Transspinal Versus Epidural Stimulation for Exoskeletal Assisted Walking After Spinal Cord Injury

NCT04241250

May 16, 2023

Richmond Institutional Review Board
Consent Form

Template Version Date: (1/29/2019)

Title of Research Study: Transspinal versus Epidural Stimulation for Exoskeletal Assisted Walking after SCI

Sponsor: N/A

Protocol No.: N/A

Investigator Name & Address: Robert Trainer, MD
1201 Broad Rock Blvd
Richmond, VA 23249

KEY INFORMATION:

We are asking you to choose whether or not to take part in this research study about implanting an epidural stimulator (leads which conducts electricity and are placed in the spinal canal to activate your spinal cord) or use external electrical stimulation (placed outside on the spine). Patches for electrical stimulation will be placed on your lower back and on the bony parts of your pelvis. We hope to facilitate standing and to produce step like movement with the support of wearing an exoskeleton (robotic suit) in persons with SCI. The expected duration of your participation is about 1.5 years (3 months of robotic training+ 6 months and two weeks of intervention and follow-up visits every 3 months up to 9 months). You will be one of 10 subjects enrolled in this study.

This initial information is provided to help you decide whether or not to participate in the study. By doing this study, we hope to learn how implantation of an epidural stimulator compared to external electrical stimulation can help you to control your leg muscles to move, stand and perform stepping. We will train you by using a robotic suit and parallel bars. We will also evaluate the effect of spinal stimulation on bladder function. The procedure of using spinal stimulation with the robotic suit is experimental (has not been approved by FDA). You would be required to come for study visits twice daily for 2

hours per day. Each visit will last approximately 1 hour in the morning and 1 hour in the evening. During these visits, you will practice walking with a robotic suit for 60 minutes followed by walking between parallel bars, or with a walker or crutches. Sessions will be separated by 2 hours of rest. You may want to participate in this study because information from the study may benefit others in the future, but you may not receive any benefit from participating in the study or you may not want to participate because of the risk of implanting the stimulator or activating your spinal cord with an external device, falls during exercise, bone fractures and other risks as described below.

Additional detailed information is provided for your review in the sections below. Ask the research team questions until you feel you have enough information to make your decision to participate or not. Participating in this research study is completely voluntary. You may withdraw at any time. Your decision to participate or not will have no effect on any of the services, benefits or rights that you are otherwise entitled.

The person in charge of this study is ***Robert Trainer***and can be reached at ***804-675-5000 ext. 5110***. Other important contact information is provided below.

1. Whom should I contact for questions? (Contacts)
If you have any questions, concerns or complaints regarding this study, unexpected reactions, or you are injured and become ill as a result of participation in this study please call AM or PM*:*

	Office	Off Hours (Pagers)
Dr. Ashraf S. Gorgey	**(804) 675-5000 ext.3386**	**(804) 750-4814**
Dr. Lance Goetz	**(804) 675-5000 ext. 2475**	**(804) 351-3423**
Dr. Timothy Lavis	**(804) 675-5455**	**(804) 351-0753**
Dr. Denise Lester	**(804) 675-5188**	**(804) 359-9954**
Dr. Robert Trainer	**(804) 675-5110**	**(804) 351-2726**
Dr. Adam Klausner	**(804) 828-9331**	**(804) 323-1180**

If you are unable to reach any of the study staff listed and need immediate medical assistance, please call the VAMC hospital operator at 800-784-8381 and ask for the Emergency Room physician to obtain advice or call the **Emergency Room directly at (804)-675-5527**. If you have any questions, concerns or complaints about your rights as a research subject you may contact the Richmond **Institutional Review Board (IRB) at (804) 675-5676.** The IRB is responsible for reviewing research in humans and making sure that their safety and rights are protected.

2. What is this research study about? (Introduction)

You are being asked to participate in this study because you have a spinal cord injury. The purpose of this research is to determine if spinal cord stimulation will help you to stand and produce step like movement with the support of an exoskeleton device (robotic suit).

There will be 2 methods of spinal cord stimulation in this study. One method involves internal spinal cord stimulation in which a device is surgically placed. This device consists of a stimulator that is implanted under the skin and leads placed in the epidural space near the spinal cord to conduct electrical impulses from the stimulator to the spinal cord. The second method uses external spinal cord stimulation using patches placed on the skin.

In this study, the effect of these two types of spinal cord stimulation on your ability to stand and produce step like movements using the exoskeleton will be compared. We will also evaluate the effect of spinal stimulation on bladder function. The use of spinal cord stimulation in this study is experimental meaning that it is not approved by the Food and Drug Administration (FDA) for general use.

The expected duration of your participation is about 1.5 years. You will be one of 10 subjects enrolled in this study. The internal epidural stimulator device is being provided by Medtronic.

3. What is expected of me? (Procedures)

If you agree to participate, you will be asked to sign this consent form after all of your questions have been answered. This study has several phases. The first phase will be used to determine if you are a good candidate to participate. The second phase will be a three-month training period for becoming familiar with the exoskeleton device. If you do well with the device, then you will have either the internal or external spinal cord stimulator devices placed. Following recovery, you will enter the third phase with exoskeleton exercise sessions for 6 months and 2 weeks. The fourth and final phase will be a 3 month follow-up period for up to 9 months without spinal cord stimulation.

You will be randomly (by chance) assigned to either the internal or external spinal cord stimulation groups. During the course of the study, you will be housed in our lodger unit for up to 1-2 weeks at times. During Phase 2 and 3, you will exercise with the exoskeleton device 3 times per week. Exercise sessions will last

approximately 60 minutes. If you require assistance with daily living activities, a companion or caregiver must be with you.

We will plan to take photographs or make voice or video recordings that will be used for research purposes and might be presented in a scientific meeting for the purpose of education and sharing knowledge. If you agree, the photographs, video and or audio recordings will be used only for the research purpose and we will make every effort to hide your identity.

During the course of the study, you will have a regular medical checkup by our SCI doctors to ensure that you are fit to participate. If you are not standing or stepping, the stimulator will be kept off. During the period of training, either the external or the implanted stimulator will be turned on only under supervision to ensure your safety.

Phases of the study

Phase 1

You will be asked to sign this consent form after you have had all of your questions answered by the study staff. You will be asked to undergo a complete physical examination (one time for 30 to 45 minutes). Your blood pressure, heart rate, an electrocardiogram (EKG, heart tracing), and surface electromyogram (SEMG; patches placed on your skin) will be measured. You will blow into an air tube to measure the health of your lungs.

If you are eligible to continue, your weight, height, waist and abdominal measurements will be taken. Your body fat, lean and bone mass will be measured using x-rays (DXA; a machine that scans your body by using very low dose of x-rays). While lying on a table, we will measure different areas of your body.

The measurements will be performed 4 times, one time before spinal stimulation, 2 times during spinal stimulation, and one time at the end of the spinal stimulation period (Phase 3). Each scan takes 20 minutes. The time commitment for each will be 2 days. You will be asked to lodge in our lodger unit to complete the measurements.

Phase 2

You will begin training to use the exoskeleton device, 2 to 3 times a week for 12 weeks. The training will involve:

- Taking your vital signs while at rest, including your blood pressure and heart rate.
- You are performing 10 reps per leg of knee extensions with epidural

stimulation (morning session) for 20 minutes.

- Training you to stand up from your wheelchair or from sitting on the mat using a standard walker (morning session) for 10 minutes.
- Training you to sit from a standing position
- Training you to walk with a robotic suit for 60 minutes twice daily followed by over ground walking (i.e. with support from the PI and research assistant) between parallel bars, or with a walker or crutches, 3 days per week for 6 months. Training sessions will be scheduled in the morning and in the evening separated by at least 2 hours. Your resting and exercise blood pressure will be monitored during the sessions.

1. As part of the fitting procedure, hip width, thigh length and leg length will be measured for the robotic suit. If you do not fit the robotic suit, you will not be able to continue in the study.
2. Based on your progress in the study, the assistance provided by the robotic suit will be gradually reduced to allow you the possibility of controlling your leg muscles on your own. This will be done under supervision to ensure your safety.
3. During some of the training sessions, a small clear mask will be placed on your face to measure energy use during sitting, standing, walking with walker or crutches and recovery from standing and sitting with the robotic suit. Your heart rate and blood pressure will be measured. The entire test should not exceed 20 minutes. You will be asked to relax in a sitting position for 5 minutes to determine the amount of energy you use at rest. The exoskeleton unit will then be placed in standing mode and the amount of energy you use while standing will be measured for 5 minutes.
4. We will place pressure sensors in the sole of your shoes to determine your walking pattern.
5. Surface electromyography (SEMG) will be used to measure the electrical activity of underlying muscle groups via pads placed on the skin. Six leg muscle groups will be measured on one side after gently shaving hair from the surrounding areas.

Phase 3:

In Phase 3, you will continue to exercise with the exoskeleton device and either internal or external spinal cord stimulation will be applied. If you are assigned to

external spinal cord stimulation, pads will be placed on your skin and Phase 3 will begin. If you are assigned to internal spinal cord stimulation, you will need to undergo procedures to have the device surgically implanted as described in detail below. You will meet with Dr. Lester or Dr. Trainer to discuss the procedure. Exercise sessions will resume when you have recovered from the implant procedure.

A. For epidural stimulation group

1. You will be given Hibiclens® (chlorhexidine, a liquid antibacterial soap to wash your body with) and Bactroban (mupirocin) 2% antibiotic ointment placed in your nose for 7 days prior to lower the risk of infection.

2. **The procedure involves getting a minimal amount of local anesthesia prior to the temporary implantation and again prior to the permanent implantation.** An anesthesia preoperative evaluation and postoperative evaluation including labs, EKG, and a urine drug screen, will be performed and you will be asked to sign a separate consent for each surgery. Anesthesia will be administered. A member of the anesthesia care team will visit you before your treatment to discuss the type(s) of anesthesia you may need and to give you more information about anesthesia. It may become necessary to alter your anesthesia care plan after this discussion. Devices may be applied to your body and placed in your veins and arteries to monitor you during your anesthesia.

3. An epidural stimulation unit (Intellis, Medtronic) will be implanted in your spinal canal to stimulate your lower extremity muscles. A Medtronic representative will be available to control the pulses delivered to your spinal cord under the supervision of Dr. Lester or Trainer.

The procedure:

Implanting a spinal cord stimulator is a 2-step process that involves temporary implantation followed by permanent implantation. This device consists of stimulating electrodes, a pulse generator (power supply), wires (leads), and a remote control. The generator sends electrical pulses through the leads to the electrodes. These pulses stimulate your spinal cord. The pulses are controlled by a remote control.

Temporary Implantation Procedure:

a. An intravenous (IV) catheter will be placed into your arm by the anesthesia team for antibiotic administration and sedation as necessary. An anesthesia provider will be present during the operation.

b. You will be taken to a procedure room and placed in a prone position, under fluoroscopy (X-Ray). The leads will be placed under sterile conditions and attached outside the body. Temporary leads will be removed within 7 days.

c. You will be sedated throughout the entire implantation procedure. Your surgeon will make one or more incisions in your back and place the electrodes in the spinal canal.

d. The temporary electrodes will be taped and glued to the skin to lessen the chance of them moving.

Following the initial implantation procedure, you will be scheduled for 3-4 days to test the best combination of electrical current that can stimulate the muscles for each leg. This testing will involve EMG electrodes being placed on the major muscle groups of your right leg followed by your left leg.

Permanent Implantation Procedure:
If the temporary leads appear to work well for you, you will be scheduled for permanent implantation and the permanent electrodes will be placed where the temporary electrodes have been.

a. Antibiotics will be administered just before the procedure of implantation to protect against the risk of infection.

b. An IV catheter will be placed into your arm by the anesthesia team for antibiotic administration and sedation as necessary. An anesthesia provider will be present during the operation.

c. You will then be taken to the operating room where you will be placed face down on a table.

d. Your surgeon will make an incision in your lower back. The generator will be anchored to a pocket of tissue between the muscles and the skin, to lessen the chances of it moving. Using a needle, the leads will be threaded under the skin. They will be connected to the electrodes.

This enables the electrodes to be positioned to stimulate the spinal cord and possibly provide control for your muscles.

e. Your surgeon will close all incisions with stitches, staples, strips of tape.

f. Stimulation parameters (ways that current is being delivered) and how to control epidural stimulation will be completed by your medical team.

g. This will be followed by a recovery period which you will be trained on how to use the epidural stimulation to stimulate your leg muscles. You will go through rehabilitation training program as described below for 6 months. The training will be in the morning and in the evening.

h. You will be discharged within 1 week, if you heal well. You will receive antibiotics and medication for pain control if needed.

B. For Surface external stimulation group

Patches for electrical stimulation will be placed on your lower back and on the bony parts of your pelvis. The electrical stimulation will be gradually increased. Surface electromyography (SEMG) will be used to measure the electrical activity of 12 muscle groups via pads placed on the skin. Pads will be placed on the same location during walking with the robotic suit. SEMG activity will be measured during the course of the study at different times.

Other procedures that will be done during the study include:

1. Near-infrared resonance spectroscopy (NIRS): We will measure energy production in the calf muscles, by using light to measure the ability of your blood cells to carry oxygen. Blood flow through the right leg will be blocked by inflating a blood pressure cuff and then releasing it to see how fast your muscles recover. This testing will be completed during walking with the robotic suit.

2. After an overnight fast for 10-12 hours, blood will be drawn from your arm using a Heplock line. You will then drink a sugary solution. The blood draws after drinking sugary solution will then be continued every 30 minutes for 3 hours. The volume of the blood draw will be in the size of a table-spoon.

3. Urodynamic Studies: Your bladder will be tested using a procedure called urodynamics. Prior to the procedure, you will drink an antibiotic liquid. During testing, you will be brought to a special room, placed on a specialized chair or stretcher, and a small catheter will be placed in your bladder and a second catheter will be placed in the rectum. These will be used to measure pressures. Saline (salt water) solution will be placed in your bladder through the catheter. Your ability to hold your urine or start the urinary stream will be monitored with either the spinal stimulator turned on or turned off. The test will be conducted 4 times during the study on different dates. A urologist will be present for the bladder testing.

Phase 4

After completion of Phase 3, you will be asked to visit us for follow-up every 3 months for 9 months. The follow-up visits will include:

1. *A small clear mask will be placed on your face to measure energy use during sitting, standing, walking with walker or crutches and recovery from standing and sitting with the robotic suit. Your heart rate and blood pressure will be measured. The entire test should not exceed 20 minutes. You will be asked to relax in a sitting position for 5 minutes to determine the amount of energy you use at rest. The exoskeleton unit will then be placed in standing mode and the amount of energy you use while standing will be measured for 5 minutes.*
2. *We will place pressure sensors in the sole of your shoes to determine your walking pattern.*
3. *Surface electromyography (SEMG) will be used to measure the electrical activity of underlying muscle groups via pads placed on the skin. Six leg muscle groups will be measured on one side after gently shaving hair from the surrounding areas.*

You can contact us any time in case of emergency or any questions about the implantation or device use. After you complete the 6-month program of epidural stimulation, you will be given the option of keeping the stimulator implanted or to remove it by the study medical team. Please note that the implanted stimulator can be removed at any time based on your request. The risks associated with removing the implant is the same as the risk of implantation. If you choose to keep the stimulator implanted, the stimulator will be turned off by the study staff at the completion of the study. For the stimulator to be turned back on, additional approval is needed from the FDA.

4. **Will my information be kept to be used in the future? (Future use of**

data/samples)

Identifiers might be removed from the identifiable private information and/or identifiable biospecimens that are collected. After that removal, the information or biospecimens could be used for future research studies and/or distributed to another investigator for future research studies without additional consent from you.

Only the study staff, will have access to the data. The data will be stored in a locked research cabinet, in a locked room.

5. Will the research benefit me? (Benefits)

No benefit is guaranteed**.** It is possible that the spinal cord stimulator may not help you. However, the information we get from this study might help others with your condition.

6. What are my alternatives to being a research subject? (Alternative Therapy)

You do not have to participate in this study to receive treatment for your condition. You can continue to participate in standard rehabilitation procedures.

7. What are my risks? (Risks, Inconveniences, Discomforts)

Participation in this study may involve risks that are unknown at this time. Your condition may stay the same, may improve or may worsen from study participation.

Pressure wound from skin irritation during exercise

Break in your skin creating a wound requiring daily wound care. This occasionally occurs. If pressure wound develops, you will be asked to avoid any further skin irritation and be kept off the pressure wound until it heals.

Risks associated with transfers

There is a risk of falls during transfers. To minimize risk, study staff will assist in all transfers and provide a slide board, or any other assistive devices needed.

Radiation from DXA Scans

This research study will require you to have 4 DEXA scans which involves exposure to radiation in the form of X-rays. This radiation exposure is not necessary for your medical care and is for research purposes only. All radiation increases the risk of developing cancer in the future. The total amount of radiation that you will receive in this study is equal to about 3 extra weeks of exposure from natural background radiation. The Richmond VA Medical Center Radiation Safety Committee has reviewed the use of radiation in this research study and has approved this use as involving acceptable risk and necessary to obtain the research information desired.

Please tell your doctor if you have taken part in other research studies or received any other medical care recently involving radiation.

Radiation from fluoroscopy (An x-ray machine that guides the insertion of the leads or wires in your spine)

This research study will require the use of fluoroscopic imaging which involves exposure to radiation in form of X-rays. This radiation exposure is not necessary for your medical care and is for research purposes only. All radiation increases the risk of developing cancer in the future. The total amount of radiation that you will receive in this study is equal to about 6-12 extra weeks of exposure from natural background radiation. The Richmond VA Medical Center Radiation Safety Committee has reviewed the use of radiation in this research study and has approved this use as involving acceptable risk and necessary to obtain the research information desired. Please tell your doctor if you have taken part in other research studies or received any other medical care recently involving radiation.

Falls during exercise
Falls could occur during training with the exoskeleton unit. This rarely occurs and a research assistant will be working with you to ensure your safety during walking with the exoskeleton. The exoskeleton is also equipped with safety features that allow the unit to protect you from falling.

Risk of Fracture
Every effort will be taken to minimize possible bone fracture; however, SCI is associated with bone weakness and weight bearing while walking may increase the risk of bone fractures. This may result in hospitalization and casting of the broken bones, or surgery.

Autonomic Dysreflexia
Symptoms of autonomic dysreflexia include sudden high blood pressure and possibly headache, sweats, blurred vision, stuffy nose, and nervousness. There is a small risk that blood pressure could become very high and sustained and cause a stroke. If AD occurs, the study is stopped, and the bladder emptied, which usually causes the AD to resolve on its own. A medication called nitroglycerin paste is kept in the laboratory in case it is needed to apply to the chest for AD. This medication can cause low blood pressure dizziness and headache, which is treated by removing the paste and leaning your head down.

Epidural Stimulator Implantation Procedure
Risks include infection, bleeding, and epidural abscess (infection inside the spine). The risk of infection is about 2.4%-3.1%.

Risk of infection, inflammation or abscess formation
It is possible that you may experience spinal infection, inflammation or formation of epidural abscess (inflamed area inside your spine) during the study. The medical team will regularly check for signs for this. You will have multiple follow-up appointments with Drs. Lester or Trainer for wound checks, device checks, and post-operative pain management in the weeks that follow implantation.

The study team will try to minimize the risk of infection.

Risk from anesthesia and surgical procedure
All forms of anesthesia involve some risk. Risks include: nausea, vomiting, and pain where an injection is given. Although rare, severe complications include: injury to blood vessels, drug reactions, bleeding, blood clots, loss of sensation or limb function, infection, paralysis, stroke, brain damage, heart attack, and death. A pre and post-operative evaluation, including labs, EKG, and a drug screening, will be completed to protect against risks of anesthesia. The use of opioids may cause drowsiness, mental fog, nausea, addiction and constipation.

Magnetic Resonance Imaging Following Device Implantation
It is recommended to turn the stimulator off before any MRI scans and consult your medical provider before conducting MRI.

Risk of device malfunction.
Your implanted device may experience malfunction, or movement of the leads and/or malfunction of the leads. Movement of the leads may require repeat surgery.
The company will replace the device, if it malfunctions; however, if the device malfunctioning causes you to get injured, the company is not liable and will not pay for your treatment. For research related injury, the VA must provide necessary medical treatment regardless of whether you are a Veteran or a non-Veteran.

Risks of medications.
All medications associated with this study can cause side effects, which will be discussed with you.

All drugs have the potential to cause allergic reactions including the drugs used in this study. Allergic reactions may be mild to severe, and include the following symptoms:

chills, fever, skin rash, hives, itching, watery eyes, swelling, headache, difficulty breathing, difficulty swallowing, severely low blood pressure, organ failure, and death. Serious allergic reactions require immediate medical attention.

Risk of using external electrical stimulation
Light-headedness, shortness of breath, altered heart rate, autonomic dysreflexia, muscle soreness at your neck and back, shoulder, arms and hands.

Risk of using exoskeleton for 9 months
Continuous use of exoskeleton may result in skin abrasion or breakdown, strained ligaments, falls, fracture.

Risk of blood draw
The risks of having blood taken from a vein in your arm are pain, bleeding, and bruising at the site where the needle goes in. There is a minor chance of infection at the site of the needle stick. Additionally, there is possibility of hep-lock failure which would need to be replaced. Fainting or light-headedness may occur, but these are uncommon, and most often resolve within a few minutes.

Risks associated with Urodynamics and Fosfomycin
Because urodynamic studies involve placing a catheter into the urethra, and possibly removing your old one if present, there is a small risk of infection. A single dose of an antibiotic drink called fosfomycin is given prior to this procedure to minimize the risk of infection. Another risk of urodynamic studies is autonomic dysreflexia (AD). A balloon is placed in the rectum with urodynamic studies. Rectal irritation or bleeding could occur, especially if hemorrhoids are present. There is also a possible risk of fosfomycin which includes diarrhea, nausea, headache, or dizziness.

Risks associated with taking antibiotics
An allergic reaction is possible to any antibiotic. We will check to make sure that you are not allergic to this medication. An allergic reaction can be mild, with a rash or hives, or severe, with difficulty breathing and low blood pressure. We will ask you about any allergies that you have. Other consequences may include vomiting and diarrhea. The study staff will discuss other risks with you.

8. Will I get paid? (Compensation)
You will not receive payment for participating in this study. The information that you are providing for this research study may lead to new clinical or educational knowledge, tests, treatments or products. These products could have some financial value. There are no plans to provide financial payment to you or your relatives if this occurs.

9. Will I have to pay? (Cost of Participation)
You will not have to pay for care received as a subject in a VA research project regardless of whether you are a Veteran or a Non-Veteran. If you get a bill for research services contact your study doctor or research nurse. Some Veterans are required to pay co-payments for medical care and services provided by the VA. These co-payment requirements will continue to apply to medical care and services provided by the VA that are not part of the study. There is no cost to participate in the current study.

10. Does pregnancy prevent me from participating? (Pregnancy)
Women are not included in the study.

11. What if I get injured? (Research Related Injury)
In the event of injury resulting from your participation in this research study, Richmond Veterans Affairs Medical Center may or may not provide compensation, depending on applicable federal regulations. A research injury is any injury or illness caused by your participation in the study. In the event of a research injury, necessary medical treatment will be provided to assist your recovery from the injury. For research related injury, the VA must provide necessary medical treatment regardless of whether you are a Veteran or a non-Veteran.

This agreement does not include treatment for injury/illness that is not a result of the study. To help avoid injury, it is very important to follow all study directions. You are not giving up any of your legal rights by signing this form.

12. Who Will See My Information? (Confidentiality)
The confidentiality of your research records will be maintained according to professional standards of confidentiality and VA regulations. Records identifying you may be reviewed by the members of the research team, the Research and Development Committee and its sub-committees, accrediting agencies, officials from the Veterans Health Administration, the Office of Research Oversight, the VA Office of the Inspector General, Richmond VAMC, and other federal oversight agencies such as the Food and Drug Administration, Office for Human Research Protections, or as required by law.

All records will be kept in a locked in filing cabinets, on computers protected with passwords, only the PI and the study team will have access to these records.

The ways your study doctor will use your study-related health information and the people who may receive it are identified in a separate form entitled, Authorization for Use & Release of Individual Identifiable Health Information for Veterans Health

Administration Research. You will be asked to sign that form to show that you give permission for these uses and sharing of your information. You do not have to sign the authorization form. However, if you do not sign, you will not be able to participate in the 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.

Information published or presented about the results of this study will not identify you.

13. Do I have to participate in this study or can I withdraw from the study? (Voluntary Participation and Withdrawal)

Participation in this study is voluntary and you may refuse to participate without penalty or loss of benefits to which you are otherwise entitled. The study staff will answer any questions you may have about the study. You are free to withdraw your consent and stop participation at any time. If you decide to withdraw from this study, you should contact Dr. Robert Trainerto discuss termination of your participation. It is important that you do this so that *Dr. Trainer*can withdraw you safely. Stopping will in no way change the quality of care you receive now or in the future at this institution or your right to participate in other studies.

Any significant new findings that develop during the research study that may affect your decision to continue participating will be provided to you as soon as possible.

Your participation in this research study may be ended without your consent for the following reasons:

- If the study doctor believes, for any reason, that it is within your best interest.
- If you develop side effects that are considered dangerous.
- If you refuse to use the epidural stimulator or fail to return for follow-up as recommended by your study doctor or fail to follow the study doctor's instructions.
- If you refuse to have tests that are needed to determine whether the epidural stimulator is safe and effective.
- If other causes prevent continuation of the clinical research study.
- FDA, Richmond IRB may also end the study at any time.

14. Date of Consent Form Revision: 08-12-2019, 4-21-2020, 8-11-2021, 5-1-2023

Subject Name:_____ **Date:**_____

Title of Research Study: Transspinal versus Epidural Stimulation for Exoskeletal Assisted Walking after SCI

Principal Investigator*:* Robert Trainer, MD**VAMC:** Richmond

RESEARCH SUBJECTS' RIGHTS: I have read or have had read to me all of the above.

Drs. Gorgey/Goetz/Lester/Trainer have explained the study to me and answered all of my questions. I have been told of the risks or discomforts and possible benefits of the study. I have been told of other choices of treatment available to me. I have been given the chance to ask questions and obtain answers.

I understand that I do not have to take part in this study, and my refusal to participate will involve no penalty or loss of rights to which I am entitled. I may withdraw from this study at any time without penalty or loss of VA or other benefits to which I am entitled. The results of this study may be published, but my records will not be revealed unless required by law. By signing below, I am agreeing to participate in this research study. I will receive a signed copy of this consent form.

Subject's Signature	**Date**
Signature of Principal Investigator	**Print name/Date**
Signature of Surgeons	**Print name/Date**