The UNIVERSITY OF CHICAGO
The Division of the Biological Sciences • The University of Chicago Medical Center

**CONSENT/AUTHORIZATION BY SUBJECT FOR PARTICIPATION IN A RESEARCH PROTOCOL**

Protocol Number: IRB16-0396 Name of Subject: _____
Medical History Number: _____

STUDY TITLE: Development and Testing of an Accurate, Rapid and Inexpensive MRI Protocol for Breast Cancer Screening = A Pilot Study


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You are being asked to participate in a 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, the risks and benefits of participation, as well as how your confidentiality will be maintained. Please take your time to ask questions and feel comfortable making a decision whether to participate or not. This process is called informed consent. If you decide to participate in this study, you will be asked to sign this form.

## WHY IS THIS STUDY BEING DONE?

You are being asked to participate in this study for one of the following reasons:

1. You have had a mammographically and/or sonographically identified finding that will require image guided biopsy
2. You are a woman between ages 40-74 with dense breasts having a mammogram
3. You have been identified as having an average or intermediate risk of breast cancer (defined as 10-20% lifetime risk based on a clinical risk model).

The purpose of this study is to test an innovative MRI breast cancer screening method in women with mammographically dense breasts as well as other women with moderately increased cancer risk. MRI, combined with other methods of risk assessment has potential to significantly improve sensitivity to cancer in dense breasts and detect cancer in all cases at a much earlier stage, with far fewer cancers missed by screening. Previous tests of MRI sensitivity show that this screening could significantly increase the chance of finding breast cancers early enough to lead to longer life for patients with breast cancer.

The rapid MRI protocol being done on this study to screen for breast cancer is not a standard of care use of MRI technology, and its use on study is therefore experimental.

## HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 200 people will take part in this study at the University of Chicago Medical Center.

## WHAT IS INVOLVED IN THE STUDY?

Whenever possible we will try to schedule this MRI scan on the same day as your standard clinical screening mammogram (x-ray of the breast).

As part of this study, we would like to collect MRI images of your breasts. Any mammography exams or biopsies will be part of your standard clinical care, and not acquired specifically for the purpose of this study. The MRI exam will be a research-only exam.

1. We will scan 50 women with mammographic or sonographic findings that require biopsy.
2. We will scan 150 healthy women with dense breasts and/or women who have intermediate or high risk of breast cancer.

The research MRI includes an injection of contrast agent. This contrast agent will be injected into your arm and will help the doctors to read the MRI more effectively. If there is a lesion (abnormality) in the breast, the contrast agent will go to the lesion first and we will be able to see it better. You will receive an MRI screening form to determine if there is a risk that your kidney function is not adequate for a contrast-enhanced exam.

You will be escorted to the MRI clinic and asked to change into a patient gown. You will be accompanied to the scan room and asked to lie on your stomach on a movable examination table. As you lie on your stomach your breasts will fit inside the two breast-shaped MRI signal detectors on the table.

The examination table will then move you into the MRI scanner, which is a long tube with a diameter of about 2 to 2.5 feet. You will be asked to lie in the MRI scanner for 15 – 30 minutes. During the periods when we are taking pictures, we will ask you to be as still as possible. After about 5 minutes – we will inject contrast agent through the IV line. We will warn you before we do this.

At any time during your MRI exam you can decide to stop the research scan. Simply inform the technologists and they will stop the research scan.

During this study, Dr. Abe and his research team will collect information about you for the purposes of this research. This will include your name, contact information (address, telephone numbers, and/or email), medical record number, insurance information, demographic information (gender, birth date, race/ethnicity), medical history (including current medications), cancer history (including diagnosis and treatment history), race, ethnicity, age, height, weight. Menopausal status and last menstrual cycle date, mammogram reports, rays and/or MRIs and reports.

You have the option of allowing Dr. Abe and his research staff to contact you for future breast imaging research studies, such as ultrasound or MRI of the breasts. You have decided that:

_____ (initials) _____ (date) _____ Yes, I agree to be contacted to see if I would be interested in participating in other studies in the future.

_____ (initials) _____ (date) _____ No, Do NOT contact me for future research purposes.

**HOW LONG WILL I BE IN THE STUDY?**

This will be a one-time scan. The duration of the entire MRI scan will be 15 – 30 minutes. Data obtained from this scan will be used and stored in a database for at least 6 years.

Your participation in the study may be stopped for the following reasons:

- At your own request
- You don't follow the study doctor's instructions
- The study doctor decides that it is in your best interest or for safety reasons.
- If the study is stopped.

The study doctor will discuss with you any safety procedures if participation is stopped.

**WHAT ARE THE RISKS OF THE STUDY?**

1. **Risks of the contrast agent**: contrast may cause: headache, nausea, hives, allergic reaction (rare). In addition, the risks to a fetus are unknown. Pregnancy testing is not done on this study. By signing this consent form, you attest that you are not pregnant. If there is any possibility that you may be pregnant, do not participate in this study.

2. **The effects of magnetic fields on metallic implants**. Metal objects may pose a serious risk to people undergoing MRI exams. This includes internally implanted objects such as surgical clips, bio-support devices (e.g., pacemakers), and in some cases artificial joints which contain metal. Metal slivers may become trapped in the eyes of individuals who have worked in or near machine and electronics shops, posing a potential hazard if exposed to a strong magnetic field. If you believe that you may have metal objects implanted in your body, if you wear any mechanical or electrical devices that cannot be removed, or if you have worked in or near machine or electronics shops you should discuss this with the attending physician or the MRI Technologists.

   Metal objects (such as heavy key chains) that are carried into the scan room can cause serious accidents. You must remove all metal objects from your body and your clothing before you enter the scan room. Please consult with the researchers or the MRI technologist regarding jewelry. Jewelry such as a gold ring is often non-magnetic. Non-magnetic jewelry does not pose a risk to you or the MRI equipment. However, it can decrease the quality of MRI scans if it is worn close to the part of the body that is being scanned.

3. **The detection of abnormalities that your physicians were not aware of**. The primary risk to study subjects associated with a clinical MRI is that some of the lesions detected by MRI are

likely to be benign. If suspicious lesions are detected by MRI they may be biopsied and in many cases the lesion will prove to be benign and the biopsy will have been unnecessary. In this case you will have had unnecessary discomfort, anxiety, and expense. However, the risk of false-positive is considered to be justified by the benefits of potentially finding cancers at an early stage when they can be easily treated. All of the standard MR images we obtain during this study will be examined carefully by an experienced radiologist. If there is anything suspicious, the radiologist or the nurse will contact you and/or your physician and discuss further imaging. They may ask you to return for a standard clinical MRI scan, a mammogram, or some other examination.

4. **Exposure to a strong magnetic field**. The MRI exam itself has no known side effects associated with the magnetic fields used to produce the images. Despite the exposure of millions of people to the magnetic fields used in MRI scanners over the last 25 years, and to the magnetic fields produced by other scientific instruments over the last 70 years, there have been no confirmed reports of any negative side effects.

5. **Exposure to a radio-frequency magnetic field**. The scanners use radio-frequency waves to acquire MRI images of your body. These are the same type of waves as those used to transmit radio programs, and the scanners are equipped with power limiters which keep their power at a safe level. In rare instances, incorrectly placed surface coils can heat up, and in extreme cases, cause burns. However, this is unlikely to happen to a person who is not sedated (under anesthesia), as the warmth is easily detected and the coil can be repositioned correctly. There is a possibility that you may experience vertigo or nausea during the MRI scan.

6. **A reaction to remaining in an enclosed space during the scan**. Some people may experience claustrophobia during the MRI exam due to the limited space available inside the bore of the magnet. If you have experienced severe claustrophobia in the past you should not volunteer for this study. Subjects with mild to moderate claustrophobia can usually complete their MRI exams successfully without medication. Using a sedative is also an option if prescribed by your doctor. The staff at the MRI clinic cannot provide this medication. If you plan on using a sedative, you should not drive yourself home and should arrange for a ride. The magnet is equipped with an intercom system and you can communicate with the operators at any time during the exam if you feel any discomfort.

7. **Loss of confidentiality**. It is possible that some of your data becomes exposed and you lose confidentiality as a result of participating in this study. This is highly unlikely, and extensive precautions are implemented to prevent this, as detailed later in this consent form.

There may be other risks that could arise that are not reasonably foreseeable. If new information becomes available which could influence your willingness to continue, this new information will be discussed with you.

**ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?**

The research images we obtain will be examined carefully by experienced Radiologists and this may result in some benefit to you if suspicious tissue is found. Your participation in this study will contribute to the development of improved imaging methods for the detection and evaluation of abnormal tissue in the breast.

**WHAT OTHER OPTIONS ARE THERE?**
Instead of participating in this study, you may receive standard of care of mammograms for your breast cancer screening. You have the option of declining to participate in this study. The decision whether or not you wish to participate in this study will not affect your care at the University of Chicago Medical Center.

**WHAT ARE THE COSTS?**
Clinical services provided during a clinical trial are either research-related or related to usual medical care. Research-related services are done to complete the research and the costs are not the responsibility of you or your insurance.

The costs that are considered research-related for this study may include any additional laboratory tests, physician visits, imaging, procedures or other clinical services that are dictated by the research protocol and only required because you are part of this study.

The costs that are considered research-related for this study include the following:

- Breast MRI
- A blood test of kidney function called GFR (standard screening procedure) for breast MRI w/contrast is only required if: over 60 years old, have hypertension or diabetes.

Usual medical care costs include any and all services that are considered medically necessary and would be done even if you were not part of this research study. This may include laboratory tests, physician visits, imaging, procedures, and other clinical services that your physician orders for your routine care. The cost of this usual, ongoing medical care will be the responsibility of you or your insurance, and may include deductibles and co-payments. Similarly, this care will be subject to all the same requirements and restrictions of your insurance.

If you have questions about whether specific clinical services are research related or usual medical care, please speak to your physician or the clinical research coordinator, Dr. Safi (RSafi@radiology.bsd.uchicago.edu, or 773-702-2777).

If you suffer an unanticipated injury as a direct result of this research and require emergency medical treatment, the University of Chicago Medical Center will provide such treatment at the University of Chicago Medical Center at no cost to you. You must notify Dr. Safi or Dr. Abe as promptly as possible after your injury in order to receive this care. An injury is "unanticipated" if it is not one of the known effects of a study drug, medical device or procedure, and is not the result of any pre-existing disease or condition. The costs of any non-emergency care for such an injury will be billed to you or your insurance in the ordinary manner. If you think that you have suffered a research related injury, you must let Dr. Safi or Dr. Abe know right away.

There will be no costs to you or your insurance company resulting from your participation in this research study. However, you or your insurance company will be responsible for costs related to your usual medical care.

**WILL I BE PAID FOR MY PARTICIPATION?**

You will be paid $75 for your participation in this research that you may choose to receive in the form of a check or a Visa gift card. Policies at the University of Chicago require the completion of a tax form. Therefore, we will be collecting personal information about you including your address, social security number, etc. If you choose to receive a check, because the process for requesting a check oftentimes takes several weeks, we will mail your check to you when it is ready. Please note that it may take 3-4 weeks after conclusion of your study participation in order for you to receive your check. If you choose to receive a Visa gift card, it will be given to you immediately after the conclusion of the study. You may also receive a coupon for food at the DCAM cafeteria and a parking voucher. In lieu of a parking voucher, you may ask the Research Coordinator to request an Uber driver for you. The Uber driver will pick you up at the location that you designate to the Research Coordinator and take you to the University of Chicago Medical Center. After the scan is complete, the Research Coordinator will call an Uber driver to take you home, or another designated location. You will not be responsible for any costs associated with Uber transportation.

**WHAT ABOUT CONFIDENTIALITY?**

Study records that identify you will be kept confidential. The University of Chicago will take steps to protect your personal data. Your study records will be available to the study doctor, research nurse, data coordinator, and other research staff. Your study records will be stored in secured databases and locked offices at the University of Chicago.

The data collected in this study will be used for the purpose described in the form. By signing this form, you are allowing the research team access to your medical records, which include Protected Health Information. Protected Health Information (PHI) consists of any health information that is collected about you, which could include your medical history and new information collected as a result of this study. These would include demographic information (age, gender, race/ethnicity), medical history, cancer history (including treatment and surgical history), dates (date of birth, consent and other medical tests), physical exam, vital signs, height, weight, performance status, laboratory reports (including blood, urine and chemistry tests), pathology reports and samples, radiological reports (including x-rays and scans), and the results of any other tests to determine your disease status. The research team includes the individuals listed on this consent form and other personnel involved in this study at the University of Chicago.

Your records may be reviewed by federal agencies whose responsibility is to protect human subjects in research including the Food and Drug Administration (FDA) and Office of Human Research Protections (OHRP). Your protected health information (PHI) may be shared with governmental agencies including the National Cancer Institute for federally mandated reporting purposes. In addition, representatives of the University of Chicago, including the Institutional Review Board, a committee that oversees the research at the University of Chicago, may also view the records of the research. If your research record is reviewed by any of these groups, they may also need to review your entire medical record.

If health information is shared outside the University of Chicago, the same laws that the University of Chicago must obey may not protect your health information.

The results from tests and/or procedures performed as part of this study may become part of your medical record.

During your participation in this study, you will have access to your medical record. Dr. Abe is not required to release to you research information that is not part of your medical record. By agreeing to participate in this study and signing this form you are also authorizing the use and disclosure of the information as described above.

This consent form will be kept by the research team for at least six years. The study results will be kept in your research record and be used by the research team indefinitely. At the time of study completion, either the research information not already in your medical record will be destroyed or information identifying you will be removed from study results. Any research information in your medical record will be kept and may be used and disclosed indefinitely.

Data from this study may be used in medical publications or presentations. Your name and other identifying information will be removed before this data is used. If we wish to use identifying information in publications, we will ask for your approval at that time.

**WHAT ARE MY RIGHTS AS A PARTICIPANT?**

Taking part in this study is voluntary. If you choose not to participate in this study, your care at the University of Chicago/University of Chicago Medical Center will not be affected. You may choose not to participate at any time during the study. Leaving the study will not affect your care at the University of Chicago/University of Chicago Medical Center.

If you choose to no longer be in the study and you do not want any of your future health information to be used, you must inform Dr. Abe in writing at the address on the first page. Dr. Abe may still use your information that was collected prior to your written notice.

We will tell you about significant new information that may affect your willingness to stay in this study.

You will be given a signed copy of this document. This consent form document does not have an expiration date.

**WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?**

You have talked to _____ about this study and you had the opportunity to ask questions concerning any and all aspects of the research. If you have further questions about the study, you may call Dr. Safi at (773)-702-2777 or Dr. Abe at (773) 702-2781.

If you have a research related injury, you should immediately contact Dr. Abe at (773) 702-2781. After hours you can page the attending Radiologist on call by dialing (773) 753-1880 and then pager #7062.

If you have any questions concerning your rights in this research study you may contact the Institutional Review Board, which is concerned with the protection of subjects in research projects. You may reach the Committee office between 8:30 am and 5:00 pm, Monday through Friday, by calling (773) 702-6505 or by writing: Institutional Review Board, University of Chicago, 5841 S. Maryland Ave, MC7132, I-625, Chicago, Illinois 60637.

**CONSENT OF SUBJECT**

**SUBJECT**
The research project and the procedures associated with it have been explained to me. The experimental procedures have been identified and no guarantee has been given about the possible results. I will receive a signed copy of this consent form for my records.

I agree to participate in this study. My participation is voluntary and I do not have to sign this form if I do not want to be part of this research study.

Name of Participant (in block letters): _____

Signature of Subject: _____
Date: _____ Time: _____ AM/PM (Circle)

**PERSON OBTAINING CONSENT**
I have explained to _____ the nature and purpose of the study and the risks involved. I have answered and will answer all questions to the best of my ability. I will give a signed copy of the consent form to the subject.

Name of Person Obtaining Consent (in block letters):

_____

Signature of Person Obtaining Consent: _____
Date: _____ Time: _____ AM/PM (Circle)

**INVESTIGATOR/PHYSICIAN**

Name of Investigator/Physician (in block letters): _____

Signature of Investigator/Physician: _____
Date: _____ Time: _____ AM/PM (Circle)