CA237607 / 19-011444

Phase IIB Randomized Trial of Oral Tamoxifen vs. Topical 4-hydroxytamoxifen gel vs. Control in Women with Atypical Hyperplasia, Lobular Carcinoma in Situ, or Increased Breast Cancer Risk

NCT04570956

Document Date: 01/08/2025

MAYO CLINIC

Name and Clinic Number

Approval Date: **January 8, 2025**
Not to be used after: **November 21, 2025**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: A Phase IIB Randomized Trial of Oral Tamoxifen vs. Topical 4-hydroxytamoxifen gel vs. Control in Women with Atypical Hyperplasia, Lobular Carcinoma in Situ, or Increased Breast Cancer Risk

IRB#: 19-011444

Principal Investigator: Amy C. Degnim 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 evaluate short-term changes in background breast tissue induced by oral tamoxifen or 4-OHT gel in women with atypical hyperplasia, LCIS, or Increased Breast Cancer Risk. You have been asked to take part in this research because you have atypical hyperplasia, lobular carcinoma in situ (LCIS) or Increased Breast Cancer Risk.
What's Involved	Study participation involves taking Tamoxifen or a placebo capsule by mouth and applying 4-OHT or placebo gel topically to your breast daily for 4 weeks. Prior to starting the medication and 4 weeks later you will be asked to complete some tests and exams.

	This will include: • Study visit by study healthcare provider for physical exam • A blood draw for a Complete blood count (CBC), Liver Function Tests, Creatinine, coagulation tests and a research sample • A blood test to verify your menopausal status, if needed, and/or current pregnancy status if you are of childbearing age • A digital mammogram • A molecular breast imaging study (Mayo Clinic participants only) • A survey • Donation of a small sample of breast tissue (a breast biopsy) before and after study treatment. The biopsy before study treatment may be optional in some cases. This study involves a placebo; it is by chance that you will receive oral Tamoxifen, 4-OHT gel, or a placebo.
Key Information	If you decide to participate in this study you will be randomized to either oral tamoxifen, 4-OHT gel, or a placebo. Neither you nor the investigator will know which one you are receiving. You will be taking a pill by mouth (with or without Tamoxifen) and using a gel (with or without 4- OHT). Some common side effects of Tamoxifen that are currently known include hot flashes, generalized muscle weakness, nausea, and paresthesia (tingling or prickling sensation). You may have some skin irritation from the gel. There is a small risk of bleeding or infection at the site of the blood draw or breast biopsy. Radiation exposure from mammograms and MBI are minimal. There is a possibility of a reaction to the radioactive tracer used for MBI. The risks associated with study participation are completely described later in this form, be sure to review them carefully. You will need to avoid pregnancy during and for 2 months after this treatment. There are no costs to you for being in the study.

	This study will not make your health better. However, after the study is over, you can request to have the medication you received unblinded to provide you with information about possible early side effects that you might experience on tamoxifen. This may be helpful if you elect to take tamoxifen in the future for breast cancer risk reduction. Additionally, others may benefit in the future from what we learn about tamoxifen and 4-OHT as breast cancer prevention medications. There are alternatives to taking part in this research. Your healthcare provider will discuss the other treatment options with you.
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:** Amy C. Degnim, MD **Phone:** (507) 284-4499 **Study Team Contact:** Study Coordinator Team **Phone:** (877) 588-9301 **Email:** RSTBBD@mayo.edu **Institution Name and Address:** Mayo Clinic 200 1st Street SW Rochester, MN 55905
▪ 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.

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 have atypical hyperplasia, LCIS or Increased Breast Cancer Risk. About 104 people will take part in this research study with approximately 62 people at Mayo Clinic Rochester.

Why is this research study being done?

The purpose of this research is to study very early breast tissue responses induced by oral tamoxifen and 4-OHT gel in women with atypical hyperplasia, LCIS, or Increased Breast Cancer Risk. These changes will be evaluated in breast tissue, on mammography and on molecular breast imaging (MBI).

Information you should know

Who is Funding the Study?
The National Cancer Institute is funding the study. The National Cancer Institute will pay the institution to cover costs related to running the study.

BHR Pharma, LLC is providing topical 4-OHT at no cost.

Information Regarding Conflict of Interest:
Your healthcare provider may be referring you to this research study. If your healthcare provider is also an investigator on this study, there is the chance that his or her responsibilities for the study could influence his or her recommendation for your participation. If you prefer, your healthcare provider will be happy to refer you to another investigator on the research study team for you to decide if you want to participate in the study and to see you for the research study activities while you are in the study.

How long will you be in this research study?

It will take you about 4-6 weeks to complete this research study.

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

If you agree to be in the study, we will ask you to come to Mayo Clinic for the following visits:

Pre-Treatment Visit

Prior to starting the study medication you will complete the following tests:

- Study visit by study healthcare provider for physical exam
- A blood draw for a Complete blood count (CBC), Liver Function Tests, Creatinine, coagulation tests and a research sample
- A blood test to verify your menopausal status, if needed, and/or current pregnancy status if you are of childbearing age
- A digital mammogram
- A molecular breast imaging study (Mayo Clinic participants only)
- A survey
- Donation of a small sample of breast tissue (a pretreatment research breast biopsy)

In some cases, the pretreatment research biopsy will be optional (if a recent breast biopsy was done within the last 6 months, has at least 4 normal breast lobules, that biopsy tissue is available for research studies, and no exogenous sex steroid use within 1 month prior to the biopsy). In this situation you will have the choice to *not* have a pretreatment research breast biopsy.

Please read the following statement and mark your choice for one of these options for your pre-treatment research biopsy:

Option 1: I agree to have the pretreatment research breast biopsy.

☐ Yes ☐ No Please initial here: _____Date: _____

Option 2: I agree to have the pretreatment research breast biopsy only if my diagnostic clinical biopsy is not adequate for pretreatment/ baseline research studies.

☐ Yes ☐ No Please initial here: _____Date: _____

Option 3: I do NOT agree to have the pretreatment research breast biopsy. If my diagnostic clinical biopsy is not adequate for pretreatment/baseline research studies, then I will not be able to participate in the study.

☐ Yes ☐ No Please initial here: _____Date: _____

During Treatment

A study team member will contact you by phone or by email about 1 week after you have started taking the medication to see if you have any questions or concerns.

Post-Treatment Visit

After you have completed the study medication, you will complete the following tests:

- Study visit by study healthcare provider for physical exam
- A blood draw for a Complete blood count (CBC), Liver Function Tests, Creatinine, coagulation tests and a research sample
- A digital mammogram
- A molecular breast imaging study (Mayo Clinic participants only)
- A survey
- Donating a small sample of breast tissue (a post treatment breast biopsy). This is required for all patients, and this sample of breast tissue may be obtained at the time of surgery if you are undergoing breast surgery after study treatment, or else it can be obtained with a needle breast biopsy.

During this study at both the Pre-Treatment Visit and the Post Treatment Visit, we will ask you to fill out a survey called the Breast Cancer Prevention Trial Symptom Survey to assess symptoms that you experience as a result of the study medication. We hope that you will answer all of the questions, but you can skip any questions you don't want to answer. The survey will take about 5 minutes to complete.

If you are of childbearing age, you will need to have a pregnancy test to confirm that you are not pregnant.

You will also need to verify your menopausal status. You may need to have a blood test (follicle-stimulating hormone level (FSH)) to determine your menopausal status.

If you are sexually active and able to become pregnant, you must agree to use at least one of the birth control methods (abstinence is not an allowed method) prior to study entry and for the duration of study participation, and for 2 months following the last dose of study medications.

During and after the four-week treatment period, effective and permitted birth control methods are: copper and Mirena IUD (intrauterine device), diaphragm/cervical cap/shield, spermicide, contraceptive sponge, condoms. Tubal Ligation is an acceptable form of birth control. Oral birth control pills may not be used for birth control DURING the four-week treatment period but may be resumed AFTER the post-treatment biopsy is done.

If you are eligible for the study, we will assign you by chance (like a coin toss) to the topical 4-OHT group, the oral Tamoxifen group, or a control group where you will receive no active medication. You and the Principal Investigator cannot choose your study group. Neither you nor the Principal Investigator will know which study group you are in. However, in case of an emergency, this information will be available.

This study uses a placebo. A placebo looks exactly like the study medication, but it contains no active ingredient. We use placebos in research studies to learn if the effects seen in research participants are truly from the study medication. You will be on the study medication for 4 weeks. If you have had some of the tests recently, they may not need to be repeated. This will be up to the Principal Investigator.

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 research-only tests done with your information and samples will not be provided to you. Results from the MBI breast imaging study will be shared with you (see detail in next section below). In the rare event that a research-only 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?

As with any medications, allergic reactions are possible.

Tamoxifen side effects include flushing, hot flashes, changes in menstruation, vaginal discharge, generalized muscle weakness, nausea, and paresthesia (tingling or prickling sensation). More serious side effects could include blood clot, rash, visual disturbances and increased risk of getting cataracts. Rare but serious side effects could include stroke, scarring of lungs, cancer of the uterus, severe skin rash, liver toxicity, and elevated triglycerides with risk of pancreatitis (sources: NCI CTEP: Tamoxifen Side Effects, Nolvadex USPI).

Topical 4-OHT gel can cause some skin irritation. There may be other risks of topical 4-OHT that are currently unknown.

In previous studies, up to 6% of (in 100 people receiving 4-OHT, or fewer) women have experienced skin irritation where the gel has been applied. 4-OHT gel contains 60% alcohol that is flammable so should not be applied near fire, flame or while smoking. Once dry, the gel is no longer flammable. The 4-OHT gel may also cause some of the same side effects as the oral Tamoxifen listed above, as well as possible skin irritation.

The effect of Tamoxifen or 4-OHT 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.

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

MBI and mammograms use a small dose of radiation. This has a low risk of harmful effects. Pregnant women and women who are nursing should not have a mammogram or MBI because of concerns that the radiation may affect the baby.

MBI uses an injection of a radioactive tracer, called technetium-99m sestamibi. This tracer has been safely used in clinical practice for over 30 years. Rarely, patients receiving this tracer experience mild effects such as flushing, a rash, a brief metallic taste, or an allergic reaction (rash, itching, hives, and/ or shortness of breath).

You may be asked to fast for 3 hours before your MBI test. If you do not fast, the MBI test can still be performed but the test may be better quality if you do fast.

You should be well hydrated prior to the MBI test. You may drink water, diet soda, or black coffee (no cream or sugar).

If anything concerning is found on your MBI screening test, you may be asked to return for additional testing or be recommended to have a breast biopsy.

If abnormalities are found on the MBI test, the radiologist may recommend you undergo additional clinical tests of your breast, which are not part of the study. These tests may include:

1) Diagnostic mammogram
2) Diagnostic ultrasound of the breast

3) Magnetic resonance imaging (MRI) of the breast
4) Follow up molecular breast imaging (MBI) in six months
5) Follow up ultrasound in six months
6) Fine needle aspiration (removing a small amount of breast fluid through a needle)
7) Breast biopsy (removing a small amount of breast tissue)

There is a risk of possible bleeding or infection at the site of the blood draw or core biopsy. If your biopsy clip has migrated/moved away from the biopsy location, the radiologist may need to place a new biopsy clip when the research biopsy is done.

Currently there are no specific plans for genetic testing as part of this study, but genetic testing might be performed in the future on your stored samples. 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.

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

For your safety during this study, call the study team BEFORE you take any:

- New medications prescribed by your healthcare provider
- Other medications sold over-the-counter without a prescription
- Dietary or herbal supplements

Are there reasons you might leave this research study early?

You may decide to stop at any time. You should tell the Principal Investigator/ study team 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 are pregnant or 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.

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.

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

This study may not make your health better. However, others may benefit in the future from what we learn in this study to prevent breast cancer.

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 with oral Tamoxifen or other medical options. Talk to the Principal Investigator or your doctor if you have any questions about any of these 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 the study medications, tests and procedures which are done just for this research study. These tests and procedures are covered by the study:

- Pregnancy test and/ or FSH level
- Baseline and end of treatment CBC, liver function tests, creatinine and coagulation tests
- Study visit by study healthcare provider for physical exam
- Collection and processing of biological specimens (Blood and breast tissue)
- Digital Mammogram
- MBI (Mayo only)
- Breast Cancer Prevention Trial Symptom Survey
- Tamoxifen gel and pills and/or placebo

If an abnormality is noted on the MBI and further testing or procedures are recommended to evaluate this abnormality, the study will not pay for these tests and procedures. You and 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 may include:

- Diagnostic mammography

- Diagnostic ultrasound examination
- Additional MBI test
- Breast magnetic resonance imaging (MRI)
- Fine needle aspiration
- Needle biopsy
- Breast surgery
- Cancer treatment

You will also be responsible for any co-payments and deductibles.

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?

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

If you choose to have an optional pretreatment research breast biopsy, you will receive a total of $500.00 for completing the study. This will be paid as $150 upon completion of the pretreatment research study biopsy, and the remaining $350 upon completion of study intervention and post treatment tests and biopsy.

If you do not have the optional pretreatment research breast biopsy, you will receive $350 upon completion of study intervention and post treatment tests and biopsy.

You will also receive a water bottle as a token of appreciation for participating in this study.

Payment for participation in research is considered taxable income and reportable to the Internal Revenue Service (IRS). Your name, address and Social Security number will be required to issue your payment. If you receive research payments totaling $600 or more in a calendar year, a tax Form 1099 will be sent to you. For Mayo Clinic employees, research payments are included in your paycheck with applicable taxes withheld and reported on your Form W2 after calendar year-end.

Will your information or samples be used for future research?

Unless you give your permission below, your information or samples collected for this study will not be used or shared for future research, even if the identifiable information such as your name, Mayo Clinic number or date of birth is removed.

We would like to keep your information and samples for future research. You can still take part in this current study even if you don't want your information or samples used for future research. Researchers at Mayo Clinic who aren't involved with this study may ask to use your information and/or samples for future research. Researchers at other institutions may also ask for a part of your information and/or samples for future studies. Unless you indicate otherwise, the future research may be on any topic. No direct benefits to you are expected from the future research. Your information and/or samples will only be shared consistent with your consent, and with all applicable laws and regulations.

If you approve release of your information and/or samples by checking 'yes' below, Mayo may send the information and/or samples to researchers who request them, but Mayo will not send your name, address, phone number, social security number, or any other identifying information with the information and/or samples. Your information and/or samples may be sent with a code, and only the researchers for this study at Mayo Clinic would be able to link the code to you.

Some future studies may examine your DNA, 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 reidentified 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 of breast cancer prevention at Mayo Clinic:

☐ Yes ☐ No Please initial here: _____Date: _____

2. I permit my information and samples 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: _____

3. I permit Mayo Clinic to give my information and samples to researchers at other institutions:

☐ 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.

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.

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
- Researchers involved in this study at other institutions.
- 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, 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.

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Name and Clinic Number

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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
200 1st Street SW
Plummer Building, PL 3-02
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 until the end of this study, unless you cancel it. The study does not end until all data has been collected, checked (or audited), analyzed, and reported. Because research is an ongoing process, we cannot give you an exact date when the study will end. Sometimes this can be years after your study visits and/or activities have ended.

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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