Targeting the Shared Substrates of Alcohol Misuse and Cognitive Impairment: Accelerated rTMS for Older Adults With Alcohol Use Disorder Informed Consent Form

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Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Targeting the Shared Substrates of Alcohol Misuse and Cognitive Impairment: Accelerated rTMS for Older Adults with Alcohol Use Disorder

PARTICIPANT CONSENT

Concise Summary

You are being asked to volunteer for a clinical research trial because you have acknowledged that you are a treatment-seeking heavy alcohol user between 60-85 years old and has mild cognitive impairment (MCI). Research trials are voluntary and include only people who choose to take part. The purpose of this study is to evaluate transcranial magnetic stimulation (TMS), specifically TMS at a frequency known as theta burst stimulation (TBS), as a tool to see how it affects the brain in relation to heavy drinking days and cognitive impairment. TMS and TBS are stimulation techniques that use magnetic pulses to temporarily excite specific brain areas in awake people (without the need for surgery, anesthetic, or other invasive procedures). TBS, which is a form of TMS will be applied over the left dorsolateral prefrontal cortex (DPFC), which has been shown to be involved with reductions in alcohol consumption and craving and improve your memory, and thinking. The purpose of this study is to see if brain stimulation can be used to improve memory, thinking, and mood, and decrease alcohol use.

If you agree to participate, you will undergo an eligibility visit to confirm if this study is right for you. If you are found eligible, you will complete questionnaires, interviews, memory and thinking skills tests, and a brain Magnetic Resonance Image (MRI). Then, you will begin your Transcranial Magnetic Stimulation (TMS) treatment visits. During your TMS treatment days you will also review some videos and slides that describe the signs and symptoms of problematic drinking, the pros and cons of cutting back, and practical tips for cutting back or quitting drinking. You will do five days of treatment within seven days. About a week after treatment, you will again complete questionnaires, and tests of memory and thinking. About one week after your last TMS session, you will again complete questionnaires, tests of memory and thinking, and another brain MRI. About one month later, you will repeat the questionnaires, interviews, and tests of your memory and thinking. The total time you will be in this study is about two months. During your participation in this study, we will collect blood and urine samples to evaluate how much alcohol is in your blood and urine.

There are risks to the study treatment that are described in this document. Some of the risks include potential risk of seizure, headaches, worsening of memory or mood symptoms, effects on brain tissue, hearing loss, facial twitching or skin irritation, risk of a first-degree burn, delay of other treatments, and MRI risks. TMS is an FDA-approved treatment for depression. However, TMS has not yet been approved for MCI or AUD.

Some participants may experience improvement in depression and MCI symptoms, but this is not guaranteed. This study is a Phase I clinical trial meaning that we are evaluating the safety, and evaluating side effects associated with this stimulation on this population. You do not have to participate in this study to have your condition treated.

If you are interested in learning more about this study, please continue to read below.

A. PURPOSE OF THE RESEARCH

Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. You are being asked to participate in this study because you have both mild cognitive impairment (MCI) and alcohol use disorder (AUD). The study is sponsored by the National Institutes of Health. The investigator in charge of this study at Medical University of South Carolina (MUSC) is Dr. Lisa McTeague. Approximately 35 people will take part in this study.

The goal of this clinical research study is to determine whether non-invasive brain stimulation is an effective treatment for patients with mild cognitive impairment (MCI) and alcohol use disorder (AUD). We want to see if brain stimulation can be used to improve memory, thinking, and mood. The brain stimulation treatment used in this study is called repetitive transcranial magnetic stimulation (rTMS). rTMS works by rapidly turning a focused magnetic field on-and-off repeatedly using a coil held over your head. Magnetic pulses pass directly through your hair, scalp, and skull and onto your brain, and can temporarily increase brain activity under the magnetic field. rTMS is a Food and Drug Administration (FDA)-approved treatment for depression. In this study, we will be using a form of rTMS called intermittent theta burst rTMS (iTBS-rTMS). iTBS-rTMS has not been FDA-approved for MCI or AUD. We hope to determine whether iTBS-rTMS can improve memory, thinking, and mood in MCI and reduce the urge to drink. Some participants may experience improvement in AUD and MCI symptoms, but this is not guaranteed. You do not have to participate in this study to have your condition treated.

B. PROCEDURES

Week 0: Pre-treatment Assessment, Blood Draw & Brain MRI (4 hours):

If you are eligible to participate in the study, you will be scheduled to come to the clinic for the Week 0 study visit. At this visit you will do the following:

Blood draw. The blood sample will be taken by a trained lab technician from our certified laboratory. The blood sample will be used to detect alcohol use.

Urine collection. This will include a urine alcohol screen and a urine drug screen to detect alcohol and substance use. The urine alcohol screen and the urine drug screen will be provided by natural means. Pregnancy test will also be administered and only those who test negative can participate.

Questionnaires and Clinical Interview. A member of the study team will record information about your demographics, family and individual health histories, and the medications that you take. You will complete questionnaires and clinical interviews that ask you about your behavior, mood, and mental function.

Memory and thinking skills tests. You will undergo these tests using an iPad. These questions include asking you to remember certain words, remember organization of pictures, among other similar tasks.

Brain MRI. Magnetic resonance imaging (MRI) uses a magnet and radio waves to make images of your brain. You will be asked to lay on a narrow bed and then slid into a small tunnel approximately 6 feet in length and over 2 feet in diameter. You will hear a loud machine-like noise. The images gathered are seen by MR technologists and if necessary, referred to a radiologist if there are incidental findings. If there are incidental findings of note, you will be notified.

Week 1: Treatment (3 hours each treatment day for 5 treatment days)

You will do five days of treatment within seven days. You can choose which five days work best for you.

Each day of intermittent theta burst (iTBS) repetitive transcranial magnetic stimulation (rTMS) treatment will include ten 3-minute TMS sessions, which are separated by 10 to 15-minute breaks. You can wait longer between same-day sessions if you prefer.

During of 7 of these 10-15 minute breaks over the five days, you will also review some videos and slides that describe the signs and symptoms of problematic drinking, the pros and cons of cutting back, and practical tips for cutting back or quitting drinking. It is important to note that these slides and videos, developed by the National Institute of Health are not considered therapeutic, in contrast to the rTMS. Rather, they were developed to provide research participants with helpful tips for managing drinking while in medication trials. In this study we have revised the materials to apply to rTMS.

You are welcome to take breaks at anytime. The total time spent in-treatment on a given treatment day is about 3 hours. rTMS and iTBS are stimulation techniques that use magnetic pulses to temporarily excite specific brain areas in awake people (without the

need for surgery, anesthetic, or other invasive procedures). TBS, which is a form of TMS will be applied over the left dorsolateral prefrontal cortex (DPFC), which has been shown to be involved with reductions in alcohol consumption and craving and improve your memory, and thinking. The purpose of this study is to see if brain stimulation can be used to improve memory, thinking, and mood, and decrease alcohol use. TMS for MCI and AUD is investigational and not yet an FDA-approved indication.

Urine collection. This will include a urine alcohol screen and a urine drug screen to detect alcohol and substance use. The urine alcohol screen and the urine drug screen will be provided by natural means.

Questionnaires. You will complete questionnaires and clinical interviews that ask you about your behavior, mood, and mental function.

Memory and thinking skills tests. You will undergo these tests using an iPad. These questions include asking you to remember certain words, remember organization of pictures, among other similar tasks.

Week 2: Post-treatment Assessments & Brain MRI (2 hours):

Within one week of completing treatment (Week 2), you will repeat questionnaires about your behavior, mood, and mental function, tests of your memory and thinking skills, and brain MRI.

Blood draw. The blood sample will be taken by a trained lab technician from our certified laboratory. The blood sample will be used to detect alcohol use.

Urine collection. This will include a urine alcohol screen and a urine drug screen to detect alcohol and substance use. The urine alcohol screen and the urine drug screen will be provided by natural means. Pregnancy test will also be administered and only those who test negative can participate.

Questionnaires. You will complete questionnaires and clinical interviews that ask you about your behavior, mood, and mental function.

Memory and thinking skills tests. You will undergo these tests using an iPad. These questions include asking you to remember certain words, remember organization of pictures, among other similar tasks.

Weeks 2-5: Post-treatment Online Assessment:

Beginning at Week 2, you will be asked to complete online questionnaires identical to the ones you have answered previously. These questionnaires will be emailed to you for you to complete.

Questionnaires. You will complete questionnaires and clinical interviews that ask you about your behavior, mood, and mental function.

Week 6: Post-treatment Assessments (2.5 hours):

One month after completing rTMS treatment (Week 6), you will repeat questionnaires about your behavior, mood, and mental function, tests of memory and thinking, and clinical interview.

Blood draw. The blood sample will be taken by a trained lab technician from our certified laboratory. The blood sample will be used to detect alcohol use.

Urine collection. This will include a urine alcohol screen and a urine drug screen to detect alcohol and substance use. The urine alcohol screen and the urine drug screen will be provided by natural means.

Questionnaires. You will complete questionnaires and clinical interviews that ask you about your behavior, mood, and mental function.

Memory and thinking skills tests. You will undergo these tests using an iPad. These questions include asking you to remember certain words, remember organization of pictures, among other similar tasks.

Early withdrawal from study:

You have the right to withdraw from the clinical investigation at any time. The Principal Investigator for any of the following reasons may discontinue your participation.

- You are found to have entered the study in violation of the protocol.
- You withdraw consent to participate in the study.
- You are noncompliant with procedures set forth in the protocol.
- You experience an Adverse Event that warrants withdrawal from the study.
- It is in the Investigator's opinion that it is not in your best interest to continue.
- You display abnormal laboratory, medical or clinical findings for which clinical intervention should take precedence over study participation including:
    a) Development of mania/hypomania
    b) Generalized seizure

c) Inpatient hospitalization
d) Unable to complete desired treatment in the designated time frame

The Principal Investigator reserves the right to discontinue study participation for any individual who is determined to be a threat to self, staff or other study participants or who is unable to complete the study assessments, sessions or provide informed consent.

C. DURATION

Participation in the study will take about 8 visits over a period of about two months.

D. RISKS AND DISCOMFORTS

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful thought. Please talk with Dr. McTeague if you have any questions.

Common adverse events occurring in approximately 15% of subjects:

Risks of Emotional Distress. You will be asked at some of these appointments to think and talk about emotional experiences including difficulties related to anxiety and depression. This may cause you to become upset, especially if you have been trying to avoid these thoughts. You may also feel frustrated while completing the memory and thinking tasks. If you want to discontinue at any time, let the study staff know. A study doctor will immediately meet with you privately to discuss how you are feeling, how to manage your distress, and to plan follow-up care if necessary.

Less common adverse events occurring in approximately 5% of subjects:

TMS & Pain. Some people report some mild discomfort when the magnetic pulses are applied over the scalp, and a small number of people (approximately 5%) report headache following TMS. However, these side effects are temporary and typically manageable with common over-the-counter pain remedies, such as acetaminophen or ibuprofen. You will be monitored closely for any potential side effects including any discomfort and headaches. We will discuss with you how to manage the side effects if they occur. Accumulating evidence suggests TMS provides temporary relief from pain, a temporary decrease in sensitivity to pain, or no effect at all.

MRI & Pain. Some people report some mild back and/or neck discomfort due to remaining still in the scanner for up to an hour at a time.

MRI & Claustrophobia. Having an MRI may mean you may be bothered by feelings of claustrophobia and by the loud banging noise during the study.

MRI & Metal. Because the MRI machine acts like a large magnet, it could move iron-containing objects in the MRI room during your examination, which could in the process possibly harm you. Precautions have been taken to prevent such an event from happening; loose metal objects, like pocketknives or key chains, are not allowed in the MRI room. If you have a piece of metal in your body, such as a fragment in your eye, aneurysm clips, ear implants, spinal nerve stimulators, or a pacemaker, you will not be allowed into the MRI room and cannot have an MRI. It is important that you consider whether you have ever been in a situation where metal fragments may have ended up in your body and you inform us of any such possibilities.

Rare adverse events occurring in 0.5% of subjects:

TMS & Seizure. TMS stimulates brain cells at a level below what triggers seizures. TMS is safe and well tolerated without enduring side effects. This specific treatment has not been FDA-approved for this study population. The research team has a plan for dealing with seizures, and every TMS researcher is familiar with it. If you have a seizure, you will be made to lie down with your legs elevated. An emergency response team will be called. Most seizures, including those caused by TMS, last less than 60 seconds and do not require any medication. Once you recover from the seizure, you will be seen by a neurologist. Any participant who has a seizure cannot continue with the study.

Hearing Sensitivity. The discharge of the TMS coil and the MRI scanner generate loud, sustained noises that may cause damage to the inner ear. Humans exposed to TMS have shown temporary increases in auditory threshold (especially at high frequencies) lasting at least 5 minutes and less than 4 hours. Although uncommon, ringing in the ear has been reported after TMS exposure. Foam earplugs can protect against these changes and you will be required to wear these during TMS sessions.

Confidentiality Risks. There is a risk of a loss of confidentiality (privacy) of your personal information because of participation in any study. This is why all study records will be placed in a locked, secure, limited access location. Your participation in the study and the information you provide will be treated as confidential. The information we collect will contain a code number and not your name to protect your confidentiality. Codes linking numbers and names will be kept in a locked secure location and will not be accessible to anyone outside the research team. Despite these efforts to maintain subjects' anonymity and confidentiality, there is always some minimal risk of people other than the study investigators gaining access to your health information. Every effort will be made to ensure that your health information will be collected and stored in a manner that ensures the highest level of protection of confidentiality.

You should also know that if you threaten to harm yourself or others or give information about child or elder abuse, this information will be reported to appropriate clinical staff

and other persons outside the research program as necessary to protect yourself and others and as mandated by law.

Incidental Findings & MRI. The scans performed in this study are for specific research purposes and are not optimized to find medical abnormalities The investigators and MUSC are not responsible for failure to find existing abnormalities with these MRI scans. However, on occasion study staff may notice a finding on an MRI scan that seems abnormal. When this occurs, a physician will be consulted as to whether the findings need further investigation, in which case the investigator will contact you and your primary care physician and inform you of the finding. The decision as to whether to proceed with further examination or treatment lies solely with you and your physician. The investigators, the consulting physician, and MUSC are not responsible for any examination or treatment that you undertake based on these findings.

Other risks relate to finding out that you may have a medical abnormality that you had not been aware of before. This knowledge could cause psychological stress to you or your family and possibly affect your health insurance coverage in the future.

Potential risks of venipuncture: Participants may experience a slight pinch in their arm when the blood sample is taken, and subsequent slight bruising at the venipuncture site. While these effects commonly occur during this fairly routine procedure, these are transient and unlikely to cause persistent discomfort. Participants will be informed of this risk prior to the venipuncture to enhance their preparedness.

Unknown Risks. The experimental treatments may have unknown side effects.

If any study related injury occurs further information may be obtained from the Medical University of SC Hospital Medical Director (843) 792-9537 concerning medical treatment.

E. MEDICAL RECORDS and CERTIFICATE OF CONFIDENTIALITY

Information about your study participation will not be in your medical record. This means that neither your research participation nor any of your research results will be included in any MUSC medical record.

This research is covered by a Certificate of Confidentiality from the Federal government. This means that the researchers may not disclose information or biospecimens that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, nor can the information or biospecimens be used as evidence, unless you have consented to this disclosure. Information or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research unless you have consented to the disclosure. More

specifically, identifiable information or biospecimens will not be shared with your medical providers who are not involved in this research unless you authorize the study to disclose information to them, or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must authorize the researchers to release it.

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law. Examples of required disclosure include: child abuse and neglect, or harm to self and others, but there could be others.

Finally, a Certificate may not be used to withhold information from the Federal government needed for auditing or evaluating Federally funded projects or information needed by the FDA.

F. BENEFITS

iTBS-rTMS is an FDA-cleared treatment for depression and early evidence suggests that it may improve memory and thinking. As such, some participants may experience improvement in MCI symptoms and reduction of alcohol use. There is no currently accepted treatment for the symptoms associated with MCI or AUD. There is also a chance of no direct benefit to you. In addition to the potential direct benefits of participation in this study, participants will help investigators understand the utility of iTBS-rTMS as a potential future treatment for patients with MCI and AUD.

G. COSTS

There will be no cost to you as a result of participation in this study.

H. PAYMENT TO PARTICIPANTS

In return for your time, effort and travel expenses, you will be paid up to $500 for participation in this study. If you do not complete the study, you will receive the following for each completed procedure:

Visit	Week	Compensation ($)
Consent & Eligibility Assessment		$25.00
Pre-Treatment Assessments & Brain MRI	Week 0	$50.00
iTBS-rTMS Treatments	Week 1	$50.00/treatment day ($250

		total)
Post-treatment Assessments & Brain MRI	Week 2	$50.00
Post-treatment Assessments	Weeks 2 -5	$12.50/week ($50 total)
Post-treatment Assessments	Week 6	$75.00
		= $500 upon completion of all procedures

You will receive payments after completion of each procedure. Payment for study visits will be made using a pre-paid debit card, called a ClinCard. It works like a bank debit card and you may use the card to purchase goods or services everywhere Debit MasterCard is accepted. You will be given a ClinCard at the beginning of the study. Each time you receive payment for participation in this study, the money will be added to the card, as outlined in the payment schedule above.

Payments that you receive from MUSC for participating in a research study are considered taxable income per IRS regulations. Payment types may include, but are not limited to: checks, cash, gift certificates/cards, personal property, and other items of value. If the total amount of payment you receive from MUSC reaches or exceeds $600.00 in a calendar year, you will be issued a Form 1099.

In addition to visit payments above, if you travel more than 60 miles each way, additional reimbursement options are listed below.

- If you use your own transportation you will be reimbursed 0.625 cents per mile (but cannot exceed $250)
- If you use public transportation such as taxi, bus, or shuttle, you will be reimbursed for your transportation costs if you provide a receipt (but cannot exceed $250)

Transportation expenses to study visits for participants who need assistance will also be reimbursed. Reimbursement for travel costs, such as lodging, cab fare, and meals, will be made directly by MUSC via check.

I. ALTERNATIVES

Your alternative is to not participate in this study and to seek standard clinical care.

J. DATA SHARING

Information about you (including your identifiable private information and/or any identifiable biospecimens) will have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

K. DISCLOSURE OF RESULTS

Results of the research will not be shared with you.

L. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:
    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is

approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

M. SIGNIFICANT NEW FINDINGS

If there are significant new findings during the course of the study, you will be notified.

N. STUDENT AND EMPLOYEE PARTICIPATION

If you are a student or trainee in the MUSC system, your participation or discontinuance will not constitute an element of your academic performance nor will it be a part of your academic record at this Institution. Similarly, if you are an employee in the MUSC system your participation or discontinuance will not constitute an element of your job performance or evaluation nor will it be a part of your personnel record at this Institution.

O. COLLECTION OF SPECIMENS

Specimens will be collected throughout this study in order to track alcohol use over time. This will include a urine alcohol screen, a urine drug screen, and a blood sample to detect alcohol and substance use. The urine alcohol screen and the urine drug screen will be provided by natural means. The blood sample will be taken by a trained lab technician from our certified laboratory. All samples (both urine and blood samples) will be discarded once they are tested and analyzed. They will only be used solely for the purpose of this study and this study only. All identifiers will be removed from the samples. They will not be stored for future research. A urine pregnancy test will also be administered.

P. CLINICAL TRIALS.GOV

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

Q. FUTURE CONTACT

The researcher in charge of this study might like to contact you in the future about other research opportunities. If consenting on paper, please initial by your choice below and if consenting electronically scroll to the bottom of the screen and indicate your choice by selecting 'yes' or 'no' and then initial the statement confirming your choice in the item that follows.

____Yes, I agree to be contacted
____No, I do not agree to be contacted

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with you will remain confidential to the extent possible within State and Federal law. The sponsor and the Food and Drug Administration (FDA) will receive copies of the research records. The investigators associated with this study, employees of the sponsor, the FDA, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event of a study related injury, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. The data collected on you to this point remains part of the study database and may not be removed. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteer's Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Lisa McTeague, Ph.D. at (843) 792-8274. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

_____ _____

Signature of Person Obtaining Consent Date *Name of Participant

_____

Signature of Participant Date