Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

TITLE OF RESEARCH: Accelerated rTMS for Post-Stroke Apathy: Targeting Amotivation Toward Improving Whole Health and Rehabilitation Engagement

Concise Summary:
You are being asked to volunteer for a research study. Research studies are voluntary and include only people who choose to take part. This study aims to determine whether non-invasive brain stimulation is a promising and safe treatment for stroke-related apathy symptoms (e.g., lack of interest, or lack of enthusiasm). You are being asked to participate in this study because you experienced a stroke at least 6 months ago, and experience apathy (i.e. loss of motivation, drive, or desire and interest in thinks around you) as a result. You have also been asked to identify an individual close to you who can comment on how you have been doing since your stroke. This is a person who has contact with you at least once a week.

You will complete assessments that last about 4 hours total. You may elect to split these into two sessions. The assessments will look further at apathy, interest, attention, memory, emotional difficulties, and daily function. You will have an MRI scan (1 hour) to assess your stroke and to ensure safety for repetitive transcranial magnetic stimulation (rTMS). Your medical records including imaging will also be reviewed to assess for safety for rTMS by the study personnel.

Then you will have three days of rTMS treatments over a one-week period (3-4 hours each day). Stimulation will occur in 3-minute increments, 12 times per treatment day, with a 10-15 minute break between each stimulation session (or more if you prefer). During treatment days, you will be monitored for side effects and comfort. At the end of the final treatment day, you will repeat a battery of assessments to measure if anything has changed (3-4 hours). You will also have another MRI session after treatment (30-45 minutes). You will repeat short weekly questionnaires following treatment (by phone or computer), and one month after treatment you will repeat the longer set of assessments like one completed just before and after rTMS (3-4 hours).

Risks of the study treatments are described in this document below. Some of the risks include potential risk of seizure, worsening of psychiatric symptoms, effects on brain tissue, changes in cognitive function, hearing loss, facial twitching headaches, skin irritation, or a first-degree burn, and MRI risks. Benefits of participation in this study include possible reduction of apathy symptoms and improvement in overall physical and mental well-being, however, these benefits cannot be guaranteed. Participation in this study is completely voluntary and will not affect your medical care or benefits. If you are interested in learning more about this study, please continue to read below.

Your alternative is to not participate in this study. Participation in the study will include

11 visits over a period of approximately six weeks. Your total study duration will take approximately six weeks.

A. PURPOSE OF THE RESEARCH

The goal of this study is to determine whether non-invasive brain stimulation is a promising and safe treatment for stroke-related apathy (i.e., loss of interest and motivation) symptoms. Please read this consent form carefully and take your time making your decisions. 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.

Repetitive transcranial magnetic stimulation (rTMS) is an FDA-approved treatment for depression, smoking cessation and obsessive-compulsive disorder. In typical rTMS for depression, a specific brain region on the front of the head near the left temple is stimulated. It is thought that this region's connections to other brain areas involved in depression are responsible for the reduction of symptoms. In this study, we will stimulate a different region located in the middle of your head near the top of your forehead which research suggests is more closely related to apathy and motivation. Stimulation of both regions has been shown to be safe and well tolerated by previous studies. The stimulation location in this study is investigational.

rTMS works by rapidly turning a focused magnetic field on and off repeatedly near your head, which passes directly through your hair, scalp, and skull and onto your brain, where it can temporarily increase brain activity under the magnetic field. The type of stimulation in this study is investigational. However, this stimulation has been used in other populations and has been shown to be safe, tolerable, and effective. The stimulation type in this study is an "accelerated" rTMS protocol. That means that we will deliver 12 stimulation sessions a day, separated by 10–15-minute breaks, repeated three times within one-week. We are hoping to see if this treatment is tolerable and acceptable to individuals who have experienced apathy or loss of interest elated to a stroke, and to evaluate the safety of this in terms of cognitive and emotional functioning.

Your participation in this research is entirely voluntary. Your participation may help us develop a treatment to improve stroke recovery. At present, there is no FDA-approved treatment for post-stroke apathy and loss of interest. If you consent and then change your mind at any time you are free to discontinue and withdraw from the study.

The investigator in charge of this study is Dr. Parneet Grewal, MD. This study is being done at one site and will involve approximately 20 volunteers with stroke (and 20 co-participants who can describe stroke recovery).

A grant from the National Institutes of Health (NIH) will sponsor this study. Portions of the Dr. Grewal's and her research team's salaries will be paid by this grant.

B. PROCEDURES

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

Session 1: Intake visit #1 (2 hours)

1) You will complete the first part of a series of clinician-guided psychiatric interviews, questionnaires and assessments evaluating apathy, loss of interest, mental health-related symptoms, stroke-related symptoms, functional status, and cognitive symptoms. Some of these assessments and questionnaires can be completed remotely (by phone or videoconferencing software) if needed.

Session 2: Intake visit #2 (2 hours)

1) You will complete additional questionnaires and assessments to evaluate the symptoms above (apathy, mental health-related symptoms, stroke-related symptoms, functional status, and cognitive symptoms). As above, some of the assessments can be completed remotely if needed.

2) A pregnancy test will be performed on women of child-bearing potential. You cannot participate in this study if you are pregnant, breastfeeding, or trying to become pregnant.

3) A urine drug screen will be performed on your urine. People who are actively using drugs (i.e. non-prescription recreational substances) will not be allowed to participate in the study. This test will not be performed on anyone who is found to be pregnant.

4) Trained research staff will use TMS to find your motor threshold. The researchers will first determine your individual 'dose' of TMS. That is, the level of thumb muscle response to TMS pulses (called the resting motor threshold). This is done because everyone's response to TMS is a little different, and we want to make sure that we give you the right amount of TMS. The researcher will ask you to hold out your hand and fingers. He/she will then slowly and carefully move the TMS device over your head. The TMS device will send a single magnetic pulse every 1-2 seconds. The researcher will continue to move the coil until he/she finds the specific brain area that results in slight movement of your thumb. The researcher will then mark this area that controls your thumb movement using a computerized-navigation system that will be used for all TMS visits.

You may decide to complete sessions 1 and 2 on one day or over two days. That will be decided based upon how you are feeling and what your schedule allows.

Session 3: MRI scans (1-2 hours)

1) You will complete a set of MRI scans. MRI machines use a strong magnet and radiofrequency magnetic fields to make images your body. You will be asked to lay on a long narrow platform while the machine gathers data. You will not be exposed to x-rays or radiation during these scans, but rather a strong magnetic field which

you will not feel. You will hear repetitive tapping noises that arise from the strong electromagnet used by the scanner. We will provide earplugs or headphones that you will be required to wear to protect your hearing. There will be a device that looks like a birdcage around your head, which helps to make the images of your brain. The space within the large magnet in which you lie is somewhat small, although we have taken steps to relieve the "claustrophobic" feeling. If you feel uncomfortable in the scanner, you are free to discontinue at any time. During this, will collect a picture of the structure of your brain (structural MRI) as well as a scan of how different brain areas communicate (functional MRI) while you are at rest.

2) This session could be scheduled on the same day as one of your first sessions, if that works best for your schedule, or on a separate day. We typically try to separate these to give you a bit of a rest, but you should let the research staff know what would be most convenient for you.

Sessions 4, 5, and 6: rTMS treatment (3-4 hours each):

1) Three rTMS treatment days will be scheduled within a one-week period. You will receive twelve TMS sessions a day for three days for a total of 36 total rTMS treatment sessions.

2) On each treatment day, you will receive 12 rTMS treatments. Each treatment lasts about 3 minutes, and each treatment will be separated by a break of at least 10-15 minutes, or more if you desire.

3) We will closely monitor you for safety, comfort, and side effects during each treatment day.

Session 7: Immediately after treatment (2-4 hours)

We will meet with you for an appointment immediately after finishing your three days of treatment to repeat the initial assessment of apathy, stroke-related, cognitive, mental health-related, and functional symptoms as well as MRI. If you prefer, the MRI can be scheduled on a separate day.

Post-treatment Weekly Questionnaires (20 minutes each)

Following completion of treatment, you will complete weekly questionnaires assessing how you are doing in terms of emotion and thought processes as well as everyday tasks. This will take place on the 1st, 2nd, 3rd , and 4th weeks following your last treatment visit (4 times in total). The apathy questionnaire can be completed in person or remotely according to your preference.

Session 8: One-month follow-up visit (3-4 hours)

4 weeks after your last treatment you will repeat the battery of assessments evaluating motivation, emotion, attention and thinking and how much you are engaged in your daily life. As before, a portion or all of these assessments and questionnaires can be

completed remotely if preferable to you.

C. DURATION

Participation in the study will take about 10 visits over a period of 1-2 weeks, followed by one phone call at one month after treatment is completed.

APPROXIMATE PARTICIPATION TIMELINE

Session Number	Task Description	Location at Medical University of South Carolina	Approximate Time Commitment
1	**Intake visit #1** Clinical assessment battery	Brain Stimulation Laboratory in the Institute of Psychiatry	3-4 hours
2	**Intake visit #2** Clinical assessment battery (continued)	Brain Stimulation Laboratory in the Institute of Psychiatry	3-4 hours
3	**MRI scans** Safety screening Structural and functional MRIs	Center for Biomedical Imaging	1-2 hours
4 – 6	**rTMS treatments** Safety Screening 12x three-minute treatment sessions Questionnaires	Brain Stimulation Laboratory in the Institute of Psychiatry	2-3 hours
7	**Treatment completion assessments** Clinical assessment battery and MRI	Brain Stimulation Laboratory in the Institute of Psychiatry	2-4 hours
8-9	**Weekly symptom assessment** Questionnaires	Brain Stimulation Laboratory in the Institute of Psychiatry	15-30 minutes
10	**One-month follow-up assessment** Clinical assessment battery	Brain Stimulation Laboratory in the Institute of Psychiatry or remotely	3-4 hours

D. RISKS AND DISCOMFORTS

There are risks, discomforts, and inconveniences associated with any research study. These deserve careful consideration. Please read below and notify staff if you have any questions or concerns.

Emotional Distress: You will be asked to think and talk about emotional experiences including difficulties related to your stroke, anxiety, depression and other mental health conditions. This may cause you to become upset, especially if you have been trying to avoid these thoughts. You may skip any questions you choose not to answer. If you want to discontinue at any time, let research staff know. The Principal Investigator and

her trained staff will be available to immediately meet with you in private to discuss how you are feeling, how to manage your distress, and to plan follow-up care if necessary.

MRI. There have been no ill effects reported from exposure to the magnetism or radio waves used in this assessment. A known risk is that the magnet could attract certain kinds of metal. Therefore, we will carefully ask you about metal within your body (this includes certain dyes found in tattoos). If there is any question about potentially hazardous metal within your body, you will be excluded from participation in this research study. We will also keep the examining room locked so that no one carrying metal objects can enter while you are in the scanner. Please inform the study staff if you have a history of claustrophobia (extreme anxiety in close spaces). This may also be a contraindication to participation in the study.

Incidental Findings & MRI. The scans performed in this study are for specific research purposes and are not optimized to find medical abnormalities. The investigators for this project may not be trained to perform medical diagnosis. The investigators and MUSC are not responsible for failure to find existing abnormalities with these MRI scans. However, on occasion the investigator may notice a finding on an MRI scan that seems abnormal. If this occurs, a physician will be consulted as to whether the findings merit 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. Because the images collected in this study may not comprise a proper clinical MRI scan, these images will not be made available for diagnostic purposes.

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.

TMS & Pain: Some people report mild discomfort when the magnetic pulses are applied over the scalp. The frontal region targeted for stimulation in this study is closer to the face and may have a higher risk of discomfort. A small number of people (approximately 5%) report headache or toothache following TMS. These effects are temporary and typically can be managed with common over-the-counter pain remedies such as acetaminophen or ibuprofen. You will be monitored closely for any potential side effects including discomfort or headaches. We will discuss with you how to manage the side effects if they occur. In patients with chronic pain conditions, there is evidence that rTMS actually provides temporary relief from pain, temporarily decreases sensitivity to pain, or has no effect at all.

TMS & facial twitching and skin irritation: The TMS coil can cause facial twitching, skin irritation, or both, which can be acutely unpleasant. This typically often reduces over the

course of treatment. Additionally, all patients will have a foam insert placed between the coil and their scalp for comfort and this typically reduces this discomfort. Furthermore, facial twitching and skin irritation are typically only acute and subside with the end of stimulation.

TMS & Seizure: rTMS stimulates neurons at a level below that which is necessary to trigger seizures. While rTMS is generally regarded as safe and well tolerated without enduring side effects, in a sample size of several thousand patients and healthy volunteers, a total 20 cases of seizures induced with TMS were reported. The risk of seizures caused by rTMS is estimated to be less than 0.5% across all individuals. There has been one report of a seizure in a patient recovering from chronic stroke. This individual was receiving rTMS over the motor cortex, a region that is particularly sensitive to activating a seizure. In this study you will receive rTMS to a region that is less prone to seizures and further away from the motor cortex than typical rTMS for major depression. Nevertheless, we will monitor you closely for any signs of seizure throughout all procedures.

The research team has a protocol for dealing with fainting and seizures which all members of the study staff are familiar with. If you have a seizure, you will be positioned laying down with your legs elevated. An emergency response team will be called for transportation to the emergency department. 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.

TMS & Cognitive function: There have been no reports of long-term impairment (lasting more than one minute) in cognitive functions such as memory, attention, etc. following rTMS studies. On the contrary, research has shown that rTMS modestly improves cognitive function in most cases.

Hearing Sensitivity: The discharge of the TMS magnetic coil and the MRI scanner both generate loud, repetitive clicking noises that may be unpleasant and, in some cases, could 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, tinnitus (ear-ringing) has been reported after TMS exposure. Foam earplugs can protect against these changes and you will be required to wear these during TMS sessions. During the MRI scans, you will be required to wear foam earplugs or headphones.

TMS & burns: The TMS coil can heat up during use. The machine used in this study has two major protective engineering features: (1) an external heat monitor that will shut down the system if the coil gets too warm; and (2) a liquid-coiled coil design that keeps the coil much cooler than previous models. Additionally, all patients will have a foam insert placed between the coil and their scalp for comfort and also to act as additional

thermal protection. The TMS technician will periodically monitor coil temperature during each treatment.

TMS & psychiatric symptoms: Several studies have demonstrated the feasibility of rTMS to treat major depression without worsening of symptoms. There are case reports of patients with bipolar illness specifically developing symptoms of mania during the course of once-daily rTMS, thus patients with bipolar disorder will be specifically excluded from this study. Additionally, a standardized mania screening will be conducted before and after each treatment day. All patients will be assessed during each treatment day for worsening neuropsychiatric symptoms including mania specifically using a standardized measure. A battery of neuropsychiatric assessments will be obtained at baseline, immediately post-treatment, and at follow-up to further assess for any changes. All research staff will be trained to assess for worsening neuropsychiatric symptoms and/or psychosocial impairment and alert the PI of any concerning changes.

Confidentiality Risks. All study records will be kept 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 a minimal but real 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 promotes the highest level of protection of confidentiality.

Pregnancy. This protocol will exclude any participants who are pregnant, breastfeeding, or planning to become pregnant during the study period as the risks of rTMS are unknown to the unborn fetus. A urine pregnancy test will be obtained to screen all women of childbearing age for pregnancy. All women of childbearing age are further encouraged to maintain precautions against becoming pregnant while enrolled in the study by the use of birth control. Examples of effective methods of birth control include: birth control pills, hormonal patch, intrauterine device (IUD), condoms, sponge, diaphragm with spermicide, or avoiding sexual activity that could result in pregnancy.

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

E. MEDICAL RECORDS and/or 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.

Neither your research participation nor any of your research results will be included in any MUSC medical record. 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

You may receive relief from your apathy symptoms, which include loss of motivation and social withdrawal, although that cannot be guaranteed.

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 $400 for participation in this study. If you do not complete the study, you will receive the following for each completed procedure:

Consent & Session 1:	$50 for screening and intake visit #1
Session 2:	$50 for intake visit #2
Session 3:	$50 for completing MRI scans

Sessions 4-6: per visit x 3=$120	$120 for participation in rTMS sessions/questionnaires; $40
Sessions 6:	$50 for post-rTMS assessments
Session 7-9:	$30 (i.e. $10/session) for weekly follow-up questionnaires
Session 10:	$50 for 1 month follow-up assessment
Total:	$400 per participant upon the completion of all procedures.

You will receive payments after the completion of each visit according to the above payment schedule. Payments will be made using a pre-paid debit card, called a "ClinCard," or cash, or checks. The pre-paid debit card can be used to purchase goods or services wherever MasterCard debit is accepted. You will be given your ClinCard at the beginning of the study. Each time you complete a portion of the study, the corresponding amount of remuneration will be added to your account balance. Additionally, if you decide stop a part of the study before fully completing a step (for example, if you stop part of the way through a questionnaire or TMS session), you will receive a prorated amount of remuneration based on the percent of the study activity completed. For portions that are offered remotely, you will receive equal remuneration regardless of whether you choose to complete those items virtually or in-person. If you withdraw or discontinue before your first visit in-person, or if you are unable to come to the lab in person, any amount of remuneration owed to you can be paid by check or cash via postal mail. At the discretion of the investigator, the ClinCard, cash or check may be sent by postal mail to you, which could take 3-4 weeks.

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

You may choose not to participate in this study.

J. 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.

We would like to include data collected in this study and from other stroke related studies you may participate in with the Registry for Stroke Recovery (RESTORE-Pro00037803). RESTORE provides MUSC's stroke recovery research community with a database containing information on research participants including stroke type, disability status, and demographics to assist in recruitment. By including data from this study in RESTORE, MUSC researchers will have access to a more complete database

with key elements of physical function characteristics for more targeted recruitment efforts in the future. Additionally, this could reduce the burden placed on subjects by reducing the duplicative efforts of collecting common data and assessments requested by multiple studies and storing them in one centralized and secure location. If you consent to participate in RESTORE your data from this study, including your personal health information, will be included in the registry. You will be asked to sign a Release of Study Records form to share data from other stroke-related studies in which you have participated. If you authorize this Release your information from those studies will become part of the RESTORE registry study.

K. DISCLOSURE OF RESULTS

You will be provided an oral description and summary of your results over the course of the study. If you would like, we will also provide referrals for follow-up care. Additionally, if you would like your results forwarded to another healthcare professional, we will ask you to sign a release of your research-related medical records.

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 PARTICIPATION

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.

O. EMPLOYEE PARTICIPATION

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.

P. CLINICALTRIALS.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 Web site will include a summary of the results. You can search this Web site 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.

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 Parneet Grewal, PhD., at 843-792-3020. 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	