Informed Consent Form for Participants with Stroke

Dated October 1, 2019

NCT02544503

You Are Being Asked to Be in a Research Study

What Is a Research Study?

The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

Do I Have to Do This?

No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.

Taking part in a study is separate from medical care. The decision to join or not join the research study will not affect your status as a patient.

What Is This Document?

This form is an informed consent document. It will describe the study risks, procedures, and any costs to you.

This form is also a HIPAA Authorization document. It will describe how your health information will be used and by whom.

Signing this form indicates you are willing to take part in the study and allow your health information to be used.

What Should I Do Next?

1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. If there will be medical treatment, know which parts are research and which are standard care.
5. Take time to consider this, and talk about it with your family and friends.

Consent to be a Research Subject

Title: Customized Cortical Stimulation Therapy in the Rehabilitation of Stroke Patients

Principal Investigator: Cathrin M. Buetefisch, MD, PhD, Depts. Of Neurology, Rehabilitation Medicine, Radiology

Sponsor: US Dept of Health and Human Services-NIH-NINDS

Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide to consent (agree) to be in the study or not to be in the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

A description of this clinical trial will be available on 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 may search this website at any time.

Study Overview

The purpose of this study is to identify and establish how a part of the brain that controls motor function might serve as a new focus for treatment. The therapeutic intervention aims to improve motor performance after stroke. In order to understand how the brain repairs itself after stroke, we will measure changes in the brain at two different time points during a 6 month period (1 month after stroke and 6 months after stroke). At each time point multiple measures will be taken requiring about 7 visits at each time point.

Stroke is one of the leading causes of death and disability in the United States. Our understanding of the brain to recover after a stroke is limited. 50% of stroke survivors' muscular weakness affects one side of the body. Patients recovering from stroke usually receive physical therapy to help improve motor skills on their affected side. A part of the brain called the motor cortex may change following a stroke to help with the recovery of motor skills. One way of improving the learning of movement skills is to apply a brief magnetic pulse to the head that overlays the motor cortex. This technique is called Transcranial Magnetic Stimulation (TMS). Scientists know that the adaptability of part of the brain called the motor cortex to "reorganize" plays a major

role in recovery of motor skills after a stroke. In healthy people it has been shown that practicing tasks help the reorganization process and improves motor skills. It is thought that the unaffected side of the brain of patients who have suffered a stroke can help in the reorganization. The purpose of this study is to continue to understand an area of the brain in patients recovering from stroke. This will help us learn how the two motor areas of the brain work together. Further study of the brain's reorganization skill may lead to better rehab strategies and help improve recovery after stroke.

We will use non-invasive tests such as:

- Surface Electromyography (EMG)
- Transcranial Magnetic Stimulation (TMS).
- Magnetic Resonance Imaging (MRI)
- Electroencephalography (EEG)

In the event you have a device implanted that is not described in any of your medical records we may consider to obtain a plain x- ray. The x- ray will be taken of the body part that is affected by the device and will ensure the safety for MRI. For devices that are safe in the MRI and TMS environment but require preparation prior to TMS or MRI, we will contact treating physician and proceed as recommended by the physician and device manufacturer. If you have a loop recorder, we will contact the treating cardiologist to download the data prior to TMS and MRI to prevent the possibility of MRI and TMS related loss of data.

TMS was originally developed as a tool in brain research. TMS has been used to stimulate or suppress brain activity transiently in experiments of healthy people and people with stroke. This means that researchers can "turn off" and "turn on" a certain region of the brain and observe a subject's behavior. MRI of the brain is now widely used in clinical practice to take pictures of the brain. EEG is widely used in clinical practice to evaluate connectivity of the brain.

Procedures

In this study we use single-pulse, paired pulse, and low frequency repetitive Transcranial Magnetic Stimulation (TMS, ppTMS, and rTMS) and Magnetic Resonance Imaging (MRI). The study has:

- A screening visit that includes neuropsychological testing.
- A second visit will consist of an MRI scan of your brain.
- Followed by 5 experiments (and an optional 6^{th} and 7^{th} experiment)
- Concluded with another MRI scan for a total of seven sessions (9 if optional experiments are included).
- These sessions will be scheduled at 1 month post-stroke and 6 month post-stroke and completed within a 2 week timeline.

A total of 80 stroke patients:

- Age 40 to 80 years of age will be asked to take part in this research study.

All subjects will be seen in the Motor Control Laboratory (Center of Rehabilitation Medicine) at Emory University. Pictures of your brain using a technique called MRI (magnetic resonance imaging) will be taken either at the Biomedical Imaging Technology Center or at the Center for Systems Imaging, Emory University.

Screening Visit (Visit 1):

After you agree to take part in this study and sign the consent form, this screening visit will consist of:

- A short physical exam
- Determining if you are right or left handed
- Finding out the medicine you take
    - Including prescription and over-the-counter medications
- Inclusion experiment

We need to know about all medications you take because some may affect with the study results. If you are taking any of these types of medicine, you will not be able to be in the study. If you are in the study, we will not ask you to stop or change any of the medicine you are currently taking. We will also review your medical history including all of the surgeries that you have had during your lifetime.

This is to make sure you do not have:

- Any clips or implants in your head
- Known heart problems or a pacemaker
- A seizure disorder
- Migraine headaches
- History of any allergies or allergic reactions

During your screening visit, you will undergo an Inclusion experiment. We will do this to find the area of the brain that controls the muscles in your arm. Also the strength of the stimulation needed to make these muscles react will be determined. In order to do this, your arm will be placed in an armrest attached to a dental chair. The investigator will put 2 sets of 3 electromyography (EMG) electrodes on the skin overlying two muscles of the right forearm (called a target muscle). EMG is the recording of electrical activity created by the muscle. The electrodes will be attached with electrode gel and adhesive tape. A computer device will be used to position the TMS coil over a precise point on your head where we will stimulate your brain to make the muscles in your arm move (twitch). The TMS coil will give you a series of stimulations (or magnetic pulses) that produce a very brief, clicking sound so you will be asked to wear earplugs during this procedure. Brief magnetic pulses of different strengths will be generated in the coil and the electrode will measure the effect on your hand muscle. In single-pulse TMS (TMS), a single pulse will be applied to your brain. In paired pulse TMS (ppTMS), two pulses at a very short time interval will be applied to either the same side of your brain through one coil or two different areas of the brain through two coils. The single-pulse TMS session could take up to 1 hour to complete with much of the time spent positioning the equipment. No more than 150 magnetic pulses will be given during this session of the study. The physical examination and single-pulse TMS session should take 1-2 hours to complete.

If we determine that you qualify to take part in this study, we will schedule the ten experimental sessions and ask you to practice a motor task with a joystick. If it is determined that the intensity of the TMS pulse does not generate the desired response of the target muscle, then your participation will end after this session. This does not indicate a medical problem. It is expected that 30% of the subjects tested will not generate the

desired response. If it is determined that you qualify for the study at the end of the screening visit, we may practice the use of a joystick in preparation for use during the MRI. If you prefer, you can decide to practice during a separate additional visit.

MRI and fMRI (1 month post-stroke Visit 2 and 8 and 6 month post-stroke Visit 11 and 17):
If the results of the tests in Visit 1 show that you are able to be in the study, your second visit will consist of an MRI scan. The MRI will take several different pictures of your brain. The MRI of your brain will then help us to place the TMS on the scalp in relation to the brain with precision for every session. To do the scan, you will lie on your back in a scanner. The scanner is a powerful magnet in the form of a short tunnel open from both sides. You will be able to see the scanner and ask questions before the procedure starts. We are using a magnetic resonance scanner that is twice the strength of a regular hospital scanner. The Food and Drug Administration (FDA) have approved the MRI procedure for routine clinical use.

You will be asked to remove all jewelry and other metal-containing objects. You will then be placed on a narrow table with a plastic-encased metal coil close to your head. You will then be slid into a small tunnel about 6 feet long and 25 inches in diameter. You will need to lie still during the scan. A small mirror will be positioned above your head so you will be able to see out of the end of the scanner. During scanning, you will hear loud knocking noises, which are normal. If you have a loop recorder, there is a possibility of feeling some vibration or discomfort around the device during the scanning.

You will also have an fMRI (functional Magnetic Resonance Imaging) scan taken along with a recording from your forearm muscles. You will be asked to trace a target that is displayed on the computer screen with a joystick. This visit should take about 2-3 hours to complete with much time spend on setting up the experiment. The actual time that you spent in the scanner is about one hour.

Experimental Sessions (1 month post-stroke, Visits 3-7 and 6 month post-stroke Visits 12-16):
During a visit, you may have more than one experimental session.
Each TMS session begins with:

- A baseline measurement
    - The TMS stimulator will generate brief magnetic pulses and the responses recorded with the surface EMG electrodes.
    - The investigator will put six to twelve EMG electrodes on the skin overlying two muscles of the each forearm, in the same manner done during the Screening Visit. A picture of your forearms may be taken to ensure accurate placement for the different sessions.
    - The electrodes will be attached with electrode gel and adhesive tape.

For all sessions, the surface EMG electrodes will be in place for the entire experimental session. The results are being transferred to a computer. Since the TMS produces a very brief, clicking sound, you will be asked to wear earplugs during every session.

Brief magnetic pulses will be generated by either one or two single-pulse TMS devices (and/or paired pulse) and applied to your head through either one or two magnetic coils. The responses will be recorded with the surface EMG electrodes. The investigator is going to safely alter the timing and frequency of the TMS devices but you will not be told of the alterations. We will then apply weak magnetic pulses at low frequency TMS

(rTMS) for 15 minutes. Repetitive TMS (rTMS) is where pulses will be given over and over at a specific amount (900 single pulses). You will likely not feel the pulses because of their low intensity. You will get two different forms of stimulation. However, you will not know which one you are getting. A computer program will decide this before we begin (50/50 chance). Immediately after the rTMS stimulation, we will repeat the same measurements as in the first part of this session. All sessions are exactly the same with the slight differences between sessions. During one the sessions you will be asked to trace a target that is displayed on the computer screen with a joystick while receiving rTMS. This is due to randomizing the order in which measurements are taken and or the settings on the stimulator. Each session could last up to 2-3 hours for completion. A large portion of the time is spent positioning equipment.

In two rTMS experiments we will do only an abbreviated baseline measurement. In these sessions, you will be asked to trace a target that is displayed on the computer screen with a joystick. This part of the experiment takes about 10- 15 minutes. You can then relax in the dental chair while receiving repetitive TMS (rTMS) at the same low intensity as in the other experiments (900 pulses). Following the rTMS you will be asked to trace a target that is displayed on the computer screen with a joystick.

An additional (optional) TMS experiment will be completed in a different session. We will first put on the EMG electrodes on two muscles on each forearm, as described above. We will use single-pulse TMS to see the EMG responses from the two muscles as the pulses are given in different locations around a small area on your head.

All of the experimental sessions explained above will be conducted at 1 month post-stroke and 6 month post-stroke.

Optional EEG Sessions (Visits 9&10 and 18&19 in the entire study):

You may be asked to participate in two sessions using EEG where we place a special cap over your scalp to pick up signals from your brain. This cap contains little metal discs that sit over your hair. We will insert gel into the discs of the cap. This procedure is non-invasive and painless. We will then put on the EMG electrodes on one muscle on each forearm, as described above. This EEG cap and EMG electrodes may be on while we use the TMS stimulator to generate brief magnetic pulses and the responses recorded with the surface EMG electrodes. During the first visit, this EEG cap will be on while you may relax and fixate on a cross projected onto a screen and practice a motor task. During the second visit, we will use the TMS stimulator to generate brief magnetic pulses and the responses will be recorded with the surface EMG electrodes. You also may play the motor task again. Each visit should take approximately 3 hours. If you are only interested in doing the EEG sessions and are 1 month post-stroke, you may have the two visits repeated at 6 months post-stroke.

Motor Activity Log completed via phone interview

You will be contacted by phone 3 – 4 times between the date of stroke until the final study visit in order to complete the Motor Activity Log (MAL). The first phone call will be 5 - 10 weeks after stroke date. The second call will be 9 – 15 weeks after stroke date. The third phone call will be 14 – 20 weeks after stroke. The fourth phone call will be 19 – 24 weeks after stroke. In all cases, a randomization process will determine the exact

week of contact. A one-week window will be allowed for making contact and completing the MAL. The phone call should take approximately 15 minutes and will be conducted by the study coordinator.

Risks and Discomforts

TMS:
rTMS is a technique that has been used for about 15 years. The proposed TMS protocols are within the recommended safety guidelines. The introduction these safety guidelines (Wassermannn, 1998) have proven efficacious in preventing seizures Prevention occurred both in normal subjects and in patients with neurological and psychiatric diseases. This was despite the fact that such guidelines were based on a relatively restricted sample of normal subjects and considered only conventional rTMS.
When used briefly, rTMS is not believed to have long-term effects or be dangerous. It cannot interfere with critical brain functions (like breathing) because this type of stimulation does not reach brain areas that are critical for life support.

Thousands of healthy subjects have been studied using TMS. This occurred without any reported side effects except headache. Migraine headache can be triggered in people with a history of migraine headache. If you have migraines you will be excluded from participating. Also, if you have certain conditions or take certain medications, you will be excluded from the study.

It should be noted that there have been no reports of rTMS producing seizures in normal subjects. However, there have been some reports of seizures following TMS in patients:

- Who had an existing seizure disorder
- A brain injury from problems such as stroke

However, for our rTMS sessions we will not stimulated the side of the brain affected by the stroke but the opposite healthy side of the brain. Therefore, the risk for rTMS to produce a seizure should be similar to that of healthy subjects.

rTMS applied according to the safety guidelines, has not been reported to cause seizures. If you have a diagnosed seizure disorder, you will not be allowed to participate. It should be noted too that there is **no relationship between TMS and new onset of seizure disorder**.

The investigator will look at all the medications you are taking during your physical examination before the study begins. For most CNS active drugs, there are no reported problems with using these drugs during TMS. However, CNS active drugs interfere with the data collected. You would not be included in the study if you have any clips or implants in your head. TMS could make the metal in them move out of place causing injury. TMS could also affect the electrical function of a pacemaker causing it to malfunction.

You may not be in the study if:

- You have a history of migraines
- You have a diagnosed seizure disorder

- You take any Central Nervous System CNS active drugs, such as benzodiazepines, Lorazepam, Baclofen, SSRI's and other anti-depressants, etc.
- You have any clips or implants in your head
- You have a pacemaker

If it is discovered from taking the neuropsychological test, that significant problems with cognitive functions are identified you could be referred to a specialist for further evaluation at your own expense.

TMS produces a very brief clicking sound. When the TMS is set at a higher setting, the sound will be more intense like slamming a door. If necessary precautions are not taken, there is a risk TMS could cause hearing damage. The use of ear protection, such as earplugs lessens the risk.

Magnetic Resonance Imaging (MRI):
There are no known risks involved with the MRI procedure. The scanner is twice the strength of standard MRI machines and is approved by the Food and Drug Administration (FDA) for diagnostic purposes but not FDA approved for the indications they are being used for.

You cannot take part in the study if:

- There is a possibility that you are pregnant
    - Effects of MRI on human developments are unknown
- You have any type of metallic implant: Pacemaker, aneurysm clips, shrapnel, metal fragments, orthopedic pins, screws or plates, Intra Uterine Devices (IUDS) or piercing you cannot remove
    - There is a risk that the magnetic field could cause them to move or heat up

You will need to lie still for the duration of the MRI study. This may cause some discomfort. If you are uncomfortable, you may move your body slightly, but not your head, after receiving permission to do so.

The noise produced by the MRI machine could be very loud and possibly cause temporary hearing changes. You will wear the headphones to prevent damage to your hearing. The radio frequency energy used in this test has produced burns (most of them minor) in about one in one million cases. If you feel any burning sensation, you tell the investigator or MRI staff immediately, so we can stop the scan. Sometimes people feel dizzy when they first go inside the magnet; the table will be moved slowly into the MRI to prevent this. You may feel uncomfortable within the MRI scanner because it is a confined area. You will have constant contact with the MRI staff during the test. You may ask to stop at any time to be removed from the MRI and withdraw from the study.

X-Ray:
In the event we cannot identify an implanted device by your medical records, you may have an x-ray. This procedure is not necessary for your medical care and will occur because you participate in this study. The estimated radiation dose that you will receive is equal to or less than the natural environmental radiation the average person receives in the United States annually. The principal risk associated with a radiation dose is the possibility of developing a radiation-induced cancer later in life. The risk for radiation-induced cancer from this study is negligible.

EMG

There are no known risks or side effects from having a surface EMG. EMG is a noninvasive test commonly used in everyday medical practices. However, there may be an allergic reaction to the substance used in the gel and adhesive tape during the surface EMG.

EEG

There are no known risks or side effects from the EEG procedure. These procedures will be conducted according to published safety standards. Collection of EEG involves application of electrodes over the scalp to measure brain activity. All electrodes do not contact the skin. A gel provides the contact between the skin and the recording electrodes. In rare instances it is possible that your skin may be sensitive to the gel or rubbing alcohol used for surface recordings. In such cases a skin rash is possible. The conductive gel is water-soluble and washes out quickly with warm water and shampoo.

Unknown Risks

There is also the possibility of uncommon or previously unknown side effects to any of the procedures used in this study. You may ask to stop at any time and withdraw from the study. If you feel uncomfortable, you should tell the investigator and asked to be released from the study.

If you are a woman: To protect against possible side effects of the TMS and MRI, women who are pregnant or nursing a child may not take part in this study. If you are a woman of childbearing ability, you and the study doctor must agree on a method of birth control to use throughout the study. If you think that you have gotten pregnant during the study, you must tell the study doctor immediately. Pregnant women will be taken out of the study.

New Information

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Benefits

This study is not designed to benefit you directly but the knowledge gained may be of benefit to others in understanding brain activity and functioning. It is hoped that progress may be made in the design of more effective rehabilitation strategies for patients recovering from a stroke.

Compensation

You will be compensated $25 for each completed study visit. If you do not finish the study, you will be paid for the visits you have completed. You will receive $375 total, if you complete all 15 study visits or $475 total if you opt to complete the additional TMS and EEG study visits at 1 and 6 month post stroke (for a total of 19 study visits). You will be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed. Some payment methods involve mail coming to your house, which may be seen by others in your household. You can decline payment if you are concerned about confidentiality, or you can talk to the study team to see if there are other payment options.

How will you protect my private information that you collect in this study?

Emory will keep any research records that it creates private to the extent that this is required to do so by law. Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Medical Record

If you have been an Emory Healthcare patient before, then you already have an Emory Healthcare medical record. If you have never been an Emory Healthcare patient, you do not have one. An Emory Healthcare medical record will be made for you if an Emory provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory Healthcare medical record you have now or any time during the study.

Emory Healthcare may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory Healthcare medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record. For this study, those items include: MRI and TMS studies.

Tests and procedures done at non-Emory places may not become part of your Emory medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

In Case of Injury

If you get ill or injured from being in the study, Emory would help you to get medical treatment and Grady Health System would give you emergency care if you are injured by this research. Emory or Grady Health System, however has not set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proved that your injury or illness is directly caused by the negligence of an Emory or sponsor employee. "Negligence" is the failure to follow a standard duty of care.

If you become ill or injured from being in this trial, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe you have become ill or injured from this research, you should contact Dr. Buetefisch at [redacted]. You should also let any health care provider who treats you know that you are in a research study.

Costs

There will be no costs to you for participating in this study, and reimbursed for transportation expenses based on mileage. You will not be charged for any of the research activities.

Withdrawal from the Study

You have the right to leave a study at any time without penalty. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done.

The researchers also have the right to stop your participation in this study without your consent if:

- They believe it is in your best interest;
- You were to object to any future changes that may be made in the study plan;
- or for any other reason.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the main study and for any optional studies in which you may choose to participate.

Main Study

PHI that Will be Used/Disclosed:

The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:

We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information.

Use and Disclosure of Your Information That is Required by Law:

We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:

By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign

this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- NINDS is the Sponsor of the study. The Sponsor may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the research. The Sponsor may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: Office for Human Research Protections; Food and Drug Administration.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Optional additional TMS and EEG experiments:

PHI That Will be Used/Disclosed for storage and future research use of your PHI:
The PHI that we will use and/or disclose (share) for the optional storage and future research use of your PHI includes: information that pertains to inclusion criteria of the study which are age, MRI reports, and medical records related to stroke location and motor function.

Purposes for which your PHI will be Used/Disclosed for Optional Study:
We will use and disclose your PHI for the conduct and oversight of the optional research study.

Authorization for This Use of PHI is Required to Participate in Optional Study, but Not in Main Study:

You do not have to authorize the use and disclosure of your PHI. If you do not authorize the use and disclosure of your PHI for the optional study, then you may not participate in the optional research study. You can still be in the main research study even if you don't participate in the optional study.

People Who Will Use/Disclose Your PHI for Optional Study:
The following people and groups will use and disclose your PHI in connection with the optional research study:

- The same people and groups who will use and disclose your PHI for the Main Study will also do so in connection with the storage of PHI for future research.

Optional Study for Future Research:

PHI That Will be Used/Disclosed for storage and future research use of your PHI:
The PHI that we will use and/or disclose (share) for the optional storage and future research use of your PHI includes: information that pertains to inclusion criteria of the study which are age, MRI reports, and medical records related to stroke location and motor function.

Purposes for which your PHI will be Used/Disclosed for Optional Study:
We will use and disclose your PHI for the conduct and oversight of the optional research study.

Authorization for This Use of PHI is Required to Participate in Optional Study, but Not in Main Study:
You do not have to authorize the use and disclosure of your PHI. If you do not authorize the use and disclosure of your PHI for the optional study, then you may not participate in the optional research study. You can still be in the main research study even if you don't participate in the optional study.

People Who Will Use/Disclose Your PHI for Optional Study:
The following people and groups will use and disclose your PHI in connection with the optional future research study:

- The same people and groups who will use and disclose your PHI for the Main Study will also do so in connection with the storage of PHI for future research.
- In addition, the following people and groups may also use and disclose your PHI for the Optional Study:"
    - future researchers

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at: [redacted].

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the

study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact Dr. Buetefisch at [redacted]:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at 404-712-0720 or 877-503-9797 or irb@emory.edu:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

If you are a patient receiving care from the Grady Health System and you have a question about your rights, you may contact the Office of Research Administration at research@gmh.edu.

Consent and Authorization

Consent and HIPAA Authorization for Optional Studies:
Please initial below if you opt to participate in and authorize use and disclosure of your PHI in the optional studies previously described:

Please check appropriate box and place your initial next to it:

☐ The entire study (MRI and TMS combined with training related experiments) _____ *initial here*
Optional additional TMS experiment _____ *initial here*
Optional additional EEG experiment _____*initial here*

☐ A portion of the study
EEG for stroke less than 6 months (a screening call and up to four visits) _____ *initial here*
EEG for stroke greater than 6 months (a screening call and two visits) _____ *initial here*

Optional Study for Future Research:
In the future, our laboratory may offer other studies that you may qualify for. If another study becomes available, would you like to be contacted with information about this study? Please initial on the line and check the box that corresponds with your response.

_____ ☐ Yes, I give my permission to be contacted.

Phone:

Email:

_____ ☐ No, I do not give my permission to be contacted.

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in the main study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____
Name of Subject

_____ _____
Signature of Subject (18 or older and able to consent) **Date** **Time**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____
Name of Person Conducting Informed Consent Discussion

_____ _____
Signature of Person Conducting Informed Consent Discussion **Date** **Time**