the breast center
A MANA Clinic

Fuji ASPIRE Cristalle Tomosynthesis Research Project

The Procedure:

In a traditional mammogram, breast tissue is compressed between two paddles and x-rays capture two-dimensional (2D) pictures of the breast. New mammogram machines can capture 3D images of the breast, but most require a higher dose of radiation. The Breast Center of NWA is participating in a clinical trial using a ***second generation3D*** mammogram machine that ***creates clearer images of breast slices with reduced radiation.*** If you choose to participate in the study, you will receive ***BOTH*** a 2D and 3D mammogram.*

The Research:

We will compare the accuracy of the new 3D mammography to traditional mammography. We expect this new technology to advance breast cancer diagnosis by:

- Eliminating tissue overlap and "shadowy" distractions
- Creating better image quality and clarity

Confidentiality:

Your name and identifying information will be removed from all research data.

The Cost:

The Breast Center of NWA will bill your insurance for the standard 2D examination. The 3D portion will not be charged to you or to your insurance. ***Your participation in this research is voluntary and you may leave the study at any time.***

* Your overall radiation dose with 3D mammography is higher than the standard 2D mammogram, but since the Fujifilm device uses less radiation, your dose will be 20% lower than 3D studies performed on other 3D devices.

Frequently Asked Questions:

- **Why is this research study being done?**
  - The company, Fuji, wants to find out if this mammography tool is better than other similar tools at finding breast cancer.

- **How will this be different from my usual mammogram?**
  - This is a second generation 3D mammography machine that is not yet FDA approved. Therefore you will be asked to sign a consent form.
  - Any tomosynthesis examination requires more radiation than mammography. You will be exposed to a small, but additional amount of radiation because of the tomosynthesis examination. The Fuji ASPIRE actually uses 20% less radiation for tomosynthesis than other machines on the market.
  - You must agree to do the study and sign a consent form.

- **Will I get results from the study?**
  - The radiologist will read your mammogram and your tomosynthesis exam and will use information from both to prepare one report regarding your test. You will receive a letter informing you of your results, just as you usually do.

- **Will my name be published anywhere?**
  - Some of your medical history, like age and previous breast health information, will be collected along with the results of your test, but information that could identify you will be removed from the data.

- **How will I benefit from participating?**
  - You will receive a second generation 3D mammogram at no charge. The study results my help other women undergoing mammography in the future.

- **What if I sign the consent, and then decide I don't want to participate?**
  - You can ask to be removed from the study any time you wish.

- **How much will this cost me? Will I be paid to participate?**
  - We will bill your insurance for your regular mammogram, but there is no charge to you or your insurance for the tomosynthesis part of the exam. You will not receive payment for your participation in the study.

- **What if I get "called back" for additional tests from my screening study?**
  - If the radiologists want you to come back for additional studies because of a finding on your screening, the tests will be billed to your insurance as usual. Whether or not you pay out of pocket will depend on your deductible.

A CONSENT FORM IS ATTACHED SO YOU MAY READ IT AND BE INFORMED PRIOR TO YOUR EXAMINATION. YOU WILL BE ASKED TO SIGN A CONSENT FORM AT THE OFFICE, IN FRONT OF A WITNESS.

RESEARCH SUBJECT INFORMATION AND CONSENT FORM	
TITLE:	Comparison of Diagnostic Accuracy of Fujifilm Digital Tomosynthesis to Other Conventional Breast Imaging Methods

This consent form contains important information to help you decide whether to participate in a research study.

The study staff will explain this study to you. Ask questions about anything that is not clear at any time. You may take home an unsigned copy of this consent form to think about and discuss with family or friends.

- **Being in a study is voluntary – <u>your choice</u>.**
- **If you join this study, you can still <u>stop at any time</u>.**
- **<u>No</u> one can <u>promise</u> that a study will help you.**
- **Do not join this study unless all of your <u>questions</u> are <u>answered</u>.**

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 study;
- Any possible benefits to you;
- The possible risks to you;
- Other options you could choose instead of being in this study;
- How your personal health information will be managed during the study and after the study is over;
- Whether being in this study could involve any cost to you; and
- What to do if you have problems or questions about this study.

Please read this consent form carefully.

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE:	Comparison of Diagnostic Accuracy of Fujifilm Digital Tomosynthesis to Other Conventional Breast Imaging Methods
PROTOCOL NO.:	Version 7 Washington Regional IRB #1 Protocol S-108
INVESTIGATOR:	Steven E. Harms, MD, FACR
SITE(S):	The Breast Center of Northwest Arkansas Fayetteville and Bentonville, AR
STUDY-RELATED PHONE NUMBER(S):	479-442-6266
SUB-INVESTIGATOR(S):	Kevin Pope, MD, Danna Grear, MD, Stacy Smith-Foley, MD, Kelly Johnson, MD, Britton Lott, MD
STUDY COORDINATOR(S):	Lonell Ward

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.

INTRODUCTION

You are being invited to participate in a medical research study. A member of the research team will explain what is involved in this study and how it will affect you.

This consent form describes the study procedures, risks and benefits of participation, as well as how your confidentiality will be maintained throughout the length of the study. Please take your time to ask questions and feel comfortable making an informed decision about whether or not you want to participate. This process is called "informed consent". If you decide to participate in the study, you will be asked to indicate your consent by signing this consent form on the last page.

You will also be provided with a written description of how your personal health information will be used or released during the course of the study. This description will be provided to you within this consent form. By signing this consent form, you will authorize the use and sharing of your personal health information without personal identifying information.

PURPOSE OF THE STUDY

This study is being done to find out if a type of investigational mammography imaging tool, called ASPIRE Cristalle employing Digital Breast Tomosynthesis (DBT) mammography is better at detecting breast cancer than conventional breast imaging methods including traditional mammograms. DBT uses x-rays like traditional mammograms. Unlike mammograms which produce a projection of the entire breast, DBT acquires the information in a way that allows the production of thin slices in a three dimensional format. In order to do this study, we must compare your routine mammogram to the ASPIRE Cristalle DBT mammogram. An investigational device is one that is not approved by the U.S. Food and Drug Administration (FDA). The radiation dose from the Digital Breast Tomosynthesis is 50% higher than the radiation dose from Full Field Digital Mammography. Since you will be examined using both Full Field Digital Mammography and Digital Breast Tomosynthesis, you will be receiving additional radiation equivalent of 2.5 mammogram(s) which is equal to about 2.4 months of natural background radiation exposure by a person in one year. The dose is within the approved national standards for mammograms.

TOTAL NUMBER OF SUBJECTS IN THE STUDY

This study will include the collection of mammograms from at least 15,000 subjects with different results in their mammograms. Subjects will participate in this study at The Breast Center until the needed cases are collected.

PROCEDURES

You have had a mammogram or are about to have one. If you are a candidate for this study, you are invited to have an additional mammogram utilizing the ASPIRE Cristalle machine.

Before you have your additional mammogram, you will be asked questions about you, your medical history, breast symptoms and pregnancy. You will also be asked to sign the consent form if you decide to participate in this study. If you are a pregnant female, you may not participate in this study.

A radiologist specializing in mammography will review your routine mammogram as usual and you will be informed of any findings. In addition, an additional radiologist will review your ASPIRE Cristalle DBT mammogram to see if it reveals the same information that was seen on your mammogram and if it reveals more or different useful information. As a standard of practice, if your mammogram is normal, you will be asked to return for a routine mammogram in approximately one year to confirm that your breasts continue to be "normal". If necessary, your study doctor may need to evaluate your breasts further according to standard medical care.

During this study, all your mammogram images will be collected electronically via computer. To protect your confidentiality, your name, date of birth, address, and other information identifying you, will be removed from the image files before your images are sent outside to any other organization (your personal information will be de-identified).

If your family physician usually receives your mammography report, he or she will receive this as promptly as usual. The information on the report will show the findings of your mammogram. The

duration of your participation in this study will consist of the additional time it takes to obtain a second mammogram using the ASPIRE Cristalle machine. This can be from 10 minutes to half an hour.

You will not be asked to complete any questionnaires as part of this study. You also will not be required to have your blood drawn as part of this study.

POTENTIAL RISKS

There are two factors that contribute to potential risks and discomfort:

1) You will have your breasts compressed an additional time just as you had them compressed for your routine mammogram.

The medical risks of Digital Breast Tomosynthesis are the same as a Full Field Digital mammogram. The radiation dose from the Digital Breast Tomosynthesis is 50% higher than the radiation dose from Full Field Digital Mammography. Since you will be examined using both Full Field Digital Mammography and Digital Breast Tomosynthesis, you will be receiving additional radiation equivalent of 2.5 mammogram(s) which is equal to about 2.4 months of natural background radiation exposure by a person in one year. The dose is within the approved national standards for mammograms.

There is a small risk associated with loss of confidentiality of your health information. However, all personal identifying information including your name will be removed from all reports before being sent outside the Breast Center, and instead a unique subject identification number will be assigned. While the Breast Center of Northwest Arkansas cannot be certain that the forwarded health information could never be linked to you, every reasonable effort will be made to eliminate this risk.

Your study doctor will inform you of the risks associated with routine mammography or any other tests you may have to undergo according to standard medical practice.

There may be risks or side effects, which are unknown at this time.

NEW FINDINGS

You will be told about any new information that might change your decision to be in this study.

You may be asked to sign a revised consent form if this occurs.

POTENTIAL BENEFITS

This study is not designed to directly improve your health or well being. The study results may help other women undergoing mammography in the future.

COSTS

You will not be charged for the extra mammogram done by the ASPIRE Cristalle machine or any study evaluations. Your regular mammogram and other procedures you have for breast cancer screening or diagnosis will be billed to you or your insurance company as usual.

PAYMENT

You will not be paid for participating in this study.

ALTERNATIVES TO PARTICIPATING IN THE STUDY

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

VOLUNTARY NATURE OF PARTICIPATION IN THE STUDY

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

If you withdraw your permission, you will not be able to continue in this study. When you withdraw your permission, no new health information, which might identify you, will be gathered after the date. Information that has already been gathered may still be used and given to others. This would be done if it were necessary for the research to be reliable.

You will not lose any of your legal rights as a research subject by signing this consent form.

Your participation in this study may be stopped at any time by the study doctor or the Breast Center of Northwest Arkansas without your consent for any of the following reasons

- if it is in your best interest;
- you do not consent to continue in the study after being told of changes in the research that may affect you;
- or for any other reason.

PROTECTED HEALTH INFORMATION AND CONFIDENTIALITY

In order to conduct this study, certain data and images relating to your health information ("Health Information") must be collected by your radiologist/study doctor and disclosed (revealed) to the equipment manufacturer or its representatives and to other parties as described below. However, personally identifiable information will be removed (de-identified) for the purposes of this study.

During the study, Health Information related to the study will be collected on various data collection forms. Such data may include, but is not limited to, the following information:

- Digital mammograms
- X-rays
- Ultrasound results
- Biopsy or pathology test results
- Radiology reports
- Prior medical history

During the study, your radiologist/study doctor, and his/her study staff, will make your Health Information available to the equipment manufacturer, to the Washington Regional Institutional Review Board and to regulatory agencies, such as the US Food and Drug Administration (FDA) and Office of Human Research Protections (OHRP). The Breast Center may also either provide copies to regulatory agencies or allow them to review your Health Information as required by law.

This information will be shared for the purposes of doing the research, studying the research, and making sure the research was done right.

Your radiologist/study doctor will keep your Health Information for at least 2 years.

The study Breast Center may keep copies of your Health Information indefinitely.

All of your Health Information will be combined with that of other subjects from the study so that statistical analyses may be performed. The Health Information and analyses may be used to:

- Prepare reports or marketing applications to regulatory agencies
- Plan for future clinical studies or
- Prepare manuscripts for publication in scientific journals or for discussion at scientific presentations, however, no information that identifies you will be used in these publications.
- Develop or improve equipment manufacturer's products

Please read the conditions below:

- While you are not required to sign this authorization form permitting the use or disclosure of your Health Information, you cannot participate in the study if you do not sign it. However, you will still receive the standard medical treatment for your condition.
- You have the right to revoke (cancel) your authorization of the use and disclosure of your Health Information. However, this permission will not stop automatically.
- Any study data collected before the date that you revoke authorization can still be used. Also, certain data that may be collected after you revoke authorization may be used, but only if it is necessary to meet regulatory requirements.

Other than what is explained above, the radiologists participating in the study and the Breast Center will maintain the confidentiality of any Health Information reported to them. However, if you authorize disclosure as stated above, the released information may no longer be protected by the federal privacy regulations.

You have the right to access your own medical records. However, except as otherwise required by applicable law, you are not entitled to see the overall results of the study.Any cancellation of the use and disclosure of your Health Information must be submitted in writing to:

Steven E. Harms, MD, FACR, The Breast Center of Northwest Arkansas, 55 Sunbridge, Fayetteville, AR 72703

SOURCE OF FUNDING

No funding is provided specifically for this project.

QUESTIONS AND ANSWERS

Contact Lonell Ward for any of the following reasons:

- if you have any questions about your participation in this study,
- if at any time you feel you have had a research-related problem , 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:

Washington Regional Institutional Review Board

3215 N. North Hills Blvd, CSS building

Fayetteville, AR 72703

479-463-7868

Fax 479-463-5977

Washington Regional IRB 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 wish 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 received satisfactory answers to all of your questions.

If you agree to be in this study, you will receive a signed and dated copy of this consent form for your records.

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. [21 CFR 50.25(c)]

INFORMED CONSENT TO PARTICIPATE IN THE RESEARCH STUDY

1. I have read this consent form (or it has been read to me) about the study.
2. My participation is voluntary (of my free will) and I can withdraw my consent to participate at any time without affecting my right to receive medical care.
3. I have asked all questions of my study doctor and received answers to my satisfaction.
4. I have answered all questions concerning my health accurately and truthfully to the best of my knowledge.
5. I am 18 years of age or older, and legally able to give my consent.

I agree to participate in this research study.

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.

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

Subject's Name (print)

Subject's Signature

Person Conducting Informed C

Witness Signature (if required) Date

---------- Use this witnes 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.

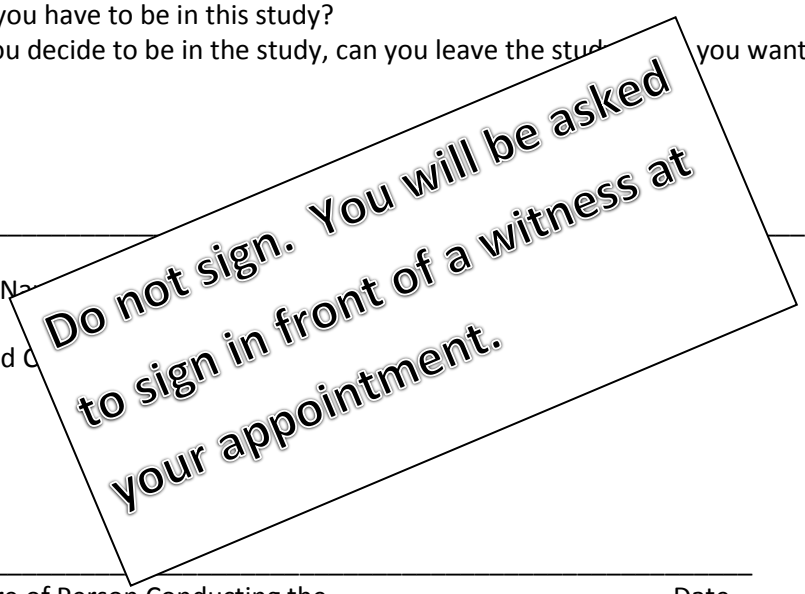
I confirm that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject. The subject freely consented to be in the research study.

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.

I confirm that the research study was thoroughly explained to the subject. I reviewed the consent form with the subject and answered the subject's questions. The subject appeared to have understood the information and was able to answer the following questions correctly:

1. What is the purpose of this study?
2. If you decide to be in the study, what will you be asked to do?
3. What is the possible benefit of participating in this study?
4. What are the possible risks of participating in this study?
5. If you decide not to participate in this study, what options do you have?
6. Will participating in this study cost you anything? If so, what will you have to pay for?
7. Do you have to be in this study?
8. If you decide to be in the study, can you leave the stud you want to?



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Signature of Person Conducting the Date

Informed Consent Discussion