Title:	TMS Related Biomarker Assessments
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UNIVERSITY of MARYLAND BALTIMORE

RESEARCH CONSENT FORM AND HIPAA AUTHORIZATION

Protocol Title: TMS related Biomarker Assessments

Study No.: HP-00103592

Principal Investigator: Xiaoming (Michael) Du Ph.D.
410-402-6036 (office); 443-882-9717 (cell)

Sponsor: None

CONCISE SUMMARY:

You are invited to participate in a research study on brain waves in people who suffer from schizophrenia and other mental illnesses. We will use a technique called transcranial magnetic stimulation (TMS) to test how it may change the brain waves. The 'transcranial' means that the magnetic stimulations can non-invasively pass the skull to reach the targeted brain regions. Brain waves measure subtle electric activities from different parts of our brain. People who suffered from brain diseases often have subtle brain wave problems. Stimulating the brain with TMS can change activity in parts of the brain. We hope to find means to correct abnormal brain waves and also correct abnormal symptoms and cognitive functions. Clinical assessments, TMS-evoked responses, brain waves measurement by electroencephalography (EEG) and functional magnetic resonance imaging (fMRI) tests will be done in two sub-studies. Your involvement in each study will be about 5 to 7 hours a day for 3 to 5 days. There are potential risks/discomforts including scalp pain, headache, hearing change, emerging psychiatric symptoms, seizure, irritation from gel/paste, and other unknown risks/discomforts. You will be closely monitored for any side-effects and discomforts during all visits. Your participation in this study is voluntary. You will receive no direct benefit from participating in this study, but your participation may help the investigators better understand how the brain works. Your alternative is not to take part. You will be one of approximately 60 subjects to be asked to participate in this protocol.

PURPOSE OF STUDY

The purpose of this research is to better understand how brain electric activities are changed during TMS. TMS is a new procedure approved by Food and Drug Administration to treat depression. It is still experimental for 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 TMS generated electric activities may improve the abnormal electrical activities seen in some individuals with psychiatric problems.

We will ask you to stay still or to perform specific tasks during the TMS experiment. The tasks you will do can be very simple, like hearing a sound, or more complex tasks that require close attention and

memory. For example, you may be asked to convert numbers to symbols as many as possible based on a key within the allowed time. We will teach you each task until you are comfortable doing them. Your involvement in this study will be about 5 to 7 hours a day for 3 to 5 days. Findings from this study may help physicians find ways to correct abnormal brain functions. By signing this consent form, you are allowing us to use your screening data and the data that we will collect during this study. Screening data may include your medical history, family history, and other information, such as age and gender. You will be one of approximately 60 people 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. This information is for screening purposes. Depending on the results, you may not qualify for the procedure. 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 or blowing into a carbon monoxide monitor. 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. Some of these tests will occur before and after the TMS to assess changes related to the TMS. The total time takes about 3-5 hours. There will be frequent breaks in-between testing. If you have done these tests in another study, you may not need to repeat some of 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 a small camera or 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 hour each time. There will be frequent breaks in-between each recording.

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. You will be inside the scanner for about 1 hour. 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 the scanning session. 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 are asked to do the MRI before and after TMS to assess the changes of TMS may have on your brain functions. You may also perform simple visual, auditory, and motor tasks. This can be done in the same or a separate MRI session.

TMS. For transcranial magnetic stimulation, 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 stimulation 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. During each TMS session, you will sit in a chair, which includes time to place and remove the electrode cap, to perform several tasks and to take frequent breaks between tasks. The research staff will give TMS while you are asked to relax or to perform tasks that require you to pay attention, recognize, or remember specific sound or pictures or to make decisions about them. Some of these tests will be given to you before and after TMS. TMS clicking noises can be loud. Ear protection can be worn during some of the procedures.

Some of the TMS is a “sham”, meaning that no magnetic field will stimulate your brain during TMS. You will not know whether you are getting a real or sham TMS at any time. The reason for giving some sham TMS is to help better determine if the effect from TMS is real. The real and the sham TMS are given in a ‘random order’, meaning that the chance of having one or the other first is like tossing a coin.

There are two sub-studies covered by this informed consent document. They are described below. You can participate in one or both of the sub-studies. The staff usually tells you ahead of time which study is recruiting and you can decide whether you want to participate in one, both, or none of them.

Study 1.
TMS experiments will be given in 2 sessions in 2 different days that are separated by one or more days. In one session you will receive active TMS. In another session you will receive sham TMS. The active or the sham TMS are delivered to one, two or three locations on your scalp. The TMS is given in about 4 minutes for each location. Therefore, in the active TMS day, you will receive 3 TMS administrations in three locations, one after another, for a total 12 minutes. In the sham TMS session, you may feel or hear similar TMS, but no actual TMS is stimulating your brain. TMS-evoked responses, brain waves, and MRI will be measured before and after each session to determine the TMS effects. It will take about 4 to 5 hours. It includes about 2 hours before and 2 hours after the TMS where we will perform clinical assessments, TMS-evoked responses, brain wave, and MRI assessments as described above. It also includes time to wear the electrode cap and remove the electrode cap and cleaning the hair after the experiment. About 30 participants will participate in this study.

Study 2.
This is similar to Sub-study 1 except that the procedure will be repeated for 3 times in a day. Specifically, TMS experiments will be given in 2 sessions in 2 different days that are separated by one or more days. In one session you will receive active TMS. In another session you will receive sham TMS. The active or the sham TMS are delivered to one, two or three locations within ~12 minutes. You will then take a break for about 60 minutes when there are no TMS but we will continue to assess you. The active or the sham TMS are then repeated the second time. You will then take another break for about 60 minutes. The active or the sham TMS are then repeated the third time. The repetitions will add another 2.5 hours or so. Therefore

it will be about 6 to 7 hours per day. About 30 participants will participate in this study.

If you participate in both Study 1 and 2, the two studies will be separated by two days or more.

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 contract is your motor threshold.

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

You will not be taken off your usual medications for participating in the study. If you are a patient with schizophrenia 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 temporarily hold it before the recording and take it after the recording. If this is not feasible, 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 or withdrawing from the study. The brain wave recording 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 brain waves will show what could be an abnormal finding. Should this occur and you need another type of brain wave examination that can diagnose such problems, you will be referred to the proper expert(s).

You may already have done some of these 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 a MRI image of your own brain to precisely locate the location for TMS. We will not separately collect this MRI. With your permission by signing this consent form, we will simply use a 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.

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 to repeat 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.

TMS: TMS has been safely used in thousands of subjects at the US and throughout the world each year. 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. According to best current evidence, risk of seizures induced by TMS is about <0.03%. A seizure has never resulted in permanent damage. Seizure, if induced by rTMS, occurs only during the application of stimulation. Beyond studies conducted specifically in patients with epilepsy, there has been no reported incidence of rTMS-associated seizure that had onset within hours or days after the stimulation procedure concluded. 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. You might be at higher risk of having a seizure with TMS if you are taking clozapine. You will not be eligible for this study if you are taking >400mg clozapine daily. 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.

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 one hour. 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 this 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 risks in this study which 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 per Guidelines. 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.

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.

POTENTIAL BENEFITS
You will not benefit directly from your participation in this study. However, your participation may help the investigators better understand how the brain works in schizophrenia spectrum disorders.

ALTERNATIVES TO PARTICIPATION
This is not a treatment study. Your alternative is to not take part. If you choose not to take part, your healthcare at University of Maryland, Baltimore will not be affected.

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. Coded urine samples will be stored at the Principal Investigator (PI)'s lab and other collaborative labs. These labs will not have access to code-keys to identifiable information. Only the PI, his data management staff or designees have access to code-keys.

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.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. The researchers also cannot provide them as evidence unless you have agreed. The Certificate DOES NOT stop reporting that federal, state or local laws require. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations. Researchers may release information about you when you say it is okay.

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.

COSTS TO PARTICIPANTS

There will be no fee to enroll in the study.

PAYMENT TO PARTICIPANTS

You will be paid $20 per hour for your participation in the interviews and testing. Travel can be reimbursed or paid for. You will be paid approximately $300 for participating in all the interviews, questionnaires, and TMS, brain wave and MRI tests for about 15 hours total for Study 1. You will be paid approximately $340 for completing Study 2. If you participated in both, the total would be about $540, because some of the initial assessments are the same for both studies. 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. You may need to report payments you receive for participating in the study as taxable income, which could affect your eligibility to receive certain government benefits (e.g., from the Maryland Supplemental Nutrition Assistance Program (SNAP) and the Maryland Temporary Cash Assistance program (TCA)). If you owe a debt to the State of Maryland or the federal government (e.g. child support, taxes), the amount you receive may be reduced.

STUDY-RELATED INJURY

If you have an injury, promptly seek medical care from any healthcare provider. <u>If you have an emergency, call 911 or go to the nearest emergency room</u>. You should tell the healthcare provider that you have participated in a research study.

If you believe the injury is related to the study, notify the study doctor. UMB, if requested, will assist you to get medical care or referrals.

UMB and/or its affiliated healthcare facilities or healthcare providers will not provide any financial compensation or reimbursement to you for the cost of medical care or other expenses arising from an injury.

In such cases, you or your insurance may be billed for the costs of medical care.

UNIVERSITY STATEMENT CONCERNING RESEARCH RISKS

The University of Maryland, Baltimore (UMB) is committed to providing participants in its research studies all rights due to them under State and federal law. You give up none of your legal rights by signing this consent form or by participating in this study. This study has been reviewed and approved by an Institutional Review Board (IRB). The IRB is a group of scientists, physicians, experts, and community representatives. The IRB's membership includes persons who are not affiliated with UMB and persons who do not conduct research studies.

If you have questions, concerns, complaints, or believe you have been harmed through participation in this 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
Institutional Review Board
Human Research Protections Office
620 W. Lexington Street, Second Floor
Baltimore, MD 21201
410-706-5037

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:_____

Health Insurance Portability and Accountability Act (HIPAA)
AUTHORIZATION TO OBTAIN, USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH

Name of Study Participant:_____
_____

Date of Birth: _____ **Medical Record Number:** _____

NAME OF THIS RESEARCH STUDY: ***TMS RELATED BIOMARKER ASSESSMENTS***

UMB IRB APPROVAL NUMBER: ***HP-00103592***

RESEARCHER'S NAME: ***XIAOMING (MICHAEL) DU, PHD***

RESEARCHER'S CONTACT INFORMATION:

MARYLAND PSYCHIATRIC RESEARCH CENTER
University of Maryland School of Medicine (UMSOM)
55 Wade Ave.
Baltimore, MD 21228
410-402-6036 (office); 443-882-9717 (cell)

This research study will use health information that identifies you. If you agree to participate, this researcher will use just the health information listed below.

THE SPECIFIC HEALTH INFORMATION TO BE USED OR SHARED:

- Health-related information you have been asked to provide for the study during interviews, via questionnaires, from diaries kept by you.
- Your medical records from MPRC relating to eligibility for the study and participation in the study including: doctors' notes or summaries, records of medications and other treatments, laboratory results, reports of x-rays and other diagnostic tests.
- Results of medical tests, laboratory tests, x-rays, research procedures carried out for the purposes of the study.
- Health information about you obtained from your clinical care providers.
- Medical records from another health care facility that may be needed to determine whether a side effect or other problem is related to the study.

Federal laws require this researcher to protect the privacy of this health information. He/she will share it only with the people and groups described here.

PEOPLE AND ORGANIZATIONS WHO WILL USE OR SHARE THIS INFORMATION:

- Dr. Xiaoming (Michael) Du and the research team.
- The sponsor of the study, or its agents, such as data repositories or contract research organizations

- Organization that will coordinate health care billing or compliance such as offices within UMSOM; the University of Maryland, Baltimore (UMB); University Physicians, Inc. (UPI) and the faculty practices of the UMB; University of Maryland Medical System (UMMS).
- Federal agencies, the University of Maryland Baltimore Institutional Review Board, University of Maryland Baltimore Research Compliance offices, and University of Maryland Baltimore Legal Counsel may review records in order to meet with federal and state regulations.
- Hospital or other accrediting agencies

THIS AUTHORIZATION WILL NOT EXPIRE. BUT YOU CAN REVOKE IT AT ANY TIME.
To revoke this Authorization, send a letter to this researcher stating your decision. This researcher will stop collecting health information about you. This researcher might not allow you to continue in this study. This researcher can use or share health information already gathered.

ADDITIONAL INFORMATION:

- You can refuse to sign this form. If you do not sign it, you cannot participate in this study. This will not affect the care you receive at:
    - Maryland Psychiatric Research Center (MPRC)
    - University Physicians, Inc. (UPI)
    - University of Maryland Medical System (UMMS)

  It will not cause any loss of benefits to which you are otherwise entitled.
- Sometimes, government agencies such as the Food and Drug Administration or the Department of Social Services request copies of health information. The law may require this researcher, the UMSOM, UPI, or UMMS to give it to them.
- This researcher will take reasonable steps to protect your health information. However, federal protection laws may not apply to people or groups outside the UMSOM, UMB, UPI, or UMMS.
- Except for certain special cases, you have the right to a copy of your health information created during this research study. You may have to wait until the study ends. Ask this research how to get a copy of this information from him/her.

My signature indicates that I authorize the use and sharing of my protected health information for the purposes described above. I also permit my doctors and other health care providers to share my protected health information with this researcher for the purposes described above.

Signature: _____Date: _____

Name (printed) _____

Privacy Questions? Call the UMSOM Privacy Official (410-706-0337) with questions about your rights and protections under privacy rules.

Other Questions? Call the researcher named on this form with any other questions.