Study Title: A Pilot Study of Transcranial Magnetic Stimulation for Treatment of Methamphetamine Use Disorder

NCT Number: NCT04449055

Informed Consent Document

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INFORMED CONSENT DOCUMENT

Project Title: **A Pilot Study of Transcranial Magnetic Stimulation for Treatment of Methamphetamine Use Disorders**

Principal Investigators: Ryan Carnahan, PharmD, MS
Alison Lynch, MD, MS

Research Team Contact: Ben Pace
Research Assistant, Department of Psychiatry
(319) 384-9302
benjamin-pace@uiowa.edu

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you have been diagnosed with a methamphetamine use disorder.

The purpose of this research study is to evaluate the effects of brain stimulation on methamphetamine use, related symptoms, well-being, and brain activity. We are interested in whether this treatment is helpful to people with methamphetamine use disorders. To stimulate the brain, we will apply transcranial magnetic stimulation (TMS) to areas of the brain called the dorsolateral prefrontal cortex and medial prefrontal cortex, which are located behind your forehead.

We will use a type of TMS called theta burst stimulation (TBS). We will apply different types of TBS to each area of the brain. We will apply intermittent TBS to the dorsolateral prefrontal cortex, which is approved by the Food and Drug Administration (FDA) for treating depression. We will also apply continuous TBS to the medial prefrontal cortex. This second type of TBS has been studied in people with cocaine use disorders, but is not approved by the FDA. We will randomly choose the order in which these are applied for you during each treatment session since we want to know whether this changes the effects, but everyone will receive both types of treatments.

We will assess your symptoms, drug use, and other things related to your well-being. We will also ask you to complete brief psychological tests related to attention and impulse control. Your brain activity will be measured using magnetic resonance imaging (MRI), which uses magnetic and radio waves to get an indication of brain activity from water molecules. You will also have the option to have your brain activity measured with an electroencephalogram (EEG).

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 10 people will take part in this study conducted by investigators at the University of Iowa. In addition, approximately 10 people will take part in this study at two other sites.

HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for 12 to 13 weeks. Visits will range from 15 minutes to 5 hours in length. This study includes a total of 19 visits, 12 of which are for TMS treatment only. The first visit will take place the week before starting treatment and will take 3-4 hours. If you choose to participate in an optional EEG and timing task, the visit will be about 1 hour longer, for a total of 4 to 5 hours.

Within one week of this visit you will start TMS treatment. TMS treatment will be provided on five days per week for the first two weeks. TMS will be provided three days per week for the second two weeks. Treatments will take place Monday through Friday, but we can start the treatments on any of those days depending on what works for your and our schedules. Each TMS treatment session will take about 15-20 minutes.

There will be additional assessments on the last treatment day of each of the first four weeks of treatment, after your TMS treatment is completed. At the end of the first and third weeks of treatment, these will take approximately 15 minutes. At the end of the second week of treatment, they will take 30-45 minutes. At the end of the fourth week of treatment, the visit will take 3-4 hours and include TMS, MRI, and other assessments. If you choose to participate in an optional EEG and timing task, the visit will be about 1 hour longer, for a total of 4-5 hours.

Follow-up visits or phone calls at four weeks and eight weeks after TMS treatment will take 30-45 minutes each.

WHAT WILL HAPPEN DURING THIS STUDY?

This is a multi-visit study involving 19 separate visits. Sixteen visits will involve TMS treatment. Two visits will involve MRI and psychological tests, with an EEG and timing task if you wish to participate in that optional procedure. Five visits will involve urine samples for drug screens, unless one was collected for clinical purposes that day or the day prior. Seven visits will involve completion of questionnaires.

At the first visit we will confirm your eligibility to continue in the study. If you are not eligible to continue, your participation will end. If you are eligible, we will complete an MRI scan and complete a number of assessments. The following tables illustrate the schedule of visits planned for this study. Information about other procedures and a more detailed table of assessments at each visit are provided further below. This is an example schedule. The specific days of treatment can vary. We will work with you to find a treatment schedule that works for your schedule and ours.

Example Study Schedule: Exact days of visits can vary. TMS starts within 1 week of the baseline visit, and as early as the first day of study participation.

Study Week	Monday	Tuesday	Wednesday	Thursday	Friday
1	First visit: determine eligibility to continue, questionnaires, psychological testing, urine drug screen if needed, MRI, optional EEG **(3-5 hours)**				
1	TMS	TMS	TMS	TMS	TMS, questionnaires, urine sample if needed **(about 30 minutes)**
2	TMS	TMS	TMS	TMS	TMS, questionnaires, urine sample if needed **(45-60 minutes)**
3	TMS		TMS		TMS, questionnaires, urine sample if needed **(about 30 minutes)**
4	TMS		TMS		TMS, questionnaires psychological testing, urine sample if needed, MRI, optional EEG **(3-5 hours)**
8	One follow-up visit or phone call to complete questionnaires **(45-60 minutes)**				
12	One follow-up visit or phone call to complete questionnaires **(45-60 minutes)**				

Transcranial Magnetic Stimulation (TMS): On your second visit we will measure your motor evoked threshold to determine the intensity of stimulation to be used in the study. This will involve the placement of the TMS device on the frontal regions of your head and the administration of pulses of electrical current while we measure movement in your hand. This is to determine the strength of the magnetic fields to use for TMS. TMS relies on the generation of brief magnetic fields using an insulated coil that is placed over the scalp. These magnetic fields are the same type and strength as those used in magnetic resonance imaging (MRI) machines. The magnetic pulses generate a weak electrical current in the brain that briefly activates neural circuits at the stimulation site. TMS has been shown to be a safe and well-tolerated procedure. This study includes 16 visits with TMS treatments. Each TMS treatment involves 3-5 minutes of brain stimulation at each of two sites. We will take your blood pressure and pulse and ask you when you last used methamphetamine before each treatment, and ask you about your craving before and after each treatment.

Magnetic Resonance Imaging (MRI): We will image the activity of your brain twice during this study using MRI, at the first visit and at the end of the fourth week of treatment. We will let you know prior to your visits what procedures will occur so you can be prepared for the length of the study.

An MRI scanner takes pictures of the inside of your body by sending out a magnetic field and radio waves. Because the MRI scanner contains a very strong magnet, you may not be able to have the MRI if you have certain kinds of metal in your body (for example: a heart pacemaker, a metal plate, certain types of heart valves, or brain aneurysm clips). Someone will ask you questions about this before you have the MRI.
In particular, you should not participate in this study if you have any of the following in your body.

- Pacemaker
- Coronary Stent
- Defibrillator
- A neurostimulation device not compatible with MRI

You also should not participate in this study if you have certain types of metal objects in your body that might interact with the magnetic field. Examples include objects such as bullets, shrapnel, or metal slivers. Please tell us if you have ever worked at or near a metal working or construction site. Also tell us if you have had surgery of any kind. You also should not participate if you have any of the following conditions.

- Claustrophobia
- Uncontrolled high blood pressure
- Atrial fibrillation
- Significant heart disease
- Hemodynamic instability
- Kidney disease
- Pregnant, trying to become pregnant, or breast feeding

Many of these conditions would not keep you from having an MRI that was ordered by your doctor. However, for research purposes, we have decided not to increase your risk of aggravating these conditions by undergoing a research study.

The MRI scanner is a large machine that contains a hollow tube. You will be asked to lie on your back on a special table that slides into the tube. The sides of the tube will be fairly close to your body and the scanner makes a loud hammering noise while you are inside. You will be able to talk to the people in the room through a speaker system. We will monitor you closely while you are inside the scanner. You will also be given earplugs to wear. The earplugs reduce the sharpness of the banging noise the MRI machine makes. However, you will still be able to hear us talk to you, and you will also be able to talk to us at any time. We will give you a squeeze ball to press in case of an emergency. This sets off an alarm that notifies the technologist that you need help.

Next, the bed will be moved into the magnet. The MRI operator will talk to you throughout the study to let you know how you are doing and what to expect next. If you become uncomfortable and wish to stop the examination at any time, tell the technologist, and we will stop and you will be moved out of the magnet. You will need to hold very still while you are in the scanner. While in the scanner, we will gather some resting and structural information. You will be in the magnet for approximately 60-90 minutes. When the study is complete, you will be moved out of the magnet. You should get up and slowly allow your body to get used to moving and being vertical again. We will ask you about any unusual sensations you may have felt. The MRI images for this study are not being used to evaluate your health. The images obtained for this study are for specific research purposes and are not being used to find medical abnormalities. These images will not be reviewed by a radiology physician to diagnose existing abnormalities.

Personal and Medical History: We will ask you about your history of substance use, other health conditions, engagement in other treatment for methamphetamine use disorder, and your current medication use. We will also ask about your marital status, education, current employment, income, and

other personal characteristics.

Symptoms and Psychological Measures: We will ask you to complete a number of questionnaires on an iPad. These include questionnaires related to mood and anxiety, substance craving, sleep quality, quality of life, behavior and personality characteristics, and substance use and recovery. You will have the option to complete these by phone at the last two follow-up visits. We will also ask you to complete a brief task to measure attention and related characteristics on an iPad. We will ask you to complete tasks on a computer. You are free to skip any questions you choose not to answer.

Urine Drug Screens: We will ask you to provide a urine sample to assess substance use at the first visit and each Friday during the four weeks of TMS treatment, unless a urine drug screen was obtained for clinical purposes in the day prior scheduled for that day, in which case we will use those results. You will be provided with a container and instructions for collection and be able to collect this alone in a private bathroom. The results of these tests will not be included in your regular medical record.

Electroencephalography (EEG) and Timing Task: If you choose to participate in the optional EEG procedure and timing task, we will attach EEG leads to your scalp which will record your brain activity. This involves the use of gel and a mesh cap. We will apply modest pressure to your scalp and face to make sure the leads stay in place. As a result, you may have some minor markings on your face and your hair may be a bit messy or damp afterwards. You will be provided with shampoo, a towel, and a private bathroom to wash your hair afterwards. You may find the cap tight or uncomfortable, although it will be sized to fit your head as best as possible. We will then measure your brain activity through these leads. The recording of brain activity is painless. Brain activity recording will take place at rest and while completing a timing task. The timing task involves you estimating the passage of a specified duration of time shown on a computer screen and pressing a response button. You will receive 2 blocks of the timing task that will take about 25 minutes. This procedure takes approximately 1 hour (25 minutes of set up, 25 minutes of the task, 10 minutes of clean up).

If you choose not to participate in the EEG, you can still participate in the rest of the study.

Medical Record Review: To better understand your health (for example, your health conditions and medication use), we will access your medical record. If you are not receiving care at the University of Iowa Hospitals and Clinics, we will use a release of information form to access your health records from outside institutions. The information we access will relate to this study directly and we will access the minimum amount of information necessary for the study.

Schedule of Assessments to Be Completed at Selected Visits

Measure	**Time to complete (minutes)**	**First Visit**	**Last TMS day week 1**	**Last TMS day week 2**	**Last TMS day week 3**	**Last TMS day week 4**	**Week 8**	**Week 12**
Interview Questions								
Personal	20	x						

information, medical history, substance use history								
Report substance use and current treatment	2	x	x	x	x	x	x	x
Urine drug screen (if needed)	10	x	x	x	x	x		
Mini International Neuropsychiatric Interview	20	x						
Written Questionnaires								
Brief Substance Craving Scale	5	x	x	x	x	x	x	x
Assessment of Recovery Capital	5-10	x				x	x	x
Brief Addiction Monitor	10	x				x	x	x
Quality of Life Enjoyment and Satisfaction Questionnaire—Short Form	5	x		x		x	x	x
Patient Health Questionnaire	3	x		x		x	x	x
Generalized Anxiety Disorder 7-item scale	2	x		x		x	x	x
Positive and Negative Affect Scale	5-10	x		x		x	x	x
Pittsburgh Sleep Quality Index	5-10	x		x		x	x	x
Big Five Inventory-2	5-15	x						
UPPS-P Impulsive Behavior Scale	15	x				x		
Difficulties in Emotion Regulation Scale-Short-Form	5	x				x		
Monetary Choice Questionnaire	5	x				x		

Psychological Testing								
Flanker Inhibitory Control and Attention	3-5	x				x		
Imaging								
MRI	60-90	x				x		
EEG and Timing Task (optional)	60	x				x		

Where will the study visits take place?

Most visits will take place at University of Iowa Hospitals and Clinics, 200 Hawkins Dr, Iowa City, Iowa (UIHC). The last two visits can be completed by phone. The first visit and the visit at the end of the fourth week of TMS will take place in the Magnetic Resonance Research Facility in the Pappajohn Biomedical Discovery Building (PBDB), 169 Newton Rd, which is near and physically connected to UIHC. The other visits that involve TMS will take place in General Hospital, in the TMS room (W240) and the TMS research room (W264). The last TMS treatment may also take place in the TMS room in PBDB, room L445, since that is near the Magnetic Resonance Research Facility. You should discuss the time and location with the research assistant each time you schedule a visit.

Data Storage for Future Use

As part of this study, we are obtaining data from you. We would like to study your data in the future, after this study is over. Your sample, information, and/or data may be placed in a central repository or other national repositories sponsored by the National Institutes of Health or other Federal agencies. If this happens, it will be stripped of identifiers (such as name, date of birth, address, etc.). Other qualified researchers who obtain proper permission may gain access to your data for use in approved research studies that may or may not be related to in the purpose of this study.

The tests we might want to use to study your data may not even exist at this time. Therefore, we are asking for your permission to store your data so that we can study them in the future. These future studies may provide additional information that will be helpful in understanding methamphetamine use disorders, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your data might be used to develop products tests, or discoveries that could be patented and licensed. In some instances, these may have potential commercial value and may be developed by the Investigators, University of Iowa, commercial companies, organizations funding this research, or others that may not be working directly with this research team. However, donors of data do not retain any property rights to the materials. Therefore, there are no plans to provide financial compensation to you should this occur.

Your data will be stored with a code which may be linked to your name, date of birth, and other identifiers. If you agree now to future use of your data but decide in the future that you would like to have it removed from future research, you should contact Ryan Carnahan at 319-384-1556. However, if

some research with your data has already been completed, the information from that research may still be used.

WILL I BE NOTIFIED IF MY DATA RESULTS IN AN UNEXPECTED FINDING?

We may learn things about you from the study activities which could be important to your health or to your treatment. If this happens, you can decide whether you want this information to be provided to you. If you choose to have this shared, you will be informed of any unexpected findings of possible clinical significance that may be discovered during review of results from your images. The results from the images we collect in this research study are not the same quality as what you would receive as part of your health care. There may be benefits to learning such results (such as early detection and treatment of a medical condition), but there are risks as well (such as feeling worried about a finding for which no treatment is available). Although your MRI images will not be reviewed specifically to look for health problems, it is possible that an apparent abnormality will be noticed incidentally by the MRI team.

The images will not typically be reviewed by a physician who normally reads such results so they will not be able to inform us if there are any unexpected findings. We cannot guarantee that abnormalities will be identified if present. We will only consult a diagnostic radiologist if the MRI team notices a possible abnormality, and that diagnostic radiologist will only tell us if they believe it needs further evaluation. We will provide you with this information so that you may discuss it with your primary care physician. However, if you believe you are having symptoms that may require care prior to receiving any information from this study, you should contact your primary care physician. The study team/study will not cover the costs of any follow-up consultations or actions.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study. Potential risks are highlighted below.

Questionnaires and Psychological Tests: You may experience anxiety, embarrassment, boredom, or fatigue while completing the questionnaires and psychological tests. Some of these questions address sensitive topics such as your medical history, mood, and substance use.

TMS: The mild magnetic stimulation applied during transcranial stimulation may cause tapping sensations, tingling, muscle twitches and/or itching. Less commonly, electromagnetic stimulation has been reported to cause stinging, pain, muscle aches, or headaches. If these occur and are uncomfortable we will stop right away. In extremely rare cases, seizures have been reported in subjects who have a history of seizures. For patients with bipolar or schizoaffective disorder, there is a risk of inducing a manic episode in rare cases. There is a theoretical but minimal risk of hearing damage from the clicking sound of the coil, but this will be mitigated with earplugs worn during the treatment if you choose. Potential side effects of TMS are listed below.

Please inform us if you are currently under the influence of methamphetamine at any visit. We will withhold TMS treatment if you are currently under the influence, or if you have used methamphetamine

too recently, because this may increase the chance of a seizure.

Likely / Common (more than 35%)

Mild

- Headache

Less Likely / Less Common (10% - 35%)

Mild

- Neck pain

Rare (less than 10%)

Life Threatening

- Seizure (less than 1 in 1,000)

Serious

- Hearing impairment (mitigated by ear plugs)
- Ringing in ears (mitigated by ear plugs)
- Mania
- Migraine Aura
- Scalp burns

Mild

- Anxiety or agitation
- Abnormal sensations
- Insomnia
- Vomiting

MRI: You may be uncomfortable inside the MRI scanner if you do not like to be in closed spaces ("claustrophobia"). During the procedure, you will be able to talk with the MRI staff through a speaker system. You can tell them to stop the scan at any time.

The MRI scanner produces a loud hammering noise, which has produced hearing loss in a very small number of patients. You will be given earplugs to reduce this risk.

A metal object flying through the air toward the magnet and hitting you presents the greatest risk associated with MRI. To reduce this risk, we require that all people involved with the study remove all metal from their clothing and pockets. No metal objects will be brought into the magnet room while you are inside the room.

There is also a risk that we will discover that you have an abnormal image. We cannot make a determination from the images that we are collecting if this abnormal image is associated with disease. If we notice an abnormality, we will show the image to a diagnostic radiologist who will then advise us on how to proceed. If the abnormal image presents a possible medical concern, a physician will contact you to explain that concern to you. You will need to follow up with your primary care physician for a

more complete assessment. We will not show you any images during your research visit, but you can make an appointment to see them later if you would like. This appointment must be at least one week after your study date.

There are no known risks associated with exposure to magnetic fields. Magnets of this strength have been in use for medical imaging for over 15 years.

There is no known risk associated with MRI to an unborn child. In fact, MRI is often used to look at problems in unborn children. However, we cannot rule out the possibility that such a risk will be discovered in the future. Its effect on the unborn child is not known. Therefore, if you are a woman of childbearing age, you should not participate if you are pregnant, trying to become pregnant, or currently breastfeeding.

EEG: EEG is painless. There are no known risks to EEG other than the possibility of minor scratching on your face or scalp. We will communicate with you while the leads are being applied and removed to minimize this risk.

WHAT ARE THE BENEFITS OF THIS STUDY?

We don't know if you will benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because we will learn more about whether TMS might be helpful for people with methamphetamine use disorders.

WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you could receive only counseling or other psychosocial therapies, and you could receive medications that might help relieve symptoms. However, no medical treatments are approved by the Food and Drug Administration (FDA) for methamphetamine use disorder. You could possibly receive TMS treatment outside of this study, but it is not FDA approved for methamphetamine use disorder so this may not be covered by insurance.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any costs for being in this research study.

You and/or your medical/hospital insurance carrier will remain responsible for your regular medical care expenses.

WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You may need to provide your address if a check will be mailed to you.

You will be paid up to a total of $255 for participating in this research study. You will be paid $50 for your first visit, which will take 3.5-5 hours. If you choose to participate in the optional EEG procedure you will be paid an additional $15. You will be paid $20 for completing the assessments on the next three Fridays, which should each take from 15 to 45 minutes. On the fourth Friday after TMS treatment is completed, you will be paid $75 for completing all assessments, which will take 3-4.5 hours. Again, you will be paid an additional $15 if you choose to participate in the EEG procedure. You will be paid $20 for each of the two follow-up visits or phone calls, which will occur 8 weeks and 12 weeks after the start of TMS treatment. If your participation in the study ends then you will be paid previous visits at which you completed all assessments. If you miss more than 4 days of planned TMS treatment (one fourth of the planned treatments) then your participation in the study will end and you will not be eligible for additional compensation.

You will also receive parking vouchers that will cover any parking costs associated with the study visits.

WHO IS FUNDING THIS STUDY?

The University and the research team are receiving no payments from other agencies, organizations, or companies to conduct this research study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

- If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.
- The University of Iowa does not plan to provide free medical care or payment for treatment of any illness or injury resulting from this study unless it is the direct result of proven negligence by a University employee.
- If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,
- the U.S. Food and Drug Administration
- auditing departments of the University of Iowa, and
- the University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, we will store some of your information in a locked, password encrypted secure research drive that is stored in a locked room. We will store other information in a secure password protected database in REDCap, a system maintained by the University of Iowa to store

and protect research data. Identifiable information such as your name will be removed from any data downloaded from this system for analysis. Any data provided to collaborating investigators at other institutions will be deidentified prior to transfer. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

The University of Iowa Hospitals and Clinics generally requires that we document your participation in research occurring in a University of Iowa Health Care facility. This documentation will be in either your medical record or a database maintained on behalf of the institution reflecting that you are participating in this study. The information included will provide contact information for the research team as well as information about the risks associated with this study. We will keep this Informed Consent Document in our research files; it will not be placed in your medical record chart.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. A copy of the informed consent document will be available on this website. This website 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.

WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires your health care provider to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research study. Once your health care provider has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff, and colleagues at other institutions who are involved in this study.

You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research-related. Your signature on this Consent Document authorizes your health care provider to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to Ryan Carnahan at 145 N. Riverside Dr., S437 CPHB, Iowa City, Iowa 52242. However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or

we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

What if I Decide to Drop Out of the Study?

If you decide to leave the study early, we ask that you inform us that you would like to stop participating. If you do not tell us but miss a visit and we are unable to reach you, we will try to call or text you up to five times and leave messages (per your preference). If we cannot reach you after three attempts, we will call your secondary contact person if you have provided one. We will call this person up to three times and leave messages stating that we are trying to reach you if needed.

Will I Receive New Information About the Study while Participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

Can Someone Else End my Participation in this Study?

Under certain circumstances, the researchers might decide to end your participation in this research study earlier than planned. This might happen because you missed more than 4 days of planned TMS treatment or missed important assessments. It might also happen if we judge that it is no longer safe for you to continue. If your participation ends, you will not be eligible to be compensated for assessments that have not been completed.

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WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Ben Pace at (319) 384-9302 or Ryan Carnahan at 319-384-1556. If you experience a research-related injury, please contact: Laren Garett at (319) 353-8557 or Ryan Carnahan at 319-384-1556.

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Please check a box below to indicate whether you would like to participate in the optional EEG.

☐ Yes, I would like to participate in the optional EEG.

☐ No, I do not want to participate in the optional EEG.

Subject's Name (printed): _____

_____	_____
(Signature of Subject)	(Date)

Statement of Person Who Obtained Consent

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____	_____
(Signature of Person who Obtained Consent)	(Date)