

Epidural and Dorsal Root Stimulation in Humans With Spinal Cord Injury

NCT04736849

August 8, 2024



Name and Clinic Number

Approval Date: **August 8, 2024**
Not to be used after: **August 7, 2025**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Pilot Study of Epidural and Dorsal Root Stimulation in Humans with Spinal Cord Injury

IRB#: 20-006104

Principal Investigator: Peter Grahn, Ph.D., and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.

It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to learn more about how electrical spinal stimulation affects and enables the function of motor nerves. You have been asked to take part in this research because you have a <u>spinal cord injury resulting from trauma</u> .
What's Involved	Study participation involves about 22 days over the course of a month. The first 3 days of the study will consist of tests and assessments aimed at characterizing details of your injury and residual nerve function. Then, a procedure to temporarily implant leads through your skin into the epidural space and dorsal root ganglion of your lower spine will be performed by a doctor specializing in pain medicine. One to three days after implantation, the doctor will inspect the implant site, and if there are no concerns, rehabilitation sessions will commence.



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	<p>You will undergo 10 days of rehabilitation sessions using electrical stimulation through the implanted leads. Then the doctor will remove the leads and clean and dress the incision site. Finally, you will undergo 3 days of the same tests and assessments that were done at the beginning of the study.</p>
Key Information	<p>The risks associated with study participation are completely described later in this form, be sure to review them carefully.</p> <p>Given the visit frequency and the duration of the study, time expenditure will be the main potential inconvenience; please discuss and concerns or possible conflicts with your study team.</p> <p>With the brief procedure to implant the stimulator leads, there are risks including infection and fluid leakage into adjoining tissues.</p> <p>Additionally, rehabilitation training and weight-bearing tasks can be accompanied by minor skin irritation or abrasions, bruising, and fatigue.</p>
Learn More	<p>If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.</p>

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.



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Contact Information

If you have questions about ...	You can contact ...
<ul style="list-style-type: none">▪ Study tests and procedures▪ Materials you receive▪ Research-related appointments▪ Research-related concern or complaint▪ Research-related injuries or emergencies▪ Withdrawing from the research study	<p>Principal Investigator: Peter Grahn, Ph.D. Phone: (507) 422-7059</p> <p>Study Team Contact: Tyson Scabeck Phone: (507) 538-1016</p> <p>Institution Name and Address: Mayo Clinic 200 First Street SW Rochester, MN 55905</p>
<ul style="list-style-type: none">▪ Rights of a research participant	<p>Mayo Clinic Institutional Review Board (IRB) Phone: (507) 266-4000 Toll-Free: (866) 273-4681</p>
<ul style="list-style-type: none">▪ Rights of a research participant▪ Any research-related concern or complaint▪ Use of your Protected Health Information▪ Stopping your authorization to use your Protected Health Information▪ Withdrawing from the research study	<p>Research Participant Advocate (RPA) (The RPA is independent of the Study Team) Phone: (507) 266-9372 Toll-Free: (866) 273-4681</p> <p>E-mail: researchparticipantadvocate@mayo.edu</p>
<ul style="list-style-type: none">▪ Billing or insurance related to this research study	<p>Patient Account Services Toll-Free: (844) 217-9591</p>

Other Information:

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.

A description of this research study will also be available on <http://www.mayo.edu/research/clinical-trials>. This Web site will not include information that can identify you. You can search this Web site at any time.



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Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you have sustained a spinal cord injury (SCI) with partial or complete loss of motor function below the injury.

Why is this research study being done?

The purpose of this study is to learn more about how spinal motor nerves respond to electrical stimulation in the epidural space (EES) and the dorsal root ganglion (DRG), and to measure any changes in motor performance over 10 rehabilitation sessions while using one or both types of stimulation.

The neural stimulation system and electrical leads are approved for treating pain. They are not approved by the U.D. Food and Drug Administration (FDA) to enable motor function, but the FDA has allowed the use of these devices in this research study.

The plan is to have 35 people take part in this study at Mayo Clinic.

Information you should know

Who is Funding the Study?

The National Institutes of Health (NIH), the Minnesota Office of Higher Education, and Abbott Medical are funding the study. The funding sources will pay the institution to cover costs related to running the study.

How long will you be in this research study?

You will be in this study for about one month.



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What will happen to you while you are in this research study?

Your participation in the study will include 1 week during which screening tests and baseline SCI characterization will take place, then lead implantation with about 2 days for recovery, 10 days of spinal stimulation rehabilitation sessions after implantation, and 1 more week of post-rehab SCI characterization after the leads are removed.

The following tests and procedures will be performed over the first week of the study:

Screening

- A pre-operative evaluation by a study physician,
- Pre-operative blood tests to rule out infection (at the study doctor's discretion),
- A physical exam to determine your neurological level of injury (also called ASIA),
- Computerized tomography (CT) and magnetic resonance imaging (MRI) for visualization of spinal structures,
- Evaluation of bone density through an x-ray scan (also called a DEXA scan),
- Assessments of your endurance, task performance, and ability to stand and step using body weight support, research staff assistance, or other assistive devices,
- Vital signs, including blood pressure, heart rate, and body weight,
- Urinalysis, to detect any signs of infection,
- Urine pregnancy screening, if you are a female of child-bearing potential,
- A spasticity assessment called the Modified Ashworth Scale,
- Assessment of spinal reflexes using transcutaneous (through the skin) electrical stimulation over the lower spine, involving surface-level skin electrodes placed with the option of ultrasound guidance.

SCI Characterization (pre)

- Surveys measuring spasticity, bowel and bladder function, sexual function, and stimulation user experience,
- Electrophysiological testing to detect and record nerve conduction and residual motor and sensory system function, using surface-level skin electrodes (electromyography, or EMG) and magnets affixed to headgear (transcranial magnetic stimulation, or TMS),
- Measurements of the current amount of intentional control of your lower extremities, assessed in back-lying, side-lying, standing, and stepping positions using surface-level skin electrodes wired to computer instruments,
- A second assessment of spinal reflexes using transcutaneous (through the skin) electrical stimulation over the lower spine.



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Implantation of Stimulator Leads

A routine surgical procedure to implant the stimulator electrodes will be performed by a doctor specializing in pain medicine. An incision above your spine will be made at the entry site for the leads, and the leads will be guided in with an insertion needle and fluoroscopic (x-ray) guidance. After the doctor confirms that the positioning is correct, the implantation site will be dressed, and the leads will be secured to your skin with an adhesive bandage. About 1-3 days after implantation, a trained healthcare professional will inspect the incision site. The study team will also inspect the incision site daily for any signs of infection or lead displacement.

Rehabilitation Sessions with Spinal Stimulation

Over the following 10 days, multiple rehabilitation activities which the research staff deem safe and appropriate for you will be performed with the application of electrical spinal stimulation:

- While lying on your back or side, with your legs supported by slings, you will train on and attempt movements of your legs.
- Utilizing parallel bars, an overhead body weight support (BWS) system, and trainer assistance, you will train on and attempt standing tasks.
- Using BWS over a treadmill, you will train on and attempt stepping activity with research trainer assistance. If appropriate for you, this may include overground movement with an assistive device such as a front-wheeled walker with a safety gait belt.
- If stimulation-enabled movement is inconsistent, an x-ray may be performed to determine if the inconsistency is due to the leads shifting position.

During motor rehabilitation sessions, your blood pressure will be monitored with a finger blood pressure monitoring device.

Rehabilitation sessions will typically last 2 – 3 hours. These following tests and assessments will be done at specific time points during the Rehabilitation phase:

- Spine CT (Day 1 and Day 10),
- Measurements of attempts to stand and generate steps using body weight support and/or assistive devices such as walkers or parallel bars (Days 1-3 and 8-10),
- Measurements of the current amount of intentional control of your lower extremities, assessed in back-lying, side-lying, standing, and stepping positions using surface-level skin electrodes wired to computer instruments (Days 1-3 and 8-10),
- Adjustment and optimization of stimulator settings, using surface-level skin electrodes wired to computer instruments (Day 1 and Day 2),
- Recording of muscle and nerve activity using surface level electrodes [EMG],
- Measurements of joint angles and movement using adhesive motion capture markers, measurement of foot pressure using shoe insole pressure sensors, and seated pressure using a pressure mat (Days 1-3 and 8-10).



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Lead Removal

After completing the Rehabilitation phase, the bandage will be removed, the incision site will be opened, and the leads will be carefully withdrawn. Then the incision site will be cleaned and dressed.

SCI Characterization (post)

During the last week of the study, many of the same tests and assessments done during Screening and the first SCI Characterization phase will be repeated, including:

- An ASIA exam,
- Assessments of your endurance, task performance, and ability to stand and step using body weight support, research staff assistance, or other assistive devices,
- Assessment of spinal reflexes using transcutaneous (through the skin) electrical stimulation over the lower spine,
- Surveys measuring spasticity, bowel and bladder function, sexual function, and stimulation user experience,
- EMG and TMS testing to detect and record nerve conduction and residual motor and sensory system function.

What are the possible risks or discomforts from being in this research study?

Risks associated with rehabilitation

Risks include skin irritation and minor bruising from pressure applied during trainer assistance and body weight support, muscle and joint soreness, fatigue, and bladder or bowel incontinence due to exertion and abdominal pressure from support harness. There is a slight risk of fracture in the lower extremities. Lightheadedness or dizziness from a sudden drop in blood pressure is a risk associated with transitioning from sit to stand quickly.

Risks associated with weight-bearing tasks:

Risks include muscle soreness, fatigue, skin irritation, fracture, changes in blood pressure, and potential for a fall.

Risks associated with lead implantation and explantation:

Risks include pain, bleeding, and infection at the site of the implantation.

Risks associated with EES leads

- Undesirable changes in stimulation due to tissue changes around the electrodes, changes in the electrode position, loose electrical connections and/or lead failure,
- Cerebrospinal fluid (CSF) leakage,



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- Fluid build-up at the incision site, and fluid drainage,
- Infection,
- Spinal cord compression, and/or paralysis,
- Discomfort due to chest wall stimulation,
- Persistent pain at the electrode site or receiver site.
- Allergic or rejection response to implant materials,
- Lead migration and/or local tissue breakdown,
- Paralysis, weakness, clumsiness, abnormal sensations such as tingling, burning, prickling, itching or numbness, or pain below the level of implantation,
- Difficulty explanting the leads.

Risks associated with DRG leads

- Undesirable changes in stimulation due to tissue changes around the electrodes, changes in the electrode position, loose electrical connections and/or lead failure.
- Stimulation in unwanted places,
- Cerebrospinal fluid (CSF) leakage,
- Fluid build-up at the incision site,
- Infection,
- Spinal cord compression, and/or paralysis,
- Tissue or nerve damage,
- Paralysis, weakness, clumsiness, abnormal sensations such as tingling, burning, prickling, itching or numbness, sensory loss, or pain below the level of the implant,
- Pain or bleeding where the lead was inserted,
- Persistent pain at the electrode site,
- Headache,
- Allergic or rejection response to the device or implant materials,
- Lead migration or local tissue breakdown, or causing changes in stimulation,
- Pain from touching the skin normally, or an exaggerated sense of pain,
- Formation of reactive tissue around the lead implant site,
- Pain from the stimulation being set too high,
- Difficulty explanting the leads.

Risks associated with electrical spinal stimulation following implantation:

Risks include hardware malfunction, discomfort or abdominal tightness during stimulation, increased or decreased spasticity, bowel or bladder incontinence, elevated blood pressure, shortness of breath, muscle soreness, and fatigue. People with mid-thoracic or higher injuries can experience autonomic dysreflexia (AD), an event in which there is a sudden onset of excessively high blood pressure in combination with a low pulse rate; AD can be accompanied by sweating and nausea.



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Risks associated with MRI:

There is no radiation associated with MRI, but people who have metal devices like pacemakers cannot have an MRI and will not be able to participate in the study.

Some people with claustrophobia may feel too closed in and may not tolerate MRI scanning. If you feel too confined in the MRI scanner you can inform the technologist and the MRI scan will be stopped. The MRI machine makes loud knocking sounds when it is scanning. Because of this you will be asked to wear earplugs while getting your MRI scan. The earplugs minimize discomfort from noise and keep the MRI noise within the safety range.

Risks associated with transcranial magnetic stimulation (TMS):

Risks include seizure, possible hearing changes, headache, and a chance of heating on the skull where the magnet is placed.

Risks associated with EMG

Risks involved with electrophysiological recordings include skin irritation and/or allergic reaction from the adhesive used to apply skin surface sensors, skin irritation and/or allergic reaction from alcohol used to prepare skin for electrode contact.

Risks associated with CT, DEXA, x-ray, and fluoroscopy:

You will be exposed to radiation from the CT's, x-ray, and fluoroscopy. The amount of radiation has a low risk of harmful effects.

Risks associated with blood draw:

The risks of drawing blood include pain, bruising, lightheadedness, and/or fainting, or rarely, infection at the site of the needle stick.

Questionnaires:

If you are uncomfortable answering any of the questions in the surveys, you may skip those you don't want to answer.

Pregnancy:

The effect of electrical spinal stimulation of the mother's spinal cord on a fetus (developing baby still in the womb), or on a breastfeeding infant, is unknown and may be harmful. Because of these risks, women cannot take part in this study if they are pregnant or breastfeeding.

If you are a female, you must have a negative pregnancy test in order to participate in this study unless you cannot become pregnant.



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If you are sexually active and able to become pregnant, you must agree to use one of the birth control methods listed below:

- Hormonal methods, such as birth control pills, patches, injections, vaginal ring, or implants
- Barrier methods (such as a condom or diaphragm) used with a spermicide (a foam, cream, or gel that kills sperm)
- Intrauterine device (IUD)
- Abstinence (no sex)

Confidentiality:

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

Photographs and videos will be taken throughout this study and will be used by the study team for data analysis. Your entire body including your face will be included. The photographs and videos will be kept until the end of this study and then destroyed.

If the researchers want to use these images for publications or presentations intended to share the study's findings, you will be asked to sign a separate Mayo Clinic authorization document. Signing this separate authorization form means these images may be available in scientific publications or presentations forever; but you do not have to sign the authorization in order to continue participating in the study.

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop, and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- If it is in your best interest,
- If you don't follow the study procedures,
- If the study is stopped.

If you decide to stop taking part in the study for any reason after lead implantation, we will ask you to make a final study visit. The final study visit will take less than an hour. At this visit, the bandage will be removed, the incision site will be opened, and the leads will be carefully withdrawn. Then the incision site will be cleaned and dressed.



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If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

What if you are injured from your participation in this research study?

Where to get help:

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries?

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.

What are the possible benefits from being in this research study?

You won't benefit from taking part in this research study. It is for the benefit of research. However, others with SCI may benefit in the future from what we learn in this research study.

What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information. You may choose not to take part in this study.



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What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- Clinical and research evaluations and examinations done for the study
- Urine testing
- Magnetic resonance imaging (MRI)
- Computed tomography (CT) and fluoroscopy
- X-ray
- Nerve conduction studies
- Neurostimulator lead implantation and explantation
- Electromyography (EMG)
- Transcranial magnetic stimulation (TMS)
- Rehabilitation training sessions
- Questionnaires
- Blood draw
- DEXA scan
- Pregnancy test

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

You won't be paid for taking part in this study; however, you will be offered parking and valet passes.

In the event of situations such as inclement weather, or a staggered scheduling timeframe for assessments or procedures over two consecutive days, the study team may offer you a complimentary stay at a local hotel.



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Will your information or samples be used for future research?

Identifiable information such as your name, Mayo Clinic number, or date of birth may be removed from your information or samples collected in this study, allowing the information or samples to be used for future research or shared with other researchers without your additional informed consent.

How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. To safeguard your confidentiality, data obtained will be coded, research materials will be stored in cabinets accessible only to the study staff, and digital data will be kept on secure computer servers. If the results of the research are made public, information that identifies you will not be used, unless you authorize this use by signing a Mayo Clinic authorization document.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research.



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The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or "authorization") to Mayo Clinic.

Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- Other Mayo Clinic staff involved in your clinical care.
- The Mayo Clinic Institutional Review Board that oversees the research.
- Abbott Medical
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used, unless you authorize this use by signing a Mayo Clinic authorization document.



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In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you.

However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private, and it may no longer be protected by the Privacy Rule.

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
Plummer Building PL 3-02
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: researchparticipantadvocate@mayo.edu.



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Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

Printed Name	/ /	:	AM/PM
	Date		Time

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name	/ /	:	AM/PM
	Date		Time

Signature