HOSPITAL FOR SPECIAL SURGERY
535 East 70th Street
New York, NY 10021

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

TITLE: Spinal Versus General Anesthesia with Popliteal and Adductor Canal Blocks for Ambulatory Foot and Ankle Surgery. A Double-Blinded Randomized Controlled Trial.

PROTOCOL NO.: 2016-0499

SPONSOR: Department of Anesthesiology

INVESTIGATOR: Jacques YaDeau, MD

SITE(S): Hospital for Special Surgery

STUDY-RELATED PHONE NUMBER(S): Dr. Jacques YaDeau, (212) 606-1206

IRB #: 2016-0499

You are being asked to take part in a research study conducted by Hospital for Special Surgery (HSS). You are being asked to participate in this study because you are undergoing ambulatory foot and ankle surgery with Dr. Ellis, Levine or Roberts, and your surgeon thinks that nerve blocks for pain relief after surgery are a good idea for you.

You will still be responsible for the cost of your medical care just as you would be if you were not part of this study. For example, any co-pays, deductibles, and co-insurance associated with your medical care.

This document provides you with information about this study. After reading this document, any questions you may have will be answered. You may take as much time as you need to review this document and ask questions to consider participating in this study before your surgery today.

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.

1. WHY IS THIS STUDY BEING DONE?

The purpose of this study is to determine if there is a difference in patient outcomes with general versus spinal anesthesia when given in addition to the popliteal and adductor canal nerve blocks you will receive for your surgery today. Popliteal and adductor canal nerve blocks are injections

of local anesthetic agents near nerves in the back and front of the knee going to the foot and ankle that provide numbness during and after surgery. These peripheral nerve blocks offer good pain control and reduce the need for opioids (opioids are pain medications such as morphine, Dilaudid, and oxycodone). General anesthesia involves the flow of oxygen and anesthesia gas through a tube which, along with additional intravenous medications, causes unconsciousness and unawareness of sensations during surgery. Spinal anesthesia involves an injection of local anesthetic in the lower back, which causes numbness below the waist. In addition to spinal anesthesia, a sedative is typically given intravenously to cause relaxation and sleepiness throughout surgery.

General, spinal, and nerve block anesthesia are all routinely used for surgery at the Hospital for Special Surgery. General or spinal anesthesia is typically used in addition to peripheral nerve blocks during foot and ankle surgery to 1) allow the surgeons to use a thigh tourniquet to reduce bleeding, 2) provide anesthesia earlier, and 3) prevent unwanted movement. However, it is unclear whether general or spinal anesthesia provides better patient outcomes when given with peripheral nerve blocks. Some reports show that on its own, spinal anesthesia has advantages over general anesthesia in terms of side effects such as nausea and pain. However, these advantages may also be gained from combining peripheral nerve blocks with general anesthesia. A previous study at the Hospital for Special Surgery showed low rates of nausea among patients who received nerve blocks with spinal anesthesia, and no nausea among patients who received a nerve block with general anesthesia. Therefore, the primary aim of this study is to determine if, as a treatment, either general or spinal anesthesia has advantages over the other treatment in terms of side effects, pain, patient satisfaction, and time it takes to leave the hospital in an ambulatory foot and ankle population.

2. WHAT WILL YOUR PARTICIPATION REQUIRE?

Participation in this study will not involve any additional visits to the hospital. If you decide to be in this study, the following routine and/or study-related procedures will be performed:

Study Visit #	Surveys / Questionnaires	Randomization	Surgery	Phone Contacts
#1 – Holding area, before surgery	X	X	SOC	
#2 – In recovery room, every 15 minutes until discharge	X			
#3 – In recovery room, 1 hour after surgery	X			
#4 – In recovery room, 2 hours after surgery	X			
#5 – Postoperative Day 1	X			X
#6 - Anesthesiologist Follow-Up (if needed)				X

X= Research procedures
SOC= Standard of care (care you would receive if you were not participating in this study)

Before surgery

In the holding area, you will be asked a series of questions to rate how you are feeling and assess your cognitive function (ability to perform tasks with your brain). You will be asked about your medication usage and history of headache/backache symptoms. An alcohol swab will be applied to both sides of your lower leg and between your first and second toes to check nerve function. A brief review of your medical chart will be conducted to collect basic information, such as age, sex, height, and weight.

During surgery

All patients will receive popliteal and adductor canal blocks, but the study will select the rest of your anesthetic treatment randomly. You will be assigned by chance to receive either **general anesthesia or spinal anesthesia**. The randomization process is comparable to (or similar to) the flip of a coin.

You have a 50% chance of receiving either of the following treatments:

1. Popliteal and adductor canal nerve blocks with standard of care **general anesthesia**
2. Popliteal and adductor canal nerve blocks with standard of care **spinal anesthesia** and sedation

If you have a preference for one of the treatments and would like to be sure to receive that treatment, you should not be enrolled in the study.

In order to fairly evaluate the two treatments, both you and the study personnel assessing you will be blinded as to which anesthetic you were given. This means you will not be told whether you received general or spinal anesthesia. If you are interested, we can contact you with the results and your treatment information when the study ends.

Please note that you will also receive other anesthetic drugs intravenously throughout the surgical procedure. These drugs will be the same regardless of whether you receive general or spinal anesthesia. During surgery, medications will be given to reduce the chance of nausea after the surgery.

After surgery

Once you are in the recovery room and your surgery is over, a study team member who does not know which treatment you received will assess your condition every 15 minutes to follow your rate of recovery. When you awake from general anesthesia or the spinal anesthesia wears off, the alcohol swab test will be applied again to test block function (by seeing if the nerve blocks made parts of the operative foot numb). After one and two hours in the recovery room, you will be

asked a series of questions to rate how you are feeling and assess your cognitive function. When you are ready to be discharged, we will ask some additional questions about your experience, satisfaction and which treatment you think you received. We will provide you with a Patient Information Sheet with information regarding the next day's follow-up.

Day after surgery

On the day after your surgery, you will be contacted by phone by a study team member and asked about how you are feeling, your cognitive function, any side effects that you may have experienced, and your overall satisfaction with your care. If it is determined that you may have had any symptoms of concern, you will be contacted by an anesthesiologist for follow-up.

Overall, your participation will occur over the course of your stay in the hospital and the day after. It may involve up to 6 study contacts, including the assessment of your condition every 15 minutes in the recovery room and any follow-ups deemed necessary by an anesthesiologist. The repeated assessment every 15 minutes is expected to last 1-2 minutes, and all other contacts are expected to last 10-15 minutes.

You and/or your insurance will be responsible for any costs of all procedures performed that are standard of care, that is, care that you would receive even if you were not in this study.

A total of 36 subjects will participate in this study at HSS.

3. WHAT ADVERSE (BAD) EFFECTS CAN HAPPEN FROM BEING IN THE STUDY? WHAT RISKS ARE KNOWN ABOUT THE STUDY DRUG/STUDY DEVICE?

All treatments applied to you as a participant in this study are standard of care. The risks from participation in this study and receiving the peripheral nerve blocks for pain relief after the surgery are the same risks you would face with your surgical anesthesia if you did not participate in this study. These risks will be discussed in detail with you by your anesthesiologist and are described below.

In addition to the nerve blocks, you need either a general anesthetic or a spinal anesthetic. The study involves randomly assigning you to receive either spinal or general anesthesia. Both spinal and general anesthesia are commonly used at HSS, as well as at other hospitals. Both spinal and general anesthesia are considered safe and effective. It is not clear whether spinal or general anesthesia is safer for patients such as yourself.

There are potential rare serious complications from both types of anesthesia. Potential rare risks of general anesthesia include problems with the heart, lungs, and cognition (thinking) after surgery. These complications may be more likely with older patients. Potential rare risks of spinal anesthesia include spinal cord injury. Older patients are more likely to have conditions that increase the risk of spinal cord injury. Most patients having spinal anesthesia for foot and ankle surgery receive intravenous sedation, so that they are 'asleep' during surgery. Sedation has

potential rare serious complications such as problems with the lungs and cognition (thinking) after surgery.

There are less serious potential risks from general anesthesia and spinal anesthesia. It is possible that patients receiving general anesthesia will be more likely to have a sore throat from the tube used to keep the airway open (a laryngeal mask airway will be used if possible). Some studies suggest that nausea and vomiting are more likely with general anesthesia (but a recent study at HSS showed no nausea after general anesthesia). It is possible to have a headache or backache after spinal anesthesia, but most headaches and backaches after surgery are not from the anesthetic. If you experience prolonged numbness from the spinal, this may cause a longer stay in the hospital, but this possible delay is in terms of hours. We will attempt to avoid prolonged numbness from the spinal by choosing an appropriate amount of local anesthetic.

Participation in this research involves the potential risk of a breach of confidentiality to your stored health information. HSS tries to minimize those risks by (i) removing some direct identifiers from stored information (i.e., names, social security numbers, medical record numbers); (ii) securing, in a separate location, and limiting access to information that would identify you; and (iii) limiting access to information stored to HSS investigators.

There may be risks or side effects that are unknown at this time. If we learn about new risks that may affect your willingness to continue your participation, we will make you aware of them and you will be asked to re-consent to continue your participate in the study.

4. WHAT BENEFIT CAN YOU EXPECT?

This study is comparing two standard of care procedures to determine which may be more effective. The knowledge gained from this study may benefit others in the future.

5. COST

Those research procedures (i.e. study questionnaires) listed in Section 2 will be covered by the study and will not be your financial responsibility.

As indicated in Section 2, those costs which are considered Standard of Care for your treatment here at Hospital for Special Surgery will be your/or your insurance's responsibility. You will be responsible for any co-pays, deductibles, and co-insurance associated with your medical care, just as you would be for any costs billed to your health insurance outside of this study. You will also be financially responsible for any medical care costs not covered by your health insurance.

HSS is committed to providing financial assistance when financially warranted and consistent with its resources, regardless of age, gender, religion, race or sexual orientation. So if you do not have health insurance, or if your health insurance does not pay for your medical care, you may seek financial assistance from HSS. Eligibility determinations are made on a case-by-case basis

in accordance with HSS's financial assistance policy. You will be responsible for any costs not covered by financial assistance, which could be all of the costs (if HSS determines that you are not eligible for financial assistance) or some of the costs (if financial assistance awarded by HSS does not cover all of the costs). For more information about the Financial Assistance Program or to request a Financial Assistance Application call (212) 606-1505 to speak with a Financial Assistance Counselor or you can visit the following site: http://www.hss.edu/patient-financial-assistance-notice.asp.

6. PREGNANCY

Due to inherent risks, HSS policy prevents pregnant women from receiving the type of intervention needed to qualify for this research study. Therefore, women who are pregnant or nursing a child may not participate in this study. You must confirm that, to the best of your knowledge, you are not now pregnant, and that you do not intend to become pregnant. If you suspect that you have become pregnant during this study, you must notify the study doctor immediately.

7. PAYMENT FOR PARTICIPATION

You will not be paid for your participation in this study.

8. COMMERCIAL ISSUES: YOUR RIGHTS IN THE RESULTS OF THE STUDY

There are no plans to compensate you for the use of the findings of this study, or any of the information or biologic materials (such as blood or tissue) collected from you during the study, even if they are used to develop or make a commercial product (such as a drug, device, biologic substance, or test).

9. ALTERNATIVES: WHAT OTHER TREATMENT IS AVAILABLE IF YOU DON'T WANT TO BE IN THE STUDY?

You do not have to participate in this study to receive treatment for your condition.

Your participation in the study is voluntary, and if you decide not to participate in the study you will receive the standard of care anesthesia including peripheral nerve blocks, and spinal or general anesthesia based on your medical condition and your preference.

10. WHO WILL BE ABLE TO SEE YOUR RECORDS AND PERSONAL INFORMATION AND KNOW THAT YOU ARE IN THE STUDY?

Federal regulations give you certain rights related to your health information. These include the right to know who will be able to see your information and why they will be able to see it. The study doctor must obtain your authorization (permission) to use or give out any health information that might identify you.

What information may be used or given to others?

If you choose to be in the study, the study doctor will get personal information about you. The information might identify you. The study doctor may also get information about your health including:

- Medical and research records
- Records about phone calls
- Records about your study visits
- Records of physical exams
- Laboratory, x-ray, and other test results
- Questionnaires
- Records about any study device you received

Who may use, disclose, or receive my information?

The following person(s) class(es) of persons, and/or organization(s) may use, disclose, or receive my information:

- The Principal Investigator and other Investigators for this study, including your study doctor.
- The research coordinator, research nurses, and other members of the HSS research team working on this study.
- Every research site for this study, including Hospital for Special Surgery and its affiliates, New York-Presbyterian Hospital, and Memorial Sloan-Kettering Cancer Center. This includes the research staff and medical staff at each institution.
- The Patient Advocate or Research Ombudsman at these institutions.
- Staff members of HSS responsible for administering clinical trials and other research activities
- Any laboratories and other individuals and organizations that analyze your health information for this study.
- Any health care provider that you have used in the past or may use up to the time this study ends.
- The sponsor of this study. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor.
- Any Contract Research Organization (CRO) the sponsor may use. (A CRO is an independent entity with which a research sponsor contracts to oversee and facilitate various aspects of the clinical research process on the research sponsor's behalf.)
- The United States Food and Drug Administration (FDA), the federal Office for Human Research Protections (OHRP), any federal agency that provides support for this study, and

any federal, state, or local agency responsible for overseeing HSS, the study doctor, or any other member of the HSS research team involved in this study.

- The members and staff of the affiliated Institutional Review Boards (IRBs) at HSS, New York-Presbyterian Hospital, and Memorial Sloan-Kettering Cancer Center. An IRB is a committee of health care providers, community representatives, and others that initially approves and periodically reviews biomedical and behavioral research that involves human subjects in order to protect the rights, safety and welfare of study participants.
- Data Safety Monitoring Boards and others authorized to monitor the conduct of this study for safety or quality assurance, for example a Clinical Events Committee.

Why will this information be used and/or given to others?

Your health information may be given to others to carry out this study. The sponsor will analyze and evaluate the results of this study. People working for the sponsor also visit HSS and other research sites to make sure this study is being done correctly.

Your health information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can get approval to market new products resulting from this study. Your information may also be used to meet the reporting requirements of governmental agencies.

The results of this study may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

What if I decide not to give permission to use and give out my health information?

By signing this informed consent form, you are giving permission to use and give out your health information as described above. If you refuse to give permission, you cannot be in this study.

May I review or copy the information obtained from me or created about me?

You have the right, in accordance with Hospital policy and applicable law, to review and copy your health information that is created or obtained in the course of this study. However, if you decide to be in this study and sign this informed consent form, you will not be able to look at or copy your information until after the study is completed if doing so would impact the validity of the study (for example, if the study is "blinded" so that during the study you will not know what treatment or other intervention you are receiving).

May I revoke (take back) my permission?

Yes. Your permission will never expire unless you revoke it. To revoke your permission, you must write to the study doctor at Hospital for Special Surgery, 535 East 70th Street, New York, NY 10021.

You may revoke your permission to use and disclose your health information at any time. If you revoke your permission, you cannot continue to participate in this study.

After you revoke your permission, no new health information that might identify you will be gathered. Information that has already been gathered may still be used and given to others. This would be done if the information is needed for this study to be reliable.

Is my health information protected after it has been given to others?

Some persons who receive your health information may not be required to protect it, and they may share your information with others without your permission, if permitted by laws governing them. Therefore, there is a risk that your information will be released to others without your permission.

11. CONFLICT OF INTEREST NOTIFICATION

HSS is concerned about possible conflicts of interest in research, and has policies that require all investigators and senior research staff to report to HSS significant financial interests (such as stock ownership, royalty payments, and consulting agreements) and relationships (such as membership on a scientific advisory board) that are related to their research studies. When an investigator reports a significant financial interest or relationship that relates to one of his/her studies, HSS's Conflict of Interest Committee for Research reviews the information to evaluate the risk that the interest or relationship might influence how the investigator conducts the study or interprets the results of the study. HSS may also take steps to minimize that risk.

☒ The Conflict of Interest Committee for Research has determined that there are no conflicts of interest associated with this study.

☐ The Conflict of Interest Committee for Research has determined that there is a potential conflict of interest associated with this study. Please read the information below carefully.

12. VOLUNTARY PARTICIPATION/WITHDRAWAL

Your decision to take part in this study is completely voluntary. You are free to choose not to take part in the study and may change your mind and withdraw at any time. Your relationship with physicians at HSS and your medical care at HSS, now or in the future, will not be affected in any way if you withdraw or refuse to participate. You will not lose any benefits to which you are otherwise entitled.

The study doctor and/or the sponsor may terminate your participation in this study at any time without your consent if, in their judgment, it is inadvisable for you to continue.

13. COMPENSATION FOR INJURY

If you are injured as a result of participating in this study, the study doctor, other members of the research team, or other HSS professional medical staff will provide you with emergency medical treatment (or arrange to have such treatment provided to you), and will assist you in obtaining appropriate follow-up medical treatment. However, there is no plan to routinely provide compensation for additional medical care or other costs.

Your health insurance may or may not pay for treatment of injuries as a result of your participation in this study.

14. SOURCE OF FUNDING

Funding for this study will be provided by the Department of Anesthesiology at the Hospital for Special Surgery.

15. QUESTIONS

If you have any additional questions later on, or if you wish to report a medical problem that may be related to this study, Dr. Jacques YaDeau can be reached at 212-606-1206 during office hours.

If you have any questions about your rights as a participant in this study or any questions about your participation that you would like to ask an institutional representative who is not part of this study, you can call the Manager of the HSS Institutional Review Board at (212) 774-7154.

If you would like to have more information about the Hospital's financial disclosure review process in general, or in regard to this study, you may contact the Hospital's Office of Legal Affairs at (212) 606-1592. You may also ask the Hospital's patient advocate at (212) 774-2403, to arrange for you to have this information.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Agreement to Participate: Witnessing and Signature

To be in this study, you or your legal representative must sign the next page of this informed consent form. By signing the next page, you are voluntarily agreeing to be in this study at HSS.

Before signing, you should be sure of the following:

- You have read all of the information in this "Informed Consent to Participate in Research" form (or had it read to you).
- You have discussed the implications of your being in this study with your doctor, your study doctor and/or the study coordinator.
- You have had the chance to ask questions about this study.
- You received answers to your questions.
- If you did not understand any of the answers, you asked the study doctor or the study coordinator to explain them to you.
- The information given to you is based on what is now known about the study drug(s), device(s), or procedure(s). There may be other risks or complications that are not known at this time.
- You have had time to think about the information and decide whether or not to be in the study.

Please check one of the following:

☐ I AM NOT in another research study at this time.

☐ I AM in another research study at this time.

If you decide to be in this study:

- You are expected to follow the study procedures.
- You are expected to provide the information needed by the study doctor, the study coordinator, nurses, or other staff members for the study.
- You will be told in a timely manner of any significant new information that may affect your willingness to stay in the study.
- You may freely choose to stop being in the study at any time.

By signing below, you are voluntarily agreeing to be in this study.

You must be given a signed copy of this informed consent form to keep for yourself.

_____	_____	
Print Name of Participant	Signature of Participant	Date
_____	_____	
Print Name of Parent/Legal Guardian (if applicable)[1]	Signature of Parent/Legal Guardian	Date
_____	_____	
Print Name of Person Obtaining Consent	Signature of Person Obtaining Consent	Date

_____
As an HSS representative, please sign here to indicate that you have given a signed copy of this informed consent form to the participant

<u>NOTE TO INVESTIGATORS</u>:

- **THE ORIGINAL OF THIS INFORMED CONSENT FORM MUST BE PLACED IN THE PARTICIPANT'S STUDY FILE.**
- **A SIGNED COPY OF THIS INFORMED CONSENT FORM MUST BE GIVEN TO THE PARTICIPANT.**
- **A COPY OF THE INFORMED CONSENT FORM MUST BE PLACED IN THE PARTICIPANT'S HOSPITAL MEDICAL RECORD IF THE PARTICIPANT IS (OR WILL BE) HOSPITALIZED AT ANY TIME DURING THE STUDY**.

[1] The parent or legal guardian of a child participant should sign this form on behalf of the child. The signature of one parent is sufficient when the research is of minimal risk to the child, or when the research presents the prospect of direct benefit to the child. The signature of both parents is required when the research involves greater than minimal risk with no prospect of direct benefit to the child. The requirements for signature of both parents may be waived if one parent is deceased, unknown, incompetent, or not reasonably available, or when one parent has sole legal responsibility for the care and custody of the child. If the participant is a child who is capable of giving assent, the child should also sign the attached Assent Form.