Consent Form Cover Sheet

Study Name: Pericapsular Nerve Group Block for Arthroscopic Hip Surgery: A randomized, placebo-controlled trial
Brief Title: PENG Block for Arthroscopic Hip Surgery
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UVA IRB ID: HSR200214
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Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Participant's Name_____ Medical Record #_____

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a copy of this form.

Who is funding this study?

This study is being funded by the Department of Anesthesiology at the University of Virginia.

Key Information About This Research Study

Principal Investigator:	Peter Amato, MD University of Virginia Department of Anesthesiology, PO Box 800710, Charlottesville VA 22908 Telephone: (434) 806-8266
Funding Source:	Internal funding from the Department of Anesthesiology at the University of Virginia.

You are being asked to take part in a research study. You do not have to take part in this study. You should only agree to take part in this study after reading this consent form and discussing it with the study team. You may also discuss this with your family, friends, health care providers or others before you make a decision.

What problem is this study trying to solve?

Hip arthroscopy is a minimally invasive procedure in which an orthopedic surgeon uses a special scope to visualize and examine the inside of the hip joint. This procedure allows the surgeon to diagnose the cause of hip pain or other problems in your joint. This procedure can, however, be painful.

The purpose of this study is to evaluate the difference in pain relief following hip arthroscopy when a nerve block is either provided before surgery or is not provided before surgery.

The current practice at UVA is to give you a combination of oral and IV pain medicine for your pain following surgery. Nerve blocks prior to surgery are not considered standard of practice at UVA.

Researchers are evaluating a type of nerve block called ultrasound-guided peripheral nerve block or Pericapsular Nerve Group (PENG) block. This newer block uses a Food and Drug Administration (FDA) approved drug called Ropivacaine. We want to see if this nerve block given prior to surgery can help with your pain after the surgery.

Why would you want to take part in this study?
You might like to take part in this study because this nerve block could help with your pain after surgery if you are assigned to that study group.

Why would you NOT want to take part in this study?
You might not want to take part in this study because you do not wish to receive a nerve block prior to surgery.

What will I have to do if I take part in this study?
Full details of all the procedures are found later in this form.
If you take part in this study the following will happen:

- Right before your surgery you will be randomized (like the flip of a coin) to either receive the hip nerve block or not. Neither you nor your surgeon will know whether you received the nerve block prior to surgery or not.
- After surgery we will check your pain and see how satisfied you are with your care.
- Once you leave to go home, we will call you for the next two days, and then at 1 week. At these times, we will ask you to rate your level of pain and ask how much pain medicine you are taking.
- Following the week 1 telephone call, your participation in the study will be complete.

What is the difference between being in this study and getting usual care?
If you take part in this study, the following things will be done differently than if you do not take part in this study.

- By participating in this study, you may or may not receive a nerve block prior to surgery. At UVA, the standard of practice is to give you a combination of oral and IV pain medicine for your pain following surgery. Nerve blocks prior to surgery are not considered standard of practice.

NOTE: You will sign a separate hospital consent for your hip surgery that will explain the procedure and the risks involved.

What other treatments may I receive if I decide to not take part in this study?
The following alternative treatments are available to you if you decide not take part in this study:

- You will receive regular care whether you choose to participate in this study or not. The only difference is that you will not receive a nerve block outside the study.

You are being asked to be in this study because you are having arthroscopic hip surgery as part of your clinical care.

Up to 70 people will be in this study at UVA.

How long will this study take?

Your participation in this study will require additional phone contacts after your surgery, which should not take more than 10 minutes each on four separate occasions.

What will happen if you are in the study?

SCREENING:

A member of the study team will review your medical history to make sure you are eligible to participate. If you are eligible to participate, you will be asked to review the consent, ask questions and if agree, sign the consent before any study related procedures take place. This visit will be done during your pre-surgery consultation with your surgeon.

RANDOMIZATION and STUDY PROCEDURES
Day of Surgery:

You will be randomly assigned (like the flip of a coin) to 1 of 2 study groups. You have an equal chance of being assigned to either of the groups. Neither you nor your study doctor/surgeon can choose which group you are assigned. Your assignment will not be revealed until the study is done. But if your study doctor/surgeon needs to know, the people doing this study can find out.

GROUP 1: Ultrasound-guided hip nerve block with 0.5% Ropivacaine. Ropivacaine is approved by the Food and Drug Administration as a drug used for a nerve block.

GROUP 2: Sham hip nerve block: small volume of salt water injected just under the skin that does not contain any active medication

Prior to surgery, regardless of which group you are assigned, you will receive pain medicine by mouth, a combination of narcotic and non-narcotic medicines, which is standard of practice for this surgery. Your surgeon will discuss these medications as part of your preparation for surgery.

Regardless of which group you are assigned, you will receive IV (intravenous-through a needle in your arm) pain medicines and IV anti-nausea medicines during surgery before you wake up.
Once the surgery is finished, you will be taken to the recovery room and when you are awake the nurse will ask about how much pain you are experiencing and give you pain medicines should you need it.
You will be contacted via telephone the first day, the second day, and one week following surgery. At this time, investigators will ask you about your pain and how much pain medicine you are taking.

END OF STUDY:

After you have completed the post-operative week 1 telephone visit, your participation in the study is complete.

If you want to know about the results before the study is done:

The study leader, Dr. Amato, will let you know of any information that may be important to your health. In addition, as the research moves forward, your study leader will keep you informed of any new findings that may be important for your health or may help you decide if you want to continue in the study. The final results of the research will not be known until all the information from everyone is combined and reviewed. At that time, you can ask for more information about the study results.

What are the risks of being in this study?

Risks and side effects related to the nerve block procedure with Ropivacaine includes:

Likely

- Stress prior to receiving the nerve block

Less Likely

- Discomfort during the administration of the nerve block

Rare but serious

- An overdose of Ropivacaine which may present as ringing in the ears, numbness around the mouth, and in extreme cases seizures. You will be carefully monitored throughout the course of the procedure.
- Damage to nerves, which may result in prolonged numbness and/or tingling in the region
- Damage to adjacent structures near the nerve, which may include blood vessels

Other unexpected risks:
You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Could you be helped by being in this study?

You may or may not benefit from being in this study. Possible benefits include: receiving a preoperative hip nerve block that may provide additional pain control after surgery**.** In addition, information researchers get from this study may help others in the future.

What are your other choices if you do not join this study?

You do not have to be in this study to be treated following your surgery. You can get the usual treatment even if you choose not to be in this study. The usual treatment would include:

- Standard pain medicines by mouth and through your IV. Nerve blocks prior to surgery are not considered standard of practice.

If you are an employee of UVA, your job will not be affected if you decide not to participate in this study. If you are a student at UVA, your grades will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?

You will not get any money for being in this study.

Will being in this study cost you any money?

The following procedures/tests, which are being done for research purposes, will be provided at no cost to you or your health insurance: sham block. If you are randomized to receive the nerve block with Ropivacaine, you or your insurance company will be responsible for the cost of the Ropivacaine as well as the cost of the administration.

You and/or your insurance company must pay for any tests or care given beyond what is required in this study. In addition, you and/or your health insurance may also have to pay for other drugs or treatments that are given to help you control any side effects. You will have to pay for any costs not covered by your health plan. You may be responsible for any co-payments or deductibles. You may wish to ask your insurance company for an estimate of what these costs might be or if pre-approval is required.

What if you are hurt in this study?

You do not give up any legal rights, such as seeking compensation for injury, by signing this form. If you feel you have been injured as a result of this study, you may contact the Principal Investigator or the IRB (phone numbers are located near the end of this form). If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The

charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover.

What happens if you leave the study early?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader can take you out of the study.
If you decide to stop being in the study, we will ask you to contact a researcher to let them know either before the day of your scheduled surgery or the day of your scheduled surgery before you receive any medication.

How will your personal information be shared?

The UVA researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address and date of birth
- Social Security number ONLY IF you are being paid to be in this study
- Your health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly
- The sponsor(s) of this study, and the people or groups it hires to help perform or review this research
- Insurance companies or other organizations that may need the information in order to pay your medical bills or other costs of your participation in the study
- Tax reporting offices (if you are paid for being in the study)
- People who evaluate study results, which can include sponsors and other companies that make the drug or device being studied, researchers at other sites conducting the same study, and government agencies that provide oversight such as the Food and Drug Administration (FDA) if the study is regulated by the FDA.

- If you tell us that someone is hurting you, or that you might hurt yourself or someone else, the law may require us to let people in authority know so they can protect you and others.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

A description of this clinical trial will be available on *http:// www.ClinicalTrials.gov,* as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form or complete the "Leaving the Study Early" part of this form and return it to the researchers. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

Please contact the Principal Investigator listed earlier in this form to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator/Study Leader:
Peter Amato, MD
University of Virginia
Department of Anesthesiology,
PO Box 800710, Charlottesville VA 22908 Telephone: (434) 806-8266

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22908 Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

You may also report a concern anonymously by calling the UVA Compliance Hotline phone number at 1-800-235-8700.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

Consent from Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Notification of My Health Care Provider

Your health care provider will be notified of your participation in this study.

Leaving the Study Early

Signatures should be obtained in this section if the subject decides to leave the study early.

If you leave the study early, the study leader will ask if you agree to keep the data collected about you up until the time you leave the study to help determine the results of the study. Please indicate with your initials below:

_____ Yes, the study team may continue to collect study related information from my medical record after I leave the study.

_____ No, the study team MAY NOT collect any study related information about me after I leave the study.

Consent from Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

Person Obtaining Consent

By signing below, you confirm that you have fully explained the implications of withdrawing from the study to the subject and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT(PRINT)	DATE