Investigator: Gregory P. Nicholson, MD

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Title of Study: Multimodal Anesthesia and Analgesia for Total Shoulder and Reverse Total Shoulder Arthroplasty: A Randomized Controlled Trial

Sponsor: Department of Orthopedics, Rush University Medical Center

RUSH

Subject Information Sheet and Consent Form

Introduction

You are being invited to take part in this research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the information in this form carefully, as it may contain words you do not understand. You may wish to discuss it with your doctor, family, and/or friends. If there is anything that you do not understand or you would like more information, please ask questions and the study doctor or study staff will try their best to answer them. Once the study has been explained and you have had all your questions answered to your satisfaction, you will be asked to sign this form if you wish to participate. Before anything is done for this study, you must sign this form. A copy of this signed form will be given to you.

You do not have to take part in this study. You are free to withdraw from this study at any time you choose without giving a reason. This will not affect any future care you will receive. No promises can be made about the outcome of this as far as your current condition, either positive or negative. People who take part in research are called "subjects" instead of "patients".

Why are you being invited to participate in this study?

You are being asked to take part in this study because you are indicated to and have decided to undergo a total shoulder arthroplasty or a reverse total shoulder arthroplasty and will be prescribed opioid pain medication to control postoperative pain.

What is the purpose of this study?

Pain after total shoulder arthroplasty or reverse total shoulder arthroplasty is very common and remains a focus of the physicians caring for you. Many patients are prescribed opioid medication after their surgeries to control pain, but opioid medications have been associated with some side effects. By adding several types of medications to control pain after your surgery, it is possible that you will need less opioid medication. The purpose of this study is to identify which pain medications are best for pain control after shoulder surgery.

How many study subjects are expected to take part in the study?

We expect 74 patients to take part in the study at Rush University Medical Center.

What will you be asked to do?

Once enrolled in the study, you will be randomly assigned into one of two groups. In the first group, you will attend all regularly scheduled pre- and post-operative appointments with your surgeon. You will take opioid medications as directed by your physician after your surgery. After surgery, you will answer questions about your pain as well as satisfaction at different times after

your surgery.

If you are part of the second group, you will still attend all regularly scheduled pre- and post-operative appointments with your surgeon and answer questions about your pain and satisfaction at different times after your surgery. In addition, you will be prescribed and take several anti-inflammatory medications in addition to opioid medications. All medications are standard of care medications that can be prescribed to people that are undergoing shoulder surgery.

How long will you be in the study?

You will be in the research study for 90 days, as we ask you about your recovery after your surgery. Participation in this study is completely voluntary, and you can withdraw at any time.

You may be removed from this study without your consent. Possible reasons may be that the study doctor decides that continued participation in the study will be harmful to you, you are unable to take the treatment as directed, or the study is canceled.

What are the possible risks of the study?

All drugs will be given within standard doses, but there is the possibility of unforeseeable risks in the administration of the drugs.

There may be risk of allergy to one or more of the drugs used in this study. Signs of an allergic reaction may include redness, itching, swelling or (in rare cases) difficulty with breathing, and lightheadedness. Severe allergic reactions may result in death. If you feel that you are experiencing a severe allergic reaction, first seek treatment and then call **(Gregory P Nicholson, MD)** at **(312-432-2464)** to follow up about your treatment.

There is the possibility of emotional discomfort when answering questions about your pain and satisfaction. This is no more than minimal risk of emotional discomfort, but you may contact an investigator immediately if this occurs.

There is always the risk of potential for breach of confidentiality and/or privacy.

Are there benefits to taking part in the study?

There may be no direct benefit to you for participating in this study**.** Indirect benefits to society include the potential future benefit of better pain control and limitation of side effects of pain medication for patients who have shoulder arthroplasty surgery.

What other options are there?

Instead of participating in this study, you may choose another form of treatment such as the current treatment given to patients after surgery. You do not need to participate in this study to undergo your procedure.

What about confidentiality of your information?

Records of participation in this research study will be maintained and kept confidential as required by law. A breach of confidentiality and/or privacy is a risk of this study. To prevent this, all collected data will be stored electronically in password-protected files to protect patient identity and information. All information will be collected and reviewed by the research team only. Data will be maintained on a password-protected computer that will be accessible only to the study team. No patient identifiers will be maintained in the database.

A description of this study will be available on http://www.clinicaltrials.gov as required by U.S. law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

If you withdraw from this study, the data already collected from may not be removed from the study records. The study doctor and/or study team may ask you whether they can continue to collect follow-up data on you. If follow-up information will be requested, you will be asked to sign a separate consent form before this information can be collected.

Your identity will not be revealed on any report, publication, or at scientific meetings. In order to conduct the study, the study doctor, Gregory Nicholson, MD, will use and share personal health information about you. This includes information already in your medical record, as well as information created or collected during the study. Examples of the information that may be shared include your medical history, physical exam and laboratory test results. The study doctor will use this information about you to complete this research.

Confidentiality and disclosure of your personal information is further described in the attachment to this form. The attachment is titled HIPAA Authorization to Share Personal Health Information in Research (2 pages).

The Rush Institutional Review Board (IRB) will have access to your files as they pertain to this research study. The IRB is a special committee that reviews new and ongoing human research studies to check that the rules and regulations are followed regarding the protection of the rights and welfare of human subjects.

What are the costs of your participation in this study?

All costs that are part of your usual medical care, such as pain medication will be charged to you or your insurance company. You will be responsible for all costs that are not paid by your insurance company. You should check with your insurance company before you enroll in this research study.

Will you be compensated or paid?

You will not receive compensation for study participation.

Your participation in this research study may contribute to the development of commercial products from which the Sponsor company or others may derive economic benefit. You will have no rights to any products, patents or discoveries arising from this research, and you will receive no economic benefit.

What happens if you experience a research related injury?

If you experience any injury or illness as a direct result of your participation in this research study, immediate treatment will be provided. However, the cost of that treatment will be billed to you or your insurance company. Please check with your insurance company regarding coverage.

If you have any medical problems during the study, please contact the study doctor. He or she will explain your treatment options to you and/or help you find a place to get treatment.

Rush University Medical Center has no program for financial compensation or other

forms of compensation for injuries which you may incur as a result of participation in this study.

What happens if you need emergency care?

If you need emergency care while you are participating in this study, it is important that you tell emergency personnel of your participation in this study and notify the study doctor as soon as possible.

Whom do you call if you have questions or problems?

Questions are encouraged. If there are any questions about this research study or if you experience a research related injury, please contact: **Gregory P Nicholson, MD, (312) 432-2464**. Questions about the rights of research subjects may be addressed to the Rush Research & Clinical Trials Administration Office at 1-800-876-0772.

By signing below, you are consenting to participate in this research study. You have read the information given or someone has read it to you. You have had the opportunity to ask questions, which have been answered satisfactorily to you by the study staff. You do not waive any of your legal rights by signing this consent form.

SIGNATURE BY THE SUBJECT

_____	_____	_____
Name of Subject	Signature of Subject	Date of Signature

SIGNATURE BY THE INVESTIGATOR/INDIVIDUAL OBTAINING CONSENT:

I attest that all the elements of informed consent described in this consent document have been discussed fully in non-technical terms with the subject. I further attest that all questions asked by the subject were answered to the best of my knowledge.

_____	_____
Signature of Individual Obtaining Consent	Date of Signature

SIGNATURE OF THE PRINCIPAL INVESTIGATOR

I attest that I am aware of the enrollment of this subject in the study discussed in this consent document.

_____	_____
Signature of the Principal Investigator	Date of Signature

Check here if Principal Investigator obtained consent and a separate signature is not required.