

21-002713

3D Ultrasound Microvessel Imaging for Breast Masses

NCT04925817

Document Date: 03/24/2023



Name and Clinic Number

Approval Date: March 24, 2023
Not to be used after: March 23, 2024

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: 3D Ultrasound Microvessel Imaging for Breast Masses

IRB#: 21-002713

Principal Investigator: Dr. Shigao Chen and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.

It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	<p>The purpose of this research is to study the effectiveness of a new ultrasound imaging method for diagnosis of breast mass.</p> <p>You have been asked to take part in this research because you are scheduled to have biopsy of your breast mass as part of your clinical care.</p>
What's Involved	Study participation involves one study visit of about 45 minutes, during which ultrasound imaging will be performed on your breast mass.



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Key Information	<p>This study will not make your health better. The ultrasound study imposes no discomfort. No drugs or procedures that involve entering the body will be used in this study.</p> <p>The risks of this research study are minimal, which means that we do not believe that they will be any different than what you would experience at a routine clinical visit or during your daily life.</p> <p>You will not have to pay for the research ultrasound exam.</p>
Learn More	<p>If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.</p>

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you either a printed or electronic copy of this form to keep.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.



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Contact Information

If you have questions about ...	You can contact ...
<ul style="list-style-type: none">▪ Study tests and procedures▪ Materials you receive▪ Research-related appointments▪ Research-related concern or complaint▪ Research-related injuries or emergencies▪ Withdrawing from the research study	<p>Principal Investigator: Shigao Chen Phone: (507) 284-8252</p> <p>Study Team Contact: Bobbie Ott Phone: (507) 293-0922</p> <p>Institution Name and Address: Mayo Clinic 200 First Street SW Rochester, MN 55905</p>
<ul style="list-style-type: none">▪ Rights of a research participant	<p>Mayo Clinic Institutional Review Board (IRB) Phone: (507) 266-4000 Toll-Free: (866) 273-4681</p>
<ul style="list-style-type: none">▪ Rights of a research participant▪ Any research-related concern or complaint▪ Use of your Protected Health Information▪ Stopping your authorization to use your Protected Health Information▪ Withdrawing from the research study	<p>Research Participant Advocate (RPA) (The RPA is independent of the Study Team) Phone: (507) 266-9372 Toll-Free: (866) 273-4681</p> <p>E-mail: ResearchParticipantAdvocate@mayo.edu</p>
<ul style="list-style-type: none">▪ Billing or insurance related to this research study	<p>Patient Account Services Toll-Free: (844) 217-9591</p>



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Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you are going to have a biopsy of your breast mass as part of your clinical care.

The plan is to have about 50 people take part in this study at Mayo Clinic.

Why is this research study being done?

The purpose of this research is to study the effectiveness of a new ultrasound imaging method for diagnosis of breast mass.

Information you should know

Who is Funding the Study?

The National Institutes of Health is funding the study.

Information Regarding Conflict of Interest:

Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.



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How long will you be in this research study?

You will be in this study for about 45 minutes.

What will happen to you while you are in this research study?

If you agree to be in the study, you will be asked to participate in the following:

You will be asked to lie down for an ultrasound examination. A handheld ultrasound imaging tool will be used to collect ultrasound data from your breast mass. Liquid ultrasound gel will be placed on your skin to help collect data. The procedure should cause no discomfort. You will be asked to hold your breath for short periods of time (30 secs at most) during the study. During each breath hold, one ultrasound measurement will be made. Multiple measurements will be made during the evaluation. We may use more than one ultrasound scanner to collect data from you. One scan will be done on a clinical ultrasound scanner to set a baseline image. You will then have a 3D image taken from another scanner so that we can compare the imaging performance of different scanners. No drugs or procedures that involve entering the body will be used in this study.

Your medical record will be reviewed for information related to your breast biopsy and overall health.

Tests done only for research purposes are not meant to provide clinical information or help care for you. The results are only important for research. Therefore, the results of tests done with your information and samples will not be provided to you. In the rare event that a finding might affect the health of you or your family, we will contact you and you can choose whether to receive or refuse the information. If you decide to follow up and further medical testing or care is needed, the costs will be billed to you or your insurance.



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What are the possible risks or discomforts from being in this research study?

The risks of this research study are minimal, which means that we do not believe that they will be any different than what you would experience at a routine clinical visit or during your daily life.

Ultrasound imaging imposes no discomfort and does not involve radiation risks. No drugs or procedures that involve entering the body will be used in this study.

Pregnant women will not be allowed to enroll on this study. Please tell your study doctor if you are pregnant or think you might be pregnant.

As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

Are there reasons you might leave this research study early?

Taking part in this research study is voluntary. You may decide to stop at any time. You should tell the researcher if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the researchers, or Mayo may stop you from taking part in this study at any time:

- If it is in your best clinical interest,
- If you do not follow the study procedures,
- If the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.



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What if you are injured from your participation in this research study?

Where to get help:

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries?

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.

What are the possible benefits from being in this research study?

There will be no direct benefit to you by taking part in this research study. It is for the benefit of research.

What alternative do you have if you choose not to participate in this research study?

This study is only being done to gather information. You may choose not to take part in this study.

What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study.



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These tests and procedures are:

- Ultrasound examination performed during your research study visit

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles.

These tests and procedures may include:

- Mammography (if any)
- Ultrasound examination as part of your clinical care (if any)
- Ultrasound guided breast mass biopsy

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

Will you be paid for taking part in this research study?

We will pay you \$50 for participating in the study.

Payment for participation in research is considered taxable income and reportable to the Internal Revenue Service (IRS). Accounts Payable at Mayo Clinic will be given your name, address and Social Security number in order to issue a check for your study participation. If you receive research payments totaling \$600 or more in a calendar year, a tax Form 1099 will be sent to you. For Mayo Clinic employees, research payments are included in your paycheck with applicable taxes withheld and reported on your Form W2 after calendar year-end.

Will your information or samples be used for future research?

Identifiable information such as your name, Mayo Clinic number, or date of birth may be removed from your information or samples collected in this study, allowing the information or samples to be used for future research or shared with other researchers without your additional informed consent.



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How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

A code consisting of numbers and letters will be assigned to each subject to protect privacy. Data in electronic format will be stored on secured computer database with restricted access. Materials in paper form (e.g., consent forms) will be filed in a locked file cabinet.

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission (or “authorization”) to Mayo Clinic.

Your health information may be collected from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study.
- The sponsor(s) of this study and the people or groups hired by the sponsor(s) to help perform this research.
- Our collaborators: identifiable information such as your name, Mayo Clinic number, or date of birth will be removed when we share the information.
- The Mayo Clinic Institutional Review Board that oversees the research.



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- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other United States agencies) or government agencies in other countries that oversee or review research.

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy; however, once your information is shared outside Mayo Clinic, we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.



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You can cancel your permission for Mayo Clinic to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
201 Building 4-60
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: ResearchParticipantAdvocate@mayo.edu.

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number and /or study name, and
- Your contact information.

Your permission for Mayo Clinic to use and share your health information lasts forever, unless you cancel it.

There is no expiration or end date related to the Sponsor's use of your health information received from Mayo Clinic as part of this study.



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Enrollment and Permission Signatures

Your signature documents your permission to take part in this research.

Printed Name	Date (mm/dd/yyyy)	Time (hh:mm am/pm)
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Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

Printed Name	Date (mm/dd/yyyy)	Time (hh:mm am/pm)
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Signature