**Randomized Double Blinded Study Comparing Timing of PEC Block for Post-Operative Pain in Bilateral Mastectomy Patients**

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**INFORMED CONSENT DOCUMENT**

Project Title: **Randomized Double Blinded Study Comparing Timing of PEC Block for Post-Operative Pain in Bilateral Mastectomy Patients.**

**Principal Investigator:** Melinda Seering

**Research Team Contact:** **Melinda Seering, MD**
[redacted]

**Ingrid Lizarraga, MD**
[redacted]

This consent form describes the research study to help you decide if you want to participate. This form provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research subject.
If you have any questions about or do not understand something in this form, you should ask the research team for more information.
You should discuss your participation with anyone you choose such as family or friends.
Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

## WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We are inviting you to participate in this research study because you have been diagnosed with breast cancer and are undergoing a bilateral mastectomy and possible reconstructive surgery.
The purpose of this research study is to evaluate if timing of the nerve block for pain control will affect post-operative pain scores and pain medication needs.

## HOW MANY PEOPLE WILL PARTICIPATE?

Approximately **35** people will take part in this study conducted by investigators at the University of Iowa**.**

## HOW LONG WILL I BE IN THIS STUDY?

If you agree to take part in this study, your involvement will last for **3-6 months.**

## WHAT WILL HAPPEN DURING THIS STUDY?

After you give consent to participate in the study, you will be given a pamphlet describing the nerve block including the procedure, risks and complications.

On the day of surgery, you will be asked to fill out a questionnaire that determines your pain levels and mood. You will be randomly assigned to one of the study groups (Research only)

After the standard check in process and safety checklists are completed, you will be given oral pain medication in the pre-operative area. (Standard of care)

You will then be taken to the operating room, where the anesthesiology team will start administering the general anesthetic to put you to sleep during surgery. (Standard of care)

After the general anesthesia has been safely administered, patients in group I will have the block performed before the surgical incision is made. The area of the breast will be exposed and cleaned with antiseptic solution. The muscle layers between which the local anesthetic medication is to be administered are identified with ultrasound and the medication is injected under ultrasound guidance. (Standard of care)

If you have been assigned to Group II after the general anesthetic has been safely administered, the area of the breast will be exposed and appropriately prepped and draped and the surgeon will perform the mastectomy. After the mastectomy has been performed, the nerve block will then be performed under ultrasound guidance. The muscle layers between which the local anesthetic/ numbing medication is to be injected will be identified and the injected under ultrasound guidance. (Research only)

**What will I be asked to do if I participate?**
You will be asked to complete a form describing your pain score and mood on the day of surgery. (Research only)

Immediately in the post-operative period, the nurses in the recovery unit will assess your pain scores. (standard of care)

Nurses in the admission unit after surgery will also continue to assess your pain scores until discharge. (standard of care)

You will be asked to maintain a pain diary and respond to text regarding your pain levels on post-operative days 2, 3, 5, 7. (Research only)

On post –operative day 14, at your clinic visit to the surgery clinic you will be asked to fill another form about your pain scores and mood. (Research only)

At 3 mos and 6 mos, you will complete a form describing your pain score and mode the day of your visit (Research only)

The consent will be obtained in a private room. The nerve block will be performed in the operating room. Verbal pain assessments will be performed in the recovery room and admission unit.

No experimental drugs or procedures are involved in this study.

In the questionnaire provided on the day of surgery to assess pain levels and mood, you are free to skip any question you are not comfortable answering.

**HIPAA INFORMATION** (See also the WILL MY HEALTH INFORMATION BE USED section):

We will collect medical information to be used in the study including age, weight, allergies. (Standard of care)

We will record vital signs – heart rate, blood pressure, pulse oximetry in the pre-operative, intra-operative and post-operative period. (Standard of care)

We will record your pain scores in the immediate post-operative period and during your hospitalization. (Standard of care)

We will ask you to maintain a pain diary and collect pain scores on post-operative day 2, 3, 5, 7 and 14. (Research only)

**WHAT ARE THE RISKS OF THIS STUDY?**

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Risks related to the nerve block itself.

**Less Likely / Less Common (10% - 35%)**

Mild
Bleeding
Infection
Fever
Failure to have adequate block ( numbness of surgical area and breast)

**Rare (less than 10%)**

Life Threatening
Seizure
Cardiac arrest (Code Blue)
Respiratory failure
Patient death
Hypotension (low blood pressure)
Pruritis
Serious
Local Anesthetic toxicity

## WHAT ARE THE BENEFITS OF THIS STUDY?

We don't know if you will benefit from being in this study.

However, we hope that, in the future, other people might benefit from this study because of knowledge gained about ways to improve pain control in patients undergoing mastectomy for breast cancer.

## WHAT OTHER TREATMENT OPTIONS ARE THERE?

Before you decide whether or not to be in this study, your doctor will discuss the other options that are available to you. Instead of being in this study, you could either choose to not have a block or you could choose to have a block and not participate in the study. If you choose to have the block and not participate in the study, the block will be performed pre-operatively before you are under general anesthesia.

## WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any additional cost for being in this research study.
You and/or your medical/hospital insurance carrier will remain responsible for your regular medical care expenses.

## WILL I BE PAID FOR PARTICIPATING?

You will not be paid for being in this research study.

## WHO IS FUNDING THIS STUDY?

The University and the research team are receiving no payments from other agencies, organizations, or companies to conduct this research study.

## WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?

If you are injured or become ill from taking part in this study, medical treatment is available at the University of Iowa Hospitals and Clinics.

The University of Iowa does not plan to provide free medical care or payment for treatment of any illness or injury resulting from this study unless it is the direct result of proven negligence by a University employee.

If you experience a research-related illness or injury, you and/or your medical or hospital insurance carrier will be responsible for the cost of treatment.

## WHAT ABOUT CONFIDENTIALITY?

We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- federal government regulatory agencies,
- auditing departments of the University of Iowa,
- University of Iowa Institutional Review Board (a committee that reviews and approves research studies)

To help protect your confidentiality, we will keep paper record in a locked office in the anesthesia research office and electronic data will be coded by subject number without identifying patient information on a password protected computer. The procedure is done in an area where patient privacy is maintained, and we will maintain the protocol. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

The University of Iowa Hospitals and Clinics generally requires that we document your participation in research occurring in a University of Iowa Health Care facility. This documentation will be in either your medical record or a database maintained on behalf of the institution reflecting that you are participating in this study. The information included will provide contact information for the research team as well as information about the risks associated with this study. We will keep this Informed Consent Document in our research files; it will not be placed in your medical record chart.

A description of this clinical trial 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.

## WILL MY HEALTH INFORMATION BE USED DURING THIS STUDY?

The Federal Health Insurance Portability and Accountability Act (HIPAA) requires University of Iowa Health Care to obtain your permission for the research team to access or create "protected health information" about you for purposes of this research study. Protected health information is information that personally identifies you and relates to your past, present, or future physical or mental health condition or care. We will access or create health information about you, as described in this document, for purposes of this research study and for your treatment. Once your health care provider has disclosed your protected health information to us, it may no longer be protected by the Federal HIPAA privacy regulations, but we will continue to protect your confidentiality as described under "Confidentiality."

We may share your health information related to this study with other parties including federal government regulatory agencies, the University of Iowa Institutional Review Boards and support staff.

You cannot participate in this study unless you permit us to use your protected health information. If you choose *not* to allow us to use your protected health information, we will discuss any non-research alternatives available to you. Your decision will not affect your right to medical care that is not research-related. Your signature on this Consent Document authorizes your health care provider to give us permission to use or create health information about you.

Although you may not be allowed to see study information until after this study is over, you may be given access to your health care records by contacting your health care provider. Your permission for us to access or create protected health information about you for purposes of this study has no expiration date. You may withdraw your permission for us to use your health information for this research study by sending a written notice to Dr. Melinda Seering, MD, University of Iowa Healthcare, Department of Anesthesia; 200 Hawkins Dr., Iowa City, IA 52242. However, we may still use your health information that was collected before withdrawing your permission. Also, if we have sent your health information to a third party, such as the study sponsor, or we have removed your identifying information, it may not be possible to prevent its future use. You will receive a copy of this signed document.

## IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

### What if I Decide to Drop Out of the Study?

There will be no adverse effects if you decide to drop out of the study.

### Will I Receive New Information About the Study while Participating?

If we obtain any new information during this study that might affect your willingness to continue participating in the study, we'll promptly provide you with that information.

### Can Someone Else End my Participation in this Study?

Under certain circumstances, the researchers might decide to end your participation in this research study earlier than planned. This might happen because the nerve block was unable to be placed. Theis may be due to not being able to see the nerves correctly and safely under ultrasound to place the nerve block.

## WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: **Dr. Melinda Seering [redacted] or Dr. Ingrid Lizarraga:.** If you experience a research-related injury, please contact: **Dr. Melinda Seering [redacted] or**

**Dr. Ingrid Lizarraga [redacted] Regional Anesthesia Follow-up Clinic [redacted].**
**After hours, contact [redacted], ask for the [redacted] resident on call.**

If you have questions, concerns, or complaints about your rights as a research subject or about research related injury, please contact the Human Subjects Office, 105 Hardin Library for the Health Sciences, 600 Newton Rd, The University of Iowa, Iowa City, IA 52242-1098, (319) 335-6564, or e-mail irb@uiowa.edu. General information about being a research subject can be found by clicking "Info for Public" on the Human Subjects Office web site, http://hso.research.uiowa.edu/. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Subjects Office at the number above.

This Informed Consent Document is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by signing this Informed Consent Document. Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a copy of this form.

Subject's Name (printed):

_____ _____
(Signature of Subject) (Date)

**Statement of Person Who Obtained Consent**

I have discussed the above points with the subject or, where appropriate, with the subject's legally authorized representative. It is my opinion that the subject understands the risks, benefits, and procedures involved with participation in this research study.

_____ _____
(Signature of Person who Obtained Consent) (Date)