University of Pittsburgh

School of Medicine
Department of Medicine - Division of Geriatric Medicine

Kaufmann Medical Building, Suite 500
3471 Fifth Avenue
Pittsburgh, Pennsylvania 15213
412-692-2360
Fax: 412-692-2370

CONSENT TO ACT AS A SUBJECT IN A RESEARCH STUDY

STUDY TITLE: Impact of Behavioral Treatment of Insomnia on Nighttime Urine Production

PRINCIPAL INVESTIGATOR:

Shachi Tyagi, MD, MS
Assistant Professor, Division of Geriatric Medicine
University of Pittsburgh
3471Fifth Avenue
Pittsburgh, Pennsylvania 15213
Telephone: 412-647-1274
Email: tyagis@upmc.edu

CO-INVESTIGATORS:

Kandy Newell, RN
University of Pittsburgh
3471 Fifth Avenue
Pittsburgh, PA 15213
Telephone: 412-647-1271
Email: kln40@pitt.edu

If you have any questions about your rights as a research subject or wish to talk to someone other the research team, please call the University of Pittsburgh Human Subjects Protection Advocate toll-free at 866-212-2668.

SOURCE OF SUPPORT: NIH (National Institute on Aging)

Why is this research being done?

We would like your permission to enroll you in a research study. Its purpose is to improve our understanding of impact of sleep on nighttime urine production among those over the age of 60 and how improving sleep affects nighttime urine production.

If you agree to participate, and are eligible, you may be randomized either to receive a 4-week behavioral sleep intervention with 2 visits to or to receive information to improve sleep with support provided over the phone. You will also be asked to complete research related assessments at home at two different time points—before and after sleep intervention.

Because we are committed to educating the next generation of clinicians and researchers, health sciences students who have received appropriate instruction about privacy and confidentiality of medical information may attend study visits as observers.

Who is being asked to take part in this research study?

People aged 65 years and older who have poor sleep and wake up >2 times a night to void will be asked to participate. The study will enroll 60 participants for the research procedures.

First study visit – Screening/enrollment

This visit at the Continence Research Unit on the 5th floor of Montefiore Hospital will last approximately 2 -3 hours. It consists of the following:

- An introduction to the study, and how you will participate, and we will ask you to sign consent forms.
- Health, sleep and bladder history: Collect information about you, your medical history, particularly your sleep and bladder habits in detail. We also will ask questions to test your mental ability.
- Physical examination: A short physical examination.
- Postvoid residual: We will ask you to empty your bladder then will measure what remains in the bladder by ultrasound.
- Blood test: We will draw blood to test for hemoglobin, kidney function, albumin, and blood tests to check for poorly controlled diabetes or heart failure
- Urinalysis: We will also collect a urine specimen. When asked to void, we will ask you to provide a clean catch specimen which will be tested for any urinary infection and electrolytes in urine.
- 3-day bladder diary: If you qualify to be in the study, we will ask you to keep a record of your sleep and voids for 3 days after you get home.
- Consensus Sleep Diary: We will also ask you to complete is a self-report instrument assessing sleep and wakefulness, which will be completed daily for 7 days. The sleep diary comprises both bedtime and wake time portions.

- Zmachine®: For the duration of the sleep diary, you will be asked to wear Zmachine while sleeping. Zmachine® processes a single channel of spontaneous EEG data from the differential-mastoid (A1-A2) location to determine the sleep stage of the user as wake, light sleep, or deep sleep. The sleep staging output is updated every 30 seconds throughout the recording.
- Actigraphy: The wrist actigraph is a wrist-watch sized device worn on the non-dominant arm for several days or weeks at a time. Each minute, the device records how many arm movements have been made, and stores them in memory. We will use actigraphy to obtain objective measure of the cycle of rest and activity. We will use the Actiwatch2© manufactured by Philips Respironics (Murrysville, PA). Participants will wear the Actiwatch for 7 days concurrently with the completion of 3-day bladder diary.

You will be given an addressed envelope to return Zmachine, actiwatch devices and complete diary back to study personnel. Once we receive the devices and completed bladder-sleep diary, you be randomized either to the 4-week behavioral intervention or sleep-related information only.

Study Intervention

You will be randomly assigned to either of the following groups:

Brief Behavioral Treatment of Insomnia (BBTI)
The behavioral sleep intervention we utilize for our study is BBTI. It was developed locally by the researchers at Western Psychiatry Institute and Clinic. The BBTI consists of a 45- to 60-minute individual intervention session followed by a 30-minute follow-up session 2 weeks later and 20-minute telephone calls after 1 and 3 weeks. BBTI includes sleep education and discussion of homeostatic and circadian mechanisms of human sleep regulation. The intervention will be delivered by our study RN Kandy Newell.

Information Control (IC)
If randomized to the IC group you will be provided written information regarding sleep and circadian rhythm. The content of these publications overlaps substantially with BBTI but without individualized behavioral instructions. Two weeks later, IC participants will receive a 10-minute follow-up telephone call.

Study Follow-up

Post 4-week intervention you will be asked to repeat the in-home sleep and bladder assessments you completed after the first study visit including 3-day bladder diary, the consensus sleep diary, Zmachine, and actigraphy
What are the possible risks, side effects, and discomforts of this research study?
The possible risks of this research study may be due to the blood draws during the first visit.

Blood draws
Blood draws are frequently used for various study procedures. This will be completed by trained staff with ample experience in these procedures. Not more than 10 ml will be drawn for the test

procedures.

Likely risks:

- Pain/bruising at the site
- Lightheadedness/ dizziness

Rare risks:

- Introduction of an infection into the blood stream; minimized by using strictly sterile (germ-free) conditions.
- Fainting during the test.

Breach of confidentiality

Since we store personal information about you, there is a risk of breach of confidentiality. To protect against this, paper-based records are kept in a secure location and are accessible only to personnel involved in the study. Computer-based files will be made available only to personnel involved in the study through the use of access privileges and passwords. Prior to being granted access to any study-related information, personnel will be required to sign statements agreeing to protect the security and confidentiality of such information and adhere to HIPAA (Health Insurance Portability and Accountability Act) guidelines. Whenever feasible, identifiers will be removed from study-related information.

Certificate of Confidentiality

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally-funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or harm to self or others.

What are possible benefits from taking part in this study?

There are no direct benefits to you from taking part in the study. However, you may experience some satisfaction from taking part in a study that may ultimately improve understanding of increased nighttime urine production in the elderly.

If I agree to take part in this research study, will I be told of any new risks that may be found during the course of the study?
You will be promptly notified if any new information, either good or bad, about the procedures we are using develops during the course of this study and might cause you to change your mind about continuing to participate.

Will my insurance provider or I be charged for the costs of any procedures performed as part of this research study?

Neither you nor your third-party insurance provider will be billed for any of the research procedures. The study will pay for all research services and procedures, including laboratory tests, or any study related procedures.

Will I be paid if I take part in this research study?
You will be compensated for taking part in this research study as follows.

- $40 on completion of study visit 1
- $50 on completion of pre-intervention study procedures
- $50 on completion of post-intervention study procedures

Who will pay if I am injured as a result of taking part in this study?
University of Pittsburgh investigators and their associates who provide services at the UPMC recognize the importance of your voluntary participation to their research studies. These individuals and their staffs will make reasonable efforts to minimize, control, and treat any injuries that may arise as a result of this research.
If you believe that you are injured as a result of the research procedures being performed, please contact immediately the Principal Investigator listed on the cover sheet of this form. Emergency medical treatment for injuries solely and directly relating to your participation in this research will be provided to you by hospitals of the UPMC. It is possible that the UPMC may bill your insurance provider for the costs of this emergency treatment, but none of these 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. There is no plan for monetary compensation. You do not, however, waive any legal rights by signing this form.

Who will know about my participation in this research study?

All written and printed records about your involvement in this research study will be stored in a file cabinet in a secure area in the continence research unit. This information will be accessible to the investigators listed on the first page of this form and their research study staff. Computer records will be kept on a password-protected computer in the same suite.

If we publish the results of the study, the publications will not include any information that would make it possible to identify you.

Will research data be placed in the medical record?
We will not access your medical records or place any research related information in your

medical record. During the course of this research study if we find any abnormal results, for example, if you screen positive for severe sleep apnea, you will be notified of the results. We will offer referral for further evaluation and treatment for sleep apnea and you will be advised to follow-up with their primary care providers.

Who will have access to identifiable information related to my participation in this research study?
In addition to the investigators listed on the first page of this authorization (consent) form and their research staff, the following individuals will or may have access to your identifiable medical record information related to your participation in this research study:

- Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable medical record information for the purpose of monitoring the appropriate conduct of this research study.
- Authorized representatives of the UPMC hospitals or other affiliated health care providers may have access to your identifiable medical record information in the event of an emergency.
- If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.
- Authorized representatives of the sponsor of the study, National Institutes of Health/ National Institute of Aging, may review or obtain your identifiable information (which may include identifiable medical record information) for the purpose of monitoring the accuracy and completeness of the research data and for performing required scientific analyses of the research data. While the NIH understands the importance of maintaining the confidentiality of your identifiable medical record information, UPMC and the University of Pittsburgh cannot guarantee the confidentiality of this information after it has been obtained by the NIH.
- Authorized representatives of U.S. Food and Drug Administration and Office for Human Research Protections (OHRP) may review your data.

For how long will the investigators be permitted to use and disclose identifiable information related to my participation in this research study?
The investigators may continue to use and disclose, for the purposes described above, identifiable information (which may include your identifiable medical information) related to your participation in this research study for as long as it may take to complete this research study. Per the University of Pittsburgh policy, we will maintain records for at least 7 years following final publication or reporting of a project.

May I have access to my medical information that results from my participation in this research study?
In accordance with the UPMC Notices of Privacy Practices document that you have been provided, you are permitted access to information (including information resulting from your participation in this research study) contained within your medical records filed with your health care provider.

Is my participation in this research study voluntary?
Your participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above, is completely voluntary. (Note, however, that if you do not provide your consent for the use and disclosure of your identifiable information for the purposes described above, you will not be allowed, in general, to participate in the research study.)
Whether or not you provide your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Whether or not you provide your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.
Your doctor may be involved as an investigator in this research study. As both your doctor and a research investigator, s/he is interested both in your medical care and the conduct of this research study. Before agreeing to participate in this research study, or at any time during your study participation, you may discuss your care with another doctor who is not associated with this research study. You are not under any obligation to participate in any research study offered by your doctor.

May I withdraw, at a future date, my consent for participation in this research study?
You may withdraw, at any time, your consent for participation in this research study, to include the use and disclosure of your identifiable information for the purposes described above. (Note, however, that if you withdraw your consent for the use and disclosure of your identifiable medical record information for the purposes described above, you will also be withdrawn, in general, from further participation in this research study.) Any identifiable research or medical information recorded for, or resulting from, your participation in this research study prior to the date that you formally withdrew your consent may continue to be used and disclosed by the investigators for the purposes described above.
To formally withdraw your consent for participation in this research study you should provide a written and dated notice of this decision to the principal investigator of this research study at the address listed on the first page of this form.
Your decision to withdraw your consent for participation in this research study will have no effect on your current or future relationship with the University of Pittsburgh. Your decision to withdraw your consent for participation in this research study will have no effect on your current or future medical care at a UPMC hospital or affiliated health care provider or your current or future relationship with a health care insurance provider.

If I agree to take part in this research study, can I be removed from the study without my consent?
It is possible that you may be removed from the research study by the researchers for a number of different reasons: for example, if you are unable to complete the bladder-sleep diary.

****

VOLUNTARY CONSENT

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by a qualified individual or by the investigators(s) listed on the first page of this consent document at the telephone number(s) given. I understand that I may always request that my questions, concerns, or complaints be addressed by a listed physician investigator.
I understand that I may 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
By signing this form, I agree to participate in this research study for the purposes described above. A copy of this consent form will be given to me.

_____	_____
Participant's Name (Printed)	Date
_____	_____
Participant's Signature	Time

CERTIFICATION of INFORMED CONSENT

I certify that I have explained the nature and purpose of this research study to the above-named individual(s), and I have discussed the potential benefits and possible risks of study participation. Any questions the individual(s) have about this study have been answered, and we will always be available to address future questions as they arise. I further certify that no research component of this protocol was begun until after this consent form was signed.

_____	_____
Printed Name of Person Obtaining Consent	Role in Research Study
_____	_____
Signature of Person Obtaining Consent	Date

.