Connecting Hope and Medical Science

INFORMED CONSENT FOR PARTICIPATION IN A CLINICAL TRIAL

Study Title for Study Participants:
Comparison of Mammography to a Fast MRI in Breast Cancer Screening in Women with Dense Breasts

Official Study Title for Internet Search on https://ClinicalTrials.gov:
Comparison of Abbreviated Breast MRI and Digital Breast Tomosynthesis in Breast Cancer Screening in Women with Dense Breasts (EA1141)

You have been invited to participate in this research study, which is being conducted by the Colorado Cancer Research Program (CCRP). It has been reviewed and approved by the National Cancer Institute's Central Institutional Review Board (NCI CIRB), which acts for CCRP and its consortium hospitals and affiliates. The Principal Investigator of CCRP is Keren Sturtz, M.D.

This is an important form. Please read it carefully or you may ask that it be read to you. It tells you what you need to know about this research study. If you agree to take part in this study, you need to sign this form. Your signature means that you have been told about the study and what the risks are. Your signature on this form also means that you want to take part in this study.

This is a clinical trial (a type of research study). Clinical trials include only patients who choose to take part. Please take your time to make your decision. Discuss it with your doctor, your friends and your family. You should also inform your study doctor of all prescription medications, over-the-counter medications, herbal products, and dietary supplements you take before you agree to take part in the study, and if you decide to participate you should consult with your study doctor before starting anything new while on study.

What is the usual approach to my breast cancer screening?

You are being asked to read this consent form because you are eligible to enroll in a clinical trial which will compare fast MRIs (also known as an abbreviated breast MRI) and 3D mammograms for breast screenings. A fast MRI is a shortened MRI of the breast that is performed in less than 10 min. Clinical trials include only participants who choose to take part.

Please take time to make your decision. Participation in this study is voluntary.

You are being asked to take part in this research study because you have partially dense (non-fatty) breasts and are scheduled to have a 3D mammogram (digital breast tomosynthesis) as part of your routine breast cancer screening. 3D mammograms appear to be more optimal than prior 2D mammograms for women with dense breast tissue noted on prior exams.

The usual approach to breast cancer screening is annual mammography which includes a new type of 3D mammogram called digital breast tomosynthesis. In some women, the mammogram is also supplemented by other screening tests such as ultrasound.

A National Cancer Institute-sponsored Program

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

If you decide not to take part in this study, you have other choices for your care. For example:

- you may choose to have only the 3D mammogram for which you were originally scheduled or you may consult with your doctor if you prefer to have only a 2D mammogram.
- you may choose to take part in a different research study, if one is available
- you may consult with your doctor about having a 2D or 3D mammogram supplemented by another breast cancer screening test such as ultrasound

Why is this study being done?

The main purpose of this research study is to compare if a new type of fast MRI can detect more breast cancers than a 3D mammogram. This study will also compare whether there is a difference in the number of additional tests recommended after the fast MRI and 3D mammogram, and if there is a difference in the types of tumors detected on each test.
In addition, another purpose of this study is to evaluate how women compare the experience of having each test (fast MRI and 3D mammogram).

There will be about 1450 people taking part in this research study.

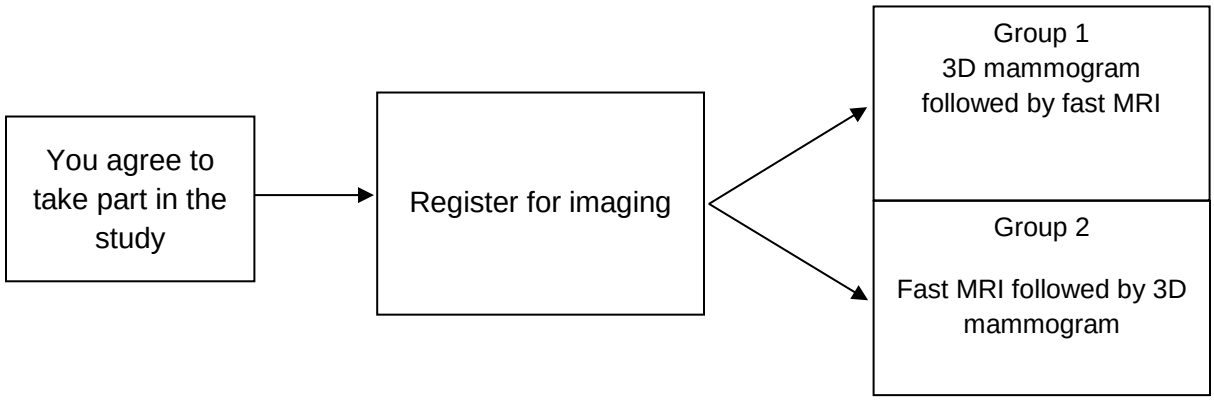
What are the study groups?

This research study has two groups.

All research study participants will have both the 3D mammogram and the fast MRI as part of their breast cancer screening. Sometimes, additional tests such as ultrasound or MRI are used together with mammography to screen for breast cancer. Addition of breast MRI might be optimal. Unfortunately, sometimes findings noted on breast ultrasound do not end up being worrisome for cancer. This occurs less often with MRI.

Research study participants will be randomly assigned by a computer to be in one of two study groups. Both groups will have both the fast MRI and the 3D mammogram. The only difference will be the order in which the two tests are performed. Group 1 will have the 3D mammogram first followed by the fast MRI. Group 2 will have the fast MRI first followed by the 3D mammogram. Participants will undergo both of these tests on the same day, regardless of which group they are in. Patients will be informed of the test results after both tests have been examined by their physician; because of the timing of these tests, results will not be available for participants until both tests have been examined by their physician.

Another way to find out what your experience will be during this research study is to read the following chart. Start reading at the left side and read across to the right, following the lines and arrows.



Based on the results of the MRI or 3D mammogram, there is a possibility of a need to do additional imaging and/or biopsy if the results are suspicious for cancer. If a biopsy shows evidence of cancer, samples of the tumor may be sent for various tests.

How long will I be in this study?
You are being asked to participate in the study for a total of 4 years after your first exam. After the 1-year follow up 3D mammogram and fast MRI, you will return to your usual breast cancer screening program. We will follow the results of your routine screening tests for the next 3 years.

What extra tests and procedures will I have if I take part in this study?
Most of the exams, tests, and procedures you will have are part of the usual part of breast screenings. However, there are some extra tests that you will need to have if you take part in this research study.

Study Visit Table:

Test/Procedure	**Pre-Screen**	**First Visit**	**Second Visit**
Blood Test *for creatinine levels*	X		X
Pregnancy Test	X	X	X
3D Mammogram		X	X
Fast MRI		X	X
Questionnaire/survey		X	
Biopsy *ONLY if a tumor is detected*		X	X

You will have the following additional studies/tests before being in this research study:

- For women unsure if they could be pregnant, to determine if you are eligible to be on this research study you will be required to undergo a pregnancy test (blood or urine).The reason for this is outlined below under “reproductive considerations”.
- Blood test for creatinine levels, only if required by local site as standard of care.

You will have the following additional studies/tests during the research study:

- Fast breast MRI-all study participants
- Blood test for creatinine levels, only if required by local site as standard of care.
- A pregnancy test must only be done prior to the first and second visit imaging studies in women suspected of being pregnant or unsure of their pregnancy status as per local site standard of practice.
- Questionnaire/survey - this will be performed after the baseline fast MRI and 3D mammogram
- If a tumor is detected, a biopsy will most likely be performed to collect samples of the tumor tissue for testing or surgery may be performed to remove the tumor. The procedures and tests will be explained to you by your doctor and are part of your standard care. Copies of these reports will be sent to ECOG-ACRIN to learn more about the types of tumors detected by the different methods. If any tissue is left after these tests, and you agree, we would like to have some of the tumor tissue for research. The consent to allow ECOG-ACRIN to be given some of your tissue is at the end of this consent.
- DCIS, ductal carcinoma in situ, is the presence of abnormal cells in breast milk ducts. If DCIS is detected, your doctor may decide the tumor tissue will be sent for the DCIS score test (also known as Oncotype DX Breast Cancer Assay for DCIS, and owned by Genomic Health, Inc, Redwood, CA (GHI)). If this test is performed, tumor tissue is tested to measure a specific group of genes in the tumor. The results of the test are reported as a score (called the DCIS Score). The DCIS Score will be sent to your doctor and will be placed in your medical record. This score may be used to help assist in planning your treatment. If this test is done, a copy of the results will be sent to ECOG-ACRIN to be used to learn more about DCIS.
- You will have a breast MRI (including both breasts) on the same day as the 3D mammogram.
  MRI is a medical imaging method that uses magnets to make images of the body. MRI helps doctors to tell the difference between cancer and normal tissue in the body. MRI uses a dye (“contrast agent”) that is injected into a vein to help see images of the body’s tissues.

Questionnaires/Surveys:

- You will be asked to provide contact information for the Outcomes and Economics Assessment Unit (OEAU) located at Brown University. You will receive e-mail communications from the OEAU to help you set-up an on-line account that you will use to complete surveys and access to the website.

You will receive a survey following the baseline screening time point regarding your experience during each exam. The survey should take no more than 10 minutes to complete.

What possible risks can I expect from taking part in this study?

If you choose to take part in this research study, there is a risk that 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. In some cases, side effects can be serious, long lasting, or may never go away.

As with any medical test, you may experience anxiety from having the 3D mammogram and/or fast MRI. You should talk to your doctor if you experience any increased anxiety.

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

Possible side effects related to the <u>MRI exam</u>:

Likely:

- Anxiety/stress
- Claustrophobia
- Discomfort

Rare, but serious:

- Injury related to the presence of metallic or surgical implants or metal pieces in the body and the MR magnet; it is important that you let the MRI team know about whether you have these before the MRI procedure.

<u>Risks of MRI</u>

Because the MRI machine acts like a large magnet, it could move objects containing iron in the MRI room during your examination, which could possibly harm you. We will take precautions to prevent this from happening. Loose metal objects, like pocket knives 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.

Having an MRI may mean some added discomfort for you. In particular, you may be bothered by feelings of claustrophobia (a "closed-in" feeling) and by the loud banging noise during the test. Temporary hearing loss has been reported from this loud noise. This is why we will ask you to wear earplugs. At times during the test, you may be asked not to swallow for a while, which can be uncomfortable.

Risks and side effects related to the contrast used for MRI (called Gadolinium):

There are no likely risk or side effects related to the contrast agent used for MRI.

Less likely:

- Headache
- Nausea
- Vomiting
- Hives
- Temporary low blood pressure
- Allergic-like reaction

Rare but serious: These reactions occur in ~15/100,000 people.

- Kidney impairment

There is also a risk of death. The risk is extremely small and occurs in 1/100,000 women.

Possible side effects related to the IV Needle Placement:

Likely:

- Minor discomfort

Less likely:

- Swelling
- Bleeding
- Infection
- Bruising

Let your study doctor know of any questions you have about possible side effects. You can ask the study doctor questions about side effects at any time.

False Positives:
Based on the results of the fast MRI, a biopsy may be recommended if the results are suspicious for cancer. Some of these biopsies will be recommended for findings that turn out not to represent cancer, which are called “false positives”. You may experience anxiety because of the recommendation for a biopsy. The false positive rate of fast MR is similar to other supplemental screening tests such as regular breast MRI and is less than the false positive rate of whole breast screening ultrasound.

Patient Surveys:
You will be asked to complete patient surveys 2 weeks following the initial fast MRI and 3D mammogram. You may experience fatigue or anxiety while completing the survey.

Reproductive considerations:

This research study may involve unforeseen risks to you or to your embryo or fetus if you or your partner should become pregnant during treatment. You should not become pregnant or father a baby while on this study because the drugs in this study can affect an unborn fetus. Women should not breastfeed a baby while on this study. It is important that you understand that you need to practice responsible parenthood and use appropriate methods of birth control while on this study. Check with your study doctor about what kind of birth control methods to use and how long to use them. If you, or your partner, become pregnant while you are taking part in this study, you must tell your study doctor as soon as possible. If you are female, your treatment will be stopped.

For more information about risks and side effects, ask your study doctor or nurse.
You must not be pregnant or breast-feeding while on this study. The gadolinium enhanced MRI and screening DBT used in this study could be very damaging to an unborn baby. If you are of childbearing potential and are uncertain if you could be pregnant, you must have a blood test or urine study within 2 weeks prior to randomization to rule out pregnancy.

You are considered “of childbearing potential” if you are a woman, regardless of sexual orientation or whether you have undergone tubal ligation, if you meet the following criteria: 1) have not undergone a hysterectomy or bilateral oophorectomy; or 2) have not been naturally postmenopausal for at least 24 consecutive months (i.e., have had menses at any time in the preceding 24 consecutive months).

If you are of childbearing potential, you are strongly advised to use an accepted and effective method of contraception or to abstain from sexual intercourse for following year until the Year 1 studies are performed. Check with the study doctor about what types of birth control, or pregnancy prevention, to use while in this study.

You will not be able to participate in the study if you are pregnant or breast-feeding and cannot have the initial and 1 year follow up fast MRI and 3D mammogram. If you become pregnant while on this study, it is important the following is understood: During pregnancy, X-rays and MRI tests are usually not performed in asymptomatic subjects to avoid any possible risk to the fetus. In women who breast-feed, we prefer not to use imaging contrast agents in order to avoid any possible risk to the baby. However, in patients with breast abnormalities such as lumps or abnormal nipple discharge, these tests might be appropriate despite pregnancy or breast feeding.

What possible benefits can I expect from taking part in this study?

Taking part in this study may or may not make your health better. This research study has a chance of helping you by finding additional breast cancers on the fast MRI not detected on the 3D mammogram. It is not possible to know at this time if the study approach is better than the usual approach so this study may or may not help you. We do know that the information from this study will help doctors learn more about breast cancer screening. This study will help researchers learn things that will help people in the future.

Can I stop taking part in this 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 safely.

It is important to tell the study doctor if you are thinking about stopping so any risks from the study treatment can be evaluated by your study doctor. Another reason to tell your study doctor that you are thinking about stopping is to discuss what follow-up care and testing could be most helpful for you.
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.

The study doctor may take you out of the study:

- If your health changes and the study is no longer in your best interest
- If new information becomes available
- If you do not follow the study rules
- If the study is stopped by the sponsor, IRB or FDA.

What are my rights in this study?

Taking part in this research study is your choice. No matter what decision you make, and even if your decision changes, there will be no penalty to you. You will not lose medical care or any legal rights.

For questions about your rights while taking part in this study, call the NCI Central Institutional Review Board at 1-888-657-3711. You may also contact the study doctor at the telephone number listed on the signature page.

What are the costs of taking part in this study?

You and/or your health plan/insurance company will need to pay for some or all of the costs of screening for cancer in this study. Some health plans will not pay these costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Please note that Medicare should be considered a health insurance provider.

You will have the 3D mammogram that was originally ordered by your doctor as your routine annual screening mammogram. The cost of the 3D mammogram will be billed according to routine clinical practice and you would be responsible for any co-pays.

As part of the research study, you will also have a fast MRI. The cost of the fast MRI including the gadolinium contrast and the costs associated with placing the IV for the contrast will be borne by the study and you will not be responsible for associated costs. Therefore, participating in this study should not impact any of your costs associated with the fast MRI.

If additional imaging or biopsies are recommended or if you are diagnosed with breast cancer during the study, the costs for your care will be billed according to routine clinical practice. You and/or your health plan/insurance company will need to pay for all costs of treating your cancer, including the cost of tests, procedures, or medicines to manage any side effects, unless you are told that certain tests are being done at no charge. This study does not provide any support for treatment or tests associated with cancer care.

Patients on this study will not be financially responsible for the Oncotype DX Breast Cancer Assay for DCIS

You should contact your insurance company before enrolling in the study if you have any additional questions regarding potential costs.

You will not be paid for taking part in this research study.

What happens if I am injured or hurt because I took part in this study?
If you are injured or hurt as a result of taking part in this research study and need medical treatment, please tell your study doctor. You should seek medical help for any injury. The study sponsors will not pay for medical treatment for injury. Your insurance company may not be willing to pay for research study-related injury. If you have no insurance, you would be responsible for any costs.

If you feel this injury was a result of medical error, you keep all your legal rights to receive payment for this even though you are in a research study.

Who will see my medical information?
Your privacy is very important to us and the researchers will make every effort to protect it. Your information may be given out if required by law. For example, certain states require doctors to report to health boards if they find a disease like tuberculosis. However, the researchers will do their best to make sure that any information that is released will not identify you. Some of your health information, and/or information about your specimen, from this study will be kept in a central database for research. Your name or contact information will not be put in the database.

The ECOG-ACRIN Cancer Research Group is conducting this study. ECOG-ACRIN is a cancer research group that conducts studies for the National Cancer Institute. Your doctor is a member of ECOG-ACRIN or another group that is participating in this study. To help protect your privacy, ECOG-ACRIN has obtained a Confidentiality Certificate from the Department of Health and Human Services (DHHS). With this Certificate, ECOG-ACRIN cannot be forced (for example, by court subpoena) to disclose information that may identify you in any federal, state or local civil, criminal, administrative, legislative or other proceeding. Disclosure will be necessary, however, upon request of DHHS for audit or program evaluation purposes.

There are organizations that may inspect your records. These organizations are required to make sure your information is kept private, unless required by law to provide information. Some of these organizations are:

- The Institutional Review Board, IRB, is a group of people who review the research with the goal of protecting the people who take part in the study.
- The Colorado Cancer Research Program (CCRP) Denver, Colorado, and its research staff
- The National Cancer Institute in the U.S., and similar ones if other countries are involved in the study.
- Other regulatory agencies and/or their designated representatives
- Central Laboratories who receive your samples for testing or research
- Cancer Trials Support Unit (CTSU). The CTSU is a research group sponsored by the National Cancer Institute (NCI) to provide greater access to cancer trials.
- The ECOG-ACRIN Research Group, which is coordinating the study
- Your healthcare providers who care for you during the research study
- Outcomes and Economics Assessment Unit (OEAU) located at Brown University

Optional Studies Section:

This section is about optional studies you can choose to take part in.
This part of the consent form is about optional studies that you can choose to take part in. You will not get health benefits from any of these studies. The researchers leading this optional study hope the results will help other people with cancer in the future.

You will not be billed for these optional studies. You can still take part in the main study even if you say 'no' to any or all of these studies. If you sign up for but cannot complete any of the studies for any reason, you can still take part in the main study.

Optional Sample Collections for Biobanking for Possible Future Studies.
Researchers are trying to learn more about cancer and other health problems. Much of this research is done using samples of tissue, blood, urine, or other fluids. Through these studies, researchers hope to find new ways to prevent, detect, treat, or cure health problems.

Some of these studies may be about genes. Genes carry information about features that are found in you and in people who are related to you. Researchers are interested in the way that genes affect how your body responds to treatment.

If you participate in the main part of this study, and cancer is detected, we would like samples of the tumor tissue from your surgery or biopsies for research to learn more about cancer and other health problems. If you agree that your tumor tissue may be sent to be used for research, samples of your tumor tissue will only be sent if there is any leftover after the tests needed to determine your care. If you agree but no tumor tissue can be sent it will not affect your participation in the main part of this trial.

If an abnormality is detected and recommended for biopsy during your participation in the main part of this study, we would like samples of blood for research projects that may be done at a later date.

These specimens will be stored in a “biobank”. The Biobanks are run by ECOG-ACRIN staff and researchers and they are financially supported by the National Cancer Institute.
If DCIS is detected and samples of the DCIS tumor tissue are sent to Genomic Health, Inc. we ask that GHI be told that you are participating in this study. After the test, GHI will send the leftover tumor tissue to the ECOG-ACRIN biobank. Results of this test will be sent to your doctor and will be placed in your medical record.

If another type of cancer, called invasive, is detected, we would like to have samples of your tumor tissue for a research test which will look at the DNA in your tumor. The results of this test will not be returned to your doctor, will not be placed in your medical record, and will not affect your care. This test will be for research purposes only. We would also like to keep some of the tumor tissue for future research studies.

What is involved if you provide your samples for research?

If you agree to take part, here is what will happen next:

1. Tumor tissue samples from a biopsy or surgery will be sent to and stored in the ECOG-ACRIN Biobank.
2. About three (3) teaspoons of blood will be collected from a vein in your arm after your imaging tests.
3. With your tumor tissue and blood samples, some related health information will be stored in the Biobank. The information will be kept with samples and information from other people who took part in this or other research studies.
4. If you agree, your tumor tissue will be sent for the research studies described above.
5. The tumor tissue samples stored for research will be kept until they are used up. Information from your medical record will be updated from time to time.
6. Only qualified researchers can submit a request to use the materials stored in the Biobanks. A committee of experts at ECOG-ACRIN, and/or the National Cancer Institute, will review each request to use the samples for research. All research projects using these samples will also be reviewed by an ethics or institutional review board to ensure that the request is necessary and proper. Researchers who use your samples stored in the ECOG-ACRIN Biobank will not be given your name or any other information that could directly identify you.
7. Neither you nor your study doctor will be notified when research will be conducted or given reports or other information about any research that is done using your samples.
8. Results from the research may be placed in centralized storage systems called databases. It is possible that some of your genetic information and your health information may be placed in these databases. It is also possible that some of these databases may be public.

What are the possible risks in providing your samples for research?

- The most common risks related to drawing blood from your arm are brief pain and possibly a bruise.

- There is a risk that someone could get access to the personal information in your medical records or other information researchers have stored about you.
- There is a risk that someone could trace the information in a central database back to you. Even without your name or other identifiers, your genetic information is unique to you. The researchers believe the chance that someone will identify you is very small, but the risk may change in the future as people come up with new ways of tracing information.
- In some cases, this information could be used to make it harder for you to get or keep a job or insurance. There are laws against the misuse of genetic information, but they may not give full protection. There can also be a risk in knowing genetic information. New health information about inherited traits that might affect you or your blood relatives could be found during a study. The researchers believe the chance these things will happen is very small, but cannot promise that they will not occur.

When my samples are used for research, how will information about me be kept private?

Your privacy is very important to the researchers and they will make every effort to protect it. Here are just a few of the steps they will take:

1. When your samples are sent to the researchers, no information identifying you (such as your name) will be sent. Samples will be identified by a unique code only.
2. The list that links the unique code to your name will be kept separate from your sample and health information. Any Biobank and ECOG-ACRIN staff with access to the list must sign an agreement to keep your identity confidential.
3. Researchers to whom ECOG-ACRIN sends your sample from the Biobank and information will not know who you are. They must also sign an agreement that they will not try to find out who you are.
4. Information that identifies you will not be given to anyone, unless required by law.
5. If research results are published, your name and other personal information will not be used.

What are the Possible Benefits of allowing my samples to be used for research?

You will not benefit from taking part.
The researchers, using the samples from you and others, might make discoveries that could help people in the future.

Are there any costs or payments associated with providing my samples for research?

There are no costs to you or your insurance. You will not be paid for taking part. If any of the research leads to new tests, drugs, or other commercial products, you will not share in any profits.

What if I change my mind about allowing my samples to be used for research?

If you decide you no longer want your samples to be used, you can call the study doctor, at the telephone number listed on the signature page who will let the researchers know. Then, any samples that remain in the bank will no longer be used and related health information will no longer be collected. Samples or related information that have already been given to or used by researchers will not be returned.

Where can I get more information?
You may visit the NCI Web site at http://cancer.gov/ for more information about studies or general information about cancer. You may also call the NCI Cancer Information Service to get the same information at: 1-800-4-CANCER (1-800-422-6237).

A description of this clinical trial will be available on https://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.

Who can answer my questions about this study?
You can talk to the study doctor about any questions or concerns you have about this study or to report side effects or injuries.

Please circle your answers to show whether or not you would like to take part in each option:

SAMPLES FOR THE LABORATORY STUDIES:

If a tumor is detected, may we have some of the tumor tissue for the laboratory research studies described above?

I agree to have my samples collected and I agree that my samples and related information may be used for the laboratory studies described above.

YES **NO**

SAMPLES FOR FUTURE RESEARCH STUDIES:
If a tumor is detected, may we have some of the tumor tissue and may we keep any tumor tissue leftover after the research studies (if you participate), and if an abnormality is detected and recommended for biopsy may we have some of your blood for research in the future?

- **My samples and related information may be kept in a Biobank for use in future health research.**

YES **NO**

This is the end of the section about optional studies.

SIGNATURE

I have been given a copy of all pages of this form. I have read it or it has been read to me. I understand the information and have had my questions answered. I will contact my study doctor_____ **(name)** at _____ **(24-hour telephone number)** if I have additional questions or concerns during the study. I agree to take part in this study.

DATED_____ _____

Participant Name (Printed)

_____

Signature of Participant or
Legal Representative

DATED_____ _____

Signature of Person Conducting the
Informed Consent Discussion

_____

Telephone Number of Person Conducting
the Informed Consent Discussion

DATED_____ _____

Physician

NAMES AND ADDRESSES of <u>three</u> (3) people (other than spouse) who can always reach patient. Include at least <u>one</u> (1) from patient's hometown, if out of state.

Name: _____

Last First M.I.

Address: _____

Street

_____

City State Zip Code

Phone: _____

Full Name of Spouse:_____

_____

Name: _____

Last First M.I.

Address:_____

Street

_____

City State Zip Code

Phone: _____

Full Name of Spouse:_____

_____

Name: _____

Last First M.I.

Address _____

Street

_____

City State Zip Code

Phone: _____

Full Name of Spouse: _____