Department of Veterans Affairs

RESEARCH CONSENT FORM

Title of Study: Toileting at Night in Older Adults: Light to Maximize Vision, Minimize Insomnia	
Title of Consent (if different from Study Title):	
Principal Investigator: **Jamie M. Zeitzer, Ph.D.**	VAMC: VA Palo Alto HCS

What is this research about?

The purpose of this study is to examine how light affects balance in older individuals at night and whether a specially designed light could enhance balance without increasing alertness.

What is expected of me? (Procedures)

The first part of the study is a screening visit during which we will test your vision, hearing, and memory and give you questionnaires to complete that examine various aspects of your physical and mental wellbeing. This should take about 2 hours to complete.

We will then ask you to keep a regular sleep/wake schedule at home for one-week prior to coming into the Stanford/VA Sleep Lab for an overnight visit. During this week at-home, you will be expected to wake up and go to sleep within 30 minutes of target times. Your compliance will be documented with a sleep log and an actigraph, a small device that you will wear on your wrist that can measure your activity patterns. If you do not keep a regular sleep/wake schedule, you will not be permitted to continue in the study. You will come to the Stanford/VA Sleep Lab on the evening of your overnight stay. Upon entry to the laboratory, we will test your urine and saliva for the presence of illegal drugs and alcohol, respectively. The presence of either will result in your not being able to participate in the study. We will familiarize you with the testing, which includes subjective and objective measures of alertness, measures of vision, and a measure of mobile (walking) balance. We will be monitoring your performance on these tests, as well as monitoring your eye movements and your brain wave activity and muscle activity using electrodes that are taped or glued onto your skin. You will wear these electrodes during sleep as well. You will go to sleep at your habitual bed time and later be woken from sleep to do a testing sequence (including the measures of alertness, vision, and balance) for 15 minutes. During this time of awakening in the night, you will be exposed to one of three lighting regimes – very dim light (barely enough to see by), normal room light, or a special colored light. The light to which you are exposed will be different at each of your three visits, but your three overnight stays in the laboratory will otherwise be the same. After the 15 minute testing session, you will be allowed to sleep until your habitual wake time. Upon awakening, your alertness will be tested and the electrodes removed. You will be provided a hospital cafeteria breakfast and then discharged.

Preceding each of the three overnight stays, you will be expected to keep a regular sleep/wake schedule for one week (total of three weeks). Your total participation time will be no more than 24 days.

What are the possible risks or discomforts?

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. You should talk with Dr. Zeitzer if you have any questions. The following explains the precautions we are taking and the risks involved in these procedures:

- **Saliva sampling.** There are no known risks associated with providing a saliva sample.
- **Urine sampling.** There are no known risks associated with providing a urine sample.
- **Actigraph.** There is the possibility of developing a rash ("contact dermatitis") underneath the actigraph. If this were to occur, the actigraph can be moved to a different location on the wrist and lotion can be applied to the rash. There are no other known risks associated with wearing an actigraph, other than the inconvenience of wearing it.
- **Sleep recording.** There is the possibility of developing a rash ("contact dermatitis") underneath the electrodes attached to your skin. Wearing the electrodes might also be uncomfortable and make it more difficult to sleep. This device is the standard of recording in patient care and has no other known risks associated with using it.
- **Cognitive testing.** There are virtually no risks involved in the cognitive testing and psychosocial measurements other than the anxiety that can be associated with any test. It is possible that you might become tired or frustrated by some of our testing. You may find answering the questionnaires annoying, boring, or repetitive. You may also choose not to answer any specific question.
- **Balance testing.** We are testing mobile (walking) balance during the night when you would otherwise be sleeping. You may feel less confident in your balance and might fear falling. We will have a technician with you during the mobile balance testing to help prevent falls. We will place a tether around your waist and the technician will constantly hold this tether so that if you begin to fall, the technician can help to stabilize your balance and prevent the fall.
- **Vision testing.** There are no known risks associated with the vision testing that we will conduct. We are not using any eye drops that would cause pupil dilation and visual discomfort.
- **Travel.** You will need to travel to our offices for your appointments; for some people, this is an inconvenience.

Will I benefit from the study?
We do not anticipate that you will receive any direct benefit from taking part in this study.

What are my alternatives to being in this study?
Besides not participating, there are no known alternatives to taking part in this study.

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Will I get paid?
You will be paid $75 for each of the three overnight stays in the sleep lab and an additional $75 for completing all three of the overnight stays. You could, therefore, make up to $300 if you complete all aspects of the study. You will not be paid for the at-home portion of the study.

Will I have to pay anything?
You will not have to pay anything to be in this study.

Do I have to be in this study?
Participation in this study is voluntary. A decision not to participate in this study will not result in any penalty or loss of benefits to which you might be entitled.

Can I change my mind later and stop being in this study?
You can withdraw from the study at any time without penalty or loss of benefits to which you might be entitled.

Will my information be protected from the public?
We will keep your name and all the information you tell us in this study confidential as possible. We may publish the results of this study for others to read about, but you will not be identified in any articles about the study by name, social security number, address, telephone number, or any other direct personal identifier. Also, other federal agencies as required, such as the VA Office of Research Oversight and the VA Office of the Inspector General may have access to your information.

Who can I talk to if I have questions about the research, problems related to the study or if I think I've been hurt by being a part of the study?
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 principal investigator, Dr. Jamie Zeitzer (650-493-5000 x62410. You should also contact him at any time if you feel you have been hurt by being a part of this study.

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, and would like to speak someone independent of the research team please contact the Stanford Institutional Review Board (IRB) at 1-650-723-5244 or toll free at 1-866-680-2906. You can also write to the Stanford IRB, Stanford University, 3000 El Camino Real, Five Palo Alto Square, 4th Floor, Palo Alto, CA 94306.

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What are my rights if I take part in this study?

You have the 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.

_____ _____

Signature of Participant Date

_____

Print Name of Participant

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Person Obtaining Consent:

_____ _____

Signature of Person Obtaining Consent Date

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Print Name of Person Obtaining Consent