University of Wisconsin (UW) - Madison
Research Participant Information and Consent and Authorization Form

Study Title: Optimizing topical pain control for breast cancer patients undergoing preoperative radiotracer injection for sentinel lymph node mapping: a randomized clinical trial

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Invitation
You are invited to take part in a research study about pain control for injections of radioactive tracer before sentinel lymph node biopsy. You are invited because you will be or are scheduled to have a sentinel lymph node biopsy as part of your breast cancer treatment. Your participation is completely voluntary. About 180 patients will participate in this study at UW Health University Hospital/University of Wisconsin.

What is the purpose of this form?
The purpose of this consent and authorization form is to give you the information you need to decide whether you'd like to be in the study. It also explains how health information will be used for this study and requests your permission to use your health information. Please ask questions about anything in this form that is not clear. If you want to talk to your family and friends before making your decision, you can. Once we have answered all of your questions, you can decide whether or not you'd like to participate in this study. This process is called "informed consent."

What is the purpose of the study?
Patients who have a sentinel lymph node biopsy for breast cancer have a safe radioactive tracer liquid injected in the breast the day of surgery or the day before surgery. The radioactive tracer collects in the sentinel lymph nodes. Surgeons can then find and remove the sentinel lymph nodes with the help of the radioactive tracer. Some patients say the injection of radioactive tracer is quite painful. We are studying different pain treatments for the injection of radioactive tracer.

The purpose of this study is to compare four different pain treatments for the injection of radioactive tracer that breast cancer patients receive for sentinel lymph node biopsies. These pain treatments have all been used for other minor procedures. However, they have not been compared with each other to see whether they specifically reduce pain with the injections of radioactive tracer.

This study is funded by a grant from the National Institutes of Health.

What will my participation involve?
If you decide to participate in this research, we will ask you to sign and date this consent form. We will then ask one brief question about any current pain you are

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experiencing. The rest of the study occurs on the day of your sentinel lymph node surgery.

Before you receive the injection of radioactive tracer on the day of your sentinel lymph node surgery, the hospital staff involved in the injection will explain to you the pain treatment you will receive. You will then receive the pain treatment, followed by the injection of radioactive tracer. After you receive the injection but before your surgery, you will be asked to complete a short survey about your experience with the radioactive injection. The survey should take less than 10 minutes to complete. Your active participation in the study will be over after you complete the survey.

The research staff will also review your medical record to collect basic information about you and your cancer (such as your age, medical conditions, use of medications, cancer stage and treatment, and other information).

What are the study groups?

In this research study, 180 people will be registered and randomized to four study groups. If you decide to participate in this study, you will be assigned through a process called randomization to one of four study groups:

- Ice on the breast (usual treatment)
- Lidocaine patch on the breast
- A vibrating distraction device (Buzzy®) and ice on the breast
- Lidocaine patch on the breast followed by a vibrating distraction device (Buzzy®) and ice on the breast

Randomization means neither you nor the study doctor or study staff will be able to pick which study group you are in. If you agree to be randomized, you will have an equal chance of being assigned to either study group. You will be informed of your study group assignment on the day of your surgery.

The usual treatment that all patients currently receive at UW Health University Hospital is ice on the breast. If you do not participate in the study, you will receive ice on the breast as part of routine care. The other possible treatments listed above have not been studied before for this specific injection and involve a pain control device and/or medicine placed on the breast.

Who can be a part of this study?
This study will include women who have been diagnosed with breast cancer and who will be undergoing sentinel lymph node biopsy with a standard injection of radioactive tracer before surgery.

You may **not** participate in this study if you:
- Are pregnant
- Are younger than 18 years of age
- Have an allergy to lidocaine or other topical anesthetics
- Have a medical contraindication to lidocaine or other topical anesthetics (for example, individuals taking certain drugs to control heart rhythm would not be eligible)

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- Are scheduled to have your radioactive injection happen the day before surgery or during surgery

When and where will this study happen?
This research will be conducted on the day of your surgery at the UW Health University Hospital on 600 Highland Ave.

How long will I be in this study?
Your active participation will take place on two separate occasions. In the first occasion, after you agree to participate in the study, we will spend one minute or less on a brief question about any current pain you are experiencing. The rest of your active participation will take place on one day (the day of your surgery) and last approximately 20 minutes. Participation in the study includes receiving your pain treatment and completing a short survey within 3 hours of receiving the injection. The survey should take less than 10 minutes to complete. Your active participation will end after you complete the survey and before your surgery.

How is being in this study different from my regular health care?
All breast cancer patients who need sentinel lymph node biopsy surgery get an injection of radioactive tracer to help identify the sentinel lymph nodes. At the UW Health University Hospital, patients get one standard pain treatment with this injection unless they are getting the injection during their surgery. By being in this study, you may get a different pain treatment for the injection than what you would get if you were not in the study. It is also possible that you would get the same pain treatment that you would get if you were not in the study. You will be asked to complete a brief one-question pain assessment on the day you agree to participate in the study. On the day of your surgery, you will also be asked to complete a second survey about your experience with the radioactive tracer injection if you are in this study.

If you decide not to participate in this study, you will receive the usual pain treatment for the injection of radioactive tracer. You will not be asked to complete any surveys.

What are my other choices if I do not take part in this study?
You do not have to be in this research study to get care for your breast cancer. If you decide to not take part in the study, you will continue to get care for your breast cancer according to usual practice.

Are there any benefits to me?
There are no direct benefits to participation in this research. Some people may experience improved perceptions of pain with the radioactive tracer injection. Your participation is likely to help us identify the most effective pain treatment. There may not be any benefit to the society at this stage of the research. However, future breast cancer patients are likely to benefit.

Will I be paid or receive anything for being in this study?
- You will not be paid to take part in this study.
- Researchers may develop products from the information you provide for this study. Some of these products may have commercial value. If the research team or others use your information to develop products of commercial value,

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you will not receive any profits from products created from your samples or information.

Will being in this study cost me anything?

- There will be no cost to you for any of the study activities or procedures.
- You or your insurance company will have to pay for all costs for medical care related to your treatment for your breast cancer, including co-payments and deductibles. You will have to pay for any costs your insurance does not cover. If you have any questions about these costs, or what out-of-pocket expenses you may have, you should contact your insurance company. If you do not have health insurance, you will have to pay all costs for your medical care just as you would if you did not take part in this study.

Are there any risks to me?

There is a risk that your information could become known to someone not involved in this study. However, the study team makes every effort to protect your privacy.

In addition, there is a small risk that you could have a skin reaction to the pain treatment you receive. A skin reaction could include redness, itchiness, swelling, or pain. We expect any skin reactions to be temporary and to go away on their own. If you experience significant discomfort from the pain treatment, let your care team know, and the pain treatment can be immediately stopped. It is also possible that you develop an allergic reaction to the pain treatment you receive. An allergic reaction could range from something as small as a rash to difficulty swallowing. If you were to develop any severe allergic reaction, you would be treated with the appropriate allergy medicines.

Do I have to be in the study? What if I say "yes" now and change my mind later?

No, you do not have to be in this study. Taking part in research is voluntary. This means that you decide if you want to be in the study. If you decide to take part now but later change your mind, you can choose to leave the study at any time. Let the researchers know if you choose to leave the study.

If you decide not to take part in the study, or if you choose to leave the study, your choice will not affect any treatment relationship you have with your healthcare providers at UW-Madison, UW Health, or any affiliated organizations, or any services you receive from them. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

Your authorization for researchers to use your protected health information (PHI) will last until the research study is complete. However:

- You can choose to take back your authorization for researchers to use your health information. You can do this at any time before or during your participation in the study.
- If you take back your authorization, information that was already collected may still be used and shared with others; however, the researchers will no longer be able to collect NEW information about you.
- If you take back your authorization, you will not be able to take part in the research study. To take back your authorization, you will need to tell the Lead

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Researcher by writing to Heather B. Neuman, K6/142 CSC, 600 Highland Ave, Madison, WI 53792-1690.

Protected health information (PHI) used in this study
Protected health information, also called PHI, is information about your physical or mental health that includes your name or other information that can identify you, such as your date of birth or medical record number. To do this study, we will use the following kinds of PHI:

- Things you tell the researchers about your health.
- Information currently in your medical record as well as information added to your medical record during the course of this study. This information could include demographics (such as age and race), pain medications you take, pain conditions you have, type of axillary surgery, cancer stage and receptor status, and prior cancer treatments. Operative data will also be collected, such as the number of lymph nodes removed during surgery.

How will my confidentiality be protected?
We have strict rules to protect your personal information and protected health information (PHI). We will limit who has access to your name, address, phone number, and other information that can identify you. We will also store this information securely. We may publish and present what we learn from this study, but none of this information will identify you directly without your permission.

The information that we collect from this research project will be kept confidential in password-protected and secure computers and servers. Information about you that will be collected during the research will be put away, and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and this information will also be password-protected on secure computers and servers. It will not be shared with or given to anyone except those involved in the research. Any physical documents involved with research (e.g., paper surveys) will be locked in a secure location and destroyed at the end of the study.

However, we cannot promise complete confidentiality. Federal or state laws may permit or require us to show information to university or government officials and the National Cancer Institute responsible for monitoring this study. We may also have to tell appropriate authorities, such as child protective services or health care providers, if we learn during the study that you or others are at risk of harm (for example, due to child or elder abuse, or suicidal thoughts).

Authorizing the research team to use your PHI means that we can release it to the people or groups listed below for the purposes described in this form. Once your health information is released outside UW-Madison or UW Health it may not be protected by privacy laws and might be shared with others. Also, with appropriate institutional permissions and confidentiality protections, we might use information that we collect during this study for other research or share with other researchers without additional consent or authorization from you or your legally authorized representative.

Who at UW-Madison can use my information?

- Members of the research team

- Offices and committees responsible for the oversight of research

Who outside the UW-Madison may receive my information?

- U.S. Office for Human Research Protections
- The U. S. Food and Drug Administration (FDA)
- 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.
- The study team has a Certificate of Confidentiality from the National Institutes of Health for this study. A Certificate of Confidentiality prohibits researchers from disclosing information [or biospecimens] that may identify you in a legal proceeding or in response to a legal request without your consent.

Will information from this study go in my medical record?

- Some of the information we collect for this study may go in your medical record. Depending on which pain treatment you receive, the fact that you received a certain treatment will be included in your medical record.

What happens if I am injured or get sick because of this study?

If you are injured or get sick because of this study, medical care is available to you through UW Health, your local provider, or emergency services – as it is to all sick or injured people.

- If it is an emergency, call 911 right away or go to the emergency room.
- For non-emergency medical problems, contact the UW Breast Center.
- Call the Lead Researcher, Dr. Heather Neuman, at 608-262-2025 to report your sickness or injury.

Here are some things you need to know if you get sick or are injured because of this research:

- If the sickness or injury requires medical care, the costs for the care will be billed to you or your insurance, just like any other medical costs.
- Your health insurance company may or may not pay for this care.
- No other compensation (such as lost wages or damages) is usually available.
- UW-Madison and UW Health do not have a program to pay you if you get sick or are injured because of this study.
- By signing this consent form and taking part in this study, you are not giving up any legal rights you may have. You keep your legal rights to seek payment for care required because of a sickness or injury resulting from this study.

Whom should I contact if I have questions?

You may ask any questions about the research at any time. If you have questions about the research after today, you should contact the Principal Investigator Heather Neuman at (608) 262-2025.

If you have any questions about your rights as a research subject or have complaints about the research study or study team, contact UW Health Patient Relations at 608-263-8009. The Patient Relations Representatives work with research subjects to address concerns about research participation and assist in resolving problems.

If you would like to email us your scanned or photographed consent document, we will request your email address. Email is generally not a secure way to communicate about your health as there are many ways for unauthorized users to access email. You should avoid sending sensitive, detailed personal information by email. Email should also not be used to convey information of an urgent nature. If you need to talk to someone immediately, please contact Principal Investigator Heather Neuman at (608) 262-2025. You do not have to provide your email address to participate in this study.

Agreement to participate in the research study

You do not have to verbally agree to participate in this study. If you refuse to verbally agree to participate in this study, you cannot take part in this research study.

If you verbally agree to participate in this study, it means that:

- You have read this consent and authorization form.
- You have had a chance to ask questions about the research study, and the researchers have answered your questions.
- You want to be in this study.
- You give authorization for your protected health information to be used and shared as described in this form.

If you agree to participate in this study, please state your full name, date of birth and the following:

“I hereby verbally agree to participate in the study as outlined in this consent and authorization document.”

****You will receive a copy of this form****