

16-008522

Density MATTERS [Molecular Breast Imaging (MBI) And
Tomosynthesis To Eliminate the Reservoir]

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RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Density MATTERS [Molecular Breast Imaging (MBI) And Tomosynthesis To Eliminate the Reservoir]

IRB#: 16-008522

Principal Investigator: Dr. C. Hruska and Colleagues

Please read this information carefully. It tells you important things about this research study. A member of our research team will talk to you about taking part in this research study. If you have questions at any time, please ask us.

Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision.

To help you decide if you want to take part in this study, you should know:

- Taking part in this study is completely voluntary.
- You can choose not to participate.
- You are free to change your mind at any time if you choose to participate.
- Your decision won't cause any penalties or loss of benefits to which you're otherwise entitled.
- Your decision won't change the access to medical care you get at Mayo Clinic now or in the future if you choose not to participate or discontinue your participation.

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.

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 a copy of this form to keep. A copy of this form will be put in your medical record.



Name and Clinic Number

Approval Date: February 3, 2022

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CONTACT INFORMATION

You can contact ...	At ...	If you have questions about ...
Principal Investigators: Carrie Hruska, PhD Katie Hunt, MD Study Team Contact: Mayo Clinic MBI Program	Phone: (507) 284-4399 Phone: (507) 266-1206 E-Mail: mbi@mayo.edu Institution Name and Address: Mayo Clinic 200 First St SW Rochester, MN 55905 Phone: (608) 392-6405 Phone: (608) 392-9719 Institution Name and Address: Mayo Clinic Health System - LaCrosse 700 W Ave South La Crosse, WI 54601	<ul style="list-style-type: none">▪ Study tests and procedures▪ Research-related injuries or emergencies▪ Any research-related concerns or complaints▪ Withdrawing from the research study▪ Materials you receive▪ Research-related appointments
Mayo Clinic Institutional Review Board (IRB)	Phone: (507) 266-4000 Toll-Free: (866) 273-4681	<ul style="list-style-type: none">▪ Rights of a research participant



Name and Clinic Number

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You can contact ...	At ...	If you have questions about ...
Research Subject Advocate (The RSA is independent of the Study Team)	Phone: (507) 266-9372 Toll-Free: (866) 273-4681 E-mail: researchsubjectadvocate@mayo.edu	<ul style="list-style-type: none">▪ Rights of a research participant▪ Any research-related concerns or complaints▪ Use of your Protected Health Information▪ Stopping your authorization to use your Protected Health Information▪ Withdrawing from the research study
Patient Account Services	Toll-Free: (844) 217-9591	<ul style="list-style-type: none">▪ Billing or insurance related to this research study

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.

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

You are being asked to participate in this study because you have dense breast tissue and you are scheduled to have breast screening with digital breast tomosynthesis, also known as a 3D mammogram.

About 3000 women will take part in this research study.

2. Why is this research study being done?

The purpose of this study is to compare two screening tests – digital breast tomosynthesis (DBT) and the combination of DBT with supplemental molecular breast imaging (MBI) – in patients with dense breast tissue.



Name and Clinic Number

Approval Date: February 3, 2022

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Molecular breast imaging (MBI) uses an injection of a small amount of radioactive material that is taken up in tissues of the body that are actively changing, such as breast cancer. A specialized camera, called a gamma camera, takes pictures of the gamma rays emitted by this material. Previous studies done at Mayo Clinic have shown that MBI can detect cancers that are not visible on mammograms. In this study, we want to find out how MBI testing compares to digital breast tomosynthesis screening.

3. Information you should know

Who is Funding the Study?

National Institutes of Health (NIH), Susan G. Komen Foundation, and Mayo Clinic Center for Individualized Medicine are funding this study.

Information Regarding Conflict of Interest:

This research has been reviewed by the Mayo Clinic Conflict of Interest Review Board and is being conducted in compliance with Mayo Clinic Conflict of Interest policies. One or more of the investigators associated with this project and Mayo Clinic have a Financial Conflict of Interest in technology used in the research and that the investigator(s) and Mayo Clinic may stand to gain financially from the successful outcome of the research. Both the Mayo Clinic Conflict of Interest Review Board and the Institutional Review Board have reviewed the Financial Conflict of Interest for one or more of the investigators and/or Mayo Clinic related to this research and they have determined that this Financial Conflict of Interest poses no additional significant risk to the welfare of participants in this research project or to the integrity of the research.

Additional information is available to any interested study participant regarding the details of this Financial Conflict of Interest and how it is being managed by contacting the study coordinator or the Office of Conflict of Interest Review at (507) 284-0075.

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 refer you to another investigator on the research study team for you to decide if you want to participate in the study.



Name and Clinic Number

Approval Date: February 3, 2022
Not to be used after: February 2, 2023

4. How long will you be in this research study?

You will be in this research study for up to 30 months. During this time, you will be asked to complete 2 in person study visits approximately 1 year apart.

5. 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 read and sign this consent form. Tests or evaluations to determine whether or not you qualify for the study will be conducted. Signing the informed consent does not guarantee that you will be qualified to enroll in the study.

Enrollment Visit:

- Screen you for eligibility confirmation.
- Discuss and document informed consent.
- Review your current medication list.
- Ask you to complete a breast health history and risk assessment survey. (In order to minimize the amount of time you will be asked to spend at this visit, we can give you the option of e-mailing you the breast health history and risk assessment survey. If you choose this option, you will need to have this survey completed and submitted before study visit 1. If you have not yet submitted the survey prior to study visit 1, we will ask you to complete the survey while in-person prior to your scheduled radiology imaging).
- Complete study-related questionnaires.
- Obtain your height and weight.

Study Visit 1 (Year 0) – may be completed over the duration of 3 business days:

- If you are of child-bearing potential, you will be asked to provide a urine sample for a pregnancy test. If you are confirmed to be pregnant, you will not be allowed in the study.
- Digital breast tomosynthesis screening which you have scheduled as part of your clinical care.
- Molecular breast imaging (MBI) screening test.
- Study-related questionnaires not completed at enrollment visit.
- Review your current medications.



Name and Clinic Number

Approval Date: February 3, 2022

Not to be used after: February 2, 2023

The following information describes the molecular breast imaging (MBI) test:

- You may be asked to fast for 3 hours before your MBI test. If you do not fast, the MBI test can still be performed but the test may be better quality if you do fast.
- You should be well hydrated prior to the MBI test. You may drink water, diet soda, or black coffee (no cream or sugar).
- You will be asked to remove your clothing from your waist up and put on a gown.
- You may be given a warm blanket to put around your shoulders and over your breasts. Warming the breast tissue will improve the MBI test.
- An MBI technologist will perform the examination.
- In the examination room, you will receive an injection of a small amount of radiotracer called technetium-99m sestamibi, in a vein in your arm.
- You will be seated in a chair and positioned at the MBI gamma camera.
- As during a mammogram, the technologist places your breast between two plates.
- The plates are lightly compressed (much less compression than during a mammogram) in order to keep your breast still during the exam. The technologist will make adjustments to your position and use pillows to make you as comfortable as possible during the test.
- Usually, two pictures of each breast are taken.
- Each picture takes about 10 minutes, for a total of 40 minutes to complete all four pictures.
- You should sit very still while the picture is taken but you may breathe normally.
- You may watch a program or listen to music during the MBI test.
- A report of your MBI test results will be placed in your Mayo Clinic Medical Record.
- If anything concerning is found on your MBI screening test, you may be asked to return for additional testing or be recommended to have a breast biopsy.

If abnormalities are found on the MBI test or your digital breast tomosynthesis screen, the radiologist may recommend you undergo additional clinical tests of your breast, **which are not part of the study**. These tests may include:

- 1) Diagnostic mammogram
- 2) Diagnostic ultrasound of the breast
- 3) Magnetic resonance imaging (MRI) of the breast
- 4) Follow up molecular breast imaging (MBI) in six months
- 5) Follow up ultrasound in six months
- 6) Fine needle aspiration (removing a small amount of breast fluid through a needle)
- 7) Breast biopsy (removing a small amount of breast tissue)

PLEASE NOTE: The Enrollment visit may occur on the same day as Study Visit 1.



Name and Clinic Number

Approval Date: February 3, 2022

Not to be used after: February 2, 2023

Study Visit 2 (Year 1):

- If you are of child-bearing potential, you will be asked to provide a urine sample for a pregnancy test. If you are confirmed to be pregnant, you will not be allowed to continue in the study.
- Digital breast tomosynthesis screening which you have scheduled as part of your clinical care.
- Ask you to complete an abbreviated breast health history and risk assessment survey
- Molecular breast imaging (MBI) screening test.
- You will be asked how you are feeling, and if there were any changes to the medications you are using since your previous visit.

At various times during the study, we may contact you by phone or mail. In addition, we are asking your permission to review your medical record through the end of the study period (up to 30 months from enrollment). This would include things such as breast-related clinical notes, radiology and pathology reports.

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

The risks directly associated with this study are minimal.

Molecular breast imaging (MBI) uses an injected radioactive drug, called technetium-99m sestamibi. This drug has been safely used in clinical practice for over 30 years. Rarely, patients receiving sestamibi experience mild effects such as flushing, a rash, or a brief metallic taste. You will receive a small dose of radiation from gamma rays emitting by this drug. The amount of radiation you will receive has a low risk of harmful effects. Pregnant women and women who are nursing should not get MBI because it is unknown if this radiation may affect the baby. If you are able to become pregnant, you must have a negative pregnancy test in order to participate in this study.

We have been studying MBI for ten years at Mayo Clinic. In our research to date, we find an MBI abnormality in about 7% of women with dense breasts who have no corresponding abnormality on their screening mammogram. When this group returns for additional evaluation, we are able to conclude that there is no worrisome finding in most by doing an additional mammogram and ultrasound, and in rare cases an MRI. However, in 14% of patients with an abnormal MBI, we have found a cancer that was not visible on the mammogram.



Name and Clinic Number

Approval Date: February 3, 2022

Not to be used after: February 2, 2023

Finding an abnormality on the study testing can be emotionally distressing to participants. You may be recommended to undergo additional testing (such as a diagnostic mammogram, a diagnostic ultrasound examination, additional MBI examination, a magnetic resonance imaging [MRI] test, a fine needle aspiration, or a needle biopsy) which have their own risks and additional financial costs that are not covered by the study. If an abnormality is detected on the tests for this study, you will be informed of the abnormality and you will be offered a referral for consultation and further management.

The topics discussed in interviews or in questionnaires may cause you to feel embarrassed or uncomfortable. You may choose to skip any questions you do not want to answer.

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

7. Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator 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 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 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.



Name and Clinic Number

Approval Date: February 3, 2022
Not to be used after: February 2, 2023

8. 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. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments, and coinsurance.

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

This study may not make your health better. However, the molecular breast imaging test may find breast cancer that would not otherwise have been detected at that time, which may provide a benefit to you.

10. 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 molecular breast imaging. This is a standard clinical test. Talk to the Principal Investigator or your doctor if you have any questions about breast screening tests.



Name and Clinic Number

Approval Date: February 3, 2022

Not to be used after: February 2, 2023

11. 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:

- Molecular breast imaging (MBI)
- Urine pregnancy test (if applicable)

The study does not pay for your digital breast tomosynthesis screening test.

If an abnormality is noted on the MBI or your digital breast tomosynthesis screen and further testing or procedures are recommended to evaluate this abnormality, the study will not pay for these tests and procedures. You and your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care. These tests and procedures may include:

- Diagnostic mammography
- Diagnostic ultrasound examination
- Additional MBI test
- Breast magnetic resonance imaging (MRI)
- Fine needle aspiration
- Needle biopsy
- Breast surgery
- Cancer treatment

You will also be responsible for any 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.

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

You won't be paid for taking part in this study.



Name and Clinic Number

Approval Date: February 3, 2022
Not to be used after: February 2, 2023

13. 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. To safeguard your confidentiality, a study number will be assigned to you at study entry and all your study related data will be linked by this study number and stored in a password protected server. All paper records are kept in a locked area.

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.

Health information may be collected about you from:

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

Why will this information be used and/or given to others?

- To do the research.
- To report the results.
- To see if the research was done correctly.

If the results of this study are made public, information that identifies you will not be used.

Who may use or share your health information?

- Mayo Clinic research staff involved in this study.

With whom may your health information be shared?

- The Mayo Clinic Institutional Review Board that oversees the research.
- Other Mayo Clinic physicians involved in your clinical care.
- Researchers involved in this study at other institutions.
- 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.
- The sponsor(s) of this study and the people or groups it hires to help perform this research.
- A group that oversees the data (study information) and safety of this research.



Name and Clinic Number

Approval Date: February 3, 2022
Not to be used after: February 2, 2023

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 Privacy Rights

You do not have to sign this form, but if you do not, you cannot take part in this research study.

If you cancel your permission 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.

If you choose not to take part or if you withdraw from this study, it will not harm your relationship with your own doctors or with Mayo Clinic.

You can cancel your permission 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
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@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 lasts until the end of this study, unless you cancel it. Because research is an ongoing process, we cannot give you an exact date when the study will end.



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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