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UNIVERSITY OF CALIFORNIA, SAN FRANCISCO
CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Study Title: *Contrast-enhanced MRI for the Characterization of Ductal Carcinoma in Situ (DCIS)*

This is a medical research study. Your study doctor(s), Nola Hylton, PhD, and Bonnie Joe, MD, PhD, from the UCSF Department of Radiology, and Laura Esserman, MD, from the UCSF Department of Surgery, or the study coordinator, Margarita Watkins, will explain this study to you.

Medical research studies include only people who choose to take part. Take your time to make your decision about participating. You may discuss your decision with your family and friends and with your health care team. If you have any questions, you may ask your study doctor.

You are being asked to take part in this study because you have had a biopsy and have been diagnosed with ductal carcinoma in situ (DCIS) or atypical ductal hyperplasia (ADH).

Why is this study being done?

The purpose of this study is to develop and refine MR imaging methods for characterizing DCIS or ADH, and to use MRI to monitor patient's response to pre-surgical endocrine or immunotherapy treatment for their DCIS or ADH.

Who pays for this study?

This study is being paid for by grant funding from the National Institute of Health.

How many people will take part in this study?

About 130 people will take part in this study.

What will happen if I take part in this research study?

Before you begin the main part of the study...

You have been diagnosed with DCIS or ADH, and you have already had a biopsy.
You should not be pregnant or become pregnant during this study. If there is a possibility that you are pregnant you will be required to undergo a pregnancy test.

During the main part of the study...

If you can be in the study, and you choose to take part, then you will have the following tests and procedures.

- *If you have biopsy proven DCIS or ADH* you will have a diagnostic, contrast-enhanced MRI exam as part of your standard clinical care. Additional functional MRI sequences will also be performed but these do not require additional contrast agent. For the MRI exam, you will lie

down on a narrow bed that will then be placed in a tunnel that is 6 feet long by 22 inches wide and open at each end. You will need to lie there quietly and remain still for the duration of the exam, during which time there will be a loud banging noise. You may feel warm during this procedure. If you are scheduled to receive pre-surgical endocrine or immunotherapy treatment for your DCIS or ADH, you will return after you have started your treatment for a second and/or third contrast-enhanced diagnostic MRI using the same sequences as before.

Study location: All study procedures will be done at a UCSF Department of Radiology Imaging center.

How long will I be in the study?

Participation in the study will take a total of 1-3 hours over a period of up to 6 months, depending on whether you are receiving pre-surgical treatment. You may have a total of up to 3 MRI scans and each scan will take about 60 minutes.

Can I stop being in the study?

Yes. You can decide to stop at any time. Tell the study doctor if you are thinking about stopping or decide to stop. He or she will tell you how to stop your participation safely.

The study doctor may stop you from taking part in this study at any time if he/she believes it is in your best interest, if you do not follow the study rules, or if the study is stopped.

What side effects or risks can I expect from being in the study?

You may have side effects while on the study. Everyone taking part in the study will be watched carefully for any side effects. However, doctors don't know all the side effects that may happen. Side effects may be mild or very serious. Your health care team may give you medicines to help lessen side effects. Many side effects go away soon after the MRI exam. In some cases, side effects can be serious, long lasting, or may never go away.

You should talk to your study doctor about any side effects you experience while taking part in the study.

Risks and side effects related to the MRI exam include:

- **MRI risks:** Because the MRI machine acts like a large magnet, it could move iron-containing objects in the MRI room during your examination, which could in the process possibly harm you. Precautions have been taken to prevent such an event from happening; loose metal objects, like pocketknives or key chains, are not allowed in the MRI room. If you have a piece of metal in your body, such as a fragment in your eye, aneurysm clips, ear implants, spinal nerve stimulators, or a pacemaker, you will not be allowed into the MRI room and cannot have an MRI. All subjects are screened for contraindications to MRI prior to beginning the study.

Having an MRI may mean some added discomfort for you. In particular, you may be bothered by feelings of claustrophobia and by the loud banging noise during the study. Temporary hearing loss has been reported from this loud noise. This is why you will be asked to wear earplugs.

Since the risks to fetuses are unknown, you should not be pregnant while undergoing MRI procedures.

- **Intravenous catheter risks:** Less frequent risks associated with the temporary placement of the IV include infiltration of IV fluids under the skin, redness and pain. Much less frequent would be phlebitis, or an inflammation of the vein.

- **Contrast agent (gadolinium) risks:** A few side effects of gadolinium injection such as mild headache, nausea, and local pain, may occur. Rarely (less than 1% of the time) low blood pressure and lightheadedness occurs. This can be treated immediately with intravenous fluids. Very rarely (less than one in one thousand), patients are allergic to gadolinium. These effects are most commonly hives and itchy eyes, but more severe reactions have been seen which result in shortness of breath.
- Patients with severe kidney disease sometimes have a bad reaction to gadolinium contrast. The condition is called nephrogenic systemic fibrosis (NSF). It can cause skin to tighten or scar and can damage internal organs. Sometimes it can be life threatening. There are no reports of NSF in patients with normal kidney function. Before you have a MRI scan requiring an injection of gadolinium contrast, you will have a blood test in order to check the function of your kidneys. Based on your medical history and the results of the test, a doctor will decide whether it is safe for you to undergo the MRI scans. Gadolinium can build up in the brain; however, it is unknown how this will impact your health. Some types of gadolinium are more strongly linked to buildup in the brain. UCSF prefers to use gadobutrol, which is less likely to build up in the brain, compared to other types of gadolinium. However, for some types of liver imaging, a less stable agent called gadoxetate is sometimes required. Gadolinium as an MRI imaging agent will only be used when medically necessary for your care. When it is medically necessary, the study doctors believe that the clear benefits of using gadolinium for imaging outweigh the unknown risks, which is minimized by using gadobutrol.

- **Incidental findings:** MRI is a very sensitive diagnostic tool. Therefore, the study investigators expect that in some women, MRI will demonstrate abnormalities that cannot be seen on either mammography or physical examination. These are more common in pre-menopausal women because of the added background activity of normal glandular tissue in the breast. If there is an incidental finding that the investigators consider clinically significant on your MRI, you and your doctor will be notified by one of the study doctors or their designate. For this reason, it is very important that accurate, up-to-date contact information for you and your physician be provided. Additional follow-up may be required based on these incidental findings, which may include additional imaging, evaluation by a breast specialist and/or breast biopsy. This follow-up will not be covered by the study.

- **Unknown Risks:** MRI may have side effects that no one knows about yet. The researchers will let you know if they learn anything that might make you change your mind about participating in the study.

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

Are there benefits to taking part in the study?

There will be no direct benefit to you from participating in this study. However, this study will help doctors learn more about imaging DCIS and ADH, and it is hoped that this information will help in the treatment of future patients with DCIS and ADH.

What other choices do I have if I do not take part in this study?

There are no other choices other than to not participate in this study. Choosing to not participate will have no effect on your clinical care. Please talk to your doctor about your choices before deciding if you will take part in this study.

Will my medical information be kept private?

Participation in research involves some loss of privacy. We will do our best to make sure that information about you is kept confidential, but we cannot guarantee total privacy. Some information from your medical records will be collected and used for this study. If you do not have a UCSF medical record, one will be created for you. Your signed consent form and some of your research tests will be added to your UCSF medical record. Therefore, people involved with your future care and insurance may become aware of your participation and of any information added to your medical record as a result of your participation. Study tests that are performed by research labs, and information gathered directly from you by the researchers will be part of your research records but will not be added to your medical record. Your personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your name and other personal information will not be used.

Will any research-related procedures be billed to me?

Two types of procedures will be done during this study. Some are part of your standard medical care and others are only for research. You or your insurer will be billed for the standard medical care. You will be responsible for your co-pays, deductibles, and any other charges that your insurer will not pay. There is a possibility that your insurer may not cover all standard medical care costs if you are receiving medical services out of network. Any procedures done only for research will not be charged to you or your insurer.

Will I be paid for taking part in this study?

You will not be paid 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 coordinator, Margarita Watkins, if you feel that you have been injured because of taking part in this study. You can tell the coordinator in person or call her [redacted].

- **Treatment and Compensation for Injury:** If you are injured as a result of being in this study, the University of California will provide necessary medical treatment. The costs of the treatment may be billed to you or your insurer just like any other medical costs, or covered by the University of California or the study sponsor the National Institute of Health depending on a number of factors. The University and the study sponsor do not normally provide any other form of compensation for injury. For further information about this, you may call the office of the Institutional Review Board at 415- 476-1814.

What are my rights if I take part in this study?

Taking part in this study is your choice. You may choose either to take part or not to take part in the study. If you decide to take part in this study, you may 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 affect your medical care. You can still get your medical care from our institution.

We will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

In the case of injury resulting from this study, you do not lose any of your legal rights to seek payment by signing this form.

Who can answer my questions about the study?

You can talk to your study doctor about any questions, concerns, or complaints you have about this study. Contact your study doctor(s) Nola Hylton PhD [redacted].

Additionally you may contact your study coordinator, Margarita Watkins, [redacted].

For questions about your rights while taking part in this study, call the office of the **Committee on Human Research**, UCSF's Institutional Review Board (a group of people who review the research to protect your rights) at **415-476-1814**.

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CONSENT

You have been given copies of this consent form and the Experimental Subject's Bill of Rights to keep.

You will be asked to sign a separate form authorizing access, use, creation, or disclosure of health information about you.

PARTICIPATION IN RESEARCH IS VOLUNTARY. You have the right to decline to participate or to withdraw at any point in this study without penalty or loss of benefits to which you are otherwise entitled.

If you wish to participate in this study, you should sign below.

Date	Participant's Signature for Consent
Date	Person Obtaining Consent