PATIENT INFORMED CONSENT FOR CLINICAL RESEARCH

Acupuncture to Reduce Chemotherapy-induced Peripheral Neuropathy Severity During Neoadjuvant or Adjuvant Weekly Paclitaxel Chemotherapy in Breast Cancer Patients: A Pilot Study
– Intervention Phase

You have been asked to participate in a research study. In order to decide whether or not you should agree to be part of this research study, you should know enough about its risks and benefits in order to make a sound judgment. This process is known as informed consent.

This is a clinical trial, a type of research study. Your study doctor will explain the clinical trial to you. Clinical trials include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your friends and family. You can also discuss it with your healthcare team. If you have any questions, you can ask your study doctor for more explanation.

This consent form gives you detailed information about the research study. Once you understand the study, its risks, and its benefits, you will be asked to sign the form if you wish to take part. You will be given a copy to keep.

You are being asked to take part in this study because you have been diagnosed with breast cancer, are getting chemotherapy containing weekly paclitaxel that may damage the nerves, and have developed nerve damaging symptoms (tingling, numbness, pain) that affected your function.

Why is this study being done?

The purpose of this study is to find out the effects of acupuncture on reducing nerve damage.

Acupuncture is a medical technique of inserting very thin needles into the "energy points" on the body with the aim to restore health and well-being. It has been used widely to treat pain, such as lower back pain and joint pain. In this study we will assess if acupuncture can be used to ease the pain, tingling and numbness that may be caused by chemotherapy and improve your quality of life during chemotherapy.

A recent assessment by the chemotherapy nurse shows that you have developed function limiting nerve damage from the chemotherapy. Study doctors want to find out if:

- Acupuncture can prevent worsening of nerve damage
- Acupuncture can make nerve damage symptoms better
- Acupuncture can make nerve conduction studies better
- Specific blood tests can help find out how acupuncture works

Is there a potential conflict of interest for this study?

There are no known investigator and/or institutional conflicts of interest for this study.

How many people will take part in the study?

About 27 people will participate in this part of the study (intervention phase) at Memorial Sloan Kettering, which will involve being treated with weekly acupuncture.

What will happen if I take part in this research study?

Before you begin the study …

An assessment by the chemotherapy nurse during the screening phase of this study showed that you have developed nerve damage from chemotherapy that affects your function.

During the study…

If you are eligible to take part in this study and choose to do so, then you will receive weekly acupuncture treatment in your ears, hands, arms, feet and legs.

If you participate in the study, you will receive acupuncture during your weekly visits. Your study visits will take place at MSK's Evelyn H. Lauder Breast Center (300 E. 66th Street @ 2nd Avenue), MSK's Brooklyn Infusion Center (557 Atlantic Avenue, between 3rd and 4th Avenues), MSK's Bendheim Integrative Medicine Center (1429 First Avenue @ E. 74th Street), or MSK's Westchester Center (500 Westchester Ave, West Harrison) . If you choose to receive your acupuncture treatments at the Brooklyn Infusion Center, there will be two additional appointments for study measurements one before your first acupuncture treatment and one after your last acupuncture treatment. If you choose to receive your acupuncture treatments at MSK Westchester, and choose to complete the optional nerve conduction tests, you will need to travel into Manhattan (160 E 53rd St). You will receive acupuncture until you complete your chemotherapy: weekly paclitaxel (Taxol®). We will record how much chemotherapy you received all together.

During the course of the study, several assessments will be done:

- Height and Weight will be measured at the beginning of the study.
- Nerve Symptom Questionnaires: You will complete 2 questionnaires about your nerve damage symptoms each week. The questionnaires are for research and take about 5 minutes to complete. The chemotherapy nurse will continue to assess your symptoms before each weekly chemotherapy session throughout the study.
- Cryotherapy Usage Form: You will be asked weekly whether or not ice is placed on your hands and/or feet during chemotherapy treatment.
- Medication: You will be asked about any pain medication you take.
- Side effects: During acupuncture treatment, you will be asked to record any side effects you may experience from the acupuncture and report them to the research team.
- Research Blood Test: At the beginning of the study and when you've completed chemotherapy, a sample of your blood will be collected (about 1 teaspoon) to check your blood for nerve growth factors levels. These are components in your blood that may show

how the body responds to chemotherapy and acupuncture. This sample is taken for research purposes only.

- Vibration Sensation Test: A tuning fork will be placed on your toes before the start of acupuncture treatment and after the last acupuncture treatment on the same day as your last chemotherapy session to test your nerve function. You will feel a buzzing sensation. There is no risk associated with this test.
- Nerve Conduction Studies: Nerve conduction studies will be done with your permission.

After the study…

If you have previously consented to the nerve conduction studies, we will ask you to return to clinic at about 4 weeks after your last chemotherapy treatment for a final visit with the study staff. At this visit we will ask you again to complete the final nerve conduction studies. Subjects who do not consent to the nerve conduction studies do not need to return to clinic 4 weeks after chemotherapy. Our research assistants will call you at approximately 12 weeks after the completion of chemotherapy to administer nerve symptom questionnaires over the phone. A clinician will also call to assess nerve damage at this time.

Study Calendar				
Procedure	Consent /Baseline	Week		
		1, 2, 3, 4, 5, 6, 7, 8, etc. (weekly until chemotherapy is done)	Last chemotherapy treatment/after last acupuncture session	4-12Weeks After Last Chemotherapy Treatment
Height and Weight	X			
Nerve Symptom Questionnaires	X	X	X	X (Week 12)
Cryotherapy Usage Form		X	X	
Chemotherapy Nurse Assessment of Nerve Symptoms	X	X		X (Week 12)
Pain Medication List	X	X	X	
Side Effects		X	X	
Research Blood Sample	X		X	
Chemotherapy Dose Recording			X	
Nerve conduction studies (optional)	X			X (only those who consented for nerve conduction studies)

Vibration sensation test	X		X	
Acupuncture		X		

How long will I be in the study?

You will be asked to take part in the study for approximately 24 weeks.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from the acupuncture treatment can be evaluated by your doctor. Another reason to tell your doctor that you are thinking about stopping is to discuss what followup care and testing could be most helpful for you. Patients that start acupuncture for CIPN outside of the protocol intervention will be removed from the study, unless they have completed their chemotherapy treatment and are in the 12 week follow up period.Patients will also be removed if they are started on anti-neuropathy medication.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest; if you do not follow the study rules; or if the study is stopped.

What side effects or risks can I expect from being in the study?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after you stop **acupuncture treatment**. In some cases, side effects can be serious, long lasting, or may never go away.

You should talk to your study doctor about any side effects that you have while taking part in the study.

Risks and side effects related to the acupuncture and drawing blood include those which are:

Likely

- Minor bleeding at acupuncture sites
- Bruises at acupuncture sites
- Pain or an unfamiliar sensation at acupuncture sites (local or radiating)
- Pain or bruising at the site where the research blood sample is drawn

Less Likely

- Local allergic reaction (hives) at the site of needle insertion
- Drowsiness, sleep disturbances (insomnia)
- Anxiety, nervousness
- Vasovagal reaction (fainting, dizziness, nausea, vomiting)

Rare but serious

- Local skin infection

Risks and side effects related to the optional nerve conduction study include those which are:

Likely

- Pain due to the electrical shocks associated with the low amount of electrical current administered during the nerve conduction study.

For more information about risks and side effects, ask your study doctor.

Are there benefits to taking part in the study?

Taking part in this study may or may not make your symptoms from nerve damage better. We do know that the information from this study will help doctors learn more about **acupuncture and nerve damage due to chemotherapy.** You may benefit from sharing your experience or from knowing that this research could help future cancer patients.

What other choices do I have if I do not take part in this study?

Your other choices may include:

- Getting treatment or care for your nerve damage due to chemotherapy without being in a study
- Taking part in another study
- Getting no treatment for your nerve damage due to chemotherapy

Talk to your doctor about your choices before you decide if you will take part in this study.

Will my medical information be kept private?

Every effort will be made to keep your study records private. It is the responsibility of the research staff at Memorial Hospital to make sure that your records are managed to protect your privacy. If information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. Trained staff at Memorial Hospital may review your records if necessary. Access to your medical information will be limited to those listed in the Research Authorization Form, which is a part of the informed consent process.

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.

What are the costs of taking part in this study?

You and/or your health plan/ insurance company will need to pay for some or all of the costs of treating your cancer in this study. Taking part in this study may or may not cost your insurance company more than the cost of getting regular cancer treatment.

You will not be billed for the following research tests and treatments:

- Services of the acupuncturist and acupuncture treatment
- Questionnaire administration
- Research blood draws
- Nerve conduction studies and the vibration sensation test

You and/or your health insurance will be billed for the following standard of care tests performed as part of this study:

- Routine visits to your oncologist
- Physical examinations, including height, weight and vital signs
- Chemotherapy

- Routine blood tests required for monitoring your condition
- A baseline pregnancy test – *women of childbearing potential only*

You will not be paid for taking part in this study.

What happens if I am injured because I took part in this study?

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for medical treatment.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions or concerns you have about this study. Contact the study principal investigator, Dr. Ting Bao at 646-888-0865.

Any hospital that does research on people has an institutional review board (IRB). This board reviews all new studies to make sure that the patient's rights and welfare are protected. The IRB at MSKCC has reviewed this study.

For a non-physician whom you may call for more information about the consent process, research patients' rights, or research related injury is Jorge Capote, RN, Patient Representative, telephone number: (212) 639-8254.

Optional Nerve conduction studies

At the start of the study, and 4 weeks after your last dose of chemotherapy, we will ask you to be examined by a neurologist to find out the extent of your nerve damage. If you choose to receive your acupuncture treatments at MSK Westchester, and choose to complete the optional nerve conduction tests, you will need to travel into Manhattan (160 E 53rd St.). Nerve conduction studies will be done on you

with your permission. Nerve conduction studies are very helpful to diagnose certain diseases of the nerves in the body. You will be asked to lie on an exam table. Electrodes will be placed on the skin over the nerve to be studied. These electrodes act as microphones to pick up any electrical signal that goes by them. An electrical stimulator is then placed on the skin near the electrodes and is used to create an electrical current strong enough to fully stimulate the nerve. A computer is used to record responses as various nerves are tested. This allows the physician to measure and calculate how fast the nerve is sending the impulses to the muscle and measure the size of the impulse. The test is not invasive, but can be a little painful due to the electrical shocks. The shocks are associated with a low amount of electrical current so they are not dangerous to anyone.

Read the sentence below and think about your choice. After reading it, check the answer that is right for you. If you have any questions, talk to your study doctor.

I permit nerve conduction studies to be done on me.

☐ Yes ☐ No

RESEARCH AUTHORIZATION

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Research Participant Name: _____

Research Participant MRN :_____

We understand that information about you and your health is personal. We are committed to protecting the privacy of your information. Because of this commitment, we must obtain approval from you before we can use your protected health information for research purposes. This form provides that authorization. This form also helps us make sure that you are informed of how this information will be used or disclosed in the future. Please read the information below carefully before signing this form.

USE AND DISCLOSURE COVERED BY THIS AUTHORIZATION

A representative of Memorial Sloan-Kettering Cancer Center must answer these questions completely before providing this authorization form to you. *PLEASE DO NOT SIGN A BLANK FORM.* ***You or your personal representative should read the descriptions below before signing this form.***

Who will have access to and/or use your health information?

The following individuals and/or organization(s) may have access to use, disclose or receive some information about you. They may only share the information to the individuals/parties indicated on this list. This information must be shared with you, the research subject and/or your personal representative, as required by law.

- ☑ Every research site for this study, including Memorial Sloan-Kettering Cancer Center and the research support staff (for example, research study assistant) and medical staff at each location
- ☑ Every health care personnel who provides services to you in connection with this study
- ☑ Any laboratories, other individuals/organizations that analyze your health information in connection with this study as defined by protocol
- ☑ The following research sponsors: *Memorial Sloan Kettering Cancer Center*
- ☑ The National Cancer Institute and/or the National Institute of Health
- ☑ The United States Food and Drug Administration and other regulatory agencies responsible for oversight.
- ☑ The members and staff of the hospital's Institutional Review Board and Privacy Board

☑ Principal Investigator and Co-Principal Investigator(s): *Ting Bao MD, DABMA, MS, Andrew Seidman MD, Xi Chen MD, Jun Mao, MD, MSCE*

☑ Members of the Research Team including the participating investigators, research assistants, clinical nurses, fellows/residents, and clerical support staff.

☑Members and staff of the hospital's Office of Clinical Research, Computing Resource Group that manages research databases, and the research management and support staff in the clinical departments

☑ Members of the Hospital's Data Safety Monitoring Board/Committee and Quality Assurance Committee

What information will be used or disclosed?

The boxes checked below should provide you with enough detail so that you can understand what information may be used or disclosed.

☒ Your entire research record
☒ Any part of your medical records held by the hospital

☒ HIV-related information. This includes any information indicating that you have had an HIV-related test, or have HIV infection, HIV-related illness or AIDS, or any information which could indicate that you have been potentially exposed to HIV. (New York State requires us to obtain special consent)

☒ The following information: Questionnaires, Blood samples, Vibration sensation test, Nerve Conduction Studies

SPECIFIC UNDERSTANDINGS

By signing this form, you give permission for the sharing of your protected health information noted above. The purpose for the use and disclosure of your information, is to conduct the research study explained to you during the informed consent process. This form also ensures that the information relating to the research is available to everyone who may need it. Your protected health information may also be used for your research treatment, to collect payment for your treatment while on the study (when applicable), and to run the business operations of the hospital.

Once we have shared your information with the individuals and organizations listed on this form, they may be able to share your information again, if they are not subject to laws that protect your privacy.

It is your right to refuse to sign this authorization form. If you do not sign this form, you will not be able to participate in the research study. You will not receive the research treatment that was described to you. Your health care outside the study will not be affected. The payment for your health care or your health care benefits will not be affected.

If you sign this authorization form, you will have the right to withdraw it at any time. To withdraw the authorization will prohibit further use or disclosure of your health information. If the hospital has already used your health information approved by your authorization or needs the information to fulfill an obligation or analyze the data, the use or disclosure can not be stopped. This authorization form will not expire unless you withdraw it. If you want to withdraw this authorization, please write to Dr. Ting Bao of the Integrative Medicine and Breast Services at the hospital.

You have a right to see and copy your health information described in this authorization form in accordance with the hospital's policies. You also have a right to receive a copy of this form after you have signed it.

Notice Concerning HIV-Related Information

If you are authorizing the release of HIV-related information, you should be aware that the individuals/organizations are prohibited from sharing any HIV-related information without your approval unless permitted to do so under federal or state law. You also have a right to request a list of people who may receive or use your HIV-related information without authorization. If you experience discrimination because of the release or disclosure of HIV-related information, you may contact the New York State Division of Human Rights at (888) 392-3644 or the New York City Commission of Human Rights at (212) 306-7500. These agencies are responsible for protecting your rights.

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Statement of professional obtaining consent

I have fully explained this clinical research study to the participant or his/her Legally Authorized Representative (**LAR**). In my judgment and the participant's or that of his/her Legally Authorized Representative, there was sufficient access to information, including risks and benefits to make an informed decision. The consent discussion will be documented in the participant's EMR.

Consenting Professional Must Personally Sign & Date		
Assent (Minor between the ages of 7 and less than 18): If the participant is a minor, I have obtained his/her assent to participate in the study to the best of their ability to understand. ☐ **YES** ☐ **NO** ☐ **N/A (Adult or Child <7)**		
Consenting Professional's Signature		**Date:**
Consenting Professional's Name (Print)		

Participant's (or Legally Authorized Representative's (LAR)) statement

I have read this form with the description of the clinical research study. I have also talked it over with the consenting professional to my satisfaction. By signing below, I am agreeing to the following: (1) to voluntarily be a participant in this clinical research study (2) authorizing for the use and disclosure of my/their protected health information (data about myself) and (3) that I received a signed copy of this consent form.

Participant/LAR Must Personally Sign & Date		
Participant/LAR Signature		**Date:**
Participant/LAR Name (Print)		
LAR Relationship to Participant		

Witness Signature (If Required)

☐ **Non-English Speaking Participant Witness and/or Interpreter:** I declare that I am fluent in both English and participant's (or LAR) language and confirm that the consent discussion was appropriately translated for the participant (or LAR).

☐ **Other:** I confirm that the consent discussion was appropriate for the participant's (or LAR's) understanding of the study.

Name of Witness: _____

Signature of Witness: _____ Date: _____
(If witness is used for consent discussion, their name must be documented in the EMR.)

The Participant/Legally Authorized Representative Must Be Provided With A Signed Copy Of This Form