Informed Consent Form

A Phase I/II Study of MLN9708 as Post-transplant Maintenance for Patients with Mantle Cell Lymphoma Undergoing Autologous Stem Cell Transplant in First Remission

NCT Number: NCT02632396

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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 And HIPAA Authorization

PHASE 1 CONSENT

Title: Winship2494-13 (X16058): A Phase I/II Study of MLN9708 as Post-transplant Maintenance for Patients with Mantle Cell Lymphoma Undergoing Autologous Stem Cell Transplant in First Remission

Principal Investigator: Jonathon Cohen, MD, MS

Sponsor: Jonathon Cohen, MD, MS

Study-Supporter: Millennium Pharmaceuticals, Inc., The Takeda Oncology Company

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 to consent (agree) to be in the study or not to be in 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.

Study Overview

The purpose of this study is to learn more about the safety of Ixazomib when administered as post-transplant maintenance in mantle cell lymphoma alone and in combination with rituximab. This study tests different doses of the drug to see which dose is safer in people when given alone and when given in combination with rituximab. We will enroll at least 18 subjects onto this clinical trial for the Phase 1 portion of this study. We do not yet know if Ixazomib will improve mantle cell lymphoma outcomes.

Approximately 62 patients will participate in this study here at the Winship Cancer Institute.

Procedures

You will receive Ixazomib (MLN9708) study drug orally on days 1, 8, and 15 of a 28-day cycle. You will begin therapy approximately 100 days after your autologous stem cell transplant and can continue therapy for a total of 10 cycles as long as your condition is improving.
You can remain on active treatment with the study drug for roughly 10 months followed by up to 2 years of observation. The entire study is expected to complete accrual in 3-4 years with an additional 2 years to complete follow-up for all patients. The study drug must be kept cool in a refrigerator during the time you participate in this study.

Some patients will also receive rituximab as part of their treatment. Rituximab is not an experimental drug but it has not been given in combination with ixazomib. If you receive rituximab, it will be given to you either intravenously or under your skin 5 times during your treatment (at the beginning of cycles 1, 3, 5, 7, and 9).

What are the study groups?
Different doses of the study drug *MLN9708 Ixazomib* will be given to several study participants, and some patients will receiving Ixazomib in combination with rituximab. The first several study participants will receive the lowest dose. If the drug does not cause serious side effects, it will be given to other study participants at a higher dose. Your treatment with the study drug will not increase over the course of the study, but may decrease if you were to experience any side effects or toxicities from the drug. The doses will continue to increase for every group of study participants up to a maximum dose of 4mg (milligrams) of the study drug unless side effects occur that require the dose to be lowered. The study team will inform you of which dose you will be taking and whether you will be receiving rituximab when you start the study as well as any dose changes that are required over the course of your participation in this study. There will be no changes to the rituximab dosing but if you have a side effect of the rituximab that means it is not felt to be safe for you, you will not receive any additional rituximab doses.

Your dose of the study drug will not be increased but may be lowered if you experience side effects.

Most of the exams, tests, and procedures you will have are part of the usual approach for your cancer. However, there are some extra procedures that you will need to have if you take part in this study.

Before you begin the study:
You may need to have the following extra *procedures* to find out if you can be in the study if you have not already had them recently as part of your routine care for your lymphoma:

- Bone marrow biopsy
- PET/CT

If the exams, tests, and procedures show that you can take part in the study, and you choose to take part, then you will need the following extra *procedures*. They are not part of the usual approach for your type of cancer.

During the study:
Examples of exams, tests, and procedures:

- Blood tests every month for 1 year

- PET/CT or CT scan of abdomen, neck, pelvis, neck twice during the first year and then every 6 months
- Bone marrow biopsy immediately after study treatment is completed

How will my medicine be provided?
The Ixazomib that you will take will be dispensed by the pharmacy and delivered to the principal investigator or study team member. If you are receiving rituximab, this will be infused in the infusion center and obtained from the typical pharmacy. The principal investigator or health care providers on his/her research team will provide the ixazomb 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, data and samples that were already collected may be still be used for this study.

Risks and Discomforts
There may be side effects from the study drug or procedures that are not known at this time. There are risks to taking part in any research study. During the study, you may have problems or discomforts and risks from MLN9708, MLN9708 and other drug combinations, and/or study procedures. The more commonly occurring discomforts and risks are listed below, as are the rare but serious discomforts and risks. You should discuss these with your study doctor. There is always the possibility that unknown risks may occur, however your doctor will watch closely for problems or discomforts and risks. Many discomforts and risks go away shortly after treatment is stopped or with treatment for the discomforts and risks, but in some cases discomforts and risks may be serious, long-lasting or permanent and may even result in hospitalization. There is also the risk of death.

If any discomforts and risks occur, you must tell your study doctor or study staff, even if you do not think they are related to the study drug.

If you do not understand what any of the discomforts and risks listed below mean, please ask the study doctor or study staff to explain these terms to you.

POTENTIAL DISCOMFORTS AND RISKS OF MLN9708
Based on studies of MLN9708, it is possible to predict some of the discomforts and risks. However, it is possible that MLN9708 may cause risks that have not yet been observed in patients. The following risks might be seen:

- Low platelet count which may increase the chance of bleeding;
- Skin rash which may range from some red areas, small flat spots, or small raised bumps that may or may not be itchy in a few areas or all over the body
- Feeling tired or weak
- Nausea
- Vomiting
- Diarrhea
- Numbness or tingling or pain feelings in hands and feet
- Fever

- Constipation
- Lowered red cells or anemia which may make you feel tired;
- Lowered white blood cells called neutrophils that may increase your risk of infection and may be associated with fever
- Distortion of the sense of taste i.e. an abnormal or impaired sense of taste.
- Trouble falling asleep, staying asleep, or both

- Other discomforts and risks reported in studies with MLN9708, which may have been due to the patient's disease, MLN9708, other medications, or some combination of these include:
  - Not feeling like eating
  - Electrolyte imbalance (blood chemical imbalance)
  - Loss of water from the body (dehydration) because of vomiting and/or loose stools
  - High blood creatinine and renal failure which creatinine means your kidneys are having trouble working well; Patients who had lost body water (dehydration) because of vomiting and/or loose stools have had high levels of creatinine indicating that the kidneys were failing to function adequately. In some severe situations, less kidney function may require temporary treatment with a machine that supports the function of the kidney (dialysis)
  - Headache
  - Flu-like symptoms and other upper respiratory tract infections
  - Feeling short of breath
  - Lung infections including pneumonia or pneumonitis
  - Cough
  - Chills
  - Pain in the abdomen or back
  - Swelling or fluid build up in the arms or legs
  - General aches or pains in muscles, joints, bones, or arms and legs
  - Feeling dizzy
  - Lowered blood pressure that can commonly cause you to feel light headed, faint or pass out when you stand up
  - Lowered white blood cells called lymphocytes
  - Pain (muscular) in extremities

Some discomforts and risks that occur with lesser frequency (<1%) than those mentioned above, should be noted because they are severe, life-threatening or fatal. With limited experience, we do not know if MLN9708 causes such problems. Stevens Johnson's Syndrome, a severe, life-threatening or deadly condition that may involve rash, skin peeling and mouth sores has been reported in ongoingMLN9708 studies. Stevens Johnson Syndrome is a disorder of the immune system, which differs from a regular skin rash.

In addition posterior reversible encephalopathy syndrome has also been reported with MLN9708 with lesser frequency (<1%). This condition affects the brain and may cause headaches, changes in your vision, changes in your mental status, or seizures (fits), but is usually reversible. Transverse myelitis, also a rare condition (<1%), is an inflammatory disease causing injury to the spinal cord which has been reported in a patient receiving MLN9708. This condition may cause varying degrees of muscle weakness, reduced movement in legs, changes in the feelings of the toes and feet, unusual muscle tightness, feelings of pain, changes in bowel (constipation) or urinary (loss of control) function or loss of leg movement. In general, recovery may be partial, complete, or not at all but most patients

experiencing transverse myelitis have good to fair recovery of symptoms. We do not know whether MLN9708 causes transverse myelitis, however, as it happened to a patient receiving MLN9708, we are not able to exclude the possibility that MLN9708 may have contributed to transverse myelitis.

One fatal case of progressive multifocal leukoencephalopathy (PML) has been reported with MLN9708 in an oncology patient who had previously received a medication associated with PML. PML is a rare, serious infection of the brain that is caused by a virus. Persons with a weakened immune system may develop PML. PML can result in death or severe disability. It is not known whether MLN9708 may have contributed to the development PML in this patient.

Additionally, it is worth noting that:

- MLN9708 is similar to the drug known as VELCADE ® (bortezomib) for Injections, which is approved for the treatment of multiple myeloma (a cancer of the plasma cell), as well as mantle cell lymphoma (a cancer of the lymph nodes) in patients who have received at least one prior therapy.
- MLN9708, like Velcade, should not be taken if you have ever had an allergic reaction to boron or boron containing products.
- MLN9708 is not currently approved by the FDA for any indication. Like Velcade, it appears to benefit patients with multiple myeloma and it is being studied also in patients with different types of lymphoma, including your type.

- The following side effects have been reported with VELCADE use and therefore may also be a risk with MLN9708:
    - Reactivation of the herpes virus infection such as herpes zoster (shingles) that can sometimes cause local pain that may last after recovery from the skin rash and does not go away for some time; and
    - Rapid death of cancer cells that may let large amounts of the cells into the blood that injur organs, such as kidneys (this is referred to as tumor lysis syndrome). Your study doctor can talk with you about other common side effects with VELCADE use.

- The more severe but rare side effects seen with VELCADE, include but are not limited to, worsening of your heart function (congestive heart failure), disorders that could affect the function of your lung that could be serious enough to result in death, and liver failure. Your doctor can talk to you further about the risks of VELCADE.

- Other drugs and supplements may affect the way MLN9708 works. Tell your doctor about all drugs and supplements you are taking while you are in this study.

If you are a woman: We do not know if the study drug MLN9708 will affect mother's milk or an unborn child. Therefore, breast-feeding and pregnant women are not allowed to take part in the study. Due to unknown risks and potential harm to the unborn child/ infant, you should not become pregnant or nurse a baby while on this study.

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 for 90 days after you stop taking the study drug. 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.

You must have a negative pregnancy test prior to enrolling in the study, and we will check a pregnancy test on day 1 of each treatment cycle while you are on the study.

Unless you cannot have children because of surgery or other medical reasons (you had an effective tubal ligation, or had the ovaries or the uterus removed; or you are post-menopausal), you must use two effective methods of birth control from the time of signing the informed consent form, for the entire study drug treatment period (including interruptions in treatment), and for 90 days after completing study drug treatment. You must use birth control, unless you completely avoid having heterosexual intercourse.

If you are a man: We do not know if using MLN9708 will affect sperm. Therefore, due to potential risk, you should not get your partner pregnant during the study drug treatment period (including interruptions in treatment). Even if you are surgically sterilized (i.e. have had a vasectomy) you must agree to use an appropriate method of barrier birth control during the entire study drug treatment period, and for 90 days after completing study drug treatment. Or, you should completely avoid having heterosexual intercourse.

All subjects (male or female): If you or your partner becomes pregnant during this study, you must tell the study doctor immediately. The doctor will advise you of the possible risks to your unborn child and discuss options for managing the pregnancy with you. For female subjects who become pregnant while on this study, the study drug will be stopped immediately and the pregnancy will be followed until conclusion.

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.

Radiation Risks
You will be exposed to radiation from nuclear medicine and CT scans. These procedures are necessary for your medical care and will occur even if you do not participate in this study. The radiation dose estimate that you will receive is equal to or less than the radiation exposure allowed to be received by a radiation worker for 2 years. The principal risk associated with a radiation dose is the possibility of developing a radiation-induced cancer later in life. Although the risk from radiation is cumulative it is not expected to adversely affect your condition or treatment. The Emory University Radiation Safety Committee has reviewed and approved the use of radiation in this research study.

Bone Marrow Biopsy Risks
Small pieces of cancer tissue will be removed during your bone marrow aspirate/biopsy procedures during this study. This sample is required in order for you to take part in this study because the research on the sample is an important part of the study.

The research biopsy is done in a similar way to biopsies done for diagnosis. Common side effects of a biopsy are a small amount of bleeding at the time of the procedure, pain at the biopsy site, which can be treated with regular pain medications, and bruising. Rarely, an infection can occur.

You will sign a separate consent form before the biopsy is taken. This will be a standard surgical consent form from the institution where the biopsy procedure takes place.

POTENTIAL RISKS ASSOCIATED WITH RITUXIMAB

Rituximab (Rituxan) will be administered to some patients enrolled on this study. This drug is commonly given to patients after a stem cell transplant for mantle cell lymphoma. We do not yet know if the combination with ixazomib will cause extra side effects

Potential side effects from rituximab include the following:
Common:
Infusion reaction
Fever
Low white blood cell count
Chills
Infection

Less common but potentially severe complications include:
Tumor lysis syndrome (a condition in which breakdown of your cancer cells causes kidney failure and electrolyte changes)
Progressive multifocal leukoencephalopathy (a neurologic condition caused by a virus that causes changes in your thinking and function and can be fatal)
Severe skin rashes
Worsening of hepatitis B infection
Severe kidney toxicities
Bowel obstruction or perforation
Abnormal heart rhythms

New Information
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.

Benefits
This study is not designed to benefit you directly. Your cancer may improve while you are in this study but it may not, and it may even get worse. This study is designed to learn more about whether the study drug will help improve the survival outcomes of patients with mantle cell lymphoma that has failed previous therapy or that has come back The study results may be used to help others in the future.

Compensation
You will not be offered payment for being in this study.

Other Treatment Outside this Study
If you decide not to enter this study, there is care available to you outside of this research. You have the option to start other treatments that are research or standard of care, instead of participating in this study. The study doctor will discuss these with you. You do not have to be in this study to be treated for mantle cell lymphoma.

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.

Medical Record
If you have been an Emory Healthcare and Saint Joseph's Hospital patient before, then you already have an Emory Healthcare and Saint Joseph's Hospital medical record. If you have never been an Emory Healthcare and Saint Joseph's Hospital patient, you do not have one. An Emory Healthcare 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 Healthcare and Saint Joseph's Hospital medical record you have now or any time during the study.

Emory Healthcare 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 Healthcare 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.

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* would help you to 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 proved 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 trial, 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. Cohen 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. Ixazomib will be provided to you at no charge. The cost of the rituximab will be the your responsibility and will be billed to your insurance carrier similar to other medications or treatments that you receive when not enrolled on a clinical trial.

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 and/or disclose (share) for the 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 disclose 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.

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 use to report child abuse or abuse of elder 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 authorize the use and disclosure of your PHI for the study, then you may not participate in the research study or receive research-related treatment. You may still receive non-research related treatment.

People that will Use and/or 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.
- Dr. Jonathon Cohen is the Sponsor of the study. The Sponsor 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 Sponsor 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 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 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: Food and Drug Administration
    - Governmental agencies in other countries where the study drug may be considered for approval
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.

  - Millennium Pharmaceuticals, Inc., The Takeda Oncology Company (drug supplier of Ixazomib) and its collaborators or designees
- 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 write to:

Dr. Jonathon Cohen
Winship Cancer Institute, Emory University
1365-C Clifton Road NE
Atlanta, GA 30322

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
Not all people and entities are covered by the Privacy Rules. HIPAA only applies to health care providers, health care payers or 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 and/or for other purposes besides this study.

<u>Contact Information</u>
Contact Dr. Jonathon 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

Please **print** your name, **sign**, and **date** below if you agree to be in this 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.

_____
Printed Name of Subject

_____ _____ ____:____ am / pm
Signature of Subject Date Time (please circle)

_____
Printed Name of Person Obtaining Consent

_____ _____ ____:____ am / pm
Signature of Person Obtaining Consent Date Time (please circle)