

AMERICAN COLLEGE OF RADIOLOGY IMAGING NETWORK

ACRIN PA 4006

INFORMED CONSENT FORM TEMPLATE

Comparison of Full-Field Digital Mammography with Digital Breast Tomosynthesis Image Acquisition in Relation to Screening Call-Back Rate

[Note: The American College of Radiology Imaging Network (ACRIN) complies with the privacy measures put forth by the Health Insurance Portability and Accountability Act (HIPAA). However, ACRIN does not monitor compliance with HIPAA; that is the responsibility of the local institutions and their Institutional Review Boards (IRBs). Local IRBs may choose to combine the authorization elements in the informed consent.]

The American College of Radiology Imaging Network (ACRIN) is conducting a research study known as a clinical trial. Research staff will explain to you the details of what is involved. This document is designed to help you understand what will happen in the study, why the study is being done, and what risks or benefits might be involved in the study. This informed consent form must be signed before any study procedures are performed and before you are registered into the clinical trial.

Clinical trials include only people who choose to take part. Please take your time in deciding whether you want to be involved. You are encouraged to discuss your decision with your friends and family. You can also discuss it with your health care team. If you have any questions, you should ask your study doctor for more explanation. If you decide to do this study, you will be asked to sign and date this form.

You are being invited to participate in this research study because it is time for your routine breast cancer screening or you have recently been screened and are returning for diagnosis of suspicious findings.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to learn the safest way to use an imaging technology called tomosynthesis (called “study imaging” in this document) while getting images that will benefit you by showing potential breast cancers. Researchers will compare your study imaging with standard care using digital mammography, and other images taken to determine your breast health. They hope to determine the best way to obtain study images, which provide good information about your breast health while exposing you to no more radiation than routine x-ray mammography. Doctors are also trying to learn whether the study imaging can be used alone or should be used with digital mammography.

About Tomosynthesis (Study Imaging)

Mammograms provide two-dimensional (2-D), flat images. Tomosynthesis can be used to create three-dimensional (3-D) images of the breast. The 3-D images may allow doctors to “scroll through” images of your breast to better see the layers of normal breast tissue that can sometimes appear to be concerning on regular 2-D mammography. This technique may see cancers that were hidden by normal tissue that

overlaps on 2-D mammography. The study imaging will be completed after your standard imaging. If a separate machine is needed for the study imaging, then your breasts will be compressed again. Once you are positioned in the machine, the study imaging will take about as much time as a routine mammography of both breasts.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 550 women with no history of breast cancer will take part in this trial. This study will be conducted at approximately two (2) breast cancer screening institutions located in Pennsylvania.

HOW LONG WILL I BE IN THE STUDY?

You will be in the study up to 18 months from your initial breast screening. For the study, you are being asked to undergo study imaging immediately after routine imaging either for screening or for diagnosis. Your treating doctors will decide your treatment (for example, biopsy). Your study doctor and other research staff will contact you, a proxy if you are unavailable, and/or your treating doctor to learn about your health up to 18 months after your screening.

This trial is expected to end after all study participants have completed the study-related visits and all follow-up information has been collected. This trial may be stopped at any time by your study doctor or by ACRIN without your consent for the following reasons:

- Your health or safety may be at risk;
- You have not been following study instruction;
- An administrative decision has been made by ACRIN or the study doctor.

These actions do not require your consent, but you will be informed of any of these decisions.

You can stop participating at any time. Your decision to stop participating in the study will not interfere with your future medical care. However, if you decide to stop participating in the trial, we encourage you to talk to the study doctor and your treating doctor first.

WHAT AM I BEING ASKED TO DO IN THE STUDY?

If you agree to take part in this study and are determined to be eligible by research staff, you will be asked to read and sign this consent form before you are enrolled to participate in this trial and before any study procedures are performed. See the Schemas and Study Chart at the end of this section for a visit-by-visit outline of what will be expected of you if you decide to participate in this trial. When you are enrolled into the study, you will have the following tests and procedures.

Standard medical procedures that are part of regular standard of care and would probably be done even if you do not join the study:

- A review of your medical history;
- Digital mammography;
- Diagnostic procedures.

Medical procedures that are being done specifically because you are in this study (these may or may not be done if you do not join the study):

- Study imaging (tomosynthesis) on both breasts;
- Follow up for as long as 18 months—the research staff will want to access your medical records from your treating doctor. If you change treating doctor during this time, research staff may call you or a proxy to ask for contact information for your new treating doctor and perhaps ask about your breast health over the phone.

If you agree to participate in this study, you will be assigned to one of two different study groups, depending on whether you are being screened for breast cancer (Group A: Screening) or are returning for further evaluation after screening (Group B: Diagnosis).

For Group A: Screening

If you are enrolled in Group A, you are going for your routine breast-cancer screening using digital mammography. You will receive the standard of care for this screening as determined by your study and treating doctors. You will also have study imaging called tomosynthesis. Your treating and study doctors may determine that no additional testing is needed after reviewing your image results; or, they may find it necessary to ask you to return for more imaging to diagnose suspicious findings that may be breast cancer. You will be asked to return for diagnosis if something suspicious is found on either digital mammography or study imaging. The study team will want to collect all of your images and results from screening and diagnostic studies.

For Group B: Diagnosis

If you are enrolled in Group B, you have already had your routine breast-cancer screening using digital mammography, and are returning to your treating doctor because of findings on the screening mammogram that were concerning and could possibly be due to a cancer. You will receive standard-of-care imaging and will have additional study imaging called tomosynthesis. The study team will want to collect all of your images and results from screening and diagnostic studies.

Most likely, you are returning for diagnosis of findings in only one breast. If you agree to join the trial, study imaging will take images of both breasts. If something concerning is found on study imaging, you may be asked to undergo more diagnostic procedures in either breast. Your treating doctor will then determine what additional steps may be needed, such as biopsy. Your treating doctor may make this decision based on findings from either standard diagnostic imaging or study imaging.

Follow Up for Both Groups A and B

The study doctor and research staff want to collect information on your breast health from your medical records up to 18 months after your screening visit. If you switch doctors during this time, it is important to let the study team know. Otherwise, they may need to contact you or, if necessary, a proxy (family member or someone who will know about your health) to learn how to contact your new treating doctor. At the very least, the research staff would like to know whether you are cancer free. If we cannot contact you or your treating doctor, the research staff may check national registries to learn about your health status.

STUDY SCHEMAS BY GROUP

(Shaded boxes contain study-related procedures.)

GROUP A

PRIOR TO IMAGING:

Eligibility and Registration

SCREENING IMAGING:

- Standard digital mammography (both breasts)
- Study imaging, tomosynthesis (both breasts)

No Findings

Call Back for Diagnostic Imaging

STANDARD CARE:

Clinical, standard diagnostic imaging

GROUP B

STANDARD CARE:

Screening imaging finds suspicious findings



Call Back for Diagnostic Imaging



PRIOR TO IMAGING:

Eligibility and Registration

DIAGNOSTIC IMAGING:

- Standard digital mammography (one or both breasts, depending on screening results)
- Study imaging, tomosynthesis (both breasts)
- Possibly followed by additional standard imaging, such as ultrasound (one or both breasts, depending on previous imaging results)

FOLLOW UP

Research staff will review your medical records and collect follow-up images for up to 18 months after your initial screening visit. You may be contacted if you have changed treating doctors.

STUDY CHART

PRIOR TO IMAGING: Group A and Group B Eligibility and Registration	<ul style="list-style-type: none">• Read and sign the informed consent form;• Provide medical history and demographic information;• Undergo pregnancy test if you are a woman of childbearing potential;• Provide telephone contact information for yourself and a proxy (someone who will be able to report on your health status).
GROUP A IMAGING: Imaging for Screening	<ul style="list-style-type: none">• Confirm contact information;• Undergo imaging:<ul style="list-style-type: none">- Standard-of-care screening imaging (both breasts); and- Study imaging (both breasts);• Answer questions about how you feel after the imaging.*
GROUP B IMAGING: Imaging for Diagnosis	<ul style="list-style-type: none">• Confirm contact information;• Undergo imaging:<ul style="list-style-type: none">- Standard-of-care diagnostic imaging (on one or both breasts, depending on your screening results);- Study imaging (on both breasts), and- Possibly other diagnostic assessment (such as ultrasound, again on one or both breasts, depending on imaging results);• Answer questions about how you feel after the imaging.*
FOLLOW UP: Group A and Group B (Up to 18 Months After Screening)	<ul style="list-style-type: none">• Provide additional information related to your breast health up to 18 months after screening. Research staff may need to review your medical records and/or contact you, a proxy, and/or your treating physician to obtain this information.

* If at any time within 30 days after study-related imaging, you have adverse effects you think may be related to the study, contact your study doctor and let him or her know.

WHAT ARE THE POSSIBLE RISKS OR DISCOMFORTS OF THE STUDY?

While on the study, you may be at risk for these side effects from the following procedures. You should discuss these with your study and/or treating doctor(s). There also may be other side effects that we cannot predict. Many side effects go away shortly after the imaging scan is stopped, but in some cases side effects can be serious, long lasting, or permanent.

Risks Associated With Study Imaging (Tomosynthesis)

Likely

- Discomfort from breast compression that is similar to routine mammography;
- Bruising similar to routine mammography.

If you are in Group A, study imaging during screening may lead to additional findings compared with standard screening imaging alone. Suspicious findings on either set of images will mean you will be

asked to return for diagnosis. If you do not join the trial, your treating doctor will use standard screening imaging to determine whether you need to return or not.

If you are in Group B, study imaging included for diagnosis may lead to additional findings and procedures compared with standard diagnostic imaging alone. You are agreeing for both of your breasts to undergo study imaging even though you may have been called back for diagnostic imaging on only one breast. This may lead to findings with study imaging that were not found during your initial screening visit. Therefore you may need to have additional diagnostic imaging of that breast. If you do not join the trial, your treating doctor will use standard imaging for diagnosis to determine whether you need further testing or not.

Radiation Risks

This research study involves exposure to radiation from the study imaging called tomosynthesis. In addition to the radiation you receive for your regular mammogram, you will be receiving a similar, second dose of radiation from the study imaging. The amount of radiation exposure will be largely dependent on your breast size. Your study doctor can explain how the dose might be higher for denser and larger breasts. Part of this study will look at radiation dose in hopes of obtaining quality images while optimizing radiation exposure to people in the future.

This radiation dose is not necessary for your standard medical care and will occur only as a result of being in this study and undergoing study imaging. The dose that you will receive will very likely have no effects at all. Radiation doses much higher than what you will receive are known to increase the risk of developing cancer after many years.

Reproductive Risks

Because possible exposure to radiation can damage an unborn baby, you will need to inform your study doctor if you are pregnant or suspect that you may be pregnant. If you are pregnant, you will not be able to participate in this study. If you are unsure, you will need to have a negative pregnancy result per usual care prior to enrolling in this trial and throughout the trial prior to imaging if you are unsure of your pregnancy status.

For more information about risks and side effects, ask your study doctor.

WHAT ARE THE POSSIBLE BENEFITS OF TAKING PART IN THE STUDY?

Taking part in this study may or may not benefit you. The results of the study imaging will be shared with your treating doctor. The study imaging for screening or diagnosis in this trial may improve your health by finding cancers not seen on standard imaging. On the other hand, study-related findings may lead to additional imaging or unnecessary treatment, such as biopsy. These risks are common in breast-cancer screening and diagnostic imaging currently available. The hope is to reduce these risks in the future with better imaging through tomosynthesis. We hope the information learned from this study will benefit other women during breast cancer screening and diagnosis in the future.

WHAT OTHER CHOICES DO I HAVE IF I DO NOT WANT TO PARTICIPATE?

You may choose not to take part in this study. If you choose not to participate, there will be no penalty or loss of benefits to which you are otherwise entitled. Please talk with your study and/or treating doctor(s) about this and other options.

WILL MY MEDICAL INFORMATION BE KEPT PRIVATE?

We will do our best to make sure that your personal information will be kept private. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. Records of your participation on this study, your progress, and images submitted while you are on the study will be kept in a confidential form at <<Institution>> and in a computer file at the headquarters of the American College of Radiology Imaging Network (ACRIN) in Philadelphia. All data sent to ACRIN over the Internet will be coded so that other people cannot read it. All personal identifiers are removed and replaced with a unique identifying number.

You further understand and agree that authorized representatives of ACRIN, the Pennsylvania Dept. of Health, the Institutional Review Board (IRB) of <<Institution>>, and other groups or organizations that have a role in this study may, without obtaining additional consent from you, have access to and copy both your medical and research records, including the results of your participation in this study. This access is necessary to ensure the accuracy of the findings, the completion of the study, and your safety and welfare. If any publication or presentations result from this study, you will not be identified by name. Results will be reported in a summarized manner in which you cannot be identified.

Your research records and images will be kept permanently on file at ACRIN and may be used for future research. All personal identifiers are removed and replaced with a unique identifying number. The studies that may be done with the information will not specifically help you. But, it might help people in the future who have or are at risk for breast cancer.

WILL I HAVE TO PAY FOR ANYTHING?

Taking part in this study may or may not lead to added costs to you or your insurance company. Please ask your study doctor about any expected added costs or insurance problems.

You and/or your health insurance will be charged for any portion of your care that is considered standard care. You and/or your insurance company will be charged for continuing medical care and/or hospitalization. You may be responsible for any co-payments and deductibles that are standard for your insurance coverage.

You or your insurance company will not be charged for the following part of this research study:

- Study imaging with tomosynthesis.

You will receive no payment for taking part in this study.

WHAT HAPPENS IF I AM INJURED BECAUSE I TOOK PART IN THIS STUDY?

It is important that you tell your study doctor, <<insert name>>, if you feel that you have been injured because of taking part in this study or if any medical emergency, injury, or illness occurs during this study. You can tell the study doctor in person or call him/her at <<insert telephone number>>.

In the case of medical emergency, injury, or illness during this study, emergency medical treatment is available but will be provided at the usual charge. You and/or your insurance will be responsible for the cost of the medical care of that illness or injury. There is no financial compensation that has been set aside to compensate you in the event of injury.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

Taking part in this study is your choice. You may choose to or not to take part in the study. If you decided to participate, you are free to leave the study at any time. No matter what decision you make, there will be no penalty to you and you will not lose any of your regular benefits. Leaving the study will not result in any penalty or loss of benefits to which you are entitled. Your decision whether or not to participate in this study will not interfere with your future care. You can still get your medical care from our institution.

During the study, we may find out more information that could be important to you. A Data and Safety Monitoring Board (an independent group of experts) may be reviewing the data from this research throughout the study. This includes information that might cause you to change your mind about being in the study. If information becomes available from this or other studies that may affect your health, welfare, or willingness to stay in this study, we will tell you about it as soon as possible.

WHO CAN ANSWER MY QUESTIONS ABOUT THE STUDY?

(This section must be completed)

You can talk with your study doctor(s) about any questions or concerns you have about this study. Contact your study doctor <<insert name>> at <<insert telephone number>>.

This document explains your rights as a study participant. If you have any questions regarding your participation in this research study or you have any questions regarding your rights as a research participant, do not hesitate to speak with your study doctor or anyone listed below.

For additional information about your health or in case of a medical emergency, you may contact:
Usually the name of the local hospital information is provided and with instructions to study participants to inform the ER doctor of their participation in a clinical trial.

Name

Telephone Number

For information about your rights as a research subject, you may contact <<Institution Name>> Institutional Review Board (a group of people who review the research to protect your rights):
(Provide the name of local IRB contact person)

Name

Telephone Number

WHERE CAN I GET MORE INFORMATION?

For more information, you may also visit the American College of Radiology Imaging Network web site, www.acrin.org. For more information about Tomosynthesis, you can go to the Patients section of the ACRIN web site.

ACKNOWLEDGEMENT

When you sign this document, you are agreeing to take part in this study. This means you have read all the above information, asked questions regarding your participation, and received answers that you understand to all your questions. You have also had the opportunity to take this consent form home for review or discussion if you want to.

You willingly give your consent to participate in this study. A copy of this signed informed consent form will be given to you.

Printed Name of Study Participant/
Legal Representative

Signature

Date

<Insert other signature and date lines as appropriate per local IRB policies and procedures>