Permission to Take Part in a Human Research Study

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Title of research study: Neurofunctional phenotyping to investigate the role of the orexin system at the intersection of opioid use disorder and insomnia among women and men receiving buprenorphine
HM20031777

Investigator: Caitlin E. Martin, MD, MPH

Key Information: The following is a short summary of this study to help you decide whether or not to be a part of this study. More detailed information is listed later on in this form.

Why am I being invited to take part in a research study?

We invite you to take part in a research study because you have sleep problems and have previously been diagnosed with opioid use disorder and take buprenorphine.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of this research is to test whether the medication lemborexant may help people with opioid use disorder sleep better, and also see if it may help people cut down or stop using drugs.

How long will the research last and what will I need to do?

We expect that you will be in this research study for about 4-5 months total, which includes a screening visit, 2-week baseline period, 8 weeks of taking the study medication, a post-medication visit and a 2-week follow-up visit.

In this study, you will take the study medication each night for 8 weeks and be asked to come for a total of 23 study visits. Most of these visits will be very short (15-30 minutes). The longer visits will include the screening visit (about 2-3 hrs), baseline visit (about 2.5 hrs), and the post-medication visit (about 2 hrs). Study visits will include things like taking surveys about your sleep, drug use, and how you've been feeling, completing urine drug testing, checking your vital signs (e.g., blood pressure), and completing interviews with the study staff. You will also be asked to provide two blood samples (one during screening and one after taking the medication). For three two-week periods, we will also ask you to wear a watch to track your sleep at home, and to keep a log of your sleep and wake times.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way being in this study could be bad for me?

We want you to know about a few key risks right now. We will give you more information in the "Detailed Risks" section.

1. Lemborexant (brand name DAYVIGO®) is a medication that has been approved by the U.S. Food and Drug Administration (FDA) to treat insomnia. The use of lemborexant in this study is investigational. An investigational use is one that is not approved by the FDA. There is a risk that you could have side

effects from taking the medication. The most common side effect of lemborexant is somnolence (sleepiness). Other side effects include temporary sleep paralysis, temporary weakness in your legs, complex sleep behaviors like sleep-walking, worsening depression and/or suicidal thoughts.
2. The home sleep apnea test at screening may make you feel uncomfortable sleeping that night and potentially disrupt your sleep.
3. The blood draw may cause pain, bleeding, and/or bruising. You may faint and could develop an infection at the site where blood is drawn.
4. The study questionnaires and interviews ask questions that are sensitive/personal (for example, about drug use, mental health, etc.) and may make you feel uncomfortable.
5. The watch used to track your sleep might feel uncomfortable if you are not used to wearing a watch. There is a very small risk that you could develop a skin rash from wearing the watch.
6. You may feel some discomfort during the ECG when the sticky electrodes are taken off, and the adhesive on the electrode patches may cause mild skin irritation if left on for too long.

Will being in this study help me in any way?

You may or may not receive any direct benefits from taking part in this research. However, possible benefits include better sleep quality. Possible benefits to others include better treatment in the future for people with opioid use disorder and insomnia.

What happens if I do not want to be in this research?

Participation in research is completely voluntary. You can decide to participate, not participate, or discontinue participation at any time without penalty or loss of benefits to which you are otherwise entitled. If you decide not to participate, you will receive the usual care for your opioid use disorder which may include discussing possible medications or behavioral therapies to help you sleep.

Detailed Information: The following is more detailed information about this study in addition to the information listed above.

Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at 804-827-3784.

This research has been reviewed and approved by an Institutional Review Board (“IRB”). You may talk to them at (804) 828-0868 or HRPP@vcu.edu if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research subject.
- You want to get information or provide input about this research.

How many people will be studied?

We expect about 100 people will be in this research study.

What happens if I say yes, I want to be in this research?

Screening: You will visit the VCU CARI research clinic for study eligibility screening. Your medical history will be taken, and a physical exam will be performed. This exam will include measurements of your weight, height, and vital signs (pulse, blood pressure, temperature, pulse oximetry [i.e., the amount of oxygen in your blood]). Blood (about 1-2 tablespoons) and urine samples will be collected for drug screen testing and routine lab tests. Women who could become pregnant will have a urine pregnancy test done, and will review with a study team member what they will use for birth control while in the research study. An alcohol breath or saliva test will also be done. You will have an electrocardiogram (ECG) where sticky pads will be placed on your chest and a machine will trace the electrical activity of your heart. You will also complete surveys on the computer and

face-to-face interviews with the study staff that ask about your current medications, sleep, drug use, health, past life experiences, and mental health. Finally, you will be asked to complete an at-home sleep apnea test which involves wearing a wristband attached to a finger probe and a chest sensor for one night. Completion of the home sleep apnea test will require you to download a free app on your phone and watch a short tutorial.

The screening visit will take about 2-3 hours. These screening tests and procedures are done to see if you are eligible to be in the study. If needed, the screening may be completed over more than one visit. Some surveys may be completed virtually.

Baseline visit 1: You will visit the VCU CARI research clinic where a member of the study team will collect vital signs and a urine drug screen. Women will be asked about their menstrual cycle status, and women who could become pregnant will have a urine pregnancy test done. You will be asked to complete surveys and tasks on the computer and face-to-face interviews with the study staff that will ask about your current medications, drug use, cravings, withdrawal, and mental health. Finally, you will be provided with a special activity watch and a sleep diary. A study team member will explain how to use the watch and sleep diary. You will be asked to wear the watch and complete the sleep diary for 7 days.

The first baseline visit will take about 2.5 hours. If needed, it may be completed over more than one visit. Some surveys may be completed virtually.

Baseline visit 2: You will visit the VCU CARI research clinic to return your watch and sleep diaries. You will review them with a member of the study team and have the opportunity to ask questions. A member of the study team will also collect a urine drug screen and ask about current medications, and see how you are feeling. You will also complete some brief surveys about your opioid craving and withdrawal and menstrual cycle status (females only). You will then be asked to continue wearing the watch and completing the sleep diary for 7 more days.

This second baseline visit will take about 30 minutes.

Baseline visit 3: You will visit the VCU CARI research clinic to return your watch and sleep diaries. You will review them with a member of the study team and have the opportunity to ask questions. A member of the study team will also collect a urine drug screen and ask about current medications, and see how you are feeling. You will also complete some brief surveys about your sleep, opioid craving and withdrawal, and menstrual cycle status (females only).

This final baseline visit will take about 30 minutes.

Medication visits (8 weeks): At your first medication visit you will be assigned to take either lemborexant or placebo pills (i.e., sugar pills). The treatment you get will be chosen by chance, like flipping a coin. This will remain your group assignment during your time in the study. You will have an equal chance of being given either lemborexant or placebo. Neither you nor the study doctor will know which treatment you are getting. However, this information will be available to the investigator if needed in an emergency.

At the time you are given your study drug, you will also receive written and verbal (by a member of our study team) instructions about how you are to take the study drug. They will also be able to answer any questions you may have about the study drug.

Each day during the 8-week medication period, you will be asked to take the study drug before bedtime and submit videos of yourself taking the drug via a secure, free app on your smartphone called Scene Health®. You will also be asked daily about any side effects you are experiencing.

You will also be asked to come to the VCU CARI research clinic twice per week. One of these visits will be a research visit. During the research visit, a study team member will take a urine drug screen, urine pregnancy test and menstrual cycle status (females only), vital signs, ask how you are feeling, and do a weekly pill count of the study medication. You will also complete questionnaires and face-to-face interviews with a member of the study staff regarding current medications, drug use, craving and withdrawal, and sleep. This research visit will take about 30 minutes. On weeks 4 and 8, this research visit will include some additional tasks and surveys on the computer, making the research visit about 1 hr long. The second weekly visit will be to provide an additional urine drug screen, check to see how you're doing, and current medications you're taking. This will be a quick (about 15 min) visit. Additionally, the day after starting the study drug (Day 2), you will come in for a

short safety visit, where a member of the study team will take your vital signs and ask about how you are feeling after taking the medication (about 15 minutes). Some assessments may be completed virtually.

During weeks 3-4 and 7-8 of the medication period, you will be asked to wear the activity watch and complete the sleep diary every day. You will bring the watches and sleep diaries back during your weekly research visits.

You may have additional physical exams and ECGs performed, if the study clinician believes it is in your best interest.

Post-medication: The post-medication visit will occur on the final day of taking the study drug. The week 8 medication study visit may occur at the same time as the post-medication visit. You will come to the VCU CARI research clinic to return your watch and sleep diaries. A member of the study team will also collect a urine drug screen, blood sample (1-2 tablespoons), and vital signs. You will have an additional physical exam and ECG to make sure you are healthy. You will also complete surveys and tasks on the computer and face-to-face interviews with the study staff that ask about your current medications, sleep, drug use, opioid withdrawal and craving, mental health, menstrual cycle status (females only), how you are feeling, how helpful you thought the medication was, and provide constructive feedback about your participation in the study. You will also have a brief (about 10-15 mins) interview with a member of the study staff to talk about your experience in the study.

The post-medication visit will take about 2 hours. If needed, the procedures may be completed over more than one visit. Some assessments may be completed virtually.

Follow-Up: The follow-up visit will occur about 2 weeks after the post-medication visit. You will come to VCU CARI research clinic where a member of the study team will collect a urine drug screen, vital signs, urine pregnancy test and menstrual cycle status (females only). You will also complete surveys and face-to-face interviews with a study staff member that ask about current medications, sleep, drug use, opioid withdrawal and craving, mental health, and how you are feeling.

This follow-up visit will take about 30 mins. Some surveys may be completed virtually.

The following table summarizes each study visit:

Visit name	Estimated duration	Visit Location
Screening	2-3 hrs	VCU CARI Center
Baseline Visit 1	2.5 hrs	VCU CARI Center
Baseline Visit 2	30 mins	VCU CARI Center
Baseline Visit 3	30 mins	VCU CARI Center
Medication Week 1 – Research Visit	30 mins	VCU CARI Center
Medication Week 1 – Day 2 Safety Check-In	15 mins	VCU CARI Center
Medication Week 1 – Urine Drug Screen	15 mins	VCU CARI Center or MOTIVATE clinic
Medication Week 2 – Research Visit	30 mins	VCU CARI Center
Medication Week 2 – Urine Drug Screen	15 mins	VCU CARI Center or MOTIVATE clinic
Medication Week 3 – Research Visit	30 mins	VCU CARI Center
Medication Week 3 – Urine Drug Screen	15 mins	VCU CARI Center or MOTIVATE clinic
Medication Week 4 – Research Visit	1 hr	VCU CARI Center
Medication Week 4 – Urine Drug Screen	15 mins	VCU CARI Center or MOTIVATE clinic

Medication Week 5 – Research Visit	30 mins	VCU CARI Center
Medication Week 5 – Urine Drug Screen	15 mins	VCU CARI Center or MOTIVATE clinic
Medication Week 6 – Research Visit	30 mins	VCU CARI Center
Medication Week 6 – Urine Drug Screen	15 mins	VCU CARI Center or MOTIVATE clinic
Medication Week 7 – Research Visit	30 mins	VCU CARI Center
Medication Week 7 – Urine Drug Screen	15 mins	VCU CARI Center or MOTIVATE clinic
Medication Week 8 – Research Visit	1 hr	VCU CARI Center
Medication Week 8 – Urine Drug Screen	15 mins	VCU CARI Center or MOTIVATE clinic
Post-Medication	2 hrs	VCU CARI Center
Extended Follow-Up	30 mins	VCU CARI Center

This study will not use your samples to sequence all or part of your DNA.

What are my responsibilities if I take part in this research?

If you decide to take part in this study, you will be required to keep your study appointments and complete all study assessments.

What happens if I say yes, but I change my mind later?

You can leave the research at any time; it will not be held against you. Please contact a member of the research team in writing if you would like to stop the study early. If you decide to stop the study early, we will ask you to come in for two follow-up visits to see how you're feeling and complete some surveys.

If you stop being in the research, already collected data may not be removed from the study database. You may be asked whether the investigator can collect data from your routine medical care. If you agree, this data will be handled the same as research data. If you stop the study because you become pregnant, we will follow your health in your medical records through the birth of the child and you will not be asked for additional consent.

Is there any way being in this study could be bad for me? (Detailed Risks)

Possible Risks Associated with Lemborexant

This study drug is approved by the U.S. Food and Drug Administration (FDA) for the treatment of insomnia. The most common side effect of lemborexant is **somnolence (sleepiness or fatigue)**. You should not drink alcohol or take other medications that can make you sleepy (unless your healthcare provider tells you to) while taking lemborexant; it can increase your chances of getting serious side effects. Other side effects include:

- **Temporary inability to move or talk (sleep paralysis)** for up to several minutes while you are going to sleep or waking up
- **Temporary weakness in your legs** that can happen during the day or at night
- **Complex sleep behaviors** such as sleep-walking, sleep-driving, preparing and eating food, making phone calls, having sex or doing other activities while not fully awake that you may not remember the next morning. Call your healthcare provider right away if you experience a complex sleep behavior.
- **Worsening depression and suicidal thoughts**. Call your healthcare provider right away if you have any worsening depression or thoughts of suicide or dying.

- **Decreased awareness and alertness**. The morning after you take lemborexant, your ability to drive safely and think clearly may be decreased. You should not drive, operate heavy machinery, do anything dangerous, or do other activities that require clear thinking if you take lemborexant and have had less than a full night of sleep (at least 7 hours) or if you have taken more lemborexant than prescribed. You may still feel drowsy the next day after taking lemborexant. Do not drive or do other dangerous activities until you feel fully awake.
- **Nightmares, abnormal dreams, or hallucinations** (experience of seeing, hearing, smelling, tasting, or feeling things that are not are not there) while falling asleep or waking up
- **Headaches or palpitations** (feeling that your heart is pounding or racing).

We will check in with you regularly to monitor for any side effects. If you experience any side effects, you can also call the study investigator at the telephone number listed on the first page of this form. If you are having suicidal thoughts or feel in crisis, you can also call or text the National Suicide & Crisis Lifeline at 9-8-8 or 1-800-273-TALK (8255). The Lifeline numbers are answered 24 hours a day every day of the year by a skilled, trained counselor. You can also present to a healthcare provider, your local emergency room, or call 9-1-1 to be connected to local emergency services.
Blood Drawing: The blood draws will involve the insertion of a small needle into your arm. Blood drawing can result in pain, bruising, and rarely infection, blood clots, dizziness and possibly fainting. You should not donate blood during the study or for one month after the study.

Reproductive risks: The research may also hurt a pregnancy or fetus in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death. While participating in the study and 3 months after, we ask that you do not attempt pregnancy (male or female), breastfeed, or donate eggs or sperm.

Activity watch risks: The watches we ask you to wear may be slightly uncomfortable, especially if you do not usually wear a watch. There is also a very small risk of skin rash associated with the watch bands.

Home sleep apnea test risks: The home sleep apnea wrist watch, finger probe, and chest sensor may be slightly uncomfortable or disrupt your sleep for the one night of testing.

ECG risks: You may experience mild discomfort when the sticky pads used to attach the ECG electrodes are taken off. There is a very minimal risk that the sticky electrode patches may cause skin irritation.

Non-physical risks: Participation in research might involve some loss of privacy. There is a small risk that someone outside the research study could see and misuse information about you. We will do our best to protect your data and samples during storage and when they are shared. However, there remains a possibility that someone could identify you. There is also the possibility that people who are not supposed to might access your data and samples. In either case, we cannot reduce the risk to zero. This study will ask you questions, interview you, and ask you to complete questionnaires about personal topics that are sensitive in nature and might be embarrassing to talk about. You may refuse to answer any question that makes you feel uncomfortable. You will also be asked about illegal activities, which could have legal and financial consequences if this information were to become known outside of the study.

Unknown or unforeseeable risks: In addition to these risks, this research may hurt you in ways that are unknown. These may be a minor inconvenience or may be so severe as to cause death. The research team will let you know of any new findings that may affect your willingness to continue participating in this study.

Costs involved: The sponsor will provide the study drug at no cost to you. You will not be charged for any study visits, tests, procedures, or equipment. You and your insurance company will be charged for the health care services that you would ordinarily be responsible to pay. You remain responsible for all deductibles, co-pays, and balances under your insurance. In some cases, insurance will not pay for services ordinarily covered because these services were performed in a research study. You should check with your insurance to see what services will be covered by your insurance and what you will be responsible to pay. A member of the study team can talk to you about what procedures would be considered standard care and the coverage of those costs. Standard message and data rates may apply for SMS reminders about daily sleep diaries.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB, FDA, and NIH, or other representatives of these organizations.

As employees of an institution of higher education in Virginia, VCU faculty and staff are all mandated reporters and are obligated to report child and elder abuse. If you tell us that you may hurt yourself or someone else, the law says that we must let people in authority know.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

If you participate in future research studies with us within the next 3 months, we may use some of the screening information from this study in order to reduce your inconvenience.

The sponsor, monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records to conduct and oversee the research. By signing this document, you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Federal law provides additional protections of your medical records and related health information. These are described in an attached document.

Will my data or samples be used for future research?

In the future, identifiers might be removed from the information you provide in this study, and after that removal, the information could be used for other research studies by this study staff or another researcher without asking you for additional consent. Biospecimens will not be used for commercial profit.

Can I be removed from the research without my OK?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include:

- You are found not eligible for the study
- The investigator or sponsor has stopped the study
- You have not followed study instructions
- Positive pregnancy test (females)
- Administrative reasons such as breaking or losing the activity watch or home sleep apnea test

- You experiencing a serious side effect or change in your health that in the opinion of the investigator would not be in your best interest to continue in the study

We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What else do I need to know?

This research is being funded by the National Institutes of Health.

If you are injured by, or become ill, from participating in this study, please contact your study clinician immediately. Medical treatment is available at the Virginia Commonwealth University Health System (VCU Health System). Your study clinician will arrange for short-term emergency care at the VCU Health System or for a referral if it is needed.

Fees for such treatment may be billed to you or to appropriate third party insurance. Your health insurance company may or may not pay for treatment of injuries or illness as a result of your participation in this study. To help avoid research-related injury or illness, it is very important to follow all study directions.

If you agree to take part in this research study, we will pay you up to $1,005 for your time and effort. You have the option to receive cash (or pre-paid card, depending on availability) following the completion of a study visit OR to delay individual visit payments in order to receive a later payment that includes compensation for multiple visits. You may also have the option to split visits, in which case you will be compensated for the items you have completed at each visit, according to the itemized breakdown below.

You will be reimbursed $20 to help cover travel expenses at each visit (up to $460 total). If you choose to split the visit into multiple visits, you will still only receive the travel reimbursement once, consistent with the maximum payment amount in the compensation schedule table below. If you need to come in again due to an error on the part of the study team you will be reimbursed $20 for the repeat visit, or by the itemized breakdown in the table below for the study procedures that need to be repeated.

Compensation Schedule

Visit Name	**Maximum Payment Amount**	**Itemized Breakdown**
Screening	Study visit: $55 Travel expenses: $20	Screener completion: $25 Blood draw: $25 Urine drug test: $5
Baseline Visit 1	Study visit: $75 Travel expenses: $20	Completion of baseline research assessments: $60 Completion of HSAT: $10 Urine drug test: $5
Baseline Visit 2	Study visit: $50 Travel expenses: $20	Completion of baseline week 1 home activity watch data: $25* Completion of baseline week 1 sleep diaries with 5-7 days of data: $15 Completion of research visit: $5 Urine drug test: $5
Baseline Visit 3	Study visit: $60	Baseline completion: $10

	Travel expenses: $20	Completion of baseline week 2 home activity watch data: $25* Completion of baseline week 2 sleep diaries with 5-7 days of data: $15 Completion of research visit: $5 Urine drug test: $5
Medication Week 1 Research Visit	Study visit: $45 Travel expenses: $20	Completion of weekly research visit: $40 Urine drug test: $5
Day 2 Safety Check-In Visit	Study visit: $15 Travel expenses: $20	Completion of research visit: $15
Medication Week 1 UDT	Study visit: $15 Travel expenses: $20	Urine drug test: $15
Medication Week 2 Research Visit	Study visit: $45 Travel expenses: $20	Completion of weekly research visit: $40 Urine drug test: $5
Medication Week 2 UDT	Study visit: $15 Travel expenses: $20	Urine drug test: $15
Medication Week 3 Research Visit	Study visit: $45 Travel expenses: $20	Completion of weekly research visit: $40 Urine drug test: $5
Medication Week 3 UDT	Study visit: $15 Travel expenses: $20	Urine drug test: $15
Medication Week 4 Research Visit	Study visit: $85 Travel expenses: $20	Completion of weekly research visit: $40 Completion of Week 3 home activity watch data: $25* Completion of Week 3 sleep diaries with 5-7 days of data: $15 Urine drug test: $5
Medication Week 4 UDT	Study visit: $15 Travel expenses: $20	Urine drug test: $15
Medication Week 5 Research Visit	Study visit: $85 Travel expenses: $20	Completion of weekly research visit: $40 Completion of Week 4 home activity watch data: $25*

		Completion of Week 4 sleep diaries with 5-7 days of data: $15 Urine drug test: $5
Medication Week 5 UDT	Study visit: $15 Travel expenses: $20	Urine drug test: $15
Medication Week 6 Research Visit	Study visit: $45 Travel expenses: $20	Completion of weekly research visit: $40 Urine drug test: $5
Medication Week 6 UDT	Study visit: $15 Travel expenses: $20	Urine drug test: $15
Medication Week 7 Research Visit	Study visit: $45 Travel expenses: $20	Completion of weekly research visit: $40 Urine drug test: $5
Medication Week 7 UDT	Study visit: $15 Travel expenses: $20	Urine drug test: $15
Medication Week 8 Research Visit	Study visit: $85 Travel expenses: $20	Completion of weekly research visit: $40 Completion of Week 7 home activity watch data: $25* Completion of Week 7 sleep diaries with 5-7 days of data: $15 Urine drug test: $5
Medication Week 8 UDT	Study visit: $15 Travel expenses: $20	Urine drug test: $15
Post-Medication	Study visit: $120 Travel expenses: $20	Completion of post-medication visit: $50 Completion of Week 8 home activity watch data: $25* Completion of Week 8 sleep diaries with 5-7 days of data: $15 Blood draw: $25 Urine drug test: $5
Safety Extended Follow-Up	Study visit: $30 Travel expenses: $20	Completion of extended follow-up visit: $25 Urine drug test: $5
Max study visit compensation : $1,005 **Max total travel expenses : $460**		

*Payment will be provided when watch is returned for data download.

You will also be eligible to earn up to an additional $413 throughout the study in “bonuses”. These bonuses are for following the study procedures. You will also have the opportunity to refer other people that you think might be eligible for this study in exchange for referral bonus compensation. You will be given 5 coupons- each coded with a unique identifier that you can give to people you think might be eligible and interested in learning more about this study. The coupons will contain the contact information for the study staff. If someone you give a coupon to calls the study contact number, and comes in for an on-site screening visit with the coupon you gave them, then you will be notified of coupon redemption using the contact information you provided. You will be compensated $15 for each successful referral (that ends in someone you referred completing an on-site study screening visit). From participating in the referral program, you could receive a maximum of $75 in additional compensation for referrals if all 5 of the referral coupons you were given are redeemed (payable in cash or check mailed to you). We will hold any payments you choose to receive in cash for to you pick up a maximum of 30 days. If you do not pick up your cash payment by the end of 30 days, we will mail a check to you at the address you provided. Your study participation will not be affected by your participation in the referral program.

If you were referred to the study using one of the coupons and you complete the screening visit, the person who provided the coupon to you will receive payment and therefore may figure out that you joined the study. The study staff will not share any information about you or your participation with the person who referred you to the research study.

These bonuses are described in the following table.

Bonus Compensation Schedule

Event name	**Maximum Payment Amount**	**Time of payment**
Successful daily Scene Health® medication adherence video uploads	$3/day (x 56 days = $168)	Paid once/week during weekly UDT visits in the medication phase
Study drug bottle return for pill counts	$10/week (x 7 weeks = $70)	Paid once/week during weeks 2-8 UDT visits in the medication phase
Completion of all study visits and procedures	$100	Extended follow-up visit
Referral vouchers	$15/voucher (x maximum 5 vouchers = $75)	Paid upon the successful referral of an individual who completes an on-site screening visit
Baseline Week 1 activity watch turn-in with 5-7 days of data	$5	After data is downloaded and confirmed for 5-7 full nights. Payment may be delayed due to processing data.
Baseline Week 2 activity watch turn-in with 5-7 days of data	$10	After data is downloaded and confirmed for 5-7 full nights. Payment may be delayed due to processing data.
Medication Week 3 activity watch turn-in with 5-7 days of data	$15	After data is downloaded and confirmed for 5-7 full nights. Payment may be delayed due to processing data.
Medication Week 4 activity watch turn-in with 5-7 days of data	$20	After data is downloaded and confirmed for 5-7 full nights. Payment may be delayed due to processing data.

Medication Week 7 activity watch turn-in with 5-7 days of data	$25	After data is downloaded and confirmed for 5-7 full nights. Payment may be delayed due to processing data.
Medication Week 8 activity watch turn-in with 5-7 days of data	$30	After data is downloaded and confirmed for 5-7 full nights. Payment may be delayed due to processing data.
Max bonus total: $518		

Total payments within one calendar year that exceed $600 will require the University to report these payments annually to the IRS and you. This may require you to claim the compensation you receive for participation in this study as taxable income. VCU is required by federal law to collect your social security number. Your social security number will be kept confidential and will only be used to process payment.

Instead of being in this research study, your choices may include:

- Taking a different insomnia medication
- Trying a behavioral therapy for insomnia
- Receive no treatment specific to insomnia

The important risks and possible benefits of these alternatives include:

- Risks: side effects from a different medication, or feeling sleepy during a behavioral therapy
- Benefits: possible improvements in your insomnia

It will be noted in your protected electronic health record at VCU Health that you are in this study. Information about the study including any medications you may receive, will be included in the record. This information is protected just as any of your other health records are protected.

Most tests done on samples in research studies are only for research and have no clear meaning for health care. If the research with your identifiable information or samples gives results that do have meaning for your health (for example, if results of the sleep testing indicate that you have sleep apnea), the researchers will *c*ontact you to let you know what they have found so you can follow-up with a healthcare provider to confirm the results and discuss potential treatment.

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

Signature of subject	Date
Printed name of subject	Date
Signature of person obtaining consent	Date
Printed name of person obtaining consent	

Virginia Commonwealth University Health System (VCU Health)
Research Subject HIPAA Authorization Form
for Use or Disclosure of Protected Health Information (PHI)
(In accordance with HIPAA Act 45 CFR 160 and 164)

Research study title: Neurofunctional phenotyping to investigate the role of the orexin system at the intersection of opioid use disorder and insomnia among women and men receiving buprenorphine
RAMS-IRB number: HM20031777

What is the purpose of this form?

Federal privacy laws protect the use and release of your protected health information ("PHI"). Under these laws, VCU Health cannot release your protected health information for research purposes unless you give your permission. Your information will be released to the research team, which includes the researchers, people hired by VCU Health or the sponsor to do the research, and people with authority to oversee the research. If you decide to give your permission and participate in the study, you must sign this form and the Consent Form. This form describes the different ways that VCU Health can share your information with the researcher, research team, sponsor, and people with oversight responsibility. The research team will use and protect your information as described in the Consent Form. However, once your health information is released by VCU Health, it may not be protected by federal privacy laws and might be shared with others. If you have questions, ask a member of the research team.

By signing this form, you give us permission to use or disclose your requested PHI (itemized below) for the conduct and oversight of the above-mentioned research study.

What Personal Health Information will be released?

If you give your permission and sign this form, you are allowing **VCU Health** to release the following medical records containing your Personal Health Information. Your Personal Health Information includes health information in your medical records, financial records and other information that can identify you.

☐ Entire Medical Record
X Inpatient Records
X Progress Notes
X Consultation
X Discharge Summary
X History & Physical Exams
☐ Operative Reports
☐ Abstract of Record*
X Lab & Pathology Reports
☐ Radiology Reports

X Psychological Tests
☐ Other Test Reports
X Emergency Dept. Records
X Outpatient/Ambulatory Clinic Records

☐ Radiology Images
☐ Diagnostic Photographs, specify: _____

☐ Financial records
X Other (describe): Substance use disorder treatment records

* An abstract of the record includes: History & Physical Exams, Operative Reports, Consultation and Discharge Summary Reports, and Diagnostic Reports (including Lab, Pathology, & Imaging).

The information used/disclosed pursuant to this authorization will not include psychotherapy notes, but may include detailed mental health information, HIV/AIDS information and/or information regarding alcohol or substance abuse consistent with 42 CFR 2.52.

People that will Use or Disclose your PHI: the following person(s), class(es) of persons, and/or organization(s) may disclose, use, and receive the information, but they may only use and disclose the information to the other parties on this list, to the research subject or his/her personal representative, or as otherwise permitted or required by law.

- The Principal Investigator and the research staff and any other people and groups authorized to help conduct the study.
- National Institutes of Health, the study sponsor for this research study. The sponsor may also use your PHI to collect and analyze the results of the research and may have other people and groups help conduct, oversee, and analyze the study. These people will use your PHI.
- Every health care provider who provides services to you in connection with this study.
- Any laboratories and other individuals and organizations that analyze your health information in connection with this study in accordance with the study's protocol.
- The Virginia Commonwealth University Institutional Review Board.
- Any government agencies that regulate research including: the Office for Human Research Protections, The Food and Drug Administration, Medicare, Medicaid, and other regulatory agencies.
- Data and Safety Monitoring Boards / Ethics Committees, research monitors and reviewers.

You do not have to sign this authorization form. If you do not sign, you may not participate in the above-mentioned research study. VCU Health providers shall not condition treatment on the receipt of this authorization, and you may still receive non-research related treatment. This Authorization to release your personal health information expires when the research ends, and all required study monitoring is over.

Revoking your Authorization:

You may change your mind and revoke (take back) this Authorization at any time. If you revoke your authorization, the researchers will not collect any more of your PHI. But they may use or pass along the information you already gave them so they can follow the law, protect your safety, or make sure the research is done properly. The information used or disclosed pursuant to this Authorization may be subject to re-disclosure by the recipient of the information and may then no longer be protected by the federal privacy regulations. This authorization for use and disclosure for research purposes indicated above is valid until the end of the study or until/unless you revoke this authorization**.**

If you do wish to revoke authorization you must write to:

Dr. Caitlin E. Martin
Institute for Drug and Alcohol Studies
203 E Cary St.
Richmond, VA 23298

Participant

If you agree to the use and release of your Personal Health Information, please print your name and sign below. You will be given a signed copy of this form**.**

_____Participant's Name (print)--*required*

_____Participant’s Signature

_____ Date