**Northwell Health**
**Campus: Long Island Jewish Medical Center**
**and Center for Advanced Medicine**
**Consent for Participation in a Research Study**

**Title**: Serratus Plane Block for Post-operative Pain Control in Breast Surgery
**Principal Investigator**: Judith Aronsohn, MD

**About this research**
You are being asked to participate in a research study.

This consent form will give you information about the study to help you decide whether you want to participate. Please read this form, and ask any questions you have, before agreeing to be in the study.

**Important Information**
This information gives you an overview of the research. More information about these topics may be found in the pages that follow.

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| **Why am I being asked to provide my consent?** | This is a research study, which is different than personal medical care. Scientists do research to answer important questions which might help change or improve the way we do things in the future. |
| **Do I have to join this research study?** | No. Taking part in this research study is voluntary. You may choose not to take part in the study or may choose to leave the study at any time. Deciding not to participate, or deciding to leave the study later, will not result in any penalty or loss of benefits to which you are entitled. |
| **Why is this research study being done?** | The purpose of this research study is to study the effects of a bupivacaine HCL "serratus plane block" on pain after a breast surgery operation. A serratus plane block is a type of anesthesia in which the drug bupivacaine HCL is injected into the muscles of the chest to numb the chest and breasts. The goal of this study is to determine whether this serratus plane block lowers the amount of pain you have after your operation. |
| **What will happen to me during the study?** | If you agree to participate in this study, you will be randomly assigned to either receive the bupivacaine HCL serratus plane block or receive a placebo injection of normal saline (salt water). A placebo is a liquid that looks like the study drug, but has no real medicine in it. The study is also double-blinded. This means that neither you nor the researchers directly involved in the study procedures will be allowed to know whether or not you received the bupivacaine HCL serratus plane block until the study is complete.<br><br>After you are asleep from the general anesthesia being given to you as part of your standard of care breast surgery, a small amount of either bupivacaine HCL or placebo will be injected into the muscles of your chest by the anesthesiologist using an ultrasound machine. The ultrasound will be used to ensure that the injection is correctly placed into |

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| | the serratus muscle. After the injection of either bupivacaine HCL or placebo, the surgery will be performed as usual.<br><br>During the procedure, you will receive a 20 ml injection of your assigned drug (Bupivacaine HCL in normal saline or placebo consisting of normal saline only) to each side of your chest that is undergoing surgery. During surgical recovery, you will be asked to provide an assessment of your pain and how nauseated you feel throughout your hospital stay. |
| **How long will I participate?** | The study procedures will last for up to one week after your surgery. The study procedures will last approximately 4-12 minutes during your surgery. You will then undergo study assessments during your stay in the hospital. In addition, you will receive a follow-up phone call within one week of your surgery. |
| **Will taking part expose me to risks?** | If you have an allergy to bupivacaine or any pain medications, please notify a study investigator. Although allergies to bupivacaine are very rare, they can be fatal. Allergic reactions include headache, dizziness, nausea, vomiting, hives (skin rash), and itching. Common side effects of bupivacaine include nausea, vomiting, and constipation. There is also a risk of the drug not working. Since the study is randomized, your group may receive less effective treatment or have more side effects.<br><br>Since the drug will be injected into your chest, there are risks associated with the injection procedure. The risks of receiving an injection are bleeding, infection, pain at the injection site, bruising, hematoma (swelling), and nerve injury. There is also a risk of getting a collapsed lung because of the injection to the chest. However, this risk is significantly minimized by the use of an ultrasound machine to see the muscle of your chest and to correctly guide the needle.<br><br>Please see the risks section of the consent form for more information and for a more detailed list of the risks associated with this study. |
| **Are there any benefits to participation?** | If you are randomized to receive bupivacaine HCL, you may directly benefit from participation by having less pain and nausea after your surgery, a shorter hospital stay, and better medical outcomes compared to standard of care treatment. However, this cannot be guaranteed. In addition, this research study may benefit individuals in the future by supporting the use of a bupivacaine HCL serratus plane block as an effective way to control post-operative pain for all individuals undergoing breast surgery. |
| **What are my alternatives to participation?** | If you do not join this study, you may undergo the standard of care surgical procedure. |

**Please review the rest of this document for details about these topics and additional things you should know before making a decision about whether to participate in this research.**

**Introduction**
You are being asked to join a research study. The purpose of a research study is to answer specific questions, sometimes about the safety of a drug or device and how well it works. Being in a research study is different from being a patient. When you are a patient, you and your doctor have freedom in making decisions about your healthcare. When you are in a research study, the researcher will follow the rules of the research study as closely as possible, while monitoring your health.

You do not have to be in this study to receive medical care. You should ask questions before you decide if you want to participate. You can also ask questions at any time during the study.

**Why is this research study being done?**
The purpose of this research study is to study the effects of a bupivacaine HCL "serratus plane block" on pain after a breast surgery operation.

A serratus plane block is a type of anesthesia in which the drug bupivacaine HCL is injected into the muscles of the chest to numb the chest and breasts. The goal of this study is to determine whether this serratus plane block lowers the amount of pain you have after your operation. The study will also evaluate whether it makes you feel less nauseated after your surgery, leads to a shorter hospital stay, improves medical outcomes, and improves your overall satisfaction with the surgery. This study will help us understand if this serratus plane block should be given to everyone undergoing breast surgery.

**Why are you being asked to participate in this study?**
You are being asked to participate in this study because you are undergoing breast surgery as part of your standard clinical care.

**Why is this research?**
This is a research study because we do not know if a bupivacaine HCL serratus plane block will decrease the amount of pain you have after your operation. In this study, some individuals will receive the bupivacaine HCL serratus plane block in addition to standard pain medications, while some individuals will receive the standard pain medications alone. The study will compare the outcomes of these individuals to determine whether performing this block is more useful in treating pain than standard pain medication alone.

**How many people will take part in this study?**
This research study hopes to enroll approximately 90 participants.

**How long will you be in this study?**
If you choose to take part in this study, the study procedures will last for up to one week after your surgery. The study procedures will last approximately 4-12 minutes during your surgery. You will then undergo study assessments during your stay in the hospital. In addition, you will receive a follow-up phone call within one week of your surgery.

**What will happen in this research study?**
If you agree to participate in this study, you will be randomized. This means that you will be assigned to a group by chance (like flipping a coin). You will have an equal chance of being in either group. You will be randomly assigned to either receive the bupivacaine HCL serratus plane block or receive a

placebo injection of normal saline (salt water). A placebo is a liquid that looks like the study drug, but has no real medicine in it. A placebo is often used in research studies because knowing whether you are getting the study drug can change the results of the study.

The study is also double-blinded. This means that neither you nor the researchers directly involved in the study procedures will be allowed to know whether or not you received the bupivacaine HCL serratus plane block until the study is complete. The study is done this way because knowing whether you are in a group can change the results of the study. We will not tell you which group you are in since the researchers will not know your group either. However, we can quickly find out which group you are in if we ever need to know for your safety.

After you are asleep from the general anesthesia being given to you as part of your standard of care breast surgery, a small amount of either bupivacaine HCL or placebo will be injected into the muscles of your chest by the anesthesiologist using an ultrasound machine (a machine that uses sound waves to create an image of the structures inside of your body). The ultrasound will be used to ensure that the injection is correctly placed into the serratus muscle. After the injection of either bupivacaine HCL or placebo, the surgery will be performed as usual. You will receive the same amount of anesthesia during the surgery and the same amount of pain relief medicine and anti-nausea medicine after your surgery as you would receive if you didn't participate in this study. However, the study will record the type and amount of medication you take following your surgery.

During the procedure, you will receive a 20 ml injection of your assigned drug (Bupivacaine HCL in normal saline or placebo consisting of normal saline only) to each side of your chest that is undergoing surgery. If you are randomized to receive bupivacaine HCL, each 20 ml injection will contain 50 mg of bupivacaine HCL. Therefore, you will receive a total of 50 mg of bupivacaine HCL if you are having surgery on one side of your chest and a total of 100 mg of bupivacaine HCL if you are having surgery on both sides of your chest. If you are randomized to receive placebo, you will only receive a 20 ml injection of normal saline to each side of your chest that is undergoing surgery.

During surgical recovery, you will be asked to provide an assessment of your pain and how nauseated you feel throughout your hospital stay. You will be asked to provide these assessments every 30 minutes for the first 4 hours and then each hour until you are discharged. A researcher will then contact you within one week of discharge to obtain information about your pain and overall satisfaction with the surgery. After the collection of this information and relevant information from your medical records regarding your health, your participation in this study is considered complete.

**What are the risks and discomforts of the research study?**
If you have an allergy to bupivacaine or any pain medications, please notify a study investigator. Although allergies to bupivacaine are very rare, they can be fatal. Allergic reactions include headache, dizziness, nausea, vomiting, hives (skin rash), and itching. Common side effects of bupivacaine include nausea, vomiting, and constipation. There is also a risk of the drug not working. Since the study is randomized, your group may receive less effective treatment or have more side effects.

Since the drug will be injected into your chest, there are risks associated with the injection procedure. The risks of receiving an injection are bleeding, infection, pain at the injection site, bruising, hematoma (swelling), and nerve injury. There is also a risk of getting a collapsed lung because of the injection to

the chest. However, this risk is significantly minimized by the use of an ultrasound machine to see the muscle of your chest and to correctly guide the needle. If your lung were to collapse, a tube would be inserted into your chest to re-expand your lung.

Although the injection procedure will add 4-12 minutes to your surgery, it is not believed that this additional time under anesthesia will pose a significant risk to you.

There are no risks associated with the completion of the pain and nausea scores. There is also a risk of a breach of confidentiality if unauthorized individuals obtain access to protected health information. The study team will take all reasonable measures to minimize this risk from occurring.

As with any new procedure or treatment, there might be side effects that are unknown at this time. You will be closely watched for side effects. You should report any unusual events to the study staff.

**What are the benefits of this research study?**
If you are randomized to receive bupivacaine HCL, you may directly benefit from participation by having less pain and nausea after your surgery, a shorter hospital stay, and better medical outcomes compared to standard of care treatment. However, this cannot be guaranteed.

In addition, this research study may benefit individuals in the future by supporting the use of a bupivacaine HCL serratus plane block as an effective way to control post-operative pain for all individuals undergoing breast surgery.

**If you do not want to take part in this research study, what are your other choices?**
If you do not join this study, you may undergo the standard of care surgical procedure.

**Are there any costs for being in this research study?**
The study drug and study procedures will be provided to you at no cost. However, you or your insurance company will be responsible for costs associated with your standard of care procedures.

**Will you receive any payments for participating in this research study?**
You will not receive any money or compensation for participating in this research study.

**What are your rights as a research participant?**
Your participation in this project is voluntary. The quality of your medical care will be the same, whether you join, refuse to join, or decide to leave the study. If you do not join the study, you will not be penalized or lose benefits to which you are entitled. If you join the study, you may withdraw at any time without prejudice to your future care at Northwell Health.

**What happens if you are injured while participating in this study?**
If you are hurt from being in the study, you will receive medical care and treatment as needed from Northwell Health. However, you will be responsible for the costs of such medical treatment, directly or through your medical insurance or other forms of medical coverage. No money will be given to you.

**Could you be taken off the study before it is over?**
It is also possible that your participation in this study may end without your consent. This decision may be made by a researcher or the Institutional Review Board (IRB- the committee that oversees research at this institution).

Reasons for withdrawal may include: failure to follow instructions, it is not in your best interest to continue on this study, or the study is stopped. If you withdraw from this study or are withdrawn from the study, any data already collected will continue to be used. However, no new data will be collected.

**What happens if new information is learned?**
You will be told of any new findings that may change your decision to continue to participate. Your consent to continue to take part in this study may be obtained again.

**What information will be collected and used for this study?**
If you agree to be in this study, we will collect health information that identifies you. We may collect the results of tests. We will also collect information from your medical record. We will only collect information that is needed for the research. This information has been described in this consent form. If you sign this consent form, you are giving us permission to collect, use and share your health information. This permission is called authorization. If you do not want to provide authorization, then you cannot participate in this research study.

**Who else will see your information?**
Study records that identify you will be kept private. You will not be identified in study records or publications disclosed outside of Northwell Health, except as detailed below.

Investigators might share information collected from this research study with:

- other researchers, and
- clinical staff not involved in the study who may be involved in your care.

The following reviewers may access your study and medical records to make sure that this study is being done properly:

- Representatives from federal and state government oversight agencies such as the Office for Human Research Protections (OHRP) and FDA.
- Representatives from the Northwell Health Human Research Protection Program (the group of people that oversee research at this institution).

We will do our best to protect the privacy of your records, but it is possible that once information is shared with people listed on this form, it will be released to others. If this happens, your information may no longer be protected by the federal law. In the future, we may publish results of this study in scientific journals and may present it at scientific meetings. If we do we will not identify you. If the researchers learn about potential serious harm to you or someone else or other public health concerns, it will be shared with the appropriate authorities.

**Will you be able to access your records?**
If your research records are used for decisions related to your clinical care, then you have the right to review this information and request changes. This is limited to information about your treatment, and

does not include information related to procedures or tests that are for research purposes only. You may access this information only after the study analysis is complete. You have the right to know who has and who will see your records. To request this information, please call the Human Research Protection Program at 516-465-1910.

**How long will your health information be kept?**
There is no limit on the length of time we will keep your information for this research because it may be analyzed for many years. We will keep it as long as it is useful, unless you decide you no longer want to take part or we close the study. You are allowing access to this information indefinitely.

**Can you change your mind?**
If you change your mind about being in the study, you may withdraw at any time. If you want us to stop collecting your health information, you need to send a letter to the researcher at the following address:

Judith Aronsohn, MD
Department of Anesthesiology
Northwell Health
270-05 76th Avenue, Room B-341
New Hyde Park, NY 11040

Your letter needs to say that you have changed your mind and do not want the researcher to collect and share your health information. You may also need to leave the research study if we cannot collect any more health information. We may still use the information we have already collected. We need to know what happens to everyone who starts a research study, not just those people who stay in it.

**Will my information be used for research in the future?**
Information collected from you for this research may be used for future research studies or shared with other researchers for future research. If this happens, information which could identify you will be removed before any information or specimens are shared. Since identifying information will be removed, there will not be an additional consent for future research. By consenting to participate in this study you are agreeing to allow your de-identified specimens and/or data to be used by future researchers without additional consent.

**Will information about this study be available to the public?**
A description of this clinical trial will be available on http://www.Clinical Trials.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 website at any time.

**Does the investigator of this study receive money if you take part?**
The investigators on this study do not receive money for your participation in this study.

**Who can answer your questions about this study?**
If you have any questions about the study, about side effects of the study, or about injuries caused by research, you may call Judith Aronsohn, MD at (718) 470-5382. If you need emergency care, dial 911 or go to the nearest Emergency Room.

If you have questions about your rights as a research participant, concerns about being in the study, or would like to offer input, you may contact the Human Research Protection Program at (516) 465-1910.

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

**Summation/Signature**
You have read the above description of the research study. You have been told of the risks and benefits involved and all your questions have been answered to your satisfaction. A member of the research team will answer any future questions you may have. You voluntarily agree to join this study and know that you can withdraw from the study at any time without penalty. By signing this form, you have not given up any of your legal rights.

_____
Printed Name of Participant

_____ _____
Signature of Participant Date

_____
Printed Name of Witness

_____ _____
Signature of Witness Date

**Investigator's Statement**
In addition to advising the above participant of other appropriate alternatives, I have offered an opportunity for further explanation of the risks and discomforts which are or may be associated with this study, and to answer any further questions relating to it.

_____
Printed Name of Investigator

_____ _____
Signature of Investigator Date