INFORMED CONSENT FOR CLINICAL RESEARCH

You have been asked to participate in a research study. In order to decide whether or not you should agree to be part of this research study, you should know enough about its risks and benefits in order to make a sound judgment. This process is known as informed consent.

A member of the study staff will explain the research study to you. Research studies include only people who choose to take part. Please take your time to make your decision about taking part. You may discuss your decision with your family and friends.

This consent form gives you detailed information about the research study. Once you understand the study, its risks, and its benefits, you will be asked to sign the form if you wish to take part. You will be given a copy to keep.

Why is this study being done?

The purpose of the study is to learn about how a woman's health history influences what her breasts looks like on an MRI and mammogram. We will also compare the information collected from the questionnaire and medical records. We hope that this will one day help identify women at high risk of developing breast cancer. If a saliva or tissue sample is collected for future use, this information will enable us to study genetic risk factors as well.

Is there a potential conflict of interest for this study?

There are no known investigator and/or institutional conflicts of interest for this study.

How was I selected to be in this study?

You are being asked to take part in this study because you have a contrast-enhanced bilateral breast MRI available at Memorial Sloan Kettering Cancer Center (MSK).

How many people will take part in the study?

Over 1,000 women will take part in this study at MSK. In total, we anticipate over 2,000 women will participate across our three participating centers (MSK, Abramson Cancer Center at the University of Pennsylvania, and the Huntsman Cancer Center at the University of Utah).

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

Before you begin the study …

The study assistant will explain the study and review the consent process. You can ask questions about the research study and then will be asked to provide informed consent.

During the study…

If you choose to take part, then you will be asked to do the following:

- Study Questionnaire: You will be asked to complete a short 5 minute eligibility screener to confirm that you are a good fit for the study and then the main questionnaire that takes about 15 minutes with a trained interviewer (in-person at clinic or via telephone) or answer the questions yourself using a secure online website. We will ask about some parts of your medical history, your reproductive history, your family history of cancer, and some health behaviors.
- Medical Record Review: We will look at your medical records to confirm details of what you answered in the study questionnaire. We will look for information on any prior benign (non-cancer) conditions, use of hormonal drugs, and whether you are pregnant or breast feeding.
- MRIs/Mammograms: We will look at recent and past copies of your MRIs and mammograms.
- Saliva Sample (optional): We are also interested in collecting a saliva sample. The Oragene Saliva Collection Kit will be used for you to provide your saliva sample and you can provide this in-person at clinic or return via postal mail. The saliva kit will be labeled with your study ID number and will not have your name on it. If you agree to provide an optional saliva sample, we will store the saliva kit and use it in the future to look at genes associated with breast cancer risk and features of breast tissue on MRIs/mammograms.
- Tissue release (optional): If you consent to tissue release, we will also look at slides and/or breast tissues if they are available.

For this study, we request two optional items for future research: a saliva sample and/or consent for release of slides or tissues, if available.

We request a saliva sample to conduct future research to identify changes in genes that may predict risk of cancer or other diseases. We may use your saliva sample to detect new genes or changes in genes that may tell us who is at risk for certain types of cancer and/or other diseases. If you allow us permission to collect tissue samples, we may also use your sample to study differences between normal and cancer cells. We may use your tissue sample(s) to study differences between normal and cancer cells or to develop new drugs which better kill cancer cells. Or some of your tissue sample may be used to make "cell lines." A cell line is a collection of cells grown from the cells taken from your body. It may last for a very long

time (many years) in a laboratory. These cell lines or your sample may be used to discover proteins or other "markers" useful in cancer diagnosis or treatment. We may also look for markers in your sample that predict who may be at higher risk of developing cancer, the side effects of treatment, or which patients are most likely to respond to treatment. Researchers at MSK may either keep indefinitely or dispose of any leftover saliva or other samples, including DNA that the samples contain.

We will make every effort to protect your privacy. DNA, saliva and other samples will be stored without personal identifiers in secure sample banks. Only study numbers will be used. If research is done on a genetic change that is already known to increase disease risk, we will protect your name and personal identifiers, but will keep a link between identifiers and the samples. Having the link will allow us to see whether the genetic marker predicts outcomes of your care and therefore learn how the marker might be useful in the care of future patients.

We will not be able to tell you any specific results of this research testing nor will we put the results in your medical record. The research will not change the care you receive at MSK, but it may be used to assist our doctors for making decisions on treating future patients. At the end of this form you will be able to choose if you will provide a saliva sample and/or permission to release tissue samples and permit us to keep your samples to learn about, prevent, or treat cancer or other diseases in the research setting. We will also ask for your permission to be contacted in the future to discuss information about your health, additional research with your samples and/or certain research findings possibly related to your sample.

After the study…

The study assistant may contact you to ask about any questionnaire answers that are unclear. If you consent to providing a saliva sample, you may also receive another request to return a saliva sample via postal mail in case your previous sample has leaked or is damaged in the mail.

If you agree, we may contact you to ask for your participation in future research projects related to breast cancer.

How long will I be in the study?

You will be in the study until you have returned all consent forms, completed the study questionnaire, had your MRI (which may have been done within the past 5 years), and provided an optional saliva sample.

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. 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.

If you agreed to provide an optional saliva sample and/or permission to release tissue, you may decide at a later date that you do not want your collected or any future collected samples to be stored in the sample bank or used for future research. If you tell us that you have changed your mind, we will not use your samples in future studies. We will destroy any portion of your sample that has not been used for research. In some case, it may not be possible to locate the samples and stop research that has already been started. In other cases, your samples may have your name and identifiers removed with no code linking them to your identity. Once your identifiers have been removed from your samples, we will not be able to stop their use in research.

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

There are no risks from the questionnaire or saliva collection. We understand some questions are personal and we ask you to do your best to provide a response. Your responses are confidential and you may withdraw from the study at any time. If any of these questions make you feel upset and you would like to discuss your feelings, we can talk with you or give you the name of a doctor if you wish.

Are there benefits to taking part in the study?

There are no direct benefits to you from being in this study. However:

- There may be benefits from what is learned.
- This study may tell us about the things that influence how a breast looks on an MRI and mammogram, and this may help us to understand changes in the breast that might be related to breast cancer.

Will I receive the results from the study?

You will receive the clinical results of the MRI and/or your mammogram from your doctor at MSK. These results are unrelated to this research study. Neither you nor your doctor will be told of the specific results of any research tests on MRIs/mammograms, questionnaire data, saliva samples or tissue samples. With your permission, we may contact you in the future about our research findings, but not your specific results.

If, at the present time, you wish to learn more about your genes and the potential for inherited risks, please speak to your doctor who can assist you with contacting the MSK Clinical Genetics Service to discuss clinical genetic testing and counseling. You and/or your insurance will be responsible for the cost of any clinical genetic testing and counseling.

Do I have to take part in this study?

Taking part in this study is voluntary. Make your choice based on what we have explained to you and what you have read about the study. Refusal to take part in the study will have no effect on your medical care.

Will my medical information be kept private?

Every effort will be made to keep your study records private. It is the responsibility of the research staff at Memorial Hospital to make sure that your records are managed to protect your privacy. If information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. Trained staff at Memorial Hospital may review your records if necessary. Access to your medical information will be limited to those listed in the Research Authorization Form, which is a part of the informed consent process.

To make sure that your results are kept private, you will be given a study number that will be used on your questionnaire and saliva sample. If your MRIs/mammograms are shared with our study collaborators, they will only contain a study number rather than your name. Questionnaire data and MRIs/mammograms will be stored in a secure password protected server that can only be accessed by people working on the study. Saliva samples will be stored in the MSK Epidemiology and Biostatistics Department, using the study number rather than your name.

It is possible that information from analyses of your samples and your medical information will be shared with other investigators or put into an access controlled online database. Only researchers who have received approval from a National Institutes of Health Data Access Committee will be allowed to access the online database. This database will not contain any identifying information about you, such as your name, address, telephone number, or social security number. Your personal identifying information will not be shared with other investigators. Your privacy is very important to us and we use many safety procedures to protect your privacy. However, we cannot guarantee that no one will ever be able to use your genetic information to identify you.

A description of this clinical trial may be available on http://www.ClinicalTrials.gov. 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 are the costs of taking part in this study?

There are no additional financial costs to you for taking part in the study:

- The MRI will be billed to your insurance company
- The saliva sample will not be billed to you or your insurance company

What happens if I am injured because I took part in this study?

You will get medical treatment if you are injured as a result of taking part in this study. You and/or your health plan will be charged for this treatment. The study will not pay for the medical treatment.

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 or concerns you have about this study. Contact the study doctor, Dr. Jonine Bernstein at (646) 888-8241 or bernstej@mskcc.org. You can also contact your own doctor with any questions.

Any hospital that does research on people has an institutional review board (IRB). This board reviews all new studies to make sure that the patient's rights and welfare are protected. The IRB at MSK has reviewed this study.

For a non-physician whom you may call for more information about the consent process, research patients' rights, or research related injury is Jorge Capote, RN, Patient Representative, telephone number: (212) 639-8254.

Additional Consent for Optional Future Studies:

The optional studies include collection of a saliva sample and/or permission to collect breast tissue to conduct future research to identify changes in genes that may predict risk of cancer or other diseases. We may use your saliva sample to detect new genes or changes in genes that may tell us who is at risk for certain types of cancer and/or other diseases. If you allow us permission to collect breast tissue samples, we may also use your sample to study differences between normal and cancer cells or DNA.

DNA, saliva and other samples will be stored without personal identifiers in secure sample banks. Only study numbers will be used. If research is done on a genetic change that is already known to increase disease risk, we will protect your name and personal identifiers, but will keep a link between identifiers and the samples at MSK. Having the link will allow us to see whether the genetic marker predicts outcomes of your care and therefore learn how the marker might be useful in the care of future patients. Researchers at MSK may either keep indefinitely or dispose of any leftover saliva or other samples, including DNA that the samples contain.

The greatest risk is release of information from health or research records in a way that violates privacy rights. It will be stated to the participant that the chance that this information will be given to an unauthorized individual without the participant's permission is very small. We will make every effort to protect your privacy.

Please provide answers to the following items for the optional future studies:

1. I agree to provide a saliva sample. ☐ Yes ☐ No
   (If the sample is not collected in the clinic, please return the saliva sample collection kit via mail. The saliva sample will be kept in a secure location and your personal identifiers will be protected.)

2. I agree to donate my tissue samples and/or slides from any breast surgeries I may have at MSK or another facility. ☐ Yes ☐ No

3. My sample may be kept for use in research to learn about, prevent, or treat cancer. ☐ Yes ☐ No

4. My sample may be kept for use in research to learn about, prevent or treat other health problems (for example: diabetes, Alzheimer's disease, or heart disease). ☐ Yes ☐ No

5. My sample can be used for research about inherited genetic factors that cause cancer as long as my personal identifiers are protected. ☐ Yes ☐ No

6. My tumor and normal samples may be used for genetic analysis to learn about the causes of cancer, as long as my personal identifiers are protected. ☐ Yes ☐ No

7. Someone may contact me in the future to ask me for more samples to be collected for biospecimen research purposes or for information about my health. ☐ Yes ☐ No

8. Someone may contact me in the future to discuss findings which may come from my sample. ☐ Yes ☐ No

9. If unavailable, I give permission to discuss research findings with a family member. ☐ Yes ☐ No

   Designated family member:

   Name: _____

   Address: _____

   _____

   Phone: _____

   Relationship _____

RESEARCH AUTHORIZATION

Research Participant Name: _____

Research Participant MRN :_____

Information about you and your health is personal. It is "Protected Health Information." We cannot use any of your health information for research unless you tell us that we can. If you take part in this research, the people or organizations that can look at your information are listed below. You will have to sign this form to tell us we have your permission to share your protected health information.

The following persons and/or organizations may use or disclose your information for purposes related to this research:

- ✓ The people in charge of the study and their assistants and support staff.

The following persons and/or organizations may look at your information for purposes related to this research:

- ✓ Members and staff of the hospital's Office of Clinical Research, Computing Resource Group that manages research databases, Data Safety Monitoring Board, and the Quality Assurance Committee.
- ✓ Members and staff of the hospital's Institutional Review Board and Privacy Board.
- ✓ The National Cancer Institute, National Institutes of Health, U.S. Food and Drug Administration, and other agencies responsible for oversight.
- ✓ The following sponsor(s) of this research: Memorial Sloan Kettering Cancer Center (MSK)
- ✓ Others: Members of research teams at participating sites including the Abramson Cancer Center at the University of Pennsylvania, the Huntsman Cancer Center at the University of Utah, and the University of Toronto.___

The following information will be used and/or disclosed for this research:

- ✓ Your entire research record.
- ✓ HIV-related information. This includes any information showing that you had an HIV-related test, have HIV infection, HIV-related illnesses or AIDS, or any information that could mean you might have been exposed to HIV. New York State requires us to obtain this consent.
- ✓ HIV-related information collected during this study if you choose to disclose it when talking to any of the staff.
- ✓ Your medical records from the hospital

- ✓ The following information: questionnaire data, MRIs/mammograms, medical record information, optional saliva samples, and optional tissue samples.

If you sign this form, it means you are giving us permission to share your protected health information. We can only share it with the people or organizations describe above. The purpose for the use and sharing of this information is to conduct this study. This signed form allows us to make sure that everyone who needs information related to this study can get it.

Your protected health information may also be used for your research treatment, to collect payment for care you receive while on the study (when applicable), and to run the business operations of the hospital.

Some of the people or organizations listed above may not be subject to privacy laws. This means they could share your information again.

You do not have to sign this form. If you do not sign it, you will not be able to take part in the study. Your health care outside the study will not be affected. The payment for your health care or your health benefits will not be affected.

You have the right to withdraw from the study at any time. If you sign this authorization form, you also the right to withdraw it at any time. If you withdraw it, we cannot use or share anymore of your research data. If the hospital has already used or shared your information, it cannot be taken back. This authorization allows us to use your information until you say we cannot use it anymore. If you want to withdraw your authorization contact Dr. Jonine Bernstein at (646) 888-8241 or bernstej@mskcc.org at the Department of Epidemiology and Biostatistics at Memorial Sloan Kettering Cancer Center.

Notice About HIV-Related Information

Once we have shared your HIV-related information, it can only be shared again if federal or state laws allow it. You have the right to ask for a list of any people who get your HIV-related information that are not listed above. There are two agencies to help protect your rights. Call them if you think you have been singled out or harmed because of HIV-related information.

- New York State Division of Human Rights (888) 392-3644
- New York City Commission of Human Rights (212) 306-7500

INFORMED CONSENT FOR CLINICAL RESEARCH

MRI Background Parenchymal Enhancement as a Risk Factor for Breast Cancer

Statement of professional obtaining consent

I have fully explained this clinical research study to the participant or his/her Legally Authorized Representative (**LAR**). In my judgment and the participant's or that of his/her Legally Authorized Representative, there was sufficient access to information, including risks and benefits to make an informed decision.

Consenting Professional Must Personally Sign & Date		
Assent (Minor between the ages of 7 and less than 18): If the participant is a minor, I have obtained his/her assent to participate in the study to the best of their ability to understand. ☐ **YES** ☐ **NO** ☐ **N/A (Adult or Child <7)**		
Consenting Professional's Signature		**Date:**
Consenting Professional's Name (Print)		

Participant's (or Legally Authorized Representative's (LAR)) statement

I have read this form with the description of the clinical research study. I have also talked it over with the consenting professional to my satisfaction. By signing below, I am agreeing to the following: (1) to voluntarily be a participant in this clinical research study (2) authorizing for the use and disclosure of my/their protected health information (data about myself) and (3) that I received a signed copy of this consent form.

Participant/LAR Must Personally Sign & Date		
Participant/LAR Signature		**Date:**
Participant/LAR Name (Print)		
LAR Relationship to Participant		

Witness Signature (If Required)

☐ **Non-English Speaking Participant Witness and/or Interpreter:** I declare that I am fluent in both English and participant's (or LAR) language and confirm that the consent discussion was appropriately translated for the participant (or LAR).

☐ **Other:** I confirm that the consent discussion was appropriate for the participant's (or LAR's) understanding of the study.

Name of Witness: _____

Signature of Witness: _____ Date: _____

The Participant/Legally Authorized Representative Must Be Provided With A Signed Copy Of This Form.