Informed Consent Form

A Phase II Evaluation of Bendamustine, Obinutuzumab and Venetoclax in Patients with Untreated Mantle Cell Lymphoma

NCT Number: NCT03872180

Document IRB Approval Date: 9/7/2022

EMORY | WINSHIP CANCER INSTITUTE
A Cancer Center Designated by the National Cancer Institute

You Are Being Asked to Be in a Research Study

What Is a Research Study?

The main purpose of research studies is to gain knowledge. This knowledge may be used to help others. Research studies are not intended to benefit you directly, though some might.

Do I Have to Do This?

No. Being in this study is entirely your choice. If you decide to join this study, you can change your mind later on and withdraw from the research study.

Taking part in a study is separate from medical care. The decision to join or not join the research study will not affect your status as a patient.

What Is This Document?

This form is an informed consent document. It will describe the study risks, procedures, and any costs to you.

This form is also a HIPAA Authorization document. It will describe how your health information will be used and by whom.

Signing this form indicates you are willing to take part in the study and allow your health information to be used.

What Should I Do Next?

1. Read this form, or have it read to you.
2. Make sure the study doctor or study staff explains the study to you.
3. Ask questions (e.g., time commitment, unfamiliar words, specific procedures, etc.)
4. If there will be medical treatment, know which parts are research and which are standard care.
5. Take time to consider this, and talk about it with your family and friends.

Emory University and Saint Joseph's Hospital
Consent to be a Research Subject / HIPAA Authorization

Title: Winship 4363: A Phase II Evaluation of Bendamustine, Obinutuzumab and Venetoclax in patients with untreated Mantle Cell Lymphoma

Principal Investigator: Jonathon B. Cohen, MD MS. Winship Cancer Institute of Emory University

Investigator-Sponsor: Jonathon B. Cohen, MD MS. Winship Cancer Institute of Emory University

Study-Supporter: Genentech, Inc.

Introduction

You are being asked to be in a medical research study. This form is designed to tell you everything you need to think about before you decide if you want to be a part of the study. **It is entirely your choice. If you decide to take part, you can change your mind later on and withdraw from the research study.** The decision to join or not join the research study will not cause you to lose any medical benefits. If you decide not to take part in this study, your doctor will continue to treat you.

Before making your decision:

- Please carefully read this form or have it read to you
- Please listen to the study doctor or study staff explain the study to you
- Please ask questions about anything that is not clear

You can take a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to participate. You may wish to discuss your decision with family or friends. Do not sign this consent form unless you have had a chance to ask questions and get answers that make sense to you. By signing this form you will not give up any legal rights.

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.

What is the purpose of this study?

The purpose of this study is to determine if the combination of bendamustine, obinutuzumab and venetoclax (also called "BOV") is effective and safe for the treatment of patients with mantle cell lymphoma.

The combination of bendamustine and rituximab ("BR") is one of the most commonly used regimens in mantle cell lymphoma and is very effective for most patients. However, not all patients will have a good outcome and we are testing a new combination of treatments. We will still use bendamustine for treatment in this research study, but instead of rituximab, will combine it with two other drugs: obinutuzumab and venetoclax.

- Obinutuzumab is a type of medication called immunotherapy that works in a way similar to rituximab, but is newer. Obinutuzumab has been extensively studied in different types of lymphoma in the past, including mantle cell lymhpoma.
- Venetoclax is medication that targets specific pathways in cancer cells that keeps them alive. It has previously been tested in mantle cell lymphoma (as well as other lymphomas and chronic lymphocyic leukemia) and is approved to be used in other diseases.

While each of the medications in the BOV regimen have been used in mantle cell lymphoma, they have not been combined for use in patients with mantle cell lymphoma like yours that have not received treatment yet. However, they have previously been combined to treat other types of lymphomas.

What will I be asked to do?

You will be treated on this study with BOV for approximately 6 months, which is the same amount of time that patients are treated with the commonly used BR regimen. After completion of your treatment, we will continue to monitor you in clinic and with blood tests and scans every 3-12 months for approximately 5 years.

Screening Phase

Prior to starting the study, your physician and the clinical trial team will order tests to ensure that you are eligible and it is safe for you to participate in the study. This may include the following assessments:

- A full evaluation and physical examination by your physician. This will include your medical and psychiatric history, medications you are taking, and measurements of height, weight, blood pressure, respiratory rate and heart rate.
- Blood draws (a needle stick) to send to the laboratory to check your kidney and liver function, as well as your blood cell counts. Other labs will also be sent, including looking at specific markers on your lymphoma.
- Blood draw to look for any evidence of viral hepatitis or HIV infection. These are standard tests for all lymphoma patients.
- A PET/CT scan (or MRI) which gives us a picture of where the lymphoma is located in your body. This is a test which gives us a picture of the inside of your body to give us information about the lymphoma. It is a non-invasive procedure. There may be contrast injected into your veins prior to the PET/CT or MRI in order to help better see the inside of your body. This is usually a painless procedure, except for some discomfort from getting an IV placed. Your doctor will use this information to help determine the stage of your lymphoma.
- A pregnancy test if you are female
- An EKG to look at your heart rhythm. This is a test that records the electrical activity of your heart.
- A bone marrow aspirate and biopsy may be required depending on how long ago your last biopsy was done and what the results were. This is a test where a needle is used to withdraw cells from inside your bone marrow.

Your doctor may recommend additional tests that are appropriate to ensure that you can safely receive treatment for your lymphoma. These test may not be required by the study but may be needed to make sure you are a candidate for treatment.

Your doctor and/or team will review all of the available results of your screening tests with you and can answer any questions that you have about these results at any time.

Treatment Phase

If you take part in this study, you will receive a combination of bendamustine and obinutuzumab, both which are given intravenously, as well as venetoclax, which is a pill given by mouth. In addition, as a prophylaxis for tumor lysis syndrome (also called "TLS", described below in detail), you will receive Allopurinol daily starting 3 days prior to your first cycle of venetoclax until 7 days after the last venetoclax dose increase. All intravenous treatments will be given at your infusion center under the supervision of your doctor. You will need to take the venetoclax pill(s) exactly as instructed. You will receive additional details from the study team, but it is important to:

- Take the oral venetoclax dose daily as prescribed. There will be a different of number of pills to take depending on the different time periods of the study. There will also be days that you are not supposed to take venetoclax pills. A calendar will be provided with the number of pills to take and the days to take the pills. It is important to follow the instructions on the calendar.
- If you forget to take the pills, or you take the wrong number of pills, you should contact the study team for additional instructions. Do not take an extra dose to "make up" for a missed dose.
- You will be provided with a pill diary to record whether or not you have taken the venetoclax pills on a given date. It is important to complete this pill diary. You will bring this pill diary as well as your pill bottles (full, partial, and empty) to every clinic visit.
- Venetoclax should be taken with a meal.
- On days you have clinic or treatment visits, do not take venetoclax before being seen by the study team. The study team will instruct you when to take the venetoclax on days when you have clinic and treatment visits.

Treatment will be given in "Cycles", which is a 28-day period. You will receive 6 cycles of treatment. The first cycle of treatment will be different than cycles 2 – 6. During the first cycle:

- You will receive intravenous treatment on days 1, 2, 8, and 15 of the cycle. Depending on the amount of lymphoma detected in your blood or the rest of your body, your doctor may recommend that you start your treatment under observation in the hospital. If this is the case your team will discuss this with you and explain why they feel it is necessary. This is only expected to occur at the beginning of the study and not for the rest of your treatments.
- You will take venetoclax orally every day. The dose will increase weekly during the cycle, as instructed on the calendar.
- You will get blood drawn for laboratory evaluation on days 1, 2, 3, 8, 15, and 22 of the cycle.
- You will receive a subcutaneous "growth factor" injection on day 3 or 4 in order to help you white blood cells (immune system cells that fight infection) recover from the chemotherapy.

During cycles 2-6:

- You will receive intravenous treatment at on days 1 and 2 only.
- You will only take venetoclax on for a certain amount of time during the cycle (usually days 1-10). The dose will be the same throughout the cycle. Your doctor and study team will tell you the schedule for your venetoclax.
- You will get labs drawn on days 1, 2 and 15 of cycle 2. You will only get labs drawn on day 1 of cycles 3-6.
- You will recive the subcutaneous "growth factor"injection on day 3 or 4.

If there are complications, you may be instructed to take the venetoclax differently. Follow the instructions of your study team. If you are at high risk of experiencing complications related to the amount of lymphoma in your body, you may be required to be admitted to the hospital 2 times for the first cycle for close monitoring. Each admission is not expected to last more than 2-3 days.

Post Treatment Follow-up Phase
After completion of therapy with the BOV regimen, you will continue to follow-up with the study team in order to monitor for any side effects from the treatment, as well as to see how the lymphoma has responded to treatment. You will receive a PET scan and blood testing at the end of treatment. If there was lymphoma present in your bone marrow at diagnosis, then you will also receive another bone marrow aspirate and biopsy to make sure that there is no lymphoma present after treatment. You will also have regular treatment visits and labs with your doctor and study team every few months after completion of therapy.

In addition to receiving treatment with the BOV regimen, you will also receive routine care as provided for all patients with mantle cell lymphoma, regardless of participation on a clinical study. This includes clinical follow-up, laboratory testing, imaging scans (for example, PET scan or MRI), and possible bone marrow aspirate and biopsy if there is concern for lymphoma in the bone marrow.

There will be other laboratory testing that is not routinely done in mantle cell lymphoma. This includes:

1. Close evaluation and blood testing for evidence of tumor lysis syndrome (also called “TLS”, described below in detail), which can occur when cancer cells die quickly and release their contents into a patient’s blood. This may require more blood samples than is commonly done for mantle cell lymphoma.
2. We will send additional blood to evaluate a new laboratory test that looks for small amounts of lymphoma in the body that may not be detected by routine imaging or scans – this is also known as minimal residual disease or “MRD”. The evaluation of this new laboratory test will not be used to modify your treatment plan in any way and you may not know the results of this test while you are on the study.

When testing for MRD, up to approximately 60mL (between 4-5 tablespoons)of blood may need to be drawn. Other days when MRD is not being tested, the amount of blood drawn will be less.

How will my medicine be provided?
The medicine that you will take will be dispensed by the pharmacy and delivered to the principal investigator or study team member. The principal investigator or health care providers on his/her research team will provide the medicine to you. If you have questions about the medicine, you should ask the principal investigator or study nurse. You may also call the pharmacy if you have questions about the medicine. The number for the pharmacy is included on your medicine package.

Who owns my study information and samples?
If you join this study, you will be donating your samples and study information. You will not receive any compensation if your samples or information are used to make a new product.

If you withdraw from the study, no further data nor samples will be collected, but data and samples that were already collected may be still be used for this study. Results of labs, scans and other clinical data that has already been collected will still be used to help investigators determine if the

combination of medications works and if it is safe. Samples of blood that have been collected to evaluate the new "MRD" test will still be sent for evaluation unless you specifically request that those samples not be evaluated and instead be destroyed.

What are the possible risks and discomforts?

There may be side effects from the study drugs or procedures that are not known at this time. Many of the risks and discomforts would be similar to those seen with the commonly used regimen of bendamustine and rituximab. There are additional unique risks with the addition of venetoclax and obinutuzumab, including risks of tumor lysis syndrome, infusion reactions, and increased rate of low blood counts and risk of infection. These are described in detail below.

The most common risks and discomforts expected in this study are:

- Infection of any type occurs in 50-75% of patients. This can usually be successfully managed with antibiotics.
- Nausea occurs in 50-75% of patients. This can usually be successfully managed with additional medications.
- Fatigue occurs in 40-60% of patients. This is most commonly mild fatigue, and manageable.
- Vomiting occursin 25-50% of patients. This can usually be successfully managed with additional medications.
- Constipation occurs in 25-75% of patients. This can usually be successfully managed with additional medications.
- Diarrhea occurs in 10-30% of patients. This can usually be successfully managed with additional medications.
- Fevers occur in 10-20% of patients. This can usually be successfully managed with additional medications.
- Poor appetite occurs in 10-20% of patients.
- Headaches occur in 10-30% of patients. This can usually be successfully managed with additional medications.
- Drug reactions or infusion reactions are often seen in between 25-50% of patients. Rarely, this can be an anaphylactic (serious or life threatening) reaction. This can usually be successfully managed with additional medications. The team managing your intravenous infusion will be well-trained to manage infusion reactions related to chemotherapy.
- Difficulty sleeping is often seen in 10-20% of patients.
- Rash is often seen in 20-30% of patients.
- Low blood counts will be seen in the majority (>75%) of patients, however, only a small number of these are expected to be severe (estimated to be less than 25%), requiring blood product transfusion or putting patients at risk of serious infection or bleeding. We minimize this risk by providing treatment with blood cell growth factors, which increases your immune system, as well as closely monitoring your blood counts.

Rare but possible risks include:

- Tumor lysis syndrome, which can be life-threatening if severe. This occurs when cancer cells die and break down rapidly, releasing their contents into the blood stream. If enough cancer cells die quickly enough, the body is not able to effectively get rid of the cellular salts and acids, and it can result in kidney damage, heart arrhythmias, seizures, and death if severe. We know that this is more likely to happen in patients with a large tumor burden or previous kidney damage, and there are special protocols to minimize the risk of this occurring.

- If a patient has been previously infected with Hepatitis B virus, treatment can rarely result in the virus coming back and causing liver damage. If there is evidence that a patient has been infected with Hepatitis B in the past, there are specific protocols to minimize this risk.
- There is a very low risk of development of progressive multifocal leukoencephalopathy. This is a rare neurological disorder associated with a certain type of viral infection called the JC virus. This can result in a variety of symptoms including confusion, balance issues, weakness and vision changes.
- Serious infections such as sepsis that can result in death

Additional blood will also be taken for testing on this study. This would be done at the same time as routine blood draws, and would not require you to experience any additional needle sticks.

Radiation risks: You will be exposed to radiation from nuclear medicine. These procedures are necessary for your medical care and will occur even if you do not participate in this study. The estimated radiation dose that you will receive is equal to or less than the annual radiation exposure limit allowed for persons who are occupationally exposed to radiation (for example, x-ray technologist, radiologist). The principal risk associated with a radiation dose is the possibility of developing a radiation-induced cancer later in life. The risk for radiation-induced cancer from this study is minimal.

MRI: MRI exams use powerful magnets to create images of the body. In addition to the possible reactions to contrast materials, you may feel claustrophobic while in the magnet, and will hear loud beeping or hammering noises. If you have tattoos or any metal items in your body such as implants, pacemakers, clips or shrapnel, we will do special screening to make sure your MRI scan is done safely.

Contrast Agents: Your PET-CT or MRI procedure may require the use of a contrast agent, which is a substance that helps the radiologist interpret the images. The contrast agent will be injected by either a hand-held needle or a machine that does the injection. Most contrast agents stay in your body for only a few minutes, but some of them can remain for a few hours or days without any harm to you or anyone near you. Contrast agents are generally quite safe, but any injection involves some risks. The injection could harm a nerve, artery or vein, or cause infection. The contrast agent could affect kidney function or cause an allergic reaction, though these outcomes are rare. The contrast agent could also leak from your veins a little, causing swelling and discomfort, which is typically treated with ice packs.

PET: For your PET scan, a small amount of radioactive material will be injected by either a hand-held needle or a machine. Such injections are generally quite safe, but any injection involves some risks. The injection could harm a nerve, artery or vein, or cause infection. The radioactive material could also leak from your veins a little, causing swelling and discomfort. After injection and a waiting period for the drug to circulate within your body, you will be asked to lie very still for several minutes while the scan takes place.

It is impossible to provide a comprehensive list of possible risks. There may also be risks that are unexpected, or that we do not yet know about. If significant new risks associated with this treatment are discovered while you are participating on the study or afterwards, the study team will make you aware of these risks.

If you are a woman: to protect against possible side effects of the study drug, women who re pregnant or nursing a child may not take part in this study. If you become pregnant, there may be risks to you, the embryo, or fetus. These risks are not yet known. If you are a woman of childbearing ability, you and the study doctor must agree on a method of birth control to use throughout the study, and should continue on this for 18 months after the final study treatment. If you think that you have gotten pregnant during the study, you must tell the study doctor immediately. Pregnant women will be taken out of the study.

If you are a man: the effect of the study drug on sperm is not known. To protect against possible side effects, if you are a man you should not get a sexual partner pregnant while taking the study drug and for 18 months after the last dose of obinutuzumab. You and the study doctor should agree on a method of birth control to use throughout the study. In addition, you must also refrain from donation sperm while taking the study drug and for 18 months after the last dose of obinutuzumab.

If you will be taking the study drug home, keep it out of the reach of children or anyone else who may not be able to read or understand the label. Do not let anyone else take the study drug besides you.

It is possible that the researchers will learn something new during the study about the risks of being in it. If this happens, they will tell you about it. Then you can decide if you want to continue to be in this study or not. You may be asked to sign a new consent form that includes the new information if you decide to stay in the study.

Will I benefit directly from the study?

You may benefit directly from this study. While we do know that each of these medications has some effect when treating mantle cell lymphoma, we do not know how well they work together. If they work well together, it may provide a benefit to you by treating the lymphoma.

Will I be compensated for my time and effort?

You will not be offered compensation for being in this study.

What are my other options?

If you decide not to enter this study, there is care available to you outside of this research study. The majority of patients would most likely get the combination of bendamustine and rituximab for treatment of their lymphoma if they were not to enroll on this study. There are other treatments as well and may be other clinical trials that you can consider. These other treatments include more intensive chemoimmunotherapy regimens which may provide more control of the lymphoma, but also carry increased risks and are not safe in many individuals. There are also less intensive chemoimmunotherapy regimens, but these often provide disease control for a shorter period of time prior to lymphoma relapse. The study doctor will discuss these with you. You do not have to be in this study to be treated for mantle cell lymphoma.

Taking part in this study, however, may make you unable to participate in some other research studies, if they exclude people who have taken certain treatments. You should discuss this with the researchers if you have concerns. You may wish to research other study options at websites like clinicaltrials.gov and ResearchMatch.org.

How will you protect my private information that you collect in this study?

Whenever possible, a study number, rather than your name, will be used on study records. Your name and other identifying information will not appear when we present or publish the study results.

Study records can be opened by court order. They also may be provided in response to a subpoena or a request for the production of documents.

Storing and Sharing your Information

De-identified data from this study, including your de-identified genetic information, may be shared with the research community at large to advance science and health. Data from this study may be placed into public databases where, in addition to having no direct identifiers, researchers will need to sign data use agreements before accessing the data. We will remove or code any personal information that could identify you before your information is shared. This will ensure that, by current scientific standards and known methods, it is extremely unlikely that anyone would be able to identify you from the information we share. Despite these measures, we cannot guarantee anonymity of your personal data.

Medical Record

If you have been an Emory and Saint Joseph's Hospital patient before, then you already have an Emory and Saint Joseph's Hospital medical record. If you have never been an Emory and Saint Joseph's Hospital patient, you do not have one. An Emory and Saint Joseph's Hospital medical record will be made for you if an Emory and Saint Joseph's Hospital provider or facility gives you any services or procedures for this study.

Copies of the consent form/HIPAA authorization that you sign will be put in any Emory and Saint Joseph's Hospital medical record you have now or any time during the study.

Emory and Saint Joseph's Hospital may create study information about you that can help with your care. For example, the results of study tests or procedures. These study results will be put in your Emory and Saint Joseph's Hospital medical record. Anyone who has access to your medical records will be able to have access to all the study information placed there. The confidentiality of the study information in your medical record will be protected by laws like the HIPAA privacy rule. State and federal laws may not protect the research information from disclosure.

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record. For this study, those items include the results of the experimental minimal residual disease test. However, the results of the non-experimental minimal residual disease test will be in your medical record.

Tests and procedures done at non-Emory and Saint Joseph's Hospital places may not become part of your Emory and Saint Joseph's Hospital medical record. Also, if you decide to be in this study, it is up to you to let your other health providers know.

In Case of Injury

If you get ill or injured from being in the study, Emory and Saint Joseph's Hospital will help you get medical treatment. Emory and Saint Joseph's Hospital and the sponsor have not, however, set aside any money to pay you or to pay for this medical treatment. The only exception is if it is proven

that your injury or illness is directly caused by the negligence of an Emory and Saint Joseph's Hospital or sponsor employee. "Negligence" is the failure to follow a standard duty of care.

If you become ill or injured from being in this study, your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurer does not pay, then you will have to pay these costs.

If you believe you have become ill or injured from this research, you should contact Dr. Jonathon B. Cohen, MD at telephone number [redacted]. You should also let any health care provider who treats you know that you are in a research study.

Costs

The study sponsor will pay for certain items and services that you may receive if you take part in this study.

You will have to pay for the items or services for which the study sponsor does not pay. The sponsor will not pay for your regular medical care. If you have insurance, Emory and Saint Joseph's Hospital will submit claims to your insurance for items and services that the sponsor does not cover. Emory and Saint Joseph's Hospital will send in only those claims for items and services that it reasonably believes your insurance will pay and that the sponsor has not paid.

The actual amount that you have to pay depends on whether or not you have health insurance and whether or not that insurance will pay for any research study costs. Generally, insurance companies will not pay for items and services that are required just for a research study. Some insurance companies will not pay for regular medical treatment or treatment for complications if you are in a study. How much you will have to pay for any co-payments, deductibles or co-insurance depends on your plan. Emory and Saint Joseph's Hospital and the sponsor will not pay for these costs.

It is a good idea to contact your insurance provider and tell them you want to be in this research study. Ask them what they will pay for and what they will not pay for. You can also ask the study team for help in figuring out what you will have to pay.

If you do not have insurance, Emory and Saint Joseph's Hospital will review your case as part of its program for low-income patient care. The standard policies of that program will apply. The program will figure out if you have to pay any costs for taking part in the study and what those costs will be.

Withdrawal from the Study

You have the right to leave a study at any time without penalty.

For your safety, however, you should consider the study doctor's advice about how to go off the study treatment. If you leave the study before the final planned study visit, the researchers may ask you to have some of the final steps done.

The researchers also have the right to stop your participation in this study without your consent for any reason, especially if they believe it is in your best interest or if you were to object to any future changes that may be made in the study plan.

Authorization to Use and Disclose Protected Health Information

The privacy of your health information is important to us. We call your health information that identifies you, your "protected health information" or "PHI." To protect your PHI, we will follow federal and state privacy laws, including the Health Insurance Portability and Accountability Act and regulations (HIPAA). We refer to all of these laws as the "Privacy Rules." Here we let you know how we will use and disclose your PHI for the study.

PHI that Will be Used/Disclosed:
The PHI that we will use or share for the main research study includes:

- Medical information about you including your medical history and present/past medications.
- Results of exams, procedures and tests you have before and during the study.
- Laboratory test results.

Purposes for Which Your PHI Will be Used/Disclosed:
We will use and share your PHI for the conduct and oversight of the research study. We will use and share your PHI to provide you with study related treatment and for payment for such treatment. We will also use and share your PHI to conduct normal business operations. We may share your PHI with other people and places that help us conduct or carry out the study, such as laboratories, data management centers, data monitors, contract research organizations, Institutional Review Boards (IRBs) and other study sites. If you leave the study, we may use your PHI to determine your health, vital status or contact information. We will use and disclose your PHI for the administration and payment of any costs relating to subject injury from the study.

Use and Disclosure of Your Information That is Required by Law:
We will use and disclose your PHI when we are required to do so by law. This includes laws that require us to report child abuse or abuse of elderly or disabled adults. We will also comply with legal requests or orders that require us to disclose your PHI. These include subpoenas or court orders.

Authorization to Use PHI is Required to Participate:
By signing this form, you give us permission to use and share your PHI as described in this document. You do not have to sign this form to authorize the use and disclosure of your PHI. If you do not sign this form, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People Who will Use/Disclose Your PHI:
The following people and groups will use and disclose your PHI in connection with the research study:

- The Principal Investigator and the research staff will use and disclose your PHI to conduct the study and give you study related treatment.
- Emory and Saint Joseph's Hospital may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
- Genentech, Inc. is the supporter of the study. The supporter may use and disclose your PHI to make sure the research is done correctly and to collect and analyze the results of the

research. The supporter may disclose your PHI to other people and groups like study monitors to help conduct the study or to provide oversight for the study.

- The research team and the supporter may use and disclose your PHI, including disclosure to insurance carriers to administer payment for subject injury.
- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory and Saint Joseph's Hospital offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Healthcare Compliance Offices, and the Emory Office for Clinical Research.
    - Government agencies that regulate the research including: Office for Human Research Protections and the Food and Drug Administration.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization
Your PHI will be used until this research study ends.

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at:

At that point, the researchers would not collect any more of your PHI. But they may use or disclose the information you already gave them so they can follow the law, protect your safety, or make sure that the study was done properly and the data is correct. If you revoke your authorization you will not be able to stay in the study.

Other Items You Should Know about Your Privacy
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers, and health care clearinghouses. If we disclose your information to people who are not covered by the Privacy Rules, including HIPAA, then your information won't be protected by the Privacy Rules. People who do not have to follow the Privacy rules can use or disclose your information with others without your permission if they are allowed to do so by the laws that cover them.

To maintain the integrity of this research study, you generally will not have access to your PHI related to this research until the study is complete. When the study ends, and at your request, you generally will have access to your PHI that we maintain in a designated record set. A designated record set is data that includes medical information or billing records that your health care providers use to make decisions about you. If it is necessary for your health care, your health information will be provided to your doctor.

We may remove identifying information from your PHI. Once we do this, the remaining information will not be subject to the Privacy Rules. Information without identifiers may be used or disclosed with other people or organizations for purposes besides this study.

Contact Information

Contact Dr. Cohen at [redacted]:

- if you have any questions about this study or your part in it,
- if you feel you have had a research-related injury or a bad reaction to the study drug, or
- if you have questions, concerns or complaints about the research

Contact the Emory Institutional Review Board at [redacted]:

- if you have questions about your rights as a research participant.
- if you have questions, concerns or complaints about the research.
- You may also let the IRB know about your experience as a research participant through our Research Participant Survey at http://www.surveymonkey.com/s/6ZDMW75.

Consent and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

Please **print** your name, **sign**, and **date** below if you agree to be in this research study. By signing this consent and authorization form, you will not give up any of your legal rights. We will give you a copy of the signed form to keep.

_____
Name of Subject

_____ _____ _____ **am / pm**
Signature of Subject (18 or older and able to consent) **Date** **Time (please circle)**

TO BE FILLED OUT BY STUDY TEAM ONLY

_____
Name of Person Conducting Informed Consent Discussion

_____ _____ _____ **am / pm**
Signature of Person Conducting Informed Consent Discussion **Date** **Time (please circle)**