Wake Forest®
School of Medicine

Department/Section of *Social Sciences and Public Health*

ACUPUNCTURE FOR CHEMOTHERAPY-INDUCED PERIPHERAL NEUROPATHY AMONG CANCER PATIENTS

Informed Consent Form to Participate in Research
Nancy Avis, PhD, Principal Investigator

SUMMARY

You are invited to participate in a research study. The purpose of this research is to see what effects (good and bad) acupuncture has on neuropathy (nerve pain or tingling in hands or feet).You are invited to be in this study because you are currently experiencing symptoms of neuropathy from your cancer treatment. Your participation in this research will involve three study visits and 4-10 acupuncture treatment sessions. Each study visit will last approximately 2-2.5 hours. Each acupuncture treatment session will last about 45 minutes. Your total time in the study will be about 12-14 weeks.

Participation in this study will involve various medical tests, questionnaires, and acupuncture treatments. All research studies involve some risks. These risks may include some discomfort or pain from study procedures. There is the possibility that you may benefit from participation in this study.

Your participation in this study is voluntary. You do not have to participate if you do not want to. There may be other choices available to you. Some other choices may include medications to treat neuropathy, creams to reduce pain, or not participating in this study. You will not lose any services, benefits, or rights you would normally have if you do not choose to participate.

The rest of this form has more detail about this study. Please read this carefully. You can ask any questions if you need help deciding whether to join the study. The person in charge of this study is Nancy Avis, PhD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study.

If you have any questions, suggestions or concerns about your rights as a volunteer in this research, contact the Institutional Review Board or the Research Subject Advocate at Wake Forest.

INTRODUCTION

You are invited to be in a research study. Research studies are designed to gain scientific knowledge that may help other people in the future. You are being asked to take part in this study because you are experiencing symptoms of neuropathy (pain or tingling in your hands or feet) from your cancer treatment. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask your study doctor or the study staff to explain any words or information in this document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to see what effects (good and bad) acupuncture has on neuropathy. Peripheral neuropathy is a common side effect of chemotherapy and experienced by many cancer patients. These symptoms can impact cancer treatment and affect people's quality of life. Acupuncture has helped reduce neuropathy for people who have other medical conditions such as diabetes and carpal tunnel syndrome. It has also helped reduce other types of pain and nausea and vomiting from chemotherapy. Acupuncture is safe and does not interfere with chemotherapy treatment. We are investigating if acupuncture may help reduce neuropathy caused by chemotherapy.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

22 people here at Wake Forest Baptist Medical Center will take part in this study.

WHAT IS INVOLVED IN THE STUDY?

At your first study visit, you will receive a physical exam of your nerve sensations and your medical history will be reviewed. If you are still eligible for our study, you will be asked to complete a questionnaire about your neuropathy pain. You will also be scheduled for your next study visit that will take place in approximately 1-2 weeks.

At your second study visit, you will receive a standard evaluation of your neuropathy. This will take place at the Wake Forest Baptist Health Neurology Clinic. This will involve a nerve conduction test, ultrasound imaging, skin biopsy, and blood draw. A skin biopsy provides the opportunity to determine if you have actual nerve damage. However, if you are unwilling to have this procedure, you will still be allowed to participate in the study. This visit will last approximately 2-2.5 hours.

After your second visit, you will be randomized into one of two study groups described below. Randomization means that you are put into a group by chance. It is like flipping a coin. You will have an *equal* chance of being placed in either group. The two study groups include an acupuncture group and a waitlist group.

Acupuncture group: If you are randomized to this group, your first acupuncture visit will be scheduled by the Study Coordinator to take place within 2 weeks. Acupuncture treatments will take place at the Wake Forest Baptist Health Integrative Medicine Clinic Center at 755 Highland Oaks Drive in Winston-Salem, NC. At your first acupuncture visit, you will receive a personal acupuncture treatment plan. You will then receive 8 acupuncture treatments (approximately 1x/week) over a period of 10 weeks at the Wake Forest Baptist Health Integrative Medicine Clinic Center. These can be scheduled at your convenience.

Waitlist group: If you are randomized to this group, you will continue to receive your usual medical care and treatments with your clinical providers, but you will not receive any acupuncture treatments. After your third study visit, which will be 10-12 weeks from today, you will be offered up to 4 acupuncture treatments at the Wake Forest Baptist Health Integrative Medicine Clinic.

Your third study visit is the 10-12 week follow-up visit. This will take place at the Wake Forest Baptist Health Neurology Clinic. At this visit, you will receive the same standard evaluation that was done at your second study visit.

For the blood draw, at both visits to the Neurology Clinic, you will have one small tube of blood (approximately 8 mL) collected from a vein A total of 2 tubes (approximately 16 mL) of blood will be collected during the study. For the skin biopsy, you will have a very small piece of skin tissue (approximately 4-5mm) extracted from your leg at two study visits. The total amount of skin tissue extracted during the study will be approximately 8-10mm.

Test results will be available in your medical record.

Identifiers (your name, address, date of birth, etc.) might be removed from the private information or blood and tissue sample that were collected as part of this research. When the identifying information is removed, your private information or blood and tissue sample may be used for future research studies or given to other research investigators without getting additional informed consent from you or your legally authorized representative.

Do you request that we send important medical findings from your study tests/exams to your personal physician?

[ ] Yes [ ] No _____ Initials

Storage of Biological Tissue

If you agree to participate in this study, we will store the two tubes of blood collected from your two study visits and take any skin tissue that was left over from the skin biopsy for future research. These samples will be kept and may be used in future research to learn more about other diseases. Your blood samples will be obtained from a phlebotomy lab at Wake Forest University Baptist Medical Center. Your skin tissue biopsy will be obtained from the Department

of Dermatopathology at Wake Forest University Baptist Medical Center. Your samples will be given only to researchers approved by Nancy Avis, PhD. An Institutional Review Board (IRB) must also approve any future research study using your tissue sample. In order to participate in this study, you are not required to provide this sample for future research.

Your *blood and tissue* sample will be stored with a unique identifier and will not include any identifiable information about you such as your name, address, telephone number, social security number, medical record number or any of the identifiers outlined in the HIPAA Privacy Rule. The unique identifier will be a randomly assigned number and only the principal investigator and study team will have access to the code that links the unique identifier to you. Your name, address, social security number, etc., will never be disclosed to future researchers and neither will the code that links your identifiers to the sample.

The research that may be done with your blood and tissue sample is not designed to help you specifically. There is no personal benefit to you from taking part in this aspect of the research study. It might help people who have diseases at some point in the future, but it is not known if this will happen. The results of the research done with your blood sample will not be given to you or your doctor. These results will not be put in your medical records. The research using your blood and tissue sample will not affect your care. Your blood and tissue sample will be used only for research and will not be sold. The findings from this research may result in the future development of products that are of commercial value. There are no plans to share any of the profits with you which may occur as a result of this research.

Sometimes blood and tissue samples used for genetic research may provide information about diseases that are passed on in families. Even if your blood and tissue sample is used for this kind of research, the results will not be told to you or members of your family, and will not be put in your health records.

The choice to let your blood and tissue sample be kept for future use is up to you. No matter what you decide to do, it will not affect your care in this study. If you decide now that your blood and tissue sample can be kept for research, you can change your mind at any time. Just contact your study investigator, ***Nancy Avis, PhD*** and let her know that you do not want your blood and tissue sample used and it will no longer be used for research. Otherwise, the blood and tissue sample may be kept until it is used up or it is destroyed.

In the future, people who do research may need to know more about your health. While the study investigator may be given reports about your health, she will NOT be given your name, address, phone number, or any other identifying information about who you are, unless you agree to be contacted in the future.

_____YES you may contact me for future research studies.

_____NO I do not want to be contacted regarding future research studies.

_____ YES I agree to tissue sample collection performed during optional skin biopsies for this study.

_____ NO I do not agree to tissue sample collection performed during optional skin biopsies for this study.

_____ YES I do want to participate in the storage of blood and tissue samples portion of this study.

_____ NO I do not want to participate in the storage of blood and tissue samples portion of this study.

How Long Will I Be in the Study?

You will be in the study for about 12-14 weeks.

You can stop participating at any time. If you decide to stop participating in the study we ask that you tell the investigators and study staff right away. There are no health or safety consequences if you withdraw.

What Are the Risks of the Study?

Being in this study involves some risk to you. You should discuss the risks with the study staff. Risks and side effects related to the nerve conduction, ultrasound, skin biopsies, blood draw, and acupuncture we are studying include:

Nerve conduction is a standard procedure performed for patients with peripheral neuropathy. This may include some discomfort or pain from the procedure. Ultrasound is a safe procedure. You may experience a slight warming and coldness from the gel. Risks associated with skin biopsies may include brief pain (common), bleeding or bruising (uncommon), or in rare instances, infection (rare). Standard precautions will be used for these tests. The risks are not expected to be different from routine clinical procedures. A numbing medicine is used for this procedure. Some patients can have an allergic reaction to the numbing medicine. There is a risk of developing an infection in the skin after any skin biopsy such as cellulitis or an abscess. If severe, this could require the need for surgery. The study team will take precautions to minimize

these risks by performing the biopsy on the outer side of the lower leg. We do not expect any long-term, or life-threatening risks.

Placement of acupuncture needles by an experienced acupuncturist is usually painless. However, acupuncture may sometimes cause temporary discomfort or pain, bleeding, bruising, or soreness. There have been very rare reports of acupuncture causing minor nerve damage, hematomas (bleeding under the skin or inside your body), infections, or pneumothorax (puncture of a lung). The chance of these major risks, however, is very low because the treatments will be administered by highly experienced acupuncturists using only sterile, disposable needles.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There may be other side effects that we cannot predict. You should tell the research staff about all the medications, vitamins and supplements you take and any medical conditions you have. This may help avoid side effects, interactions and other risks.

Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.

The principal investigator (Nancy Avis, PhD) will be assisted by other members of the research team in reviewing the data and safety from this research throughout the study.

For blood draws, you may experience discomfort, bruising and/or bleeding where the needle is inserted. Some people become dizzy lightheaded or feel faint. Infection may occur on rare occasions. Frequent donation of blood can result in low iron in your blood (iron deficient anemia).

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the information learned from this study will help other people in the future. The benefits of participating in this study may be: improvements in your neuropathy.

Based on experience with acupuncture in other research studies involving patients with chronic pain, and patients with neuropathy from other medical conditions, researchers believe acupuncture may be of benefit to participants with your condition. Because individuals respond differently to therapy, no one can know in advance if it will be helpful in your particular case.

WHAT OTHER CHOICES ARE THERE?

You do not have to be in this study to receive treatment. You should talk to your doctor about all the choices you have. Instead of being in this study, you have these options:

Medications
Topical creams
Observation

Your neuropathy may improve, stay the same, or get worse with any of these options.

WHAT ARE THE COSTS?

All study costs, including any acupuncture treatments and procedures related directly to the study, will be paid for by the study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

WILL YOUR RESEARCH RECORDS BE CONFIDENTIAL?

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. Your identity and/or your personal health information will not be disclosed unless it is authorized by you, required by law, or necessary to protect the safety of yourself or others. There is always some risk that even de-identified information might be re-identified.

Participant information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity if this study falls within its jurisdiction.

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects.

The Certificate cannot be used to refuse a request for information from personnel of the United States federal or state government agency sponsoring the project that is needed for auditing or program evaluation by the National Institutes of Health which is funding this project or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA). You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If you want your research information released to an insurer, medical care provider, or any other person not connected with the research, you must provide consent to allow the researchers to release it.

WILL YOU BE PAID FOR PARTICIPATING?

You will be provided with parking passes for all study visits. You will also receive a $25 gift card at study visit 2 and a $75 gift card at study visit 3. Patients that live 60 miles or more from WFBMC will receive an additional $50 gift card upon completion of the baseline peripheral nerve assessment and an additional $50 gift card upon completion of the follow-up assessment. These are the two visits that involve clinical measures. To receive both of these payments, you must provide your social security number, name and address so that we can comply with IRS (Internal Revenue Service) reporting requirements. When payments are reported to the IRS we do not let them know what the payment is for, only that you have been paid. If you do not wish to provide this information you can still take part in this study but you will not be paid.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by the Wake Forest Clinical and Translational Science Institute (CTSI) and Wake Forest Baptist Comprehensive Cancer Center with funding from the National Institutes of Health. The sponsor is providing money or other support to Wake Forest University Health Sciences to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

WHAT HAPPENS IF YOU EXPERIENCE AN INJURY OR ILLNESS AS A RESULT OF PARTICIPATING IN THIS STUDY?

Should you experience a physical injury or illness as a direct result of your participation in this study, Wake Forest University School of Medicine maintains limited research insurance coverage for the usual and customary medical fees for reasonable and necessary treatment of such injuries or illnesses. To the extent research insurance coverage is available under this policy the reasonable costs of these necessary medical services will be paid, up to a maximum of $25,000. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. It provides a maximum of $25,000 coverage for each claim and is limited to a total of $250,000 for all claims in any one year. The Wake Forest University School of Medicine, and the North Carolina Baptist Hospitals, Incorporated do not assume responsibility to pay for these medical services or to provide any other compensation for such injury or illness. Additional information may be obtained from the Medical Center's Director of Risk and Insurance Management.

If you are injured, the insurer may require information such as your name, social security number, and date of birth in order to pay for your care. This is because the insurer is required by law to report any payments made to cover the care of any persons who are members of a government insurance plan to the Department of Health and Human Services.

You do not give up any legal rights as a research participant by signing this consent form. For more information on medical treatment for research related injuries or to report a study related illness, adverse event, or injury you should call *Nancy Avis, PhD or the Wake*

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any *new information we collect from you* and/or *information we get from your medical records or other facilities* about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: age, body-mass index (BMI), cancer type, cancer staging, types and dosages of chemotherapy received, pain medications, and other medical conditions.

If this research study involves the diagnosis or treatment of a medical condition, then Protected Health Information collected from you during this study will be placed in your medical record, and may be used to help treat you, arrange payment for your care, or assist with Medical Center operations.

We will make every effort to keep your Protected Health Information private. We will store records of your Protected Health Information in a cabinet in a locked office or on a password protected computer.

Your personal health information and information that identifies you ("your health information") may be given to others during and after the study. This is for reasons such as to carry out the study, to determine the results of the study, to make sure the study is being done correctly, to provide required reports and to get approval for new products.

Some of the people, agencies and businesses that may receive and use your health information are the research sponsor; representatives of the sponsor assisting with the research; investigators at other sites who are assisting with the research; central laboratories, reading centers or analysis centers; the Institutional Review Board; representatives of Wake Forest University Health Sciences and North Carolina Baptist Hospital; representatives from government agencies such as the Food and Drug Administration (FDA) or the Office of Human Research Protections (OHRP), the Department of Health and Human Services (DHHS) and similar agencies in other countries.

Some of these people, agencies and businesses may further disclose your health information. If disclosed by them, your health information may no longer be covered by federal or state privacy regulations. Your health information may be disclosed if required by law. Your health information may be used to create information that does not directly identify you. This information may be used by other researchers. You will not be directly identified in any publication or presentation that may result from this study unless there are photographs or recorded media which are identifiable.

Monitors, auditors, IRB or other regulatory agencies will be granted direct access to the participant's original medical record for verification of clinical trial procedures or data, without violating confidentiality of the participant and to the extent permitted by other applicable laws.

If required by law or court order, we might also have to share your Protected Health Information with a judge, law enforcement officer, government agencies, or others. If your Protected Health Information is shared with any of these groups it may no longer be protected by federal or state privacy rules.

Any Protected Health Information collected from you in this study that is maintained in the research records *will be kept for at least six years after the study is finished. At that time any research information not already in your medical record will either be destroyed or it will be de-identified. Any research information entered into your medical record will be kept for as long as your medical record is kept by the Medical Center.* You will not be able to obtain a copy of your Protected Health Information in the research records until all activities in the study are completely finished.

You can tell Nancy Avis, PhD that you want to take away your permission to use and share your Protected Health Information at any time by sending a letter to this address:

Nancy Avis, PhD
Wake Forest School of Medicine
Dept of Social Sciences and Health Policy
Medical Center Blvd
Winston-Salem, NC 27157

However, if you take away permission to use your Protected Health Information you will not be able to be in the study any longer. We will stop collecting any more information about you, but any information we have already collected can still be used for the purposes of the research study.

By signing this form you give us permission to use your Protected Health Information for this study.

If you choose to participate in this study, your medical record at Wake Forest University Baptist Medical Center will indicate that you are enrolled in a clinical trial. Information about the research and any medications or devices you are being given as a participant may also be included in your medical record. This part of the medical record will only be available to people who have authorized access to your medical record. If you are not a patient at this Medical Center, a medical record will be created for you anyway to ensure that this important information is available to doctors in case of an emergency.

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 Web site at any time.

Laboratory test results and other medical reports created as a result of your participation in the research study may be entered into the computer systems of Wake Forest University Health Sciences and North Carolina Baptist Hospital. These will be kept secure, with access to this information limited to individuals with proper authority, but who may not be directly involved with this research study.

A North Carolina Baptist Hospital (NCBH) medical record will be created for all study participants. Information about your participation in the study will be placed in the NCBH medical record, along with any routine medical test results that were obtained at NCBH as part of this study.

WHAT ARE MY RIGHTS AS A RESEARCH STUDY PARTICIPANT?

Taking part in this study is voluntary. You may choose not to take part or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be for your best medical interest, your condition has worsened, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or in the event of a research-related injury, contact the study investigator. *After hours you can call the Wake Forest Baptist Comprehensive Cancer Center.*

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact the Chairman of the IRB or the Research Subject Advocate.

You will be given a copy of this signed consent form.

SIGNATURES

I agree to take part in this study. I authorize the use and disclosure of my health information as described in this consent and authorization form. If I have not already received a copy of the Privacy Notice, I may request one or one will be made available to me. I have had a chance to ask questions about being in this study and have those questions answered. By signing this consent and authorization form, I am not releasing or agreeing to release the investigator, the sponsor, the institution or its agents from liability for negligence.

Subject Name (Printed):_____

Subject Signature: _____ Date: _____Time:_____ am pm

Person Obtaining Consent (Printed):_____

Person Obtaining Consent:_____ Date:_____ Time:_____ am pm