UNIVERSITY of MARYLAND BALTIMORE

RESEARCH CONSENT FORM AND HIPAA AUTHORIZATION

Protocol Title: *The impact of suvorexant on cognitive function and daytime symptoms among community-dwelling older adults with insomnia: A placebo-controlled, randomized clinical trial using remote monitoring and ecological momentary assessment*

Study No.: HP-00100622

Principal Investigator: Emerson M. Wickwire, PhD., 410-706-4771

Sponsor: Division of Pulmonary and Critical Care/Department of Medicine (including funds from Merck, Sharp, & Dohme Corp)

You are being asked to provide consent to take part in a research study. Taking part is completely voluntary. Research staff can answer any questions you have.

CONCISE SUMMARY:

This study is about sleep and daytime function in older adults. Examples of daytime functions are changes in energy levels, alertness, concentration, and mood. We will compare the impact of suvorexant, an FDA-approved insomnia medication, and placebo on daytime function between people with insomnia. The word 'placebo' refers to a harmless pill with no therapeutic effect. The study will take about six to eight weeks. Once enrolled, you will complete remote assessments. This will take about 90 minutes over 1 or 2 days. The remote assessments include thinking tasks on a computer, self-report surveys, and an interview. You will also complete a home sleep apnea test (HSAT). For 16 days, you will wear an actigraph. An actigraph is worn like a watch. It has a small sensor that tracks motion. For these same 16 days, you will also complete four surveys a day on your smartphone (less than 2 min each). These surveys ask about sleep and how you are feeling.

You will receive up to $500 for completing the study.

Though rare, risks can include mild skin irritation, mild discomfort, mental tiredness from the assessments, loss of confidentiality, and side effects from the study drug. More details about risks are described below.

Participants in the treatment arm may benefit from the effects of the study drug. Direct benefits for participants in the placebo arm are minimal, but participants in the placebo arm of insomnia clinical trials often report improvements in sleep. However, you will get sleep referral information if needed. If you are interested in learning more about this study, please read below.

PURPOSE OF STUDY

The goal of this study is to see how the suvorexant, an FDA-approved insomnia medication, may affect daytime function in older adults with insomnia. Daytime function means how we feel and behave while we are awake. Examples include changes in energy levels, alertness, ability to concentrate, and mood.

Patients with insomnia have trouble falling asleep and/or staying asleep, and daytime complaint(s).

This study will use a mobile app to track sleep and daytime function. During the study, you will complete brief surveys on your mobile device. You will also wear an actigraph. An actigraph is worn on the wrist, like a watch, and works like a Fitbit. Actigraphs have small sensors to detect your movement.

The study will take about six to eight weeks to complete. This includes remote assessments, which will take place over one or two days (about 3 hours total). Next, you will have a home sleep apnea test (HSAT), and you will also complete brief surveys 4 times a day for 16 days. Each survey will take about 2 minutes or less.

You are eligible for this study because you are an older adult with insomnia. You also own a computer and a smartphone. Taking part in the study is completely voluntary. There will be about 50 people in 1 of 2 groups of 25, with a total of 50 people. Sleep groups include insomnias using study drug and those using placebo.

PROCEDURES

Participants will receive the study consent form via email (or via snail mail if requested). After, the informed consent, participants will complete remote assessments. The assessments include an interview, neurocognitive (thinking) tasks, and various questionnaires. Participants will also complete a home sleep apnea test (HSAT). The HSAT is a test to evaluate breathing during sleep. Once, study participation is confirmed participants will be randomized to drug or placebo. Throughout the study participants will wear an actigraph. An actigraph is a wristwatch-like device that detects ambulatory movement, a validated proxy for sleep. Participants will also complete brief surveys four times per day for 16 days while wearing the actigraph. At the end, participants will complete post-treatment assessments that include validated questionnaires and neurocognitive (thinking) tasks. Additional detail is presented below.

REMOTE ASSESSMENTS (Day 0)
Study staff will schedule a time for you to complete the remote assessments. These include:

- an interview (about 60 minutes),
- validated questionnaires (about 60 minutes),
- thinking tasks on a computer (about 15-20minutes),

Computer tasks measure your attention and ability to switch between tasks. To help you complete the computer tasks, study staff will email or text you a link to download the tasks onto your smartphone, laptop, or desktop computer. In the tasks you will be asked to respond to words, shapes, and colors on your screen.

You can complete the remote assessments over one day (about 90 minutes) or two days (about 45 minutes each day). If you complete the remote assessments over two days, the first day will be the consent and interview. The second day will be the questionnaires and thinking tasks. You will use a special research smartphone app for this study. During the remote assessments, you have many breaks to help you stay refreshed. You can also request a break after any task. All study tasks will be remote. This means over the phone or tele-conferencing platforms like Zoom.

HOME SLEEP APNEA TEST (Day 0)
Early in the study, you will complete a Home Sleep Apnea Test (HSAT) to check your breathing during sleep. The HSAT will determine if you have obstructive sleep apnea (OSA). The HSAT device will be mailed to you by a third-party company supporting this study. You will follow instructions on how to use the device. You will return the HSAT device using a pre-paid return mailing envelope. You will have 24-hour support if needed.

ACTIGRAPHY SETUP (About Days1-16)
Once you complete the remote assessments, you will set up your actigraph with study staff. Study staff will review instructions with you over the telephone or a video conference platform like Zoom. You will wear an actigraph on your non-dominant hand for 16 days. We will mail an actigraph to you, along with a pre-paid mailing envelope. Actigraphs are expensive research devices and must be returned. Study staff will remind you when it is time to return the actigraph.

DAILY SURVEY COMPLETION (About Days 1-16)
While you wear the actigraph, you will also complete brief surveys on your mobile phone. The surveys are sent to you 4 times a day for 16 days. Each survey takes less than 2 minutes to complete. Your phone will send you notifications for each survey. At the start of the study, you will choose what time you want surveys to start. Every morning, you will complete a survey that includes a brief sleep diary and questions about how you feel. Next, you will complete three more surveys throughout the day. These surveys also ask about how you feel. These surveys will be given at random times throughout the day, about two hours apart over the next 12 hours. Study staff will be available to answer any questions or give support. Contact information for study staff and technical support will be given to you.

POTENTIAL RISKS/DISCOMFORTS:

If you choose to take part in this study, there is a risk of:
Skin discomfort - You will wear an actigraph during the study. Though rare, you might experience discomfort or skin irritation from wearing the actigraph. If this happens, we will ask you to adjust the band or remove the actigraph and notify study staff. Actigraphy is an accepted standard in sleep research, so this risk is low.

Psychological discomfort – You will complete several research surveys during the remote assessments. Some questions are personal. They involve sensitive topics such as your mood or other mental symptoms. These surveys do not present a greater risk than routine clinical care. These surveys are very common, so this risk is low.

Mental tiredness - You may become mentally tired during the remote assessments. For the assessment days, you will take part in an interview and neurocognitive testing. You will also complete several surveys. Mental tiredness is common when doing these tasks. To lower the risk of tiredness, study staff have included many breaks. You can also request a break at any time between tasks. You may also schedule the remote assessments over two days if you choose (in shorter sessions).

Study drug risks - (The medication booklet lists full information for prescribing this medication.)

Sleepiness during the day

This medication might make you feel less alert and/or less coordinated during the day, which could impact your ability to drive. This risk increases as dosage increases, and you should be very careful or avoid next day driving or activities that require full mental alertness. In research studies, the most common adverse reaction (reported in 5% or more of patients treated with suvorexant and at least twice the placebo rate) with suvorexant was sleepiness.

Nighttime acting out behaviors

This medication might cause you to "sleep-drive" and/or engage in other behaviors while out of bed and not fully awake. This risk increases as dosage increases, with certain medications (use of CNS depressants), and with alcohol.

Depression

This medication might cause depression to worsen or might cause you to have thoughts of harming yourself. This risk increases as dosage increases.

Breathing

This medication might worsen your breathing.

Symptoms of narcolepsy

This medication might cause symptoms of a sleep disorder called narcolepsy, including sleep paralysis (waking up feeling wide awake, but at first unable to move), hypnagogic/hypnopompic hallucinations (seeing things that aren't really there, as you fall asleep or awaken from sleep), and cataplexy-like symptoms (losing control of muscles, especially during periods of strong feelings. This risk increases as dosage increases.

POTENTIAL BENEFITS

Participants in the treatment arm may benefit from the effects of the study drug. Direct benefits for participants in the placebo arm are minimal. If study staff feel it will help you, they will tell you to talk to your doctor. If you ask for contact information for specialty care, study staff will give you contact information for UMMC or UMMC-Midtown provider(s). If needed or requested, you will be given HSAT results. We may recommend you speak with your primary care doctor. If this happens, we will give you a list of possible issues to discuss.

ALTERNATIVES TO PARTICIPATION

Your alternative to participating is to not take part. If you choose not to take part, your healthcare at University of Maryland, Baltimore or the University of Maryland Medical Center will not be affected.

COSTS TO PARTICIPANTS

There will be no fee to enroll in the study. However, you or your insurance will be billed for costs of medical care that you would have needed or received if you were not in the study.

The sponsor of the study will provide the study drug (suvorexant) and placebo. You or your insurance will not be charged for the study drug or placebo.

PAYMENT TO PARTICIPANTS

The most amount of money you will receive from taking part in this study is $500. You will get:

- $25 for doing the remote assessments
- $25 for doing the HSAT
- $75 for wearing the actigraph
- Up to $200 during the 16-day survey phase
- $175 for completing the study close-out assessments

You will receive a paper check via tracked mail and/or electronic payment.

You may need to report payments you receive for participating in the study as taxable income, which could affect your eligibility to receive certain government benefits (e.g., from the Maryland Supplemental Nutrition Assistance Program (SNAP) and the Maryland Temporary Cash Assistance program (TCA).

If you owe a debt to the State of Maryland or the federal government (e.g., child support, taxes), the amount you receive may be reduced.

CONFIDENTIALITY AND ACCESS TO RECORDS

The researchers will do their best to protect the confidentiality of your study records. You will be given a random 4-digit identification code to use during the study. This will de-identify your data. The list that links your information to the ID number will be in a secure file in a secure server. It can only be seen by authorized study staff.

Study staff will limit access to your personal information, including research study and medical records, to people who have a need to see this information. We cannot promise complete secrecy. The Institutional Review Board (IRB) and other representatives of this organization may see your information.

We may publish data from the study. However, data will only be published in total. You will not be identified by name. People designated from the institutions where the study is taking place will be allowed to see sections of your research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law.

RIGHT TO WITHDRAW

Taking part in this study is voluntary. You do not have to take part in this study. You are free to withdraw your consent at any time. You will not lose any benefits if you refuse to take part in the study or if you stop taking part. If you decide to:

- stop taking part
- if you have questions, concerns, or complaints
- or if you need to report a medical injury related to the research, please contact the investigator Emerson M. Wickwire, PhD at 410-706-4771

If you want to withdraw, you must tell the study personnel. You will be shown how to delete the app from your phone and return the actigraph. There will be no negative consequences (physical, social, economic, legal, or psychological) if you stop taking part in the study.

If you withdraw your consent to take part in this study, it does not cancel your HIPAA Authorization Form. This form allows the use/disclosure of your protected health information. To cancel your HIPAA Authorization Form, please send a letter to the principal investigator.

CAN I BE REMOVED FROM THE RESEARCH?

The principal investigator (PI) can remove you from the research study.
The research team wants you to remain safe and healthy. If you indicate thoughts of self-harm, you will be administratively withdrawn from the study to help connect you with care as quickly as possible. In such instance you would be advised to contact your primary care provider and/or your mental health professional. If you do not have a primary care provider or mental health professional you will be

provided referral information to the Carruthers Clinic/Outpatient Mental Health at the UMMC-Midtown Campus, as well as advised to call or text the national suicide hotline directly at 988 (or 800-273-8255) 911, and/or to report to the nearest emergency room.

Additional possible reasons include failing to follow instructions. You can also be removed if the PI feels the research is no longer in your best interest. The funder can also end the research study early, although this is unlikely. If this happens, the research team will inform you. You will be given a chance to ask questions.

Any participant who is withdrawn will be given a chance to ask questions. Participants who are withdrawn from the study will be compensated for study procedures completed.

OTHER INFORMATION

The principal investigator of this study Emerson Wickwire, PhD, has served as a scientific consultant and been paid professional fees by Merck, Sharp, & Dohme Corp. All outside professional and consulting activities are approved and governed by policies and procedures of the University of Maryland, Baltimore. An approved conflict of interest management plan is in place via the University of Maryland, Baltimore.

STUDY-RELATED INJURY

If you have an injury, promptly seek medical care from any healthcare provider. If you have an emergency, call 911 or go to the nearest emergency room. You should tell the healthcare provider that you have participated in a research study.

If you believe the injury is related to the study, notify the study doctor. UMB, if requested, will assist you to get medical care or referrals.

UMB and/or its affiliated healthcare facilities or healthcare providers will not provide any financial compensation or reimbursement to you for the cost of medical care or other expenses arising from an injury.

In such cases, you or your insurance may be billed for the costs of medical care.

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS

The University of Maryland, Baltimore (UMB) is committed to providing participants in its research studies all rights due to them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in this study. This study has been reviewed and approved by an Institutional Review Board (IRB). The IRB is a group of scientists, physicians, experts, and community representatives. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research studies.

If you have questions, concerns, complaints, or believe you have been harmed through participation in this study as a result of researcher negligence, you can contact members of the IRB or the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland, Baltimore
Institutional Review Board
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign your name below.

_____
Participant's Signature

Date:_____

_____

Investigator or Designee Obtaining Consent Signature

Date:_____

The researchers may conduct future studies related to sleep.

_____I do not authorize that the researchers may contact me to offer participation in future studies related to sleep.

_____I authorize that the researchers may contact me to offer participation in future studies related to sleep.

Health Insurance Portability and Accountability Act (HIPAA)
AUTHORIZATION TO OBTAIN, USE AND DISCLOSE
PROTECTED HEALTH INFORMATION FOR RESEARCH

Name of Study Participant:_____

Date of Birth: _____ **Medical Record Number:** _____

NAME OF THIS RESEARCH STUDY: The impact of suvorexant on cognitive function and daytime symptoms among community-dwelling older adults with insomnia: A placebo-controlled, randomized clinical trial using remote monitoring and ecological momentary assessment

UMB IRB APPROVAL NUMBER: HP-00100622

RESEARCHER'S NAME: EMERSON WICKWIRE PhD
RESEARCHER'S CONTACT INFORMATION: Sleep Section, Division of Pulmonary and Critical Care
University of Maryland School of Medicine
100 N, Greene St, 2nd Floor, Baltimore, MD 21201
(410) 706-4771

This research study will use health information that identifies you. If you agree to participate, this researcher will use just the health information listed below.

THE SPECIFIC HEALTH INFORMATION TO BE USED OR SHARED:

- Sleep study test results and clinic notes (if applicable) for possible diagnosis of Obstructive Sleep Apnea (OSA)

Federal laws require this researcher to protect the privacy of this health information. He will share it only with the people and groups described here.

PEOPLE AND ORGANIZATIONS WHO WILL USE OR SHARE THIS INFORMATION:
The research team.

THIS AUTHORIZATION WILL NOT EXPIRE. BUT YOU CAN REVOKE IT AT ANY TIME.
To revoke this Authorization, send a letter to this researcher stating your decision. He will stop collecting health information about you. This researcher might not allow you to continue in this study. He can use or share health information already gathered.

ADDITIONAL INFORMATION:

- You can refuse to sign this form. If you do not sign it, you cannot participate in this study. This will not affect the care you receive at:
  - University of Maryland Faculty Physicians, Inc. (FPI)
  - University of Maryland Medical System (UMMS)
- It will not cause any loss of benefits to which you are otherwise entitled.
- Sometimes, government agencies such as the Food and Drug Administration or the Department of Social Services request copies of health information. The law may require this researcher, the UMSOM, FPI, or UMMS to give it to them.

- This researcher will take reasonable steps to protect your health information. However, federal protection laws may not apply to people or groups outside the UMSOM, UMB, FPI, or UMMS.
- Except for certain special cases, you have the right to a copy of your health information created during this research study. You may have to wait until the study ends. Ask this researcher how to get a copy of this information from him.

My signature indicates that I authorize the use and sharing of my protected health information for the purposes described above. I also permit my doctors and other health care providers to share my protected health information with this researcher for the purposes described above.

Signature: _____Date: _____

Name (printed) _____

Privacy Questions? Call the UMSOM Privacy Official (410-706-0337) with questions about your rights and protections under privacy rules.

Other Questions? Call the researcher named on this form with any other questions.