Cover Page for:

rTMS for Stimulant Use Disorders (CTN-0108)

NCT04907357

Consent Document

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Medical University of South Carolina
CONSENT TO BE A RESEARCH PARTICIPANT

rTMS for Stimulant Use Disorders

You are being asked to participate in a research study. This study is completely voluntary and includes only those who choose to take part. The purpose of this study is to evaluate the use of repetitive transcranial magnetic stimulation (rTMS) on individuals who use methamphetamine or cocaine. Repetitive TMS is a non-invasive technique that uses magnetic pulses to temporarily stimulate specific brain areas in awake people (without the need for surgery, anesthetic, or other invasive procedures).

If you agree to participate, you will undergo screening assessments to make sure the study is a good fit for you. This screening will include a medical history and physical exam. You will be asked questions about your substance use history, seizure history, your mood and nerves, and current medications. A urine drug screen will be performed, and if you are a female you will also have a urine pregnancy test. The screening process may take up to 2 weeks to complete. You will then be randomized to receive either real rTMS or placebo. You will have 2 to 5 rTMS sessions per week (based on your availability) to receive a maximum of 30 sessions over 8 weeks. You will be given access to a smart phone app that will provide online cognitive behavioral education during the 8 weeks of rTMS sessions. At each study visit you will have a urine drug screen and will be asked about your substance use as well as how you are doing. At some visits you will also be asked about your sleep patterns. You will also receive very brief surveys (via email or text) that you will be asked complete daily during your participation. You will also be given an ActiGraph, which is a watch-like device that you will wear on your wrist to monitor your sleep quality. You will also have an electroencephalogram (EEG), where you will wear a special cap on your head to measure your brain waves. This will happen after you have been randomized, and again approximately 4 weeks later. You will have follow-up visits at 12 and 16 weeks after you sign this consent document. Depending on how long the screening process takes, your study participation will take between 16 and 18 weeks.

There are risks associated with this study that are described in this document. There is a very small risk of seizure during rTMS sessions. Headaches and scalp discomfort where the magnet rests on your skin are the most common side effects that have been reported. There is also a risk of loss of confidentiality. Participation in this study may improve your substance use, but that cannot be guaranteed or promised. If you choose not to participate in the study, alternative treatments may include talk therapy and/or medications, however there are no FDA approved treatments for methamphetamine or cocaine use disorders at this time.

If you are interested in learning more about the 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 the research staff discusses this consent form with you, please ask them to explain any words or information that you do not clearly understand. You are being asked to participate in this study because you are interested in cutting back or stopping your use of methamphetamine and/or cocaine.

rTMS has been approved by the Food and Drug Administration (FDA) as an add-on treatment for obsessive compulsive disorder, as a treatment for depression, and it was also recently FDA approved to aid in smoking cessation. However, rTMS is not approved by the FDA as a treatment for stimulant use disorders. There have been case reports and small studies that have found rTMS to be safe in individuals with stimulant use disorders resulting in some improvement in craving for stimulants. In this study, the investigators hope to determine whether individuals with methamphetamine or cocaine use disorders are willing and able to attend repetitive TMS (rTMS) sessions at the schedule described in this study, to collect additional information on the safety of rTMS, and to assess whether rTMS decreases substance use.

This is a multi-site study sponsored by the National Institute on Drug Abuse. The Lead Investigators for this study are Dr. Kathleen Brady here at the Medical University of South Carolina (MUSC), and Dr. Madhukar Trivedi at University of Texas Southwestern Medical Center (UTSW). The investigator in charge of this study at MUSC is Dr. Karen Hartwell. Portions of her salary and her research team's salaries will be paid by this grant. The study is being done at 2 sites. Approximately 160 people will take part study-wide and up to 80 will take part at this institution.

B. PROCEDURES

If you agree to be in this study, the following will happen:

1. **Screening:** You will have screening assessments to make sure the study is a good fit for you. This screening process will take at least 2 visits, but may be broken into more visits if needed. Screening must be completed no more than 2 weeks prior to randomization. You will be asked questions about your substance use and psychiatric symptoms.

   If you are female, you will have a pregnancy test, and if you are pregnant, you will not be able to participate in the study. All women will be asked to use birth control during the course of the study. Acceptable forms of birth control include: birth control pills, patch, IUD, condom, sponge, diaphragm with spermicide, or avoiding sexual activity that could cause you to become pregnant. If you are not pregnant, or are a male participant, you will have a urine drug screen. You will also have a brief physical exam (including height, weight, blood pressure, and pulse rate), and medical history, and you will be asked if you have any metal implants above the waist. Because rTMS may cause metal that is near the rTMS coil to heat, you will not be able to participate if you have a metal implant that could be in close proximity to the rTMS coil.

2. **Randomization:** If you are female, you will have a repeat pregnancy test, and if you are pregnant, you will not be able to participate in the study. If you are not pregnant, or are a male participant, and the physical examination and test results show that you are eligible for the study, you will be randomly assigned to one of two groups. This means that you have a 50/50 chance (like flipping a coin) of being in either group. Neither the researchers nor you will make the choice to which group you are assigned. Also, neither you nor the research staff will know which group you are in. The two groups are real rTMS or placebo rTMS. If you are randomized to the placebo rTMS, you will still hear similar noises and feel similar vibrations, but you will not actually receive the rTMS intervention. Regardless of your group assignment, you will have some flexibility of when you have your rTMS sessions. It is expected that you will

come in 2 to 5 days a week (Monday through Friday) for a maximum of 30 rTMS sessions over the 8-week treatment phase. If you are interested and scheduling allows, you may have two rTMS sessions in a single day. If you do this, the two sessions must be separated by at least an hour. It may also be possible, although not required, to have your rTMS visit on a weekend.

3. **rTMS/ placebo rTMS sessions**: You will be asked to remove any metal jewelry including necklaces, earrings, or other piercings. If you request it, a topical anesthetic (numbing cream or gel) may be applied to your scalp 20 minutes before rTMS and removed immediately before the rTMS machine is started to reduce potential discomfort. Before you begin the rTMS (or placebo rTMS) sessions, the researchers will first determine your individual level of thumb muscle response to rTMS pulses (called the resting motor threshold rMT). This is done because everyone's response to rTMS is a little different, and we want to make sure that we give you the right "dose" of rTMS. The researcher will ask you to hold out your hand and fingers. In order to determine your rTMS dose, the researcher will put the rTMS coil over the part of your brain that moves your hand and find the lowest amount of magnetic stimulation needed to move your thumb. The researcher will use that thumb-twitch dose to find your individual study-treatment dose. This procedure will be repeated a few times during the 8-week course of treatment and may be repeated based on your recent substance use.

   Prior to each rTMS session, you will be asked to think about using cocaine or methamphetamine, and you will be shown pictures, or cues, of cocaine or methamphetamine products and paraphernalia. This may cause you to experience mild craving during the rTMS session. During the rTMS/placebo rTMS session, you will have a coil placed over your forehead, and you will hear clicks and other noises. You will be given ear plugs to decrease the noise and protect your hearing. Each rTMS session will last approximately 30 minutes.

4. **Cognitive Behavioral Education:** Regardless of which type of rTMS you receive, you will also be given access to a smartphone app for cognitive behavioral education modules that can be done from your smartphone or other device. You will be asked to download the free app on your personal smartphone. If you do not have a device, are unable to download the app, or prefer to not use your smartphone, a study smartphone device will be made available for you to use during the study. You will return this device at the end of the study. There are 20 modules to choose from, and you can access them as many times as you like during the 8-week treatment phase of the study.

5. **EEG:** You will have an electroencephalogram (EEG) after you have been randomized, and again approximately 4 weeks later. You will have a specialized cap put on your head which will measure your brain waves. It is important for you to have clean, dry hair with no gels or other hair products because they may interfere with the electrodes' ability to measure the brain signals. You will wear this cap for approximately 30 minutes.

6. **Sleep Monitoring:** After randomization you will receive an ActiGraph, which is a watch-like device that you will wear on your wrist to monitor your sleep. You will be asked to wear this watch 24 hours a day. This device can be worn in the shower. You will wear this device during the 8-week rTMS treatment phase.

7. **Daily Surveys:** After randomization you will receive daily surveys (via either text or email) that will include several questions about your methamphetamine or cocaine use, craving, ability to resist using, mood, and sleep. As mentioned in 4 above, if you do not have a smartphone, or if

you prefer not to use your smartphone, a study smartphone device will be made available for you to use during the study. You will return this device at the end at of the study.

8. **Study Visits during 8-week treatment phase:** As stated above, you will have up to 30 study visits over 8 weeks with no more than 5 visits in a week. Each week you will have one long and several short visits. The first visit of each study week will be the long visit (approximately 90 minutes including rTMS), with each subsequent visit that week being approximately 45 minutes, including rTMS. You will have a urine drug screen collected at each visit. If you are female, you will have a urine pregnancy test at the long visits for weeks 4 and 8, and if you are pregnant, you will not be able to continue in the study. If you are not pregnant, or are a male participant, you will then have a urine drug screen.

   At the weekly long visits you will be asked questions about your mood and your sleep, as well as your substance use since the last weekly visit. You will also be asked about any side effects or medications you have taken. You will be asked to remove the ActiGraph device from your wrist so that the research staff can obtain the sleep information from it.

   The weekly short visits will include a urine drug screen, and you will be asked questions about any side effects or medications you have taken and changes in your caffeine use.

   Once these assessments are done, you will have your rTMS session. After your rTMS session, you will be asked to rate your craving and ability to resist using cocaine or methamphetamine.

9. **End of Treatment Visit**: At the end of your rTMS sessions (week 8) you will complete an end of treatment visit. This may occur at your last visit in week 8 or up to a week later, depending on your availability. If you end your study participation early, the researchers will also ask you to have an end of treatment visit. You will have a urine drug screen, your weight will be measured, and you will be asked about your substance use since your last visit as well as your cigarette smoking, sleep, mood, quality of life. You will also be asked about your satisfaction with rTMS and the other study procedures and whether you think you received real or placebo rTMS. The visit will last approximately 1 hour. You will also return the ActiGraph device at this visit.

10. **Follow-up Visits**: You will have a follow-up visit approximately 12 weeks after randomization, and again at 16 weeks after randomization. At these visits you will have a urine drug screen, your weight will be measured, and you will be asked about your substance use since your last visit as well as your cigarette smoking, sleep, mood, quality of life. You will also be asked about your satisfaction with rTMS and the other study procedures and whether you think you received real or placebo rTMS. These visits should take approximately 1 hour.

    If you received a borrowed smartphone device to use during the study, you will return it at the week 16 visit.

Staying in Touch During the Study:
The research team will use several methods of contact to keep in touch with you. We will ask you to provide us with phone numbers, e-mail addresses, current home and work addresses, and contact information of family and friends who may know how best to reach you. You will be asked if your contact information has changed during your visits.

Study Withdrawal:
You may be withdrawn from this study without your consent if the researchers believe it is in your best interest or if you fail to follow study procedures. Your withdrawal from the study may be for reasons related solely to you (such as not following study-related directions from the investigator), as a result of what is in your best medical interest, because of discontinuation of funding, or because the entire study is terminated.

You may choose to withdraw from the study at any time. If you choose to withdraw, please contact Dr. Karen Hartwell, whose contact information is below:

Karen Hartwell, MD
MUSC, Department of Psychiatry
67 President Street, 4 North
Charleston, SC 29425
843-792-4606

Your decision to withdraw from the research study will not result in any penalty or loss of benefits to which you are otherwise entitled.

If you decide to stop taking part in the research study:

- Return the ActiGraph wrist device, as well as the study phone (if you borrowed one).
- If you are willing, you may be asked to complete an end of treatment visit.

Participant Responsibilities:
While you are part of this study, the researchers will follow you closely to determine whether there are problems that need medical care. It is your responsibility to do the following:

- Ask questions about anything you do not understand.
- Keep your appointments.
- Follow the researchers' instructions.
- Let the researchers know if your telephone number or address changes.
- Report to the researchers any injury or illnesses while you are in the study even if you do not think they are related to your participation in the study.
- Tell the researchers before you take any new medication, even if it is prescribed by another doctor for a different medical problem.

C. DURATION

Participation in the study will take about 35 visits over a period of 16-18 weeks.

D. RISKS AND DISCOMFORTS

1. Risks of rTMS:

Side effects that have occurred in less than 10% of people include:

- Eye pain, facial pain, and toothache when the magnetic pulses are applied

Side effects that have occurred in 10-25% of people include:
- Twitching of the scalp or facial muscles during repetitive rTMS
- Mild scalp discomfort when the magnetic pulses are applied over the scalp
- Headache following rTMS
- Nausea

Potential hearing loss:

The discharge of the rTMS coil generates a high-energy click that may cause damage to the inner ear. People exposed to rTMS have shown temporary decreased hearing (especially at high frequencies) lasting at least 5 minutes and less than 4 hours. Foam earplugs can protect against these changes and will be worn during rTMS sessions.

Potential risk of a seizure:

There is a small risk of seizure with rTMS. To date, eight seizures have been noted in the literature. Six of them have been in healthy people who did not have a previous history of seizures. The risk of rTMS causing seizures is related to the intensity, duration, and frequency settings of the stimulation. After those seizures occurred, safety guidelines for the rTMS settings were developed to keep people safe. Following the adoption and widespread use of the safety guidelines, 1 seizure was reported since 1997, and it involved using settings higher than the safe range. Although rTMS is thought to be safe with no identified damage to the brain, treatment response may be different in individuals with pre-existing brain lesions. Therefore, if you have a history of any type of brain tumor or lesion, you will not be able to participate in this study.

Potential risk of changes in mood:

It is possible that rTMS may affect your mood. It is FDA approved to treat depressed mood, so it is possible that it can improve your mood or increase it too much (called mania). You could also have decreased mood. The study team will assess your mood throughout the study. If you have a history of mania when not using stimulants, you will not be able to participate in the study.

Potential change in cognitive function:

rTMS may cause brief changes in memory or attention, with changes lasting a minute or less.

Pregnancy Risk:

This study will exclude pregnant women. The risks of using rTMS with pregnant women are currently unknown and may involve risks to pregnant women as well as the embryo or fetus. If you are pregnant, or think you might be pregnant at any point during this study, please inform the investigators and the rTMS will be discontinued immediately.

Placebo rTMS:

If you receive the placebo rTMS, you will not receive active medical treatment (other than the cognitive behavioral educational phone app) for your stimulant use problem.

2. Risks of EEG

There are no associated risks of EEG. You may experience skin irritation or discomfort from the electrodes or cap.

3. **Risks of Topical Anesthetic (EMLA, Lidocaine or Lidocaine/Prilocaine):**

   If you request the use of numbing cream or gel prior to rTMS/sham, it is possible that you may experience irritation, redness, swelling, stinging, burning, or numbness in places where the cream or gel is applied. There is also the risk of having an allergic reaction which could include hives, swelling to the face, throat, lips, or tongue, itching, or difficulty breathing.

4. **Stimulant Cues:**

   You may experience mild cravings when you are exposed to the cocaine or methamphetamine pictures.

5. **Randomization:**

   The treatment you receive may prove to be less effective or to have more side effects than the other study treatment(s).

6. **Psychological Stress:**

   Some of the questions we will ask you may make you feel uncomfortable, upset, embarrassed, or disappointed. Questions will cover your personal habits, lifestyles, and drug or alcohol use. You may refuse to answer any of the questions, take a break, or stop your participation in this study at any time.

7. **Loss of Confidentiality:**

   Any time information is collected, there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. Another way in which there may be a loss of confidentiality includes researchers contacting you via email or text message to complete daily surveys. All of the data will be protected to help safeguard your identity. You should also take steps to secure your smartphone.

8. **Unknown Risks:**

   The experimental treatments may have unknown side effects. The researchers will let you know if they learn anything during the course of the study that might make you change your mind about participating in the study.

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 except if you have consented to the disclosure, including for your medical treatment, or if it is used for other scientific research, as allowed by federal regulations protecting research participants.

A Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research.

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 or 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

There may or may not be direct benefits to you. You may experience a decrease in your drug use, however this cannot be guaranteed or promised. The researchers hope the information learned from this study will benefit others with drug use problems in the future.

G. COSTS

There will be no cost to you for any of the study procedures. You could have some costs associated with using your cellular data plan to view the cognitive behavioral education modules or complete the mobile surveys. If you use your own phone, you will receive $40 to cover these potential costs (see section H below).

H. PAYMENT TO PARTICIPANTS

In return for your time and effort, you will be paid up to $1,665 for participation in this study. If you do not complete the study, you will receive payment for each completed visit/assessment as described below:

Screening:	$50 – this may be broken up into several payments during the screening process plus $15 bonus if you arrive to your first scheduled screening visit on time = $65
TMS Visits:	$25 per visit x 30 visits = $750; if 2 visits are done in one day, you will get $50 for that day
Daily surveys:	$5 for each survey completed for up to 112 days = $560
End of Treatment:	$25
Week 12:	$50
Week 16:	$75 plus $40 for return of borrowed cell phone or to compensate you for data usage on your phone = $115
EEG:	$50 for each of 2 possible EEGs = $100

In addition to the compensation above, you may earn visit attendance bonuses of $20 (received up to 3 times during the 8-week treatment period). Attendance bonus of $20 is earned if you attend 10 visits within the first 3 weeks of the treatment period. An attendance bonus of $20 is earned if you attend 20 visits within the first 6 weeks of the treatment period. An attendance bonus of $20 is earned if you attend 30 visits within 8 weeks of the treatment period.

In addition to the above, you may be eligible to receive mileage reimbursement based on the current IRS medical mileage amount.

If you would like to recommend the study to others, you will be compensated $10 for each person who qualifies and enrolls in the study.

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 a 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. Details of the debit card system are explained on an additional sheet.

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.

I. ALTERNATIVES

If you choose not to participate in this study, you could receive other treatments for your condition. Although there are currently no treatments that are FDA approved for treating methamphetamine or cocaine use disorders, you can receive counseling and/or medications, or other behavioral treatments, including self-help programs.

J. SIGNIFICANT NEW FINDINGS

If there are significant new findings during the course of the study which may relate to your willingness to continue your participation, you will be notified.

K. DATA SHARING

Information about you (including your identifiable private information and/or any identifiable biospecimens) may 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.

L. DISCLOSURE OF RESULTS

Your individual research results will not be disclosed to you.

M. 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;
- Emmes, serving as both the Clinical Coordinating Center, as well as the Data and Statistics Center for 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.

N. CLINICAL TRIALS.GOV

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. 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.

Additionally, de-identified data from this study will be available to researchers on another website, http://datashare.nida.nih.gov/ after the study is complete and the data analyzed. The primary outcome(s) publication will also be included along with study underlying primary data in the data share repository, and it will also be deposited in PubMed Central http://www.pubmedcentral.nih.gov/. These websites will not include information that can identify you. You can view these websites at any time.

O. SPONSOR COMMITMENT:

During your participation in this research, if you suffer physical injury or physical illness, the study site will provide immediate medical treatment and a referral to an appropriate health care facility if necessary. This study does not offer funds for the treatment of research-related injury or illness. You or your insurance carrier will be expected to pay the costs of all services rendered to you.

P. FUTURE CONTACT:

The researcher in charge of this study might like to contact you in the future about other research opportunities. Please note that participation in any additional study is entirely voluntary and refusing to volunteer for an additional study will not affect your participation in this study. Please initial by your choice below:

____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. The study sponsor will 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 or to discontinue your participation at any time will not affect your current or future medical care or any benefits to which you are entitled and will not involve any penalty.

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.

Volunteers 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 ***Dr. Karen Hartwell at 843-792-4606.*** 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 participant 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 Participant Date

_____

Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date