UNIVERSITY of MARYLAND
THE FOUNDING CAMPUS

RESEARCH CONSENT FORM

Protocol Title: Circuitry-Guided Smoking Cessation in Schizophrenia

Study No.: HP-00077085

Principal Investigator: Xiaoming Du Ph.D. 410-402-6036

Sponsor: National Institute on Drug Abuse

You are invited to participate in a clinical research on treatment for nicotine addiction in patients with schizophrenia spectrum disorders. We will use a technique called repetitive transcranial magnetic stimulation (rTMS) to help you reduce/quit smoking. Clinical assessments, brain waves measurement by EEG and functional magnetic resonance imaging (fMRI) tests will be done at different periods of the rTMS treatment. Your participation in this study is voluntary.

PURPOSE OF STUDY

The purpose of this research is to provide an effective rTMS treatment for nicotine addiction in patients with schizophrenia spectrum disorders. rTMS is a new procedure approved by Food and Drug Administration to treat depression. It is still experimental for nicotine addiction, schizophrenia and other brain problems. It works by sending a magnetic field into the brain. This affects brain activity by generating electric activities. This study is to test whether these rTMS generated electric activities may correct the abnormal brain activities related to nicotine addiction.

You will be asked to stay still during the rTMS. The rTMS will be delivered for up to 1 hour a day (1 session) for up to 20 sessions. Your involvement in this study will be about 1-2 hours a day. There are also additional visits where clinical assessment, brain wave measurement, and the fMRI will occur. One to three follow-up visits will occur within one year after the end of rTMS treatment, although phone interview is an option. Findings from this study may help physicians find ways to correct abnormal brain functions for nicotine addiction. By signing this consent form, you are allowing us to use the data that we will collect during this study, including your screening data. Screening data may include your medical history, family history, and other information. Data is only destroyed if you do not qualify for the study or if you request it to be destroyed. You will be one of approximately 150 subjects to be asked to participate in this study.

PROCEDURES

If you participate in this study, you will be asked to do a number of different types of tests. Each of these tests is described below:

Clinical assessments. You will meet with a member of the research team. We will ask questions about your mental health and mental illness in your family. We will also ask you questions about your physical health. You may be asked to give a urine sample for measurement of chemicals, test for illegal drug use or other drugs that may be in your body and/or pregnancy testing. This

information is for measuring cotinine level, screening purposes and used to determine eligibility. You may be tested for recent alcohol use by blowing into a tube. You may not participate if you have alcohol in your breath. You may be tested for recent smoking by questions and blowing into a machine. You will be asked many questions through interviews and several questionnaires. These questions will inquire about your past and current thinking and emotional experiences, any unusual experiences, and medical history. We may also ask you about present or past food intake and drug use. We will also perform cognitive and functional testing. Cognitive functions are our thinking and reasoning abilities. You will be asked to do a number of computer, paper and pencil, and role play tests that measure how well you solve problems and remember things. This part of the study will take about 4 hours. If you have done these tests in another study, you may not need to repeat them.

Brain Wave Measures. Our brains produce small amounts of electricity when they are active. As part of this study you will be asked to wear a cap that measures this electrical activity while you listen to click sounds or view presentations. These tasks involve resting, passive listening or viewing, and more active performance when we ask you to pay attention, remember, and/or respond using a response pad. In one of the tasks some clicks will be loud enough to cause you to startle or blink. The electrical activity caused by the movement of the eye muscles will be recorded using padded wires taped near your temple. We may also monitor your eye movements in some tasks using electrodes around your eyes. We will teach you how to do each task. Most of the tasks are done on a computer. These tests should take about 1- 2 hours each time. Brain wave can be recorded with or without TMS. There will be frequent breaks in-between each recording.

Training. You could be trained to do some tasks in a mock scan session. This training session will give you a chance to practice the tasks and allow you to become familiar with the MRI process.

MRI. Your head will be placed inside a special headset in the MRI machine. This machine uses a strong magnet and radio waves to take pictures of your brain. The MRI pictures will be used to see how your brain works while you perform the tasks. When the MRI scanner is working, it is normal for the machine to make loud banging and clicking noises. We will give you earplugs or headphones for your comfort during the exam. You will be inside the scanner for about 1 - 2 hours. While you are doing the tasks, we may also measure your vital signs or other bodily functions. It is important that you keep your head still. We may use firm padding, headband, foam, bite bar (a mold of your teeth that you bite on to help keep your head in the same spot), and/or vacuum pillows to assist you in reducing head movement. You will be asked to perform several tasks divided into multiple sessions within these 1 - 2 hours. Some of the times we will ask you to rest (but to stay awake). We may also ask you to perform tasks that test your memory, attention, decision-making, task performance speed and accuracy. These tasks require you to pay full attention and to respond by pressing on a response pad. Your eye movements can be measured using a special camera. You may also perform simple visual, auditory, and motor tasks. This can be done in the same or a separate MRI session.

TMS. For rTMS, a wire coil is held on the scalp. Brief electrical currents are passed through the coil and create one or more magnetic pulses that stimulate the brain. You will hear clicks and may feel a pulling sensation on the skin under the coil. Also there may be a twitch in muscles of

the face, neck, arm or leg. During the stimulations we may ask you to perform simple muscle movements. We will make some marks on your scalp. The marks will be removed at the end of the session. The actual TMS stimulation will be 1 hour or so per day. During each TMS session, you will sit in a chair for up to 1- 2 hours, which includes time to setup the equipment and its accessories. The research staff will give TMS while you are asked to relax. TMS clicking noises can be loud. Ear protection needs to be worn during the TMS procedures.

You may be assigned to receive only 'sham' TMS, meaning that no magnetic field will stimulate your brain during TMS. This is called 'placebo' or 'control'. In this study, for every three participants, two will be receiving real TMS and one will be receiving sham TMS. Your chance to receive one or the other is random, like flipping a coin.

If you are assigned to the sham TMS. No actual magnetic stimulation will occur, but you will still hear the TMS sound and a skin sensation. The skin sensation is generated by transient electrical pulses from an electrical stimulator powered by a 9-volt battery to mimic the skin sensations of real TMS. You will not know whether you are getting a real or a sham TMS at any given time. The reason for giving some sham TMS is to help better determine if the effect from TMS is real. You will receive either real rTMS treatment only or sham rTMS treatment only. However, we strongly encourage you to try to quit smoking regardless of which group you may be in.

At the beginning of the study, a motor threshold will be determined. A trained member of the research staff will do this. He/she will hold a magnetic coil against your head. An electric current is generated in the coil. This current produces a magnetic field. The minimum power needed to cause a muscle in your finger to twitch is your motor threshold.

There is a chance that data for specific tests may need to be recollected in the same day or a different day due to equipment failure or other unforeseen circumstances. You have the right to refuse re-testing and still continue participation in the study. You will be paid for your time.

You will not be taken off your usual medications for participating in the study. If you are a patient with schizophrenia spectrum disorders and have not been taking medication for your illness, you can still participate in the study. In the meantime, we will encourage you to see your doctor to determine whether you need medications. Certain types of medications called benzodiazepine or antihistamine could affect your performance if you are taking them. On the day of TMS tests, we will ask you to not take these medications until after the recording. If you cannot do this, we may ask you not to participate in the study.

Your participation is voluntary and there will be no penalty or loss of benefits for not participating in or withdrawing from the study. The brain wave recording, MRI and TMS testing are for research purposes only and are not the type used to look for problems like a tumor. It will not be routinely reviewed for these sorts of problems. However, sometimes the test will show what could be an abnormal finding. Should this occur and you may need another type examination that can diagnose such problems, your test results or you can be referred to the proper expert(s).

You may already have done some of the above tests as part of other studies. If so, we will examine this information, and if appropriate use it rather than redo the test. You may also participate in other studies (for example, a brain imaging study), and if you agree to participate, you are also giving us permission to examine those results and see how they relate to what is being collected here. You do not have to complete every part of the study, although we encourage you to complete all tests if possible.

Most of the TMS experiments use an MRI image of your brain to precisely locate the location for TMS. The MRI we use for TMS navigation will either be collected as part of this study or from other studies you have done at the MPRC. With your permission by signing this consent form, we can use an MRI scan you have done when you have participated in a previous MRI study at the MPRC. MRI images of your brain and skull typically do not change much.

Study Schedule. The clinical assessment, MRI scan and brain waves recording will be done four to seven times (before TMS session, after TMS session-5, after TMS session-10, after TMS session-20; if significant TMS effects were observed at the end of TMS treatment, MRI scans may be repeated in one of the follow-up visits) and each of them takes about 1 hour. An additional clinical assessment will be done after TMS session-15. Each TMS treatment session takes about 1 hour too and there are no more than 20 sessions. The first visit includes clinical related assessments and interviews. Depending on your schedule and the availability of our equipment, MRI and EEG recording could be done in the same visit or the following one or two visits. Each TMS session includes rTMS and additional clinical and safety assessments before and after rTMS. There are up to 20 rTMS sessions in separate days. Breaks between visits are allowed. After some rTMS sessions, clinical assessments, MRI scan and EEG recording will be repeated. One typically completes the rTMS sessions in 28 days, then comes back for up to three follow-up visits within a year. Follow-up visits include clinical assessments. MRI scan and EEG recording may be repeated in one of the follow-up visits. The following table illustrates the ideal study schedule.

Study Session	Study Day	Total duration per session	Consent	Clinical assessments and interviews [a]	EEG	MRI	TMS	QSU, MNWS, TMS screening; POMS; RHS	CPD; CO level; Salivary and Urinary cotinine
Screening	About [e] 1 day	~ 1 hour	X						
Baseline	About [e] 3 days	~ 6 hours		X	X	X			X
TMS sessions	One session/day; about [e] 5 days	~ 1 hour					X	X [d]	X
Intermittent	About [e] 3 days	~ 5 hours		X	X	X			X
TMS sessions	One session/day; about [e] 5 days	~ 1 hour					X	X [d]	X
Intermittent	About [e] 3 days	~ 5 hours		X	X	X			X
TMS sessions	One session/day; about [e] 5 days	~ 1 hour					X	X [d]	X
Intermittent	About [e] 2 days	~ 2 hours		X					X
TMS sessions	One session/day; about [e] 5 days	~ 1 hour					X	X [d]	X
End-of-TMS	About [e] 3 days	~ 5 hours		X	X	X			X
Follow-up [b]	About [e] 3 days	~ 5 hours		X	X [c]	X [c]			X
Follow-up [b]	About [e] 3 days	~ 5 hours		X	X [c]	X [c]			X
Follow-up [b]	About [e] 3 days	~ 5 hours		X	X [c]	X [c]			X

[a] We may use some clinical assessments such as SCID done in other studies or previous clinical assessment if repeating them is not necessary. [b] There will be up to 3 follow-up visits within one year. [c] EEG and MRI recording in follow-up sessions are optional. [d] QSU, MNWS, and RHS will be done before TMS stimulations; TMS screening and POMS will be done both before and after TMS stimulations. [e] more or less days due to scheduling related issues are not considered deviations.

We may wish to contact you for future studies. You may be asked to come in for additional visits to complete clinical interviews or training, or to repeat a test. We sometimes contact people to repeat the tasks to determine whether measures are stable over time, or because the data recorded earlier have some problems. Please indicate by initials below whether we may contact you later or not.
____ Yes
____ No

WHAT ARE MY RESPONSIBILITIES IF I TAKE PART IN THIS RESEARCH?

If you take part in this research, you will be responsible to attend all appointments and follow instruction from the researchers.

POTENTIAL RISKS/DISCOMFORTS

General: There is a possibility of breaching of confidentiality. We plan to keep all your records confidential. Some of the procedures can cause boredom. In some of the interviews and questions we will be discussing and asking sensitive information (for example, feelings of sadness, unusual experience, alcohol use, mental illness in family members). You may feel embarrassed or distressed talking or giving out information. It is important to obtain accurate information from you to make the research valid and worthwhile. However, you can always stop and not participate without penalty. Our interviewers are experienced and should provide needed counseling.

COVID-19 is extremely contagious and is believed to spread by person-to-person contact. In some of the research procedures (e.g., TMS, EEG, and MRI), there may be increased risk of exposure to COVID-19 due to prolonged exposure to a research staff where social distancing cannot be maintained. There is an inherent risk of becoming infected if you agree to participate in this study. COVID-19 could infect people with a wide range of consequences from no or minimum symptoms to severe symptoms, disability, and even death.
_____ I understand the above risks and would like to participate in the study.
_____ I do not wish to participate in the study.

TMS: TMS has been safely used in hundreds of subjects at the US and throughout the world. Occasionally people may find the stimulations uncomfortable or even painful or causing headache, scalp or facial twitching or pain, or dental or muscle pain. If you find the procedure too uncomfortable you may discontinue it at any time. Headaches and pain usually go away promptly with over the counter pain medications. The magnetic pulse could heat up the scalp metal electrodes that could cause burning. The electrodes we use do not have metal that directly contacts the scalp. However, you should promptly inform the staff if you feel any increased heating. The skin stimulation sham electric pulses may cause skin discomfort, tingling, muscle twitching, headache or pain. As in real TMS, if you find the procedure too uncomfortable you may discontinue it at any time.

TMS can be loud and could cause temporary and, in one case, permanent decreases in hearing especially without hearing protection. You will be fitted with earplug or ear phones to wear during the study. This is to protect your hearing from the noise. You will sit in a position with

minimal head motion. Sitting in a fixed position for a long time could be uncomfortable with possible body ache. There will be frequent breaks. You can ask for a break at any time.

Magnetic stimulation will not be performed in people who have pacemakers, implanted pumps or stimulators, or who have metal objects inside the eye or skull. Please inform the investigators if you have any of these conditions.

The most severe risk from TMS is seizure. The possibility that TMS used in this study will cause a seizure is very low. You will be carefully watched during each session. Staff is trained to promptly manage a seizure should one occur. Having a seizure could affect your future ability to drive, hold a job, or get insurance. Therefore, there may be financial risk with being in this study. Sleep deprivation, recent change in medication, alcohol consumption or too much caffeine intake may increase the risk of seizure. We will ask you to postpone the study if you had a recent change in certain medication, did not have a good night sleep, or consumed too many caffeinated drinks on the day of TMS or any alcohol within the 24 hours before TMS.

Other possible adverse events include fainting, nausea, changes in blood pressure and heart rate. If you feel you are not comfortable and weak, you should inform staff immediately, or you can stop at any time. Although TMS has been used to reduce suicidal ideation, it is possible that in certain cases TMS may induce suicidal ideation.

Another potential side effect from TMS treatment is changing of mood and occasionally other psychiatric symptoms such as increased psychosis, temporary changes in attention and memory. Heightened euphoria (mania) has happened to some people, most of whom had a history of mania or depression when they started TMS treatment.

The effects of TMS during pregnancy are unknown. If you are a female and are possibly pregnant (if you have child-bearing potential but are not taking contraceptives and missing menstrual period; or by your own report; or by positive a pregnancy test), you should not participate in this study. No one should enter the study that plans on fathering or conceiving a child between the times of study enrollment and completing the study. If you are female and are able to have children you must agree to use an approved birth control method. Acceptable birth control methods include the birth control pill, intrauterine device, or depot hormonal preparation (ring, injection implant). Correct use of a diaphragm, sponge with spermicide, or condom is also acceptable. We do not know if the experimental procedure affects fetal development.

MRI: The process itself is painless. There will be no x-rays or radioactivity in the MRI. However, you will be exposed to a high magnetic field. The magnetic field and radio waves used for MRI scans are considered too weak to do any damage to your body. However, nothing can be proven to be absolutely safe. There are potential side effects from the MRI scans. The first possible side effect is a mild backache from lying still for about two hours. You may experience claustrophobia, which is fear of small enclosed places. The MRI machine makes loud banging noises. You will be given earplugs or headphones that will lessen the sound. You may still experience some brief problems hearing soft sounds after the exam. Lying still for many hours may be a risk for the development of Deep Vein Thrombosis. This is blood clotting, usually in the legs, in persons with certain medical conditions. Persons with a history of thrombosis, family history of thrombosis, or medical conditions that may lead to an increased chance to develop

blood clots cannot take part in this study. Please inform us immediately if you believe you should not take part for this reason.

Metal: The MRI machine contains a strong magnet. If you have certain metal in or on your body, the magnet may move it. That could be painful and/or harmful. Metal implants may also cause burns from the radio frequency energy used in the exams. If there are metal objects on or in your body that cannot be removed you need to tell us. These include bone pins, braces, and artificial joints. If you have a skull plate, surgical metal clips in the brain, inner-ear implants, metal within the eye, cardiac pacemaker, neurostimulator or a deep brain stimulation device, you cannot be in this study. We will give you a metal screening survey that will allow us to make sure that this procedure is safe for you. You need to inform us if your work now or in the past may have involved welding, metal drilling or similar work where small metals may enter your eyes while you have not worn eye protection. If this is true, we will ask you to have an x-ray of your head to make sure there is no metal in your eyes before you have the MRI scan. The radiation dose which you will receive as a result of participating in this study includes radiation from an AP and Lateral head X-ray. Using the standard way of describing radiation dose, you will receive 4 mRem (or 0.004 Rem) of total body effective dose. The UMB HUSC of the Radiation Safety Committee, a group of experts on radiation matters, has reviewed the use of radiation in this research study and has approved this use as being Within the UMB Radiation Safety Guidelines for research subjects of 3 Rem to any tissue in a 13-week period and 5 Rem in one year. The radiation dose you will receive is in the range of 0-0.3 Rem, which is equivalent to the level of natural background radiation that you would be exposed to each year living in the area of the country. Background radiation levels will vary from place to place, but this level of exposure has never been associated with any definite adverse effects.

Please be aware that this radiation exposure is necessary for this research study only and is not essential for your medical care.

Please advise your doctor if you have participated in research studies at UMB or other institutions that involved the use of radiation so that it may be determined that the total radiation dose from all studies is not excessive. Examples of such studies include X-ray studies conducted in radiology departments, cardiac catheterizations, and fluoroscopy as well as nuclear medicine studies, e.g. technetium scans.

Brain wave recording: A paste is used to attach the electrodes during brain wave testing, which may irritate the skin on the scalp or face. Irritation is mild and usually resolves quickly. We may ask you to not use hair products on the day of testing (or it has to be washed out prior to testing, which may be inconvenient). The electrode cap you wear can be tight and not comfortable, but it can be adjusted. The tasks can be quite long, boring, or even annoying. Some of the sounds can be loud and uncomfortable. We will give frequent breaks in-between. You can always ask for a break or re-schedule for another time to complete the study.

All safety measures to lessen any side effects will be taken. If you feel that you want to leave the study, you are free to do so at any time. If we feel that you should not continue, we will end the study. We may do this even if you do not want to end the study.

Because TMS is relatively new, its long-term effects are still unknown. We will monitor you at every visit. There may be side effects and discomforts that are not yet known. You will be told of any new findings during the course of this study that may affect your participation. If you feel that you have an illness or symptoms related to your being in the study you should call us.

We will follow University COVID-19 Research Safety Guidelines to minimize the risks of COVID-19 infections. You as well as research staff will be required to wear masks. Social distancing will be maintained whenever possible. You must inform the staff if you are sick, have any symptom(s) of COVID-19, or have had any recent contact with COVID-19 case(s). You and staff are encouraged to frequently use hand sanitizer or hand washing. You may be informed if you had any potential contact with suspected COVID-19 infected person(s). If you have symptoms potentially related to COVID-19, we may stop your participation and may refer you for appropriate medical care and testing. You need to be on-site and in-person for TMS visits. The smoking cessation educational procedure and clinical interview and assessment procedures will be done during those on-site visits whenever possible to minimize the number of your on-site visits. The smoking cessation educational procedure and clinical interview and assessment procedures may be done through telephone or video covering the same contents to reduce risk of exposure when you are in a safe and private space. The telephone or video methods are optional.

POTENTIAL BENEFITS
You will receive no direct benefit from participation in this study. However, your participation may help the investigators better understand how the brain works and how to treat nicotine dependence in schizophrenia spectrum disorders.

ALTERNATIVES TO PARTICIPATION
Your alternative is not to take part. If you choose not to take part, your healthcare at the University of Maryland, Baltimore, will not be affected. There are a number of alternative medications and therapies that can aid smoking cessation. You do not need to participate in this study to quit smoking. We strongly encourage you to quit smoking regardless of if you are interested to participate in this study.

COSTS TO PARTICIPANTS
The study procedures will be provided at no cost to you.

PAYMENT TO PARTICIPANTS
You will be paid $50 for completing each MRI scan. You will be paid $15 per hour for your participation in the interviews and testing. Travel can be reimbursed or paid for. You will be paid up to approximately $785 for participating in all the interviews, questionnaires, and fMRI and TMS tests for up to about 39 hours total. If you complete only parts of the tests, you will still receive payment based on the hours you participated on the same rate. The processing of payment may take about 4 to 6 weeks.

This institution does not plan to pay royalties to you if a commercial product is developed from data obtained from you during this study. If you are paid in excess of $600 in a calendar year, you are responsible to report this as income to the IRS.

If you are injured because of study participation, you will receive emergency medical care if needed and you will receive assistance in getting other medical care as needed. You or your insurance carrier will be billed for the cost of care, just as you would be billed for any other medical care. If you incur uninsured medical costs, they are your responsibility. The study staff can give you more information about this if you have a study injury.

CONFIDENTIALITY AND ACCESS TO RECORDS

Your medical records will be kept confidential, except for the professionals involved in this study and the clinical staff of the Maryland Psychiatric Research Center; individual subject identity will be kept confidential. All records are kept in locked cabinets in a locked room or secured computers. We will do everything we can to keep others from learning about your participation in the research. However, you should understand that the investigator is not prevented from taking steps, including reporting to authorities, to prevent serious harm to yourself or others.

Confidential information will be coded and your name will not be used. The data from the study may be published. However, you will not be identified by name. People designated from the institutions where the study is being conducted and people from the sponsor will be allowed to inspect sections of your medical and research records related to the study. Everyone using study information will work to keep your personal information confidential. Your personal information will not be given out unless required by law. The monitors, auditors, the IRB, the Food and Drug Administration will be granted direct access to your medical records for verification of the research procedures and date. By signing this document you are authorizing this access.

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

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

RIGHT TO WITHDRAW

Your participation in this study is voluntary. You do not have to take part in this research. You are free to withdraw your consent at any time. Refusal to take part or to stop taking part in the study will involve no penalty or loss of benefits to which you are otherwise entitled. If you decide to stop taking part, if you have questions, concerns, or complaints, or if you need to report a medical injury related to the research, please contact the investigator Dr. Du at 410-402-6036 or Dr. Hong at 410-402-6828, or 410-337-5970 after hours. There are no adverse consequences (physical, social, economic, legal, or psychological) of a participant's decision to withdraw from the research. If you are a student, your academic standing at UMB will not be affected by your participation or non-participation in this study.

If you withdraw from this study, already collected data may not be removed from the study database. If you agree, this data will be handled the same as research data.

CAN I BE REMOVED FROM THE RESEARCH
The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include, failure to follow instructions of the research staff, or if the person in charge decides that the research study is no longer in your best interest. The sponsor can also end the research study early. The study doctor will tell you about this and you will have the chance to ask questions if this were to happen.

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS
The University of Maryland, Baltimore (UMB) is committed to providing participants in its research the rights due them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in the research project. This research has been reviewed and approved by the Institutional Review Board (IRB). Please call the Institutional Review Board (IRB) if you have questions about your rights as a research subject.

Participating in research may result in an injury, as explained above. If you suffer an injury directly related to your participation in this project, UMB and/or one of its affiliated institutions or health care groups will help you obtain medical treatment for the specific injury and provide referrals to other health care facilities, as appropriate. UMB and/or its affiliated institutions or health care groups will not provide you with financial compensation or reimbursement for the cost of care provided to treat a research-related injury or for other expenses arising from a research-related injury. The institution or group providing medical treatment will charge your insurance carrier, you, or any other party responsible for your treatment costs. If you incur uninsured medical costs, they are your responsibility. Uninsured medical costs to treat research related injuries not caused by the drug or device under study are your responsibility. The study staff can give you more information about this if you have a study injury.

By signing this Consent Form, you are not giving up any legal rights. If this research project is conducted in a negligent manner and you are injured as a direct result, you may be able to recover the costs of care and other damages from the individuals or organizations responsible for your injury.

If you have questions, concerns, complaints, or believe you have been harmed through participation in this research study as a result of researcher negligence, you can contact members of the IRB or the Human Research Protections Office (HRPO) to ask questions, discuss problems or concerns, obtain information, or offer input about your rights as a research participant. The contact information for the IRB and the HRPO is:

University of Maryland, Baltimore
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

If you receive your clinical care at a Department of Health and Mental Hygiene (DHMH) facility, you may also contact members of the DHMH IRB to ask questions, discuss problems or

concerns, obtain information, or offer input about your rights as a research participant. The contact information for the DHMH IRB is:

Gay Hutchen, IRB Administrator
201 W Preston Street
Baltimore, MD 21201
410-767-8448

Signing this consent form indicates that you have read this consent form (or have had it read to you), that your questions have been answered to your satisfaction, and that you voluntarily agree to participate in this research study. You will receive a copy of this signed consent form.

If you agree to participate in this study, please sign your name below.

_____	_____
Participant's Signature	Investigator or Designee Obtaining Consent Signature
Date:_____	Date:_____

HP-00077085 UM IRB Approval Date 1/7/2022
Do Not Sign this Form after this Date 1/6/2023