University of Pennsylvania

Informed Consent Form

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UNIVERSITY OF PENNSYLVANIA
RESEARCH SUBJECT INFORMED CONSENT AND HIPAA AUTHORIZATION FORM

Protocol Title: Comparison between single shot versus continuous infraclavicular brachial plexus block for postoperative analgesia after distal radius fracture, a prospective randomized open label study

(Protocol # xxxxxx)

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Why am I being asked to volunteer?

You are being invited to participate in a research study because you will be having surgery to repair a wrist fracture and you will receive a nerve block to numb up your arm and wrist as part of your pain control protocol after surgery. Your participation is voluntary which means you can choose whether or not you want to participate. If you choose not to participate, there will be no loss of benefits to which you are otherwise entitled. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. The research team is going to talk to you about the research study, and they will give you this consent form to read. You may also decide to discuss it with your family, friends, or family doctor. You may find some of the medical language difficult to understand. Please ask the study doctor and/or the research team about this form. If you decide to participate, you will be asked to sign this form.

What is the purpose of this research study?

You are scheduled to undergo distal radius fracture (wrist) surgery with your orthopedic surgeon. To help you with your pain control after surgery, you will receive a nerve block to numb up your arm and wrist. It can be numbed up by putting numbing medicine around a nerve using ultrasound.

Receiving the nerve block before wrist fracture surgery and additional sedation to make you sleepy during operation is a routine practice at Presbyterian Medical Center.

Regional anesthesia - nerve block involves numbing up your arm by injecting numbing medication around the nerve that provides feeling to the arm. Patients having wrist surgery receive the nerve block in the holding area before surgery. The nerve block begins to work about 20 minutes after the needle injection. The anesthesiologist has the option to leave a catheter (similar to a thin fishing wire) next to the nerve for 48-60 hours. There will be numbing medicine going through this catheter to help with your pain control after surgery.

The purpose of this study is to determine if there is any difference in between receiving a single shot of numbing medication versus a catheter left in for 48-60 hours. We aim to look at recovery outcomes and overall patient satisfaction.

How long will I be in the study? How many other people will be in the study?

We plan to enroll 50 subjects who are scheduled to distal radius surgery at Penn Presbyterian Medical Center. Your expected length of participation is about 3 months. The study will follow your progress from the time of your surgery until day 3 post operation and again on your 3 month clinical visit post operation.

What am I being asked to do?

If you sign the consent and agree to participate in this study, you will still receive monitored sedation and a nerve block. This is not by any means a change from the standard of care for any patient.
For this study, the nerve block will either be a single shot or a catheter left in place for 48-60 hours. All medications used are approved by the Food and Drug Administration (FDA). This study wishes to look at the difference in patient satisfaction and recovery outcomes between the lengths of time for the proposed blocks.

If you agree to participate:
You will be randomized to receive either one of two nerve blocks. This is a process of chance, similar to being assigned by the flip of a coin. The doses of the medicine will be according to the standard of practice in the PPMC.

By chance you will be assigned to receive one of the following:

- Ultrasound guided shoulder block by single shot
- Ultrasound guided shoulder block with catheter for 48-60 hours

You will also be asked to allow the research team to collect data after the surgery. This will include information regarding what your pain is after your surgery, the amount and type of pain medication you take up to 3 days, and how the pain is impacting your recovery and sleep. You will be asked to complete questionnaires that will assess your pain, your general well-being, and how you are able to control your pain, and how your pain affects your return to your daily life.

A member of the research team will call you after surgery Day 1 and Day 3 post-operative. If you admitted to the hospital a team member will see you while in the hospital. You will be asked about your pain and your general well-being.

The research assistant will assist you with completing the questionnaires described here:

Quality of Recovery Scale

You will be asked to complete this survey a total of three times after your surgery. These time points will be 24 hours and 72 hours after your surgery. This questionnaire will ask you questions about how you are feeling both physically and mentally and how much pain you are feeling. This will take about 5 minutes to complete.

Insomnia Severity Index

This survey asks about your sleeping habits and takes about 3 minutes to complete.

Pain Diary

You will be given a pain diary to complete up to 72 hours post operatively. Information obtained from the pain diary includes pain scores at different times during the day and pain medications taken. In order to assess duration of block the patients will be asked to write down the time that they first noticed pain as well as the time that they needed their first dose of oral pain medication. You will also be contacted at home 24 and 72 hours later to obtain pain, analgesic consumption, satisfaction, and quality of recovery data.

You will also rate your pain and tell us about the medication you used to treat this pain and if there is anything in particular that makes this pain better or worse. The Pain Diary should take about 10 minutes to complete at each time point.

See the table below for the data that the research team will be collecting and the different time points that it will be collected.

	Pre-Regional Block	Immediately After the Block	20 mins after the block and every 20 minutes while in PACU	At discharge time to home from the PACU	Every 6 hours while at home for 72 hours after the block	24 hours after the block
Pain Scores	X	X	X	X	X	
Pain medication use	X	X	X	X	X	
How long block lasted					X	
Sleep Survey						X
Quality of Recovery						X

Disabilities of the Arm, Shoulder, and Hand Survey (DASH)

As part of standard of care you will be seen about 3 months after your surgery by your surgeon. At this visit a research team member will give you a survey known as the DASH. This survey asks questions about the use and movement of your arm, shoulder, and hand after surgery. It takes about 5 minutes to complete.

The medical, surgical, and anesthesia care that you entitled to receive for this surgical procedure will not change because you are in this study. All before surgery, surgical, and post-surgery care in the recovery room will be the same as any other patient undergoing this surgery.

What are the possible risks or discomforts?

We do not foresee any risks for participation in this study that are different than the standard of care. All medications used for the nerve block are FDA approved to be used alone and in combination for anesthesia.

A risk which is common to all studies which include randomization of patients to different treatment groups is the removal of the physician's choice of block type. Since both nerve blocks are safe for the patients enrolled in this study, we do not foresee this to be a major risk to patients enrolling in this study.

**Most patients receive single shot blocks for wrist fractures. We are seeking to provide the added benefit of catheters for more patients who are getting wrist fracture surgery.*

You will have been screened by both your surgical and anesthesia team for allergies to any medications including those commonly used for anesthesia and post-surgery pain control. If you have any previous history of allergies to any of the medications used for the block or the standard of care post-surgery and discharge medications, you will not be able to participate in this study.

The anesthesia team will have discussed the risks of both general and regional (nerve block) anesthesia with you and obtained your consent for each type of anesthesia prior to your surgery.

You will receive care and be monitored throughout and following your surgery per hospital standards as would any other non-study subject. (Standard protocol is the rules and regulations that must be followed for patient safety and quality of care).

Since a member of the research team will be phoning you at home to assist you in the completion of the questionnaires, you may feel some discomfort if it occurs at an inconvenient time of the day.

Risks of breaches of confidentiality are small but nonetheless possible. However, we have taken several measures to protect your identity. All study data will be stored in confidential research files of the research investigator. Records will not contain your name or any other personal identifiers.

What if new information becomes available about the study?

During the course of this study, we may find more information that could be important to you. This includes information that, once learned, might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

What are the possible benefits of the study?

You may not receive additional benefits from being in this research study. The pain control after receiving the block will help with pain control after surgery.

What other choices do I have if I do not participate?

If you do not participate in this study you will receive the standard of care protocol anesthesia regimen per the Penn Presbyterian Medical Center for the shoulder surgery procedure. The choice of medications used in your anesthesia regimen will be determined by your anesthesia provider.

Will I be paid for being in this study?

You will not be paid for participating in this study.

Will I have to pay for anything?

There is no fee for participating in this study. You and/or your health insurance will be billed for the costs of medical care during this study given these expenses would have happened even if you were not in the study, or if your insurance agrees in advance to pay.

What happens if I am injured or hurt during the study?

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the University of Pennsylvania to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

If you think you have been injured as a result of taking part in this research study, tell the person in charge of the research study as soon as possible. The researcher's name and phone number are listed in the consent form.

When is the Study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. If you do enroll in this study and later decide to withdraw your consent, whether before or after your procedure, you will be asked to notify a member of the study team. Their information can be found on page 1 of this consent form.

If you are unable to complete the procedure with the study medications, the anesthesiologist will withdraw you from the study and make sure you are able to complete your procedure. You will be sedated during this process and unable to participate in decisions, as is typical of patients undergoing procedures with sedation.

Who can see or use my information? How will my personal information be protected?

We will do our best to make sure that the personal information in your medical record will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

What is an Electronic Medical Record?

An Electronic Medical Record (EMR) is an electronic version of the record of your care within a health system. An EMR is simply a computerized version of a paper medical record.

Since you are receiving care or have received care within the University of Pennsylvania Health System (UPHS) (outpatient or inpatient) and are participating in a University of Pennsylvania research study, results of research-related procedures (i.e. laboratory tests, imaging studies and clinical procedures) may be placed in your existing EMR maintained by UPHS.

Once placed in your EMR, these results are accessible to appropriate UPHS workforce members that are not part of the research team. Information within your EMR may also be shared with others who are determined by UPHS to be appropriate to have access to your EMR (e.g. health insurance company, disability provider, etc).

What personal health information is collected and used in this study, and might also be disclosed?

The following personal health information will be collected, used for research, and may be disclosed during your involvement with this research study:

- Name, address, telephone number, date of birth
- Personal and family medical history
- Current and past medications or therapies
- Results of tests and procedures you will undergo during this research study as described in the informed consent form.
- Medical record number
- All information in the Medical Record

Why is your personal contact and health information being used?

Your personal contact information is important for the research team to contact you during the study. Your personal health information and results of tests and procedures are being collected as part of this research study. In some situations, your personal health information might be used to help guide your medical treatment.

Which of our personnel may use or disclose your personal health information?

The following individuals may use or disclose your personal health information for this research study:

- The Principal Investigator and the Investigator's study team

- Authorized members of the workforce of the UPHS and the School of Medicine, and University of Pennsylvania support offices, who may need to access your information in the performance of their duties (for example: for research oversight and monitoring, to provide treatment, to manage accounting or billing matters, etc.).

Who, outside of UPHS and the School of Medicine, might receive your personal health information?

As part of the study, the Principal Investigator, the study team and others listed above, may disclose your personal health information, including the results of the research study tests and procedures. This information may be disclosed to those listed below:

Regulatory and safety oversight organizations

- The Office of Human Research Protections
- The University of Pennsylvania Institutional Review Board

If your personal health information is disclosed to others outside of UPHS or the School of Medicine, it may no longer be covered by federal privacy protection regulations. The Principal Investigator or study staff will inform you if there are any additions to the list above during your active participation in the trial. Any additions will be subject to University of Pennsylvania procedures developed to protect your privacy.

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.

How long may UPHS and the School of Medicine be able to use or disclose your personal health information?

Your authorization for use of your personal health information for this specific study does not expire. Your information may be held in a research repository (database). However, UPHS and the School of Medicine may not re-use or re-disclose information collected in this study for a purpose other than this study unless:

- You have given written authorization to do so
- The University of Pennsylvania's Institutional Review Board grants permission after ensuring that appropriate privacy safeguards are in place
- As permitted by law

Will you be able to access your records?

During your participation in this study, you might not be able to access some or all of your medical records. For example, access to portions of your medical records may be denied in studies where your knowledge of study results included in such records could affect the reliability of the study. You will have access to your medical record information when the study is over or earlier, if possible. The Principal Investigator is not required to release research information to you that is not part of your medical record.

Can you change your mind?

Yes, at any time you may withdraw your approval to allow the use and disclosure of your personal health information as described here. You must do so in writing to the Principal Investigator at the address on the first page. Even if you withdraw your permission, your personal health information that was collected before we received your written request may still be used and disclosed, as necessary for the study. If you withdraw your permission to use your personal health information, you will also be withdrawn from the research study.

Who can I call with questions, complaints or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on page one of this form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Office of Regulatory Affairs with any question, concerns or complaints at the University of Pennsylvania by calling (215) 898-2614.

When you sign this form, you are agreeing to take part in this research study. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer. Your signature also means that you are permitting the University of Pennsylvania to use your personal health information collected about you for research purposes within our institution. You are also allowing the University of Pennsylvania to disclose that personal health information to outside organizations or people involved with the operations of this study.

A copy of this consent form will be given to you.

Name of Subject (Please Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Please Print)	Signature	Date