

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: A Comparison of Short Acquisition Time Breast Tomosynthesis Mammography and Conventional Mammography in the Visualization of Breast Abnormalities Recommended for Biopsy

PROTOCOL NO.: KR-001
WIRB® Protocol #20091694

SPONSOR: Kern Radiology Imaging Systems
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United States

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STUDY-RELATED

PHONE NUMBER(S): David P. Schale, M.D.
661-395-3008, extension 7333
661-326-9600 (24 hours)

Wendy Hendricks, RT (Study Coordinator)
661-395-3008, extension 7333

This consent form may contain words that you do not understand. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand. You may take home an unsigned copy of this consent form to think about or discuss with family or friends before making your decision.

SUMMARY

You are being asked to be in a research study. The purpose of this consent form is to help you decide if you want to be in the research study. Please read this consent form carefully. To be in a research study, you must give your informed consent. "Informed consent" includes:

- Reading this consent form;

- Having the study doctor or study staff explain the research study to you;
- Asking questions about anything that is not clear; and
- Taking home an unsigned copy of this consent form. This gives you time to think about it and to talk to family or friends before you make your decision.

You should not join this research study until all of your questions are answered.

Things to know before deciding to take part in a research study:

- The main goal of a research study is to learn things to help patients in the future.
- The main goal of regular medical care is to help each patient.
- No one can promise that a research study will help you.
- Taking part in a research study is entirely voluntary. No one can make you take part.
- If you decide to take part, you can change your mind later on and withdraw from the research study.
- The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.
- Parts of this study may involve standard medical care. Standard care is the treatment normally given for a certain condition or illness.
- Other parts of this study may involve experimental (investigational) procedures, that are being tested for a certain condition or illness. An investigational device is one that has not been approved by the U.S. Food and Drug Administration (FDA).
- After reading the consent form and having a discussion with the research staff, you should know which parts of the study are experimental and which are standard medical care.
- Your medical records may become part of the research record. If that happens, your medical records may be looked at and/or copied by the sponsor of this study and government agencies or other groups associated with the study.
- Your medical insurance may be billed for any standard medical care you receive during the research study. If your insurance company is billed then it may have access to the research records. Insurance companies may not pay for treatment that is part of a research study. Taking part in a research study could affect your current or future insurance coverage.

After reading and discussing the information in this consent form, you should know:

- Why this research study is being done;
- What will happen during the research;
- What study device or study procedures will be used;
- Any possible benefits to you;
- The possible risks to you;

- The other medical procedures or devices that could be used instead of being in this research study; and
- How problems will be treated during the study and after the study is over.

If you take part in this research study, you will be given a copy of this signed and dated consent form.

PURPOSE OF THE STUDY

This study will see how a tomosynthesis mammogram compares to a standard mammogram in finding breast abnormalities.

Tomosynthesis mammography uses three-dimensional (3D) imaging while standard mammography uses two-dimensional (2D) imaging. The 3D imaging makes pictures of the breast in slices (as you would slice a loaf of bread.). Looking at the breast tissue in layers removes tissue overlap that occurs on a 2D mammogram. Tissue overlap can hide cancers and also cause false findings. Both 2D and 3D imaging use x-rays.

The machine used in this research is an investigational machine. This means that it has not been cleared by the U.S. Food and Drug Administration (FDA) for sale in the United States. This investigational machine can take both standard (2D) and tomosynthesis (3D) mammograms while the breast remains in a single compression.

The 3D mammogram may find cancers at an earlier stage.

You are being asked to be in this study because you are scheduled for a routine screening mammogram or a breast biopsy.

About 165 women will be in this research study.

PROCEDURES

If you agree to take part in this study, you will have two research tomosynthesis mammograms of each breast, in addition to your standard care screening or diagnostic mammograms. Each research tomosynthesis mammogram will include having a combination low-dose 2D mammogram and a 3D mammogram under the same compression. Your breast will be positioned for each view just like for a standard mammogram. Compression will last for about 15 seconds for each view. The same compression will be used for both the 2D and 3D mammograms so that they can be equally compared.

RISKS AND DISCOMFORTS

There will be some risks or possible discomfort to you because you are in this study.

Tomosynthesis machine:

Each breast will be compressed twice for about 15 seconds. Bruising from compression may occur, but this is unlikely. Mild discomfort or pain may be felt during compression. Skin irritation and scratching are also possible, but not likely.

Radiation exposure:

You will have a 2D and a 3D tomosynthesis mammogram of each breast. The amount of radiation you will receive because of this will be about the same as three months of background radiation to your whole body. Background radiation is what you receive from natural sources like the sun and the earth as well as from man-made sources. The radiation you will receive in this study will be almost entirely to your breasts. This radiation will be in addition to the radiation from the standard mammograms you will have as part of your regular care. The exposure risk builds up over a lifetime, and you should keep your total exposure to radiation as low as possible. Please discuss this with your study doctor.

Other risks:

A new suspicious finding may show up on the research mammograms. You and your regular care doctor will be informed of any new suspicious findings. The study doctor may recommend additional imaging scans, such as regular mammograms, ultrasounds, or an MRI. The new finding may prove to be a hidden cancer which means you could treat it earlier. It could also turn out to be normal or benign. If so, you might have had unnecessary anxiety and wasted time.

Pregnancy:

If you are pregnant or think you are pregnant, you should not be in this research study. You must tell the study doctor if you think you are pregnant.

NEW INFORMATION

You will be told about anything new that might change your decision to be in this study. You may be asked to sign a revised consent form if this occurs.

BENEFITS

This study is not designed to benefit you directly. The tomosynthesis research mammograms may show a new suspicious finding and additional testing may be recommended. If a hidden cancer is found, it could be treated earlier. Earlier treatment might benefit you, but this cannot be promised. Information learned from this study may help patients with breast cancer in the future.

COSTS

There is no additional cost for the tomosynthesis research study.

If the tomosynthesis mammograms show a new finding and you choose to have additional standard diagnostic imaging, there will be no charge to you for this imaging. However, if you have a biopsy based on the follow-up standard diagnostic imaging, you or your insurer will be charged as is usual for a biopsy.

PAYMENT FOR PARTICIPATION

There is no financial payment provided for your participation.

ALTERNATIVE TREATMENT

This is not a treatment study. Your alternative is not to participate in this study.

COMPENSATION FOR INJURY

If you are injured as a result of being in this study, call the study doctor, David P. Schale, M.D., immediately at 661-395-3008, extension 7333 or 661-326-9600 (24 hours). The study doctor will provide emergency medical treatment. Your insurance will be billed for this treatment. The sponsor will pay any charges that your insurance does not cover. No other payment is routinely available from the study doctor or sponsor.

VOLUNTARY PARTICIPATION AND WITHDRAWAL

Taking part in this study is voluntary. You may decide not to take part or you may leave the study at any time. Your decision will not cause any penalty or loss of benefits to which you are entitled.

The study doctor or the sponsor may stop your participation in this study at any time without your consent for any of the following reasons:

- it is in your best interest;
- you do not consent to any changes that may be made in the study plan;
- or for any other reason.

SOURCE OF FUNDING FOR THE STUDY

Kern Radiology Imaging Systems will fund this study. A grant has been provided by Hologic, Inc., the makers of the tomosynthesis machine, to support tomosynthesis research.

QUESTIONS

Contact: Dr. David P. Schale at 661-395-3008, extension 7333 or 661-326-9600 (24 hours) or Wendy Hendricks, RT, research coordinator, at 661-395-3008, extension 7333 for any of the following reasons:

- if you have any questions about this study or your part in it;
- if you feel you have had a research-related injury; or
- if you have questions, concerns, or complaints about the research.

If you have questions about your rights as a research subject or if you have questions, concerns, or complaints about the research, you may contact:

Western Institutional Review Board® (WIRB®)
3535 Seventh Avenue, SW
Olympia, Washington 98502
Telephone: 1-800-562-4789 or 360-252-2500
E-mail: Help@wirb.com.

WIRB is a group of people who do independent review of research.

WIRB will not be able to answer some study-specific questions, such as questions about appointment times. However, you may contact WIRB if the research staff cannot be reached or if you want to talk to someone other than the research staff.

Do not sign this consent form unless you have had a chance to ask questions and have gotten satisfactory answers.

If you agree to be in this study, you will receive a signed and dated copy of this consent form and the Experimental Subject's Bill of Rights for your records.

CONSENT

I have read this consent form (or it has been read to me). All my questions about the study and my part in it have been answered. I freely consent to be in this research study.

By signing this consent form, I have not given up any of my legal rights.

Subject Name

CONSENT SIGNATURE:

Signature of Subject

Date

Printed Name of Person Conducting Informed Consent Discussion

Signature of Person Conducting Informed Consent Discussion

Date

----- Use the following only if applicable -----

If this consent form is read to the subject because the subject is unable to read the form, an impartial witness not affiliated with the research or investigator must be present for the consent and sign the following statement:

I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to be in the research study.

Printed Name of Impartial Witness

Signature of Impartial Witness

Date

Note: This signature block cannot be used for translations into another language. A translated consent form is necessary for enrolling subjects who do not speak English.

Ver. 01-07-2008

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

What information may be used and given to others?

The study doctor will get your personal and medical information. For example:

- Past and present medical images and imaging records
- Research records
- Records about your study visit
- Information gathered for this research about:
 - Physical exams
 - Laboratory, x-ray, and other test results
- Records about the study device.

Who might get this information?

The sponsor of this research. “Sponsor” means any persons or companies that are:

- working for or with the sponsor, or
- owned by the sponsor.

A copy of the breast tomosynthesis research mammograms and other associated breast images, radiology, and pathology (condition produced by disease) reports will be provided to Hologic, Incorporated (Bedford, Massachusetts), manufacturers of the tomosynthesis machine for research and development. However, your name and other identifiers will be removed from the images.

Your information may be given to:

- The U.S. Food and Drug Administration (FDA)
- Department of Health and Human Services (DHHS) agencies
- Governmental agencies in other countries
- Western Institutional Review Board[®] (WIRB[®]).

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

- to do the research,
- to study the results, and
- to see if the research was done right.

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

What if I decide not to give permission to use and give out my health information?

Then you will not be able to be in this research study.

May I review or copy my information?

Yes, but only after the research is over.

May I withdraw or revoke (cancel) my permission?

This permission will be good until December 31, 2050.

You may withdraw or take away your permission to use and disclose your health information at any time. You do this by sending written notice to the study doctor. If you withdraw your permission, you will not be able to stay in this study.

When you withdraw your permission, no new health information identifying you will be gathered after that date. Information that has already been gathered may still be used and given to others.

Is my health information protected after it has been given to others?

There is a risk that your information will be given to others without your permission.

Total confidentiality cannot be guaranteed because of the need to give information to these parties. The results of this research study may be presented at meetings or in publications. Your identity will not be given out during those presentations.

Authorization:

I have been given the information about the use and disclosure of my health information for this research study. My questions have been answered.

I authorize the use and disclosure of my health information to the parties listed in the authorization section of this consent for the purposes described above.

Subject Name

Signature of Subject

Date

Printed Name of Person Conducting Informed Consent Discussion

Signature of Person Conducting Informed Consent Discussion

Date

EXPERIMENTAL SUBJECT'S BILL OF RIGHTS

California law, under Health & Safety Code Section 24172, requires that anyone who is asked to be in a research study (medical experiment), or who is asked to agree for someone else to be in a research study, has the right to know the following, in a language in which the person is fluent:

1. Both the nature and reason for the research study or experiment.
2. What will happen during the research study, and what drug or device will be used.
3. Any expected discomforts and risks from taking part in the research.
4. Any possible benefits to being in the research.
5. The risks and benefits of any non-experimental medical procedures, drugs, or devices that could be used instead of being in the research.
6. How research related complications will be treated during and after the research study is over.
7. Questions can be asked about the research and about anything that will be done during the research study.
8. The research subject can stop taking part in the research study at any time for any reason without penalty or loss of benefits.
9. A copy of their signed and dated consent form will be given to subjects.
10. The research subject can take the time needed to decide if they want to take part in the research study. No one can pressure, force or unduly influence any person to take part in research.

Signature of Subject

Date