Title: Open Label Pilot Study of Perampanel for the Treatment of Alcohol Use Disorder

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RESEARCH PARTICIPANT INFORMATION AND CONSENT FORM

STUDY TITLE: Open Label Pilot Study of Perampanel for the Treatment of Alcohol Use Disorder

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SPONSOR: National Institute on Alcohol Abuse and Alcoholism/ NIH/ DHHS

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 study doctor 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, and effectiveness of the drug Perampanel when used in persons who drink and wish to stop drinking. Perampanel has been approved by the U.S. Food and Drug Administration (FDA) for the treatment of seizures but has not yet been approved to treat alcohol use disorders. For this reason, it is considered an investigational drug. Some people in this study will receive Perampanel alone and some people will receive Perampanel and Disulfiram, this will be determined by the pharmacy.

What will happen if I participate?

In this study, you will be asked to take a medication (Perampanel or Perampanel + Disulfiram) every day for approximately 8 weeks and have weekly study visits. At these visits, you will be asked questions about your medical history, drinking behavior and life events, have bloodwork checked routinely, have regular medication counseling, and

perform some computer tasks. Throughout the study, there will be regular phone calls from staff. You will also be asked to use a device called “Soberlink” which is like an at-home breathalyzer test to help track your progress throughout the study.

You will be randomly assigned (like the flip of a coin) to receive either Perampanel alone or Peramanel and Disulfiram. You have an equal chance of being assigned to any one of the groups.

Your participation in this study will last up to 10 weeks. Approximately 20 individuals will participate in this study.

This study will use your samples to sequence all or part of your DNA. This is a necessary part of the study and if you do not want to have your blood taken for a DNA sample, then you will not be able to participate in this study.
Deoxyribonucleic acid (DNA) is the “blueprint” or “recipe” that gives the body’s cells instructions on how to do their jobs. Scientists can use a test called whole genome sequencing to determine the order of all or part of the molecules that make up your DNA, like reading all the letters in a book. Sequencing is usually done to look for changes in the molecules of DNA that may cause health problems.

Before starting the study, you may be referred to an alcohol detoxification program (medical treatment of an alcoholic), if clinically indicated. You should NOT be taking any other alcohol treatment medications such as Disulfiram, Acamprosate or Naltrexone at the time of study enrollment.

What alternative treatments or procedures are available?
This is not a treatment study, it is a clinical trial of a medication that is not currently approved to treat people who want to stop drinking.

If you decide not to enter this study and want to seek treatment to help you stop drinking alcohol, staff will give you resources on local programs or offices where you can get help. If you are interested in being treated with just Disulfiram or other medications approved to help people stop drinking, we can help you find resources for treatment. You can receive the usual care that you would receive even if you were not in the study. This includes being treated by a physician with other approved medications to help people stop drinking. The study doctor will discuss these options with you. You do not have to participate in this study to be treated for alcohol use.

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.

Risks and Discomforts	Benefits to You and Others
. There is a risk that study drug may not be as good as the usual approach for treating alcohol dependence or alcohol use disorder. . There is also a risk that you could have side effects from taking a study drug. Below are some of the most common side effects: Dizziness, Headache Mood changes (irritability, aggression) Nausea or abdominal pain Fatigue or change in memory Change in ability to balance which may result in decreased coordination, or falls Rash or bruising Drowsiness that could impair ability to drive or operate heavy machinery There may be some risks that the study doctors do not know about yet, so we will let you know of any new findings. Blood draws may cause pain, bleeding, and/or bruising. You may faint and could develop an infection at the site where blood is drawn. The study questionnaires ask questions that are personal and sensitive in nature and may make you feel uncomfortable. 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.	There is some evidence anticonvulsants may be effective in alcohol use disorder because of how they affect the brain. Perampanel is an anticonvulsant. However, it is unlikely that it will work with everyone, and we cannot promise that it will help you. This study may help the study doctors learn things that may help other people in the future. 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 alcohol dependence.

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 effectiveness of the medication Perampanel in people who want to stop drinking alcohol. Perampanel is an anticonvulsant, which means it is used to treat seizures and is not currently approved by the FDA for the treatment of alcohol cessation. For this reason, it is considered an investigational drug because it is being tested to see if it can help people stop drinking. If you participate in this study, you will either be placed on Perampanel or Perampanel + Disulfiram. Disulfiram is FDA approved to help people stop drinking, and has been marketed under the name "Antabuse". You will be randomly assigned (like flipping a coin) by the pharmacy to be in one of those two groups.

WHAT WILL HAPPEN IF I PARTICIPATE IN THE STUDY?
If you agree to participate in this study, you will complete an initial screening that includes a medical history, physical examination, blood and urine samples will be taken for routine lab evaluations and electrocardiogram (EKG) to ensure that you are medically healthy. A urine sample will be used for drug screening. At each visit, you will be asked to spit into a cup and will need to have a saliva alcohol level of less than .08, and may be asked to wait until your level is suitable or possibly reschedule if you come in either with a higher level than .08 or if you appear to be intoxicated. You will also complete a psychiatric evaluation. You will be asked to complete questionnaires at every visit.

Female subjects will have a blood pregnancy test performed at screening and a urine pregnancy test performed on each test day. To your knowledge, you are not pregnant at this time. You also agree to avoid becoming pregnant. If you change your mind about becoming pregnant we ask that you tell us immediately because these medications are not safe for use in pregnancy and could harm a fetus.

Based on the results of these evaluations, we will determine whether you may be eligible to participate in the clinical study. Usually the screening can be completed in 1 visit, although sometimes you might have to come back for a second appointment to finish everything.

You will be asked to provide a blood sample for DNA analysis. This is not optional, but we will only collect the sample when we have determined that you are eligible to

participate in this study. In most cases, we will draw the blood sample when you come in to pick up your first set of take-home medication. The sample will be used to see if common (and some less common) variations in genes affect the response to the medication and alcohol. It may also be used to see if those genetic variations affect drinking and other behaviors measured in this study.

Screening will last about 3-4 hours and may be split into two separate visits.

Once all of your screening information is reviewed and if it is determined that you are eligible, you will be asked to come in for a short baseline visit (30-60 minutes) where you will complete several surveys. You will first receive counseling and you will be given a week (7 day) supply of a low dose of the study medication (Perampanel or Perampanel + Disulfiram) to take prior for the following week. If you are assigned to receive Perampanel alone, you will be given the medication in tablet form. If you are assigned to receive Perampanel + Disulfiram, you will be given the medication in liquid form. All liquid study medication must be kept refrigerated during the length of the study.

You will begin with a low dose of Perampanel (2mg) and will slowly increase your dose over a period of 4 weeks until you are at 8mg per day. If you are in the group that is taking the Perampanel + Disulfiram, the dose of Disulfiram will increase from 62.5mg per day until you are at 250mg per day. From weeks 4-8, you will take the 8mg dosing of Perampanel, or Perampanel at 8mg and 250 mg dosing of Disulfiram. At visit 10 you will be instructed to slowly decrease your dose every 4 days. There will be a follow-up visit once a week for 2 weeks after your complete the medication regimen.

Here is an example of the medication schedule:

Week	***Perampanel dose***	***+/-Disulfiram dose***
1	**2 mg daily**	**62.5 mg daily**
2	**4 mg daily**	**125mg daily**
3	**6 mg daily**	**187.5 mg daily**
4-8	**8 mg daily**	**250 mg daily**

During the 8-week treatment period. You will come to the clinic for a visit within 1 week after starting the study medication (week 1) and then weekly for visits until the end of the study. At each visit, you will have a saliva alcohol level test, weight and vital signs will be measured. Female subjects will have a urine pregnancy test. Blood and urine samples will be collected. You will complete questionnaires and be interviewed by the

study team about any medications you are taking, and asked about any side effects that you may be experiencing.

At every treatment visit, you will receive Medical Management (MM) intervention counseling, advise on how to reduce or stop drinking and instructed on the importance of daily medication compliance. You will be given medication at each visit with instructions that tell you how you should take your study medication. We will review with you how you should take your study medication at each visit. You should keep all medication out of the reach of children.

A study nurse or Research Assistant will contact you by phone once between each visit to check in and see how you are doing and answer any questions you may have. You may be asked to come to the research center for evaluation if there are any concerns about your safety.

You will be asked to download a video application to your phone or tablet. If you do not own a phone or tablet, one will be provided for your use during the study. You will use the app to video yourself taking study medications daily (full face recording). Only the Investigator and Clinical Study Nurse Practitioner will have access to view your videos to confirm medication is taken daily. Videos are identified using your study identification number and are stored on a secure server for up to 6 months following study completion, after which time, they will be deleted.

You may also be asked to download a video application called “Zoom”. This application can be downloaded to your smartphone or tablet. Rather than video yourself taking the study medication daily, you will click on a provided link each day and have a live “zoom” meeting with Dr. Arias, or another member of the study staff. The staff member will ask you to take your medication, and will confirm medication is taken daily.

Two weeks after you complete the study medication you will be asked to visit the clinic weekly, for two weeks (visits 11 and 12). These visits will last approximately 1 hour and you will be asked to complete surveys and discuss how you are doing with decreasing the medication.

Throughout the study, we will repeat bloodwork at least 5 times to make sure there are no unwanted effects on your health and if we have any concerning results, we will share them with you as soon as we can.

You will also be asked to use a device called “Soberlink”, which is a handheld breathalyzer. This will help researchers track your progress and help give us a better

idea of whether or not the medication may help people to stop drinking. This device must be returned to us at the end of the study.

You will also be asked to refrain from taking any illicit drugs while you are in this study.

The investigators will also collect information from your medical records about your health history. Medical record information will be collected during your participation in the study.

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

Risks due to the study medication (perampanel):
This medication is approved by the U.S. Food and Drug Administration (FDA) for the treatment of Epilepsy. The FDA and Sponsor of Perampanel suggest avoiding the use of Perampanel with strong CYP3A inducers (enzymes which remove toxins from the body) like rifampin or St. John's wort, as it could weaken or strengthen Perampanel.

The most common side effects seen with perampanel have been: dizziness, excessive sleepiness (drowsiness), irritability, headache, fall, and problems with coordination. Dizziness and excessive sleepiness were common in epilepsy trials.

Due to possible drowsiness and excessive sleepiness, the ability to drive, operate heavy machinery, or perform other tasks requiring alertness and coordination may be impaired. For this reason, you should avoid driving or operating heavy machinery until you are familiar with the effects of this medication.

Side effects occurring in 1-10% of subjects in epilepsy clinical trials were appetite changes, aggression, anger, anxiety, confusion, irritability, difficulty with coordination, double vision, blurred vision, nausea, back pain, room-spinning dizziness, headache, difficulty walking and falls.

You will be monitored closely for rare potential side effects such as violent or homicidal thoughts, as these symptoms have been reported (though rarely) in epilepsy trials with the medication. You will be monitored regularly for suicidal thoughts, as this can be a risk with all anticonvulsants.

Serious or life threatening psychiatric and behavioral adverse reactions, including aggression, hostility, irritability, anger, and homicidal thoughts and threats have been reported in patients taking perampanel. If suicidal intent or other major clinical findings are detected during clinical or research assessments, the study physician will be notified immediately. You would not be allowed to leave the clinic until you are considered safe to do so.

The combination of alcohol and perampanel was studied by the company that markets the drug, and they noted that perampanel impaired performance on a simulated driving task, and it basically impaired control of the body more so than just with alcohol alone. You will be informed of any new risks that become known with regard to combining the two. There is the possibility that alcohol and perampanel, when combined, could make you feel tired, or you may have difficulty driving a car or operating machinery.

Because perampanel is newly FDA approved, all the side effects may not yet be known. However, we will work to anticipate possibilities for additional side effects known to occur with similar medications, such as problems producing blood cells in the right amount. The US Drug Enforcement Agency (DEA) has determined that there is some potential for people to abuse perampanel.

Risks due to the study medication (Disulfiram): Disulfiram can cause damage to the liver, and throughout the study we will check bloodwork to monitor your liver function. If you drink alcohol (this includes cough syrups or other medications which may contain a form of alcohol) within 12 hours of taking disulfiram, you may become ill and experience various symptoms, including vomiting, nausea, stomach pain, flushing, chest pain, difficulty breathing, loss of consciousness dizziness or in severe cases heart attack, seizure, death. The effects of disulfiram can last up to two weeks.

Disulfiram should not be taken if you have been diagnosed with severe myocardial disease (which could cause a heart attack), coronary occlusion (blocked arteries) or psychoses (symptoms of impaired reality).

You should not be exposed to ethylene dibromide (poison used in pesticides, insecticide, additive in leaded gasoline) or its vapors as the combination has been linked to higher rates of tumors and death in rats.

You should not take phenytoin, also called Dilantin and Phenytek. Pheytoin is an anti-convulsant and taking it with disulfiram may cause the medication levels to become unstable and potentially too high for your safety.

You should not take anticoagulants such as warfarin, also called Coumadin. Coumadin is a commonly used blood thinner and taking it with disulfiram may cause the medication levels to become unstable and potentially too high for your safety.

You should not take metronidazole, also called Flagyl. Metronidazole is a common antibiotic and taking it with disulfiram can damage your liver and cause the medication levels to become higher than they should be. If you have a skin sensitivity to rubber and things containing rubber then you might not be a good candidate to take disulfiram.

FOR WOMEN: Because alcohol has adverse effects on the fetus, and some medications like perampanel can be harmful to a fetus, you will not be able to participate in this study if you are pregnant or breastfeeding. If you are pregnant or become pregnant, this research may have a bad or unforeseen effect on a fetus and

should not be done during pregnancy. To your knowledge, you are not pregnant at the present time and you agree to avoid becoming pregnant (use contraceptives, take precautions against becoming pregnant, etc.) during this study. If you are a woman, you will be screened for pregnancy before and during your participation in the study. You will not be allowed to participate if you are pregnant or breastfeeding.

Perampanel may lower your oral contraceptive's ability to prevent pregnancy if your oral contraceptive contains levonorgestrel. Because of this, women will be asked to use at least two forms of contraception, such as condom with spermicide, and at least one form must be non-hormone based such as a barrier method like a condom. If you change your mind about becoming pregnant we ask that you tell us immediately. You will receive a blood pregnancy test at the initial screening appointment and a urine pregnancy test on each test day. You will be excluded (dropped) from the study if you become pregnant**.**

Reproductive Risks

As the study procedures might injure an unborn child, pregnant women may not participate. 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 and several months after treatment is stopped. 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.

Only the study participant can take the study drug. It must be kept out of the reach of children and persons who may not be able to read or understand the label.

During this study you will be asked to have multiple blood draws (we estimate no more than 10TBSP of blood) to monitor for any negative effects on your body. Because this is for your safety, if you do not want your blood drawn then you may be asked to leave the study. Blood draws can be uncomfortable, may cause bruising, dizziness and some people experience passing out during blood draws. If this is a problem for you, please

tell staff immediately. Although the amount is less than a typical blood donation (16 ounces), you should refrain from blood donations eight weeks before and after testing.

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.

Questionnaires may contain questions that are sensitive or personal in nature. You may refuse to answer any question that makes you feel uncomfortable.

This study will ask you questions about personal topics that might be embarrassing to talk about and that could affect your family relationships if this information were to become known outside of the study. 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.

Genetic Risks:
If known to employers or insurance companies, the results of genetic tests might affect a person's ability to obtain a job or health or life insurance. If this information were released, it could be misused. Such misuse could be distressing, and it could cause you or your family members to have difficulty obtaining insurance coverage and/or a job.

A federal law called the Genetic Information Nondiscrimination Act (GINA) makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, this legal protection still may not keep someone from trying to discriminate against you in this way.
While all efforts are aimed at protecting and guarding your blood and/or DNA samples, there remains the possibility that VCU could be compelled by a court or a law enforcement agency to produce such samples. In more than six years of collecting DNA samples at VA Connecticut, where similar studies were previously run, in which many hundreds of samples have been collected, no outside agency has ever tried to gain access to any research participant's blood or DNA samples. Dr. Arias believes that the risk of this happening to your sample is extremely small.

Unknown or Unforeseeable Risks
Perampanel involves risks that are currently unknown or unforeseeable. The researchers will let you know about any significant new findings (such as additional risks, side effects or discomforts) that might make you change your mind about participating in the 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.

You will need reliable transportation throughout the study because you will have weekly visits. If you do not have reliable transportation, please tell staff and we will discuss any available options with you.

WILL I BE PAID TO PARTICIPATE IN THE STUDY?

You will be paid in cash, by check or clincard and if you complete all scheduled study visits, you will have received a total of $800. If you withdraw before the end of the study, you will only be paid for completed visits.

After completion of the screening visit you will receive $50, and $75 for each weekly treatment visit (8) that is scheduled. At the endpoint visit, you will be paid $100, and then $25 at each post-treatment 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.

Please be aware that the investigative team and the University may receive money for the conduct of this 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 doctor immediately. You will be given an emergency wallet card with the study doctor's contact information on it. Medical treatment is available at the Virginia Commonwealth University Health System (VCU Health System). Your study doctor 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.

If you leave the study before the final regularly scheduled visit, we may ask you to have a few clinic visits so that we can safely reduce your medication dosing if necessary. Perampanel is normally tapered because in people who take it for seizures, it can cause someone to be more likely to have seizures if it is not tapered.

If you are taking Disulfiram, you should not drink any alcohol or take any medications that contain alcohol (such as cough syrups) for at least 12 hours after your last dose. Disulfiram can stay in your body at a low level for up to 2 weeks, and there is the risk of having a reaction if you drink alcohol while Disulfiram is still in your system.

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

- the study doctor 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 but are 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, such as the medications you receive, may 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.

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

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.

In the future, identifiers might be removed from the information and samples you provide in this study, and after that removal, the information/samples 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. If this certificate is obtained, it will offer 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 that there is the risk of abuse to others or harm to yourself or others.

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. 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	☒ Diagnosis & treatment codes	☒ Discharge summary
☒ History and physical exam	☒ Consultation reports	☒ Progress notes
☒ Laboratory test results	☒ X-ray reports	☒ X-ray films / images
☐ Photographs, videotapes	☐ Complete billing record	☐ Itemized bill
☒ Information about drug or alcohol abuse	☒ Information about Hepatitis B or C tests	
☒ Information about mental health	☒ Information about sexually transmitted diseases	

☐ Other physical or mental health information (specify):

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 research study involves the use of a Data Registry or Sample Repository and will never expire.

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

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OPTIONAL STORAGE FOR FUTURE RESEARCH STUDIES
To advance science, it is helpful for researchers to share information. They do this by putting data or samples into one or more scientific databases (called registries or repositories), where it is stored along with information from other studies. Researchers can then study the information in other ways and combine information from many studies to learn even more about health and disease.

As part of this study, we would like to keep the information and/or samples that you provide in a registry/repository to be available for other research studies in the future. Your information and samples would be stored at VCU by Dr. Albert Arias and could be used for other research studies about any topic. Your data/samples will be protected, but there is always a possibility that information could be accessed by individuals

without authorization. There is no limit on the length of time we will store your information/samples.

Your samples, genomic data and/or health information will be stored indefinitely by VCU in one or more scientific databases, and shared with other researchers. The samples and information will be available for any research question, such as research to understand what causes certain diseases (for example heart disease, cancer, or psychiatric disorders), development of new scientific methods, or the study of where different groups of people may have come from. This information will not be labeled with your name or other information that could be used to easily identify you. However, it is possible that the information, when combined with information from other public sources could be used to identify you, though we believe it is unlikely that this will happen.

Your individual genomic data and health information will be put in a controlled-access database at the National Institutes of Health. This means that only researchers who apply for and get permission to use the information for a specific research project will be able to access the information. Your genomic data and health information will not be labeled with your name or other information that could be used to identify you. However, it is possible that the information from your genome, when combined with information from other public sources could be used to identify you, though we believe it is unlikely that this will happen. Researchers approved to access information in the database will agree not to attempt to identify you.

In the future, if you decide that you don't want to be part of this registry, you can request that your information/samples be removed and destroyed by contacting Dr. Albert Arias. However, information that has already been shared with other researchers will continue to be used.

In addition, identifiers will only be kept for 5 years following study conclusion. After that time, withdrawal will no longer be an option because the individual specimens will no longer in any way be linked to the person from which they were originally drawn.

Permission to Store Data and/or Samples for Future Research Studies
I agree that my blood, DNA, tissue and other data may be stored and used for future research as described in this document. I understand that by choosing "NO", I will be unable to participate in this study and am opting out.

Please circle your answer and initial:

YES NO Initials _____

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

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

Dr. Albert Arias
Institute for Drug and Alcohol Studies
203 E Cary St, Richmond, VA 23298
860-558-2273 or (804) 828-5793
Email: albert.arias@vcuhealth.org

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/volunteers.htm

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	
_____ Adult Participant Name (Printed)	
_____ Adult Participant's Signature	_____ Date
_____	

Name of Person Conducting Consent Discussion (Printed)	
_____	_____
Signature of Person Conducting Consent Discussion	Date
_____	_____
Principal Investigator Signature (if different from above)	Date