MC1137 / 11-007860

Breast Cancer Genome Guided Therapy Study (BEAUTY)

NCT02022202

Document Date: 01/17/2014

MAYO CLINIC

Name and Clinic Number

Approval Date: **January 17, 2014**
Not to be used after: **January 16, 2015**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: "MC1137: Breast Cancer Genome Guided Therapy (BEAUTY)"

IRB#: 11-007860

Principal Investigator: Dr. M. Goetz and Colleagues

Please read this information carefully. It tells you important things about this research study. A member of our research team will talk to you about taking part in this research study. If you have questions at any time, please ask us.

Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision.

To help you decide if you want to take part in this study, you should know:

- Taking part in this study is completely voluntary.
- You can choose not to participate.
- You are free to change your mind at any time if you choose to participate.
- Your decision won't cause any penalties or loss of benefits to which you're otherwise entitled.
- Your decision won't change the access to medical care you get at Mayo Clinic now or in the future if you choose not to participate or discontinue your participation.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you a signed copy of this form to keep.

If you are signing this consent form for someone else, "you" in the consent form refers to the participant.

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CONTACT INFORMATION

You can contact …	At …	If you have questions or about …
Principal Investigators: Dr. Judy Boughey Dr. Matthew Goetz Dr. Donald Northfelt Dr. Richard Gray Dr. Alvaro Moreno Aspitia Dr. Sarah McLaughlin	**Phone:** (507) 284-2511 (480) 301-8000 (904) 953-2000 **Address:** Mayo Clinic 200 First Street Southwest Rochester, MN 55905 Mayo Clinic Arizona 13400 East Shea Boulevard Scottsdale, AZ 85259 4500 San Pablo Road Jacksonville, FL 32224 (904) 953-2000	▪ Study tests and procedures ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints ▪ Withdrawing from the research study ▪ Materials you receive ▪ Research related appointments
Mayo Clinic Institutional Review Board (IRB)	**Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681	▪ Rights of a research participant

Research Subject Advocate (The RSA is independent of the Study Team)	**Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchsubjectadvocate@mayo.edu	▪ Rights of a research participant ▪ Any research-related concerns or complaints ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information
Research Billing	**Rochester, MN:** (507) 266-5670 **Florida:** (904) 953-7058 **Arizona:** (800) 603-0558	▪ Billing or insurance related to this research study

1. Why are you being asked to take part in this research study?

You are being asked to take part in this research study because you and your doctor are considering treating your newly diagnosed breast cancer with chemotherapy before your surgery (also known as neoadjuvant therapy).

2. Why is this research study being done?

The purpose of this research study is to better understand the reasons why or why not breast cancers are destroyed by standard chemotherapy. This information will be used to develop new and better cancer therapies.

The project will look at genetic changes associated with your cancer. We will compare the genetic material from your cancer tissue with the genetic material found in your blood to find the differences. By looking at this information it may be possible to identify the changes that cause your cancer to respond to standard chemotherapy. This knowledge may help allow doctors to develop better therapies for the treatment of cancer. With this knowledge, future treatments for breast cancer could become customized to a patient's unique genetic make-up.

If you are being seen in Rochester, the study will also use molecular breast imaging (MBI) to see how your cancer responds to the chemotherapy treatment. Molecular breast imaging is an imaging technique in which a tracer is injected into your arm and then a scan is done of your breasts to see how the tracer is taken up in the breasts and in the tumor. This will help your doctors to see the size of your tumor and to assess how your tumor is responding to your standard chemotherapy treatment.

3. Information you should know

Who is Funding the Study?

Mayo Clinic is funding this study.

Information Regarding Conflict of Interest:

One or more of the investigators associated with this project and Mayo Clinic have a financial interest in technology used in the research and that the investigator(s) and Mayo Clinic may stand to gain financially from the successful outcome of the research. Both the Mayo Clinic Conflict of Interest Review Board and the Institutional Review Board have reviewed the financial interest for one or more of the investigators and/or Mayo Clinic related to this research and they have determined that this financial interest poses no additional significant risk to the welfare of participants in this research project or to the integrity of the research. Additional information is available to any interested study participant regarding the details of this financial interest and how it is being managed by contacting the study coordinator or the Office of Conflict of Interest Review at (507) 284-0075.

4. How long will you be in this research study?

You will be in this study for up to 5 years after surgery.

5. What will happen to you while you are in this research study?

If you agree to participate in this research study you will need to complete the following tests and procedures:

- History and physical exam which includes weight and an assessment of your ability to perform daily activities
- Mammogram and ultrasound will be done two times: once before you begin chemotherapy and after you complete your first round of chemotherapy. A third ultrasound will be performed prior to surgery only if axillary nodes (lymph glands of the armpit) are positive at diagnosis.
- An additional mammogram will also be done after your first biopsy.
- Standard of care Magnetic Resonance Imaging scan (MRI scan)
- Research MRI scan
- Research blood tests will be done before you begin chemotherapy
- Tumor tissue biopsies will be done 3 times: before you start chemotherapy, after you complete your first round of chemotherapy, and when you have surgery
- Tumor tissue sample from surgery
- Standard of care pregnancy test
- If your cancer comes back after surgery you will be asked to return to Mayo for an exam and tissue biopsy. If you are unable to return to Mayo, you will be asked to sign a form which allows Mayo to request tissue and medical information from your treating institution.

If you are being seen in Rochester you will also be asked to participate in molecular breast imaging (MBI):

A female imaging technologist will give you an injection of a small amount of radioactive drug in a vein in your arm. In this test you will be given a drug routinely used for breast imaging.

During the test with the routine drug, the Molecular Breast Imaging will start about 5 minutes after your injection. To do the test you will be asked to sit in a chair. The technologist will position your breast between two small cameras. The cameras will apply a very light compression to your breast to make sure there is no movement during the picture. We will take two pictures of each breast. Each picture takes 10 minutes. Women with very large breasts may need 1 or 2 extra images of each breast in order to include the entire breast in the picture. Occasionally an injection may be infiltrated and a second injection may need to be given. The MBI will be done three times while you are on the study.

6. What are the possible risks or discomforts from being in this research study?

Molecular Breast Imaging Risks (Rochester only):
There is slight discomfort from inserting the needle in an arm vein to inject the radioactive drug. There is a slight risk of bruising or infection at the injection site. The amount of radiation you will receive has a low risk of harmful effects.

Mammogram Risks (Florida only):
There is a slight discomfort from compression of the breasts during a mammogram. The amount of radiation you will receive during a mammogram is low and has a low risk of harmful effects.

Biopsy Risks:
The risks of biopsies can include: pain and discomfort, bleeding, tenderness, and scarring at the biopsy site. Rarely, an infection may occur at the biopsy site.

Blood Draw and Injection Risks:
The risks of drawing blood and injection include pain, bruising, lightheadedness, and/or fainting, or rarely, infection at the site of the needle stick.

It is possible that your study doctor or nurse may ask you to donate a second blood sample. This might happen if we do not obtain enough blood the first time. If you are asked for a second blood sample, study staff will try to time it with a regularly scheduled blood draw and/or clinic visit so that you do not need to make a special trip.

Genetic Testing Risks:
This study involves testing your DNA, which is the genetic information you inherited from your parents (also known as genetic testing). If a researcher finds that results from the genetic testing performed on your samples may be useful for your health care, you have the choice to be contacted and given the choice to learn the test results. At this time, you will be given general information on the potential risks, benefits, and costs of choosing to learn the test results. The risks of learning genetic test results may include emotional upset, insurance or job discrimination, and/or changes in family relationships because test results may affect other blood relatives. No genetic test results will be put into your medical record unless you choose to learn the results of the testing.

Approval Date: **January 17, 2014**
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A Federal law, called the Genetic Information Nondiscrimination Act (GINA), generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. This law generally will protect you in the following ways:

- Health insurance companies and group health plans may not request your genetic information that we get from this research.
- Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums.
- Employers with 15 or more employees may not use your genetic information when making a decision to hire, promote, or fire you or when setting the terms of your employment.

All health insurance companies and group health plans must follow this law.

Be aware that this new Federal law doesn't protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

I am interested in learning more about my genetic test results:

If you check yes, you may be contacted by a genetic counselor who can help explain the possible risks and benefits of learning this information, as well as what these results could mean for you and your family. After talking to the genetic counselor, you will still have the option of declining to learn your test results.

If you check no, you will not be contacted about your genetic test results.

☐ Yes ☐ No Please initial here: _____Date: _____

MRI Risks:

Having an MRI may mean some added discomfort for you. In particular, you may be bothered by feelings of claustrophobia and by the loud tapping noise during the scan. If you experience a sensation of claustrophobia while in the magnet, the MRI will be immediately stopped. Some people with claustrophobia and others may feel too closed in and may not be able to tolerate MRI scanning. If you feel too confined in the MRI scanner, you can ask for medication (such as lorazepam) that will relax you before the scan is started. The MRI machine makes loud knocking sounds when it is scanning. Temporary hearing loss has been reported from this loud noise. This is why you will be asked to wear earplugs.

Pregnancy Risks:
If you are sexually active and able to become pregnant, you must agree to use one of the birth control methods listed below until the end of the study:

- Hormonal methods, such as birth control pills, patches, injections, vaginal ring, or implants
- Barrier methods (such as a condom or diaphragm) used with a spermicide (a foam, cream, or gel that kills sperm)
- Intrauterine device (IUD)
- Abstinence (no sex)

The effect of radiation, given during the molecular breast imaging scans, on a fetus (developing baby still in the womb), or on a breastfeeding infant, is unknown and may be harmful. Because of these risks, women cannot take part in this study if they are pregnant or breastfeeding.

If you are a female, you must have a negative pregnancy test in order to participate in this study unless you cannot become pregnant.

Standard of Care Risks:
Your doctor will discuss the risks of the standard chemotherapy, mammogram, ultrasound, and the breast MRI scan (magnetic resonance imaging) as these tests and procedures are part of your standard clinical care.

7. Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator if you decide to stop and you will be advised whether any additional tests may need to be done for your safety.

In addition, the Principal Investigator or Mayo Clinic may stop you from taking part in this study at any time:

- if it is in your best interest,
- if you don't follow the study procedures,
- if you become pregnant,
- if the study is stopped.

If you leave this research study early, or are withdrawn from the study, no more information about you will be collected; however, information already collected about you in the study may continue to be used.

We will tell you about any new information that may affect your willingness to stay in the research study.

8. What if you are injured from your participation in this research study?

Where to get help:

If you think you have suffered a research-related injury, you should promptly notify the Principal Investigator listed in the Contact Information at the beginning of this form. Mayo Clinic will offer care for research-related injuries, including first aid, emergency treatment and follow-up care as needed.

Who will pay for the treatment of research related injuries:

Care for such research-related injuries will be billed in the ordinary manner, to you or your insurance. Treatment costs for research-related injuries not covered by your insurance will be paid by Mayo Clinic.

9. What are the possible benefits from being in this research study?

This study will not make your health better. However, information learned from this study may benefit other patients in the future by helping to develop new and better cancer therapies.

10. What alternative do you have if you choose not to participate in this research study?

You don't have to be in this study to receive treatment for your condition. Your other choices may include standard chemotherapy, another research study, receiving no treatment at all. Talk to the Principal Investigator or your doctor if you have any questions about any of these treatments or procedures.

11. What tests or procedures will you need to pay for if you take part in this research study?

You won't need to pay for tests and procedures which are done just for this research study. These tests and procedures are:

- Molecular Breast Imaging (Rochester only)
- Research Mammogram (Florida only)
- Research MRI
- Research Blood Tests
- Research Biopsies
- Genetic testing

However, you and/or your insurance will need to pay for all other tests and procedures that you would have as part of your clinical care, including co-payments and deductibles. These tests and procedures may include:

- Breast biopsy
- Standard of care pregnancy test
- Standard of care breast examinations at time of diagnosis and prior to surgery which include:
  - Mammography
  - Ultrasound
  - MRI
- Breast surgery
- Chemotherapy

12. Will you be paid for taking part in this research study?

We will pay you $400 after you complete the study. If you don't complete the study, we will pay you $100 for completion of the first visit, $200 for completion of the second visit, and $100 for completion of the third visit. If you start the study, but stop before finishing the study you will receive payment for each completed visit.

13. What will happen to your samples?

Your sample of blood and tumor tissue from several time points through your treatment will be kept at Mayo for use as described in this study.

Your tumor tissue will be kept alive for ongoing research. Your sample will be stored forever.

Information from your samples will be sent to researchers at other institutions involved in this study. Your sample will be sent to researchers in a coded format, which protects your identity.

Identification information:
The sample will be stored at Mayo and would be given a code (instead of your name) while it is stored and when it is used in research. This code allows your sample to be used without anyone knowing that it is your sample just by looking at the label.

Information from analyses of your coded samples and your coded medical information will be put into databases along with information from the other research participants. These databases will be accessible by the Internet. The purpose of making sequence and medical information available is so that they can be used by scientific researchers to study cancer and other diseases.

- Anonymous information from the analyses will be put in a completely public database, available to anyone on the Internet.

Your coded medical information and information from more detailed analyses of your coded samples will be put in a controlled-access database. The information in this database will be available only to researchers who have received approval from Mayo Clinic.

There is a very small chance that some commercial value may result from the use of your donated sample. If that happens, you will not be offered a share in any profits.

This study will examine the genes you inherited from your parents (genetic testing), as well as the genetic changes within your tumor. If at any time, genetic results are found to have clinical relevance, IRB review and approval will be sought to notify participants of the results. You will then be contacted and given the choice to learn the test results. At that time, you will be given general information on the potential risks, benefits, and costs of choosing to learn the test results. The risks of learning genetic test results may include emotional upset, insurance or job discrimination, and/or family conflicts from learning unknown information about your parents or blood relatives. Test results will only be put into your medical record if you chose to learn the results. Sometimes results should be released only through a genetic counselor, who can help explain the possible risks and benefits of learning the results.

MAYO CLINIC

Name and Clinic Number

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Exceptions when your samples may be used without your permission:

1) When government rules allow your sample to be used without identifying you, even with a code.
2) When use of the sample is not considered human subject research.

At all other times:
-You can let Mayo use your sample.
-You can say NO to have your sample used by Mayo.

Please read the following statements and mark your choices:

1. I permit my blood samples to be stored and used in future research of breast cancer at Mayo Clinic:

☐ Yes ☐ No Please initial here: _____Date: _____

2. I permit my tissue samples to be stored and used in future research of breast cancer at Mayo Clinic:

☐ Yes ☐ No Please initial here: _____Date: _____

3. I permit my blood sample to be stored and used in future research at Mayo Clinic to learn about, prevent, or treat any other health problems:

☐ Yes ☐ No Please initial here: _____Date: _____

4. I permit my tissue sample to be stored and used in future research at Mayo Clinic to learn about, prevent, or treat any other health problems:

☐ Yes ☐ No Please initial here: _____Date: _____

5. I permit Mayo Clinic to give my sample to researchers at other institutions for future research:

☐ Yes ☐ No Please initial here: _____Date: _____

6. I permit my molecular breast imaging scans to be stored and used in future research at Mayo Clinic:

☐ Yes ☐ No Please initial here: _____Date: _____

7. I agree to allow Mayo Clinic to request my diagnostic slides/blocks:

☐ Yes ☐ No Please initial here: _____Date: _____

You may request to have your sample destroyed by writing to:

Dr. Judy Boughey
Surgery
200 First Street Southwest
Rochester, MN 55905

Dr. Matthew Goetz
Medical Oncology
200 First Street Southwest
Rochester, MN 55905

Because we cannot predict how your sample will be used in the future, we cannot promise that the samples can be retrieved and destroyed.

14. How will your privacy and the confidentiality of your records be protected?

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study.

Your tissues, blood sample, and medical information will be labeled with a code. Only Mayo has the information that matches the code to identifying information, such as your initials, birth date or medical record number. Mayo will keep the information that matches the code to this identifying information in a safeguarded database. Only very few, authorized people, who have specifically agreed to protect your identity, will have access to this database. All other researchers and personnel, including those who will be working with your samples and medical information, will not have access to any information that can be used to identify you.

Representatives from the Mayo Clinic Institutional Review Board (the committee that reviews, approves, and monitors research on human subjects) may inspect study records during internal auditing procedures. However, these individuals are required to keep all information confidential.

Approval Date: **January 17, 2014**
Not to be used after: **January 16, 2015**

During this research, information about your health will be collected. Under Federal law called the Privacy Rule, health information is private. However, there are exceptions to this rule, and you should know who may be able to see, use and share your health information for research and why they may need to do so. Information about you and your health cannot be used in this research study without your written permission. If you sign this form, it will provide that permission.

Health information may be collected about you from:

- Past, present and future medical records.
- Research procedures, including research office visits, tests, interviews and questionnaires.

Why will this information be used and/or given to others?

- To do the research.
- To report the results.
- To see if the research was done correctly.

If the results of this study are made public, information that identifies you will not be used.

Who may use or share your health information?

- Mayo Clinic research staff involved in this study.

With whom may your health information be shared?

- The Mayo Clinic Institutional Review Board that oversees the research.
- Other Mayo Clinic physicians involved in your clinical care.
- Researchers involved in this study at other institutions.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other US or government agencies in other countries) that oversee or review research.
- The sponsor(s) of this study, and the people or groups it hires to help perform this research
- A group that oversees the data (study information) and safety of this research.
- MD Anderson Cancer Center
- University of Minnesota

Is your health information protected after it has been shared with others?

Mayo Clinic asks anyone who receives your health information from us to protect your privacy, however once your information is shared outside Mayo Clinic we cannot promise that it will remain private and it may no longer be protected by the Privacy Rule.

Approval Date: **January 17, 2014**
Not to be used after: **January 16, 2015**

Your Privacy Rights

You do not have to sign this form, but if you do not, you cannot take part in this research study.

If you cancel your permission to use or share your health information, your participation in this study will end and no more information about you will be collected; however, information already collected about you in the study may continue to be used.

If you choose not to take part or if you withdraw from this study, it will not harm your relationship with your own doctors or with Mayo Clinic.

You can cancel your permission to use or share your health information at any time by sending a letter to the address below:

Mayo Clinic
Office for Human Research Protection
ATTN: Notice of Revocation of Authorization
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Subject Advocate at: researchsubjectadvocate@mayo.edu

Please be sure to include in your letter or email:

- The name of the Principal Investigator,
- The study IRB number, and /or study name, and
- Your contact information.

Your permission lasts forever, unless you cancel it.

ENROLLMENT AND PERMISSION SIGNATURES

Your signature documents your permission to take part in this research.

	/ /	: AM/PM
Printed Name	Date	Time

Signature

Person Obtaining Consent

- I have explained the research study to the participant.
- I have answered all questions about this research study to the best of my ability.

	/ /	: AM/PM
Printed Name	Date	Time

Signature