Consent Form
University of Oklahoma Health Sciences Center (OUHSC)
Stephenson Cancer Center
OU Medical Center

TITLE: A Feasibility Study for the use of Multispectral Optoacoustic Tomography in the Detection of Solid Tumors and Lymph Nodes (MSOT-001)

PROTOCOL NO.: OU-SCC-MSOT
WIRB® Protocol #20193430
11534

SPONSOR: The University of Oklahoma Health Sciences Center - Stephenson Cancer Center

PRINCIPAL INVESTIGATOR: Lacey McNally, PhD
800 NE. 10th Street
Oklahoma City, Oklahoma 73104
United States

STUDY-RELATED PHONE NUMBER(S): (405) 271-4022 (24 hours)

This is a research study. Research studies involve only individuals who choose to participate. Please take your time to make your decision. Discuss this with your family and friends.

RESEARCH CONSENT SUMMARY

You are being asked for your consent to take part in a research study. This document provides a concise summary of this research. It describes the key information that we believe most people need to decide whether to take part in this research. Later sections of this document will provide all relevant details.

What should I know about this research?

- Someone will explain this research to you.
- Taking part in this research is voluntary. Whether you take part is up to you.
- If you don't take part, it won't be held against you.
- You can take part now and later drop out, and it won't be held against you
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

How long will I be in this research?
You will be actively enrolled only for the duration of pre-op through surgical recovery, and until discharge unless any study-related adverse event occurs. Medical record review will occur up to 6 months to allow for follow-up pathology assessments to be gathered and provide information to allow for analyses to be performed.

Why is this research being done?
The purpose of this study is to assess the safety and evaluate the potential of a new experimental imaging instrument called multispectral optoacoustic tomography (MSOT).

What happens to me if I agree to take part in this research?
If you decide to participate in this studyimages will be taken of your skin using the MSOT device prior to and after surgery.

Could being in this research hurt me?
There is no guarantee that the device will help your condition. The researchers do not know all of the side effects that could happen. For a complete description of known risks, refer to the Detailed Information section of the consent form.

Will being in this research benefit me?
If you agree to take part in this study, there may not be direct medical benefit to you. We hope that the information learned from this study will benefit other patients with this disease in the future.

What other choices do I have besides taking part in this research?
This is not a treatment study. You do not have to be in this study to receive medical treatment for your cancer. You should talk to your doctor about all the choices you have. Instead of being in this study, you have these options of standard treatment:

- Standard tumor margin
- lymph node assessment

Taking part in this study will not exclude you from receiving standard medical treatment for your cancer or from taking part in another clinical study.

DETAILED INFORMATION ABOUT THE RESEARCH STUDY

WHY IS THIS STUDY BEING DONE?
The purpose of this research study is to assess the safety and evaluate the potential of a new imaging instrument, Multispectral optoacoustic tomography (MSOT), for the identification of tumor and positive lymph nodes. Imaging is important in the management of all cancer types, including intraoperative identification of surgical margins and evaluation of tumor-positive lymph nodes. This new procedure uses a “light-in and sound-out” approach which specifically includes a laser and ultrasound detector to study the tissue. We hope that with this method, tumor

and tumor affected lymph nodes detection can be improved compared to current methods.

In this study, we will compare the results of the conventional tumor/lymph node identification methods and pathological examinations with those of the new MSOT method. The investigation is embedded in the normal course of treatment and is not expected to prolong the procedure significantly. Clinical decisions about your care will not be made from the results of this study.
MSOT is an investigational device. This means it has not been approved by the U.S. Food and Drug Administration (FDA). Devices that do not have approval by the FDA cannot be sold or prescribed by your physician.

WHY HAVE I BEEN ASKED TO PARTICIPATE IN THIS STUDY?
You are being asked to participate in this research study because you have been diagnosed with cancer and will undergo surgery to remove your cancer.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?
Fifty people at *a single* research site will take part in this study.

WHAT IS INVOLVED IN THE STUDY?
This study will utilize the MSOT device and evaluate the device for safety. This consists of placing a probe, similar to an ultrasound, which emits light and detects sound. The probe will be covered in a plastic sleeve and gel will be placed on your skin to allow pictures to be taken of your tissue. The MSOT probe will be placed near the tumor or lymph node location. The MSOT scanning will be done prior to and after your surgery in the operating room.

If you take part in this study, you will have the following tests and procedures:
You will go through standard care procedures to prepare for surgery which includes complete standard imaging prior to surgery to prepare for surgery. The MSOT device will be used to detect the tumor or lymph node margins based upon hemoglobin prior to surgical removal of tumor or lymph nodes. You will undergo standard surgery to remove the tumor and/or lymph nodes. The resected tumor will undergo standard pathological assessment. The findings of the pathological assessment will be compared to the MSOT images. The temperature of your skin will also be measured prior to and after MSOT imaging.

HOW LONG WILL I BE IN THE STUDY?
Each scan will take approximately 3-5 minutes. We will access your records for up to 6 months to allow for comparison of the pathological assessment to the images. You will be in the study for about 6 months.

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. The study investigator may remove or withdraw you from the study for any reason.

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. Risks and side effects related to the MSOT device we are studying include:

- Slight, reversible reddening
- Lightening of the skin and /or scarring which may not be apparent until weeks or months after the use of light based devices
- Temperature increase of sensitive skin from the probe

Standard ultrasound gel will be applied prior to use of MSOT. This ultrasound gel could potentially cause redness or rash to the skin where applied.

There may be risks that are currently unknown.

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.

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 daily life or from routine physical or psychological examinations or tests. 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. 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. Because some methods of birth control are not 100% reliable, a pregnancy test is required at least 10 days from your last normal menstrual period, if you are a sexually active woman of childbearing potential.

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 DO I HAVE BESIDES TAKING PART IN THIS RESEARCH?
This is not a treatment study. Your other choices besides taking part in this study may include:

- Getting treatment or care for your cancer without being in a study
- Taking part in another study
- Getting no treatment

Taking part in this study will not exclude you from receiving standard of care medical treatment for your cancer or from taking part in another clinical study. Talk to your doctor about your choices before you decide if you will take part in this study.

WHAT ARE THE COSTS?
All study costs, including any study medications 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?
Efforts will be made to keep your personal information confidential. You will not be identifiable by name or description in any reports or publications about this study. We cannot guarantee absolute confidentiality. Your personal information may be disclosed if required by law.

There are organizations outside the OUHSC that may inspect and/or copy your research records for quality assurance and data analysis. These organizations include the US Food & Drug Administration and other regulatory agencies, and the Western Institutional Review Board (WIRB). Certain departments at OUHSC may also inspect and/or copy your research records, i.e. HRPP office, university compliance and regulatory offices.

A description of this clinical trial will be available on https://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.

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. There are no plans to provide you with financial compensation or for you to share in any profits if this should occur.

What if I am Injured or Become Ill While Participating in this Study?
In the case of injury or illness resulting from this study, emergency medical treatment is available.

No other funds have been set aside by The University of Oklahoma Health Sciences Center, OU Medical Center, or the Stephenson Cancer Center to compensate you in the event of injury, illness, or for other damages related to your event of injury or illness.

You will get medical treatment if you are injured as a result of taking part in this study. The study will not pay for medical treatment. If you are injured as a result of this study, you do not give up your right to pursue a claim through the legal system.

WHO IS SPONSORING THIS STUDY?
This study is being sponsored by The University of Oklahoma Health Sciences Center Stephenson Cancer Center (OUHSC SCC). The sponsor is providing money or other support to OUHSC SCC to help conduct this study. The researchers do not, however, hold a direct financial interest in the sponsor or the product being studied.

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 otherwise 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.

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

HIPAA
If you decide to sign this document, University of Oklahoma Health Sciences Center (OUHSC) researchers may use or share information that identifies you (protected health information) for their research. Protected health information will be called PHI in this document.

PHI To Be Used or Shared. Federal law requires that researchers get your permission (authorization) to use or share your PHI. If you give permission, the researchers may use or share with the people identified in this Authorization any PHI related to this research from your medical records and from any test results. Information used or shared may include all information relating to any tests, procedures, surveys, or interviews as outlined in the consent form; medical records and charts; name, address, telephone number, date of birth, race, government-issued identification numbers, and personal information such as your name, address, telephone number, date of birth, race, government-issued identification number, medical records, and charts relating to any tests or procedures outlined in the informed consent form.

Purposes for Using or Sharing PHI. If you give permission, the researchers will use your PHI to: fulfill the research purposes as listed in this document.

Other Use and Sharing of PHI. If you give permission, the researchers could also use your PHI to develop new procedures or commercial products. They could share your PHI with the research sponsor, the Western Institutional Review Board (WIRB), inspectors who check the research, and government agencies like the Food and Drug Administration (FDA) and the

Department of Health and Human Services (HHS). The researchers may also share your PHI with the HRPP office, the OUHSC compliance and regulatory offices as well as the organizations listed in confidentiality section above.

Confidentiality. Although the researchers may report their findings in scientific journals or meetings, they will not identify you in their reports. The researchers will try to keep your information confidential, but confidentiality cannot be guaranteed. The law does not require everyone who might see your information covered by this document to keep it confidential, so it might be released to others and federal law may no longer protect it.

YOU UNDERSTAND THAT YOUR PROTECTED HEALTH INFORMATION MAY INCLUDE INFORMATION REGARDING A COMMUNICABLE OR NONCOMMUNICABLE DISEASE.

Voluntary Choice. The choice to give OUHSC researchers permission to keep or share your PHI for their research is voluntary. It is completely up to you. No one can force you to give permission. However, you must give permission to use or share your private health information if you want to participate in the research.

Refusing to give permission will not affect your ability to get usual treatment or health care unrelated to this study from OUHSC.

Canceling Permission. If you give the OUHSC researchers permission to use or share your PHI, you have a right to cancel your permission whenever you want. However, canceling your permission will not apply to information that the researchers have already used or shared or to information necessary to maintain the reliability or integrity of the research.

End of Permission. Unless you cancel it, permission for OUHSC researchers to use or share your PHI for their research will never end.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?
For questions, concerns, or complaints about the study or in the event of a research-related injury, contact the study investigator, Lacey McNally at 405-271-4022 (24 hours) If you believe you have been injured, you will be referred for treatment.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (800) 562-4789, help@wirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.

- You have questions about your rights as a research subject.

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

SIGNATURES

By signing this form, you are agreeing to participate in this research study and to permit your information to be used and shared under the conditions described above. You have not given up any of your legal rights or released any individual or entity from liability for negligence. You have been given an opportunity to ask questions. You will be given a copy of this consent document.

I agree to participate in this study:

PARTICIPANT SIGNATURE (age ≥18)	Printed Name	Date
SIGNATURE OF PERSON OBTAINING CONSENT	Printed Name	Date