DUKE UNIVERSITY HEALTH SYSTEM

Consent To Participate In A Research Study
Evaluation of utility of ultrasound guided posterior capsule block for posterior knee pain after total knee arthroplasty.

CONCISE SUMMARY

The purpose of this study is to determine the effectiveness of a nerve block, called the iPACK (interspace between the popliteal artery and capsule of the knee) block, on physical therapy after surgery. The information we can gain from this study may help us improve our future knee replacement patients' abilities to participate in physical therapy, which can improve long-term recovery after surgery.

Participants in this study will undergo the iPACK block with numbing medicine or placebo (inactive agent) prior to surgery. Per our usual protocol for knee replacements, a physical therapist will evaluate your knee within 8 hours after surgery. You will be enrolled in our study for 24 hours after surgery.

If you agree to take part in this study, there may be direct medical benefits to you. If you receive the iPACK block with the numbing medicine, you may experience better movement in your knee while in the recovery room. However, this cannot be guaranteed. If you receive placebo, there is not expected to be a benefit above standard of care.

The risks of this study are mainly due to the iPACK intervention. This includes minor pain or discomfort, injury to arteries, veins or nerves affecting the limbs, residual numbness or weakness or paralysis, headache, muscle soreness, infection, allergy or adverse drug reaction, intravascular injection of local anesthetic causing seizure or cardiac arrest.

You are being asked to take part in this research study because you are having total knee replacement surgery. As part of the pain control for this surgery, you would be getting a nerve block called an iPACK (interspace between the popliteal artery and capsule of the knee) block, also known as a posterior capsule block to help control the pain in the back of your knee. This study is being funded by the Department of Anesthesiology at Duke University Medical Center.

Research studies are voluntary and include only people who choose to take part. Please read this consent form carefully and take your time making your decision. As your study doctor or study staff discusses this consent form with you, please ask him/her to explain any words or information that you do not clearly understand. We encourage you to talk with your family and friends before you decide to take part in this research study. The nature of the study, risks, inconveniences, discomforts, and other important information about the study are listed below.

Please tell the study doctor or study staff if you are taking part in another research study.

WHO WILL BE MY DOCTOR ON THIS STUDY?

If you decide to participate, *Dr. William (Michael) Bullock* will be your doctor for the study and will be in contact with your regular health care provider throughout the time that you are in the study and afterwards, if needed.

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WHY IS THIS STUDY BEING DONE?

The purpose of this study is to learn if using a nerve block, the iPACK block that numbs the small nerves going to the back of the knee, makes it easier to straighten your leg (extend your knee) after your surgery. This block will not affect the way you move your knee and will last about 10-12 hours. Many hospitals, including Duke, use the iPACK block for patients having knee replacements hoping to provide better pain relief and better motion after surgery.

For knee replacement surgery at Duke University Hospital, it is typical to numb up different nerves in your leg to help control pain after surgery in both front and back. The front part is numbed by an adductor canal block, which includes the use of numbing medicine through a tube or catheter. As a result, patients usually will have pain in the back of the knee, which makes it harder to straighten the leg during physical therapy. We are trying to see if numbing the nerves going to the back of the knee makes better leg straightening easier. Previous studies show that better leg straightening makes your long-term recovery better.

HOW MANY PEOPLE WILL TAKE PART IN THIS STUDY?

Fifty-two (52) subjects will take part at Duke University Hospital.

WHAT IS INVOLVED IN THE STUDY?

If you agree to be in this study, you will be asked to sign and date this consent form. If you do not sign this consent form, you will continue to receive your regular care, but not as a part of this study.

As part of your anesthesia care, you will get an iPACK block in the preoperative block area. For this study, you will be randomized to one of two different groups. "Randomized" means that, like the flip of a coin, will be put into one of two different groups. This is done before you get here and neither you nor the doctors doing the block will know what group you are in until the end.

Before we begin, you will be placed on a monitor to see your vital signs and receive oxygen. You will also get some intravenous medications for relaxation and pain (midazolam and fentanyl). A spinal anesthetic will be placed in the preoperative area to numb your lower body throughout the surgery. After the spinal, the iPACK block is placed using an ultrasound machine to help the anesthesiologist place the needle in the correct area behind your knee. Once the needle is in the right place, either numbing medicine (ropivacaine) or placebo (saline) is injected through the needle and the needle is then taken out.

For the surgery itself, you will be taken back to the operating room where you will be given sedation (propofol) through your IV. After your surgery is finished, you will be moved to the recovery room. You will then have an adductor canal catheter block procedure to help control pain for a different part of your knee. This is standard of care at Duke. Also, you will get the same pain medicines you would normally get if you were not in the study. This includes numbing medicine through the adductor canal

catheter and variety of pain medications through the IV and by mouth in the recovery room and in your hospital room. If your pain is not well controlled, you and your study doctor can discuss the best plan for pain control. Within 8 hours of arriving in the recovery room, a physical therapist will evaluate your knee, as is usual after knee replacement surgery.

HOW LONG WILL I BE IN THIS STUDY?
You will be in this study for up to 24 hours after your knee replacement surgery. You can choose to stop participating at any time without penalty or loss of any benefits to which you are entitled. However, if you decide to stop participating in the study, we encourage you to talk to your doctor first.

WHAT ARE THE RISKS OF THE STUDY?
Risks of this study includes the following:

- Regional Anesthesia (iPACK)- minor pain or discomfort, injury to arteries, veins or nerves affecting the limbs, residual numbness or weakness or paralysis, headache, muscle soreness, infection, allergy or adverse drug reaction, intravascular injection of local anesthetic causing seizure or cardiac arrest.

If receiving placebo, you may receive more pain postoperatively.

Female
Being a part of this study while pregnant may expose the unborn child to significant risks, some of which may be currently unforeseeable. Therefore, pregnant women will be excluded from the study. If you are a woman of childbearing potential, a blood pregnancy test will be done (using 1 teaspoon of blood drawn from a vein by needle-stick), and it must be negative before you can continue in this study.

Drug and Food Interactions:
For your safety, you must tell the study doctor or nurse about all the prescribed medical foods and drugs, herbal products, over-the-counter (OTC) drugs, vitamins, natural remedies, and alcohol that you are taking before you start the study and before starting to take any of these products while you are on the study.

There may be risks, discomforts, drug interactions or side effects that are not yet known.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?
If you agree to take part in this study, there may be direct medical benefits to you. If you receive the iPACK block with the numbing medicine, you may experience better movement in your knee while in the recovery room, but it is not known yet whether this will be the case. We hope what we learn from this study will benefit other people undergoing knee replacement with iPACK nerve blocks. If you are randomized to the placebo group, there is not expected to be any benefit above standard of care. Your pain may be increased if you receive placebo.

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ALTERNATIVES TO PARTICIPATION IN THE STUDY

You do not have to participate in this study. If you do not participate, you will receive the iPACK with your anesthesia care, which is part of the usual procedure for patients undergoing Total Knee Arthroplasty at Duke.

WILL MY INFORMATION BE KEPT CONFIDENTIAL?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total confidentiality. Your personal information may be viewed by individuals involved in this research and may be seen by people including those collaborating, funding, and regulating the study. We will share only the minimum necessary information in order to conduct the research. Your personal information may also be given out if required by law.

As part of the study, results of your study-related laboratory tests, x-rays, and procedures may be reported to Duke University Department of Anesthesiology and its affiliates. In addition, your records may be reviewed in order to meet federal or state regulations. Reviewers may include representatives from the Food and Drug Administration, representatives and affiliates of Duke University Department of Anesthesiology, the Duke University Health System Institutional Review Board, and others as appropriate. If any of these groups review your research record, they may also need to review your entire medical record.

As part of this study, you will be asked to have certain procedures performed. Some of these procedures would have been done as part of your regular care. The study doctor will use these results both to treat you and to complete this research. These test results will be recorded in your medical record and will be reported to the Duke University Department of Anesthesiology. Results of tests and studies done solely for this research study and not as part of your regular care will **also** be included in your medical record.

While the information and data resulting from this study may be presented at scientific meetings or published in a scientific journal, your name or other personal information will not be revealed.

Some people or groups who receive your health information might not have to follow the same privacy rules. Once your information is shared outside of DUHS, we cannot guarantee that it will remain private. If you decide to share private information with anyone not involved in the study, the federal law designed to protect your health information privacy may no longer apply to the information you have shared. Other laws may or may not protect sharing of private health information.

WHAT ARE THE COSTS?

You or your insurance provider will be responsible and billed for all costs related to your routine medical care, including copayments and deductibles. Routine medical care services are those that you would have received for your condition if you were not participating in this research study. Not all

services are covered by insurance. Some procedures or scans may require pre-authorization by your insurance plan. We will notify you if we learn that a service is not covered by your insurance plan as part of the pre-authorization process. If it is not covered, you will be responsible for paying for it. The amount of your out-of-pocket expense will depend on your insurance plan. For beneficiaries with Medicare Advantage Plans, traditional Medicare is billed for the routine cost of a research study. You may have more or higher co-pays than with a Medicare Advantage plan. Please discuss the costs of the study with Dr. Bullock. At your request, a Financial Counselor in the clinic may provide you with an estimate of costs for routine services.

WHAT ABOUT COMPENSATION?
You will not be compensated for your participation in this study.

WHAT ABOUT RESEARCH RELATED INJURIES?
Immediate necessary medical care is available at Duke University Medical Center in the event that you are injured as a result of your participation in this research study. However, there is no commitment by Duke University, Duke University Health System, Inc., or your Duke physicians to provide monetary compensation or free medical care to you in the event of a study-related injury.

For questions about the study or research-related injury, contact *Dr. Bullock* at *919-681-6437* during regular business hours, or at *505-715-7000* after hours and on weekends and holidays.

WHAT ABOUT MY RIGHTS TO DECLINE PARTICIPATION OR WITHDRAW FROM THE STUDY?
You may choose not to be in the study, or, if you agree to be in the study, you may withdraw from the study at any time. If you withdraw from the study, no new data about you will be collected for study purposes other than data needed to keep track of your withdrawal.

Your decision not to participate or to withdraw from the study will not involve any penalty or loss of benefits to which you are entitled, and will not affect your access to health care at Duke. If you do decide to withdraw, we ask that you contact Dr. Bullock in writing or by telephone (505-715-7000) and let him know that you are withdrawing from the study. His mailing address is Department of Anesthesiology, DUMC 3094, Durham, NC, 27710.

We will tell you about new information that may affect your health, welfare, or willingness to stay in this 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.

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WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions about the study or a research-related injury, or if you have problems, concerns, questions or suggestions about the research, contact Dr. Bullock at 505-715-7000 during regular business hours, after hours and on weekends and holidays.

For questions about your rights as a research participant, or to discuss problems, concerns or suggestions related to the research, or to obtain information or offer input about the research, contact the Duke University Health System Institutional Review Board (IRB) Office at (919) 668-5111.

STATEMENT OF CONSENT
"The purpose of this study, procedures to be followed, risks and benefits have been explained to me. I have been allowed to ask questions, and my questions have been answered to my satisfaction. I have been told whom to contact if I have questions, to discuss problems, concerns, or suggestions related to the research, or to obtain information or offer input about the research. I have read this consent form and agree to be in this study, with the understanding that I may withdraw at any time. I have been told that I will be given a signed and dated copy of this consent form."

_____	_____	_____
Signature of Subject	Date	Time
_____	_____	_____
Signature of Person Obtaining Consent	Date	Time