MAYO CLINIC

Name and Clinic Number

Approval Date: **June 3, 2020**
Not to be used after: **June 2, 2021**

RESEARCH PARTICIPANT CONSENT AND PRIVACY AUTHORIZATION FORM

Study Title: Pilot Study of the Effect of Liraglutide on Weight Loss and Gastric Functions in Obesity

IRB#: 15-001783

Principal Investigator: Dr. Camilleri and Colleagues

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

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

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

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

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.

If you decide to take part in this research study, you will sign this consent form to show that you want to take part. We will give you a copy of this form to keep. A copy of this form will be put in your medical record.

MAYO CLINIC

Name and Clinic Number

Approval Date: **June 3, 2020**
Not to be used after: **June 2, 2021**

CONTACT INFORMATION

You can contact …	At …	If you have questions about …
Principal Investigator(s): Dr. Michael Camilleri **Study Team Contact:** Deb Eckert Ann Taylor Irene Busciglio	**Phone:** (507) 776-2305 **Phone:** (507) 538-5860 (507) 266-3421 (507) 266-6615 **Address:** 200 First Street SW Rochester, MN 55905	▪ Study tests and procedures ▪ Research-related injuries or emergencies ▪ Any research-related concerns or complaints ▪ Withdrawing from the research study ▪ Materials you receive ▪ Research-related appointments
Mayo Clinic Institutional Review Board (IRB)	**Phone:** (507) 266-4000 **Toll-Free:** (866) 273-4681	▪ Rights of a research participant
Research Subject Advocate **(The RSA is independent of the Study Team)**	**Phone:** (507) 266-9372 **Toll-Free:** (866) 273-4681 **E-mail:** researchsubjectadvocate@mayo.edu	▪ Rights of a research participant ▪ Any research-related concerns or complaints ▪ Use of your Protected Health Information ▪ Stopping your authorization to use your Protected Health Information
Patient Account Services	**Toll Free:** (844) 217-9591	▪ Billing or insurance related to this research study

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

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

You are being asked to take part in this research study because you have been identified as someone who is healthy and overweight or obese.

2. Why is this research study being done?

This study is being done to assess the stomach emptying effect of a maximum dose of 3 mg Liraglutide compared to placebo in subjects who are overweight or obese. Liraglutide is a medication approved by the Food and Drug Administration (FDA) for routine clinical use.

The plan is to have about 200 people aged 18 to 65 complete this study at Mayo Clinic.

3. 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:

- This research has been reviewed by the Mayo Clinic Conflict of Interest Review Board and is being conducted in compliance with Mayo Clinic Conflict of Interest policies.
- Both the Mayo Clinic Conflict of Interest Review Board and the Institutional Review Board have reviewed the Financial Conflict of Interest for one or more of the investigators and/or Mayo Clinic related to this research and they have determined that this Financial Conflict of Interest poses no additional significant risk to the welfare of participants in this research project or to the integrity of the research.
- Additional information is available to any interested study participant regarding the details of this Financial Conflict of Interest and how it is being managed by contacting the study coordinator or the Office of Conflict of Interest Review at 507-284-0075.

- One or more of the investigators associated with this project and Mayo Clinic have a Financial Conflict of Interest in technology used in the research and that the investigator(s) and Mayo Clinic may stand to gain financially from the successful outcome of the research.

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

You will be in this study for about 18 weeks from the date of the first visit to the end of the study.

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

The following summarizes the activities involved in the study:

Screening:
You will come to the Clinical Research Trials Unit (CRTU).

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) within 48 hours prior to this test
- Record the electrical activity of your heart by performing an electrocardiogram (ECG)
- Ask you to complete 8 questionnaires about your general health and well-being and any bowel issues you have experienced during the past year
- The study physician will decide if you need any additional blood/urine tests to determine your eligibility

This visit will last approximately 1 to 1.5 hours.

Baseline Period:
You will have the following tests and procedures. Note: There must be one day between the Gastric Emptying test and the Gastric Volume Test.

Baseline Gastric Emptying Test and DEXA body composition scan: 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, 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.

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
- Measure your hip and waist circumference and upper arm skin fold thickness
- Test your fasting blood glucose by sticking your finger for a drop of blood
- Administer the Gastric Emptying Test: The test involves eating a meal of scrambled eggs, 1 slice of bran bread toast and 1 cup of skim milk within 10 minutes. The eggs in this meal contain a small amount of radioactive material (Notify the study team in advance if you have any allergies or intolerances to these foods). 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 5 hours to be completed. Please do not eat or drink anything (except water) until after the 4 hour scan.
- Administer the DEXA body composition scan: You will have your total body fat measured using an external machine (called DEXA) that uses a very small dose of x-ray. This involves lying (face up) on an x-ray bed for about 15 minutes.

Baseline Nutrient Drink 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.

At this visit we will:

- Place an IV catheter in your forearm for repeated blood draws at fasting, 15, 45 and 90 minutes.
- Draw a blood sample for DNA (baseline test only)
- 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 2 hours.

Baseline 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. Buffet meal to follow approximately 5 hours later.

Baseline Buffet Meal:
You will report to the CRTU about 5 hours after your Gastric Volume test. Notify the study team in advance if you have any food allergies or intolerances.

At this visit:

- You will be given a meal of lasagna, pudding and milk and allowed to eat as much of each item as you wish until you are full.

This visit will last approximately 30-45 minutes.

Randomization and study medication dispensed:
You will report to the CRTU fasting.

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.
- Measure your height and weight
- Measure your hip and waist circumference and upper arm skin fold thickness
- Measure your fasting blood glucose by sticking your finger for a drop of blood
- Give you the *Mayo Clinic Diet* book, which is a commercially available education manual for weight loss, and have you meet with a Behavioral Interventionist to discuss the *Mayo Clinic Diet* and receive guidance in healthy lifestyle changes
- Instruct you how to self-inject the study medication
- Dispense a four-week supply of your study medication with instructions. You will be randomized to the 3 mg of Liraglutide treatment group or the placebo group (inactive). A placebo contains no active ingredient. We will supply all needles and supplies needed for you to self-administer your study medication. You will also receive instructions how to store the study medication.
- You will be asked to record the date and time that you take your injections on a daily medication diary for the remainder of the study.

This visit will last approximately 1 to 1.5 hours.

Dose Escalation Period

Your self-injection of the study medication will begin on the date scheduled for you and continue daily as instructed. The first weeks of dosing will involve an escalation of the dose.

Study medication dose escalation visits:

You will come to the CRTU weekly at an agreed upon time for a minimum of four visits to receive your dose escalations of study medication. Bring your study medication and supplies to these visits. You will continue to self-inject your study medication. These visits will last approximately 15 minutes.

Treatment Period

Month 1 Study medication dispensed:
You will report to the CRTU fasting. Bring your study medication and supplies to this visit.

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 study medication being dispensed.
- Measure your "vital signs" (blood pressure, temperature, heart and breathing rates)
- Measure your height and weight
- Measure your hip and waist circumference and upper arm skin fold thickness
- Measure your fasting blood glucose by sticking your finger for a drop of blood
- Have you meet with a Behavioral Interventionist to discuss the *Mayo Clinic Diet* and receive guidance in healthy lifestyle changes.
- Dispense your four-week supply of study medication and you will self-inject your study medication for 4 more consecutive weeks.

This visit will last approximately 1 hour.

Interim Gastric Emptying Test:
After receiving approximately 5 weeks of study medication, you will come to the CRTU at the prescheduled time after an overnight fast (nothing to eat or drink except water for 8 hours prior to your visit). Refrain from alcohol use for 48 hours prior to testing. Refrain from caffeine (e.g. tea, coffee, energy drinks, caffeine-containing sweets) for 24 hours before and until the end of testing.

- Self-inject your study medication before you come in for the testing.
- Note this time and provide this time to the nurse/study staff so they can document the time of your dosing that day.

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
- Measure your hip and waist circumference and upper arm skin fold thickness
- Test your fasting blood glucose by sticking your finger for a drop of blood

- Administer the Gastric Emptying Test: The test involves eating a meal of scrambled eggs, 1 slice of bran bread toast and 1 cup of skim milk within 10 minutes. 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 test takes about 5 hours to be completed. Please do not eat or drink anything (except water) until after the 4 hour scan.

Month 2 Study medication dispensed:
You will report to the CRTU fasting. Bring your study medication and supplies to this visit.

At this visit we will:

- Females of child-bearing potential will be asked to have a urine pregnancy test (which must negative) within 48 hours prior to study medication being dispensed.
- Measure your "vital signs" (blood pressure, temperature, heart and breathing rates)
- Measure your height and weight
- Measure your hip and waist circumference and upper arm skin fold thickness
- Measure your fasting blood glucose by sticking your finger for a drop of blood
- Have you meet with a Behavioral Interventionist to discuss the *Mayo Clinic Diet* and receive guidance in healthy lifestyle changes.
  Dispense your four-week supply of study medication and then you will self-inject for 4 consecutive weeks.

This visit will last approximately 1.5 hours.

Month 3 Study medication dispensed:
You will report to the CRTU fasting. Bring your study medication and supplies to this visit.

At this visit we will:

- Females of child-bearing potential will be asked to have a urine pregnancy test (which must negative) within 48 hours prior to study medication being dispensed.
- Measure your "vital signs" (blood pressure, temperature, heart and breathing rates)
- Measure your height and weight
- Measure your hip and waist circumference and upper arm skin fold thickness
- Measure your fasting blood glucose by sticking your finger for a drop of blood

- Have you meet with a Behavioral Interventionist to discuss the *Mayo Clinic Diet* and receive guidance in healthy lifestyle changes.
- Dispense your four-week supply of study medication and then you will self-inject for 4 consecutive weeks.

This visit will last approximately 1 hour.

End of Treatment Testing:
You will have the following tests and procedures. Note: There must be one day between the Gastric Emptying test and the Gastric Volume Test.

- Self-inject your study medication in the morning before you come in for the 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 Emptying Test
Same as Baseline Gastric Emptying Test, 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 test takes about 5 hours to be completed

Nutrient Drink Test
Same as Baseline Nutrient Drink Test, this visit will take approximately 2 hours.

Gastric Volume Test
Same as Baseline Gastric Volume Test, this visit will take approximately 1 hour.

Buffet Meal
Same as Baseline Buffet Meal, this visit will take approximately 30-45 minutes.

DEXA Body Composition Scan
Same as Baseline DEXA Body Composition Scan, this visit will take approximately 30 minutes.

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

Most common side effects of Liraglutide are as follows:

- bladder pain
- bloody or cloudy urine
- cough or hoarseness
- diarrhea
- difficult, burning, or painful urination
- fever or chills
- frequent urge to urinate
- general feeling of discomfort or illness
- headache
- joint pain
- loss of appetite
- lower back or side pain
- muscle aches and pains
- nausea
- runny nose
- shivering
- sore throat
- sweating
- trouble sleeping
- unusual tiredness or weakness
- vomiting

Liraglutide may cause serious side effects, including:

- **Inflammation of your pancreas (pancreatitis).** Stop using Saxenda® and call your health care provider right away if you have severe pain in your stomach area (abdomen) that will not go away, with or without vomiting. You may feel the pain from your abdomen to your back
- **Low blood sugar (hypoglycemia).** Your risk for getting low blood sugar may be higher if you use liraglutide with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin

  Signs and symptoms of low blood sugar may include:
  - dizziness or light-headedness
  - blurred vision
  - anxiety, irritability, or mood changes
  - sweating
  - slurred speech
  - hunger
  - confusion or drowsiness
  - shakiness
  - weakness
  - headache
  - fast heartbeat
  - feeling jittery

- **Kidney problems (kidney failure).** In people who have kidney problems, diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration) which may cause kidney problems to get worse.
- **Gallbladder problems**. Saxenda® may cause gallbladder problems including gallstones. Some gallbladder problems need surgery. Call your healthcare provider if you have any of the following symptoms:
- Pain in your upper stomach (abdomen)
- Fever
- Yellowing of your skin or eyes (jaundice)
- Clay-colored stools

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

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 tests, the Gastric Volume tests and the DEXA Body Composition Scan 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: 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.

Electrocardiogram (ECG): Is a harmless procedure that records the electrical activity of your heart. No electricity is sent through your body.

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.

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

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

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

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

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

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

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

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

Where to get help:

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

Who will pay for the treatment of research related injuries:

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

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

Others who are overweight or obese may benefit in the future from what we learn in this research study.

10. 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.

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

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

- Vital signs
- Physical exam
- Questionnaires
- Blood tests
- Urine pregnancy tests
- Electrocardiogram (ECG)
- Body Measurements
- Height and Weight
- Placebo/Study Medication (syringes and needles if needed)
- Gastric Emptying test
- Nutrient Drink test
- Gastric Volume test
- DEXA-Body Composition scan
- Buffet Meal 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.

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

You will be paid $1200 if you complete the whole study. If you don't complete the study, we will pay you part of the money. At your randomization visit, you will receive a copy of *The Mayo Clinic Diet* and at week 8 a token of thanks (Mayo Clinic water bottle).

13. What will happen to your samples?

Your samples will be used for this study, but we would also like to keep some of your samples for future research. You can still take part in this current study even if you don't want your sample used for future research. If you agree to give your sample, it will be the property of Mayo Clinic. Your sample will be stored in a coded format, which protects your identity. Mayo Clinic may destroy the sample at any time without telling you.

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

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

Please read the following statements and mark your choices:

1. I permit my sample to be stored and used in future research of weight loss at Mayo Clinic:

☐ Yes ☐ No Please initial here: _____Date: _____

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

☐ Yes ☐ No Please initial here: _____Date: _____

3. I permit Mayo Clinic to give my sample to researchers at other institutions:

☐ Yes ☐ No Please initial here: _____Date: _____

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

You may request to have your sample destroyed by writing to the Principal Investigator. The address is found in the "Contact Information" section of this consent form.

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

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

Mayo Clinic is committed to protecting the confidentiality of information obtained about you in connection with this research study. Your information will be stored in secured areas and password-protected 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.

Health information may be collected about you from:

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

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

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

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

Who may use or share your health information?

- Mayo Clinic research staff involved in this study.

With whom may your health information be shared?

- The Mayo Clinic Institutional Review Board that oversees the research.
- Other Mayo Clinic physicians involved in your clinical care.
- Researchers involved in this study at other institutions.
- Federal and State agencies (such as the Food and Drug Administration, the Department of Health and Human Services, the National Institutes of Health and other 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.

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 Privacy Rights

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

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

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

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

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

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

Approval Date: **June 3, 2020**
Not to be used after: **June 2, 2021**

Please be sure to include in your letter or email:

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

Your permission lasts forever, unless you cancel it.

ENROLLMENT AND PERMISSION SIGNATURES

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

	/ /	: AM/PM
Printed Name	Date	Time

Signature

Person Obtaining Consent

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

	/ /	: AM/PM
Printed Name	Date	Time

Signature