Official Title: Mastectomy Flap Temperature and Clinical Implications
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Informed Consent

Department of Plastic Surgery

MASTECTOMY FLAP TEMPERATURES AND CLINICAL IMPLICATIONS

Informed Consent Form to Participate in Research

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SUMMARY

You are invited to participate in a research study. The purpose of this research is to measure tissue temperatures and generate a prospective database of patients undergoing mastectomy with breast reconstruction at Wake Forest Baptist Hospital (WFBH) in order to answer research questions that may improve the care of breast surgery patients. You are invited to be in this study because you are planning to have a mastectomy at WFBH. Your participation in this research will involve the same number of visits as required to complete your mastectomy and/or breast reconstruction. There will be no additional visits for study purposes. You will be a part of the study until your mastectomy and, if applicable, breast reconstruction is complete.

Participation in this study will involve collecting any/all data at planned office/OR visits. All research studies involve some risks. A risk to this study that you should be aware of is that you will be required to provide confidential/private information. Information that is gathered will be logged into a confidential databased based on a unique study number assigned to you. You are not expected to benefit from participation in this study.

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

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the

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study. The person in charge of this study is Adam Katz, MD. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study his contact information is:

Dr. Adam Katz
[redacted]

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

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

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study because you will have a mastectomy with breast reconstruction at Wake Forest Baptist Hospital. 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 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 purpose of this research study is to measure tissue temperatures and generate a prospective database of patients undergoing mastectomy with breast reconstruction at Wake Forest Baptist Hospital (WFBH) in order to enable and facilitate the evaluation of important and novel research questions - and quality improvement (QI) ideas/objectives - that may improve the care of breast surgery patients.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

Researchers intend to enroll 30 people at one research site (WFBH) to take part in this study.

WHAT IS INVOLVED IN THE STUDY?

After you are scheduled for mastectomy with breast reconstruction, study personnel will review this consent with you to determine whether you are willing to participate in this study. The study involves asking your permission to measure tissue temperatures and gather and store health information during the course of your breast surgery treatment. If you agree, the study team will gather information about you related to your medical history, and other information deemed to be important to potentially understanding the safety and success of breast surgery better. Information that is gathered will be logged into a confidential database based on a unique study number assigned to you. This will help to keep your information confidential and make it hard for anyone to know that a given set of information is linked to you. The only way the information will be linked to you is through a separate, confidential, password-protected master file that links your study ID to your birthday and medical record number (MRN). Only a few, select people on the study will have access to this master/linkage file. During the course of your breast surgery, study personnel will use a myocardial probe to take the temperature of your breast skin in different anatomical breast areas at multiple time points during your surgery. The myocardial probe is a needle that measures temperatures.

The skin site for introducing the myocardial probe will be small enough that you would not notice that temperatures have been collected. If you have multiple operations, temperatures may be collected at each operation. Evaluation of the data collected in this study may allow us to identify variables, or changes that help us understand their role in potential complications in breast surgery.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study for the duration of your mastectomy with breast reconstruction surgery and follow up appointments. You will not have any additional visits specifically to collect information for this research study. You can stop participating at any time.

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.

Taking part in this research study may involve providing information that you consider confidential or private. 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. There is always some risk that even de-identified information might be reidentified. All information/data will be collected during your standard care operation(s). There is a risk of bleeding, infection, and/or wound healing complications at the surgical site that may or may not be associated with collecting temperature data.

The risk of harm or discomfort that may happen as a result of taking part in this research study is not expected to be more than in routine physical or psychological examinations or tests for surgical patients. You should discuss the risk of being in this study with the study staff.

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 risks 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.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

You are not expected to receive any direct benefit from taking part in this research study. We hope the information learned from this study will benefit other people in the future.

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 the option to decline participation.

WHAT ARE THE COSTS?

There are no costs to you for taking part in this study.

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.

WILL YOU BE PAID FOR PARTICIPATING?

You will receive no payment or other compensation for taking part in this study. The findings from this research may result in the future development of products that are of commercial value to optimize patient outcomes. 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 Baptist Health Department of Plastic and Reconstructive Surgery. The researchers do not, however, hold a direct financial interest in the sponsor or devices being used in this studied.

WHAT ABOUT MY HEALTH INFORMATION?

In this research study, any new information we collect from you and 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 but is not limited to: medical record number, date of birth, height, weight, medical history, surgical history, allergies, tobacco use status, race/ethnicity, date of surgery and procedures performed, details of surgical procedures, evaluation of surgical sites at postoperative visits for any wounds, redness, bruising, fluid/fluctuation, or tenderness, duration of drain placement, any antibiotic use and duration of therapy.

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

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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.

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 an indeterminate period of time. This authorization does not expire.

You can tell Adam Katz, MD 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:

Adam Katz, MD
[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.

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, your condition worsened, new information becomes available, you had an unexpected reaction, you failed to follow instructions, or because the entire study has been stopped. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

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, Adam Katz, MD at [redacted].

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] or the Research Subject Advocate 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

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