Consent Form

Title of Research Study: ***Evaluation of diaphragm movement after an Interscalene block***

Investigator Team Contact Information: Dr. Jason Habeck

For questions about research appointments, the research study, research results, or other concerns, call the study team at:

Investigator Name: Dr. Jason Habeck Investigator Departmental Affiliation: Anesthesiology Phone Number: 612-624-9990 Email Address: habe0073@umn.edu	Study Staff: Melissa Cohen, Jason Hall, Ryan Eskuri, Ken Kiberenge Phone Number: 612-625-7116 Email Address: cohen045@umn.edu

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Financial Interest Disclosure: The primary investigator does not have any financial interest.

Key Information About This Research Study

The following is a short summary to help you decide whether or not to be a part of this research study. More detailed information is listed later on in this form.

What is research?

Doctors and investigators are committed to your care and safety. There are important differences between research and treatment plans:

- The goal of research is to learn new things in order to help groups of people in the future. Investigators learn things by following the same plan with a number of participants, so they do not usually make changes to the plan for individual research participants. You, as an individual, may or may not be helped by volunteering for a research study.
- The goal of clinical care is to help you get better or to improve your quality of life. Doctors can make changes to your clinical care plan as needed.

Your doctor, who is also responsible for this research study, is interested in both your clinical care and the conduct of this research study. You have the right to discuss this study with another person who is not part of the research team before deciding whether to participate in the research.

Why am I being asked to take part in this research study?

We are asking you to take part in this research study because you are receiving an interscalene block with liposome bupivacaine for shoulder surgery.

What should I know about a research study?

- Someone will explain this research study to you.
- Whether or not you take part is up to you.
- You can choose not to take part.
- You can agree to take part and later change your mind.
- Your decision will not be held against you.
- You can ask all the questions you want before you decide.

Why is this research being done?

The purpose of this study is to evaluate the movement of the diaphragm after an interscalene block with liposome bupivacaine. The diaphragm is a muscle that helps your lung function normally when you breath. Sometimes when we perform a nerve block (interscalene block) to numb your shoulder the nerve that controls the diaphragm(the phrenic nerve) is affected. We want to see if there is prolonged phrenic nerve paralysis when using liposome bupivacaine in an interscalene block. Liposomal bupivacaine is a long acting anesthetic. It is liposome encapsulated bupivacaine which allows for prolonged release of bupivacaine over a 72-hour period. Currently it is the standard of care to use this medication in an interscalene block at the University of Minnesota. However, it's effects on diaphragm function has not been adequately evaluated. Thus we want to see if a long acting numbing agent has a longer effect on blocking the nerve for the muscle of the diaphragm.

How long will the research last?

We expect that you will be in this research study for 2 days following shoulder surgery. However, we will

continue to monitor your chart for adverse events up to 30 days post-procedure.

What will I need to do to participate?

You will be asked to consent to all for a staff member to ultrasound your diaphragm and perform spirometry. There will be a baseline evaluation prior to your nerve block, there will be an evaluation while you are in the recovery room, and another evaluation on the first postoperative day while on the hospital ward.

More detailed information about the study procedures can be found under ***"What happens if I say yes, I want to be in this research?"***

Is there any way that being in this study could be bad for me?

You risk having your day interrupted by the anesthesia team to perform the ultrasound evaluation. There is also a risk of loss of privacy if you participate in this study.

Will being in this study help me in any way?

We cannot promise any benefits to you or others from your taking part in this research.

What happens if I do not want to be in this research?

You do not have to participate in this research. Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. This means that your choice not to be in this study will not negatively affect your right to any present or future medical care.

If you choose not to participate you would still receive the interscalene block as is the standard of care for patients undergoing shoulder surgery.

Detailed Information About This Research Study

The following is more detailed information about this study in addition to the information listed above.

How many people will be studied?

We expect 40 patients will be enrolled in this research study.

What happens if I say "*Yes, I want to be in this research*"?

If you choose to take part in this research you will consent for allowing your diaphragm (a muscle that supports lung function during breathing) to be ultrasounded (evaluated with a machine that looks inside your body). All patients who have had an interscalene block (nerve block that numbs your shoulder) with bupivacaine or liposome bupivacaine (a long acting numbing agent) are eligible. You will perform spirometry (a breathing exercise through a machine) and have an ultrasound examination of your diaphragm at baseline, in the recovery room and on postoperative day 1 (24 hours after interscalene block). Diaphragmatic movement will be evaluated and to be examined in an upright sitting position and scanned on your side. The range of diaphragmatic movement from the resting expiratory position to deep inspiration (sigh test) will be recorded as well as the range of diaphragmatic movement from resting expiratory position when quickly inhaling through the nose (sniff test). This will occur three times. At baseline prior to surgery, in the recovery room, and on the ward on postoperative day 1.

What are my responsibilities if I take part in this research?

You will be responsible for taking a sigh breath and a sniff type breath for the ultrasound examination and once for spirometry.

What happens if I say "Yes", but I change my mind later?

You can leave the research study at any time and your care will not be affected by your decision.

Choosing not to be in this study or to stop being in this study will not result in any penalty to you or loss of benefit to which you are entitled. This means that your choice not to be in this study will not negatively affect your right to any present or future medical care.

If you stop being in the research, information about you that has already been collected may not be removed from the study database. You will be asked whether the investigator can collect information from your routine medical care, such as your medical records. If you agree, this information will be handled the same as the information obtained for the research study.

What are the risks of being in this study? Is there any way being in this study could be bad for me? (Detailed Risks)

You risk having your day interrupted by the anesthesia team to perform the ultrasound evaluation. There is also a risk of loss of privacy if you participate in this study.

What do I need to know about reproductive health and/or sexual activity if I am in this study?

The ultrasound should have no effect on your reproductive health or sexual activity.

Will it cost me anything to participate in this research study?

You will not be billed for the use of ultrasound to evaluate your diaphragm function or the spirometry, therefore there are no extra cost to the you for your participation.

What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot guarantee complete confidentiality. Organizations that may inspect and copy your information include the Institutional Review Board (IRB), the committee that provides ethical and regulatory oversight of research, and other representatives of this institution, including those that have responsibilities for monitoring or ensuring compliance.

The sponsor, monitors, auditors, the IRB, the University of Minnesota Research Compliance Office and other University compliance units, the US Office of Research Integrity (ORI), the US Office for the Protection of Human Research Protections (OHRP), the US Food and Drug Administration (FDA) may be granted direct access to your medical records to conduct and oversee the research. By signing this document you are authorizing this access. We may publish the results of this research. However, we will keep your name and other identifying information confidential.

A description of this clinical trial will be available at 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.

Will anyone besides the study team be at my consent meeting?

You may be asked by the study team for your permission for an auditor to observe your consent meeting. Observing the consent meeting is one way that the University of Minnesota makes sure that your rights as a research participant are protected. The auditor is there to observe the consent meeting, which will be carried out by the people on the study team. The auditor will not document any personal (e.g. name, date of birth) or confidential information about you. The auditor will not observe your consent meeting without your permission ahead of time.

Whom do I contact if I have questions, concerns or feedback about my experience?

This research has been reviewed and approved by an IRB within the Human Research Protections Program (HRPP). To share feedback privately with the HRPP about your research experience, call the Research Participants' Advocate Line at 612-625-1650 or go to https://research.umn.edu/units/hrpp/research-participants/questions-concerns. You are encouraged to contact the HRPP if:

- Your questions, concerns, or complaints are not being answered by the research team.
- You cannot reach the research team.
- You want to talk to someone besides the research team.
- You have questions about your rights as a research participant.
- You want to get information or provide input about this research.

Will I have a chance to provide feedback after the study is over?

The HRPP may ask you to complete a survey that asks about your experience as a research participant. You do not have to complete the survey if you do not want to. If you do choose to complete the survey, your responses will be anonymous.

If you are not asked to complete a survey, but you would like to share feedback, please contact the study team or the HRPP. See the "Investigator Contact Information" of this form for study team contact information and "Whom do I contact if I have questions, concerns or feedback about my experience?" of this form for HRPP contact information.

Can I be removed from the research?

The person in charge of the research study or the sponsor can remove you from the research study without your approval. We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

What happens if I am injured while participating in this research?

In the event that this research activity results in an injury, treatment will be available, including first aid, emergency treatment and follow-up care as needed. Care for such injuries will be billed in the ordinary manner, to you or your insurance company. If you think that you have suffered a research related injury let the study physicians know right away.

Will I be compensated for my participation?

No compensation will be provided for participation in this study.

Use of Identifiable Health Information

We are committed to respect your privacy and to keep your personal information confidential. When choosing to take part in this study, you are giving us the permission to use your personal health information that includes health information in your medical records and information that can identify you. For example, personal health information may include your name, address, phone number or social security number. Those persons who get your health information may not be required by Federal privacy laws (such as the 1099 Rule) to protect it. Some of those persons may be able to share your information with others without your separate permission. Please read the HIPAA Authorization form that we have provided and discussed.

The results of this study may also be used for teaching, publications, or for presentation at scientific meetings.

Your signature documents your permission to take part in this research. You will be provided a copy of this signed document.

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Signature of Participant Date

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Printed Name of Participant

_____ _____

Signature of Person Obtaining Consent Date

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Printed Name of Person Obtaining Consent