Cardiometabolic Disease and Pulmonary Hypertension

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Partners HealthCare System
Research Consent Form

Subject Identification

Certificate of Confidentiality Template
Version Date: January 2018

Protocol Title: Cardiometabolic Disease and Pulmonary Hypertension

Principal Investigator: Jennifer E. Ho, MD

Site Principal Investigator:

Description of Subject Population: Adults age 30-80 years with history of obesity

About this consent form

Please read this form carefully. It tells you important information about a research study. A member of our research team will also talk to you about taking part in this research study. People who agree to take part in research studies are called "subjects." This term will be used throughout this consent form.

Partners HealthCare System is made up of Partners hospitals, health care providers, and researchers. In the rest of this consent form, we refer to the Partners system simply as "Partners."

If you have any questions about the research or about this form, please ask us. Taking part in this research study is up to you. If you decide to take part in this research study, you must sign this form to show that you want to take part. We will give you a signed copy of this form to keep.

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 is this research study being done?

We are doing this research study to find out if metformin can help people with obesity and high pressures inside their lung blood vessels (pulmonary hypertension). Metformin improves blood vessel function in metabolic syndrome, a condition of metabolic abnormalities and often seen

with obesity and diabetes. Animal models have shown that metformin improves pulmonary hypertension.

Metformin is approved by the U.S. Food and Drug Administration (FDA) to treat diabetes, but metformin is not approved by the FDA to treat pulmonary hypertension.

This research study will compare metformin to placebo. The placebo looks exactly like metformin, but contains no metformin. During this study you may get a placebo instead of metformin. Placebos are used in research studies to see if the results are due to the study drug or due to other reasons.

We are asking you to take part in this research study because you are overweight or have history of obesity. Obesity can predispose people to develop high pressures inside the lung blood vessels, a condition called pulmonary hypertension. Pulmonary hypertension in turn, can lead to shortness of breath and other health complications such as heart failure.

About 250 subjects will take part in this research study. All subjects will take part at Massachusetts General Hospital (MGH).

The National Institutes of Health is paying for this research to be done.

How long will I take part in this research study?

It will take you about 4-5 months to complete this research study. During this time, we will ask you to complete up to 7 study visits.

What will happen in this research study?

If you choose to take part in this study, we will ask you to sign this consent form before we do any study procedures.

Screening Visit (Visit 1)

The Screening Visit will take about 3 hours. At this visit, we will do some tests and procedures to see if you qualify to take part in this research study. The study doctor will review the results of these tests and procedures. If you don't qualify, the study doctor will tell you why.

At this visit, we will:

- Ask you about your medical history

- Review your medical records (to determine whether you qualify for our study)
- Measure your height, weight, blood pressure, heart rate, waist circumference
- Draw a fasting blood sample (no eating or drinking, except for water after midnight)
- Do an electrocardiogram (ECG)
- Collect endothelial cells from a vein (cells from the inner lining of a blood vessel). We will insert a soft J-shaped wire through the IV in your arm (placed as part of the OGTT) and then remove the wire. We will repeat the wire insertion up to three additional times. We have learned that during this process a small number of endothelial cells stick to the wires and can be washed off for study under the microscope.
- Perform an echocardiogram. You will lie down on a table. A technician will place an ultrasound probe on your chest and gently press down to take pictures of your heart. You will be asked to remain still for the duration of the procedure, which will take approximately 45 minutes. We may give you echo contrast through the IV, a fluid which helps us visualize the blood flow through your heart.
- Test your blood for pregnancy, if you are a woman able to become pregnant. Pregnant women cannot take part in the remainder of this research study (Visits 2-5).
- Draw no more than 100 ml of blood (about 7 tablespoons) during this first visit.

At this visit, we may also:

- Perform an oral glucose tolerance test (OGTT). This test looks at how your body responds to a sugary drink. First, a blood Glucose (BG) measurement will be checked with a fingerstick to make sure it is safe to proceed with an OGTT. If your blood sugar is too high, we will not do the OGTT. If it is safe, we will place an IV to test your glucose and insulin levels before and after you drink a high sugar drink (30 min and 2 hours after glucose drink). We will draw less than 3 tablespoons of blood for the OGTT (less than one-tenth of what would be drawn for blood donation).
- Perform a 6-minute walk test. We will have you walk back and forth in a hallway at a comfortable pace for 6 minutes. The object is to see how far you can walk at your best pace in 6 minutes. We will be with you to check your symptoms and to record how far you were able to walk.

In addition, we would like your permission to contact you about participating in future research projects related to cardiovascular and metabolic diseases. Based upon the results of this visit and test results, we may contact you by phone or in writing about future studies. You can say no to participating in these studies.

Do you agree to let us contact you in the future about participating in other studies related to cardiovascular and metabolic disease?

☐ Yes ☐ No Initials_____

Study Visit (Visit 2) – Baseline Measures and Assignment to a Study Group

Visit 2 will take about 4 hours. At this visit, we will:

- Ask about any changes to your medical history or potential side effects
- Measure your blood pressure and heart rate
- Draw a blood sample
- Perform an invasive cardiopulmonary exercise test with hemodynamic evaluation. This test measures the function of your heart and pressures inside your lung blood vessels at rest and during exercise, and is described in detail below. The hemodynamic evaluation, exercise test, and ventriculography described below may have already been ordered and/or completed by your regular physician and be part of your regular medical care. If this is the case, you have the option of potentially combining the first and second visit of the study, depending on what may be more convenient for you.
- Perform ventriculography. This test involves administering a radioactive tracer through an IV in your arm. We then take pictures of your heart at rest and during exercise to examine your heart function with a camera that can detect the tracer. If you have not previously had ventriculography as part of your regular clinical care and are able to become pregnant, we will test your blood for pregnancy before we perform this test.
- Perform pulmonary artery endothelial cell collection at the end of the exercise test. After the exercise test, we remove the IV catheter that was used during the test. We wash the tip of it to collect any cells that may be stuck to the plastic tubing, so we can study the cells.
- Test your blood for pregnancy, if you are a woman able to become pregnant. Pregnant women cannot take part in the remainder of this research study.
- Assign you to a study group if you are eligible
- Draw no more than 150 ml of blood (about 10 tablespoons) during this second visit.

Invasive cardiopulmonary exercise testing including right heart catheterization

This test accurately measures the function of your heart and pressures inside the lung blood vessels at rest and during exercise. This test is done in a special room in the hospital that is designed for this type of procedure called a cardiac catheterization laboratory. To perform this procedure, the study doctor will numb up the skin, then make a small puncture in your skin of your neck to insert a special tube called a catheter into your vein to measure various pressures in your heart. During the procedure, you will have a special but common x-ray procedure, called fluoroscopy. Measurements will be taken while you are resting and lying down.

You will then be accompanied to the cardiopulmonary exercise laboratory (next door to the cardiac catheterization laboratory). There, we will place an arterial catheter in one of the arteries in the arm. This allows heartbeat-to-heartbeat monitoring of your blood pressure, as well as frequent blood sampling for various tests. We will also be monitoring your ECG during the procedure. You will then pedal a bicycle while we continue to measure pressures in your heart

for about 10-15 min. During exercise, we will have you breathe in and out of a tube so we can measure the amount of oxygen your body consumes, and how much carbon dioxide your body produces. Blood samples to determine oxygen saturation levels will also be collected during this procedure.

After you finish exercising, there will be a 5-10 min recovery period where we continue to monitor your heart rate and blood pressures. After the test is over, we will remove the catheter from your neck, and take its tip to isolate cells that may be stuck to it. These cells will be sent to our collaborators at Boston University for further studies. The sample will not contain any of your medical information, and our collaborators at Boston University will not have access to any of your other information.

Assignment to study group
If you still qualify for the study, we will assign you by chance (like a coin toss) to the metformin group or the placebo group. You and the study doctor cannot choose your study group. You will have an equal chance of being assigned to the metformin or the placebo group.

You and the study doctor won't know which study group you are in, but s/he can find out if necessary.

Taking the Study Drug
We will give you a supply of study drug (500 mg capsules) to take home with you. You will take study drug 1 capsule by mouth twice a day with meals for 1 week, and then increase to 2 capsules by mouth twice a day with meals for a total of approximately 3 months. It is important for you to follow our instructions about how to take the study drug. Bring any unused study drug with you to your next study visit. We will call you approximately 1 week after starting the study drug to ask you how you are feeling. You will be asked to avoid excessive alcohol intake while you are taking the study drug.

Study Visit (Visit 3) – Interim Measures
Visit 3 will take place approximately 2-4 weeks after you start taking metformin or placebo. This visit will last about 30 min and take place at MGH or remotely.

At this visit, we will:
- Ask you about your medical history or potential side effects in person or by telephone
- Draw a fasting blood sample (no eating or drinking, except for water after midnight) at MGH or at a local lab
- Test your blood for pregnancy, if you are a woman able to become pregnant. Pregnant women cannot take part in the remainder of this research study.
- Draw no more than 100 ml of blood (about 7 tablespoons) during this third visit.

At this visit, we may also:

- Measure your weight, blood pressure, and heart rate

Study Visit (Visit 4) – Interim Measures

Visit 4 will take place approximately 7-12 weeks after you start taking metformin or placebo. This visit will last 1 hour.

At this visit, we will:

- Ask you about your medical history or potential side effects
- Measure your height, weight, blood pressure, heart rate, waist circumference
- Draw a fasting blood sample (no eating or drinking, except for water after midnight)
- Test your blood for pregnancy, if you are a woman able to become pregnant. Pregnant women cannot take part in this research study.
- Collect endothelial cells from a vein. This procedure is described under Visit 1
- Do an electrocardiogram (ECG)
- Draw no more than 100 ml of blood (about 7 tablespoons) during this fourth visit.

Study Visit (Visit 5) – Final Measures

Visit 5 will take place approximately 3 months (give or take 2 weeks) after you start taking metformin or placebo. This visit will last about 4 hours. At this visit, we will:

- Ask you about your medical history or potential side effects
- Measure your blood pressure and heart rate
- Draw a blood sample
- Test your blood for pregnancy, if you are a woman able to become pregnant.
- Perform an invasive cardiopulmonary exercise test with hemodynamic evaluation, and pulmonary artery endothelial cell collection at the end of the procedure. This procedure is described under Visit 2
- We will draw no more than 150 ml of blood (about 10 tablespoons) during this final visit.

Additional Visits

If more than 30 days pass between Visit 1 and Visit 2 or between Visit 4 and Visit 5, we may ask you to come in for an additional visit. This is to get updated bloodwork and an electrocardiogram (ECG) for the invasive cardiopulmonary exercise test that happens on Visit 2 and Visit 5. This is to assure procedural safety and allows us to comply with cath lab protocols.

Due to the COVID-19 pandemic, some study procedures may require you to have a COVID test before you come to your visit. If this is the case, the study will pay for this test. We will pay you $20 upon completion of each test.

After You Complete the Study

After you complete the study, we will refer you back to your own doctor for your ongoing medical care.

Stopping the Study Early

If you decide to stop taking part in the study for any reason, we will ask you to make a final study visit. You will need to return all unused study drug at this visit. The final study visit will take about 30 min. At this visit, we will:

- Ask you about your medical history or potential side effects
- Measure your height, weight, blood pressure, heart rate, and waist circumference
- Draw a fasting blood sample (no eating or drinking, except for water after midnight)

Also, the study doctor may take you out of the study without your permission. This may happen because:

- The study doctor thinks it is best for you to stop taking the study drug
- You can't make the required study visits
- The Sponsor decides to stop the study
- We stop doing the study for other reasons

If this happens, the study doctor will explain why you need to stop taking part in the study. We will ask you to come in for a final study visit as described above.

Review of Medical Records from Hospital Admissions or Emergency Department Visits

Partners has an electronic system that lets your study doctors know if you are admitted to a Partners Hospital, or if you visit a Partners Hospital Emergency Department. We want to make sure the study doctors know about any possible problems or side effects you experience while you are taking part in the study.

Sending Study Information to Research Collaborators Outside Partners

We will send your study information and/or samples to researchers working with us at Boston University. We will label all your study materials with a code instead of your name. The key to the code connects your name to your study information and samples. We will keep the key to the code here at Partners and will not share it with our research collaborators. No one outside of Partners will know which study information or samples are yours.

Storing Samples and Health Information at MGH for Future Use

We would like to store some of your samples and health information for future research related to cardiometabolic disease. We will label your samples and health information with a code

instead of your name. The key to the code connects your name to your samples and health information. The study doctor will keep the key to the code in a password protected computer.

Do you agree to let us store your samples and health information for future research related to cardiometabolic disease?

☐ Yes ☐ No Initials_____

If later you change your mind and want your samples destroyed, contact the study doctor.

Study Information Included in Your Electronic Medical Record

A notation that you are taking part in this research study may be made in your electronic medical record. Information from the research that relates to your general medical care may be included in the record (for example: list of allergies, results of standard blood tests done at the hospital labs).

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

Risks of Blood Draws and IV placement

You may have a bruise (a black and blue mark) or pain where we take the blood samples. There is also a small risk of infection, lightheadedness, and/or fainting.

Risks of Echocardiogram

This test will involve placing an ultrasound probe over your chest and pressing down gently. It may result in mild discomfort due to the pressure of the probe. The potential risk of giving you echo contrast includes an allergic reaction (about 1 in 10,000 people).

Risks of 6-minute walk test:

You may feel tired and breathless during this test.

Risks of OGTT

Potential risks include nausea, stomach discomfort, diarrhea, and constipation.

Risks of endothelial cell collection from a vein.

You may have a bruise (a black and blue mark) or pain where we place the IV. There is also a small risk of infection, inflammation and blood clot.

Risks of a Right Heart Catheterization:

The risks of placing a catheter in the vein or artery are uncommon (less than 1 in 100 people), and include the following:

- allergic reaction to local anesthetic
- pain
- bleeding
- infection

Other rare but serious complications (less than 1 in 1000 people) may include:

- abnormal heart rhythms
- injury to the nerve around the insertion site
- partial collapse of the lung
- air embolism
- blood clot
- injury to the heart or blood vessels – this is quite rare but can require additional procedures and even result in permanent damage, bleeding, and rarely death

Risks of invasive cardiopulmonary exercise test:

The risks of the exercise test are uncommon (less than 1 in 100 people). These complications have resulted in hospitalization in approximately 2.5 patients per 10,000 tests.

- abnormally low or high blood pressure
- fainting
- irregularities in heart rate (too rapid or too slow)
- chest pain or heart attack

Risks of Radiation Exposure

As a result of your participation in this study you will be exposed to radiation from X-ray fluoroscopy studies and radioactive tracer. Please note that this radiation is not necessary for your medical care and is for research purposes only. The total amount of radiation exposure you will get from taking part in this study is up to a whole body exposure of 6.7 milliSieverts (mSv). A mSv is a unit of radiation dose. This amount of radiation is about the same as you would normally get in about 2 years from natural background sources from the earth and the sky. Scientists disagree on whether radiation doses at these low levels are harmful. A possible effect that could occur at doses used in this study is a slight increase in the risk of developing cancer later in life. If you are pregnant or breast feeding, you may not be able to participate in this research study.

Risks of Taking Metformin

Taking metformin may cause you to have one or more of the side effects listed below.

Common side effects:

- Diarrhea (12 to 53 out of 100 people reported this side effect)
- Nausea/vomiting (7 to 26 out of 100 people reported this side effect)
- Flatulence (12 out of 100 people reported this side effect)
- Weakness (9 out of 100 people reported this side effect)

Less common side effects (1 to 10 of 100 people reported this side effect):

- Cardiovascular: chest discomfort, flushing, palpitations, headaches, dizziness, lightheadedness
- Gastrointestional: indigestion, abdominal discomfort or distention, abnormal stools, constipation, dyspepsia/ heartburn, taste disorder
- Respiratory: trouble breathing, upper respiratory tract infection
- General: chills, rash, muscle aches, hypoglycemia, decreased vitamin B_{12} levels (a nutrient that is important in body function like making red blood cells),breaking out in a sweat, flu-like syndrome, changes in color or thickness of finger or toe nails

Uncommon side effects (less than 1 of 100 people reported this side effect):

- Abnormal increase of acid in the bloodstream
- Inflammation of blood vessels
- Low blood count
- Inflammation of the lung

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

The condition of abnormal increase of acid in the bloodstream will be monitored by the blood draw that we are doing at the interim study visit. If the level of lactic acid becomes abnormal, we will ask you to stop the study drug. Lactic acidosis is a rare but serious side effect due to metformin accumulation. When lactic acidosis occurs it is fatal in approximately half of cases. Symptoms include feeling general discomfort, muscle aches, trouble breathing, increasing tiredness, and nonspecific abdominal distress. The risk of abnormal increase of acid can be higher if you are given intravenous dye that is sometimes used in x-ray procedures. If you require such a radiologic study as part of your medical care, we would ask that you stop study drug for 48 hours prior to the study, and only resume once your kidney function has been checked using a blood test.

As with any drug, an allergic reaction can occur. Allergic reactions can be mild or more serious, and can even result in death. Common symptoms of an allergic reaction are rash, itching, skin problems, swelling of the face and throat, or trouble breathing. If you think you are having an allergic reaction, call the study doctor right away. If you are having trouble breathing, call 911 immediately.

Risks to an Embryo or Fetus, or to a Breastfeeding Infant

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

- Pregnant
- Trying to become pregnant
- Breastfeeding

If you are a menopausal woman and have not had a menstrual period for the past 12 months or more, you will not need to have a pregnancy test. Also, if you have had any well-documented method of surgical sterilization, you will not need to have a pregnancy test. Methods of surgical sterilization include having had a hysterectomy (removal of the uterus), bilateral oophorectomy (removal of both ovaries), a tubal ligation (having your tubes tied), and transvaginal occlusion (plugging the opening of the tubes with a coil). All other female subjects must have a negative pregnancy test before starting the study drug.

If you are sexually active and able to become pregnant, you must agree to use one of the birth control methods listed below. You must use birth control for the entire study.

Acceptable birth control methods for use in this study are:

- hormonal methods, such as birth control pills, patches, injections, vaginal rings, 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)

If you miss a period, or think you might be pregnant during the study, you must tell the study doctor immediately. If you become pregnant, you must stop taking the study drug and stop taking part in the study. The study doctor may ask for your permission to collect information about the outcome of your pregnancy and the condition of your newborn.

Risks of Taking Metformin with Other Medications

Do not take acetazolamide, cimetidine, topiramate, sulfonylurea (glibenclamide, glimepiride), or insulin while you are in the study. Taking these drugs and metformin together may cause serious side effects.

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

- new medications prescribed by your own doctor

- other medications sold over-the-counter without a prescription
- dietary or herbal supplements

There may be other risks and side effects that are not known at this time.

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

You may not benefit from taking part in this research study. Others with obesity may benefit in the future from what we learn in this study.

What other treatments or procedures are available for my condition?

You do not have to take part in this research study to be treated for obesity. Other treatments or procedures that are available to treat obesity include: lifestyle changes, medications including phentermine, orlistat, and methamphetamine, and bariatric surgery.

Talk with the study doctor if you have questions about any of these treatments or procedures.

Can I still get medical care within Partners if I don't take part in this research study, or if I stop taking part?

Yes. Your decision won't change the medical care you get within Partners now or in the future. There will be no penalty, and you won't lose any benefits you receive now or have a right to receive.

Taking part in this research study is up to you. You can decide not to take part. If you decide to take part now, you can change your mind and drop out later. We will tell you if we learn new information that could make you change your mind about taking part in this research study.

What should I do if I want to stop taking part in the study?

If you take part in this research study, and want to drop out, you should tell us. We will make sure that you stop the study safely. We will also talk to you about follow-up care, if needed.

Also, it is possible that we will have to ask you to drop out of the study before you finish it. If this happens, we will tell you why. We will also help arrange other care for you, if needed.

Will I be paid to take part in this research study?

We will pay you for each visit completed as follows: you will receive $50 for Visit 1; $150 for Visit 2; $50 for Visit 3; $50 for Visit 4; and $250 for Visit 5. For each additional visit we ask you to complete, we will pay you $50. We will pay for parking in the hospital garage during study visits.

We may use your samples and information to develop a new product or medical test to be sold. The Sponsor, hospital, and researchers may benefit if this happens. There are no plans to pay you if your samples are used for this purpose.

What will I have to pay for if I take part in this research study?

Study funds will pay for all study-related procedures and visits that are done only for research.

What happens if I am injured as a result of taking part in this research study?

We will offer you the care needed to treat any injury that directly results from taking part in this research study. We reserve the right to bill your insurance company or other third parties, if appropriate, for the care you get for the injury. We will try to have these costs paid for, but you may be responsible for some of them. For example, if the care is billed to your insurer, you will be responsible for payment of any deductibles and co-payments required by your insurer. Injuries sometimes happen in research even when no one is at fault. There are no plans to pay you or give you other compensation for an injury, should one occur. However, you are not giving up any of your legal rights by signing this form.

If you think you have been injured or have experienced a medical problem as a result of taking part in this research study, tell the person in charge of this study as soon as possible. The researcher's name and phone number are listed in the next section of this consent form.

If I have questions or concerns about this research study, whom can I call?

You can call us with your questions or concerns. Our telephone numbers are listed below. Ask questions as often as you want.

Jennifer Ho, MD is the person in charge of this research study. You can call her at [redacted] M-F 9-5 or ask to page her at [redacted] You can also call the study coordinator at [redacted] M-F 9-5 or email them at [redacted] with questions about this research study.

If you have questions about the scheduling of appointments or study visits, call the study coordinator at [redacted] M-F 9-5 or email them at [redacted]

If you want to speak with someone **not** directly involved in this research study, please contact the Partners Human Research Committee office. You can call them at 857-282-1900.

You can talk to them about:

- Your rights as a research subject
- Your concerns about the research
- A complaint about the research

Also, if you feel pressured to take part in this research study, or to continue with it, they want to know and can help.

If I take part in this research study, how will you protect my privacy?

Federal law requires Partners to protect the privacy of health information and related information that identifies you. We refer to this information as "identifiable information."

In this study, we may collect identifiable information about you from:

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

Who may see, use, and share your identifiable information and why:

- Partners researchers and staff involved in this study
- The sponsor(s) of the study, and people or groups it hires to help perform this research or to audit the research
- Other researchers and medical centers that are part of this study
- The Partners ethics board or an ethics board outside Partners that oversees the research
- A group that oversees the data (study information) and safety of this study

- Non-research staff within Partners who need identifiable information to do their jobs, such as for treatment, payment (billing), or hospital operations (such as assessing the quality of care or research)
- People or groups that we hire to do certain work for us, such as data storage companies, accreditors, insurers, and lawyers
- Federal agencies (such as the U.S. Department of Health and Human Services (DHHS) and agencies within DHHS like the Food and Drug Administration, the National Institutes of Health, and the Office for Human Research Protections) state agencies, and foreign government bodies that oversee, evaluate, and audit research, which may include inspection of your records
- Public health and safety authorities, if we learn information that could mean harm to you or others (such as to make required reports about communicable diseases or about child or elder abuse)
- Other researchers within or outside Partners, for use in other research as allowed by law.

Certificate of Confidentiality

A federal Certificate of Confidentiality (Certificate) has been issued for this research to add special protection for information and specimens that may identify you. With a Certificate, unless you give permission (such as in this form) and except as described above, the researchers are not allowed to share your identifiable information or identifiable specimens, including for a court order or subpoena.

Certain information from the research will be put into your medical record and will not be covered by the Certificate. This includes records of medical tests or procedures done at the hospitals and clinics, and information that treating health care providers may need to care for you. Please ask your study doctor if you have any questions about what information will be included in your medical record. Other researchers receiving your identifiable information or specimens are expected to comply with the privacy protections of the Certificate. The Certificate does not stop you from voluntarily releasing information about yourself or your participation in this study.

Even with these measures to protect your privacy, once your identifiable information is shared outside Partners, we cannot control all the ways that others use or share it and cannot promise that it will remain completely private.

Because research is an ongoing process, we cannot give you an exact date when we will either destroy or stop using or sharing your identifiable information. Your permission to use and share your information does not expire.

The results of this research may be published in a medical book or journal, or used to teach others. However, your name or other identifiable information **will not** be used for these purposes without your specific permission.

Your Privacy Rights

You have the right **not** to sign this form that allows us to use and share your identifiable information for research; however, if you don't sign it, you can't take part in this research study.

You have the right to withdraw your permission for us to use or share your identifiable information for this research study. If you want to withdraw your permission, you must notify the person in charge of this research study in writing. Once permission is withdrawn, you cannot continue to take part in the study.

If you withdraw your permission, we will not be able to take back information that has already been used or shared with others, and such information may continue to be used for certain purposes, such as to comply with law or maintain the reliability of the study.

You have the right to see and get a copy of your identifiable information that is used or shared for treatment or for payment. To ask for this information, please contact the person in charge of this research study. You may only get such information after the research is finished.

Informed Consent and Authorization

Statement of Person Giving Informed Consent and Authorization

- I have read this consent form.
- This research study has been explained to me, including risks and possible benefits (if any), other possible treatments or procedures, and other important things about the study.
- I have had the opportunity to ask questions.
- I understand the information given to me.

Signature of Subject:

I give my consent to take part in this research study and agree to allow my identifiable information to be used and shared as described above.

_____	_____	_____
Subject	Date	Time (optional)

Signature of Study Doctor or Person Obtaining Consent:

Statement of Study Doctor or Person Obtaining Consent

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

_____	_____	_____
Study Doctor or Person Obtaining Consent	Date	Time (optional)

Consent Form Version: 08/14/2020