# INFORMED CONSENT DOCUMENT

Project Title: **Investigating Mechanisms of Human Spinal Cord Stimulation for Purpose of Treating Restless Leg Syndrome**

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**Co Investigator:** **Gary L. Pierce PhD**

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This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.

- If you have any questions about or do not understand something in this form, you should ask the research team for more information.
- You should discuss your participation with anyone you choose such as family or friends.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

## WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you have or are planning to undergo spinal cord stimulation implantation (SCS) for chronic pain in your thoracolumbar region. You also may or may not have Restless Leg Syndrome (RLS). Those who don't have RLS will be considered control subjects.

The purpose of this research study is to determine if the effectiveness of spinal cord stimulation in patients with restless leg syndrome and patients without restless leg syndrome will improve the blood flow to the lower limbs. Also, the purpose of this research study is to determine the extent to which spinal cord stimulation in patients with restless leg syndrome and patients without restless leg syndrome will affect ambulatory 24-hour blood pressure.

## HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 50 people will take part in this study conducted by investigators at the University of Iowa. The study will have 25 without restless leg syndrome and 25 with restless leg syndrome**.** Approximately 20 subjects will participate in wearing the 24-hour ambulatory blood pressure cuff.

## HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for the following amounts of time.

- There will be a total of 2 study visits in the Clinical Research Unit Visit 1 will last approximately 4.5 hours, and visit 2 will last approximately 4 hours

You may be eligible to come back for a third visit if you haven't completed all research-related interventions during one of the two scheduled visits.

The investigator and/or your doctor may decide to end your participation in the study, if in their judgment that it is in your best interest.

## WHAT WILL HAPPEN DURING THIS STUDY?

Study procedures will take place at the Clinical Research Unit at the University of Iowa Hospitals and Clinics (UIHC) located on the 2nd floor of Boyd Tower (2BT). Below is a detailed description of each study visit.

**Informed consent and screening (30 min):**

Informed Consent: You will read this informed consent to learn about the study and will have a chance to ask questions about the study. If you agree to participate in the study you will sign the informed consent. You must have received your spinal cord stimulation implant before you attend the first study visit. Also, if you agree to participate, you will receive instructions to turn off your SCS unit 48 hours prior to Visit #1 and #2. If you have a diagnosis of RLS and are currently taking medication for RLS symptoms you will be asked to discontinue your RLS medications 48 hours prior to the start of your study visits.

After Informed Consent is obtained, a member of the research team will ask questions to complete a data collection form for visit #1. Questions will include: What time did you turn off your SCS? What time was your last meal? When was the last time you exercised? Have you taken any over-the-counter medications in the last 48 hours? Have you had an illness in the last 2 weeks? Did you bring your morning medications with you?

If participating in wearing the 24-hour ambulatory blood pressure cuff, you will receive instructions to turn off your SCS unit for approximately 24 hours while wearing the blood pressure cuff (24 hours SCS on, 24 hours SCS unit off). If you have a diagnosis of RLS and are currently taking medication for RLS

symptoms you will be asked to discontinue your RLS medications while wearing the blood pressure cuff. After Informed Consent is obtained, a member of the research team will provide you with a diary to record time of activities, sleeping, any medications, and when the stimulator is activated and deactivated. This log will be returned to the Clinical Research Unit along with the blood pressure cuff.

**Please place your initials in the blank next to 'Yes' or 'No' for the question below:**

I would like to participate in the ambulatory blood pressure measurement:

_____Yes _____ No

**Visit #1 (4-4,5 hours):** 1st Study Visit at the CRU

***Arrival:*** You will arrive at the Clinical Research Unit at UIHC between 7-10am. Please adhere to the following criteria in preparation for your visit:

- Fast overnight for at least 8 hours (overnight) which means we want you to refrain from eating and drinking (no food or caffeine containing drinks) until you come in for your visit
- It is okay to drink 8 ounces of water prior to your visit
- Refrain from moderate or vigorous exercise for at least 24 hours
- Refrain from alcoholic beverages for at least 24 hours prior to your visit.
- If you take any morning medications, the research team asks you to not take them in the morning, but bring them with you to the study visit. You will be able to take your morning medications at the end of the visit.
- Please bring your current medications and/or a list of your current medications, including dosage and frequency, with you to the study visit.
- Please bring gym shorts or sweatpants to change into for the studies below. If you are scheduled to have DEXA scan done during your first visit, you will be asked to remove any metallic items on/from your body (jewelry, under wire bras, piercings that can be removed easily, etc.) If the items to be removed involve clothing, you will be allowed to change in a private restroom, and you will be given disposable shorts to be wear.
- Important: Females will undergo a urine pregnancy test. A negative test is required before proceeding with the study. If the pregnancy test is positive, you will no longer be eligible to continue with the study.
- If you consent to having audio/ video recordings and photographs done during the visit, they will done throughout the visit.

***Blood sample:*** You will be taken to a private exam room and asked to change into your gym shorts or sweatpants and lie down on an exam table with a pillow. A research nurse will insert a small IV catheter into a vein in your arm. After 20 minutes, the nurse will draw blood (about 6 tablespoons) for measurement of sugar, insulin, cholesterol, and catecholamines. Blood samples may also be taken from the catheter periodically during the study.

***Pulse wave velocity:*** A research staff member will place a blood pressure cuff around your upper arm and record your blood pressure 2-3 times. You will also have 3 electrocardiogram stickers placed on

your chest so we can monitor your heart rate and rhythm. We will then place a non-invasive tonometer probe on your wrist (radial artery), arm (brachial artery), neck (carotid artery), upper/inner thigh (femoral artery), and ankle (tibial artery) and record your pulse at these sites. We will then use a tape measure to measure the distance from you neck to your wrist, your neck to your arm, and your neck to your upper/inner thigh and ankle sites.

***Calf Blood Flow measurement***: You will lie on your back. You will have a blood pressure cuff placed around your upper thigh that will inflate and deflate periodically. You will also have a blood pressure cuff placed around your ankle. A rubber band-like device called a strain gauge will be placed around your calf which will measure changes in blood flow by sensing changes in leg volume.

***Blood Flow Measurement:*** Blood flow to the arm or leg may also be measured by placing a probe on the skin over the femoral artery of your leg or the brachial artery of your arm. This probe will provide a measure of the speed at which your blood is traveling through your artery and will allow for the calculation of blood flow.

***24-hour blood pressure monitor***: A small portable blood pressure monitor will be placed on you to wear at home for 24 hours. You will return it to the investigators when you come in for Visit 2 or make other arrangements with the research staff.

***Partial pressure of oxygen and carbon dioxide via recordings:*** Oxygen and carbon dioxide measures will be obtained continuously via monitors placed on both your chest and foot. This is a safe and non-invasive technique that is often used in neonatal units.

**Dual-energy X-ray absorptiometry *(DEXA) Scan:*** The test is completed once during either the first or second, visit. The purpose of this scan is to help determine body type, because this can influence blood flow. You will be asked to remove metal and/or reflective pieces. You will be asked to lie on your back on an open DEXA scan table and try to stay as still as possible while the scanner passes over your body. The scan generally takes 10-15 minutes.

You will be asked to turn off your SCS unit 48 hours prior to Visit #2. If you have a diagnosis of RLS and are currently taking medication for RLS symptoms you will be asked to discontinue your RLS medications 48 hours prior to the start of your study visits.

You may keep an image result from a DEXA scan if you wish but we will not provide interpretation of the findings. DEXA images for this study are not being used to evaluate your health and may not be useful for measuring bone density. The images obtained for this study are for specific research purposes and are not being used to find medical abnormalities. These images will not be reviewed by a physician to diagnose existing abnormalities.

**Visit #2 (4 -4,5 hours):** 2nd Study Visit at the CRU

A member of the research team will ask questions to complete a data collection form for visit #2. Questions will include: What time did you turn off your SCS? What time was your last meal? When was the last time you exercised? Have you taken any over-the-counter medications in the last 48 hours? Have

you had an illness in the last 2 weeks? Did you bring your morning medications with you?

***Arrival:*** You will arrive at the Clinical Research Unit at UIHC between 7-10am. Please adhere to the following criteria in preparation for your visit:

- Fast overnight for at least 8 hours (overnight) which means we want you to refrain from eating and drinking (no food or caffeine containing drinks) until your study visit
- It is ok to drink 8 ounces of water prior to your visit.
- Refrain from moderate or vigorous exercise for at least 24 hours
- Refrain from alcoholic beverages for at least 24 hours prior to your visit.
- If you take any morning medications, the research team asks you to not take them in the morning, but bring them with to the study visit. You will be able to take your morning medications at the end of the visit.

- Please bring gym shorts or sweatpants to change into for the studies below. . If you are scheduled to have DEXA scan done during your second visit, you will be asked to remove any metallic items on/from your body (jewelry, under wire bras, piercings that can be removed easily, etc.) If the items to be removed involve clothing, you will be allowed to change in a private restroom, and you will be given disposable shorts to be wear.
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  - Important: Females will undergo a urine pregnancy test. A negative test is required before proceeding with the study. If the pregnancy test is positive, you will no longer be eligible to continue with the study.
  - If you consent to having audio/ video recordings and photographs done during the visit, they will be done throughout the visit.

***Blood sample:*** You will be taken to a private exam room and asked to change into your gym shorts or sweatpants and lie down on an exam table with a pillow. A research nurse will insert a small IVcatheter into a vein in your arm. After 20 minutes, the nurse will draw blood (about 6 tablespoons) for measurement of blood sugar, insulin, cholesterol, and catecholamines. Blood samples may also be taken from the catheter periodically during the study.

***Calf Blood Flow measurement***: You will lie on your back. You will have a blood pressure cuff placed around your upper thigh that will inflate and deflate periodically. You will also have a blood pressure cuff around your ankle. A rubber band-like device called a strain gauge will be placed around your calf which will measure changes in blood flow by sensing changes in leg volume.

***Blood Flow Measurements:*** Blood flow to the arm or leg may also be measured by placing a probe on the skin over the femoral artery of your leg or the brachial artery of your arm. This probe will provide a measure of the speed at which your blood is traveling through your artery and will allow for the calculation of blood flow.

***Partial pressure of oxygen and carbon dioxide via recordings:*** Oxygen and carbon dioxide measures will be obtained continuously via monitors placed on both your chest and foot. This is a safe and non-invasive technique that is often used in neonatal units.

***Microneurography (sympathetic nervous system activity to leg muscles):*** We will measure your heart rate using an electrocardiogram. Your blood pressure will be monitored indirectly with an automatic cuff device on one of your fingers. We will measure the sympathetic nervous system activity to your leg muscles. A tiny microelectrode will be placed in a nerve in your right leg located just below your knee on the outer part of the leg. First, the course of the nerve will be determined by electrically stimulating through the skin with a pencil shaped electrode. When the nerve is stimulated, involuntary twitching and/or tingling sensations of the lower leg or foot will occur. The twitching or tingling will disappear when the stimulation is stopped. Once the nerve is found, two tiny, sterile, microelectrodes will be inserted through the skin. One is a reference electrode placed just above the nerve site (2 cm) and the other is the recording electrode. The recording electrode will be advanced into the nerve. When the tip of the electrode enters the nerve, you may briefly notice either pressure or tingling sensations in the leg or foot. At this point, minor adjustments in the position of the electrode will be made until we begin to record the nerve signals.

**Dual-energy X-ray absorptiometry *(DEXA) Scan:*** The test is completed once during the first or second visit. The purpose of this scan is to help determine body type, because this can influence blood flow. You will be asked to remove metal and/or reflective pieces. You will be asked to lie on your back on an open DEXA scan table and try to stay as still as possible while the scanner passes over your body. The scan generally takes 10-15 minutes.

You will be asked to turn off your SCS unit 48 hours prior to Visit #2. If you have a diagnosis of RLS and are currently taking medication for RLS symptoms you will be asked to discontinue your RLS medications 48 hours prior to the start of your study visits.

You may keep an image result from a DEXA scan if you wish but we will not provide interpretation of the findings. DEXA images for this study are not being used to evaluate your health and may not be useful for measuring bone density. The images obtained for this study are for specific research purposes and are not being used to find medical abnormalities. These images will not be reviewed by a physician to diagnose existing abnormalities.

**Blood/Data Storage for Future Use**

As part of this study, we are obtaining a blood sample from you. We would like to study your blood in the future, after this study is over.

The tests we might want to use to study your blood sample may not even exist at this time. Therefore we are asking your permission to store your blood sample so that we can study them in the future. These future studies may provide additional information that will be helpful in understanding RLS, but it is unlikely that what we learn from these studies will have a direct benefit to you. It is possible that your blood sample might be used to develop products or test that could be patented or licensed. There are no plans to provide financial compensation to you should this occur.

If you agree now to future use of your blood, but decide in the future that you would like to have it removed from future research, you should contact Dr. Marshall Holland 319-356-2771 or Dr. Gary Pierce at 319-335-9487. However, if some research with your blood has already been completed, the information from that research may still be used. You may still participate in the current research study without giving your permission to store samples for future use.

**Please place your initials in the blank next to 'Yes' or 'No' for the question below:**

My blood may be stored/shared for future research in RLS

_____Yes _____ No

**Future Studies**

We also plan future related studies. If you think you might want to be in one of our future studies, we would like to keep your name, address, phone number, and email address to contact you in the future for other studies that you may qualify for. However, participating in the current study does not obligate you to participate in one of our future studies. A separate Informed Consent Document for future studies would be required for you to review and sign before participation. **Please place your initials in the blank next to 'Yes' or 'No' for the question below:**

Would you like us to keep your information as described above for future studies?

_____ Yes _____ No

**Audio Recording/Video Recording/Photographs**

One aspect of this study involves making audio/ video recordings and taking photographs of you. The recordings and photographs will be used to make posters and give presentations regarding the research study to educate other health care workers. The audio/ video recordings and photographs will be used by the department of Neurosurgery for presentations. It is unknown at this time how long the department will use the media information for their presentations.

The audio/ videotaping and photographs are an optional part of the study. You can consent to being a part of the study and refuse to be photographed and having video and audio recordings made.

[ ] Yes [ ] No I give you permission to make audio/ video recordings and take photographs of me during this study.

## WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

There are no foreseeable emotional or psychological risks with this study. But there is risk of inadvertent disclosure of PHI which could cause emotional or psychological risk.

***Microneurography:*** The nerve recording procedure may cause the following side effects which rarely occur and last no more than a couple of minutes. The procedure may result in the leg muscles feeling tired, a pins-and-needles feeling, and may have a greater sensitivity to touch in the leg.

***Blood sample:*** A total of approximately 10 ½ tablespoons of blood will be obtained from a vein in your arm during the course of the study. Potential risks and discomforts associated with obtaining blood samples include slight bruising, pain, a temporary feeling of faintness, and rarely, infection at site of blood draw. All blood draws will be performed by a research nurse or research staff trained in drawing blood.

***Pulse wave velocity:*** There are no known risks associated with the use of a non-invasive pulse transducer for pulse wave velocity. ECG electrodes may cause minor irritation to the skin.

***Fasting for 8 hours:*** The most common risk when fasting is dehydration, therefore you will be encouraged to drink plenty of water. Subjects may experience hunger and irritability and if they experience fainting, nausea, or vomiting they will be instructed to stop fasting.

***24-hour ambulatory blood pressure monitoring****:* A member of the research team will fit the monitor properly before you leave and give you instructions about the monitor. It is recommended you wear the cuff under your clothing, even when sleeping to reduce the risk of becoming entangled in the tube or case strap. You may also experience some discomfort or be awakened by the cuff inflating. You could get a bruise, scratch, or reddened skin from the cuff when it inflates. You may remove the monitor and cuff if it becomes too uncomfortable or interferes with your activities or sleep or your notice any bruising or other physical harm.

**For RLS Subjects:** By not taking RLS medication for 48 hours prior to the study appointment may cause the return of RLS Symptoms which may include increase pain in legs and potential for difficulty to sleep.

Turning off your SCS for 48 hours: By having your SCS off prior to both of your visits, you may experience an increase amount of pain.

**RADIATION RISKS:**

The maximum amount of radiation from the research-related radiation procedures in this study is about equal to the average environmental radiation everyone experiences in 1 day. Although there are no proven harmful effects from this amount of radiation, long term effects on your health such as cancer cannot be ruled out with certainty. This dose estimate takes into account only the exposure to research procedures in this project. If you have participated in other research studies involving radiation exposure, you should be aware that the risk of effects from radiation is believed to increase with each exposure you receive (including studies performed as part of your medical care).

**Radiation Exposure in Women Capable of Becoming Pregnant**

You may not participate in this study if you are pregnant. If you are capable of becoming pregnant, we will perform a pregnancy test before each exposure to research-related radiation. You must tell us if you may have become pregnant within the previous 14 days because the pregnancy test is unreliable during that time.

## WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study. We hope that, in the future, other people might benefit from this study because we will be able to determine if using the SCS will increase blood flow to the lower limbs.

## WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

There will be no cost to you for being in this research study. You and/or your medical/hospital insurance carrier will remain responsible for your regular medical care expenses.

## WILL I BE PAID FOR PARTICIPATING?

You will be paid for being in this research study. You will need to provide your social security number (SSN) in order for us to pay you. You may choose to participate without being paid if you do not wish to provide your social security number (SSN) for this purpose. You may also need to provide your address if a check will be mailed to you. If your social security number is obtained for payment purposes only, it will not be retained for research purposes.

- Total compensation for visit 1 - $100
- Total compensation for visit 2 - $100
  If you complete both visit 1 and 2, you will be paid an additional $50 as a bonus

You will also receive parking and food vouchers for each of the two visits.
If participating in only wearing the 24-hour ambulatory blood pressure cuff, total compensation is $75. The blood pressure cuff must be returned before receiving compensation.

## WHO IS FUNDING THIS STUDY?

The University of Iowa is not receiving any payments to support the activities required to conduct the study.

## WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

- If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.
- The University of Iowa does not plan to provide free medical care or payment for treatment of any illness or injury resulting from this study unless it is the direct result of proven negligence by a University employee.
- If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

## WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,
- auditing departments of the University of Iowa, and
- The University of Iowa Institutional Review Board and the Clinical Research Unit protocol committee (the committees that review and approve research studies)

To help protect your confidentiality, we will do the following:

- All hard copies of records will not contain any personal identifiers but only an individual subject code.
- Papers will be kept in a folder to keep out of public view when transported from Clinical Research Unit to the research staff's office.
- All data folders will be kept in a folder and locked in a storage cabinet in research staff's office that is locked when they are not in the office.
- Signed informed consent documents will be kept in a separate folder in a different locked file cabinet in the research staff's office.
- Data will be entered into the web-based database application that is password protected and only research staff on the IRB approved study will be allowed access.
- Basic blood chemistries will be sent to the UIHC pathology lab for analysis. Remaining biological specimens such as blood, urine and DNA samples will be stored in the Principal Investigator's laboratory in a -80°C freezer. All samples will be labeled with date collected and subject ID code only. No personal identifiable information will be labeled on the sample. Only the PI and his research staff will have access to the samples.
- If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified. The DEXA scan report will be analyzed by the person conducting the procedure. Your personal information will be removed. The DEXA scan report will only contain your individual subject's code. One copy will be kept in a locked cabinet in the CRU unit, and a second copy will be stored in a locked cabinet with a study coordinator.

The University of Iowa Hospitals and Clinics generally requires that we document in your medical record chart that you are participating in this study. The information included in the chart will provide contact information for the research team as well as information about the risks associated with this study. This document is called the "Record of Consent." We will keep this "Informed Consent Document" that you sign today in our research files; it will not be placed in your medical record chart.

## WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires University of Iowa Health Care to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information

that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research study and for your treatment. Once University of Iowa Health Care has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff, National Institutes of Health, and the Federal Drug Administration. You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research-related. Your signature on this Consent Document authorizes University of Iowa Health Care to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to Dr. Marshall Holland, 200 Hawkins Drive, Neurosurgery Department, Iowa City, Iowa 52242. However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

## IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

### What if I Decide to Drop Out of the Study?

If you decide to leave the study early, we will ask you to call the study coordinator and inform them as soon as possible.

### Will I Receive New Information About the Study while Participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

## WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Dr. Marshall Holland 319-356-2771 or Dr. Gary L. Pierce 319-335-9487. If you experience a

research-related injury, please contact: **Dr. Marshall Holland 319-356-2771 or call 319-356-1616 and ask for pager #3020**

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

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This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed): _____

**Do not sign this form if today's date is on or after EXPIRATION DATE: 02/12/21.**

_____ _____
(Signature of Subject) (Date)

**Statement of Person Who Obtained Consent**

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)