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Quantitative Transmission Imaging Evaluation (QTIE Study) Compared With MRI As Supplemental Screening In Patients With High Lifetime Risk Of Breast Cancer

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MAYO CLINIC

Name and Clinic Number

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RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Quantitative Transmission Imaging Evaluation (QTIE Study) compared with MRI as supplemental screening in patients with high lifetime risk of breast cancer

IRB#: 24-008575

Principal Investigator: Dr. Tiffany Sae-Kho

Key Study Information

This section provides a 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	The purpose of this research is to compare the diagnostic performance of 3D US of the breast (QTI) as a potential new screening tool to the current standard screening MRI and other standard of care imaging. You have been asked to take part in this research because you are a woman with an elevated lifetime risk of breast cancer >20%.
What's Involved	Study participation involves undergoing a single 3D ultrasound test (QTI) in addition to your already scheduled screening MRI and other standard of care imaging. The would be a one-time scan using a 3D ultrasound technique (QTI) to exam the breast tissue.
Key Information	The examination takes approximately 15 minutes for each breast. The images are acquired while you are laying on your stomach with your breast placed in a water bath.

	The risks of undergoing this additional test are minimal and include minor discomfort from the scanning table which you would be lying on. Findings on this scan will be compared to your obtained screening MRI and other standard of care imaging. The 3D US is obtained for research purposes only and no clinical decisions will be made from this scan. There will be no cost to undergo the 3D US imaging. This cost will be covered by the study at no expense to you.
Learn More	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.

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 …
▪ 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	**Principal Investigator:** Dr. Tiffany Sae-Kho **Phone:** [redacted] **Study Team Contact:** Dr. Jillian Kennedy **Phone:** [redacted] **Institution Name and Address:** Mayo Clinic **200 First St. SW** **Rochester, MN 55920**
▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ 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	**Research Participant Advocate (RPA)** **(The RPA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Other Information:

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.

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 a woman that is 18 years of age or older with an elevated lifetime risk of breast cancer greater than 20%.

Why is this research study being done?

We are performing an initial study looking at the effectiveness of 3D breast ultrasound (Quantitative Transmission Imaging (QTI)) as a screening tool for breast cancer. We will be comparing this method to the traditional screening MRI exam and other standard of care imaging that high-risk patients typically undergo.

25 to 30 people will participate in this initial research study.

Information you should know

Who is Funding the Study?

Funding will be provided by QT Imaging.

Information Regarding Conflict of Interest:

The principal investigator and research team have no conflicts of interest to disclose.

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.

How long will you be in this research study?

Your participation in the research study will include the one-time 3D ultrasound (QTI) of your breasts, about 30 minutes total.

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

You will be asked to undergo a 3D ultrasound of your breasts (QTI). This will include putting your breast in a water bath to obtain images. There will be an adhesive retention pad that will gently be placed near your areola to help minimize motion of the breast while inside the water bath. You will be lying on your stomach while the images are obtained with one breast in the water bath at a time. It takes approximately 15 minutes to obtain imaging of each breast. During this time, you will be asked to hold still. Upon completion of imaging everything will be removed from your breast, and you will be free to leave the department.

What are your responsibilities?
If you take part in this research, you will be expected to:

- Come to the study visit and follow the instructions you are given by the study doctor or other study staff.
- Immediately report to the study doctor or other study staff any changes in your health or regular medications.
- Tell your study doctor or study staff if you think you are experiencing a harmful effect from the study participation.
- Let the study doctor know if you are pregnant.
- Do not participate in other research studies while participating in this study before discussing with your study doctor or study staff.
- Tell the study doctor or study staff if you want to stop being in this research study.

Tests done only for research purposes are not meant to provide clinical information or 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.

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

There are minimal risks associated with this research study. You may have some discomfort from laying on your stomach during the image acquisition. You will not be exposed to any additional radiation as ultrasound is a nonionizing imaging modality.

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?

Your participation is voluntary, and you can leave the study at any point in time.

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

- If it is in your best interest,
- If you don't follow the study procedures,
- If you are pregnant, lactating, or have open wounds
- If the study is stopped.

If additional diagnostic imaging is requested based on the result of your standard of care imaging such as screening MRI or screening mammogram, this will be performed for clinical purposes outside of this study.

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?
The principal investigators do not anticipate any injuries from the QTI examination. On the remote chance that any injury is incurred, any standard of care treatment will be paid for by the study.

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

You won't benefit from taking part in this research study. It is for the benefit of research.

Others with high lifetime risk for breast cancer may benefit in the future from what we learn in this research study.

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

You don't have to be in this study to receive treatment for your condition. Your other choice is to resume with standard of care imaging for screening patients with high lifetime risk of breast cancer. This may include planned clinical screening mammography and MRI.

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. These tests and procedures are:

- QTI scan

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.

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

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

You will not be paid for participation in this study.

Will your information be used for future research?

Your information collected for this study will not be used or shared for future research studies even if the identifiable information such as your name, Mayo Clinic number, or date of birth is removed.

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

General Protections
Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. Patients will be de-identified. The complete image study set for each subject will consist of QT Ultrasound Breast Scanner images will be stored on a dedicated Mayo cClinic research computer or laptop.

Authorization to Use and Disclose Protected Health Information (HIPAA)
During this research, information about your health will be collected. Under Federal law called the Privacy Rule (also referred to as Health Insurance Portability and Accountability Act [HIPAA]), 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.
- Other Mayo Clinic staff involved in your clinical care.
- Other healthcare providers involved in your clinical care.
- Researchers involved in this study at other institutions.
- The sponsor(s) of this study and the people or groups hired by the sponsor(s) to help perform this research.
- The Mayo Clinic Institutional Review Board that oversees the research.
- 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.
- A group that oversees the data (study information) and safety of this 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.

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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.

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
Plummer Building PL 3-02
200 First St. 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 until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

The Sponsor QT Imaging will store your coded images for a maximum of 10 years.

There is a 10-year expiration related to the Sponsor's use of your health information received from Mayo Clinic as part of this study.

Enrollment and Permission Signatures

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

	/ /	: AM/PM
Printed Name	Date	Time

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.

	/ /	: AM/PM
Printed Name	Date	Time

Signature