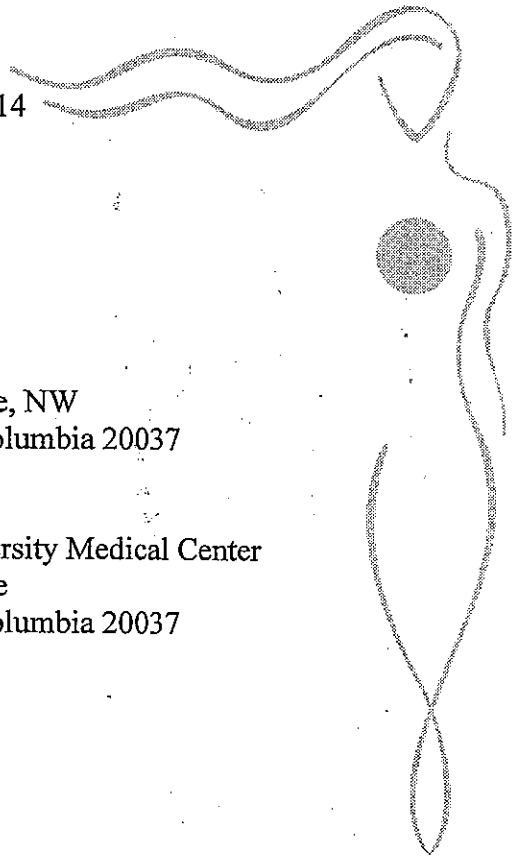
APPROVED
AS MODIFIED
Feb 09, 2009
WIRB®

RESEARCH SUBJECT INFORMATION AND CONSENT FORM

TITLE: A prospective multicenter matched-pair clinical study to evaluate the sensitivity and specificity of ABUS and Digital X-Ray Mammography (XRM) together as a breast cancer screening method compared to XRM alone in women with > 50% parenchymal density.



PROTOCOL NO.: 2008002, Version 1
WIRB® Protocol #20082014

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San Jose, California
United States

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STUDY-RELATED PHONE NUMBER(S): Rachel Brem, M.D.
202-741-3031

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 if you would like to think about participating in the study or if you would like to discuss your participation with family or friends before making your decision.

STUDY DOCTOR'S STATEMENT

We are asking you to be in a research study. The purpose of this consent form is to give you the information you will need to help you decide whether to be in this study. Please read this consent form carefully. You may ask questions about the purpose of the research, what we will ask you to do, the risks, the benefits, your rights as a subject, and anything else about the

research or this consent form that is not clear. When we have answered all of your questions, you can decide if you want to be in this study or not. This process is called "informed consent". We will give you a signed and dated copy of this consent form for your records.

SUMMARY

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

- Reading this consent form,
- Having the study doctor or 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 or 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.
- You should know after reading the consent form and having the discussion with the research staff, which items 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 that is given to you during the research study. If your insurance company is billed, then it may have access to the research records. Insurance companies may or may not pay for treatment that is part of a research study.

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 procedures will be used;
- Any possible benefits to you;
- The possible risks to you;

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

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

PURPOSE OF THE STUDY

This is a study to determine if having somo·v™ (U-Systems, Inc.) Automated Breast Ultrasound (ABUS) done together with a routine screening mammogram (x-ray), is more sensitive to detecting breast cancer in women with dense breast tissue than getting a routine screening mammogram without ABUS. You have been asked to participate in this study because you are expected to undergo routine screening mammography at our breast center.

Breast cancer is one of the most commonly diagnosed cancers in American women with an estimated 210,000 new cases diagnosed in 2007. Death rates in women with breast cancer are much lower when the cancer is detected at an early stage, and less intense forms of treatment can be used at early stages when cancerous lesions are the smallest. It is for this reason that annual routine mammograms are recommended by the American Cancer Society for women 40 years of age and older and are the current standard of care for breast cancer screening.

One thing that is known to interfere with the early detection of breast cancer with mammogram is a woman's breast density. Breast density is a way to describe the types of tissue that make up the breast. The breast is made up of a combination of glandular tissue, fibrous connective tissue and fatty tissue. The amount of each of these tissues varies from one woman to another. Women who have more fibrous connective and glandular tissue than fatty tissue in their breasts have more breast density. Women under age 50 tend to have more density in their breasts than women who are older, but density may be present in women of all ages and is estimated to exist in 40% to 60% of all women undergoing mammographic screening.

Breast density can make breast cancer difficult for a radiologist to see on a mammogram. Also, research has shown that women who have dense breast tissue are more likely to develop breast cancer in their lifetime than women who do not have dense breast tissue. Automated Breast Ultrasound (ABUS) is a breast imaging technology which is less affected by a woman's breast density, and is currently FDA approved when used in combination with mammography. It is most commonly use by doctors and sonographers in the diagnostic setting, when a woman has a known breast abnormality or symptom.

This study will try to help us find out if ABUS can also be a helpful part of routine breast screening in women who do not have any known abnormalities or symptoms, but do have dense breast tissue which could impact the accuracy of their yearly mammograms. Unlike mammography, ABUS does not use radiation. ABUS uses sound waves at a safe frequency to create pictures of the internal breast tissue. Ultrasound has been shown to find cancer not visible with mammography in women with dense breasts. The ABUS, which will be used in this study, automatically scans the breast and may help detect cancers in dense tissue.

All women who volunteer to participate in this study and who also meet the study requirements will receive ABUS at the same appointment they have their routine screening mammogram. The outcome of this screening will be recorded and followed for up to one year. Study participation will be finished at the completion of the next annual routine mammogram, or the diagnosis of breast cancer, after follow-up or testing recommended by the study doctor, whichever comes first.

HOW MANY SUBJECTS WILL TAKE PART IN THE STUDY?

Of the 51,500 women nationwide who sign this consent form after being invited to participate in this study, approximately 20,600 women (about 3,400 at The George Washington University Medical Center) will meet the inclusion requirement of having > 50% dense breast tissue and will be enrolled in this study.

PROCEDURES

If you agree to participate in this study, the following will happen:

1. You will agree to have all routine standard care that is recommended by the study doctor, which may include diagnostic procedures like additional imaging or a biopsy, OR, if the results of your screening are negative (normal or benign), you will agree to attend an annual routine screening mammogram one year from now and notify the study doctor if you have any breast changes or symptoms during this year. You will also agree to allow the study doctor, or one of the study staff members, to contact you if you do not complete the recommended follow-up procedures or if you do not return to the clinic in one year for an annual routine screening mammogram.
2. You will agree to have an Automated Breast Ultrasound (ABUS) of one or both of your breasts, if your mammogram shows that you have dense breast tissue. You will be asked to lie down on the scan table, comfortably resting on your back. The technician will apply a hypoallergenic ultrasound lotion to your breasts before the scan. The ABUS system will require gentle pressure on each breast during the scan. The study includes as many as three ultrasound scans of each breast, each scan lasting one minute. Unlike a mammogram, ABUS does not involve any mammography-like compression. Instead, the breast will be lightly pressed against your body during the scan.
3. If your mammogram shows that your breast tissue is not dense, you will not be eligible for further participation in the study and you will not undergo an ABUS. You will still receive the same standard care and treatment you would normally receive.
4. You will agree to notify the study doctor if you should change your mind about participating in this study or if you no longer want your information to be used.
5. You will also agree to notify the study doctor if you are concerned that you may be having an abnormal reaction or adverse (bad or harmful) effect from participation in the study.

6. In addition to your responses to the questions in the Study Subject Questionnaire, the study doctor will collect the following information from your medical records: breast health history, cancer treatment history, mammogram results, ABUS results, results of biopsy or aspiration, diagnosis and the outcome of your follow-up mammogram one year from now. Information, like your name, date of birth and medical record number, which can directly link you to these data, will be removed by the study doctor and/or clinic staff before these data are reported and analyzed.

HOW LONG WILL I BE IN THIS STUDY?

Participating in this study will take approximately 30 minutes of your time in addition to the time you would normally spend in the office. In order for the study doctors to gather data on the accuracy of mammography and ABUS, they will need to collect the results of your mammogram and ABUS, as well as results from any other breast evaluations, procedures or testing you receive for the next year, until you complete your next annual routine mammogram. The outcome of your next mammogram will also be recorded. Since this data collection is part of standard care, this follow-up will not require any more time in addition to the time you would normally spend.

RISKS AND DISCOMFORTS

There are no known, harmful effects of breast ultrasound, although the procedure itself may be uncomfortable if your breasts are tender or sensitive to gentle pressure. If an abnormality is seen on the ABUS examination or on the mammogram, the study doctor may recommend additional tests, which are the standard of care in this facility and might include a biopsy. If any potential abnormalities are observed from the ABUS that are not seen on the standard mammogram, you and your study doctor will be informed and any testing that may be ordered as a result of the abnormal ABUS will be the same standard tests that would be ordered for an abnormal mammogram.

Other risks of participating in the study include:

1. Unknown risks. There may be risks or side effects which are unknown at this time and participation in the study may involve additional risks that are currently unknown.
2. Loss of confidentiality. Just as with your other medical information from routine medical care, all study related information will be kept as confidential as possible. Study information will be kept in locked files and in databases with password protected access. Your name and any other identifying information about you will not be released from the clinic and it will not be used in any published reports about this study. There is a need to share your protected health information with the study staff at the clinic and because of this, absolute confidentiality cannot be guaranteed.

Women who are pregnant or nursing a child may not take part in this study. If you think that you have become pregnant during the study, you must tell your study doctor immediately. Pregnant women will be taken out of the study.

BENEFITS
There is no guarantee that you will receive any direct benefit from being in this study. There is a possibility that this scan machine may be better in detecting early breast cancer than mammogram or physical examination alone. Early detection of breast cancer may lead to more effective treatment.

This study presents subjects with the opportunity to receive ABUS at no additional cost to them or their insurance when they would otherwise not be entitled to this benefit. Currently, ABUS is FDA approved for use in women who have known breast abnormalities, and those women are not eligible for the study. Women who choose not to participate in the study, and women who are not eligible for the study, will not receive a screening ABUS exam at no cost to them or their insurance.

As a subject, you would be helping us evaluate a new use for the FDA approved ABUS system. If ABUS is proven to improve early breast cancer detection rates in women with dense breast tissue, the standard of care for breast screening may change so that all women with dense breast tissue may receive ABUS as part of standard care in addition to screening mammography, and will reduce the number of women who die from breast cancer every year. If no improvement in breast cancer is proven, the standard of care will not change and future patients and doctors will benefit from the knowledge that routine screening mammography is the most effective program for early breast cancer detection.

NEW INFORMATION
We will tell you about new information, which we receive, that may affect your health, welfare, or that might change your decision to be in this study. You may be asked to sign a new consent form if this occurs.

COSTS
You or your insurance company will still be billed at the usual charge for:

- Any standard medical care given as part of your routine breast screening during this research study.
- Any additional complications that occur during participation in the study.

There will be no cost to you for the ABUS scan and interpretation of the ABUS images by the study doctor. It is possible that the ABUS scan might lead to further evaluation of one or both of your breasts, and even a breast biopsy. You or your insurance provider will be billed for all other costs. Depending on your contracted benefits, your health insurance company may or may not pay for these charges. You should talk with your insurance company about its payment policy for standard medical care given during a research study. If your insurance company does not pay, you will be billed for those charges.

PAYMENT FOR PARTICIPATION
You will not be reimbursed for your time in participating in this study and you will not receive any payment for participating in the study.

ALTERNATIVE TREATMENT
This is not a treatment study. The alternative is to choose not to participate in the study. You may choose to not participate in this study. By not participating in this study, you will in no way affect your present or future care at The George Washington University Medical Center. If you choose not to participate in this study, you will receive the same treatment as all patients who come to this clinic for medical care.

COMPENSATION FOR INJURY
You may have medical problems or side effects from taking part in this research study. If you believe that you have been injured or have become ill from taking part in this study, you should seek medical treatment right away. This can be done through:

- GWU Hospital and/or the GWU MFA or
- your physician or
- treatment center of your choice.

You or your insurance company will be billed for this care. Your insurance company may not pay for such care because you are participating in a research study. You should contact the study doctor as soon as possible about any research related illness or injury.

There are no plans for GWU, GWU Hospital and/or the GWU MFA to pay you for any injuries or illnesses. By signing this form you will not give up any legal rights.

VOLUNTARY PARTICIPATION AND WITHDRAWAL
Taking part in this study is voluntary. You may choose 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.

Your participation in this study may be stopped at any time by the study doctor or the sponsor without your consent for any of the following reasons:

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

FINANCIAL DISCLOSURE
Dr. Brem has received consulting fees from the sponsor in the past twelve months. Please feel free to ask any further questions you might have about this matter.

SOURCE OF FUNDING FOR THE STUDY
The sponsor, U-Systems, Inc., will pay for this research study and provide funding to the study doctor for study related procedures and management of the study records.

QUESTIONS

For any of the following reasons, you may contact Rachel Brem, M.D. at 202-741-3031:

- if you have any questions about this study or your part in it
- if you feel you have had a research-related injury or a bad reaction to the study procedure, 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 perform 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 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.

AUTHORIZATION TO USE AND DISCLOSE INFORMATION FOR RESEARCH PURPOSES

Access to your study records will be limited to those who need the information for purposes of this study, as well as your health care providers if they need access to the information. All records will be kept in a secure location and access will be limited to research study personnel.

Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct personal identifier. The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed, unless you give the appropriate authorization.

Federal law requires that hospitals, researchers and other healthcare providers (like physicians and labs) protect the privacy of health information that identifies you. This kind of information is known as "protected health information" or "PHI." This section tells you your rights about your protected health information in the study. This section also lists who you let use, release, and get your protected health information. You are free to not allow these uses and releases by not signing this form. If you do that though, you cannot participate in the study.

Protected health information that may be used and released (disclosed) in this study includes information such as:

- This consent form;
- Demographic information. Only date of birth and anonymous privacy #.
- Information about your breast-related medical history from your medical records and your doctor's office;
- Information obtained from you to be used in the Study as a result of tests or procedures;
- Pathology results obtained on specimens collected from you (tissue);
- Medical images like x-rays, CT scans, MRIs, and ultrasounds;
- Questionnaires/surveys you complete, Participant Questionnaire;
- Other data created or collected during this study.

By signing this form, you allow the use, sharing, copying, and release of your protected health information to carry out the study by:

- Your healthcare providers (like doctors and hospitals) which are not part of the study,
- The study doctor and his or her research team, and
- Other healthcare providers such as labs which are part of the study.

You also allow the study doctor and the research team, and other healthcare providers which are part of the study to release your health information to:

- GWU Institutional Review Board ("IRB") or its authorized representatives, as well as representatives of the Office of Human Research Protections (OHRP) who may review your records to ensure that your rights as a research subject are protected;
- Western Institutional Review Board (WIRB);
- The sponsor of the study and any contractors or partners it may have. (research monitors and auditors);
- Research collaborators participating in this multi-site study at other institutions (Data receiving center(s) responsible for collecting, monitoring and /or analyzing data from all the sites participating in this study);
- Regulatory agencies such as the U.S. Food and Drug Administration (FDA) to review data on the safety and effectiveness of the product that is being tested in this study and other Federal and state agencies that regulate research;
- Accrediting agencies and GWU legal counsel;
- GWU workforce and your health insurer to discuss payment or get paid for services that are not paid for by the research;
- Clinical staff who are not involved in the study who may become involved in your care, if it might be relevant to your care; and
- GWU, GWU Hospital or GWU MFA workforce who are involved with the research;

You may request to review or have a copy of your personal health information collected during this study and placed in your medical record. This right to review and copy your personal health information only extends to information that is placed in your medical record; it does not extend to information that is placed in your research record.

This permission does not end unless you cancel it, even if you leave the study. You can cancel this permission any time. Such cancellation will not affect information a healthcare provider has already used in reliance on your permission to do so. Even if you cancel this authorization, the researchers may still use and disclose protected health information they already have obtained about you as necessary to maintain the integrity or reliability of the research. However, no new PHI or new biological specimens will be collected from you after you revoke your authorization.

To cancel your authorization, you will need to send a letter to your study doctor. This letter must be signed and dated and sent to this address: Rachel Brem, M.D., Department of Radiology, 2150 Pennsylvania Avenue, NW, Washington, District of Columbia 20037. A copy of this revocation will be provided to the study doctor and his or her research team. Not signing this form or later canceling your permission will not affect your health care treatment outside the study, payment for health care from a health plan, or ability to get health plan benefits.

Your protected health information will be treated confidentially to the extent permitted by applicable laws and regulations. Federal law may allow someone who gets your health information from this study to use or release it in some way not discussed in this section and no longer be protected by the HIPAA Privacy Rule.

By signing this form you authorize the study doctor and members of the research team to use and share with others (disclose) your PHI for the purpose of this study. If you do not wish to authorize the use or disclosure of your PHI, you cannot participate in this study because your PHI is necessary to conduct this study.

CONSENT

I have read all the above information in this consent form (or it has been read to me). I have had an opportunity to ask questions, and I am satisfied with the answers I received. All my questions about the research study and my part in it have been answered. I willingly give my consent 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.

SOMO INSIGHT

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AS MODIFIED
Feb 09, 2009
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By signing this consent form, I have not given up any of my legal rights.

CONSENT SIGNATURE:

Dita Verheij
Printed Subject Name

Signature of Subject

8/03/10
Date

Megan Kann
Printed Name of Person Conducting Informed Consent Discussion

Signature of Person Conducting Informed Consent Discussion

8/3/10
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 participate in the research study.

Printed Impartial Witness Name

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