

## RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

**STUDY TITLE:** Phase Ib/2a drug-drug interaction study of lemborexant as an adjunctive treatment for buprenorphine/naloxone for opioid use disorder

**VCU INVESTIGATOR:** Frederick Gerard Moeller, MD, Professor, VCU Department of Psychiatry, Director, VCU Institute for Drug and Alcohol Studies, Phone: 804-828-3686

**SPONSOR:** National Institute on Drug Abuse (NIDA)

*NOTE: In this consent form, “you” always refers to the research participant.*

### ABOUT THIS CONSENT FORM

You are being invited to participate in a research study. **It is important that you carefully think about whether being in this study is right for you and your situation.**

This consent form is meant to assist you in thinking about whether or not you want to be in this study. **Please ask the investigator or the study staff to explain any information in this consent document that is not clear to you.** You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Your participation is voluntary. You may decide not to participate in this study. If you do participate, you may withdraw from the study at any time. Your decision not to take part or to withdraw will involve no penalty or loss of benefits to which you are otherwise entitled.

### AN OVERVIEW OF THE STUDY AND KEY INFORMATION

#### **Why is this study being done?**

The purpose of this research study is to test the safety, tolerability, drug interactions with buprenorphine-naloxone, and effectiveness of lemborexant when used to treat Opioid Use Disorder. You are being asked to participate in this study because you have been diagnosed with and are currently in treatment for Opioid Use Disorder and may meet the study entry requirements.

#### **What will happen if I participate?**

Lemborexant is a medication that has been approved by the U.S. Food and Drug Administration (FDA) to treat insomnia. In this study, lemborexant will be compared to placebo (a look-alike inactive substance, a “sugar pill”).

If you are eligible and choose to participate in the study, you will be randomly assigned (like the flip of a coin) to receive either lemborexant or placebo. You are twice as likely to receive lemborexant than placebo.

In this study, you will be asked to do the following things:

1. Visit the CARI clinic and/or Motivate clinic at Jackson Center to complete study screening/visits.
2. Visit the VCUHS Clinical Research Unit to complete an outpatient blood draw/testing visit.
3. Take either lemborexant or the placebo, depending upon which group you are assigned to.
4. Complete two (2) overnight study visits at the VCUHS Clinical Research Unit.
5. Complete 8 outpatient follow-up visits (broken into 2 four day visit groupings)
6. Have an EKG during screening and at each study visit (outpatient and inpatient)
7. Have an IV inserted into your arm for blood draws at the outpatient blood draw visit and each inpatient visit.
8. Record your sleep in a sleep diary.
9. Take surveys and answer questions about your health, mental health, medications used, drug use, and cravings.
10. Complete tasks on the computer.
11. Complete physical exams during screening, outpatient and inpatient visits.
12. Give permission for the researchers to collect information about your opioid treatment, medical status, and other information from your medical record.

Your participation in this study will last approximately 4 weeks. Approximately 18 people will participate in the drug interaction phase of this study.

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

#### **What alternative treatments or procedures are available?**

You do not have to take part in this study. If you do not take part in this study it will not affect your treatment at VCU Health.

#### **What are the risks and benefits of participating?**

There are both risks and benefits of participating in research studies. We want you to know about a few key risks right now. We will give you more information in the “WHAT RISKS AND DISCOMFORTS CAN I EXPECT FROM BEING IN THE STUDY?” section.

<b>Risks and Discomforts</b>	<b>Benefits to You and Others</b>
<p>1. There is a risk that you could have side effects from taking lemborexant. Below are some of the most common side effects:</p> <p>The most common side effects of Lemborexant are somnolence (sleepiness) or fatigue, headache, and nightmares or abnormal dreams. Some people have had</p>	<p>This is not a treatment study, and you are not expected to receive any direct medical benefits from your participation in the study. The information from this research study may lead to a better treatment in the future for people with Opioid Use Disorder.</p>

<p>impaired driving ability the next day after 10 mg of lemborexant. Additional risks associated with lemborexant, but are not common, are suicidal thoughts or behavior.</p> <p>2. Combining lemborexant with other sedating medicines, such as buprenorphine could increase the risk of sleepiness and or confusion. There may be some risks that the study investigators do not know about yet, so we will let you know of any new findings.</p> <p>3. The blood draw for the screening labs, and IV insertion for blood draws during your inpatient visits may cause pain, bleeding, and/or bruising. You may faint and could develop an infection at the site where blood is drawn.</p> <p>4. The study questionnaires ask questions that are sensitive/personal in nature (e.g., about drug use, mental health, etc.) and may make you feel uncomfortable.</p> <p>5. 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.</p>	
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Now that you have a general overview of the study, we want to provide the details about what your participation involves. Please read, or have someone read to you, the rest of this document. If there is anything you don't understand, be sure to ask the study staff.

### **WHY IS THIS STUDY BEING DONE?**

The purpose of this study is to test the effects of lemborexant when used in combination with opioids (including buprenorphine). We are also interested in learning if lemborexant might help improve sleep problems and problems related to opioid use (e.g., cravings, withdrawal), in people with opioid use disorder. Study participants will be randomly assigned in a two to one ratio to receive either lemborexant or placebo. Lemborexant (DAYVIGO®) is approved by the U. S. Food and Drug Administration (FDA) for treatment of insomnia.

## **WHAT WILL HAPPEN IF I PARTICIPATE IN THE STUDY?**

**You will need to wear a mask at all of your study visits, per VCU policy.**

**SCREENING:** You will visit the VCU CARI research clinic and/or Motivate 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 and vital signs (pulse, blood pressure and temperature). Blood (approximately 1 to 2 tablespoons) and urine samples will be collected for drug screen testing and routine lab tests. Women of childbearing potential will have a pregnancy test done. An alcohol breathalyzer or salivary alcohol test will also be done. Finally, 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. In addition to the medical and drug testing, you will also complete surveys on the computer and face-to-face interviews with study staff that ask about your current medications, drug use, cravings, withdrawal, mental health, and sleep. You will also be asked to complete a sleep diary.

The screening will take approximately 2½ 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 screening visit. If you qualify for the study and decide to continue participation, you have the option of extending your screening appointment visit to complete a portion of the next visit (Outpatient testing visit, described below).

**OUTPATIENT TESTING VISIT:** You will visit the VCU CARI research clinic and/or Motivate at Jackson Center for an outpatient testing visit. For this visit, you will be asked for a urine sample, which will be collected for drug screen and pregnancy (for females of childbearing potential) testing. An alcohol breathalyzer or salivary alcohol test will be done, and we will collect vital signs (pulse, blood pressure, temperature, and respiratory rate). You will then complete surveys and behavioral tasks on the computer, and face-to-face interviews with the staff that ask about your current medications, drug use, cravings, withdrawal, mental health, mood, family relationships, legal history, employment, etc. This visit will take approximately 3 ½ to 4 hours to complete (with rest breaks included). If needed, this testing may be completed over more than one visit and some of the questions may be answered over the phone.

**PREADMISSION OUTPATIENT VISIT #1:** Within approximately 3 weeks of your initial screening and assessment visit, you will be scheduled to complete a baseline (outpatient) study visit at the VCU Clinical Research Unit (CRU), located on the 8<sup>th</sup> floor of North Hospital at the VCU Medical Center, which will take about 9 hours to complete. During that visit, you will be asked to complete a brief physical exam (including electrocardiogram (ECG)), urine drug screen and (for females) pregnancy testing, and breathalyzer or salivary alcohol for alcohol. You will also take computer-based surveys and tasks, and face-to-face interviews about your drug use, cravings, withdrawal, mental health, and sleep (including completing a sleep diary).

You will also take your daily buprenorphine/naloxone (Suboxone®) dose (the medication will be provided to you as a dissolving sublingual (under the tongue) film), and an IV will be placed in your arm to collect samples of your blood at regularly scheduled times throughout the day. The amount of blood that will be collected each time is 5-10 ml (about 2 teaspoons). We will also

measure the size of your pupils using a handheld device at regularly scheduled times throughout this visit.

You may need to take a COVID-19 test prior to starting each of the inpatient CRU stay study visits to ensure that you are negative for COVID-19 (described below). The COVID-19 testing appointment will be scheduled for you by a study nurse, and you will be provided with directions on where at VCU and what time to report for testing (testing locations at VCU vary by day). The testing will be completed at no charge to you.

### **INPATIENT CRU stays**

Inpatient CRU stay #1 will take place within about 1 week of the outpatient testing visit, and Inpatient CRU stay #2 will take place within about 1-1 1/2 weeks of the first CRU stay.

#### **During each Inpatient CRU stay:**

You will come to the CRU in the late afternoon/evening (as scheduled) and will complete a brief physical exam (including vital signs), ECG, urine drug screen and (for females of childbearing potential) pregnancy testing, and breathalyzer or salivary alcohol level for alcohol. You will also answer questions about your current medications and drug use, cravings, withdrawal, and complete a sleep diary. You will be asked to take your regular daily buprenorphine/naloxone (Suboxone®) in the morning of the day you come into the CRU.

Beginning on Day 2 of the stay, you will be given your daily buprenorphine/naloxone dose (the medication will be provided to you as a dissolving sublingual (under the tongue) film) in the morning. You will also take a pill containing either lemborexant (5mg on CRU stay #1, 10mg on CRU stay #2) or placebo, depending on which group you are assigned to.

You will be assigned in a two to one ratio (twice as many people will receive lemborexant) to receive either lemborexant or placebo. This will remain your group assignment during your time in the study.

Neither you nor the study investigator will know which study drug you are receiving. This information is available to the study investigator if needed in an emergency. This is called blinding, and it is done so that a fair evaluation of results may be made.

An intravenous (IV) line will be placed in your arm to collect samples of your blood at regularly scheduled times throughout the day. The amount of blood that will be collected each time is 5-10 ml (about 2 teaspoons). We will also measure the size of your pupils at regularly scheduled times during your stay. You will also be connected to machines that will monitor your heart rate, blood pressure, respiration (breathing), to keep you safe. You will also complete computer-based surveys and tasks and interviews about your drug cravings, withdrawal, sedation, and complete a sleep diary.

At the end of inpatient visit day 2, a study doctor will give you a brief physical exam, which includes asking you to answer some general questions and follow instructions to see if you are alert and oriented enough to be safely discharged to home. If the doctor determines it is unsafe for you to be discharged to home, you will remain on the unit for a second night and will be re-examined the next morning. If you have to remain at the CRU for an extra night, your first Outpatient Follow-up visit (Outpatient follow-up visits described below) will be completed at the CRU upon your discharge from the unit.

You will need to make plans to be driven home after each of your inpatient visits. You will not be allowed to drive yourself home. If you can't find a ride, we will arrange transportation (e.g., taxi, Uber) within the Greater Richmond Region for you. This is to avoid any difficulties with driving due to the study medication.

**Outpatient Follow-up Visits:** You will complete an Outpatient Follow-up visit each day for 4 days following each discharge from the CRU. The Outpatient visits can be completed at either the Motivate Clinic or CARL research clinic (whichever is most convenient for you). If you stay a second night at the CRU, your first outpatient visit can occur at the CRU immediately following your discharge from the unit.

At each Outpatient Follow-up visit, you will be asked for a urine sample, which will be collected for drug screen and pregnancy (for females of childbearing potential) testing. An alcohol breathalyzer or salivary alcohol test will be done, and vital signs will be collected. You will then complete surveys and behavioral tasks on the computer, and face-to-face interviews with the staff that ask about your current medications, drug use, cravings, withdrawal, mental health, mood, and sleep (including completing a sleep diary). You will also be asked to complete a brief physical exam with one of the study doctors or study NPs. Each outpatient follow-up visit is estimated to take approximately 45 minutes to complete.

The investigators will also collect information from your medical records about your substance abuse treatment and medical history, laboratory tests, and medications. Medical record information will be collected during your participation in the study.

**Transportation:** If you have difficulty making transportation arrangements for any of the study visits described above, please reach out to the study staff and we will arrange transportation (e.g., taxi, Uber- within the Greater Richmond Region) for you to come to and/or from your study appointments, as needed.

#### **WHAT ALTERNATIVE TREATMENTS OR PROCEDURES ARE AVAILABLE?**

The alternative to taking part in this study is not taking part. Although lemborexant (Trade Name Dayvigo®) is approved by the FDA, it is not routinely used in patients with Opioid Use Disorder because there isn't much information about the way lemborexant may interact with opioids like buprenorphine/naloxone. That is the main reason we are doing this study.

## **WHAT ARE THE BENEFITS OF BEING IN THE STUDY?**

This is not a treatment study, and you are not expected to receive any direct medical benefits from your participation in the study. The information from this research study may lead to a better treatment in the future for people with Opioid Use Disorder.

## **WHAT RISKS AND DISCOMFORTS COULD I EXPERIENCE FROM BEING IN THE STUDY?**

### **Possible Risks Associated with Lemborexant**

This medication is approved by the U.S. Food and Drug Administration (FDA) for the treatment of insomnia (difficulty falling or staying asleep at night). The most common side effects seen with lemborexant are feeling sleepy or drowsy (up to 10%), headache (up to 5.9%), and nightmares (up to 2.2%). Because lemborexant can cause drowsiness, patients are at higher risk for falls.

Less reported side effects (occurring in less than 1% to up to 2% of subjects) were sleep paralysis, hypnagogic hallucinations, complex sleep behavior (sleep walking, eating and doing other activities while sleeping with no memory of it the next day), and palpitations. You will be monitored closely for rare potential side effects such as suicidal ideation, as these symptoms have been reported (though rarely) in clinical trials with the medication.

Combining lemborexant with other sedating medicines, such as buprenorphine could increase the risk of sleepiness and or confusion. This is the reason we are doing the study on the clinical research unit in the hospital, where you will be closely monitored. There may be some risks that the study investigators do not know about yet, so we will let you know of any new findings.

Patients taking 10 mg of lemborexant (trade name, DAYVIGO®) are advised not to drive the next day or do any activities that require complete mental alertness. You will need to make plans to be driven home after each of your inpatient visits.

**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.

**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. 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

The researchers will let you know about any significant new findings (such as additional risks or discomforts) that might make you change your mind about participating in the study.

Lemborexant involves risks that are currently unknown or unforeseeable. If you are or may become pregnant, lemborexant might involve risks to the embryo or fetus that are currently unforeseeable.

### Reproductive Risks

As the study procedures might injure an unborn child, pregnant women may not participate. As risks of the study medication to an unborn fetus are unknown, women who might become pregnant should use a medically accepted form of birth control such as total abstinence, birth control pills, an IUD, diaphragm, progesterone injections or implants, or condoms plus a spermicide. Methods of birth control other than total abstinence are not 100% effective, and should a woman become pregnant there is a risk of injury to an unborn child. For similar reasons, women who are nursing an infant may not participate.

For men, the study procedures might increase the risks for birth defects of any child conceived during treatment. Men in this study who have the potential of fathering children should be aware of this possibility and consider using a medically accepted form of birth control. For men this would include total abstinence and condoms plus a spermicide, or for the female partner, birth control pills, an IUD, diaphragm, progesterone injections or implants. Methods of birth control other than total abstinence are not 100% effective, and should a woman become pregnant there is a risk of injury to an unborn child.

### WHAT ARE THE COSTS?

Study drug will be provided by the sponsor at no cost to you. You will not be charged for any study visits, tests, or procedures.

### WILL I BE PAID TO PARTICIPATE IN THE STUDY?

You can earn up to \$1075 for completing all scheduled study visits (paid by cash or mailed check). In addition, if all study visits are completed you will earn a \$100 bonus, making a possible total compensation amount of \$1175. The payment schedule below shows you how much is earned at each study visit.

Visit name	Payment amount
Screening	\$75
Outpatient Testing Visit	\$60
Preadmission Outpatient Visit #1	\$120
Inpatient CRU Visit #1	\$250
Outpatient follow-up visits	\$40 per day (up to 4 days= \$160 max)
Inpatient CRU Visit #2	\$250
Outpatient follow-up visits	\$40 per day (up to 4 days= \$160 max)
Study completion bonus	\$100



You have the option to receive a mailed check or cash 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.

In addition to compensation for completing the study visit, participants residing within the Greater Richmond/surround counties who do not use the free transportation services available through the study will be reimbursed \$10 for bus fare/gas/travel expenses. Participants who reside outside of the Greater Richmond/surrounding counties transportation service coverage area will be reimbursed \$40 help cover gas/bus fare/travel expenses at each visit.

Additionally, in the event that it is necessary for you to return to CARI or Motivate for repeat lab testing or assessments, you will be compensated \$10 for your return outpatient retesting visit.

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.

### **COMPENSATION FOR REFERRALS**

You also have the opportunity to refer others that you think might be eligible for this study in exchange for referral bonus compensation. If you would like to participate in the referral bonus compensation program, 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 team. If someone you give a coupon to calls the study contact number, and is invited to come 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 either a "Yes" or "No" response. Are you interested in participating in the referral program?

☐ **Yes, I am interested in providing referrals for this study. \_\_\_\_\_ (initials)**

☐ **No, I am NOT interested in providing referrals for this study. \_\_\_\_\_ (initials)**

### **WHAT HAPPENS IF I AM INJURED OR BECOME SICK BECAUSE I TOOK PART IN THE STUDY?**

If you are injured by, or become ill, from participating in this study, please contact your study investigator immediately. Medical treatment is available at the Virginia Commonwealth University Health System (VCU Health System). Your study investigator 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.

### **CAN I STOP BEING IN THE STUDY?**

You can stop being in this research study at any time. Leaving the study will not affect your medical care, employment status, or academic standing at VCU or VCU Health. Tell the study staff if you are thinking about stopping or decide to stop.

Your participation in this study may be stopped at any time by the study investigator without your consent. The reasons might include:

- the study investigator thinks it necessary for your health or safety
- you are found to not be eligible for the study
- the sponsor has stopped the study
- you have not followed study instructions
- administrative reasons require your withdrawal

If you withdraw from the study, data that has already been collected about you will remain part of the study database and may not be removed.

### **HOW WILL INFORMATION ABOUT ME BE PROTECTED?**

VCU and the VCU Health System have established secure research databases and computer systems to store information and to help with monitoring and oversight of research. Your information may be kept in these databases according to VCU's policies (i.e. for a minimum of 5-6 years). It is only accessible to individuals working on this study or authorized individuals who have access for specific research related tasks.

Identifiable information in these databases are not released outside VCU unless stated in this consent or required by law. Although results of this research may be presented at meetings or in publications, identifiable personal information about participants will not be disclosed.

Personal information about you might be shared with or copied by authorized representatives from the following organizations for the purposes of managing, monitoring and overseeing this study:

- The study Sponsor, representatives of the sponsor and other collaborating organizations
- Representatives of VCU and the VCU Health System

- Officials of the Department of Health and Human Services or the Federal Food and Drug Administration

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.

In general, we will not give you any individual results from the study. If we find something of medical importance to you, we will inform you although we expect that this will be a very rare occurrence.

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 Website will include a summary of the results. You can search this Web site at any time.

There are no plans to share any money or profits with you if the use of your sample(s) results in inventions or discoveries that have commercial value.

If you tell us that you may hurt yourself or someone else, the law says that we must let people in authority know.

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 team or another researcher without asking you for additional consent.

### **Certificate of Confidentiality**

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. This certificate offers the protections described here. A Certificate of Confidentiality helps the researchers keep your information private. For example, researchers can refuse to give out your information in a court case. Researchers may have to give your information if the study is audited, or if the information is required by the Food and Drug Administration (FDA).

The researchers may share information about you or your participation in the research project without your consent if you disclose information about current child or elder abuse or neglect, or harm to self or others.

If you test positive for COVID-19 during any of the study-related COVID-19 testing visits, Virginia state law requires reporting of results of positive tests for COVID-19 to a local health agency.

The researchers cannot prevent you or others, for example a member of your family, from sharing information about you or your involvement in this research. If you give an insurer, employer, or other person permission to receive research information, then the researchers may not use the Certificate to withhold that information.

### **HOW WILL MY HEALTH INFORMATION BE USED AND SHARED DURING THIS STUDY?**

As part of this research study, we will ask you to share identifiable health information with us and/or permit us to access existing information from your healthcare records. New health information may also be created from study-related tests, procedures, visits, and/or questionnaires and added to your healthcare records. This type of information is considered "Protected Health Information" that is protected by federal law.

### **What type of health information will be used or shared with others during this research?**

The following types of information may be used for the conduct of this research:

<input checked="" type="checkbox"/> Complete health record	<input checked="" type="checkbox"/> Lab test results
<input checked="" type="checkbox"/> History and physical exam	<input checked="" type="checkbox"/> Drug and alcohol use information
<input checked="" type="checkbox"/> Mental health records	<input checked="" type="checkbox"/> Diagnosis and treatment codes

### **Who will use or share protected health information about me?**

VCU and VCU Health are required by law to protect your identifiable health information. By consenting to this study, you authorize VCU/VCU Health to use and/or share your health information for this research. The health information listed above may be used by and/or shared with the following people and groups to conduct, monitor, and oversee the research:

- Principal Investigator and Research Staff
- Health Care Providers at VCU Health
- Institutional Review Boards
- Government/Health Agencies
- Others as Required by Law
- Study Sponsor
- Data Coordinators
- Research Collaborators
- Data Safety Monitoring Boards

Once your health information has been disclosed to anyone outside of this study, the information may no longer be protected under this authorization.

### **When will this authorization (permission) to use my protected health information expire?**

This authorization will expire when the research study is closed, or there is no need to review, analyze and consider the data generated by the research project, whichever is later.

### **Statement of Privacy Rights**

You may change your mind and revoke (take back) the right to use your protected health information at any time. However, even if you revoke this authorization, the researchers may still use or disclose health information they have already collected about you for this study. If you revoke this Authorization, you may no longer be allowed to participate in the research study. To revoke this Authorization, you must write to the Principal Investigator at Dr. F. Gerard Moeller, MD, VCU Institute for Drug and Alcohol Studies, 203 E Cary Street, Richmond VA 23219.

### WHOM SHOULD I CONTACT IF I HAVE QUESTIONS ABOUT THE STUDY?

The investigator and study staff named below are the best person(s) to contact if you have any questions, complaints, or concerns about your participation in this research:

**Dr. F Gerard Moeller, 203 E Cary Street, Suite 202. Phone: 804-828-4134**

and/or

**Dr Albert Arias, 203 E Cary Street, Suite 202. Phone: 804-828-5793**

**On weekends and after 5pm, please call the VCUHS Telepage office at (804) 828-0951, and ask them to call pager number 9548.**

If you have general questions about your rights as a participant in this or any other research, or if you wish to discuss problems, concerns or questions, to obtain information, or to offer input about research, you may contact:

Virginia Commonwealth University Office of Research  
800 East Leigh Street, Suite 3000, Box 980568, Richmond, VA 23298  
(804) 827-2157; <https://research.vcu.edu/human-research/>

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

**STATEMENT OF CONSENT**

I have been provided with an opportunity to read this consent form carefully. All of the questions that I wish to raise concerning this study have been answered. By signing this consent form, I have not waived any of the legal rights or benefits to which I otherwise would be entitled. My signature indicates that I freely consent to participate in this research study. I will receive a copy of the consent form for my records.

Signature Block for Enrolling Adult Participants	
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Adult Participant Name (Printed)	
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Adult Participant's Signature	Date
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Name of Person Conducting Consent Discussion (Printed)	
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Signature of Person Conducting Consent Discussion	Date
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Principal Investigator Signature (if different from above)	Date
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