Informed Consent Form

Biomechanical and neural mechanisms of post-stroke gait training

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NCT04380454

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

Title: **Biomechanical and neural mechanisms of post-stroke gait training**

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study, you will be one of 60 people who are being studied at Emory University.

Why is this study being done?

This study is being done to answer the question: How does walking training modify the quality of walking patterns and the strength of brain and spinal cord connections in stroke survivors. You are being asked to be in this research study because you have experienced a stroke.

Do you have to be in the study?

It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?

If you are eligible and want to be part of the study, you will participate for approximately 18 weeks (total 12 training sessions and 18-20 evaluation sessions). For the evaluation sessions, the researchers will ask you to do the following: answer questionnaires regarding your health and physical activity status, clinical evaluation of your walking function and leg strength, non-invasive stimulation to measure the strength of connections between your brain / spinal cord and your muscles, and motion capture to quantitatively measure the movement of your legs when you walk. For the training sessions, the researchers will ask you to do the following: complete treadmill walking at a fast speed either with or without electrical stimulation delivered to your ankle muscles. Some of these procedures will be paid for by the study.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question. In the long run, this study will help improve our understanding of how to enhance the efficacy of walking rehabilitation for stroke survivors. There is a chance that you may perceive short-lasting improvements in strength or walking speed after completing the study, but we cannot guarantee that your walking will change.

What are the risks or discomforts I should know about before making a decision?
The study will take time. The walking training that is being tested may not work any better than regular care and may even cause harm. The evaluation sessions may cause discomfort or minor risks as well. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include risk of falls, muscle soreness or injury, fatigue, skin irritation or burns, headaches, dizziness, other risks associate with walking exercise, loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study
Because this is not a treatment study, the alternative is not to participate.

Costs
You WILL NOT have to pay for any of the study procedures.

What Should I Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar words, more details on specific procedures, etc.). Take time to consider this and talk about it with your family and friends.

Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: **Biomechanical and neural mechanisms of post-stroke gait training**

Principal Investigator: Trisha Kesar, PT, PhD, Department of Rehabilitation Medicine

Sponsor: National Institute of Child Health and Human Development

Investigator-Sponsor: Trisha Kesar, PT, PhD

Study-Supporter: National Institute of Child Health and Human Development

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 if you want to be a part of 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 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.

What is the purpose of this study?
The purpose of this study is to understand how participation in a walking training comprising fast treadmill walking with or without electrical stimulation changes movement patterns (walking quality) and circuits responsible for controlling walking (brain and spinal cord connections with leg muscles). If you are eligible and want to be part of the study, you will participate for about 9-12 weeks in total. The study includes 12 training sessions and 12-20 evaluation sessions. All study procedures (both training and evaluation) are experimental. We will use a method similar to flipping a coin to decide whether you are assigned to the training group that receives fast treadmill walking only or fast treadmill walking with electrical stimulation.

What will I be asked to do?

If you are eligible and want to be part of the study, you will participate for about 12 weeks. During the 12-week study period, we will request you to visit our laboratory at Emory 3 times per week (e.g. Monday, Wednesday, Friday). Each session or visit will last about 2.5 to 4 hours. During this 12-week period, your visits will include 12 training sessions and 12-20 evaluation sessions. All study procedures (both training and evaluation) are experimental. We will use a method similar to flipping a coin to decide whether you are assigned to the training group that receives fast treadmill walking only or fast treadmill walking with electrical stimulation.

Screening to confirm that you are eligible for the study:

We will ask about your medical history to confirm that you qualify for the study. We will use clinical tests to measure aspects of your walking function such as walking speed, lower limb strength and sensation, etc. We will ask your physician for clearance to take part in the treatment phase of this study. We will refer you for an exercise stress test to confirm that you can safely participate in walking exercise sessions, and to measure your heart rate response during exercise. We will also refer you for a brain scan (MRI). We will use this information to confirm that you meet the study criteria.

Evaluation sessions:

The evaluation sessions will be conducted before, during, immediately after, and at follow-up (3-week, 6-week, 12-week) period after the 12 training sessions. Each set of evaluations may be completed in 1 to 4 visits or sessions. Two weeks before starting the walking training, we will conduct a series of evaluations to measure (1) clinical tests of walking and leg function, (2) movement patterns while you walk (walking quality), (3) the status of circuits that control walking (brain and spinal cord), and (4) how much oxygen you use while walking. More information about the evaluations is listed below.

(1) Clinical tests of walking and leg muscle function:

A physical therapist will check your leg function and walking. For example, we may measure how fast you walk over ground and on a treadmill, how far you can walk in 6 minutes, how much you can bend your knee, how much sensation you have in your legs, your balance, etc. During this session, we may also measure how strong the muscles surrounding your hip, knee, and ankle are. To test your muscle strength, we may use our hands to resist your muscles or use a special chair that has a force measuring device. During the strength tests, we may use straps to keep your trunk, thighs, and lower leg stable. For example, for testing the knee, we may ask you to 'kick out' or 'pull your leg in' with as much force as you can. For testing the ankle, we may ask you to pull your foot toward you or to push it away from you with as much force as possible. When you push with your muscle, we may also send a short (less than half a second long) electric current to your muscle through surface pads attached to the skin. This current will add to the force your muscle is producing and will help us to measure your muscles strength accurately. In addition, we may ask you to complete some questionnaires about your activity levels, community participation, balance confidence, cognition, and survey about your perceptions or experiences related to the stroke or the study participation, etc. and provide you small pedometers (like Fitbits) to measure your stepping activity during the study duration. This part may take 45-minutes to 1.5 hours.

(2) Motion capture to measure your movement patterns while you walk:

For motion capture, you will walk over ground and/or on a treadmill. When you walk over ground, an investigator will be close by to assist you if needed. During treadmill walking, throughout the session, you will walk wear a safety harness. A set of 7 special cameras placed around the room will be used to precisely measure your movements during walking.

Elastic bands will be wrapped around your thighs, calves, and pelvis. Small reflective balls will be attached to your shoes, your upper back, shoulder, hip, knee, and ankle joints with non-irritating skin tape. We will also attach small sensors to the skin over muscles of your thigh and calf with skin tape. These sensors will help us to measure how hard your muscles are working.

When you are walking on the treadmill, you can also rest your fingertips on the handrail if needed. We will slowly increase the treadmill speed and first, let you get comfortable with the treadmill walking. We will collect data while you walk at a range of speeds (slow, medium, fast). The recorded walking trials will be 15-seconds to 1-minute long. We may also collect data during other walking conditions (walking with or without stimulation, walking with both belts going at different speeds, walking while performing a cognitive task, etc.).

During the session, we ask you to rate how tired you feel at regular intervals. Also, your heart rate and blood pressure will be checked at regular intervals. If you feel tired, you can take a seated break. This part may take 45-minutes to 1.5 hours.

(3) Status of circuits that control walking (brain and spinal cord):

Testing the connections between your brain and muscles: We will measure the strength of the connections between your brain and your leg muscles. We will record your muscle's responses to brain stimulation through small sensors attached on the skin of your legs and arms. We will use a large 8-shaped coil to deliver very short (less than half a second long) magnetic pulses to your head. The coil will touch your head during the stimulation. We will find the areas of your brain that control the hand and leg muscles that we are measuring. While the magnetic pulses are being delivered, we may monitor your muscle's activity. We may provide you with cues to help you better relax the muscle or to lightly push with your muscle. You will hear a click every time the magnetic pulse is delivered. We may deliver single-pulses or a pairing of 2-pulses. The magnetic pulse will feel like a tap on your head. Your hand, leg, or face muscles may twitch in response to the magnetic pulse delivered to your brain. Additionally, we may measure pathways travelling in the opposite direction(leg to brain) by sending very short (less than half-second long) electrical pulses delivered over the nerves of your leg and measuring electrical brain response through non-invasive recording electrodes placed on your head with a cap with gel. This part will take approximately 3 hours.

Testing the connections between your nerves and your muscles: We may measure the strength of the connections between your nerves and muscles. We will record your muscle's responses to very short (less than half-second long) electrical pulses delivered over the nerves of your leg. Muscle responses will be measured through small sensors attached on the skin of your legs and arms. We will locate the point on the skin of your leg (e.g. behind the knee) where we get the best response from your muscles by moving a small electrode around and delivering small electric pulses. Next, we will stick stimulation pads to the skin over your muscles and deliver a series of electric pulses (1 every 3-5 seconds). You will be asked to relax your muscles or maintain a low level of muscle activity during this testing. In addition, we may deliver the electric nerve pulses in the same session and paired with the brain stimulation pulses described above (at different timing intervals) separately or repetitively. This part may take 1-2 hours.

(4) **Measurement of how much oxygen you use while walking:** We will measure the composition of the air that you breathe out while you walk on a treadmill at a range of speeds. First, we will get your comfortable to the treadmill and provide a brief warm-up. We will set up the energy cost equipment and provide you a mask to wear over your face or nose. We will slowly increase the treadmill speed and incline and make recordings. We will provide you rest breaks as needed. We will ask you how tired you feel using a numeric rating scale and record your heart rate and blood pressure during this test. This part may take 1-2 hours.

Walking training sessions:

The walking training phase of the study will comprise a total of 12 training sessions (3 sessions per week) over the period of 6-8 weeks. You will either be assigned to walking training with electrical stimulation or without electrical stimulation. A similar structure or protocol will be used for all training sessions. The procedures for both kinds of training are similar, except for the presence or absence of stimulation.

To setup for the training, we will confirm that you are wearing comfortable walking shoes. To set up for electrical stimulation, we will attach pads to the muscles in front of your leg and your calf. We will deliver short (half-second long) currents to your muscles to check your response to the stimulation. The stimulation gives a tingling or 'pins and needles' sensation but should not be painful. Based on your tolerance and based on the muscle responses we are targeting for walking, we will set the strength of current to be used for stimulation during the session.

During walking, a safety harness suspended from the ceiling will be used for safety. At the beginning of training, as a warm-up, you will walk at your comfortable speed for 1-2 minutes. During each training session, you will complete five 6-minute bouts of treadmill walking (total 30-minutes of walking) at a fast speed. You can take a seated rest break between bouts. When you are walking on the treadmill, you can rest your fingertips on the handrail if needed. After completing 6 bouts of treadmill walking, you will also walk for 6 minutes over ground at a fast speed. The training will take approximately 1.5-2.5 hours including rest breaks.

Depending on the type of training it is, electrical stimulation timed with your walking pattern may be delivered to the muscles in front of and back of your legs. The electrical stimulation will help your muscles to work more strongly and at the correct time during walking. If needed, you can ask the investigator to reduce the strength of the electrical stimulation.

Additionally, during some or all of the training sessions, we may measure your walking patterns using motion capture and muscle activity using sensors (similar to the procedures described for motion capture above).

Who owns my study information and samples?

If you join this study, you will be donating your data and study information. You will not receive any compensation if your data are used to make a new product. If you withdraw from the study, data that were already collected may be still be used for this study.

What are the possible risks and discomforts?

There may be side effects from the study procedures that are not known at this time.

The most common risks and discomforts expected in this study are:

- There is a risk of falls during the walking testing or training. To avoid falls, a physical therapist will remain near you while you walk. You will wear a harness and be able to hold a handrail when you walk on the treadmill.
- You may experience fatigue and/or muscle soreness similar to the soreness that you might feel after you lift weights or exercise vigorously after a long break.
- Injuries such as muscle strains are possible.

The less common risks and discomforts expected in this study are:

- Minor skin irritation may occur from the adhesive tape or EEG recording electrodes or gel.

Rare but possible risks include:

- During electrical stimulation, the potential for equipment malfunction is present, which might result in burns to the skin. However, the equipment used is highly reliable and prolonged exposure necessary to cause the risk of skin damage is highly unlikely with this experimental design. The risks associated with the measurement of the connections between your nerves and muscles are the same as the risks of electrical stimulation described here.
- You may feel dizzy, faint, or anxious while wearing the mask over your nose and mouth that measures how much oxygen you use while walking. To minimize risks associated with the mask, we may remove the mask and stop the test any time you are uncomfortable. Additionally, a clinician will be present to guard you should you experience dizziness or faintness while walking.

The risks caused by the brain stimulation (optional part of the study) are:

- Metal and conductive objects close to the coil may be damaged during magnetic brain stimulation. We will therefore exclude individuals who have implants in their head.
- You may feel twitches in the muscles of your arm, leg, or face during the magnetic brain stimulation, but these twitches should not be painful
- Rare cases of the development of seizures during or immediately after magnetic brain stimulation have been reported. However, this risk is reported not with the type of brain stimulation we use in our study (single or double pulses) but with a different type of brain stimulation involving repetitive pulses (rTMS). To exercise extra caution against this risk, people who have a history of seizures not managed by medication in the past 6 months will be excluded from study.
- Some individuals experience headaches, scalp discomfort, dizziness, and/or light-headedness during or after the magnetic stimulation. If they occur, these effects are usually mild and short-lasting.
- A click may be heard during magnetic brain stimulation. Some individuals find the sound of the click uncomfortable. You will be provided with foam earplugs that may help to minimize any annoyance from this clicking noise.

Risks associated with collection of brain signals with electrodes embedded in a cap: Collection of brain signals involves application of electrodes over the scalp of the head to measure brain activity. All electrodes do not contact the skin. A gel helps provide better 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.

MRI

The risks caused by the MRI (brain imaging) are listed here. The energy levels used to make MRI measurements are far less than those used in a single X-ray. While MRI is painless and there are no significant risks from MRI as it is to be performed, participation may mean some added discomfort for you. For example, you may be bothered by the beeping and hammering sounds made by the scanner as it collects measurements. Disposable earplugs will be provided to diminish the noise. The magnet is a small enclosure and some people become claustrophobic inside it. You may also experience mild numbness or tingling in your fingers and toes. This feeling is similar to the feeling you get when your arm has fallen “asleep” – not the painful “needling” feeling, but the numb tingling you feel afterward. Again, you are free to quit the experiment at any time you choose. The MRI room may be cold. You may ask for a blanket. You may become tired or bored from lying in the scanner. Some people feel nervous or claustrophobic while lying in the scanner. You may ask to leave the scanner at any time. Because the MRI scanner attracts certain metals, it could move metallic objects within the MRI room during your examination, which could possibly harm you. Precautions will be made to prevent such an event from happening. Further, because of the high magnetic field, people with pacemakers, heart rhythm disturbances, or certain metallic implants in their body cannot participate in this study. You will be screened for these conditions.

If you are a woman: to protect against possible side effects of the study procedures (brain stimulation, fast treadmill walking, etc.), women who are pregnant may not take part in this study. These risks are not yet known. If you are or plan to get pregnant, you should not be in the study. If you think that you may have gotten pregnant during the duration of the study, you must tell the study doctor immediately. To prevent the chance of any unknown risks, pregnant women will be taken out of the study.

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.

Will I benefit directly from the study?

This study is not designed to benefit you directly. Your walking speed or function may improve while you are in this study, but it may not, and it may even get worse. This study is designed to learn more about how walking training changes walking patterns and function, strength of circuits that control walking, and energy cost during walking. The study results may be used to help others in the future.

Will I be compensated for my time and effort?

You will be compensated for being in this study. You will get $30 for each completed study visit, to compensate you for your time and effort. If you do not finish the study, we will compensate you for the visits you have completed. Additionally, you will get $50 bonus if you complete all 12 training sessions and all the post-training evaluations, and an additional $50 bonus if you complete all study procedures (including and up to the 6-week follow-up evaluations).

You may be asked to fill out a tax form, including your Social Security or Taxpayer Identification Number, in order to be reimbursed, depending on the amount and method of payment. 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.

What are my other options?

If you decide not to enter this study, there is care available to you outside of this research study. For example, you may be able to enroll in walking rehabilitation or physical therapy at a clinic. The study doctor will discuss these with you. You do not have to be in this study to be treated for rehabilitation of walking after stroke.

Taking part in this study, however, may make you unable to participate in some other research studies, if they exclude people who have taken certain treatments. You should discuss this with the researchers if you have concerns. You may wish to research other study options at websites like clinicaltrials.gov and ResearchMatch.org.

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

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.

Certificate of Confidentiality

There is a Certificate of Confidentiality from the National Institutes of Health for this Study. The Certificate of Confidentiality helps us to keep others from learning that you participated in this study. Emory will rely on the Certificate of Confidentiality to refuse to give out study information that identifies you. For example, if Emory received a subpoena for study records, it would not give out information that identifies you.

The Certificate of Confidentiality does not stop you or someone else, like a member of your family, from giving out information about your participation in this study. For example, if you let your insurance company know that you are in this study, and you agree to give the insurance company research information, then the investigator cannot use the Certificate to withhold this information. This means you and your family also need to protect your own privacy.

The Certificate does not stop Emory from making the following disclosures about you:

- Giving state public health officials information about certain infectious diseases,
- Giving law officials information about abuse of a child, elderly person or disabled person.
- Giving out information to prevent harm to you or others.

Giving the study sponsor or funders information about the study, including information for an audit or evaluation.

Storing and Sharing your Information

De-identified data from this study (data that has been stripped of all information that can identify you) may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Your data from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

We will use your data only for research. We will not sell them. However, the results of this research might someday lead to the development of products (such as a commercial product or rehabilitation device) that could be sold by a company. You will not receive money from the sale of any such product.

As they become available, do you want us to contact you and ask whether you want to receive your results? If so, let the study team know, and they will contact you as the results become available.

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.

In Case of Injury

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

If you get ill or injured from being in the study, Emory will help you to get medical treatment. Neither Emory nor the sponsor will pay for your medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

Emory and the sponsor have not, however, set aside any money to pay you if you are injured as a result of being in this study or to pay for this medical treatment. For Emory, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory employee. “Negligence” is the failure to follow a standard duty of care. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence.

Costs

There are no costs, research or standard of care related, associated with the study. There will be no costs to you for participating in this study, other than basic expenses like transportation. You will not be charged for any of the research

activities. If the study procedures result in any medical complications that would not fall under "injury", the cost of treatment for those complications may be charged to you or your insurance.

Withdrawal from the Study
You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment. If you leave the study before the final planned walking training session, the researchers may ask you to have some of the final steps done, specifically:

- Clinical tests of walking and leg muscle function
- Motion capture to measure your movement patterns while you walk
- Status of circuits that control walking (brain and spinal cord)
- Measurement of how much oxygen you use while walking

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

These are the expected reasons why the researchers may stop your participation:

- Lower limb injury or pain that interferes with your walking
- Change in your medications that influence your walking or tone
- Unanticipated events that affect your walking
- During walking training, you fail to complete at least 1 walking training session per week or miss 3 consecutive training sessions

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 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.
- Data collected during evaluation procedures, tests, and gait training sessions 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.

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.

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 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.
- National institutes of health (NIH) 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.
- 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.

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: Trisha Kesar, [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 Trisha Kesar 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
- 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.

Please select (initial) one of the following:

_____I give my permission for photographs or videos of me that DO include my face to be used in scientific publications, presentations, and/or for educational purposes.

_____I give my permission for photographs or videos of me that DO NOT include my face to be used in scientific publications, presentations, and/or for educational purposes.

_____I DO NOT give permission for photographs or videos of me to be used in scientific publications, presentations, and/or for educational purposes.

Please select (initial) one of the following:

_____I give my permission for the researchers to contact me again for possible future participation in a different study.

_____I DO NOT give my permission for the researchers to contact me again for possible future participation in a different study.

Was time allowed to ask/answer questions? Yes / No

If not, please explain: _____

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research 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**