THIS STUDY?
The study will last about 9 months. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled.

WHAT ARE THE COSTS?
There will be no additional costs to you as a result of being in this study. All study-related costs associated with your being in this study will be paid by the funding source, the National Institutes of Health. However, routine medical care for your condition (care you would have received whether or not you were in this study) will be charged to you or your insurance company. You may wish to contact your insurance company to discuss this further.

WHAT ABOUT COMPENSATION?
The assessments and the 6-week intervention program are offered to research subjects free of charge. You will be reimbursed up to $300 for your study participation as follows: $200 at 12-week assessment, $100 at 6-month assessment. If you do not qualify for the study, you will be reimbursed $20.

WHAT ARE THE RISKS OF THE STUDY?

Risks of blood draw
Risks associated with drawing blood from your arm include momentary discomfort and/or bruising. Infection, excess bleeding, clotting, or fainting are also possible, although unlikely.

Risks of 24-hour ambulatory blood pressure monitoring
Risks of ambulatory blood pressure monitoring may include discomfort in the arm while the blood pressure cuff is inflated, and more rarely, skin irritation and bruising.

Risks of confidentiality loss
There is the potential risk of loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Some of the questions we will ask you as part of this study may make you feel uncomfortable. You may refuse to answer any of the questions and you may take a break at any time during the study. You may stop your participation in this study at any time.

Risks of mobile app (if sleep apnea test needed)
Information collected by mobile applications or "apps" is subject to their terms of use, which you should read carefully. Many apps make claims that they are very secure, compliant with federal privacy

regulations, and used and tested by other academic centers. However, any mobile app that is downloaded carries potential security risks, and Duke cannot guarantee that these mobile apps are free of risk.

It is recommended that you run a current operating system (OS) on your device, review the privacy/security settings often, and restrict any unnecessary access. These applications may run in the background of your device. Mobile apps may have unanticipated impact on the operations of your device (e.g., battery drainage). If you do not have an unlimited data/text plan, you may incur additional charges. At the conclusion of the study, we will provide you instructions on how to remove the mobile apps from your device.

As with all technology, we ask you to wait until you are in a safe environment, use good judgment and follow prevailing laws. Do not perform study-related activities while you are driving.

Use of Duke loaned devices

If you are loaned a Duke phone for use during this study and you use it for non-study related reasons, this could add your personal information onto the device and potentially result in it being sent to unauthorized persons. The device will be preset with security settings. Please do not alter these during the course of the study. When you return the device at the end of the study, the device will be cleaned to remove any of your personal information. If the device is lost or stolen during the course of the study, please contact the study team immediately.

There may be risks or discomforts that are not yet known.

Reproductive Issues

For women: Although all of the tests or therapies in this study are safe to use during pregnancy or breastfeeding, pregnancy or breastfeeding can themselves affect both sleep quality and blood pressure. Therefore, women who are pregnant, planning a pregnancy, or breastfeeding are not allowed to participate in this study.

If you are a woman who could possibly become pregnant (you have not completed menopause, or you have not had a hysterectomy and/or both tubes and/or both ovaries removed) and you have a partner who is able to father children, a urine pregnancy test will be done at the beginning of the study and must be negative to continue.

You and your partner should use an effective method of contraception for the duration of this study. Effective methods include (a) partner vasectomy, (b) bilateral tubal ligation, (c) intrauterine devices (IUDs), (d) hormonal methods (birth control pills, implants, injections, patches, vaginal rings), and (e) barrier methods (condoms, diaphragms, cervical caps) when used with spermicide. If you are not using one of these methods, your study doctor will discuss options with you, given your medical condition and

your personal preferences. If you do become pregnant during the study, you should inform your study coordinator right away.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there may be direct medical benefits to you, including 24-hour monitoring of your blood pressure, which is the gold standard of blood pressure measurement, assessments of your sleep quality, and CBT-I treatment to improve your sleep.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?
Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, results of your study-related laboratory tests and procedures may be reported to The National Institutes of Health and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include The National Institutes of Health, the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.
As part of this study, you will be asked to have certain tests and/or procedures performed. Results of tests and studies done solely for this research study will **not** be included in your medical record. All audio recordings will be stored on a secure server and will be available only to authorized study personnel as necessary to review the content of the sessions. All audio recordings will be destroyed at the end of the study.

A description of this clinical trial will be available on www.ClinicalTrials.gov, as required by US law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

Certificate of Confidentiality:
The Department of Health and Human Services (HHS) has issued a Certificate of Confidentiality to further protect your privacy. With this Certificate, the investigators may not disclose research information that may identify you in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings, unless you have consented for this use. Research information protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless:

1) there is a law that requires disclosure (such as to report child abuse or communicable diseases but not for legal proceedings);

2) you have consented to the disclosure, including for your medical treatment; or

3) the research information is used for other scientific research, as allowed by federal regulations protecting research subjects.

Disclosure is required, however, for audit or program evaluation requested by the agency that is funding this project.

You should understand that a Confidentiality Certificate does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it. This means that you and your family must also actively protect your own privacy.

Finally, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

Expiration date or event for the retention of records
The study results will be retained in your research record for at least six years after the study is completed. At that time, either the research information not already in your medical record may be destroyed or information identifying you will be removed from such study results at DUHS. Any research information in your medical record will be kept indefinitely.

This information may be further disclosed by the sponsor of this study. If disclosed by the sponsor, the information is no longer covered by federal privacy regulations.

If this information is disclosed to outside reviewers for audit purposes, it may be further disclosed by them and may not be covered by federal privacy regulations.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.
Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?

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You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes unless the data concerns an adverse event (a bad effect) related to the study. If such an adverse event occurs, we may need to review your entire medical record. All data that have already been collected for study purposes, and any new information about an adverse event related to the study, will be sent to the NIH. If you do not sign this consent form, you will continue to receive care, but not as a part of this study.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Andrew Sherwood, Ph.D. in writing and let him know that you are withdrawing from the study. His mailing address is Box 3119, Duke University Medical Center, Durham, NC 27710. At the time of your withdrawal from the study, you will be asked to complete the same procedures that you completed at the baseline assessment.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this study.
Dr. Sherwood may decide to take you off this study if your condition gets worse, if you have serious side effects, or if he determines that it is no longer in your best interest to continue. The sponsor or regulatory agencies may stop this study at any time without your consent. Reasons why this might occur include: if you develop a condition that suggests your safety is at too high a risk; if you are enrolled and it is later determined that you are not eligible according to test results; and/or if you do not follow the instructions of the study staff.

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WHAT ABOUT RESEARCH-RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury. For questions about the study or a research-related injury, contact Dr. Andrew Sherwood at (919) 684-8835 during regular business hours and at (919) 673-6849 after hours and on weekends and holidays.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns or suggestions about the research, contact Dr. Andrew Sherwood at (919) 684-8835 during regular business hours and at (919) 673-6849 after hours and on weekends and holidays.
For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time