Department of Veterans Affairs

VA RESEARCH CONSENT FORM

Subject Name: _____ **Date** _____

Title of Study: Peripheral nerve blocks for upper leg amputations

Principal Investigator: José R. Soberón, Jr., MD **VAMC:** North Florida/South Georgia Veterans Health System

UF Institutional Review Board
UNIVERSITY of FLORIDA

INFORMED CONSENT FORM
to Participate in Research

INTRODUCTION

Name of person seeking your consent:_____

Place of employment & position: NF/SG Veterans Health System / Staff Anesthesiologist

Please read this form which describes the study in some detail. A member of the research team will also describe this study to you and answer all of your questions. Your participation is entirely voluntary. If you choose to participate you can change your mind at any time and withdraw from the study. You will not be penalized in any way or lose any VA or other benefits to which you would otherwise be entitled if you choose not to participate in this study or to withdraw. If you have questions about your rights as a research subject, concerns, complaints, wish to discuss problems or talk to someone independent of the research staff, obtain information, or offer input, please call either of the following offices: (1) the University of Florida Institutional Review Board (IRB) office at (352) 273-9600; or (2) the North Florida/South Georgia Veteran's Health System Research Service Office at (352) 548-6069.

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GENERAL INFORMATION ABOUT THIS STUDY

1. Name of Participant ("Study Subject")

_____

For PI Use:

Participant Social Security Number: _____

SSN should be written on this consent form by the research team prior to scanning into the VHA health record; if the subject does not have a VHA health record, this requirement is N/A.

2. What is the Title of this research study?

Peripheral nerve blocks for upper leg amputations

3. Who can you call if you have questions, concerns, or complaints about this research study?

Principal Investigator: José R. Soberón, Jr, MD
Department of Anesthesiology
NF/SG Veterans Health System
1601 Archer Road
Gainesville, Florida 32608
Pager: (352) 413-2317

4. Who is paying for this research study?

The sponsor of this study is Veterans Administration

5. Why is this research study being done?

Agreeing to become involved in any research is always voluntary. By signing this form, you are not waiving any of your legal rights. If you decide not to participate in this research, you will not be penalized in any way and you will not lose any benefits to which you are entitled. If you have questions about your rights as a research subject,

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please call the University of Florida Institutional Review Board (IRB) office at (352) 273-9600 or the North Florida/South Georgia Veteran's Health System Research Service Office at (352) 548-6069.

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

The purpose of this research study is to evaluate the ability of peripheral nerve blocks in the leg to provide anesthesia for patients undergoing above-the-knee amputation or knee disarticulation. At the present time, this procedure is performed under general anesthesia, which may pose increased risks for this patient population. It is not known if these blocks could reliably be used to avoid general anesthesia. You will receive a follow-up phone call or visit 24-48 hours after surgery and your medical records will be reviewed 30 days after surgery. After that, you are no longer involved in the study.

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

A nerve block involves injecting numbing medications around nerves to numb the leg. An ultrasound machine is used to help see the needle and injection of numbing medicine. When an ultrasound machine is used during a block it is called an ultrasound-guided block.

You are being asked to be in this research study because you are scheduled to have an upper leg amputation. Nerve blocks will be performed in all four of the major nerves to the upper leg.

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

Risks of nerve blocks include bleeding, infection, and nerve damage. These are rare (<1%) and discomfort will be minimized by administration of sedative (relaxing) medication through your IV.

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

Potential benefits include avoidance of general anesthesia and its related side effects as well as improved pain control after surgery.

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

Participation in this study is completely voluntary. However, you will likely receive nerve blocks and intravenous sedation as well as general anesthesia for your surgery regardless of your decision to participate.

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.

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

WHAT CAN YOU EXPECT IF YOU PARTICIPATE IN THIS STUDY?

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

Normal clinical care is medical or other treatment or services that you would receive even if you did not participate in this research study. You may receive peripheral nerve blocks, intravenous sedation, or general anesthesia for your procedure regardless of whether or not you choose to participate in the study.

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

If you agree to be in this study, we will ask you to do the following things:

You will be given relaxing medication through the IV and asked to lay on your side. An injection of numbing medication will be made around the sciatic nerve and a nerve catheter will be placed. Once the sciatic block is completed, you will be asked to lay on your back and a similarly procedure will be performed on the femoral nerve (a nerve on the upper leg). One time injections will also be done to block the other two major nerves that go to the leg. The ultrasound machine will be used to direct the needle and where to inject the numbing medication.

Your surgery will be performed as per normal standard of care. Peripheral nerve block techniques, as well as general anesthesia, are currently in use at this facility.

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After the injections are complete, we will check your leg every 5-10 minutes to determine how numb it is before surgery. You will then go to the operating room and receive additional relaxing medication. General anesthesia will be administered if the block is not completely set up or if there is a medical emergency.

Medications given during surgery and in the recovery room will be recorded. After you arrive to the recovery room, we will ask about pain, nausea, and other side effects.

You will be called 24-48 hours after surgery to see if there were any complications with your procedure and to ask about your level of satisfaction with the care you received.

A pregnancy may be performed as part of normal clinical care before consenting for participation in the study.

The Principal Investigator listed in question 3 of this form and the research team conducting the research procedures described above will monitor how you do during the research. If you have any questions about the research procedures now or at any time during the study, please contact one of the research team members listed in question 3 of this form.

Once this research study is completed, any information that could identify you might be removed from any identifiable private information or identifiable biospecimens collected and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from you or your legally authorized representative.

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

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

After the follow-up phone call, your medical record will be reviewed in 30 days to determine your overall health status.

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

Up to 36people are expected to take part in this study.

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

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

The nerve block, intravenous sedation, and general anesthesia are commonly performed and acceptable techniques for patients undergoing surgery. Relaxing medication will be given through the IV to keep you comfortable at all times. Very rarely, pain or swelling may occur at the site of a nerve block. While peripheral nerve blocks have a long record of safety and efficacy, participants may experience the following: nerve damage, intravascular injection of local anesthetic, cardiac arrest, seizure, bleeding/hematoma, infection, pain at the injection site, or numbness or tingling (paresthesia). Complications with the blocks are very rare (<1%). Ineffective or failed blocks may require administration of analgesic agents or general anesthesia.

Researchers will take appropriate steps to protect any information they collect about you. However there is a slight risk that information about you could be revealed inappropriately or accidentally. Depending on the nature of the information such a release could upset or embarrass you, or possibly even affect your insurability or employability.

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

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

Throughout the study, the researchers will notify you of any new information that may become available and might affect your decision to remain in this study. This includes, but is not limited to, information that may affect your safety, well-being or medical care.

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

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

Avoiding general anesthesia, a breathing tube, and other anesthesia-related side effects are potential benefits of a nerve block. Patients undergoing upper leg amputations are generally considered to be at increased risk of anesthesia- and pain medication-related complications, so a nerve block and sedation may be safer than general anesthesia. Nerve blocks also help with pain control after surgery so you may require less pain medication and have fewer side effects.

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

This study will help future anesthesia providers decide which technique (nerve blocks or general anesthesia) is better for patients having upper leg amputations.

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

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

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

Nerve blocks, intravenous sedation, or general anesthesia will be administered whether you choose to participate in the study or not.

13a. Can you withdraw from this study?

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

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

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

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

If you withdraw from this study, your research information will no longer be collected. However, information that has already been collected will continue to be used to the extent that the researchers have used it in this research study.

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

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

- the study doctor thinks it necessary for your health or safety;
- you have not followed study instructions;
- the sponsor has stopped the study; or
- administrative reasons require your withdrawal.

WHAT ARE THE FINANCIAL ISSUES IF YOU PARTICIPATE?

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

There will be no costs to you for any procedure, treatment or testing done as part of this research study. However, medical care and services provided by the VA that are not being done only for this study (e.g., normal hospital and prescription expenses which are not part of the research study) will be charged to you or your insurance. These costs may not be charged if you are a veteran and you are being treated at the North Florida/South Georgia Veterans Health System (NF/SG VHS), however 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 VA-provided medical care and services that are not part of this study.

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

You will not be paid for taking part in this study.

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

If you experience an injury or illness as a result of your participation in this VA approved research study, all medical treatment considered necessary by your physician (emergency as well as medical treatment beyond emergency) will be

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provided by the VA. There will be no cost to you, unless you fail to follow the directions of the study procedures. Care will be provided at a VA medical facility unless the VA medical facility is not capable of providing the care. If this occurs, you will be treated by a private facility or physician and the VA will pay the private facility or physician for the reasonable cost of your care. In some cases the VA may approve private care for a non-veteran.

If you do not follow study procedures, you may be treated by the VA on the basis of your veteran's eligibility. If you are not a veteran and have not followed study procedures the VA can only provide limited care at your expense.

No additional money has been set aside for pain, suffering or any money losses you may suffer during your treatment. You have not waived any legal rights by signing this form.

In the event of a research-related injury, have questions about any discomforts that you experience while participating in this study or if you experience an adverse reaction, please immediately contact the Principal Investigator listed in question 3 of this form during the day and 786-247-2749 after business hours. If you seek emergency hospitalization in a private hospital because you are unable to come to the VA, have a family or friend contact your study doctor so that the VA can coordinate care with the private hospital.

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

Information collected about you will be stored in locked filing cabinets or in computers with security passwords. Only certain people have the legal right to review these research records, and they will protect the secrecy (confidentiality) of these records as much as the law allows. These people include the researchers for this study, certain University of Florida officials, the hospital or clinic (if any) involved in this research, and the Institutional Review Board (IRB; an IRB is a group of people who are responsible for looking after the rights and welfare of people taking part in research). Certain federal agencies such as the Office for Human Research Protections (OHRP), the VA Office of Research Oversight (ORO), or the VA Office of the Inspector General (OIG), that oversee human subject research may also have the legal right to review your records. Otherwise your research records will not be released without your permission unless required by law or a court order.

Researchers will take appropriate steps to protect any information they collect about you. However there is a slight risk that information about you could be revealed

inappropriately or accidentally. Depending on the nature of the information such a release could upset or embarrass you, or possibly even affect your insurability or employability.

If the results of this research are published or presented at scientific meetings, your identity will not be disclosed.

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SIGNATURES

As an investigator or the investigator's representative, I have explained to the participant the purpose, the procedures, the possible benefits, and the risks of this research study; the alternatives to being in the study; and how privacy will be protected:

_____ _____

Signature of Person Obtaining Consent Date

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

You voluntarily agree to participate in this study. By signing this form, you are not waiving any of your legal rights.

_____ _____

Signature of Person Consenting Date