University of California, San Diego
Consent to Act as a Research Subject

A Randomized, Subject-Masked, Active-Controlled, Parallel-Arm Clinical Trial Comparing Erector Spinae and Paravertebral Nerve Blocks

Who is conducting the study, why you have been asked to participate, how you were selected, and what is the approximate number of participants in the study?

Brian Ilfeld, MD, MS, and colleagues, are conducting a research study. This study will determine if the *insertion site* of local anesthetic—or numbing medicine—affects the amount of pain relief that is experienced after surgery. You have been asked to participate because you are scheduled to undergo breast surgery and you have indicated the desire to have a peripheral nerve block of the nerves that go to the breast which is being operated on.

Approximately 120 people will participate in this research.

Why is this study being done?

Currently, there are two different places that the local anesthetic may be placed: at the "erector spinae" site and "paravertebral" location. Both of these sites are in the upper back area on the side of your planned surgery, and differ by less than an inch in depth. Each of these locations is considered "standard" at UCSD—they both are used on a regular basis. Which is used for each specific patient is currently determined by the anesthesiologists based on personal preferences. There is no information currently available that suggests one of these locations is better than the other, which is the reason why we are currently doing this study—to determine if there are benefits and/or risks to each of these two different locations.

What will happen to you in this study and which procedures are standard of care and which are experimental?

1. When you arrive for surgery, we will confirm some baseline information about you that is currently in your chart (for example, your age, weight, height, contacting phone numbers).

2. You will have monitors placed (such as a blood-pressure cuff) and an intravenous line placed. You will be given some medicines through your intravenous line to make you sleepy and more comfortable during the placement of the nerve block. This is standard-of-care (will occur whether or not you choose to participate in this study).

3. An anesthesiologist will then use an ultrasound machine to guide a needle to the nerves in your back that go to your breast (this is standard-of-care). However, if you choose to participate in this study, the location of the peripheral nerve block—erector spinae vs. paravertebral—will be determined randomly, like a flip of a coin. Your chance of being assigned to each group is 1

out of 2. This is experimental. If you do not choose to participate in this study, you will still receive one of these two locations—it's just that your anesthesiologist will choose which to use instead of the decision being made in a random fashion.

4. You will be discharged home when ready with a prescription for pain pills (standard-of-care) and asked to record the first time you take one of these pills as well as the time when you think the local anesthetic block starts to wear off. You will be called the morning after surgery to see how you are doing—this is standard-of-care.

5. You may contact Dr. Ilfeld through the page operator at 619-543-6222 who will be available to you 24 hours/day, 7 days/week, should you have any discomfort, questions or concerns.

How much time will each study procedure take, what is your total time commitment, and how long will the study last?

If you participate in the study, it will not add to your time commitment since you have chosen to have a peripheral nerve block for postoperative pain control regardless of study participation. You will be called the day after returning home, but this is done regardless of study participation. You will begin study participation the morning of surgery, and complete it 1 or 2 days after surgery with a phone call. Therefore, your total duration of study participation will be 1 or 2 days.

What risks are associated with this study?

Participation in this study may involve some added risks or discomforts. These include the following: Because the optimal block location is not known, we cannot assure you that there may be a benefit to participation in this study. That is, we cannot offer a specific benefit from using one location over the other. The risks of paravertebral blocks are rare but include bleeding, infection, damage to nerves, inadequate pain relief, and injection into nearby structures including blood vessels, near or into spinal canal, and lining of the lung. The risks of erector spinae blocks have not been fully established. Taking part in this study will help us determine which block location is safer. There is a potential for the loss of confidentiality from collecting your information for research. We will minimize this risk by storing your information in a locked office and in your official medical chart. Computers used to store your information are password-protected, encrypted, and only accessible by study investigators. Since this is an investigational study, there may be some unknown risks that are currently unforeseeable. You will be informed of any significant new findings. If you choose not to participate in this study, you can still have the peripheral nerve block as you have indicated that you want; but the anesthesiologist will simply choose which location to use instead of a computer determining this randomly (by chance).

What are the alternatives to participating in this study?

The alternatives to participation in this study are not participating as a research subject. You will still receive a nerve block for pain control after your surgery. The block location you receive by the anesthesiologist may or may not be the same location you would receive if you enroll in the study.

What benefits can be reasonably expected?
There are no direct medical benefits to volunteers. If we are able to determine that one block location is more adventageous than the other, future patients could receive improved pain control following breast surgery using this technique. In addition, if you, yourself, have future breast surgery and we determine that one location is more advantageous than the other, then you might benefit from this research in the future.

Can you choose to not participate or withdraw from the study without penalty or loss of benefits?
Participation in research is entirely voluntary. You may refuse to participate or withdraw at any time without penalty or loss of benefits to which you are entitled. If you decide that you no longer wish to continue in this study, you are free to do so at any time during your participation period.

Can you be withdrawn from the study without your consent?
You may also be withdrawn from the study if the investigator feels it is in your best interest or for other study-related purposes. You may also be withdrawn from the study if you do not follow the instructions given you by the study personnel.

Will you be compensated for participating in this study?
There is no compensation for participating in this study.

Are there any costs associated with participating in this study?
There are no costs to you for participating in the research study.

What if you are injured as a direct result of being in this study?
If you are injured as a direct result of participation in this research, the University of California will provide any medical care you need to treat those injuries. The University will not provide any other form of compensation to you if you are injured. You may call the Human Research Protections Program Office at (858) 246-4777 for more information about this, to inquire about your rights as a research subject or to report research-related problems.

What about your confidentiality?
Research records will be kept confidential to the extent allowed by law. Your study record will be de-identified using randomized numbers. Paper copies of study documents will be kept in locked medical offices. Any digitized records containing personal health information will be stored as password-protected and encrypted files. Research records may be reviewed by the UCSD Institutional Review Board.

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.

This study is being funded by the Department of Surgery.

Who can you call if you have questions?

Dr. Brian Ilfeld, and/or his colleagues has explained this study to you and answered your questions. If you have other questions or research-related problems, you may reach Dr. Brian Ilfeld through the UCSD page operator at 619-543-6222.

You may call the Human Research Protections Program Office at (858) 246-4777 to inquire about your rights as a research subject or to report research-related problems.

Your Signature and Consent

You have received a copy of this consent document and a copy of the "Experimental Subject's Bill of Rights" to keep.

You agree to participate.

_____ _____

Subject's signature Date