RESEARCH SUBJECT INFORMATION AND CONSENT FORM AND AUTHORIZATION FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

TITLE: THERMALOGICAL ANALYSIS OF A COHORT OF WOMEN UNDERGOING MAMMOGRAPHIC ANALYSIS.

PRINCIPAL INVESTIGATOR: Dr. Haitham Elsamaloty

TELEPHONE: 419-383-4000 (24 hours)

This consent form contains important information to help you decide whether to participate in a research study.

The study staff will explain this study to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

- Being in a study is voluntary – your choice.
- If you join this study, you can still stop at any time.
- No one can promise that a study will help you.
- Do not join this study unless all of your questions are answered.

After reading and discussing the information in this consent form you should know:

- Why this research study is being done;
- What will happen during the study;
- Any possible benefits to you;
- The possible risks to you;
- Other options you could choose instead of being in this study;
- How your personal health information will be treated during the study and after the study is over;
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

Please read this consent form carefully.

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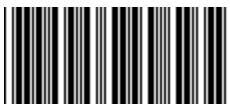


RESEARCH SUBJECT INFORMATION AND CONSENT FORM AND AUTHORIZATION FOR USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

TITLE: **THERMALOGICAL ANALYSIS OF A COHORT OF WOMEN UNDERGOING MAMMOGRAPHIC ANALYSIS.**

PROTOCOL NO.: Sponsors Protocol # SBS II
UT IRB# 202277

SPONSOR: First Sense Medical, LLC
Pontiac, MI
United States

PRINCIPAL INVESTIGATOR: Dr. Haitham Elsamaloty
3000 Arlington Ave
Toledo OH 43614
United States

SUB-INVESTIGATOR(S): Terrence Lewis

SITE(S): University of Toledo
3000 Arlington Ave
Toledo OH 43614
United States

STUDY-RELATED PHONE NUMBER(S): Dr. Haitham Elsamaloty
PI Phone: 419-383-4000 (24 hours)

Clinical Research Coordinators
Stephanie Smiddy RN, BSN, CCRC
Jill Sholl RN, BSN, CCRA
419-383-6962

This consent form may contain words that you do not understand. Please ask the study doctor or study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about participating in the study and to discuss it with your family or friends before making your decision.

Schulman Institutional Review Board, Inc. has approved the information in this consent document and has given approval for the study doctor to do the study. An institutional review board (IRB) is an independent committee established to help protect the rights of research subjects. This does not

mean the IRB has approved your participation in the study. You must think about the information in this consent document for yourself. You must then decide if you want to be in the study.

What you should know about this research study:

- You are being given this consent form so that you may read about the purpose, risks, and benefits of this research study. All information in this form will also be explained to you verbally by the research staff.
- Routine clinical care is based upon the best-known treatment and is provided with the main goal of helping the individual patient. The main goal of research studies is to gain knowledge that may help future patients.
- Being in this research may not benefit you personally. This research can have minor side effects.
- You have the right to refuse to take part in this research. You may also agree to take part now and change your mind later.
- If you decide not to take part in this research, or if you decide to take part now but change your mind later, your decision will not affect your routine care.
- Please review this form carefully. Ask any questions before you make a decision about whether or not you want to take part in this research. If you decide to take part in this research, you may ask any additional questions that you may have at any time.
- Your participation in this research is voluntary.

PURPOSE (WHY THIS RESEARCH IS BEING DONE)

You are being asked to take part in a research study of early breast cancer screening techniques.

The purpose of the study is to evaluate the functionality and performance of the First Sense Medical Sentinel Breast Scanner II (FSM SBSII) /Therma-Scan System and use the data to provide further updates to the system software.
. First Sense Medical® has developed a new way to screen for breast cancer that is painless, non-contact, non-invasive, radiation free, and has a projected sensitivity (ability to detect a potential abnormality in the breast) of 95%.

In this study, we seek to collect several images of your breasts with a special camera that measures the temperature map of your breast tissue. This special camera, known as a thermal camera, is included in a new medical device being developed by First Sense Medical®. This special camera is used in conjunction with mirrors to record the heat profile of the breast tissue.

The Sentinel Breast Scanner II is an investigational device. An investigational device is one which has not been approved by the U.S. Food and Drug Administration (FDA).

You were selected as someone who may want to take part in this study because you are a female that is at least 18 years of age and are planning on being screened for breast abnormality with a mammogram.

The estimated number of study participants to be enrolled at the University of Toledo for testing is 2000.

OVERVIEW AND DURATION OF YOUR INVOLVEMENT

If you decide to take part in this study, the investigational testing will take approximately 10 minutes. The study will also ask that you complete the Sentinel Breast Scanner II imaging with any routine mammogram or breast MRI for up to the next 5 years. The study will not ask for the Sentinel Breast Scanner II images to be completed more frequently than your routine mammogram or breast MRI imaging, or more frequent than every 6 months.

SCHEDULE OF ASSESSMENTS AND STUDY PROCEDURES

If you agree to take part in this study, you will be asked to disrobe from the waist up and sit in a chair facing the First Sense Breast Exam® device. During the screening, a camera, in conjunction with mirrors, will continually collect thermal images of your breasts to record temperatures in breast tissue.

The SBS II device will blow cool air on your breasts for up to 3.5 minutes during the exam. The resulting thermal images and three-dimensional thermal maps will not identify you by first name or last name. The original thermal images will never be published. They are only being collected to help First Sense Medical® further develop and refine the device software. The test itself involves no drugs, injections, or x-rays, and your breasts will remain untouched. The test should take approximately 10 minutes.

If your mammogram shows any breast anomaly, the study staff will collect information from your medical chart about your follow up care. If your mammogram is normal, but the SBS II shows an abnormality, the study will request that you complete a follow up breast ultrasound. This additional breast ultrasound will be paid for by the study, if there is no abnormality seen on your routine mammogram.

RISKS AND DISCOMFORTS

If you agree to participate in this research, there is a risk of loss of confidentiality (i.e. others may find out private information about you). The Confidentiality section of this form explains how the researchers will work carefully to protect your privacy and keep your information confidential.

There may be discomfort associated with sitting disrobed from the waist up for the purposes of this study. Cold air will be blown onto the breasts for 3 minutes, which may cause minor discomfort.

Ask the study doctor if you have questions about the signs or symptoms of any side effects you read about in this consent form.

Whether or not you think they are related to the study, please tell the study doctor or study staff right away if you have any side effects or any other problems with your health or the way you feel during the study. This research study might involve risks that are currently unknown.

RISKS TO UNBORN CHILDREN

Special Notes About Pregnancy and Breastfeeding during the Study

This research represents an unknown risk to unborn children. Therefore, you may not take part in this study if you are breastfeeding, are pregnant, or think that you may be pregnant. If you are pregnant or breastfeeding, there may be risks to you and the baby that are not known at this time.

Ask your study doctor any questions that you may have about the risk to you at any time before or, if you decide to enroll, while you are taking part in this research.

PAYMENT OR OTHER COMPENSATION TO THE RESEARCH SITE
The University of Toledo is receiving money or other benefits from the study sponsor for conducting this research study.

NEW FINDINGS
Any new important information which is discovered during the study and which may influence your willingness to continue participation in the study will be made available to you. You may be asked to sign a revised consent form if this occurs.

POSSIBLE BENEFITS TO YOU IF YOU DECIDE TO TAKE PART IN THIS RESEARCH
There is no direct benefit to you from your participation in this study. The test does not replace the need for standard medical care, mammograms, MRI's, or other FDA approved tests.
We cannot and do not guarantee or promise that you will receive any direct medical benefits from this research study.

COSTS TO YOU FOR TAKING PART IN THIS STUDY
There will be no cost to you to participate in this study.

While you are in the study, you still need to get regular medical care. You (and/or your health care insurance) will be billed for the costs of your regular medical care that are not a part of this study.

If your First Sense Breast Exam shows an abnormal reading and your mammogram is normal, we intend to contact you. We will encourage you to obtain an ultrasound and a referral will be provided for this additional test. These further tests may or may not be warranted depending upon their results. They may falsely induce stress and concern, or they may actually point to a reason to undergo a breast biopsy. These additional tests will be paid for entirely by First Sense Medical.

Ask your study doctor to discuss the costs that will or will not be covered by the sponsor. This discussion should include the costs of treating possible side effects. Otherwise, you might have unexpected expenses from being in this study.

PAYMENT OR OTHER COMPENSATION TO YOU FOR TAKING PART IN THIS RESEARCH
If you decide to take part in this research you will receive the investigational test at no cost.

You will also be given a $20 Target gift card each time you have the SBS II done, for your time to participate.

ALTERNATIVES TO TAKING PART IN THIS RESEARCH
If you decide not to enter this study, it will not affect your care or available treatment options.
This research study is for research purposes only. The only alternative is to not participate in this study.

AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION FOR RESEARCH PURPOSES
Federal regulations give you certain rights related to your health information. These include the right to know who will be able to get the information and why they may be able to get it. The study doctor must get your written authorization (permission) to use or give out any health information about your medical condition or treatment that might identify you.

What information may be used and given to others?
By agreeing to take part in this research study and signing this document, you give to The University

of Toledo, the study doctor, and all personnel associated with this research your permission to use or disclose (release) your health information that we obtain in connection with this study. This may include information that might identify you. The study doctor may also obtain information about your health including:

- Past and present medical records
- Medical records related to your follow up care if your mammogram shows any breast anomaly
- Research records
- Records about phone calls made as part of this research
- Records about your study visits
- Information obtained during this research about
  - Physical exams
  - Medical history
  - Laboratory and other test results such as radiology tests and biopsy results
- Records about any medications you are taking

Who may use and give out information about you?
Information about your health may be used and given to others by the study doctor and staff. They might see the research information during and after the study. You may be asked to sign additional permission (authorization) forms for this purpose.

Who might get this information?
Your information may be given to the sponsor of this research. "Sponsor" includes any persons or companies that are working for or with the sponsor, or are owned by the sponsor. For this study, "sponsor" also includes:

First Sense Medical

Information about you and your health, which might identify you, may also be given to:

- The U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- The Schulman Institutional Review Board
- The University of Toledo
- The University of Toledo Institutional Review Board
- The University of Toledo Research and Sponsored Programs
- State of Ohio agencies

Why will this information be used and/or given to others?
Information about you and your health that might identify you may be given to others to carry out the research study. We will also use this information ourselves for the purpose of conducting the research study as described in this consent form. The sponsor will analyze and evaluate the results of the study. In addition, people from the sponsor and its consultants will be visiting the research site. They will follow how the study is done, and they will be reviewing your information for this purpose.

The information may be given to the FDA. It may also be given to governmental agencies in other countries. This is done so the sponsor can receive marketing approval for new products resulting

from this research. The information may also be used to meet the reporting requirements of governmental agencies.

The results of this research may be published in scientific journals or presented at medical meetings, but your identity will not be disclosed.

The information may be reviewed by the Schulman IRB. The Schulman IRB is a group of people who perform independent review of research as required by law.

The information may also be reviewed by the University of Toledo Biomedical Institutional Review Board and Research and Sponsored Programs of the University of Toledo for compliance audits.

We may also disclose your protected health information when required by law, such as in response to court orders.

What if I decide not to give permission to use and give out my health information?
By signing this consent form, you are giving permission to use and give out the health information listed above for the purposes described above. If you refuse to give permission, you will not be able to participate in this research.

May I review or copy the information obtained from me or created about me?
You generally have the right to review and copy your health information. However, if you decide to be in this study and sign this consent form you will not be allowed to look at or copy your information related to this research study until after the research is completed.

May I withdraw or revoke (cancel) my permission?
Yes, but this permission will not stop automatically.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to **Dr. Haitham Elsamaloty** at the University of Toledo, ***3ooo Arlington Ave, Toledo OH 43614***. If you withdraw your permission, you will not be able to continue being in this study.

When you withdraw your permission, no new health information, which might identify you, will be gathered after that date. Information that has already been gathered may still be used and given to others as necessary to maintain the integrity of the research study.

Unless you revoke (cancel) your authorization, this authorization to use and disclose your health information has no expiration date.

Is my health information protected after it has been given to others?
There is a possibility that the information we disclose may be re-disclosed by the persons we give it to, and no longer protected by privacy regulations. However, we will encourage any person who receives your information from us to continue to protect and not re-disclose the information.

How can I obtain a copy of The University of Toledo's Privacy Practices?
A more complete statement of University of Toledo's Privacy Practices is set forth in its Joint Notice of Privacy Practices. If you have not already received this Notice, a member of the research team will provide this to you. If you have any further questions concerning privacy, you may contact the University of Toledo's Privacy Officer at 419-383-6933.

IN THE EVENT OF A RESEARCH RELATED INJURY
A research-related injury is an injury caused by the properly administered investigational products(s) used in this research (e.g. investigational drug or device) or a properly performed study procedure

required by this study's protocol. If you suffer a research-related injury, medical treatment is available.

The study sponsor, University of Toledo, and The University of Toledo Medical Center do not offer reimbursement for medical expenses or other compensation for research-related injuries. In the event of any medical expenses, they will be billed to you or your insurance.

By signing this form you do not give up any of your legal rights if you are injured.

In the event of a research-related injury, contact:

Dr. Haitham Elsamaloty at 419-383-4000 (24 hours)

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Your participation in this study is voluntary. You may decide not to participate or you may leave the study at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled. If you decide not to participate or to discontinue participation, your decision will not affect your future relationship with the University of Toledo or The University of Toledo Medical Center.

If you decide to withdraw from the research study for any reason, please contact the study doctor immediately.

Your participation in this study may be stopped by the study doctor or the sponsor at any time with or without your consent for any of the following reasons:

- your study doctor considers it to be in your best interest,
- you do not follow instructions given to you by your study doctor,
- you suffer a complication,
- the Schulman Associates Institutional Review Board requests that you be withdrawn,
- you do not later consent to any future changes that may be made in the study plan,
- you become pregnant,
- or for any other reason.

This could also happen if your study doctor, the Schulman Institutional Review Board, or the sponsor, ends the study.

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.

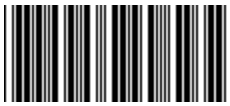
OTHER QUESTIONS

At any time you may speak with **Dr. Haitham Elsamaloty** or a member of his study staff to answer any questions, complaints or concerns that you may have about the study.

Dr. Haitham Elsamaloty at 419-383-4000 (24 hours)

If you have questions about your rights as a research subject or if you have questions, concerns or complaints about the research, you may write:

Schulman Institutional Review Board
4445 Lake Forest Drive – Suite 300
Cincinnati, Ohio 45242
OR
Call toll-free 1-888-557-2472 during business hours



Monday - Friday 8:00 a.m. to 6:00 p.m. EST.

The Schulman IRB is a group of people who perform independent review of research.

Schulman IRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact Schulman IRB if the research staff cannot be reached or if you wish to talk to someone other than the research staff.

If you have questions beyond those answered by the research team or your rights as a research subject or research related injuries, please feel free to contact the Chairperson of The University of Toledo Biomedical Institutional Review Board at 419-383-6796.

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

Please indicate below whether you want us to notify your primary care physician or your specialist of your participation in this study.

_____ Yes, I want the study doctor to inform my primary care physician/specialist of my participation in this study.

_____ No, I do not want the study doctor to inform my primary care physician/specialist of my participation in this study.

_____ I do not have a primary care physician/specialist.

_____ The study doctor is my primary care physician/specialist.

If you agree to participate in this study, you will receive a signed and dated copy of this consent form for your records.

CONSENT FOR RESEARCH PARTICIPATION AND AUTHORIZATION TO USE AND DISCLOSE PROTECTED HEALTH INFORMATION

By signing this consent form, I agree that all of the following statements are true:

- I have read and understood all of the above information (or it has been read to me), and all my questions have been answered to my satisfaction.
- The purpose of the research, the study procedures, and the possible risks or discomfort have been explained to me.
- Alternatives to my participation in this research study have been discussed with me.
- I voluntarily agree to participate in this study, as indicated by my signature below.
- I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.
- I understand that by signing this consent form, I am not giving up any of my legal rights.

_____
Subject Name (Please Print)

_____ _____ a.m. p.m.
Signature of Subject Date Time

_____ _____
Name of Person Conducting Informed Consent Discussion (Please Print) Position

_____ _____ a.m. p.m.
Signature of Person Conducting Informed Consent Discussion Date Time

----------Use the following only if applicable ----------

If this consent/authorization form is read to the subject because the subject is unable to read this form, an impartial witness not affiliated with the research or investigator must be present for the consent process, and sign and date the following statement:

I confirm that the information in this consent/authorization form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to participate in the research study.

_____ _____

Signature of Impartial Witness Date

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.