Pharmacodynamics, Pharmacogenetics, Clinical Efficacy and Safety of Cannabidiol for Gastroparesis and Functional Dyspepsia

NCT03941288

April 27, 2022

MAYO CLINIC

Name and Clinic Number

Approval Date: **April 27, 2022**
Not to be used after: **March 22, 2023**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Pharmacodynamics, Pharmacogenetics, Clinical Efficacy and Safety of Cannabidiol for Gastroparesis and Functional Dyspepsia

IRB#: 19-002483

Principal Investigator: Dr. Michael Camilleri 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 compare the effects of a cannabidiol medication versus placebo on stomach function in people with gastroparesis (a paralyzed stomach) and people with dyspepsia (an upset stomach caused by improper functioning of the stomach's muscles or nerves). You have been asked to take part in this research because you have been diagnosed with either gastroparesis or functional dyspepsia.
What's Involved	Study participation involves comparing the effects of a cannabidiol medication versus placebo on stomach function in people with gastroparesis or dyspepsia. Study participation may last about 10 weeks from the date of the first visit to the end of the study. Participants will undergo testing including gastric emptying, nutrient drink, gastric volume, as well as having blood samples drawn.

	Participants will be randomized to either cannabidiol or placebo, which will be taken for 5 weeks. Participants have a 50 percent chance of receiving placebo instead of cannabidiol medication.
Key Information	Possible side effects of cannabidiol include rash, diarrhea, a decrease in appetite, sleep disturbance, and increase risk of infections, suicidal thoughts and behaviors, and elevated liver enzymes. You will also be exposed to radiation during the Gastric Emptying and Gastric Volume test, but the amount of radiation that you receive has a low risk of any harmful effects. Others with gastroparesis and functional dyspepsia may benefit in the future from what we learn in this research study. This research study is voluntary and you may choose not to take part in this study. Cannabidiol is a liquid taken by mouth, and it was recently approved by FDA for use in patients with a seizure disorder. It may reduce pain arising from internal organs such as the stomach.
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.

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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. Michael Camilleri **Phone:** (507) 266-2305 **Study Team Contact:** Maggie Breen-Lyles **Phone:** (507) 293-0237 Ann Taylor **Phone:** (507) 266-3421 Deb Eckert RN **Phone:** (507) 538-5860 Monique Torres **Phone:** (507) 538-6599 Irene Busciglio **Phone:** (507) 266-6615 **Institution Name and Address:** Mayo Clinic 200 First 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 Subject Advocate (RSA)** **(The RSA is independent of the Study Team)** **Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchsubjectadvocate@mayo.edu

If you have questions about …	You can contact …
▪ 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 been diagnosed with gastroparesis (a paralyzed stomach) or functional dyspepsia (an upset stomach caused by improper functioning of the stomach's muscles or nerves).

Why is this research study being done?

This research will compare the effects of a cannabidiol medication versus placebo on stomach function in people with gastroparesis (a paralyzed stomach) and people with dyspepsia (an upset stomach caused by improper functioning of the stomach's muscles or nerves.

Information you should know

Who is Funding the Study?
The National Institutes of Health is funding the study. The National Institutes of Health will pay your study doctor or the institution to cover costs related to running the study.

Information Regarding Conflict of Interest:
There are no individual or institutional conflicts of interest related to this study.

How long will you be in this research study?

You will be in this study for about 10 weeks from the date of the first visit to the end of the study. This includes the screening and baseline visits, the study medication period, and end of study visits.

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

If you agree to be in the study, you will be asked to participate in the following:

Screening visit:
You will come to the Clinical Research Trials Unit (CRTU) on Charlton 7, fasting is not required.

After discussing the study and having a chance to have your questions answered, you will be asked to sign the informed consent form. During this visit, we will give you some questionnaires and review your medical history to see if you are eligible to take part in this research study. The Study Physician will review the results. If you aren't eligible, we will tell you why.

At this visit we will:

- Ask you about your medical history and current medications or supplements
- Perform a physical exam, including measuring your height, weight, and "vital signs" (blood pressure, temperature, heart and breathing rates)
- Females of child-bearing potential will be asked to have a urine pregnancy test which must be negative
- Ask you to complete questionnaires about your general health and well-being and any bowel issues you have experienced during the past year
- Draw a blood sample to check on your ability to receive the medication safely and for DNA (genetic testing).
- The study physician will decide if you need any additional blood/urine tests to determine your eligibility
- Provide you with a study schedule of visits

This visit will last approximately 1 to 1.5 hours.

Baseline Visits:

You will have the following test done. The Gastric Emptying test and Medication Dispense visit can be combined on the same day. If you have not previously completed a Gastric Emptying test, your baseline Gastric Emptying test may be used to determine eligibility and can be combined with your screening visit.

Baseline Gastric Emptying Test: You will come to the CRTU after an 8 hour fast (nothing to eat or drink prior to your visit). Refrain from alcohol use for 48 hours prior to testing. Refrain from caffeine (e.g., tea, coffee, energy drinks, and caffeine-containing sweets) for 24 hours before and until the end of testing. Notify the study team in advance if you have any food allergies or intolerances. Diabetic volunteers should bring their own insulin medications and supplies.

At this visit we will:

- Females of child-bearing potential will be asked to have a urine pregnancy test (which must be negative) within 48 hours prior to this test.
- Measure your "vital signs" (blood pressure, temperature, heart and breathing rates)
- Measure your height and weight
- Test your fasting blood glucose by sticking your finger for a drop of blood, if you are diabetic
- Administer the Gastric Emptying Test: The test involves eating a 320 kcal meal of scrambled eggs, 1 slice of bran bread toast and 1 cup of skim milk within 10 minutes (Notify the study team in advance if you have any allergies or intolerances to these foods). The eggs in this meal contain a small amount of radioactive material. This allows us to time the movement of food through your stomach by taking pictures (scans) through the use of an external camera.
- At the completion of the breakfast test meal, you will be instructed to stand in front of a special camera and pictures will be taken at specific intervals. Each of these scans will take approximately 5 minutes. This entire test takes about 4 hours to complete. Please do not eat or drink anything (except the meals provided and water) until after the 4 hour scan.

This visit will last approximately 4 to 5 hours.

Randomization and study medication dispensed:

You will report to the CRTU, fasting is not required unless you are combining this visit with the Baseline Gastric Emptying test.

At this visit we will:

- Measure your "vital signs" (blood pressure, temperature, heart and breathing rates)
- Females of child-bearing potential will be asked to have a urine pregnancy test (which must be negative) within 48 hours prior to study medication being dispensed.
- Dispense a five-week supply of your study medication with instructions on how to stepwise increase the dose of medication in accordance with guidance from FDA, as detailed below. You will be randomized to the 20mg/kg of Cannabidiol treatment group or the placebo group (inactive). A placebo contains no active ingredient. Your chance of receiving the study medication is 50%, like the flip of a coin.
- The starting dosage is 2.5 mg/kg twice daily (5 mg/kg/day). You will receive a Dosing Information sheet which shows the amount of study medication to ingest.
- You will receive a separate form called Patient Medication Guide, which is information provided by the Food and Drug Administration to inform patients receiving the study medication of potential risks.
- After one week, you will be contacted by phone by a member of the study team. If there are no side effects, the dosage may be increased to a maintenance dosage of 5 mg/kg twice daily (10 mg/kg/day).
- After 2 weeks you will be contacted by phone by a member of the study team. If there are no side effects, the dosage will be increased to a 10mg/kg twice daily to a maximum of 20mg/kg.
- Equal amounts of placebo will be provided to correspond to the amounts shown for cannabidiol medication.
- During the treatment, you will be asked to complete daily diaries that document your symptoms.

End of Treatment Testing:

You will have the following tests and procedures at the end of the 4th week of study treatment. The Gastric Volume and Nutrient Drink tests are combined on the same day. You will still be self-administering the medication daily on the morning of the test while you are still fasting.

Take your study medication in the morning before you come in for the end of treatment testing. Do not eat anything for at least 8 hours before you attend the Clinical Research Unit for testing.

- Note this time and provide this time to the nurse/study staff so they can document the time of your dosing that day.

Gastric Volume Test
You will come to the CRTU after an 8 hour fast (nothing to eat or drink prior to your visit). Refrain from alcohol use for 48 hours prior to testing. Refrain from caffeine (e.g. tea, coffee, energy drinks, and caffeine-containing sweets) for 24 hours before and until the end of testing. Note this test and the baseline buffet meal must occur on the same day.

At this visit we will:

- Females of child-bearing potential will be asked to have a urine pregnancy test (which must prove negative) within 48 hours prior to this test.
- Administer the Gastric Volume Test: This test involves SPECT imaging to measure the volume of your stomach with an external camera that revolves around the abdomen, while you are lying on a mattress and table. Stomach volume will be checked during fasting, starting 10 minutes after an intravenous injection of a radioactive material.
- You will ingest 300 mL of a liquid nutrient drink (flavored Ensure) and one more image of the stomach will be obtained over the next 30 minutes.

This visit will last approximately 1 hour.

Nutrient Drink Test
One hour after drinking Ensure for the Gastric Volume Test the Nutrient Drink test will start.

At this visit we will:

- Administer the Nutrient Drink Test: This test involves drinking Ensure at a rate of one ounce per minute until you cannot tolerate any more. At the same time, you will record your symptoms while you drink the Ensure and 30 minutes after you have reached the maximum volume you could bear.

This visit will last approximately 60-90 minutes.

Gastric Emptying Test

- Same as Baseline Gastric Emptying Test, this visit will last approximately 4-5 hours.
- Draw blood sample for end of one month treatment tests. This sample will study your serum transaminases (ALT and AST) and total bilirubin levels.
- Collect the daily diaries that document your symptoms.
- You will meet with a study physician to discuss any symptoms or changes to your health.

The day following this visit, you will start the de-escalation plan described in your Dosing Information sheet.

End of Treatment Visit (optional)
At this visit we ask that you return any unused medication so Mayo may properly dispose of the medication. If this visit means that you will be traveling a good distance, we will give you a medication disposal bag with instructions during your last testing day on how to dispose of the remaining medication properly. This medication should not be flushed down the toilet/sink or kept any longer than when you have completed the de-escalation of the medication as it expires at that time.

This visit will last approximately 10-20 minutes.

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?

Most common side effects of Cannabidiol are as follows:

- Rash
- Diarrhea
- Decrease in appetite
- Sleep disturbance
- Liver dysfunction including elevated liver enzymes, itching, jaundice (whites of eyes and skin turns yellow)
- Somnolence
- Fatigue
- Increase risk of infections
- Suicidal thoughts and behaviors
- Risk of injury if operating heavy machinery

If you develop any of these side effects, you are asked to contact a member of the study team as shown in contact information on page 3 of this consent form.

If you develop any clinical signs or symptoms suggestive of hepatic dysfunction (e.g., unexplained nausea, vomiting, right upper quadrant abdominal pain, fatigue, anorexia, or jaundice and/ or dark urine); a blood draw to test serum transaminases (ALT and AST) and total bilirubin levels will be performed.)

As with any medication, allergic reactions are a possibility, including itching, rash, or difficulty breathing.

There may be other risks of Cannabidiol that are currently unknown.

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

Radiation: You will be exposed to radiation during the Gastric Emptying and the Gastric Volume tests in this research study. The amount of radiation you will receive has a low risk of harmful effects.

Test Meals: Participation in this study requires the consumption of standardized test meals. You should inform the study team if you have any food allergies or intolerances.

Questionnaires: During this study, we will ask you to fill out questionnaires about emotional health and mood. Some questions you will be asked to answer in the study questionnaires may make you feel uncomfortable. You may choose not to answer any questions that make you feel uncomfortable.

Genetic Testing: This study involves testing your DNA, which is the genetic information you inherited from your parents (also known as genetic testing). You will not be notified of the genetic test results for it may take several years for an accurate interpretation of the results to be developed and they will not be put into your medical record.

Pregnancy and Birth Control:
Women of child-bearing-potential will be able to participate in this study if they have a negative pregnancy test and agree to use acceptable birth control (see below) since the risks to an unborn child are either unknown or potentially serious.

- Surgical sterilization
- Approved hormonal methods, such as birth control pills, patches, injections, vaginal ring, or implants

- Barrier methods (such as a condom or diaphragm) used with a spermicide (a foam, cream, or gel that kills sperm)
- Intrauterine device (IUD)
- Abstinence (no sex)

There is not enough medical information to know what the risks might be to a breast-fed infant or to an unborn child carried by a woman who takes part in this study. Breast-feeding mothers must stop breast-feeding to take part in this study.

As part of this study a pregnancy test is required for all women who are able to become pregnant. Urine pregnancy tests will be done (at the beginning and end of the study and throughout the study whenever you will be exposed to radiation and/or start your medication) on all women of child bearing potential. You will be told the results of the pregnancy test. If the pregnancy test is positive, you will not be able to take part in the study. If you are postmenopausal, it must be documented in your medical history. This will confirm your postmenopausal status and no urine pregnancy testing will be required of you.

Are there reasons you might leave this research study early?

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

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. 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. Others who have gastroparesis or functional dyspepsia may 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?

This study is only being done to gather information. You may choose not to 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:

- Vital signs
- Physical exam
- Questionnaires
- Blood tests
- Urine pregnancy tests
- Height and Weight
- Placebo/Study Medication
- Gastric Emptying test
- Nutrient Drink test
- Height and Weight
- Placebo/Study Medication
- Gastric Emptying test
- Nutrient Drink test
- Gastric Volume test

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

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 be paid $800 if you complete the whole study. If you don't complete the study, we will pay you part of the money. You will be paid $200 for completing baseline tests and $200 for completing the Clinical Research Unit visit after 2 weeks of treatment. You will receive $200 for completion of 4 weeks of treatment and you will be paid $200 upon completion of the end of treatment testing. Payment for participation in research is considered taxable income and reportable to the Internal Revenue Service (IRS). Accounts Payable at Mayo Clinic will be given your name, address and Social Security number in order to issue a check for your study participation. 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.

If you live more than 50 miles away, you are eligible for reimbursement of travel expenses including lodging, up to a total of $400. In order to receive reimbursement, you must provide a copy of the original receipts for those expenses.

There is a very small chance that some commercial value may result from the use of your sample. This 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?

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.

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 gastroparesis or functional dyspepsia 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.

We will be storing research material in secure areas and password-protecting study data stored on computers.
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 about you from:

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

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

- 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.
- The Mayo Clinic Institutional Review Board that oversees the research.
- 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.

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.

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 Subject Advocate at: researchsubjectadvocate@mayo.edu.

Please be sure to include in your letter or email:

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

Your permission 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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Name and Clinic Number

Approval Date: **April 27, 2022**
Not to be used after: **March 22, 2023**

Enrollment and Permission Signatures

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

	/ /	: AM/PM
Printed Name	Date	Time

Signature

Person Obtaining Consent

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

	/ /	: AM/PM
Printed Name	Date	Time

Signature