Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Participant's Name_____MRN_____

Principal Investigator:	Matthew Miller MD University of Virginia Hospital Medical Center Department of Radiology and Medical Imaging Box 800170 Charlottesville, VA 22908 (434) 297-5830

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a signed copy of this form.

Who is funding this study?

Funding for this study is from the UVA Cancer Center received as a gift from the Charlottesville Women's 4 Miler race. The Four Miler supports UVA Cancer Center's Breast Care Program

Why is this research being done?

The purpose of this study is to evaluate how well women may adopt a Contrast-enhanced Spectral Mammography (CESM) as their yearly breast screening test compared to the standard 2-D or 3-D mammogram.

CESM is approved by the Food and Drug Administration (FDA) for screening and diagnostic exams.

CESM is a mammogram performed after the injection of IV contrast. CESM is used most often when additional information is needed after a standard mammogram. CESM has also been used to determine the extent of a known breast cancer, to screen patients at high risk for developing breast cancer due to a family history or positive cancer genes, and for women with dense breast tissue. Two images are taken almost at the same time during the exam, after the iodine based contrast injection is administered. The first image is comparable to a regular mammogram. The second image shows areas that take up the contrast (enhance) showing increased blood flow. Breast cancers often enhance with contrast due to a greater amount of blood vessels. Non-cancerous lesions can also have greater blood flow. These brighter areas can only be seen on the mammogram with contrast and cannot be seen on a routine mammogram or ultrasound.

CESM has the potential to become a beneficial screening exam for women who have dense breast tissue as it may be a more sensitive procedure for viewing any abnormalitites in dense breast tissue.
You are being asked to be in this study, because you have dense breast tissue noted on a previous screening mammogram (within the last 2 years) and are currently scheduled to receive your screening mammogram as part of your clinical care.

Up 210 people will be in this study at UVA.

How long will this study take?

Your participation in this study will require 1 study visit that will take the place of your annual breast screening mammogram. The completion of questionnaire and the CESM procedure will add about 60 additional minutes to your scheduled procedure.

What will happen if you are in the study?

If you agree to participate, you will sign this consent form before any study related procedures take place. A member of the study team will review you medical history to make sure you are eligible and it is safe for you to participate. The study procedures will take place at the UVA Breast Care Center, Suite 200, 652 Peter Jefferson Parkway, Charlottesville, VA 22911.

STUDY PROCEDURES

Day of scheduled mammogram:

On the day of your appointment, you will be asked to complete a questionnaire that will ask you about your general attitude toward Contrast-Enhanced Spectral Mammography (CESM). Questions will include:

- Thoughts regarding risk of breast cancer
- Concerns regarding contrast procedures such as the CESM
- Past mammogram/breast imaging experience

This questionnaire will take about 5 minutes to complete.

Before you have your mammogram, the following procedures will take place as part of this research:

- A urine pregnancy test will be done if you have a menstrual cycle in the last year.
- If you are age 60-69 years, we will need to confirm that your kidney function is normal. We will draw a small volume of blood and check this, unless you have had a lab test showing normal kidney function in the last 30 days as part of your care.
- A Breast Imaging Technologist or Registered Nurse will place an IV (intravenous catheter) in your arm and a contrast media will be injected in preparation for the CESM.
- After two minutes, the Breast Imaging Technologist will take two images of each breast.
- After the CESM is complete, your IV will be removed.

- Before and after the CESM, you will fill out a pre and post-procedure survey that should take about 5 minutes to complete. .

At the conclusion of the CESM and post survey, your participation in the study is complete.

What are your responsibilities in the study?

You have certain responsibilities to help ensure your safety. These responsibilities are listed below:

- You must be completely truthful about your health history.
- Follow all instructions given.
- You should tell the study doctor or study staff about any changes in your health or the way you feel.
- Answer all of the study-related questions completely.
- You should tell us if you have any of the following: Iodine Allergy, Heart or Vascular disease, Asthma, Sickle Cell Anemia, Diabetes, Multiple Myeloma or are currently on Dialysis.

If you want to know about the results before the study is done:

You will receive your CESM screening results the same way you currently receive your annual screening mammogram results, via letter from your Radiologist. Because this is a screening procedure, the results will not be read by the Radiologist immediately.

What are the risks of being in this study?

Risks and side effects related to the CESM procedure include:

This study involves radiation exposure from mammographic views of your breast. As part of everyday living, everyone is exposed to a small amount of background radiation. Background radiation comes from space and naturally occurring radioactive minerals. The radiation dose you will receive from this additional view will give your body the equivalent of about 6 months' worth of this natural radiation. This radiation dose is what you will receive from this additional view only and does not include any exposure you may have received or will receive from other tests or exams. The precise risk from this dose is not known but is thought to be small. This radiation exposure is not necessary for your medical care but is necessary to obtain the research information desired. If you are pregnant, you may not participate in this research study. It is best to avoid radiation exposure to unborn children since they are more sensitive to radiation than adults.

Risks related to contrast dye used for the CESM procedure:

Likely -Mild reactions include:

- nausea and vomiting
- headache
- itching
- flushing
- mild skin rash or hives

Less Likely -Moderate reactions include:

- severe skin rash or hives
- wheezing
- abnormal heart rhythms
- high or low blood pressure
- shortness of breath or difficulty breathing

Rare but serious -Severe reactions include:

- difficulty breathing
- cardiac arrest
- swelling of the throat or other parts of the body
- convulsions
- profound low blood pressure
- death

IV insertion site:
When an iodine-based contrast material is injected into your bloodstream, you may have a warm, flushed sensation and a metallic taste in your mouth that lasts for a few minutes. The needle may cause you some discomfort when it is inserted. Once it is removed, you may experience some bruising.

Risks from Completing Questionnaires
Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and to the next question

Risks for women:
The CESM and iodine-based contrast material used in this study can harm an unborn or nursing baby. Therefore, you cannot be in this study if you are pregnant or nursing a baby. If you are pregnant now, please tell us right away.

Other unexpected risks:
You may have side effects that we do not expect or know to watch for now. Call the study leader if you have any symptoms or problems.

Could you be helped by being in this study?

You may or may not benefit from being in this study. Possible benefits include: CESM as your screening procedure which may allow breast imaging doctors detailed views of your dense breast tissue**.** In addition, information researchers get from this study may help others in the future.

What are your other choices if you do not join this study?

You have the choice to not to be in this study and only have your scheduled 2D or 3D mammogram performed. Additional screening procedures that may be available to you are Ultrasound and MRI, as recommended by your physician.
If you are a patient at UVa your usual care will not be affected if you decide not to participate in this study.
If you are an employee of UVa your job will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?

You will not get any money for being in this study.

Will being in this study cost you any money?

The following procedures/tests, which are being done for research purposes, will be provided at no cost to you or your health insurance: Contrast-enhanced portion of your mammogram (IV contrast), urine pregnancy test and/or kidney function test (if necessary), and completion of study related questionnaire/surveys.

You and/or your insurance company must pay for any tests or care given beyond what is required in this study. In addition, you and/or your health insurance may also have to pay for other drugs or treatments that are given to help you control any side effects. You will have to pay for any costs not covered by your health plan. You may be responsible for any co-payments or deductibles. You may wish to ask for an estimate of your financial costs. You may also wish to check with your insurance company before the study starts. Ask what they will cover and if they require you to get their permission before you decide to be in the study.

You will be responsible for the cost of travel to come to any study visit and for any parking costs.

What if you are hurt in this study?

If you are hurt as a result of being in this study, there are no plans to pay you for medical expenses, lost wages, disability, or discomfort. The charges for any medical treatment you receive will be billed to your insurance. You will be responsible for any amount your insurance does not cover. You do not give up any legal rights, such as seeking compensation for injury, by signing this form.

What happens if you leave the study early?

You can change your mind about being in the study any time. You can agree to be in the study now and change your mind later. If you decide to stop, please tell us right away. You do not have to be in this study to get services you can normally get at the University of Virginia.

Even if you do not change your mind, the study leader can take you out of the study.

How will your personal information be shared?

The UVa researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

If you sign this form, we may collect any or all of the following information about you:

- Personal information such as name, address and date of birth
- Your health information if required for this study. This may include a review of your medical records and test results from before, during and after the study from any of your doctors or health care providers.

Who will see your private information?

- The researchers to make sure they can conduct the study the right way, observe the effects of the study and understand its results
- People or groups that oversee the study to make sure it is done correctly
- Insurance companies or other organizations that may need the information in order to pay your medical bills or other costs of your participation in the study
- People who evaluate study results, which can include sponsors and other companies that make the drug or device being studied, researchers at other sites conducting the same study, and government agencies that provide oversight such as the Food and Drug Administration (FDA) if the study is regulated by the FDA.

Some of the people outside of UVa who will see your information may not have to follow the same privacy laws that we follow. They may release your information to others, and it may no longer be protected by those laws.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were in the study.

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.

What if you sign the form but then decide you don't want your private information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form. Then you will no longer be in the study. The researchers will still use information about you that was collected before you ended your participation.

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures or treatments
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Principal Investigator:
Matthew Miller MD
University of Virginia

Department of Radiology and Medical Imaging,
PO Box 800170, Charlottesville, VA 22908
Telephone: (434) 297-5830

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483 Charlottesville, Virginia 22908 Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

To be completed by participant if 18 years of age or older.

Person Obtaining Consent

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Consent from Impartial Witness

If this consent form is read to the subject because the subject is blind or illiterate, an impartial witness not affiliated with the research or study doctor must be present for the consenting process and sign the following statement. The subject may place an X on the Participant Signature line above.

I agree the information in this informed consent form was presented orally in my presence to the **identified individual(s)** who has had the opportunity to ask any questions he/she had about the study. I also agree that the **identified individual(s)** freely gave their informed consent to participate in this trial.

Please indicate with check box the identified individual(s):

☐ Subject

_____	_____	_____
IMPARTIAL WITNESS (SIGNATURE)	IMPARTIAL WITNESS (PRINT)	DATE