CONSENT FORM AND AUTHORIZATION FOR DISCLOSURE OF PROTECTED HEALTH INFORMATION

STUDY TITLE: PSOAS COMPARTMENT BLOCK VERSUS PERIARTICULAR LOCAL ANESTHETIC INFILTRATION FOR PAIN MANAGEMENT FOR TOTAL HIP ARTHROPLASTY: A PROSPECTIVE, RANDOMIZED STUDY

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Hospital: **William Beaumont Hospital – Royal Oak**

INTRODUCTION

Why is this study being done?

You are being asked to participate in a clinical research study. The purpose of clinical research is to look at the nature of disease and try to develop improved methods to diagnose and treat disease. The doctor or clinician in charge of the study believes you meet the initial requirements to take part in the study. Before agreeing to participate, it is important for you to read and understand the following explanation of the research procedures. This Consent and Authorization form describes the purpose, procedures, benefits, risks and discomforts of the study. It also describes the alternatives available to you, and your right to withdraw (quit) from the study at any time.

Please read this information carefully and ask as many questions as you like before deciding whether or not you would like to take part in this research study.

The goal of this study is to compare the effectiveness of pain relief after total hip replacement surgery via anterior approach with a psoas compartment block versus a periarticular local anesthetic injection. The anterior approach (via the front side of the body) for total hip replacement is a tissue-sparing alternative to traditional hip replacement surgery (which uses an approach on the back side of the body) that provides the potential for less pain, faster recovery and improved mobility. The technique allows the surgeon to work between muscles and tissues without detaching them from either the hip or thighbones - sparing the tissue from trauma. Despite these advantages, total hip replacement can still be associated with significant pain in the immediate postoperative period. Surgeons use various methods intraoperatively to alleviate postoperative pain. One technique that is possible with the anterior approach is called a psoas compartment block. The psoas is an anterior hip muscle that helps with flexion. With an anterior approach, an anesthetic drug can be injected directly into the psoas muscle, where it spreads to the nerves responsible for sensation around the surgical site, allowing for pain relief. Alternatively, the surgeon can use a periarticular local anesthetic injection. In this technique an anesthetic "cocktail" of four drugs is injected to the surrounding tissues at several locations at the surgical site. Either of these techniques can be used as standard of

care and the local anesthetics being used are all approved by the United States Food and Drug Administration (FDA).

A total of 100 of Dr. Verner's patients will take part in the study at William Beaumont Hospital Royal Oak.

How long will I be in the study?
If you decide to take part in this study, your participation is expected to last approximately 3 weeks. To take part you must be undergoing a primary total hip replacement with an anterior approach, and be able to comply with the study requirements. You may not take part in this study if you are currently enrolled in another related research study which could alter or influence the study results.

DESCRIPTION OF THE STUDY
What will happen if I take part in the research study?
You are being asked to take part in this research study because you are undergoing total hip arthroplasty with an anterior approach. The results of this study will compare the effectiveness of two different techniques for managing postoperative pain.

If you agree to take part in this study you will be randomized (like the flip of a coin) to receive either:

A. An intraoperative psoas compartment block
B. An intraoperative periarticular anesthetic injection

You are being invited to participate because you are eligible for the study based on your information so far. None of the information collected so far will be used for research unless you agree to participate in this study by signing this Consent and Authorization Form.

If you agree to be in this study and sign and date this Consent and Authorization form, you will be asked to do the following things; below is a table describing what will occur during participation:

Schedule of Events Table

	Preop	**Surgery**	**3 hours postop**	**POD 1 9 am**	**POD 1 5 pm**	**POD 2 9 am**	**POD 2 5 pm**	**3 weeks postop**
Window	**-21 to 0 days**	**N/A**	**± 1 hours**	**± 2 hours**	**± 3 hours**	**± 2 hours**	**± 3 hours**	**± 1 week**
Consent review and signature	X							
Intervention (psoas block or periarticular injection)		X						
Pain assessment	X		X	X	X	X[a]	X[a]	X

Quality of recovery questionnaire				X		X[a]		
Opioid-related symptom distress questionnaire				X		X[a]		

POD = postoperative day
a. If you have been discharged before this time point questionnaires will not be collected

After your surgery, you will be asked to report on a sheet of paper your pain scores both while resting and while you are up and moving. Additionally, you will be asked to fill out two questionnaires on postoperative days one and two to assess how you are reacting to your pain medications and how well you are recovering from your surgery.

PARTICIPANT RESPONSIBILITIES
You will be asked to note any side effects or medical problems you may experience while you are taking part in this study. For any illnesses or injuries, you should contact the study doctor immediately at the number listed on this consent form or in an emergency situation call 911 (or go to the nearest hospital emergency room).

RISKS, SIDE EFFECTS AND DISCOMFORTS
Ask your physician what the standard of care risks are as well as the study risks.
What side effects or risks can I expect from being in the study?

Standard of Care Risks:

Less Frequent (occurring from 1% to 10% of the time)
- Low blood pressure
- Nausea
- Vomiting
- Low heart rate
- Anxiety
- Numbness of skin
- Pain
- Itching
- Fever
- Dizziness
- Chills
- Reduced sensation of your hip area (where the surgery will take place)
- Block failure (this is when the block does not work, thus causing pain after surgery)

Rare (occurring less than 1% of the time)
- Runny nose
- Allergic reaction
- Temporary or permanent nerve damage
- Infection

- Perioperative injury secondary to numbness or weakness, such as falling if trying to walk before the block wears off

There is a rare risk of breach of confidentiality (release of information which personally identifies you). Every research study involves some risk to your confidentiality. It is possible that other people could find out you are in the study or see your study information. But we will take every step to keep this from happening.

BENEFITS

What are the benefits of taking part in this study?

There may be no direct benefit to you from taking part in this study. However, you may have improved pain relief if one technique proves superior. It is hoped that the results of this study will help doctors learn which treatment is most effective for pain management.

ALTERNATIVE OPTIONS

What are my choices other than taking part in this study?

You do not have to take part in this study to receive treatment for your condition. Your alternative is to not participate in this study and receive standard medical care as prescribed by your doctor (which may include one of the study treatments).

ECONOMIC CONSIDERATIONS

What are the costs of taking part in this study?

There will be no additional cost to you for the study procedures (questionnaires, pain scores) described in this consent. Routine procedures you would have had done even if you were not taking part in this study, such as your surgery, hospitalization, anesthesia, and pain medications will be billed to your health insurance company and/or group health plans as usual. If these routine care costs are <u>not</u> covered by your health insurance/group health plan, the cost will be your responsibility. The study will cover the cost of the questionnaires.

COMPENSATION

What happens if I am injured because I took part in this study?

Your involvement in this study is voluntary. The possible risks and side effects which might occur during the course of the research study have been described in this Consent and Authorization form. A research injury is any physical injury or illness caused by your participation in this study.

Should you experience a research injury, there are no designated funds provided for subsequent medical care or compensation by either the study doctor/clinician or William Beaumont Hospital.

Every effort to prevent any injury resulting from this study will be taken by your study doctor and William Beaumont Hospital. Immediate necessary care, emergency treatment, and professional services will be available to you, just as they are to the general community. You and/or your insurance company will be responsible for the costs. Compensation (such as for lost wages and/or pain and suffering) is not available.

What are my rights if I take part in this study?
You are not giving up any of your legal rights by signing this form.

CONFIDENTIALITY, DISCLOSURE AND USE OF YOUR INFORMATION
Will my medical information be kept private?
In order for this research study to take place, you must also authorize the researchers to access and use some of your protected health information (PHI). PHI is information which could identify you as an individual such as name, address, date of birth, etc. By signing this Consent and Authorization Form, you give William Beaumont Hospital permission to use and/or disclose (release) your health information related to this research. Your medical and billing records collected for the purpose of the study will remain confidential, but may be disclosed (released) or used by the following and/or their representatives:

- The investigators (study doctor/clinician, research staff)
- William Beaumont Hospital
- The Food and Drug Administration
- Other governmental regulatory agencies (domestic and/or foreign)
- Your health insurance company and/or group health plans and their intermediaries (companies contracted to process claims) may also have access to your medical and billing records of the study.

The purpose for this disclosure (release) or use is, for example, to assure compliance with the study protocol, to evaluate the effectiveness of the study, and/or to provide protection to you as a research study participant. The disclosure and use of your information will continue after your involvement in the study has ended. There is no expiration date for the use of your medical and billing records from the study. Any information about you disclosed to the parties identified above may be re-disclosed by them; however, such re-disclosure is not under the protections of this Consent and Authorization.

You will not be identified in any publication or other release of study results, data, and other information (such as in professional writings or at professional meetings).

If you decide to withdraw your authorization for the researchers to access and use your personal health information before the end of the study, you will be withdrawn from the research study. However, where the study relied on your Consent and Authorization for the time you participated in the study, your Consent and Authorization cannot be withdrawn and the information already collected may still be used and disclosed as you previously authorized.

STOPPING STUDY PARTICIPATION
What if I decide to stop taking part in the study?
Taking part in this research study is completely voluntary. You may choose not to take part or to stop being in the study (withdraw) at any time without penalty or loss of benefits to which you are otherwise entitled, or without jeopardizing your medical care by your physician at William Beaumont Hospital. However, if you do not agree to sign this Consent and Authorization Form, you will not be able to take part in this study.

Your participation in this study may be stopped by the study doctor/clinician, without your consent, for any reason, which will be explained to you. Examples include:

- The study procedures appear to be medically harmful to you.
- You fail to follow directions for participating in the study.
- It is discovered you do not meet the study requirements.
- The study is canceled.
- It is determined to be in your best interest (for example, your disease has progressed despite treatment).

Any significant new findings developed during the course of this research that might affect your willingness to participate will be provided to you and your study doctor. While participating in this study, you should not take part in any other study. This is to protect you from possible injury that may arise.

CONTACTS

Who can answer my questions about the study?

You may talk to the study doctor/clinicians about any questions or concerns regarding your study participation, or if you think you may have suffered a research-related injury. The doctor in charge of the study, Dr. James Verner, may be reached at (248) 663-1900 to answer your questions. Your contact person is Kelly Slade, RN. You may contact her at (248) 551-0194.

If you have questions regarding your rights as a research participant, or have problems, concerns, complaints, want information or would like to offer input, you may contact the Institutional Review Board (Human Investigation Committee) Chairperson at (248) 551-0662. The Human Investigation Committee is charged with the oversight of all human participant research conducted at William Beaumont Hospital facilities.

STATEMENT OF VOLUNTARY PARTICIPATION

I have read the above, have asked questions and have received answers about this study to my satisfaction. I understand what I have read and willingly give my consent to participate in **PSOAS COMPARTMENT BLOCK VERSUS PERIARTICULAR LOCAL ANESTHETIC INFILTRATION FOR PAIN MANAGEMENT FOR TOTAL HIP ARTHROPLASTY: A PROSPECTIVE, RANDOMIZED STUDY.** I understand I will receive a signed copy of this document and will be promptly informed of any new findings regarding this study. I further authorize the use or disclosure of my health and personal information contained in records as described above.

_____
RESEARCH PARTICIPANT NAME (PLEASE PRINT)

_____ _____ _____
RESEARCH PARTICIPANT SIGNATURE DATE TIME

ALTERNATIVE SIGNATURE (IF RESEARCH PARTICIPANT UNABLE TO SIGN)

AS THE PERSONAL/LEGAL REPRESENTATIVE OF THE STUDY PARTICIPANT, PLEASE PRINT PARTICIPANTS NAME ABOVE IN THE RESEARCH PARTICIPANT SECTION, AND CHECK ONE OF THE BOXES BELOW AS THE BASIS FOR YOUR AUTHORITY TO SIGN THIS CONSENT AND AUTHORIZATION:

☐ COURT-APPOINTED GUARDIAN ☐ DURABLE POWER OF ATTORNEY ☐ NEXT OF KIN
*COURT LETTER IS REQUIRED *ATTORNEY LETTER MUST BE PRESENT & VERIFIED BY 2 PHYSICIANS

_____ _____
NAME (PLEASE PRINT) RELATIONSHIP TO PARTICIPANT

_____ _____ _____
SIGNATURE DATE TIME

☐ WITNESS TO SIGNATURE ON CONSENT ☐ WITNESS TO CONSENT PROCESS AND SIGNATURE

_____
WITNESS NAME (PLEASE PRINT)

_____ _____ _____
WITNESS SIGNATURE DATE TIME

AUTHORIZED CONSENT PROVIDER STATEMENT:

I have explained this study and have offered the study participant an opportunity for any further discussion or clarification.

_____ _____ _____
NAME (PLEASE PRINT) CREDENTIALS PHONE NUMBER

_____ _____ _____
SIGNATURE DATE TIME