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Wake Forest®
School of Medicine

Department of Plastic and Reconstructive Surgery

Radiofrequency Hyperthermia Safety Study (RHySS)

Informed Consent Form to Participate in Research
Nicole Levi, PhD, Principal Investigator

INTRODUCTION

You are invited to participate in a research study. Research studies are designed to gain scientific knowledge that may help you or other people in the future. You are being asked to take part in this study to help the scientific community determine the safety of a new type of tissue heating device. Your participation is voluntary. Please take your time in making your decision as to whether or not you wish to participate. Ask the study staff to explain any words or information contained in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

WHY IS THIS STUDY BEING DONE?

The Thermofield radiofrequency device has been developed to provide topical heating for the purpose of elevating tissue temperature to temporarily increase local blood circulation. However, the Thermofield radiofrequency device has not yet been approved by the FDA for the treatment of any disease, and its use is investigational in this study. The purpose of this study is to evaluate whether radiofrequency heating can safely warm tissue to a precise temperature and maintain the temperature for a specific period of time.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

There will be a total of 20 subjects involved in this study. The study will involve healthy participants at Wake Forest University Health Sciences. All participants will receive therapeutic radiofrequency heating applied to the lower leg (calf) area.

WHAT IS INVOLVED IN THE STUDY?

If you agree to participate in the study, you will first be asked to sign this consent form and provide authorization so that your medical records may be reviewed to ensure that you have no underlying medical ailment that would be unsuitable for the application of the heat- generating device. During the first weekly visit, your overall health will be evaluated, including your weight and height. You will also be asked to provide information regarding your cardiovascular health, including history of elevated blood pressure, diabetes, medications that you are taking, current exercise regime, and history of lower limb swelling or blood clots. A measurement will be taken of the circumference of your calf. Following the initial screening, if you are eligible to participate in the study your lower legs will be photographed. A laser Doppler will be used for

measuring blood perfusion before the radiofrequency heating pad is applied. Then the radiofrequency heating pad will be applied to each leg. The radiofrequency device consists of a heating pad, which will be applied directly to your skin. The pad is designed to apply a specific temperature, between 39.7 and 40.0 degrees Celsius (103.5 – 104 degrees Fahrenheit) with a goal of maintaining 40.0 degrees Celsius (104 degrees Fahrenheit) consistently during the application time. This temperature is mild and may feel like a drugstore heating pad. The device will be turned on one leg and will remain off on the other. The total time for the heating will be 40 minutes, during which you will remain resting in a reclined position. Following the heating application your legs will be photographed using a thermal imaging camera and you will be asked to rate your levels of comfort/ discomfort, including how you feel about the length of time for the heating application. A laser Doppler will again be used for measuring blood perfusion after the radiofrequency heating pad is applied. After one week you will return for your second radiofrequency heating treatment. You will have weekly sessions where the radiofrequency heating is applied for one hour, followed by completing questions about how you feel and photographs of your legs. Heat treatments will be applied once weekly for 4 weeks. Then you will have four weeks with no treatment or visits, followed by one final assessment visit, where you will again answer questions about how you feel and will have photographs of your legs taken. During the course of the study you must not apply either heat or cold to the treated area (no heating pads or cold compresses). Including your first visit and one follow up visit 4 weeks after the last treatment, the total time that you will be involved in the protocol is up to 9 weeks. You will have the same treatment each week of the study, and completion of the surveys.

As part of this research study, your legs will be photographed. This is being done to observe the nature of your skin before and after radiofrequency heating. You may request that the photos be stopped at any time during the course of the research study. You can also withdraw your consent to use and disclose the photograph before it is used. You should also understand that you will not be able to inspect, review, or approve the photographs, before they are used in this study.

Please choose one of the following regarding the use and disclosure of the photograph/videotape/audiotape used in this research study:

_____ I would like the photographs of me to be destroyed once their use in this study is finished.

____ The photographs of me can be kept for use in future studies provided they are kept secure and any future study will be reviewed by an IRB. I understand that I will not be able to inspect, review or approve their future use.

Photographs 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 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.

How Long Will I Be in the Study?

You will be in the study for a maximum of 9 weeks total. This will include four treatment visits and one follow-up visit to re-evaluate the skin where the radiofrequency was applied.

You can stop participating at any time. 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. There are not expected to be any serious consequence to your health if you suddenly withdraw from the study.

What Are the Risks of the Study?

Being in this study involves some risk to you. You should discuss the risk of being in this study with the study staff. Side effects related to treatment with the Thermofield radiofrequency device we are studying may include: itching, redness, tingling, mild swelling, and warmth in the skin. Risks of the study may include increased sensation in the limb, which should not be painful. There is also a small risk that you become sensitive to repeated hyperthermia treatments and develop a first degree burn (like a sunburn). There may also be tenderness at the site.

In addition, there is a slight risk of a breach of confidentiality. We will do our best to protect your confidential information. There also 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.

Reproductive Risks and other Issues to Participating in Research

Pregnant women are excluded from participation in this study. Due to unknown risks of radiofrequency heating to the unborn fetus, sexually active women of childbearing potential must use a reliable method of birth control while participating in this study. Reliable methods of birth control are: abstinence (not having sex), oral contraceptives, intrauterine device (IUD), DepoProvera, tubal ligation, or vasectomy of the partner (with confirmed negative sperm counts) in a monogamous relationship (same partner). An acceptable, although less reliable, method involves the careful use of condoms and spermicidal foam or gel and/or a cervical cap or sponge. We encourage you to discuss this issue further with the study staff if you have any questions.

Are There Benefits to Taking Part in the Study?

This study is not intended to provide direct benefit to you. We hope the information learned from this study will benefit other people in the future, including ensuring the comfort of patients

during radiofrequency heating.

WHAT OTHER CHOICES ARE THERE?

Participation in this study is voluntary. You do not have to be in this study to receive treatment.

WHAT ARE THE COSTS?

All study costs, including radiofrequency heating 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.

The purpose of this research study is to obtain data or information on the safety and effectiveness of the Thermofield radiofrequency heating device, for safely heating skin and the underlying tissue. The results will be provided to the sponsor, Thermofield, the Food and Drug Administration and other federal and regulatory agencies as required.

This study involves taking photographs of your wound. The images will be stored on a private, secure server at Wake Forest University Health Sciences. Images may be stored for up to twenty years after completion of the study. During the study you may request that photography be stopped at any time.

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 research study. Information about the research and any treatments you receive 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.

WILL YOU BE PAID FOR PARTICIPATING?

You will be paid $20 for participating in each of the five study visits (4 for radiofrequency heating and 1 follow-up visit). In total, you will receive $100 for completing this study.

Although there are no current plans for commercialization, the findings from this research may result in the future development of products that are of commercial value. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Wake Forest University Health Sciences and Wake Forest University. This study is being sponsored by Thermofield, who is providing the Thermofield radiofrequency heating device to Wake Forest University Health Sciences to help conduct this study. The researchers do not 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. Wake Forest University Baptist Medical Center holds the insurance policy for this coverage. 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 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, at [redacted]

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 Dr. Nicole Levi at [redacted] (or [redacted] after hours).
You may also contact Dr. Lucian Vlad:
[redacted]
Wake Forest Baptist Health
Medical Center Blvd.
Winston Salem, NC 27157

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you about your health or behaviors is considered Protected Health Information. The information we will collect for this research study includes: review of your medical records, photographs and information about the skin where the heat is applied.

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), 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. This includes representatives from government agencies such as the US Food and Drug Administration (FDA), or the Department of Health and Human Services (DHHS).

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 and 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 Dr. Nicole Levi 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:

Dr. Nicole Levi, PhD
[redacted]

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.

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 because, it is in your best medical interest, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire

study has been stopped. Over the 9 week course of the study you may not apply other forms of heat or cold to the skin where the radiofrequency device has been applied. Failure to comply with this guideline will result in your termination from the study.

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, Dr. Nicole Levi at [redacted] (or [redacted] after hours).

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 at [redacted].

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