Study Title:

MC1931 Pharmacodynamic Study of Estrogen Suppression Threshold-Directed Therapy (ESTDT) of Anastrozole as Adjuvant Therapy for Early Stage Breast Cancer

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Name and Clinic Number
Protocol #: MC1931 **Version #: Initial** **Version Date: 21Nov2022**

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RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: MC1931 Pharmacodynamic Study of Estrogen Suppression Threshold-Directed Therapy (ESTDT) of Anastrozole as Adjuvant Therapy for Early Stage Breast Cancer

IRB#: 19-006637

Principal Investigator: Tufia C. Haddad, 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 find out more about how anastrozole works to prevent recurrence of breast cancer. You have been asked to take part in this research because you have been diagnosed with estrogen receptor positive breast cancer and have been recommended to start adjuvant endocrine treatment with an aromatase inhibitor.
What's Involved	Study participation involves taking an aromatase inhibitor (AI) called anastrozole (the brand name is Arimidex®) for 8-10 weeks. Then your blood will be checked to see if: 1) the anastrozole is in your blood, and 2) the anastrozole is having an effect on your blood estrogen levels.

	If the anastrozole is working fine and lowering your blood estrogen levels, then you will be done with the study. If the anastrozole is not working well, then you will be asked to take a higher dose of anastrozole for 8-10 weeks and have your blood checked again. After this higher dose regimen, you will take 8-10 weeks of a different aromatase inhibitor, letrozole (the brand name is Femara®), for 8-10 weeks and have your blood checked a third time. After this blood test you will be done with the study. Your oncologist will determine if you should remain on letrozole following the study.
Key Information	This study will take less time than most research studies and about the same amount of time as regular care for your cancer or maybe a bit less. Post-menopausal women diagnosed with estrogen-receptor positive breast cancer are often prescribed aromatase inhibitors to control the amount of estrogen in their bodies to prevent the cancer from coming back. The risks from the aromatase inhibitors are the same whether you are on a study or not. The most common risks are those associated with a loss of estrogen: hot flashes, hair thinning, vaginal dryness, joint or bone stiffness or aches.
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.

For purposes of this form, Mayo Clinic refers to Mayo Clinic in Arizona, Florida and Rochester, Minnesota; Mayo Clinic Health System; and all owned and affiliated clinics, hospitals, and entities.

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:** Tufia C. Haddad, M.D. Brenda J. Ernst, M.D. (AZ) Konstandinos Sideras, M.D. (FL) **Phone:** (507) 284-2511 AZ: (480) 301-8000 FL: (904) 953-2000 **Institution Name and Address:** Mayo Clinic 200 First St SW Rochester MN 55905 Mayo Clinic 5777 E Mayo Boulevard Phoenix, AZ 85054 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 ▪ 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 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.

A description of this research study will be available on 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 be in this study because you have been diagnosed with estrogen receptor positive breast cancer and you have been recommended adjuvant endocrine therapy with an aromatase inhibitor.

The plan is to have about 240 women take part in this study at Mayo Clinic.

Why is this research study being done?

This study is being done to find out why some women do not respond well to the aromatase inhibitor, anastrozole (Arimidex®). Everyone in this study will receive anastrozole.

Those women who do not lower their estrogen levels with anastrozole will receive a course of a higher dose of anastrozole as well as subsequent course of a different aromatase inhibitor, letrozole (Femara®). Anastrozole (1mg daily) and letrozole (2.5 mg daily) are approved by the FDA for treatment of women diagnosed with estrogen receptor (ER) positive breast cancer. Anastrozole (10mg daily) dose is considered “investigational” by the FDA, because the safety and efficacy of this dose are unknown. Anastrozole (10mg) daily is not approved by the FDA.

Information you should know

Who is Funding the Study?
This study is being funded by the Mayo Clinic Breast Cancer Specialized Program of Research Excellence (SPORE) and the Mayo Clinic Cancer Center.

How long will you be in this research study?

You will be in this research study for up to 6 months.

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

Before You Start this Study
If you agree to be in this study, you will sign this informed consent document.

All patients will need to have the following exams, tests, or procedures to find out if you can be in the study. These exams, tests, or procedures are part of regular clinical care and may be done even if you do not join the study:

- Physical exam including complete medical history, height, weight and vital signs (blood pressure, pulse, temperature)
- Assessment of your performance status (ability to carry out daily activities)
- Routine blood tests

During this Study
We will also collect blood samples (about 2.5 tablespoons) for research before you start treatment.

You will start treatment with anastrozole, which is a tablet (pill) you take once per day with water.

If you miss a dose of anastrozole, take it as soon as possible. However, if it is almost time for your next dose, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose.

You will take anastrozole once every day for 8-10 weeks. You will need to keep a diary of when you take anastrozole and bring the diary and the medication bottles with you to your appointments.

After about 8 weeks, you will have blood testing to see if the anastrozole is in your blood and to check the levels of two types of estrogen in your blood. The two types of estrogen are E1 (estrone) and E2 (estradiol). It is expected that anastrozole will lower E1 and E2 levels.

If your blood E1 and E2 levels are sufficiently lowered by anastrozole, you will be done with the study. Your regular cancer doctor will determine if you should keep taking the anastrozole.

If your E1 and E2 levels are not sufficiently lowered by anastrozole, you will be offered to take a higher dose of anastrozole (10mg) (ANA10). If you are eligible and choose to take the higher dose, you will take it every day for 8-10 weeks. You will need to keep a diary of when you take anastrozole and bring the diary and the medication bottles with you to your appointments.

After about 2-4 weeks a nurse will call you to see how you are doing and refill your supply of ANA10.

If you are one of the first six patients to take the higher dose of anastrozole (ANA10), you will need to return to the clinic about 4-5 weeks after you start ANA10 to see the study team. You will have your blood drawn for safety testing. If everything is okay, your supply of ANA10 will be refilled.

After about 8 weeks, you will have research blood testing. Then you will discontinue the higher dose of anastrozole and start taking a different aromatase inhibitor, letrozole, which is a tablet you take once every day with water. You will take letrozole every day for 8-10 weeks. You will need to keep a diary of when you take letrozole and bring the diary and the medication bottles with you to your appointments.

You will need to come to the clinic about 30 days after your last dose of anastrozole (10 mg daily) for blood testing and to review any symptoms you may have.
After about 8 weeks of taking letrozole, you will have blood testing for research, and then you will be done with the study. Your regular cancer doctor will determine if you should keep taking letrozole or another drug.

Tests done only for research purposes are not meant to provide clinical information or help care for you. The results are only important for research. Therefore, the results of tests done with your information and samples will not be provided to you. In the rare event that a finding might affect the health of you or your family, we will contact you and you can choose whether to receive or

refuse the information. If you decide to follow up and further medical testing or care is needed, the costs will be billed to you or your insurance.

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

Risks and side effects of anastrozole (Arimidex®)

Very common risks of anastrozole *(events occurring more than 10% of the time)*

- Hot flashes - sensation of warmth and flushing accompanied by sweating in the chest, shoulders, neck, and head
- Joint pain and stiffness (arthralgia)
- Feeling weak (asthenia) or tired (fatigue)
- Thinning of the bones which may lead to a break in the bone (osteopenia, osteoporosis)

Common risks of anastrozole *(events occurring 1-10% of the time)*

- Loss of appetite
- Nausea (feeling sick to your stomach)
- Headache
- Increased cholesterol in the blood
- Drowsiness or excessive sleepiness (somnolence)
- Pain, burning, or tingling in the hand (carpal tunnel syndrome)
- Loose stools (diarrhea)
- Vomiting
- Changes in liver enzymes as seen on blood tests (ALT, AST)
- Mild hair loss (alopecia)
- Allergic reaction that may involve swelling of the face, lips, or tongue (hypersensitivity reactions)
- Bone pain
- Vaginal dryness
- Vaginal bleeding (typically occurs in the first few weeks of treatment – if it persists, tell your doctor)
- Muscle pain
- Skin rash

Uncommon risks of anastrozole *(events occurring <1% of the time)*

- Changes in liver enzymes as see on blood tests (GGT and bilirubin)
- Inflammation of the liver (hepatitis)
- Hives or rash

- Trigger finger – a thumb or finger which locks into a bent position
- Increased calcium in the blood (hypercalcemia)

Rare but serious risks of anastrozole *(events occurring 0.01-1.0% of the time)*
- Red skin rash with raised swollen papules (erythema multiforme)
- Skin rash caused by hypersensitivity reactions
- Small areas of bleeding (red or purple patches) in the skin; very rarely accompanied by joint, stomach, and kidney pain, or blood in the urine (Henoch-Schonlein Purpura)

Very Rare risks of anastrozole *(events occurring less than 0.01% of the time)*
- Extremely severe skin reaction with ulcers or blisters (Stevens-Johnson syndrome)
- Serious allergic reaction (anaphylaxis) – may involve hives, itching, shortness of breath, swelling of the lips or throat, difficulty breathing, may be life-threatening

If either of these happen to you, call an ambulance or see a doctor immediately – you may need urgent medical treatment.

Risks and side effects of letrozole (Femara®)
Some of these side effects, such as hot flashes, hair loss or vaginal bleeding, may be due to the lack of estrogen in your body.

Very Common risks of letrozole *(events occurring more than 10% of the time)*
- Hot flashes
- Fatigue
- Excessive sweating (diaphoresis)
- Bone or joint aches and pains
- Thinning of the bones which may lead to a break in the bone (osteopenia, osteoporosis)

Common risks of letrozole *(events occurring 1 to 10% of the time)*
- Increased cholesterol in the blood (hypercholesterolemia)
- Skin rash
- Headache
- Dizziness, feeling lightheaded
- Sense of discomfort or unease (malaise)
- Feeling sick to your stomach (nausea)
- Throwing up (vomiting)
- Sour stomach (indigestion)
- Difficulty passing stool (constipation)
- Loose, frequent stools (diarrhea)

- Increased or decreased appetite
- Muscle pain
- Swelling of arms, hands, legs, or feet (edema)
- Feeling down or blue (depression)
- Weight gain
- Hair thinning or loss (alopecia)
- High blood pressure (hypertension)
- Abdominal pain
- Dry skin
- Vaginal bleeding or spotting

Uncommon risks of letrozole *(events occurring less than 1% of the time)*

- Anxiety
- Nervousness
- Irritability
- Drowsiness or Excessive sleepiness (somnolence)
- Difficulty falling or staying asleep (insomnia)
- Impairment of sensation, especially of touch
- Blurred vision
- Eye irritation
- Heart palpitations
- Rapid heartbeat (tachycardia)
- Itching, hives (urticaria)
- Vaginal discharge
- Vaginal dryness
- Joint swelling and pain (arthritis)
- Breast pain
- Fever
- Excessive thirst
- Changes in taste
- Dry mouth
- Dryness of mucous membranes (like those lining nose and mouth)
- Weight loss
- Infection of the bladder and or kidney (urinary tract infection)
- Frequent urination
- Cough
- Increased level of liver enzymes in the blood

Rare risks of letrozole *(events occurring 0.01-1% of the time)*

- Weakness, paralysis or loss of feeling in any part of the body (particularly arm or leg), loss of coordination, nausea, or difficulty speaking or breathing (sign of a brain disorder, e.g. stroke)
- Sudden oppressive chest pain (sign of a heart disorder)
- Difficulty breathing, chest pain, fainting, rapid heart rate, bluish skin discoloration, or sudden arm, leg or foot pain (signs that a blood clot may have formed)
- Swelling and redness along a vein which is extremely tender and possibly painful when touched
- Severe fever chills, or mouth ulcers due to infections (lack of white blood cells).
- Severe persistent blurred vision

You should inform the doctor immediately if you experience any of the following symptoms during treatment.

- Swelling mainly of the face and throat (signs of allergic reaction)
- Yellow skin and eyes, nausea, loss of appetite, dark-colored urine (signs of hepatitis)
- Rash, red skin, blistering of the lips, eyes or mouth, skin peeling, fever (signs of skin disorder)

Risks for Pregnancy and Nursing
Because you are post-menopausal, there is very little risk that you might become pregnant. However because the drugs used in this study can affect an unborn fetus or nursing child, you must not get pregnant or nurse a child while on this study. If you become pregnant, you need to tell your doctor immediately.

Standard of Care Risks
Your doctor will discuss the risks of other tests and procedures, which are part of regular care for your cancer.

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

Genetic Information Nondiscrimination Act (GINA)
The Genetic Information Nondiscrimination Act (GINA) may help protect you from health insurance or employment discrimination based on genetic information.

The law provides that health insurance companies and group health plans

- may not ask for genetic information from this research and
- may not use genetic information when making decision about eligibility or premiums

The law will not stop health insurance companies from using genetic information to decide whether to pay claims. The law also will not help you get other types of insurance (such as: life, disability or long-term care).

Risks Associated with Genomic Testing
Despite the GINA protections and the best efforts of the research team, there may still be a risk if information about you were to become known to people outside of this study.

Genetic information is unique to you, even without your name or other identifiers. For this reason, genetic information like DNA may be used to identify you and possibly your family members. We have procedures (such as, labeling your biospecimens with a password protected code known only to select research staff) to prevent people working with your DNA from discovering if it belongs to you. However, there is the risk this can happen as new ways of tracing genetic information are being developed that may make re-identification of genetic information possible.

Unforeseeable Risks
Side effects may range from mild to severe. 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.

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.

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 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.

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

This study may not make your health better. However, it may allow you and your cancer doctor to know if your body responds well to anastrozole. It may also allow other patients with breast cancer to benefit in the future from what we learn in this research study.

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: treatment for your cancer without being on a study, treatment on a different research study, or no treatment. Talk to the Principal Investigator or your doctor if you have any questions about any of these alternative treatments or procedures.

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 samples
- Routine blood testing at the end of normal dose anastrozole (1mg)

If you are assigned to higher dose of anastrozole (10mg) and start Cycle 2, you won't need to pay for the following tests and procedures done just for this study:

- Supply of higher dose of anastrozole (10mg) for 8-10 weeks
- Clinic visit and routine and research blood testing at the end of Cycle 2 and 30 days after your last dose of higher dose anastrozole (10mg)

If you are one of the first 6 patients to continue on to Cycle 2 in the study and take the higher dose of anastrozole (10 mg), you won't need to pay for the following tests and procedures which are done just for this study:

- Routine and research blood testing for safety while you are taking anastrozole 10 mg
- Clinic visit during Cycle 2 between Days 28 and 35 just for this research study

You and/or your insurance will need to pay for all other tests and procedures that are part of this research study and/or needed for your clinical care including copayments and deductibles.

You and/or your insurance will need to pay for (standard dose) anastrozole and letrozole used in this study, because they are part of regular 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.

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 donated samples. This could include new products like a drug or a test to diagnose a disease. If that happens, you won't be offered a share in any profits.

Will your information or samples be used for future research?

Your information and samples will be sent to the Sponsor, Mayo Clinic. The Sponsor can use your data and samples for research purposes only as described in the research study. Your data and samples will be sent to the Sponsor in a coded format, which protects your identity. Mayo Clinic may destroy the samples at any time without telling you. We will test your blood as part of this study. In addition, we would like to keep your study information and samples for future research. You can still take part in this study without giving permission to use your data and samples for future research. If you agree to give your sample, it will be the property of Mayo Clinic.

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). If there are findings which may be useful for your health care, the researchers may contact Mayo Clinic, so Mayo Clinic can give you the option of learning the results. You would be given general information on the potential risks, benefits, and costs of choosing to learn about the findings.

To support future research, de-identified genetic information may be placed in databases accessible by the internet. Some of the information may be available to anyone using the internet, and some will be released only to approved researchers. Combined study information (including genomic summary results) may be published, but the information will not identify you.

Even though information traditionally used to identify you will not be shared, people may develop ways in the future to allow someone to link your genetic information back to you. For this reason, confidentiality cannot be guaranteed. It is also possible that re-identified information could be used in discriminating ways, and there could be additional unknown risks. We will make every effort to protect your confidentiality.

Please read the following statements and mark your choices:

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

☐ Yes ☐ No Please initial here: _____Date: _____

2. I permit my information and 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):

☐ Yes ☐ No Please initial here: _____Date: _____

3. 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: _____

You may withdraw your consent for future use of your information and/or samples at any time, by writing to the Principal Investigator at the address provided in the "Contact Information" section of this consent form.

Your information and/or samples would be removed from any repository where they are stored, if possible. Information and/or samples already distributed for research use will not be retrieved.

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

It is possible that information identifying your samples or your data could be removed. These samples and data will no longer be linked to you. If that were to happen, the samples and data could be used for future research studies or given to another researcher without asking for your permission.

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. All of your research samples given to Mayo Clinic will be labeled with a code number and kept in locked storage. Only your study team will be able to link your samples with your identity. No one working with your samples will know your identity. If the results of the research are made public, information that identifies you will not be used.

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.

Your health information may be collected from:

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

Your health information will be used and/or given to others to:

- Do the research.
- Report the results.
- See if the research was conducted following the approved study plan, and applicable rules and regulations.

Your health information may be used and shared with:

- Mayo Clinic research staff involved in this study
- Other Mayo Clinic staff involved in your clinical care

- The sponsor(s) of this study and the people or groups hired by the sponsor(s) to help perform this research
- The Mayo Clinic Institutional Review Board that oversees the research
- 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
- A group that oversees the data (study information) and safety of this research

How your information may be shared with others:

While taking part in this study, you will be assigned a code that is unique to you, but does not include information that directly identifies you. This code will be used if your study information is sent outside of Mayo Clinic. The groups or individuals who receive your coded information will use it only for the purposes described in this consent form.

If the results of this study are made public (for example, through scientific meetings, reports or media), information that identifies you will not be used.

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, 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.

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
201 Building 4-60
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