Consent Revision Date: 04/14/2016

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

Intraoperative electrical stimulation of the acupoint P6 to prevent post-operative nausea and vomiting in women undergoing breast surgery
2015-0170

Study Chair: Alicia M. Kowalski

1.

Participant's Name _____ Medical Record Number _____

You are being asked to take part in this clinical research study at The University of Texas MD Anderson Cancer Center ("MD Anderson"). This consent and authorization form explains why this research study is being done and what your role will be if you choose to take part. This form also describes the possible risks connected with being in this study. After reviewing this information with the person responsible for your enrollment, you should know enough to be able to make an informed decision on whether you want to take part in the study.

You are being asked to take part in this study because you are scheduled to have surgery on your breast(s) and you are at increased risk for post-operative nausea and vomiting (PONV).

2. PURPOSE OF STUDY

The goal of this clinical research study is to learn if light electrical stimulation to the wrist area during surgery is feasible in women having breast surgery.

3. DESCRIPTION OF STUDY

Screening Visit
Signing this consent form does not mean that you will be able to take part in this study. You will be asked screening questions to help the doctor decide if you are eligible. These questions will be about your medical history and should take about 3 minutes to answer.

The study doctor will discuss the screening results with you. If the screening questions show that you are not eligible to take part in the study, you will not be enrolled. Other options will be discussed with you.

Study Groups
If you are eligible to take part in this study, you will be randomly assigned (as in the flip of a coin) to 1 of 2 study groups. This is done because no one knows if one study group is better, the same, or worse than the other group.

If you are in **Group 1**, you will receive light electrical stimulation to the wrist area during surgery. You will also receive standard of care drugs to reduce PONV. If you have nausea or you are vomiting after surgery, you will receive additional standard of care drugs for those symptoms. You may ask the study staff for information about how the drugs are given and their risks.

If you are in **Group 2**, you will receive standard of care drugs to reduce PONV only (you will not receive electrical stimulation). If you have nausea or you are vomiting after surgery, you will receive additional standard of care drugs for those symptoms.

Electrical Stimulation
The electrical stimulation is applied through a small sticky pad that is connected to a machine called a neuromuscular blockade monitor (NMBN). NMBNs are routinely used by anesthesiologists to monitor drug levels in muscles during surgery.

The pad will be placed on your wrist after you receive anesthesia and removed at the end of surgery so you will not know what group you are in.

Study Procedures
Both Groups:

- You will have blood (about 2 teaspoons) collected intravenously (through your IV) during surgery. This blood will be used for genetic testing that may explain why people respond differently to treatments for nausea and vomiting.
- You will complete a questionnaire about your pre-treatment expectations and your nausea every 15 minutes after you wake up after surgery until you leave the clinic. It should take about 2-3 minutes to complete the questionnaire each time.

Length of Study
Your participation in this study will be over once you leave the clinic after surgery.

This is an investigational study. The NMBM monitor is commercially available and FDA approved for use by anesthesiologists to monitor drug levels in the muscles during surgery. Its use in this study to control nausea/vomiting is investigational.

The electrical stimulation to the wrist will be provided at no cost to you.

You and/or your insurance provider will be responsible for the cost of any standard of care drugs you receive to control nausea and vomiting.

Up to 176 participants will be enrolled in this study. All will be enrolled at MD Anderson.

4. RISKS, SIDE EFFECTS, AND DISCOMFORTS TO PARTICIPANTS

While on this study, you are at risk for side effects listed in this form. You should discuss these with the research nurse/anesthesiologist. The known side effects are listed in this form, but they will vary from person to person. Many side effects go away shortly after the procedures are stopped, but in some cases side effects may be serious, long-lasting, or permanent.

Electrical stimulation may cause a tingling sensation. However, this should not be felt as you will be under anesthesia.

The gel in the electrode pad on your skin may rarely cause an allergic reaction including skin inflammation. If this is noted, the pad will be removed.

Blood draws will be performed through an IV that is standard to be placed during surgery. Placement of an IV may cause pain. Accessing an IV may cause infection.

The type of **genetic testing** being performed in this study will not provide you or your doctor information about diseases that are passed down in families. It will not tell the study researchers anything that will prevent you from getting health insurance, and it will not tell the study researchers anything about any diseases or conditions you may get in the future.

This study may involve unpredictable risks to the participants.

5. POTENTIAL BENEFITS

Receiving electrical stimulation to the wrist may help prevent PONV. Future patients may benefit from what is learned in this study. There may be no benefits for you in this study.

6. ALTERNATIVE PROCEDURES OR TREATMENTS

You may choose not to take part in this study. You may choose to receive standard of care drugs for PONV only. You may choose to receive other investigational therapy, if available. You may choose not to have treatment for PONV at all. In all cases, you will receive appropriate medical care.

Additional Information

7. You may ask the study chair any questions you have about this study. You may contact the study chair, Dr. Alicia M. Kowalski, at 713-745-5089. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-2933 with any questions that have to do with this study or your rights as a study participant.

8. Your participation in this research study is strictly voluntary. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson.

9. This study or your participation in it may be changed or stopped at any time by the study chair, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP - a regulatory agency that oversees research in humans), or the IRB of MD Anderson.

10. You will be informed of any new findings that might affect your willingness to continue taking part in the study.

11. MD Anderson may benefit from your participation and/or what is learned in this study.

STUDY COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-2933 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Certain tests, procedures, and/or drugs that you may receive as part of this study may be without cost to you because they are for research purposes only. However, your insurance provider and/or you may be financially responsible for the cost of care and treatment of any complications resulting from the research tests, procedures, and/or drugs, including hospitalization, nausea, vomiting, low blood cell counts, and dehydration. Standard medical care that you receive under this research study will be billed to your insurance provider and/or you in the ordinary manner. Before taking part in this study, you may ask about which parts of the research-related care may be provided without charge, which costs your insurance provider may pay for, and which costs may be your responsibility. You may ask that a financial counselor be made available to you to talk about the costs of this study.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research. You will receive no compensation for taking part in this study.

Authorization for Use and Disclosure of Protected Health Information:

A. During the course of this study, the research team at MD Anderson will be collecting and using your protected health information. This information may include personal identifying information about you (such as your name, race, date of birth, gender, city, and zip code), your medical history, study schedule, and the results of any of your tests, therapies, and/or procedures. The purpose of collecting and sharing this information is to learn about how the study procedures may affect the disease and any study-related side effects. Your doctor and the research team may share your study information with the parties named in Section D below.

B. Signing this consent and authorization form is optional. However, if you refuse to provide your authorization to use and disclose your protected health information for this study, you will not be able to participate in this research project.

C. MD Anderson will take appropriate steps to keep your protected health information private when possible, and it will be protected according to state and federal law. However, there is no guarantee that your information will remain confidential, and it may be re-disclosed at some point. Federal agencies (such as the FDA, OHRP, or National Cancer Institute [NCI]), and the IRB of MD Anderson might view or receive your record in order to collect data and/or meet legal, ethical, research, and safety-related obligations. In some situations, the FDA could be required to reveal the names of participants.

D. Your protected health information may be shared with the following parties:

- Federal agencies that require reporting of clinical study data (such as the FDA, NCI, and OHRP)
- The IRB of MD Anderson
- Officials of MD Anderson
- Clinical study monitors who verify the accuracy of the information
- Individuals with medical backgrounds who determine the effect that the treatment procedures may have on the disease
- Individuals who put all the study information together in report form

E. There is no expiration date for the use of your protected health information. You may withdraw your authorization to share your protected health information at any time in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP). You may contact the IRB Staff at 713-792-2933 with questions about how to find the NPP. If you withdraw your authorization, you will be removed from the study, and the study chair and staff will no longer use or disclose your

protected health information in connection with this study, unless the study chair or staff needs to use or disclose some of your research-related personal health information to preserve the scientific value of the study. Data collected about you up to the time you withdrew will be used and included in the data analysis. The parties listed in Section D above may use and disclose any study data that were collected before you canceled your authorization.

F. 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.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS

SIGNATURE OF PARTICIPANT _____ DATE _____

LEGALLY AUTHORIZED REPRESENTATIVE (LAR)

The following signature line should only be filled out when the participant does not have the capacity to legally consent to take part in the study and/or sign this document on his or her own behalf.

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS

SIGNATURE OF LAR _____ DATE _____

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS

RELATIONSHIP TO PARTICIPANT _____

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under Protocol **2015-0170**.

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS

SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) _____ DATE _____

A witness signature is only required for vulnerable adult participants. If witnessing the assent of a pediatric participant, leave this line blank and sign on the witness to assent page instead.

PERSON OBTAINING CONSENT

I have discussed this clinical research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS

SIGNATURE OF STUDY CHAIR OR PERSON AUTHORIZED TO OBTAIN CONSENT _____ DATE _____

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into _____ and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS

NAME OF TRANSLATOR	SIGNATURE OF TRANSLATOR	DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line below.)

SAMPLE -- NOT FOR USE IN CONSENTING PATIENTS

SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION (OTHER THAN TRANSLATOR, PARENT/GUARDIAN, OR STUDY CHAIR)	DATE