NCT07146685

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_____

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 University of Virginia.

Key Information About This Research Study

Principal Investigator:	Leon Grinman, DO University of Virginia 1215 Lee Street Charlottesville, VA 22908

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 is the purpose of this study?

The purpose of this study is to learn if the amount of a numbing medicine called bupivacaine affects how much pain people feel after shoulder replacement surgery. Sometimes, when a nerve block wears off, people feel a short period of stronger pain called "rebound pain."

Doctors at UVA already use two common strengths of this medicine: 0.25% and 0.5%. Both are safe and used often. We want to know if the lower strength (0.25%) causes less rebound pain than the higher strength (0.5%). This information may help doctors manage pain better after surgery.

You are being asked to join this study because you are having shoulder replacement surgery at UVA and may receive a nerve block to help control pain.

Why would you want to take part in this study?

You will not be helped by being in this study, but the information gained by doing this study may help others in the future.

Why would you NOT want to take part in this study?

You might not want to take part in this study because:

- You might not want your treatment chosen randomly (like flipping a coin).
- You might not want to fill out pain diaries or get follow-up phone calls.
- You might not want to spend extra time answering questions about your pain.

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 agree to take part in this study, you will:

- Be randomly assigned to get **one** of two strengths of bupivacaine (0.25% or 0.5%) for your nerve block before surgery.
- Keep track of your pain after surgery by filling out a pain diary or answering phone calls from the research team.
- Record your pain levels and the medicine you take for up to 72 hours (3 days) after surgery.
- Allow the study team to review your medical records for research purposes.

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.

- If you join the study, you may get **one** of two strengths of bupivacaine for your nerve block—both are already used in normal care. The main difference from usual care is that you will be randomly assigned to get one of two strengths of bupivacaine. Doctors usually decide whether to use 0.5% or 0.25% bupivacaine based on their judgment. They think about things like how long pain relief is needed, what kind of procedure is being done, and details about the patient, such as age, weight, and health conditions.
- You will also be asked to give extra information about your pain by filling out a diary or answering follow-up calls.
- Your medical record will also be reviewed for research purposes.

What other treatments may I receive if I decide to not take part in this study?

If you choose not to join the study, nothing about your medical care will change. You will still get the usual treatment for shoulder replacement surgery, including pain control with medicine and/or a nerve block. You simply will not be asked to track your pain for the study and the study team will not review your medical record for research purposes.

How many people will take part in this study?

Up to 26 people will be in this study at UVA.

How long will this study take?

Your participation in this study will last about 3 days after your surgery. During that time, you will record your pain or answer follow-up calls. After the 72-hour period, you are finished with the study.

What will happen if you are in the study?

SCREENING Before Surgery

If you agree to participate, you will sign this consent form before any study related procedures take place. Before you can start in the study, there will be a screening period. A qualified member from our research team will look at your medical records to make sure you are eligible and it is safe for you to participate. If you are eligible, you will begin the study procedures.

RANDOMIZATION and STUDY TREATMENT

Note: You will sign a separate hospital consent form for your shoulder surgery and another for the nerve block. You will have your surgery whether or not you join this study.

Random Assignment (Randomization)

You will be randomly assigned, like a flip of a coin into:

1. **One** of two medicine groups:
    - Group 1: 0.5% bupivacaine
    - Group 2: 0.25% bupivacaine

    AND

2. **One** of two pain-tracking groups:
    - Group 1: Fill out a pain diary every 4 hours while awake for 3 days
    - Group 2: Answer pain questions over the phone once a day for 3 days

You have an equal chance of being assigned to any one of the groups. A Randomization software will be used and neither you nor your doctor can choose your group. After you're randomly assigned to a group, you will not know which medicine group you are assigned to, but you will know which pain-tracking group you are placed in.

Then, your anesthesiologist will give you the nerve block with the medicine strength you were assigned.

FOLLOW UP after surgery (During the 3 Days of the study)

After the surgery, the research team will review your medical history in your medical record as part of the study's data collection.

Depending on your assigned group, you will be asked to track your pain in one of the following ways:

- **Pain Diary Group:**
  You will write down your pain levels every 4 hours while awake for the first 3 days after surgery. You will also note when you think the nerve block wears off and record any pain medicine you take every day. You will be asked to take a photo of the diary and send it to the research team each day in a text message.
- **Phone Call Group:**
  A study team member will call you at about 24, 48, and 72 hours after surgery. During each call, you will answer questions about your pain and when you felt the nerve block

wear off. You will also be provided with a medication log to record any pain medicine you take every day. You will be asked to take a photo of the medication log and send it to the research team each day in a text message.

End of Study

After the 72-hour period is over, your part in the study is finished.

Study Tasks Schedule

Time Point / **Tasks**	**Day 0 Screening** Before Surgery	**Visit 1** Day of Surgery	**Visit 2** Day 1 after surgery	**Visit 3** Day 2 after surgery	**Visit 4** Day 3 after surgery
Review Medical History for eligibility.	x				
Phone call to patient to explain study and answer questions.	x				
After phone call, send an email with the consent form and explain it to the patient. Review consent form and answer questions.	x				
Get signatures for consent form on day of surgery.		x			
Randomization- Study Treatment (Shoulder block).		x			
Participant sends diary's photo to study group every day. **(Pain Diary Group only)**			x	x	x
Phone call and medication log photo. Patient sends med log			x	x	X

What your

photo to study group every day. **(Phone Call Group only)**					
Review medical records for data collection		x	x	x	x

are responsibilities in the study?

You have certain responsibilities to help ensure your safety.

These responsibilities are listed below:

- You must be completely truthful about your health history.
- Follow all instructions given.
- You should tell the study doctor or study staff about any changes in your health or the way you feel.
- Answer all of the study-related questions completely.
- Inform the study doctor or study staff as soon as possible if you have to take any new medications, including anything prescribed by a doctor or those that you can buy without a prescription (over-the-counter), including herbal supplements and vitamins. The study doctor will let you know if you can take these medications.

What are the risks of being in this study?

A risk of allowing us to collect information about you is a potential loss of privacy. The University of Virginia will do its best to protect your records so that facts about you and your health will be kept private. The chance that information identifying you will be given to someone else is very small. However, we cannot *guarantee* it will be safe.

Risks from Answering Questions related to Pain/Medications:

Completing pain diaries or receiving phone calls might be inconvenient or tiring for you. Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and go to the next question.

If you tell us you took something for pain that is illegal, the information will be handled as confidential research data. However, we may be required to share this information with others if there is an immediate safety concern or for other research-related purposes, as described in the "Who will see your private information?" section of this form.

Risks and side effects related to the nerve block drug (bupivacaine) include:

Likely

- **Rebound pain**: There is a possibility that your pain may become more severe once the nerve block wears off, though the study is specifically looking at this phenomenon.

Less Likely

- The risks of using bupivacaine for nerve block are very low and are similar for both concentrations; these include:
    - Allergic Reactions.
    - Toxicity from Anesthetic (LAST) (Too much of the numbing medicine gets into your system).
    - Heart Problems, such as low blood pressure (hypotension), slow heart rate (bradycardia), or arrhythmias (irregular heartbeats).
    - Nerve Injury.
    - Infection.
    - Accidental injection of the medicine into the spine or a vein.
    - Muscle Weakness or Paralysis (Trouble moving muscles or complete loss of movement)
    - Breathing Problems.
    - Hematoma (a collection of blood under the skin).
    - Long-Lasting Numbness or Weakness.

- **Discomfort from follow-up procedures**: Completing pain diaries or receiving phone calls might be inconvenient for you.
- **Medication-related risks**: You may experience side effects from pain medications, including opioids, though your pain will be manage appropriately.

Rare but serious

- **General risks of surgery**: As with any surgery, there are risks of infection, bleeding, and anesthesia complications.

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 will not benefit from being in this study. However, the 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 for your illness or condition. You can get the usual treatment even if you choose not to be in this study.

The usual treatment would include:

- Getting bupivacaine for your nerve block before your shoulder replacement surgery at UVA without participating in this study.

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:

- Randomization to one of two strengths of bupivacaine for your nerve block—both are already used in normal care. The main difference from usual care is that you will be randomly assigned to get one of two strengths of bupivacaine.
- Pain tracking by filling out a diary or answering follow-up calls.
- Medical record review for research purposes.

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.

You will be responsible for the cost of travel to come to any study visit and for any parking costs.

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. Some of the reasons for doing so may include

a) The doctor is worried about your health.
b) Your condition gets worse.
c) You do not follow study instructions.
d) You do not fill out the pain diary, send photos, or answer the phone calls.
e) The study sponsor stops the study for safety or other reasons.

If you decide to stop being in the study, we will ask you to call us at (434) 327-7929.

Any data collected about you up until the time you leave the study must be kept in order to determine the results of the study.

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.
- 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
- 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.

Information about you may be given to other researchers outside of the University of Virginia after all identifiers such as name, address, phone # have been removed.
Some of the people outside of UVA who will see your information may not have to follow the same privacy laws that we follow. They may release your information to others, and it may no longer be protected by those laws.

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.

Information obtained from you during this study may be used in future research. Your information may be shared with other researchers inside or outside of the University of Virginia. They will not be sent with information that could identify you such as name, address or phone number.

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.

Your information, collected for this study, will be protected by a Certificate of Confidentiality from the federal government. If UVA receives a subpoena or court order demanding information from the study records that would identify you, we will use the Certificate to resist the demand. However, UVA will not use it in the following cases.

- You have agreed in writing to allow UVa to share the information with your employer, your insurance company for billing purposes, or someone else
- Reports to authorities where there is a danger that you may harm yourself or others, or if there is evidence of probable child or elder abuse or neglect.

In addition, the Certificate does not prevent government authorities who oversee research from reviewing this study. This Certificate does not mean that the government either approves or disapproves of this study. It just helps protect your privacy.

Please contact the Principal Investigator listed BELOW to:

- Obtain more information about the study and ask any questions regarding study procedures or study treatments/interventions.
- 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: Dr. Leon Grinman DO.
Dept of Anesthesia, 1215 Lee St.
University Hospital, Room 2807
Charlottesville, VA 22908

Phone Number: 434-710-6022
Email: HZG6VU@uvahealth.org

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 22903 Telephone: 434-924-2620

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the UVA Study Tracking Number (at the bottom 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 keep the data collected about you up until the time you leave the study to help determine the results of the study.

____ I am withdrawing my consent from the intervention or treatment part of this study but agree to continue to have follow up information about me collected by the study team.
The follow up information will be collected by:

- Obtaining information from my medical records
- Pain Diary Group: You will write down your pain levels every 4 hours while awake for the first 3 days after surgery. You will also note when you think the nerve block wears off and record any pain medicine you take every day. You will be asked to take a photo of the diary and send it to the research team each day in a text message.
- Phone Call Group:
  A study team member will call you at about 24, 48, and 72 hours after surgery. You will also be provided with a medication log to record any pain medicine you take every day. You will be asked to take a photo of the medication log and send it to the research team each day in a text message.

____ I am withdrawing my consent for this study. No additional information may be collected about me including follow up information from my medical records.

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 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