National Institute on Drug Abuse / “Phase Ib/2a drugdrug interaction study of a combination of 45mg dextromethorphan with 105 mg Bupropion (AUVELITY) as an adjunctive treatment for buprenorphine/naloxone for opioid use disorder”

Dr. Gerald Moeller

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RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM
AND
AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

Sponsor / Study Title:	**National Institute on Drug Abuse / "Phase Ib/2a drug-drug interaction study of a combination of 45mg dextromethorphan with 105 mg Bupropion (AUVELITY) as an adjunctive treatment for buprenorphine/naloxone for opioid use disorder"**
Protocol Number:	**HM20027635**
Principal Investigator: (Study Doctor)	**Frederick Moeller, MD**
Telephone:	**804-828-3686** **804-828-0951 (24 Hour)**
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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 Auvelity® 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?

Auvelity® is a drug that has been approved by the U.S. Food and Drug Administration (FDA) to treat depression. In this study, Auvelity® will be compared to placebo (a look-alike inactive substance, a "sugar pill"). The use of Auvelity® in this study is investigational. An investigational use is one that is not approved by the United States Food and Drug Administration (FDA).

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 Auvelity® or placebo. You are twice as likely to receive Auvelity® than placebo.

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

1. Complete study screening visit(s) at the Collaborative Advanced Research Imaging (CARI) clinic and/or Motivate clinic at Jackson Center. Screening includes physical exam, medical tests (including blood work and electrocardiogram (ECG)), urine drug screening, and interviews/questionnaires and computer tasks.
2. Complete a study visit at the CARI research clinic which includes drug and alcohol testing, interviews, questionnaires, and computer tasks.
3. Complete a blood draw/testing visit at either the VCUHS Clinical Research Unit (in North Hospital) or CARI research clinic. An IV will be inserted into your arm for blood draws while you are on the unit. You will also complete computer tasks and brief surveys.
4. Be randomly assigned (like the flip of a coin) to take Auvelity® or the placebo and complete daily study drug check-in study visits for 7 consecutive (one after another) days at the CARI research clinic. Your first study drug dose (and instructions) will be given to you at your first check-in visit).
5. Repeat the blood draw testing visit at either the VCUHS Clinical Research Unit or CARI research clinic.
6. Complete three follow-up visits which will include drug and alcohol testing, medical assessment/check-in, and some brief interviews.
7. 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, but could be up to 84 days, depending on time required to complete screening activities, etc. Approximately 18 people will participate in the study 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. This research study is for research purposes only. The only alternative is to not participate in this study.

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 COULD I EXPERIENCE FROM BEING IN THE STUDY?" section.

Risks and Discomforts	Benefits to You and Others
1. There is a risk that you could have side effects from taking Auvelity®. Below are some of the most common side effects: The most common side effects of Auvelity® are dizziness, headache, diarrhea, somnolence (sleepiness), dry mouth, sexual dysfunction, and hyperhidrosis (heavy sweating). Additional risks associated with Auvelity®, but are not common, are suicidal thoughts or behavior in adolescents, seizure (at high doses), and increased blood pressure. 2. 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. 3. The study questionnaires ask questions that are sensitive/personal in nature (for example, about drug use, mental health, etc.) and may make you feel uncomfortable. 4. Participation in research might involve some loss of privacy. There is a small risk that someone outside the research 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.

could see and misuse information about you.	

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 Auvelity® when used in combination with opioids (including buprenorphine). We are also interested in learning if Auvelity® might help improve mood and problems related to opioid use (for example, cravings, withdrawal), in people with opioid use disorder. Study participants will be randomly assigned in a two to one ratio to receive either Auvelity® or placebo. Auvelity® is approved by the U. S. Food and Drug Administration (FDA) for treatment of depression.

WHAT WILL HAPPEN IF I PARTICIPATE IN THE STUDY?

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).

If you have recently (within the past 3 months) completed screening for another one of our studies, we may be able to use/update some of your previously completed screening information (e.g., interview information, labs, etc), in order to reduce the time required for you to complete the current screening visit procedures. You will still receive compensation for those screening-related items. Further, information you provide during screening for this study may also be able to be used/updated for use in any of our research studies that you participate in (within the next 3 months) in order to save you time/effort.

COMPUTER TESTING/SURVEY VISIT: You will visit the VCU CARI research clinic and/or Motivate at Jackson Center for a 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 study 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.

BLOOD DRAW/TESTING VISIT #1: Within approximately 3 weeks of your initial screening and assessment visit, you will be scheduled to complete a baseline blood draw/testing study visit at either the VCU Clinical Research Unit (CRU), located on the 8th floor of North Hospital at the VCU Medical Center, or the CARI research clinic, which will take about 9 hours to complete. During that visit, you will be asked to complete a brief physical exam, 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, and mental health.

You will also take your buprenorphine medication as prescribed, 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 will also be connected to machines that will monitor your heartrate, blood pressure, respiration (breathing), to keep you safe. You will also complete computer-based surveys and tasks and interviews about your drug cravings, withdrawal, etc.

Daily Study Drug Check-in Visits: You will complete an Outpatient Follow-up visit each day for 7 days following your initial blood draw/ testing visit. The Outpatient visits can be completed at either the Motivate Clinic or CARI research clinic.

At your first visit you will be assigned to take either Auvelity or placebo pills. You will be assigned in a two to one ratio (twice as many people will receive Auvelity®) to receive either Auvelity® 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. At the time you are given your study drug, you will also receive written and oral (by a member of our medical 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.

At every study drug check-in 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 also be asked to bring us your pill bottles and all (used and unused) study drug blister packs. You will then complete surveys and behavioral tasks on the computer, and face-to-face interviews with the study staff that ask about your current medications, drug use, cravings, withdrawal, mental health, and mood, and how you have been feeling since the last visit. Medication check-in visits are 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.

BLOOD DRAW/TESTING VISIT #2: On the second PK Testing visit (Study Day 8), Auvelity® (or placebo) will be given as a single dose at approximately 8:00 AM in the CRU or at the CARI research clinic. You will also take computer-based surveys and tasks, and face-to-face interviews about your drug use, cravings, withdrawal, and mental health.

You will also take your buprenorphine medication as prescribed, 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 will also be connected to machines that will monitor your heartrate, blood pressure, respiration (breathing), to keep you safe.

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 (for example, 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 Auvelity® is approved by the FDA for the treatment of depression, it is not approved by the FDA for patients with Opioid Use Disorder because there isn't much information about the way Auvelity® 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 Auvelity®

This study drug is approved by the U.S. Food and Drug Administration (FDA) for the treatment of depression. The most common side effects seen with Auvelity® are:

- Dizziness (16%)
- Headache (8%)
- Diarrhea (7%)
- Somnolence (drowsiness) (7%)
- Dry mouth (6%)
- Sexual dysfunction (6%)
- Hyperhidrosis (excessive sweating) (5%)

Less reported side effects include suicidal thoughts and behaviors in adolescents, seizures, and increased blood pressure. You must tell your study investigator right away if you have any thoughts about hurting yourself.

If you are having suicidal thoughts or feel in crisis, call the study investigator at the telephone number listed on the first page of this form. 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.

Buproprion, which is an ingredient in AUVELITY, can increase risk for seizures, especially at high doses, and can increase blood pressure. You will be monitored closely for potential side effects from the study drug.

There may be some risks that the study investigators do not know about yet, so we will let you know of any new findings.

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.

Auvelity® involves risks that are currently unknown or unforeseeable. If you are or may become pregnant, Auvelity® 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 drug 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 (intrauterine device), 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. You must use contraception during participation in this study and for at least 30 days after your last dose of study drug.

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. You must use contraception during participation in this study.

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 $1150 for completing all scheduled study visits (paid by cash, mailed check, or prepaid credit card). In addition, you will receive a $10 bonus each time you bring your study drug bottles and (used and unused) blister packs to your study drug check-in visits (up to $60 possible), and if all study visits are completed you will earn an additional $100 bonus, making a possible total compensation amount of $1310.

The payment schedule below shows you how much is earned at each study visit.

Visit name	**Payment amount**
Screening	$75 (may receive partial payment if it is necessary to break screening into 2 or more visits)
Computer Testing/Survey Visit	$75
Blood draw/Testing Visit #1	$250
Study drug check-in visits	$50 per visit (for 7 days= $350 max)
Blood draw/Testing Visit #2	$250
Outpatient follow-up visits	$50 per visit (for 3 visits= $150 max)

Study completion bonus	$100

During the study treatment period (when you are attending your study drug check-in visits), you will be asked to bring your study drug bottle to each visit. Each time you bring it to your study drug check-in visit, you will receive a $10 bonus (up to $60 possible across study drug check-in visits).

You have the option to receive a mailed check, prepaid card, 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 $20 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 staff. 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 your decision to participate (or not participate) 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.

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
- Tou 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. 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.

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 (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
- VCU Institutional Review Board (IRB)

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 study drugs you may receive, will be included in the record. This information is protected just as any of your other health records are protected. While every effort will be made to protect the confidentiality of your information, absolute confidentiality cannot be guaranteed.

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 staff 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:

☒ Complete health record	☒ Lab test results
☒ History and physical exam	☒ Drug and alcohol use information
☒ Mental health records	☒ 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 study, 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 choose not to sign or 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 the address listed on the first page of the form.

WHOM TO CONTACT ABOUT THIS STUDY
During the study, if you experience any medical problems, suffer a research-related injury, or have questions, concerns or complaints about the study such as:

- Whom to contact in the case of a research-related injury or illness;
- Payment or compensation for being in the study, if any;
- Your responsibilities as a research participant;
- Eligibility to participate in the study;
- The Investigator's or study site's decision to withdraw you from participation;
- Results of tests and/or procedures;

Please contact the Investigator at the telephone number listed on the first page of this consent document.

If you seek emergency care, or hospitalization is required, alert the treating physician that you are participating in this research study.

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.

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.

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.

STATEMENT OF CONSENT AND AUTHORIZATION

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	
_____ Adult Participant Name (Printed)	
_____ Adult Participant's Signature	_____ Date
_____ Name of Person Conducting Consent Discussion (Printed)	
_____ Signature of Person Conducting Consent Discussion	_____ Date