OCHSNER CLINIC FOUNDATION
RESEARCH INFORMED CONSENT

Pain after total knee arthroplasty: a comparison of combined continuous adductor canal block with infiltration of local anesthetic between the popliteal artery and capsule of the knee (IPACK) block versus continuous adductor canal block alone on postoperative analgesia.

IRB# 2016.307.C

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Principal Investigator: Matthew Patterson

Sub-Investigators: Kim Sanford Bland, Clint Elliott, Kristie Osteen, Leslie Thomas, Jillian Vitter, Edward Weller, Dane Yuratich, George Chimento

Are you in any other research studies? Yes _____ No _____
please initial your response

You have been invited to participate in a research study. The doctors and staff at Ochsner study the nature of disease and attempt to improve methods of diagnosis and treatment. This is called clinical research. Understanding this study's risks and benefits will allow you to make an informed judgment about whether to be part of it. This process is called informed consent.

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

Participating in a research study is not the same as getting regular medical care. The purpose of regular medical care is to improve your health. The purpose of a research study is to gather information. Being in this study does not replace your regular medical care.

In this consent form, "you" always refers to the subject. If you are a legally authorized representative, please remember that "you" refers to the study subject.

PURPOSE

The purpose of this study is to determine whether an additional nerve block targeting

posterior nerve endings improves pain control, increases function, and speeds recovery following total knee replacement compared to no additional posterior block. You have been asked to participate in this study because you are undergoing a single-sided total knee replacement.

LENGTH OF STUDY AND NUMBER OF PARTICIPANTS

Your participation in this research study will be limited to your hospital admission for total knee arthroplasty (approximately 1-3 days). There will be one site nationwide enrolling **72** subjects for participation in this study. At Ochsner **72** subjects will be enrolled.

PROCEDURE

If you agree to be in this study, we will ask you to do the following things:
You will be randomized into one of two groups. The randomization procedure to decide which group you are in is like flipping a coin. In the study group you will receive a nerve block that targets posterior nerve endings that is currently performed at Ochsner Medical Center prior to all total knee replacements. In the other group you will receive a placebo injection. This means that a small amount of sterile saline will be injected just under the skin surface and no active medication will be given. The study will involve follow-up while in the hospital and after discharge while the continuous nerve block catheters are in place (approximately 48 hours after discharge).

RISKS

General / Unforeseeable

Risks of participating in the study are the same as with routine care. These include mild discomfort during procedure, incomplete pain relief, unlikely bleeding and infection risks, unlikely local anesthetic spread to cause temporary foot drop or expanded nerve block, rare but potentially serious nerve injury, and rare but serious local anesthetic toxicity, and rare but serious allergy. These risks will be managed as they would with routine care through use of ultrasound imaging modalities and adhering to clean procedure techniques. Your knee pain may not improve or may get worse despite participation in this research study.

Louisiana law requires us to set forth the known risks of a medical treatment, including the risks, if any, of death, brain damage, quadriplegia (paralysis in all arms and legs), paraplegia (paralysis of both legs), the loss or loss of function of any organ or limb, and disfiguring scars, which might be associated with a necessary procedure. Any clinical study carries with it risks of which we may be unaware at this time, including those listed in this paragraph.

Reproductive Risks

The treatment or procedure may involve unforeseeable risks to the subject, or embryo or fetus, if the subject becomes pregnant. Because the possibility of injury or harmful effects to an embryo or fetus exists you must not be pregnant or conceive a child while in this clinical trial. Acceptable methods of contraception include intrauterine device, spermicide and barrier (e.g., condom, diaphragm) method, oral contraceptives (birth control pills) and total abstinence. Please discuss the best choice for you and your partner with your study doctor.

If you or your partner becomes pregnant while participating in this study, you MUST contact your study doctor immediately.

POTENTIAL BENEFITS

You may not receive direct personal or health benefit from taking part in this study. However, the information gained from your participation in this study may be used to help others in the future.

COSTS

There are no known additional costs. Your insurance bill will be unchanged from what it would be with routine care if you choose not to participate in the study. Your responsibility for your co-pay is unchanged from that if you chose routine care.

Although the Sponsor may pay for certain study-related items and services, any other tests, procedures, or medications that may be necessary for the treatment of your medical condition will be billed to your insurance in the normal way. You may be responsible for co-payments or deductibles. These costs are not covered by this research study. If you have any questions about treatment for which you may be responsible for paying, please discuss this with your physician or study staff.

PAYMENT FOR PARTICIPATION AND/OR REIMBURSEMENT OF EXPENSES

No payment, reimbursement of expenses, or compensation is provided for study participants.

ALTERNATIVE METHODS/TREATMENTS

An alternative is to not take part in the study. The option of continuing with standard clinical care at Ochsner Medical Center would include the study intervention. You do not have to join this study. If you do not join, your care at Ochsner will not be affected.

STUDY RELATED QUESTIONS AND COMPENSATION FOR INJURY

If you have any questions concerning your participation in this study or if at any time you feel you have experienced a research-related injury or a reaction to a study drug, contact:

Dr. Matthew Patterson at Ochsner Medical Center
Address: Dept. of Anesthesiology, 1514 Jefferson Hwy, New Orleans LA 70121
Phone: 504-842-3755

If you believe you are injured as a direct result of your participation in this study, you should seek appropriate medical attention and immediately contact your study doctor at the number provided above. Medical treatment and/or hospitalization, if necessary for such injuries, is available. This medical treatment and/or hospitalization is not free of charge. You, your insurance company or the Sponsor may be billed for the care you receive for the injury. We will try to get these costs paid for you, but you may be responsible for some of them. You may be responsible for all co-payments and deductibles required under your insurance. By signing this consent form you have not given up any legal rights.

QUESTIONS ABOUT YOUR RIGHTS

If you have questions about your rights as a research subject, you may contact:

Ochsner Clinic Foundation Institutional Review Board
1514 Jefferson Highway
New Orleans, LA 70121
Telephone: 1-504-842-3535

The Institutional Review Board (IRB) is a group of people who perform independent review of research for human subject protection. You may contact the IRB to discuss any problems, concerns or questions you have about research. The IRB can assist you in obtaining information about research and encourages input from research subjects.

VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM THE RESEARCH

Participation in this study is voluntary. You may decide not to participate in this study or you may withdraw from this study at any time without penalty or loss of benefits to which you are otherwise entitled at this site. If you leave the study before the final regularly scheduled visit, you may be asked by the study doctor to make a final visit for some end of study procedures.

You will be informed of any significant new findings that develop during the investigation that may affect your willingness to continue in the study.

You should tell your study doctor about all of your past and present health conditions

and allergies of which you are aware, and all drugs and medications which you are presently using.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent because:

- 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.

CONFIDENTIALITY

Your identity and your personal records will be kept confidential and, to the extent permitted by the applicable laws and/or regulations, will not be made publicly available. Confidentiality will be maintained during and after your participation 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.

HIPAA AUTHORIZATION TO RELEASE INFORMATION FOR RESEARCH

Under federal law (the "Privacy Rule"), your Protected Health Information (PHI) that is created or obtained during this clinical research study cannot be "used" to conduct the research or "disclosed" (given to anyone) for research purposes without your permission. This permission is called an "Authorization". Therefore, you may not take part in this study unless you sign this Authorization. If you volunteer to take part in this research study, you have the right to know that others may know your identity. Study information may identify you in the following ways.

- Name
- Address
- Telephone number
- Other details about you including your past medical records

This study includes a number of researchers, businesses and government agencies. They may use your health information and share it with others. We want you to know who may use this information and how they may use it.

We also want to tell you about your rights concerning the use of your personal information before you agree to take part in the study.

Who may use and give out information about you?

The Investigator (study doctor) and research staff will have information about your health that tells us your identity. They may give this information to others during and after the study.

Who may see this information?

The study sponsor also may see your health information and know your identity. "Sponsor" includes any people or companies working for or with the sponsor or owned by the sponsor. They all have the right to see information about you during and after the study.

The following people, agencies and businesses may get information from us that shows who you are.

- Doctors and healthcare professionals taking part in the study
- U.S. Food and Drug Administration (FDA)
- U.S. Department of Health and Human Services (DHHS)
- Government agencies in other countries
- Government agencies that must receive reports about certain diseases
- Ochsner Clinic Foundation Research & Compliance Offices
- Ochsner Clinic Foundation Institutional Review Board (IRB)
- Third party vendors as authorized by Ochsner Clinic Foundation

What information may be used and shared?

If you decide to be in this study, medical information that identifies you and relates to your participation will be created. This may include the following types of medical information.

- Information obtained from the procedures used to find out whether you are eligible to take part in this study. This may include physical examinations, blood and urine tests, x-rays and other procedures or tests, and any other information that you may release to us, including information about your health history.

- Information obtained in the course of the study including information about your response to any study treatments you receive, information related to study visits and phone calls, physical examinations, blood and urine tests, x-rays and other tests or procedures that may be performed, and other medical information relating to your participation in this study.

Why will this information be used and/or shared?

Information about you and your health, that might identify you, may be given to others to carry out the research study. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

The 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 receive marketing approval for new products resulting from this research. The information may also be used to meet the reporting requirements of governmental agencies.

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

The information may be reviewed by the Ochsner Institutional Review Board. The Ochsner Research & Compliance Offices may review this research in their oversight and auditing roles.

What if I decide not to give permission to use and give out my health information?
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to be in this research.

May I review or copy the information obtained from me or created about me?
You have the right to review and copy your health information. However, if you decide to be in this study and sign this permission form, you will not be allowed to look at or copy your information until after the research is completed.

May I withdraw or revoke (cancel) my permission?
Yes, but this authorization (permission) will not expire (end) until it is no longer required by the Sponsor unless you revoke (cancel) it in writing.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information that might identify you will be gathered after that date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

Is my health information protected after it has been given to others?
If you give permission to give your identifiable health information to a person or business, the information may no longer be protected. If your health information is given to the parties listed above and/or to others who are not required to comply with these federal laws your information may no longer be protected. There is a risk that your information will be released to others without your permission.

Your personal information may be disclosed if required by law. Your records for this study may be sent by facsimile transmission (FAX machine) or over the Internet. It is possible that your records could be sent to the wrong person.

How long is my information kept?
Ochsner Clinic Foundation policy requires that all files related to a research study are stored for ten (10) years after the research study has been closed at the Ochsner site.

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.

If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records.

CONSENT

I have been informed about this study's purpose, procedures, possible benefits and risks, and the use and disclosure of my health care information from this research. All my questions about the study and my participation in it have been answered. I freely consent to participate in this research study. I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above. By signing this consent form I have not waived any of the legal rights that I otherwise would have as a subject in a research study.

CONSENT SIGNATURE

Patient Signature	Printed Name	Date
Signature of Legally Authorized Representative (*when applicable*)	Printed Name	Date
Authority of Subject's Legally Authorized Representative or Relationship to Subject		
Person Obtaining Consent - Signature	Printed Name	Date

---------- Use the following only if applicable ----------

IMPARTIAL WITNESS STATEMENT (IF APPLICABLE)

If this consent and authorization document is read to the subject because the subject is unable to read the document, an impartial witness (a person, who is independent of the trial, who cannot be unfairly influenced by people involved with the trial, who attends the informed consent process if the subject cannot read, and who reads the informed consent and any other written information supplied to the subject) must be present for the consent and sign the following statement:

I attest that the information in this consent and authorization was explained to, and understood by the subject. I also attest that the subject agreed to participate in this research study.

_____
Printed Name of Impartial Witness

_____ _____
Signature of Impartial Witness Date

Note: This signature block cannot be used for translations into another language. A translated consent form, with the translation approved by the IRB, is necessary for enrolling subjects who do not speak English.