MC1734 / 17-010660

Window Trial of Abemaciclib for Surgically Resectable, Chemotherapy-Resistant, Triple Negative Breast Cancer (a BEAUTY Study*)

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*Breast Cancer Genome-Guided Therapy Study

MAYO CLINIC

Name and Clinic Number
Protocol #: MC1734 **Version Date:20Feb2024**

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RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: MC1734 - Window Trial of Abemaciclib for Surgically Resectable, Chemotherapy-Resistant, Triple Negative Breast Cancer (a BEAUTY study*)
*A Breast Cancer Genome Guided Therapy Study

IRB#: 17-010660

Principal Investigator: Matthew P. Goetz, M.D., Judy C. Boughey, M.D., and Colleagues

Key Study Information

This section provides a brief summary of the study. It is important for you to understand why the research is being done and what it will involve before you decide. **Please take the time to read the entire consent form carefully and talk to a member of the research team before making your decision.** You should not sign this form if you have any questions that have not been answered.	
It's Your Choice	This is a research study. Being in this research study is your choice; you do not have to participate. If you decide to join, you can still stop at any time. You should only participate if you want to do so. You will not lose any services, benefits or rights you would normally have if you choose not to take part.
Research Purpose	The purpose of this research is to assess how the study drug, abemaciclib, impacts tumor cells and the immune system in women with operable, non-metastatic triple negative breast cancer (TNBC) that is not eliminated with neoadjuvant chemotherapy. You have been asked to take part in this research because you have been diagnosed with TNBC and you are having neoadjuvant chemotherapy and are planning to have surgery to remove the tumor.
What's Involved	Study participation involves: • Screening including a research biopsy to see if you are eligible • Taking an oral drug, abemaciclib, for 14-21 days right before your surgery • Providing research blood samples before and after you take the study drug

	• Allowing the researchers to have tissue from your surgery or having another research biopsy if you do not have surgery • Allowing the researchers to have reports from your surgery • You will be in this study for up to 3 months until we receive the reports from your surgery
Key Information	This study is being done to gather information to help patients with TNBC. This study will take place between neoadjuvant chemotherapy and breast cancer surgery. The main discomforts are from the biopsy and may include pain and swelling at the biopsy site. The study drug, abemaciclib, may cause side effects. The most common side effects are diarrhea and belly pain, but can include more serious effects such as a blood clot.
Learn More	If you are interested in learning more about this study, read the rest of this form carefully. The information in this form will help you decide if you want to participate in this research or not. A member of our research team will talk with you about taking part in this study before you sign this form. If you have questions at any time, please ask us.

Making Your Decision

Taking part in research is your decision. Take your time to decide. Feel free to discuss the study with your family, friends, and healthcare provider before you make your decision. Taking part in this study is completely voluntary and you do not have to participate.

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 either a printed or electronic copy of this form to keep. A copy of this form will be put in your medical record.

Contact Information

If you have questions about …	You can contact …
▪ Study tests and procedures ▪ Materials you receive ▪ Research-related appointments ▪ Research-related concern or complaint ▪ Research-related injuries or emergencies ▪ Withdrawing from the research study	**Principal Investigator:** Dr. Matthew Goetz (MN) Dr. Judy Boughey (MN) **Institution Name and Address:** Mayo Clinic 200 1st Street SW Rochester, MN 55905 **Principal Investigator:** Dr. Brenda Ernst (AZ) Dr. Barbara Pockaj (AZ) **Institution Name and Address:** Mayo Clinic Hospital 5777 E. Mayo Boulevard Phoenix, AZ 85054 **Principal Investigator:** Dr. Pooja Advani (FL) Dr. Sarah McLaughlin (FL) **Institution Name and Address:** Mayo Clinic 4500 San Pablo Road Jacksonville, FL 32224

▪ Rights of a research participant	**Mayo Clinic Institutional Review Board (IRB)** **Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681
▪ Rights of a research participant ▪ Any research-related concern or complaint ▪ Use of your Protected Health Information ▪ Privacy concerns related to data collected in the European Economic Area. ▪ Stopping your authorization to use your Protected Health Information ▪ Withdrawing from the research study	**Research Participant Advocate (RPA)** **(The RPA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchparticipantadvocate@mayo.edu
▪ Billing or insurance related to this research study	**Patient Account Services** **Toll-Free:** (844) 217-9591

Other Information:
A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Website will not include information that can identify you. At most, the Website will include a summary of the results. You can search this Website at any time.

A description of this research study will also be available on http://clinicaltrials.mayo.edu. This website will not include information that can identify you. You can search this website at any time.

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 are undergoing or have completed neoadjuvant chemotherapy and are planning to have surgery for your triple negative breast cancer (TNBC).

About 104 people will take part in this research study at Mayo Clinic.

Why is this research study being done?

The immune system plays a critical role in the outcomes of women with TNBC. The purpose of this study is to assess how the drug abemaciclib impacts tumor cells and the immune system in women with operable, non-metastatic TNBC that is not eliminated with neoadjuvant chemotherapy. By doing so, we hope to determine better treatment options for people with breast cancer in the future.

Information you should know

Who is Funding the Study?
Eli Lilly and Co. and Mayo Clinic are funding this study. Lilly will pay Mayo Clinic to cover costs related to running the study.

Information Regarding Conflict of Interest:
This research has been reviewed by the Mayo Clinic Conflict of Interest Review Board and is being conducted in compliance with Mayo Clinic Conflict of Interest policies.

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.

Mayo Clinic has a financial interest in technology used in the research and that Mayo Clinic may stand to gain financially from the successful outcome of the research.

How long will you be in this research study?

It will take you about 8 weeks to complete this research study. You will complete study participation about 60 days after your surgery.

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

Before you start this study, you will sign this informed consent form.

This study will take place during the time between your neoadjuvant chemotherapy and your breast cancer surgery. This time is called a "window."
If you agree to be in the study, you will be asked to participate in the following: a screening visit, one study visit after you have completed chemotherapy where you will be provided the study drug, one visit prior to your surgery after finishing treatment with the study drug, and a telephone follow-up 30-60 days after your surgery.

If you are assigned to treatment, you will receive abemaciclib for one cycle. Abemaciclib comes in tablets (pills) that you take by mouth with water. You will take it twice per day for 14-21 days until surgery. The study team will tell you how long to take it based on when your surgery is scheduled.

Screening Visit
During this visit, we will do some tests and procedures that are part of regular cancer care to see if you are eligible to take part in this research study. These tests and procedures include review of your medical record, imaging of your cancer, and routine blood testing. Your doctor will review the results of these tests and procedures. If you aren't eligible, your doctor will tell you why. At this visit we will:

- Ask you about your medical history
- Request a portion of stored tissue from your pre-chemotherapy tumor biopsy

These exams, tests or procedures are part of regular clinical care and may be done even if you do not join the study. If you have had some of them recently, they may not need to be repeated. This will be up to your doctor.

You will also have the following procedures which are done for research purposes only:

- Needle biopsy under image guidance to evaluate for residual cancer and collect tumor tissue. This is a research procedure and you will not have to pay for it.

If there is no tumor present on biopsy, we will follow you until after you complete your surgery, and we obtain copies of the reports from your surgery. You will not receive any study drug.

If you are found to have tumor present on biopsy you will continue with the following:

First Study Visit (before starting study drug)

At this visit we will:

- Ask you about any residual chemotherapy side effects or health problems
- Give you a physical exam, including performance status, height, weight, and vital signs (blood pressure, temperature, pulse)
- Draw a blood sample for clinical lab testing
- Collect a research blood sample (70ml or about 5 tablespoons) at the same time as blood is being drawn for your health care
- Provide a kit to collect a research stool sample
- Pregnancy testing if you are able to become pregnant
- Give you a supply of study drug abemaciclib to take twice per day for 14-21 days, depending on when your surgery is scheduled
- Provide you with a drug diary for abemaciclib

Second Study Visit (prior to surgery)

At this visit we will:

- Ask you about side effects or health problems since your last visit
- Draw blood for clinical lab testing
- Collect a research blood sample (70ml or about 5 tablespoons) at the same time as blood is being drawn for your health care
- Provide a kit to collect a research stool sample
- Review your drug diary for abemaciclib
- Collect any unused abemaciclib

Surgery

After you finish study drug, you will have surgery as part of regular cancer care. During your surgery, we will request a sample of your tumor for research testing.

If you do not have surgery, you will need to have a biopsy as part of this study. This biopsy will be done for research purposes and you will not have to pay for it.

End of Study - Follow-up Telephone Call for Patients who Received Abemaciclib
After your surgery or biopsy, we will call you to see how you are doing.

Standard Therapies following Surgery
Following surgery, you may receive additional standard therapies that your doctor recommends for the treatment of your cancer. These may include radiation, other chemotherapies such as capecitabine, or adjuvant hormonal therapy (for tumors that express hormone receptors).

Below is a table that shows the procedures and study visits.

Timing	What will happen
Screening	• Request tissue from initial biopsy prior to chemotherapy and have a research biopsy done
First Study Visit	• Ask you about health problems • Routine physical exam including vital signs, height, weight and performance status • Routine blood tests • Research blood collection (about 5 tablespoons) • Research stool collection • Receive supply of abemaciclib and study drug diary and directions on when to start taking it
Days 1-14 or 1-21	• Take abemaciclib twice a day every day and record in your study drug diary
Second Study Visit (Pre-surgery visit)	• Ask you about side effects or health problems since your last visit • Routine blood tests • Research blood collection (about 5 tablespoons) • Research stool collection • Return any leftover supply of abemaciclib and study drug diary
At time of surgery	• Research tissue specimen will be requested from leftover tissue collected during your surgery NOTE: If you will not have surgery at this time, you will be scheduled to have a biopsy to collect research tissue. (You will not have to pay for this biopsy.)
End of Study: About 30-60 days after surgery	• We will call you to see how you are doing and ask you about side effects or health problems since your last visit.

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

Standard of Care Risks
Your doctor will discuss the risks of procedures performed as part of the participant's standard care as these tests and procedures are part of your standard clinical care.

Risks for delaying surgery because of complications from Abemaciclib
Treatment on this study will begin approximately 3-4 weeks after your last dose of chemotherapy and will last for 14-21 days. If you experience severe side-effects from abemaciclib, these side effects may delay surgical treatment. In the event of a prolonged delay, this may theoretically impact survival.

Risks or Side Effects from Abemaciclib (LY2835219)

Very Common Side Effects of Abemaciclib *(Side effects occurring >10% of the time)*

- Diarrhea (loose stools)
- Increase in gas (flatulence)
- Nausea (feeling sick to the stomach)
- Lack of energy
- Vomiting
- Dehydration (low levels of water in the blood)
- Weight loss
- Changes in taste
- A higher risk of infection, including upper respiratory tract, lung and pharyngitis
- Decreased neutrophil count (decreased white blood cells that fight bacterial infection which could put you at increased risk of infection).
- Decreased white blood cell count (decreased white blood cells that fight infection which could put you at increased risk of infection).
- Decreased number of red blood cells that carry oxygen which could make you feel tired (anemia)
- Decreased platelet count (decreased number of blood cells that help to clot the blood which could put you at increased risk of bleeding)
- Low appetite
- Stomach pain
- Rash
- Skin itching (pruritis)
- Increase in liver enzymes in the blood which may be a sign of liver injury

- Hair loss
- Dizziness
- Increase in creatinine in the blood without decreases in kidney function
- Watering eyes (increased lacrimation)
- Sores in the mouth (stomatitis)
- Dry mouth
- Muscle weakness

Common Side Effects of Abemaciclib *(Side effects occurring 1 to 10% of the time)*

- Low levels of sodium in the blood
- Decreased levels of a protein in the blood which could mean decreased liver function
- Increased risk of serious infection (such as sepsis – an infection in the blood) related to low infection fighting cells (neutrophils)
- Increased risk of pneumonia (serious lung infection) due to low infection fighting cells (neutrophils)
- Increased risk of blood clots (venous thromboembolic events) which may be life threatening
- Decreased levels of phosphate in the blood
- Joint aches (arthritis)
- Back pain
- Blood in the urine
- Cough
- Low blood pressure
- Constipation (hard stools)
- Headache

Uncommon Side Effects of Abemaciclib (*Side effects occurring <1% of the time)*

- Pneumonitis (lung inflammation)
- Cerebral ischemia (stroke)
- Respiratory failure – trouble breathing

Persons who are breastfeeding should not take abemaciclib.

Blood Draws
The risks of drawing blood include pain, bruising, lightheadedness, and/or fainting, or rarely, infection at the site of the needle stick.

Biopsies
Biopsies are normally performed under the guidance of an imaging technique. Most use ultrasound guidance. Some sites may use mammography or MRI. Each procedure requires a separate consent prior to the biopsy. The risks may include:

- Pain and discomfort: the amount of pain and discomfort will vary, depending on the location of the biopsy site. These risks can be discussed with the study doctor.
- Minor bleeding at the biopsy site
- Tenderness at the biopsy site
- Scarring at the biopsy site
- Rarely, an infection at the biopsy site

Uncommonly, complications from biopsies can be life threatening. As with any interventional procedure, other potentially serious complications from bleeding or organ damage may occur. These might require additional surgical intervention.

Radiation risk from biopsies
If biopsy is performed using mammography, you will be exposed to radiation during this test. The amount of radiation you would get has a low risk of harmful effects.

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 while you are on this study and for up to 3 months after your last dose of study drug:

- Bilateral tubal occlusion
- Intrauterine device (IUD)
- Barrier method (such as condoms, diaphragm, cervical cap)_with spermicidal agent
- Abstinence (no sex)
- Vasectomized partner

If you miss a period, or think you might be pregnant during the study, you must tell the Principal Investigator immediately. The Principal Investigator may ask for your permission to collect information about the outcome of your pregnancy and your newborn.

The effect of abemaciclib on a fetus (developing baby still in the womb), or on a breastfeeding infant, is unknown and may be harmful. Because of these risks, patients cannot take part in this study if they are pregnant or breastfeeding.

If you are able to become pregnant, you must have a negative pregnancy test in order to participate in this study.

Confidentiality Risks
As with all research, there is a chance that confidentiality could be compromised; however, we take precautions to minimize this risk.

Genetic Testing Risks
This study involves testing your DNA, which is the genetic information you inherited from your parents (also known as genetic testing). This testing may include whole genome sequencing (mapping your entire genetic code). You will not be notified of the genetic test results, and they will not be put into your medical record.

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.

Unforeseeable Risks:
Many side effects go away shortly after the abemaciclib is stopped, but in some cases side effects can be serious, long lasting, or may never go away. There may be a risk of death. Some side effects may not be known. Side effects may range from mild to life-threatening. Other drugs may be given to make side effects less serious and less uncomfortable. Talk to the researcher and/or your healthcare provider about side effects and ask any other questions.

Are there reasons you might leave this research study early?

Taking part in this research study is voluntary. 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 do not follow the study procedures,
- 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 or changes in the study that may affect your health or your willingness to continue in the study.

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. You will be responsible for all treatment costs not covered by your insurance, including deductibles, co-payments and coinsurance. The study will not offer free medical care or payment for any bad side effects from taking part in this 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.

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

This study may not make your health better. However, if the study treatment is effective, you may benefit by having your tumor get smaller. Researchers may also gain knowledge from this study that may help other patients in the future.

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

You do not have to be in this study to receive treatment for your condition. Your other choices may include:

- Taking part in another study
- Getting treatment or care for your cancer (including breast surgery) without being in a study

You should talk to the researcher and your regular physician about each of your choices before you decide if you will take part in this study.

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:

- Research testing on blood and tissue
- Research biopsy at Baseline (Screening)
- Research biopsy at the end of the study if you do not have surgery
- Blood testing after completion of abemaciclib and prior to surgery
- Pregnancy testing
- Study drug, abemaciclib

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. These tests and procedures include:

- Standard physical exams including performance status, height, weight and vital signs (blood pressure, temperature, pulse)

- Standard blood testing
- Standard imaging (MRI, PET/CT, mammography, ultrasound)
- Standard surgery for breast cancer

You and/or your insurance will need to pay for all other tests and procedures that are part of this research study because they are part of care for your cancer. Before you take part in this study, you should call your insurer to find out if the cost of these tests and/or procedures will be covered. You will have to pay for any costs not covered by your insurance. You will also be responsible for any co-payments or deductibles.

If you have questions about any costs to you that may result from taking part in the research, please speak with the Principal Investigator. If you wish, arrangements can be made for you to speak with someone in Patient Financial Services about these costs.

If you have billing or insurance questions call Patient Account Services at the telephone number provided in the Contact Information section of this form.

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

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

There is a very small chance that some commercial value may result from the use of your sample. This chance could include new products like a drug or a test to diagnose a disease. If that happens, you will not be offered a share in any profits.

Will your information or samples be used for future research?

We will test your tissue and blood as part of this study. In addition, we would like to keep your data and any of your unused samples for future research. You can still take part in this current study even if you do not want your sample used for future research. If you agree to give your sample, it will be the property of Mayo Clinic. Your blood samples will be stored in the Mayo Clinic laboratories in Rochester, Minnesota, for research purposes only.

Other researchers at Mayo Clinic who aren't involved with this study may ask to use your sample for future research. Researchers at other institutions may also ask for a part of your sample for future studies. Your sample will be sent to researchers in a coded format, which protects your identity.

Some future studies may examine your DNA, which is the genetic information you inherited from your parents (genetic testing). The Principal Investigator may contact you if there are findings which may be useful for your health care. You would be given general information on the potential risks, benefits, and costs of choosing to learn about the findings.

Please read the following statements and mark your choices:

I permit my leftover samples to be stored and used in future research to learn about, prevent, or treat cancer:

☐ Yes ☐ No Please initial here: _____Date: _____

I permit my samples to be stored and used in future research to learn about, prevent, or treat any other health problems (for example: causes of diabetes, heart disease, and Alzheimer's, or genetic links to alcoholism):

☐ Yes ☐ No Please initial here: _____Date: _____

I agree to have my coded genetic information and coded medical information placed in password-protected secured databases for research analyses.

☐ Yes ☐ No Please initial here: _____Date: _____

4. I agree that my study doctor, or someone on the Mayo Clinic study team, may contact me or my doctor to see if I wish to participate in other research in the future.

☐ Yes ☐ No Please initial here: _____Date: _____

Your tissue and blood will be used only for research and will not be sold.

Identifiable information such as your name, Mayo Clinic number, or date of birth may be removed from your information or samples collected in this study, allowing the information or samples to be used for future research or shared with other researchers without your additional informed consent.

You have the right to change your mind about the future use of your leftover biospecimens at any time. However, you cannot withdraw your samples from studies that have already begun. We cannot get samples back once they are shared with other researchers. In addition, it may not be possible to remove your genetic information from scientific databases once it has been de-identified.

You may request to have your sample destroyed by writing to the Principal Investigator. The address is found in the “Contact Information" section of this consent form. Because we cannot predict how your sample will be used in the future, we cannot promise that samples can be retrieved and destroyed.

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.

Various methods are used to safeguard confidentiality. Some or all of the following may be used in this study: assigning a specific code or registration number to each participant’s data and samples, research materials stored in locked areas, password protected data stored on a computer.

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 (or “authorization”) to Mayo Clinic.

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
- Eli Lilly and Co., the manufacturer of abemaciclib

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 United States agencies) 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.

In addition, individuals involved in study oversight and not employed by Mayo Clinic may be allowed to review your health information included in past, present, and future medical and/or research records. This review may be done on-site at Mayo Clinic or remotely (from an off-site location). These records contain information that directly identifies you. However, the individuals will not be allowed to record, print, or copy (using paper, digital, photographic or other methods), or remove your identifying information from Mayo Clinic.

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.

Your Rights and Permissions

Participation in this study is completely voluntary. You have the right not to participate at all. Even if you decide to be part of the study now, you may change your mind and stop at any time. You do not have to sign this form, but if you do not, you cannot take part in this research study.

Deciding not to participate or choosing to leave the study will not result in any penalty. Saying 'no' will not harm your relationship with your own doctors or with Mayo Clinic.

If you cancel your permission for Mayo Clinic 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.

Approval Date: **April 4, 2025**
Not to be used after: **April 3, 2026**

You can cancel your permission for Mayo Clinic 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
Plummer Building PL 3-02
200 1st Street SW
Rochester, MN 55905

Alternatively, you may cancel your permission by emailing the Mayo Clinic Research Participant Advocate at: researchparticipantadvocate@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 for Mayo Clinic to use and share your health information lasts forever, unless you cancel it.

Enrollment and Permission Signatures

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

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

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.

Printed Name Date (mm/dd/yyyy) Time (hh:mm am/pm)

Signature