BROWN UNIVERSITY
CONSENT FOR RESEARCH PARTICIPATION

Effects of Lamotrigine on Adolescent Alcohol Use
Version 5.0 20DEC2021

We invite you to be part of a research study directed by Dr. Robert Miranda and his associates at Brown University. You were selected as a possible participant in this study because you said you're interested in reducing your alcohol use.

The researchers will explain this study to you. **Research studies are voluntary and include only people who choose to take part.** Please take your time about deciding whether to participate in this study. Before deciding:

- You can discuss this study with your parents.
- You can also discuss it with your health care doctor.
- If you have any questions, you can ask the researchers for more information.

KEY INFORMATION

- PURPOSE: This study is about whether the study medicine plus alcohol education helps teenagers reduce their alcohol use. In this document, you will see the terms *medication*, *treatment*, and *treatment period*. These are terms used in research studies; they do not mean that you will be receiving medical treatment for any condition.
- PROCEDURES: You will take a study medication for 9 weeks; answer personal questions, such as questions about drug and alcohol use, both in person and in your daily life using a smartphone; complete medical tests, including an alcohol breathalyzer, physical exam, heart rate, blood pressure, a urine drug test and, if female, a pregnancy test; provide a blood sample; go through a task where you look at water and an alcoholic drink and answer questions; and take part in 7 computerized alcohol education sessions.
- TIME INVOLVED: After screening and during the 9-week study, you will attend weekly 30-minute visits; seven 30-minute computerized alcohol education sessions; two 2-hour and one 1-hour assessment sessions; three 10-minute phone calls over two weeks when you first start taking the study medicine; two 10-minute phone interviews while you stop taking the study medicine over a 2-week period; one 10-minute phone interview 2-weeks after you finish taking the study medicine; and one 30-minute phone interview 3-months after you finish taking the study medicine.
- COMPENSATION: If you complete the study, you will receive up to $527 for your time.
- RISKS: Possible risks include discomfort or bruising with drawing blood; loss of privacy; undue influence; discomfort answering personal questions; and side effects of the medication, such as dizziness, tremor, headache, rash, blurred or double vision, fever, lack of coordination, abdominal pain, sleepiness, back pain, nausea, vomiting, diarrhea, tiredness, insomnia, dry mouth, confusion, paresthesia (burning sensations) and amblyopia (lazy eye).
- BENEFITS: The computerized alcohol education sessions may help you cutback or quit alcohol.
- ALTERNATIVES TO PARTICIPATION: We do not offer other options. There are local treatment programs, however, and you will get a list of those services.
- REMOTE OPTION: If in-person visits are not possible, we may offer you the option to have some of your visits completed remotely, via telephone or Zoom video conference. Parts of the in-person visits that cannot be done over the telephone or Zoom video conference may be excluded or rescheduled. You may be asked to sign in or download an app to use Brown University's Zoom platform for teleconferencing, depending on your device, and you will need WIFI connection.

WHY IS THIS STUDY BEING DONE?

This study will test if a medicine called lamotrigine helps young people reduce their alcohol use. Lamotrigine is a mood- stabilizing anticonvulsant or antiepileptic medication approved by the U.S. Food and Drug Administration (FDA) to treat epilepsy in patients two and older. We hope it will help youth reduce their drinking. But we don't know this for sure. There is no medicine to help teenagers reduce their alcohol use. This drug appears to reduce alcohol use in adults with co-occurring mood and alcohol problems. This study is the first to test its effects on alcohol use among teenagers who want to reduce their drinking.

WHAT WILL HAPPEN IF YOU TAKE PART IN THIS STUDY?

Before you begin the study:

Before you begin this study, we need to find out if this study is right for you. This **screening** takes about 2.5 hours. You will take an alcohol breath test and if your alcohol level is above 0.00% at any study visit you will need to return another day.

We will ask you questions about your health and alcohol and drug use. You will give urine and blood samples and have a physical exam by a study doctor. We will test urine for illegal drugs and, if female, pregnancy. If your urine is positive for any illegal drug except marijuana, you won't be able to be in the study.

Females cannot be in this study if they are pregnant or breastfeeding. It is not known if the study medication may harm an unborn baby. The study medication can reduce the effectiveness of oral contraceptives (birth control pills) or other female hormonal medicines. Sexually active females cannot be in this study if they do not agree to use a barrier method of birth control (condom).

To see if the study is a good fit, what is one thing that you will need to complete?

During the study:

- If you are a good fit for this study, you will come to our office for a **pre-medication session**. You will take an alcohol breath test, urine drug test and, if female, a pregnancy test. You will answer more questions about yourself. We will record your heart rate, blood pressure, and urge to drink alcohol while you relax and while you look at water and an alcoholic drink. This is called a **cue reactivity assessment**. It may take time for your urge to go down. If your urge remains high, you will meet with a study clinician to help manage your craving. This session will take about 2.5 hours.

- You will attend **9 weekly checkup visits** at our office, each lasting about 30 minutes. During these visits, you will complete an alcohol breath test and provide a urine sample to test for drug use and, if female, pregnancy. We will record your blood pressure and heart rate. We will also ask you about side effects, your mood, any new medications or therapy, and recent alcohol and drug use. Once you start the study medicine, you will return any unused capsules and get more.

- You will complete **three telephone interviews**. These are brief interviews that last about 10 minutes; two happen in Week 1, and one happens in Week 2. We'll ask about any side effects, other medication use or counseling, alcohol withdrawal symptoms, and the number of medication capsules you've taken. We'll also remind you about dose increases and your next scheduled visit.

- You will also receive in 7 computerized alcohol education sessions (Weeks 1, 2, 3, 4, 5, 7, and 9) about your alcohol use, including your thoughts about cutting back, how your drinking compares to others, and how alcohol is harmful. We'll help you track your drinking and set goals to cut down. Everyone will get the alcohol education program regardless of how much they drink. Each session lasts about 30 minutes. If possible, sessions will happen on the same days as your weekly checkups.

- **For nine weeks, you will take medication capsules** that contain lamotrigine or placebo. If you take lamotrigine, the dose will start at 25 mg per day for Weeks 1 and 2, then increase to 50 mg per day for Weeks 3 and 4, 100 mg/day for Week 5, 150mg Week 6 and Weeks 7-9 will be at the highest dosage of 200mg/day. You'll take the same type of capsule (lamotrigine or placebo) during the 9-week study.

  About one-half of youth will get the study medicine; the other half will take placebo pills that look like medicine but are not real. Placebo pills should have no physical effect on you. We will use a method of chance to decide the group you're in (e.g., **medication assignment**). This method is like flipping a coin. You will not know which group you are in. Neither will the researchers. A prescription for the study medicine or placebo will include your name, address, and date of birth.
- You will use a study smartphone or download an app to answer questions as you go about your daily life for nine weeks. For the first 6 weeks you will answer questions when you wake up and when you take your study medication. The last three weeks you will answer questions when you wake up, drink alcohol, take medication, and when it beeps (about 4 times per day).You'll record where you are, what you're doing, how you're feeling, urges to drink, and how many alcoholic drinks you drank (if any). We'll check in to see how you're doing and answer any questions. We recommend that you respond to the app at a time and place that allows for privacy. You can skip or delay responding when necessary. This app does not require WIFI or internet connection to work.

- During the Week 8 checkup visit, you will do a second **cue reactivity assessment** just like the first. We'll measure your urge to drink alcohol while you relax and while you look at water and an alcoholic drink. You will also provide a blood sample to test the levels of study medicine in your blood. This entire visit, combined with the alcohol education session, will take <u>about 2.5 hours</u>.

- At the end of the 9-week study, you will complete a **final in-clinic visit** that takes about 60 minutes and reduce and stop your medication dose over two-weeks. You will complete two phone interviews while you stop the medicine over two-weeks (1 each week). You will also complete a brief phone interview 2 weeks after you completely stop the study medicine.

<u>After you finish alcohol education and the study medicine</u>:
You will complete a brief **follow-up interview** over the phone, 3-months after you finish the study medicine, about your recent alcohol and drug use. This interview will take <u>about 30 minutes</u>.

Please explain two or three things that will happen if you decide to participate in this study.

SCHEDULE OF ASSESSMENTS

	Screening	Pre-Medication Session	Weekly Checkup Visits 1	2	3	4	5	6	7	8	9	Final In-Clinic Visit	Phone Checkups (Weeks 10, 11,& 13)	3-month Follow-up Interview
Alcohol breathalyzer	•	•	•	•	•	•	•	•	•	•	•	•		
Blood pressure & heart rate	•	•	•	•	•	•	•	•	•	•	•			
Blood draw	•									•				
Phone interview (10 min.)			•	•			•							
Cue reactivity assessment		•								•				
Interviews & questionnaires	•	•	•	•	•	•	•	•	•	•	•	•		
Physical Exam	•													
Smartphone assessments			•	•		•	•	•		•	•			
Urine drug test	•	•	•	•	•	•	•	•	•	•	•	•		
Urine pregnancy test	•	•	•	•	•	•	•	•	•	•	•	•		
Phone interviews (10 min.)*													•	
Phone interview (30 min.)														•

*You will complete two phone interviews while you stop the medicine over two-weeks (1 each week). You will also complete a brief phone interview 2 weeks after you completely stop the study medicine.

HOW LONG WOULD YOU BE IN THIS STUDY?

The study takes about 9 weeks plus two brief phone interviews while you are stopping the study medicine over a 2-week period and two more brief phone interviews that occur 2-weeks and 3-months after you finish taking the study medicine.

WILL YOU BE PAID FOR YOUR PARTICIPATION?

If you complete the study, you will get up to $527.00. You will be paid in gift cards for the screening session. If you are eligible and enroll in the study you will be paid in gift cards and/or ClinCard (see below), based on your choice. We will pay you for all parts of the study you complete, even if you decide to stop the study early for any reason. The payment schedule will be as follows:

Screening session	$20	
Blood tests & physical exam	$20	
Baseline session	$20	
9 weekly checkup visits	$180	$20 for each checkup completed
9-week smartphone period	$147	$1 per day for first 6 weeks $5 per day for last 3 weeks
Final in-clinic visit	$20	
Bonus	$40	For returning remaining capsules and the smartphone (if applicable)
2 phone interviews while stopping study medicine	$40	$20 for each interview completed
2-week phone interview	$20	
3 month phone interview	$20	
Total	$527	

If you choose, payment for participating in this study may be made using ClinCard, a pre-paid Mastercard that works like a debit card.

We will give you the card. You will be given one card for the entire time of your participation and this card may be used to pay you in any future Brown University studies that use ClinCard. You will also get information about how to use this card and whom to call if you have any questions. Be sure to read this information, including the cardholder agreement from Greenphire.

Money will be added to your card based on the study's payment schedule. You may use this card online or at any store that accepts Mastercard. Please read the FAQ information sheet from your study coordinator for details about the ways you can use the card, some of which may involve fees that will reduce the amount of money on the card.

If you earn $600 or more from Brown University in a single calendar year (either in a one study or across multiple studies), Brown will ask for your social security number to correctly identify you in the payment system and send you an IRS 1099 Form. You may also be asked to complete a Form W9. This may affect your taxes. Only payments for being in research studies will be used to decide if you should receive the IRS form. Money for study-related parking, food, and other expenses are not included in this IRS disclosure.

This card is administered by an outside company called Greenphire. Greenphire will be given your name, address, and date of birth. They will use this information only as part of the payment system, and it will not be given or sold to any other company. Greenphire will not receive any information about your health status or the study in which you are participating.

If your card is lost or stolen, please call the study coordinator for a free replacement card. If you request a replacement card from Greenphire directly, you may be charged a fee.

Please note that you do not need to use ClinCard to be in this study. You can chose to receive study payments in gift cards instead.

WHAT KINDS OF RISKS OR DISCOMFORTS COULD YOU EXPECT?

- **Potential study medicine risks:** Many studies have researched the effects of lamotrigine in children (ages 2 years and older), teenagers, and adults. Studies show it is safe with teenagers and it does not harmfully interact with alcohol in adults; interactions with alcohol are unknown in adolescents. Adult heavy drinkers, non-heavy drinkers, and non-drinkers tolerate this medicine equally well.

Rare but Serious Dermatological Reactions	**Serious skin rashes, such as Stevens-Johnson and toxic epidermal necrolysis, have been caused by lamotrigine.** They are more common in pediatric patients and when lamotrigine is administered with valproic acid [Depakote]). Stevens-Johnson syndrome is a rare but serious condition that could require hospitalization if not recognized and treated.

Most Common Side Effects	▪ Blurred or double vision or other changes in vision ▪ Diarrhea ▪ Nausea ▪ Vomiting ▪ Indigestion ▪ Skin rash	▪ Clumsiness or unsteadiness ▪ Poor coordination ▪ Dizziness ▪ Tiredness ▪ Trouble sleeping ▪ Headache
Less Common Side Effects	▪ Abdominal pain ▪ Constipation ▪ Sore throat or dry mouth ▪ Loss of strength ▪ Menstrual pain	▪ Unusual weight loss ▪ Anxiety ▪ Confusion ▪ Depression or irritability ▪ Chest pain

	▪ Pain ▪ Runny nose ▪ Slurred speech ▪ Trembling or shaking ▪ Vertigo or a sensation of feeling off balance	▪ Confusion ▪ Continuous, uncontrolled back-and-forth or rolling of the eyes ▪ Seizures ▪ Infection
Rare Side Effects	▪ Blistering, peeling or loosening of skin ▪ Liver failure ▪ Dark-colored urine ▪ Fever ▪ Chills ▪ Flu-like symptoms ▪ General feeling of discomfort or illness ▪ Cough ▪ Memory loss ▪ Itching ▪ Muscle cramps ▪ Red or irritated eyes ▪ Small red or purple spots on skin ▪ Sores, ulcer, or white spots on lips or mouth	▪ Swelling of face, mouth, hands, or feet ▪ Swollen lymph nodes ▪ Anemia ▪ Trouble breathing ▪ Unusual bleeding or bruising ▪ Unusual tiredness or weakness ▪ Yellow eyes or skin ▪ Loss of appetite ▪ Allergic reactions ▪ Blood dyscrasias (drop in blood counts) ▪ Suicidal thoughts or behaviors, ▪ Aseptic (non-infectious) meningitis

FEMALES SHOULD NOT TAKE LAMOTRIGINE IF THEY ARE PREGNANT OR BECOME PREGNANT DURING THE STUDY.

- **Lamotrigine can reduce the effectiveness of oral contraceptives** (birth control pills) or other female hormonal medicines. Before taking lamotrigine, tell your study physician if you are taking oral contraceptives (birth control pills) or other female hormonal medicines. Do not start or stop taking birth control pills or other female hormonal medicine until you have talked with your study physician. Tell your study physician if you have any changes in your menstrual pattern, such as breakthrough bleeding. Stopping these medicines while taking lamotrigine may cause side effects (such as dizziness, lack of coordination, or double vision). Starting these medicines may lessen how well lamotrigine works.
- Sexually active females cannot be in this study if they do not agree to use a **barrier method of birth control (condom)** every time they engage in sexual intercourse.
- **It is not known if lamotrigine may harm an unborn baby**.
- If you become pregnant during the study, notify your study physician immediately. In addition, you can talk with your study physician about registering with the North American Antiepileptic Drug Pregnancy Registry. You can enroll in this registry by calling 1-888-233-2334. The purpose of the registry is to collect information about the safety of antiepileptic drugs during pregnancy.

In addition, you should not take lamotrigine if:

- You have kidney or liver impairment
- Previous history of a harmful drug reaction that affects the skin, white blood cells, and various internal organs.
- You are allergic to lamotrigine (active ingredient: lamotrigine; inactive ingredients: lactose;

magnesium stearate, microcrystalline cellulose, povidone, sodium starch glycolate, FD&C Yellow No. 6 Lake (100-mg tablet only), ferric oxide, yellow (150-mg tablet only), and FD&C Blue No. 2 Lake (200-mg tablet only)

Before taking lamotrigine **notify us** of all health conditions (or a family history of), especially:

Suicidal thoughts or actions	Irregular heartbeat	Mania or bipolar illness
Heart problems or defects	High or low blood pressure	Depression
Had a rash or allergic reaction to anti-seizure medication	Psychosis	Mental health problems
	Kidney impairment	Liver impairment

The study medicine may change how other medications work. So, it is very important to tell us about any new medications you use during the study so we can make sure it's safe. This is especially true if you take medication that includes acetaminophen (Tylenol), valproate acid (Depakote), carbamazepine (Tegretol XR, Equetro, Epitol), phenytoin phenobarbital, primidone (Mysoline), and rifampin and protease inhibitors lopinavir/ritonavirand atazanavir/lopinavir (HIV antivirals).

Be careful driving or using machinery until you know how the medication affects you. It may make you feel sleepy or dizzy, making it hard to drive or perform other activities safely.

- **Placebo risks:** Placebo pills will contain microcrystalline cellulose, a commonly used inactivefiller, and 50 mg of riboflavin. Riboflavin is an easily absorbed water-soluble vitamin (B2). There are no known toxic or adverse reactions to riboflavin in humans.
- **Blood draw risks:** Problems drawing blood rarely occur. These include temporary discomfort from the needle stick, local bleeding, a lump or bruising and, rarely, infection, lightheadedness and fainting. Only a small amount of blood will be taken, about 2 teaspoonfuls.
- **Psychological risks:** Some questions we ask may be upsetting or you may feel uncomfortable answering them. If you do not wish to answer a question, you can skip it and go to the next.
- **Loss of confidentiality:** As this study involves the use of your identifiable, personal information, there is a chance that a loss of confidentiality or privacy will occur. We have procedures in place to reduce the chances of this happening (see "How will information about you and your participation be kept private?" section below).
- **Undue influence:** Undue influence can happen when the payment you get is large. Such pressure is unlikely in this study because payments are fair for the time and effort required and like other studies in the area. There will be no other rewards or payments. Even if you stop, we will pay you for any time you were in the study. If you decide not to participate in this study or decide to stop the study, you will not lose access to needed health services available outside the study.

Please explain two or three risks of participating in this study.

Unknown risks and discomforts:
The study medicine may have side effects that no one knows about yet. The researchers will let you know if they learn of anything that might make you change your mind about participating in this study.

WHO TO CONTACT IF YOU HAVE A STUDY-RELATED INJURY, ILLNESS, OR DISTRESS?
If you have any questions, concerns or complaints about this study or to report a study-related injury, contact Robert Miranda, Jr., Ph.D. or a study physician at **1-800-759-6045**. If you get sick or have any problems from taking the study drug you must call your study doctor at this number right away. We will provide emergency care, if necessary, but Brown University and the researchers assume no responsibility to pay for such care or to provide financial compensation for emergency or non-emergency health services.

If you are unable to reach anyone at the number listed above and you require immediate (life threatening) medical attention, please go to your nearest emergency room.

ARE THERE ANY BENEFITS IF YOU PARTICIPATE?
You may or may not directly benefit from being in this research study. You will get the alcohol education program even if you decide to stop the study medication. You will also have the chance to contribute to research that may be helpful to you or to others in the future.

WHAT OTHER CHOICES DO YOU HAVE IF YOU DON'T WANT TO PARTICIPATE?
If you decide not to participate in this study, we do not offer any other study. There are treatment programs in Rhode Island, however, and we will give you a list of those services.

HOW WILL INFORMATION ABOUT YOU AND YOUR PARTICIPATION BE KEPT PRIVATE?

Use of personal information that can identify you:
Any information we collect about you as part of this study that identifies you will remain private. Only a code number will be used to identify your private information; your name will not be matched with your private information. We will keep all information about you locked up and password protected. It will be disclosed only with your permission or as required by law. In accordance with federal FDA requirements, all study records must be retained for at least three [3] years after the completion of research.

Clinical research relies on truthful data collected from you without the fear of disclosure of your sensitive information. Congress authorized the Secretary of Health and Human Services to issue Certificates of Confidentiality that allows research investigators to refuse to disclose identifiable information about you even under a subpoena. This study has been issued a Certificate of Confidentiality from the National Institute on Alcohol Abuse and Alcoholism (NIAAA). The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you.

The Certificate cannot be used, however, to resist a demand for information from personnel of the United States federal or state government agency sponsoring the project and that will be used for auditing or program evaluation of agency funded projects or for information that must be disclosed in order to meet the requirements of the federal FDA.

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, medical care provider, or other person obtains your written consent to receive research information, then the researchers will not use the Certificate to withhold that information.

As a participant in this study, you must also do your part in protecting your identity and your sensitive information linked to this study: The Certificate of Confidentiality remains protective if you do not disclose your participation to others. Once disclosure is in the public domain, it's possible that the Certificate of Confidentiality can be challenged.

If you give us your permission by signing this document, information, which does not identify you by name, may be used for scientific purposes, including teaching or publication. Because of the investigational nature of this study, the study sponsor, the Brown University Institutional Review Board, the FDA, the Department of Health and Human Services, the Offices of Inspector General and Civil Rights have the right to review study records. Your information will be kept confidential. Your name, address, and date of birth may be used to fill an individualized prescription for lamotrigine or placebo capsules. This information will be disclosed to a study pharmacy and blood laboratory, when applicable, which adheres to the Health Insurance Portability and Accountability Act (HIPAA) practices and stores this information in a private, password protected and encrypted format.

How information about you will be stored:
We maintain all research data and records in a secure location at Brown University. Only authorized individuals will have access to it.

When will we share some of your private information with others:
Instances when information will not be kept confidential or private involve reports of child abuse, elder abuse, or threats to harm yourself or others. If you report suicidal or homicidal intent or ideation or child or elder abuse, the principal investigator, a clinical psychologist, or study physician will be notified immediately. A report will be filed with the appropriate authorities if abuse is reported.

When are the researchers required to share some of your private information with authorities?

People and agencies that will have access to your information:
The National Institutes of Health, the Brown University Institutional Review Board, the FDA, the Department of Health and Human Services, the Offices of Inspector General and Civil Rights have the right to review study records.

Members of our research team are part of the Lifespan health system and Rhode Island Hospital and will have access to the study records. An individual prescription for the study medicine or placebo will include your name,
address, and date of birth. In addition, for your blood samples to be processed, the laboratory order will include your name, sex at birth and date of birth. We will share this information with the study pharmacy and blood laboratory, which adheres to HIPAA practices and stores this information in a private, password-protected, and encrypted format.

Information collected during this study will be stored in a central repository at the National Institutes of Health (NIH). None of the information shared with the NIH can be used to identify you; it will be anonymous. Any information that could identify you will be removed. The purpose of storing data at the NIH is to make information available for use in research for this study and health-related research in the future, after the current study is completed. Sending information to the repository may give scientists valuable research material that can help them to develop new diagnostic tests, new treatments, and new ways to prevent diseases.

ARE THERE ANY COSTS FOR TAKING PART IN THIS STUDY?
There will be no cost to you for being in this study.

WHAT IF YOU WANT TO STOP PARTICIPATING IN THIS STUDY?
You do not have to be in this study if you do not want to be. Even if you decide to be in this study, you can change your mind and stop at any time. Refusing to participate in or stop the study will not affect your current or future relationship with Brown University, Dr. Robert Miranda, or other researchers. If you want to stop, it is important to tell us so that we can get any remaining medication and, if necessary, the smartphone device from you.

Can you change your mind and stop your participation in this study?

WHO CAN YOU CONTACT IF YOU HAVE QUESTIONS ABOUT THIS STUDY?

The Research Team:
You may contact Dr. Robert Miranda at 401-863-6658 or by email at Robert_Miranda_Jr@brown.edu with any questions or concerns about the research or your participation in this study. Additionally, you may contact research staff Brianna Parlette at 401-863-6687 or by email at Brianna_Parlette@brown.edu.

Brown University Human Research Protection Program (HRPP):

If you have questions about your rights while taking part in this study, or you have concerns or suggestions about the study and you want to talk to someone other than the researchers, you may contact Brown's HRPP at 401-863-3050 or email them at IRB@Brown.edu.

WHERE CAN YOU FIND PUBLIC INFORMATION ABOUT THIS STUDY?
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by US 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 website at any time.

AGREEMENT TO BE IN THE STUDY
This consent form contains important information to help you decide if you want to be in this study. If you have any questions that are not answered in this consent form, ask one of the study staff.

Please answer YES or NO to the following questions:

A.	Is this document in a language you understand?	_____
B.	Do you understand the information in this consent form?	_____
C.	Have you been given enough time to ask questions and talk about the study?	_____
D.	Have all your questions been answered to your satisfaction?	_____
E.	Do you think you received enough information about the study?	_____
F.	Do you volunteer to be in this study of your own free will and without being pressured by the investigator or study staff?	_____
G.	Do you know that you can leave the study at any time without giving a reason and with affecting your health care?	_____
H.	Do you know that your records from this study may be reviewed by the study sponsor and by government authorities?	_____
I.	Do you know that you cannot be in another study while you are in this study?	_____

You must show that you understand what this study involves by correctly answering the five questions included in this form. To sign this consent form, you must also be able to answer "Yes" to questions A-I listed directly above.

Please check whether you agree to be re-contacted for future studies and initial.

____Yes ____ No _____ (Initial)

Your signature below shows that you have read and understood the information in this document. The researchers answered your questions to your satisfaction and you agree to volunteer as a research participant for this study. We will give you a copy of this form.

Printed Name of Adult Study Participant

Signature of Adult Study Participant | Date/Time

Printed Name of Person Explaining Consent Form

Signature of Person Explaining Consent Form | Date/Time

Brown University IRB Original Approval: 05/21/2020
Brown University IRB Amendment Approval: 01/21/2021
Brown University IRB Amendment Approval: 06/15/2021
Brown University IRB Amendment Approval: 08/27/2021
Brown University IRB Amendment Approval: 12/22/2021
Brown University IRB Amendment Approval: 01/25/2022