UF | Institutional Review Board
UNIVERSITY of FLORIDA

# INFORMED CONSENT FORM
*to Participate in Research, and*

# AUTHORIZATION
*to Collect, Use, and Disclose Protected Health Information (PHI)*

## INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: _____

Please read this form which describes the study in some detail. A member of the research team will describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

## GENERAL INFORMATION ABOUT THIS STUDY

**1. Name of Participant ("Study Subject")**

_____

**2. What is the Title of this research study?**

Transcutaneous spinal direct current stimulation to enhance locomotion after spinal cord injury

**3. Who do you call if you have questions about this research study?**

Principal Investigator: Emily Fox, PT, DPT, PhD, NCS: (352) 273-6117 or (904) 742-2500

Other research staff: Study staff at Brooks Rehabilitation: (904) 345-8969

**4. Who is paying for this research study?**

The sponsor of this study is the (1) NIH-funded National Rehabilitation Research Resource to Enhance Clinical Trials (REACT); (2) Brooks Rehabilitation and (3) the University of Florida College of Public Health and Health Professions.

**5. In general, what do you need to know about this research study?**

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject, please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600.

**a) In general, what is the purpose of the research, how long will you be involved?**

The purpose of this research study is to test a new approach to walking rehabilitation for people with spinal cord injuries (SCI). SCI often causes weakness and difficulty with activities such as standing and walking. Walking rehabilitation can help improve a person's ability to walk, but often, walking is still difficult. The use of electrical stimulation, applied over the spinal cord, is now being added during rehabilitation to see if it can assist in achieving greater improvement in walking function. Our study will determine if locomotor training (repetitive walking on a treadmill with assistance) combined with electrical stimulation will further improve walking function. You will be enrolled in this study for up to four months to complete the first and second section.

**b) What is involved with your participation, and what are the procedures to be followed in the research?**

You are being asked to be in this research study because you have had a SCI, are willing to participate in this study focused on walking rehabilitation while using electrical stimulation and have met screening criteria for participation.

For part one of the study, there are two sessions where you will be asked to walk with assistance on a treadmill with a harness attached to the ceiling for support. Each session will involve non-invasive electrical stimulation applied to your midsection while you are walking and information about your walking will be recorded using non-invasive sensors attached to your skin.

For part two of the study, you will be asked to participate in 16 sessions of walking training as well as pre- and post-training testing. Training sessions will involve walking with assistance on a treadmill with a harness attached to the ceiling for support, followed by walking over ground with assistance as needed. Electrical stimulation at one of the two dosage levels will be applied to your midsection during walking training on a treadmill.

For part three of the study, you will be asked to participate in a stretching protocol as well as pre- and post-stretching tests. The stretching protocol will involve lying

down on a mat, fully supported, as a member of the study team performs stretches to three major muscle groups in both of your legs. Each stretch will be held for approximately one minute and three sets of stretches will be performed. Tests of muscle function and walking will be conducted before and after the stretch protocol.

**c) What are the likely risks or discomforts to you?**

You may become tired or experience muscle soreness during the locomotor training and testing sessions due to increased physical activity. There is the risk of losing your balance, stumbling, falling, or experiencing an injury. To reduce this risk, you will use a safety harness attached to the ceiling, a physical therapist will supervise you and activities will be adjusted to your physical level. During breathing testing, it is possible that you may become tired or feel out of breath. It is also possible that the stimulation or the use of medical tape may cause skin irritation, but any possible areas of skin irritation will be closely monitored. During the stretching protocol, you may experience discomfort. The amount of stretch will be adjusted for your comfort, and you may have rest breaks as needed

**d) What are the likely benefits to you or to others from the research?**

You may or may not benefit from participating in this research study. The possible benefits are improvements in your standing and walking function. Because this study involves walking exercise, your physical fitness and strength may improve. Others may benefit if the findings of this study contribute to improvements in the rehabilitation of walking after a spinal cord injury.

**e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?**

The only alternative is not to participate in this study.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study.

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 CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

**6. What will be done as part of your normal clinical care (even if you did not participate in this research study)?**

Normal clinical care is medical or other treatment or services that you would receive even if you did not participate in this research study. Participation in this study is not part of your normal clinical care. All procedures are for research purposes only.

**7. What will be done only because you are in this research study?**

**Overview of the research study:**

This study will examine how a mild and non-invasive form of electrical stimulation affects walking in people with SCI. If you consent to enroll in the study, you will be asked to come to the Brooks Rehabilitation to participate in a three -part set of study procedures.

For part one of the study, you will be asked to participate in two sessions each lasting approximately 3 hours, but not longer than 6 hours. During both sessions, you will be asked to walk with assistance on a treadmill with a harness attached to the ceiling for support. Each session will involve non-invasive electrical stimulation applied to your midsection while you are walking. Two different dosages will be tested, one at each session. We will record information about your walking using non-invasive sensors attached to your skin.

For part two of the study, you will be asked to participate in 16 sessions of walking training (4 days/week for 4 weeks) as well as pre- and post-training testing sessions (18 sessions total). Training sessions will last approximately 2 hours, but no longer than 3 hours and will involve walking with assistance on a treadmill with a harness attached to the ceiling for support, followed by walking over ground with assistance as needed. Electrical stimulation at one of the two dosage levels will be applied to your midsection during walking training on a treadmill.

For part three of the study, you will be asked to participate in a one-session stretching protocol as well as pre- and post-testing. The stretching protocol will involve lying down on a mat, fully supported, as a member of the study team performs stretches to three major muscle groups in both of your legs. Each stretch will be held for approximately one minute and three sets of stretches will be performed. This part three of the study will occur on the same day as your post-testing session for part two of the study.

If you decide to take part in this study, you will be randomly assigned, much like the flip of a coin, to receive electrical stimulation at one of two possible dosages. This means:

- The low dosage stimulation feels like and is given in the same way as the higher dosage but may have differing effects.

- The lower dosage is used in research studies to show what effect dosage has on the outcomes. If you are assigned to receive the lesser dosage, you may not receive the benefits or be exposed to the risks of the higher dosage, if there are any (any risks or benefits are described below).
- You will have a 1 in 2 chance of receiving the lower dosage and a 1 in 2 chance of receiving the higher dosage. In the remainder of the Consent Form, both the lower dosage and the higher dosage will be called electrical stimulation.
- You and other persons doing the study will not know whether you are receiving the lower or higher dosage, but that information is available if it is needed. We will inform you at the end of the testing which dosage you received during the training.

Pre- and post-training testing sessions will last approximately 3 hours, but no longer than 6 hours. These testing sessions will include questionnaires about your health and function and tests that measure your strength and sensation, as well as assessments of common physical activities such as sitting, standing, breathing and walking.

All training and testing procedures are non-invasive and involve activities that are common during rehabilitation and daily function. You may opt not to answer any questions and you may choose not to perform any activity for any reason. If you become tired or need a break, you may take a rest break at any time. For your safety, we will monitor your heart rate and blood pressure. A physical therapist will supervise all sessions and you will be monitored at all times by a study staff member for safety.

If you consent to have photographs, audio recordings or video recordings during the study procedures, then these types of recordings may occur during study procedures. You may choose not to provide consent to have procedures photographed or recorded.

**Detailed information about *part one* of the study procedures is detailed below**

First, we will attach non-invasive sensors to your trunk and limbs (see attachment of sensors below). We will also test your reflexes using brief electrical pulses applied behind your knee. This electrical stimulation for reflex testing may be uncomfortable at times, but it is not dangerous. The discomfort is temporary and lasts only a few seconds.

Second, we will place stimulation pads on your midsection (see application of stimulation below). We will then ask you to walk on a treadmill with assistance as needed and while supported by a harness as we record information from the sensors about how you walk. We may repeat the reflex testing during walking if needed. We will then turn on the spinal stimulation and ask you to walk for up to 30 minutes. The stimulation will be left on for up to 30 minutes. After completing the walking with stimulation, we will have you walk again for approximately 2 minutes without simulation.

All testing will be closely monitored by a physical therapist to ensure safety and comfort during all procedures; we will assess your vitals as needed to ensure safety with all testing procedures. You will be able to take as many rest breaks as needed.

Attachment of the Non-Invasive Sensors

You will be asked to wear a tank top and athletic shorts so that non-invasive sensors and markers can be attached to your skin with medical tape. We will use the sensors to record muscle activity and use the markers to measure your body movement. All of these sensors are used only for recording purposes and do not affect your muscles or brain. You will also have non-invasive sensors placed on your forehead with a strap that will record your brain activity while you perform these walking tasks. To attach some of the sensors and markers to your skin, we use double-sided hypoallergenic medical tape. For the sensors reading your muscle activity, we will clean the skin to be sure they record properly. Small areas of your skin may be shaved to make sure the sensors stick well and work properly. All sensors, markers, and tape will be removed at the conclusion of testing.

Application of the stimulation

The spinal electrical stimulation is generated from a small machine that is powered by a 9 volt battery. It is applied through small pads placed on your abdomen and back. These pads are made slightly damp with a salt solution to improve the connection with your skin. A large elastic band will be wrapped around your midsection to hold the pads in place. The stimulation may cause your skin to tingle or itch slightly, but does not cause your muscles to contract.

**Detailed information about *part two* of the study procedures is detailed below**

Pre- and post-training testing sessions (2 visits)

We will conduct a pre- and post-training session before and after the 16 training visits. During these testing sessions, we will perform several clinical tests that may include assessments of your walking, strength, mobility, breathing, and balance. We will also assess any muscle spasms you have, how well you are able to feel touch on various parts of your body or how well you are able to sit or stand. You will also be asked to complete questionnaires that ask about your health and function. Several of these assessments will include attachment of non-invasive sensors and markers as previously described above. You will be asked to walk on a treadmill with a harness for support and assistance as needed. We will also ask you to walk over ground at your comfortable speed, as fast as you can, backward or while stepping over obstacles. You can use any braces or assistive devices that you need. We will also repeat the reflex testing completed during the first part of the study. The breathing tests involve blowing out and breathing in as much air as you can through a hand-held device. The device uses disposable mouth pieces and will measure how hard you can blow the air out or breathe in. The device also measures how much air you are moving in and out of your lungs.

All testing procedures will be adjusted to your physical functional ability and may be adjusted to accommodate for fatigue, comfort or time constraints. All testing will be closely monitored by a physical therapist to ensure safety and comfort during all

procedures; we will assess your vitals as needed to ensure safety with all testing procedures. You will be able to take as many rest breaks as needed.

Training sessions (16 visits)

During the training sessions we will ask you to walk on a treadmill for up to 30 minutes with a harness attached to the ceiling for safety and physical assistance as needed. To get onto the treadmill, you will walk up a ramp with a staff member for safety. If you cannot walk up the ramp, you will be rolled up in your wheelchair. Once you are standing on the treadmill, the harness will be attached to an overhead support system positioned directly over the treadmill. The support system will support a portion of your weight to improve your ability to walk. While training, the stimulation will be applied for up to 30 minutes as described above. Once you are finished with walking training on the treadmill, we will ask you to walk over ground for up to 10 minutes with physical assistance as needed.

All training procedures will be adjusted to your physical functional ability. All training will be closely monitored by a physical therapist with experience in rehabilitation of people with SCI; this will ensure safety and comfort during all procedures. Physical therapists or others trained in locomotor training may provide assistance by stabilizing your trunk and/or moving your legs to improve the quality of your steps. We will assess your vitals as needed to ensure safety with all training procedures. To monitor how hard you are working during the session, we may ask you to wear a band around your chest that contains a heart rate monitor as well as a device on your ankle that counts the number of steps you take. You will be able to take as many rest breaks as needed.

**Detailed information about *part three* of the study procedures is detailed below**

Part three of the study will occur on the same day as the post-testing session of part two of the study. Upon completion of part two post-testing, you will be asked to perform clinical assessments of your walking function as well as tests of muscle strength and spasticity. These clinical tests will occur before and after a stretching protocol.

During the stretching protocol, you will be asked to lay down on a mat, fully supported, as a member of the research staff performs a series of stretches to three major muscle groups in both of your legs. The stretches will involve movement through full range of your hips, knees and ankles. You may experience slight discomfort, such as what is typical during stretching. The amount of pressure will be adjusted to your tolerance and to ensure you are comfortable. The muscle groups that will be stretched include those that help bring you knee up to your chest (i.e. hip flexors), muscles that bend your knee (i.e. knee flexors), and muscles in your calf that point your toes (i.e. ankle plantarflexors). Each stretch will be held for approximately one minute, rotating through each muscle group three sets.

Once this research study is completed, any information that could identify you **might** be removed from any identifiable private information collected and that, after such removal, the information could be used for future research studies or distributed to

another investigator for future research studies without additional informed consent from you or your legally authorized representative

If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

If you have any questions now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

**8. How long will you be in this research study?**

You will be enrolled in this study for up to four months to complete the first and second section.

**9. How many people are expected to take part in this research study?**

We expect 30 individuals will qualify and enroll in the study procedures.

## WHAT ARE THE RISKS AND BENEFITS OF THIS STUDY AND WHAT ARE YOUR OPTIONS?

**10. What are the possible discomforts and risks from taking part in this research study?**

You may become tired or experience muscle soreness during the locomotor training and testing sessions due to increased physical activity. This is often a normal response and would be expected to resolve in a couple days. Rest breaks will be provided throughout the testing and training sessions and you will be allowed to rest at any time needed. A harness attached to the ceiling may be used during all sessions. Despite these safety precautions, there is the risk of losing your balance, stumbling, falling, or experiencing an injury. You will be supervised by a physical therapist to ensure safety during all sessions. The walking activities are common activities of daily functioning and all activities will be adjusted to your physical level.

During breathing tests, you may become tired or briefly feel short of breath due to increased effort to breathe through the testing device. Typically, these feelings are brief and resolve after a few minutes of rest. As with all of the testing, you will be supervised by a physical therapist to ensure safety. You may take rest breaks as needed.

It is possible that the stimulation may cause skin irritation. Any possible areas of skin irritation will be closely monitored. Stimulation settings will be adjusted if skin irritation occurs. During the testing sessions, you may experience skin irritation or redness from the use of medical tape. The tape is hypoallergenic, and the redness usually only lasts for a short time.

During the third part of the study, you may report slight discomfort with some of the stretches, but the degree of pressure will be reduced to your tolerance and to help ensure comfort.

During these sessions, you will be asked to complete questionnaires about your health and function. These questionnaires will be completed in private with a study staff member. If you are not comfortable answering the questions, you may opt not to answer.

Reproductive risks: Because the treatment in this study might affect an unborn baby, you should not become pregnant while in this study. Since this treatment will not be given to any patients who are pregnant, all women of childbearing potential must take a pregnancy test prior to receiving any treatment on this study. We encourage all women enrolled on this study to use one of the effective birth control methods while enrolled in this study. These methods include total abstinence (no sexual intercourse), oral contraceptives ("the pill"), an intrauterine device (IUD), an etonogestrel implant (Implanon), or medroxyprogesterone acetate injections (Depo-Provera shots). If one of these cannot be used, using contraceptive foam and a condom are recommended. You must notify the study staff if you become pregnant during the course of the study.

Researchers will take appropriate steps to protect any information they collect about you. However, there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information, such a release could upset or embarrass you, or possibly affect your insurability or employability. Questions 17-21 in this form discuss what information about you will be collected, used, protected, and shared.

This study may include risks that are unknown at this time.

Participation in more than one research study or project may further increase the risks to you. If you are already enrolled in another research study, please inform one of the research team members listed in question 3 of this form or the person reviewing this consent with you before enrolling in this or any other research study or project.

Throughout the study, the researchers will notify you of new information that may become available and might affect your decision to remain in the study.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. With this Certificate, the researchers cannot be forced to disclose information that may identify you, even by a court subpoena, in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You have been informed that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research

information, then the researchers may not use the Certificate to withhold that information. That is, if you give written consent for the release of information, we cannot withhold that information and we cannot hold responsibility for how that person may use your information.

The Certificate of Confidentiality does not prevent the researchers from disclosing voluntarily, without your consent, information that would identify you as a participant in the research project under the following circumstances. If we learn about child abuse, elder abuse, or intent to harm yourself or others, we will report that information to appropriate authorities.

If you wish to discuss the information above or any discomforts you may experience, please ask questions now or call one of the research team members listed in question 3 in this form.

**11a. What are the potential benefits to you for taking part in this research study?**

You may or may not benefit from participating in this research study. The possible benefits are improvements in your standing and walking function. Because this study involves walking exercise, your physical fitness and strength may improve. Some individuals may demonstrate these improvements and others may not. This study is investigating the effects of this type of training with two stimulation dosages and therefore the benefits of this combination are not known.

**11b. How could others possibly benefit from this study?**

Others may benefit if the findings of this study contribute to improvements in the rehabilitation of walking after a spinal cord injury. The findings from this study may improve rehabilitation for others with spinal cord injury.

**11c. How could the researchers benefit from this study?**

In general, presenting research results helps the career of a scientist. Therefore, the Principal Investigator listed in question 3 of this form may benefit if the results of this study are presented at scientific meetings or in scientific journals.

**12. What other choices do you have if you do not want to be in this study?**

Your other choice is to decline participation in this study. If you do not want to take part in this study, tell the Principal Investigator or the research personnel and do not sign this Informed Consent Form.

**13a. Can you withdraw from this study?**

You are free to withdraw your consent and to stop participating in this study at any time. If you do withdraw your consent, you will not be penalized in any way and you will not lose any benefits to which you are entitled.

If you decide to withdraw your consent to participate in this study for any reason, please contact one of the research team members listed in question 3 of this form. They will tell you how to stop your participation safely.

If you have any questions regarding your rights as a research subject, please call the Institutional Review Board (IRB) office at (352) 273-9600.

**13b. If you withdraw, can information about you still be used and/or collected?**

If you withdraw from this study, your research information will no longer be collected. However, information that has already been collected will continue to be used to the extent that the researchers have used it in this research study. For example, we may analyze and present the data that we collect.

**13c. Can the Principal Investigator withdraw you from this study?**

You may be withdrawn from the study without your consent for the following reasons:

- The Principal Investigator or Physician decides that continuation could be harmful to you or the study procedures have a negative effect on you.
- A change in your health and physical functioning making it difficult for you to comply with the protocol or you no longer meet the requirements to qualify for the study.
- Other reasons affecting administration of the research project.
- Funding for the study stops.

## WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

**14. If you choose to take part in this research study, will it cost you anything?**

No. There will be no extra cost to you for participating in this Research Study.

**15. Will you be paid for taking part in this study?**

You will receive financial compensation on a weekly basis. You will be paid $20 for each session during the first part, $20 each for the pre-test and post-test of the second part and $10 for each training session. Compensation will be pro-rated for the number of weekly training sessions completed, up to $40.00 per week ($10/session, 4 days/week). Up to $160.00 will be compensated for the completion of the 16 training sessions. Compensation is provided for your time and travel to participate in the study. A total of $240.00 may be provided to you for completion of all testing and training procedures.

If you are paid more than $75 for taking part in this study, your name and social security number will be reported to the appropriate University employees for purposes of making and recording the payment as required by law. You are responsible for paying income taxes on any payments provided by the study. Payments to

***nonresident aliens*** must be processed through the University of Florida Payroll and Tax Services department. If the payments total $600 or more in a calendar year, the University must report the amount you received to the Internal Revenue Service (IRS). The IRS is not provided with the study name or its purpose. If you have questions about the collection and use of your Social Security Number, please visit: http://privacy.ufl.edu/SSNPrivacy.html.

Your payment for participation in this research study is handled through the University of Florida's Human Subject Payment (HSP) Program. Your information which will include your name, address, date of birth, and SSN (depending on amount of money you are paid) is protected. Access to the (HSP) Program site is limited to certain staff with the assigned security role. You will be randomly assigned a specific identification (ID) number to protect your identity.

If you have any problems regarding your payment contact the study coordinator

## 16. What if you are injured because of the study?

If you are injured as a direct result of your participation in this study, only the professional services that you receive from any University of Florida Health Science Center healthcare provider will be provided without charge. These healthcare providers include physicians, physician assistants, nurse practitioners, dentists or psychologists. Any other expenses, including Shands hospital expenses, will be billed to you or your insurance provider.

You will be responsible for any deductible, co-insurance, or co-payments. Some insurance companies may not cover costs associated with research studies or research-related injuries. Please contact your insurance company for additional information.

The Principal Investigator will determine whether your injury is related to your participation in this study.

No additional compensation is routinely offered. The Principal Investigator and others involved in this study may be University of Florida employees. As employees of the University, they are protected under state law, which limits financial recovery for negligence.

Please contact one of the research team members listed in question 3 of this form if you experience an injury or have questions about any discomforts that you experience while participating in this study.

## 17. How will your health information be collected, used and shared?

If you agree to participate in this study, the Principal Investigator will create, collect, and use private information about you and your health. This information is called protected health information or PHI. In order to do this, the Principal Investigator needs your authorization. The following section describes what PHI will be collected, used and shared, how it will be collected, used, and shared, who will collect, use or

share it, who will have access to it, how it will be secured, and what your rights are to revoke this authorization.

Your protected health information may be collected, used, and shared with others to determine if you can participate in the study, and then as part of your participation in the study. This information can be gathered from you or your past, current or future health records, from procedures such as physical examinations, x-rays, blood or urine tests or from other procedures or tests. This information will be created by receiving study treatments or participating in study procedures, or from your study visits and telephone calls. More specifically, the following information may be collected, used, and shared with others:

- Your name, phone number, and e-mail address.
- Questionnaires about your physical functioning, health, medical status
- Data generated from the study activities such as data pertaining to walking

This information will be stored in locked filing cabinets or on computer servers with secure passwords or encrypted electronic storage devices.

Some of the information collected could be included in a "limited data set" to be used for other research purposes. If so, the limited data set will only include information that does not directly identify you. For example, the limited data set cannot include your name, address, telephone number, social security number, photographs, or other codes that link you to the information in the limited data set. If limited data sets are created and used, agreements between the parties creating and receiving the limited data set are required in order to protect your identity and confidentiality and privacy.

**18. For what study-related purposes will your protected health information be collected, used, and shared with others?**

Your PHI may be collected, used, and shared with others to make sure you can participate in the research, through your participation in the research, and to evaluate the results of the research study. More specifically, your PHI may be collected, used, and shared with others for the following study-related purpose(s):

- To determine some of the underlying causes of your physical difficulties related to spinal cord injury
- To understand how rehabilitation interventions such as locomotor training with electrical stimulation can improve walking function
- To understand how rehabilitation interventions such as locomotor training with electrical stimulation alters how the brain and nervous system controls walking

Once this information is collected, it becomes part of the research record for this study.

**19. Who will be allowed to collect, use, and share your protected health information?**

Only certain people have the legal right to collect, use and share your research records, and they will protect the privacy and security of these records to the extent the law allows. These people include:

- the study Principal Investigator (listed in question 3 of this form) and research staff at Brooks Rehabilitation associated with this project.
- other professionals at the University of Florida or Shands Hospital that provide study-related treatment or procedures.
- the University of Florida Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research).
- professionals at Brooks Rehabilitation who are responsible for looking after the welfare of people taking part in research.
- professionals at Brooks Rehabilitation that provide study related procedures.

**20. Once collected or used, who may your protected health information be shared with?**

Your PHI may be shared with:

- the study sponsor (listed in Question 4 of this form).
- United States governmental agencies who are responsible for overseeing research, such as the Food and Drug Administration, the Department of Health and Human Services, and the Office of Human Research Protections .

Otherwise, your research records will not be released without your permission unless required by law or a court order. It is possible that once this information is shared with authorized persons, it could be shared by the persons or agencies who receive it and it would no longer be protected by the federal medical privacy law.

**21. If you agree to take part in this research study, how long will your protected health information be used and shared with others?**

Your PHI will be used and shared with others until the end of the study.

You are not required to sign this consent and authorization or allow researchers to collect, use and share your PHI. Your refusal to sign will not affect your treatment, payment, enrollment, or eligibility for any benefits outside this research study. However, you cannot participate in this research unless you allow the collection, use and sharing of your protected health information by signing this consent and authorization.

You have the right to review and copy your protected health information. However, we can make this available only after the study is finished.

You can revoke your authorization at any time before, during, or after your participation in this study. If you revoke it, no new information will be collected about

you. However, information that was already collected may still be used and shared with others if the researchers have relied on it to complete the research. You can revoke your authorization by giving a written request with your signature on it to the Principal Investigator.

## SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternative to being in the study; and how the participant's protected health information will be collected, used, and shared with others:

| Signature of Person Obtaining Consent and Authorization | Date |
|---|---|

You have been informed about this study's purpose, procedures, possible benefits, and risks; the alternatives to being in the study; and how your protected health information will be collected, used and shared with others. You have received a copy of this Form. You have been given the opportunity to ask questions before you sign, and you have been told that you can ask questions at any time.

You voluntarily agree to participate in this study. You hereby authorize the collection, use and sharing of your protected health information as described in sections 17-21 above. By signing this form, you are not waiving any of your legal rights.

| Signature of Person Consenting and Authorizing | Date |
|---|---|

## Consent to be Photographed, Video and/or Audio Recorded

With your permission, you will have the following done during this research (check all that apply):

☐ photographed ☐ video recorded ☐ audio recorded

Your name or personal information will not be identified on the photograph(s), video or audio recordings, and confidentiality will be strictly maintained. However, when these photograph(s), video and/ or audio recordings are shown or heard, others may be able to identify you.

The Principal Investigator (PI) of this study, _____, or *[his/her]* successor, will keep the photograph(s), video and/or audio recordings in a locked cabinet, in a folder on a password protected computer server drive, or as an encrypted electronic file. These photograph(s), video and/or audio recordings will be shown under *[his/her]* direction to students, researchers, doctors, or other professionals and persons.

Please indicate under what conditions Dr. _____ has your permission to use the photograph(s), video and/or audio recordings, and sign and date below.

☐ The following will be **destroyed once the study is closed** (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

☐ As described in the Informed Consent Form, and for the purposes of **education at the University of Florida Health Science Center**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

☐ As described in the Informed Consent Form; for the purposes of **education at the University of Florida Health Science Center; and for presentations at scientific meetings outside the University**. The PI may keep the following for an indefinite period of time in a locked file, in a password protected computer server drive, or as an encrypted electronic file (initial next to all that apply):

____ photograph(s) _____ video recording(s) _____ audio recording(s)

_____ _____

Signature Date