Emory University
Consent to be a Research Subject

TITLE: Winship 2176-11: Omacetaxine for Consolidation and Maintenance in Patients Age ≥ 55 with AML in First Remission: a Pilot Study

PRINCIPAL INVESTIGATOR: Martha Arellano, MD

STUDY SPONSOR: Martha Arellano, MD

STUDY SUPPORTER: Teva Pharmaceuticals

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 will be given a copy of this consent form, to keep. Feel free to take your time thinking about whether you would like to take part in this study. 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 may search this Web site at any time.

WHY IS THIS STUDY BEING DONE?

You are being asked to take part in this trial because you have Acute Myelogenous Leukemia (AML) and have been determined to be a candidate for our institutional standard induction chemotherapy regimen. The standard treatment of AML is clear for younger patients and includes receiving induction and consolidation chemotherapy. However, for older patients with AML, there is no standard therapy that is agreed upon by all doctors. Induction chemotherapy is the initial chemotherapy designed to achieve a remission that is to get rid of the AML cells that can be detected in the blood

and bone marrow by the best available methods that we have. It is accepted that despite being in remission, there are residual seeds of leukemia cells that remain in the marrow but cannot be detected by the available methods. Those leukemic seeds will eventually cause the leukemia to relapse. Due to this fact, the management of AML includes giving consolidation therapy. The goal of consolidation therapy is to get rid of any leukemia seeds that were left behind in the marrow after induction chemotherapy. Generally standard consolidation has been with repeated cycles of high dose cytarabine chemotherapy. Unfortunately, this treatment can be too toxic for older AML patients and still most patients older than 55 may not be cured with that treatment. Maintenance therapy is the treatment that is given after consolidation to try to keep the leukemia from returning. Currently, there is no standard for which, if any maintenance therapy should be given to AML patients. If you achieve complete remission of the AML after induction chemotherapy, you will be eligible for the experimental parts of this study, which are consolidation and maintenance therapy.

The combination of cytarabine and an anthracycline drug (daunorubicin, idarubicin or mitoxantrone) can put people into remission, even patients age 55 and older.However, there is currently no way of ensuring that the remissions are maintained and that the AML doesn't relapse.

Scientists have developed an investigational drug called Omacetaxine (OMA). OMA was approved by the Food and Drug Administration (FDA) in the United States for the treatment of Chronic Myelogenous Leukemia (CML). It has not been approved for your disease. In this study, we will be using OMA for the treatment of subjects with AML disease.

The purpose of this clinical research study is to determine the safety and tolerability of OMA and its potential effectiveness in keeping AML in remission after treatment with our institutional regimen.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

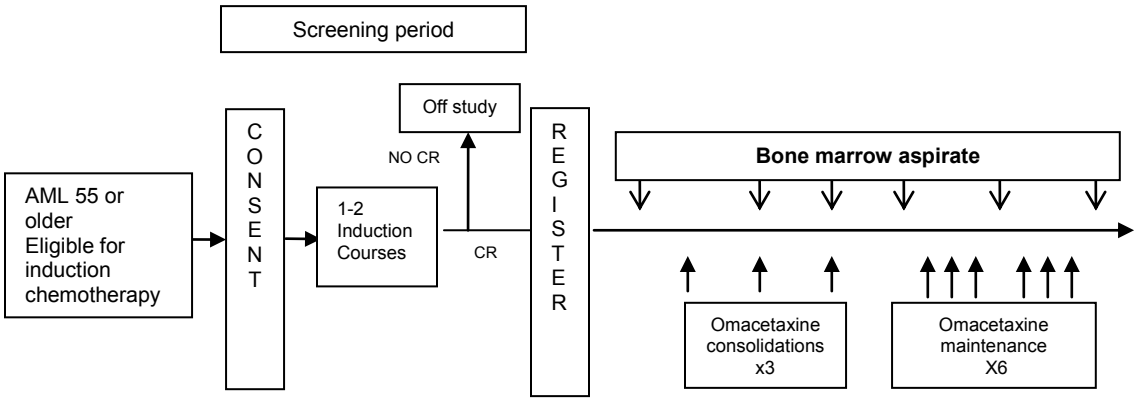
About 45 patients will undergo induction therapy at Winship Cancer Institute and Emory University Hospital. We hope to enroll all 45 in order to reach a number of 15 patients who are in remission after 2 cycles of standard induction therapy at Emory University for the experimental part of the study.

WHAT IS INVOLVED IN THIS STUDY

After you have signed the consent form, your study doctor will perform baseline tests to see if you are suitable for the study. It is possible that after reviewing your results your doctor may find that you are not eligible to take part; if so, you will be told why.

If you are eligible for the study and give your consent to take part, you will have to follow the study procedures explained below. At every visit the study doctor will ask you how you are feeling. He/she will also ask you if you have started or stopped any other medicines and if you have experienced any problems or side effects.

Flow sheet and plan of treatment:
Patients meeting inclusion criteria will start therapy as detailed below and as summarized in the Figure:



Description and Procedures of the Study

Screening Visit You will be screened to determine whether you are eligible to continue on this study. You must have AML and be in remission after induction chemotherapy. Your diagnosis will be confirmed here at Emory. The following procedures will be performed:
• Give your complete medical history to the study doctor or the study nurse including a list of medications you are currently taking. Your doctor will review your medical records to confirm you meet all the study requirements.
• Receive a physical exam (blood pressure, respiratory rate, pulse, temperature, height and weight). The height and weight measurements will be used by your doctor to determine how much medication will be prescribed.
• Have blood drawn for blood counts and blood chemistry tests (about 2 tablespoons), and 20cc of blood to perform research related to detecting any remaining leukemia on your cells.
• Have a bone marrow aspiration if not previously performed, to confirm your diagnosis and 10cc of the sample will be used for research. These cells will be studied with specialized investigational tests. One of the tests will be to study ways to detect minimal microscopic disease which may remain in the body, even after remission. If your doctor determines that it is too risky to perform a bone marrow biopsy to confirm your diagnosis (due to risk of bleeding or other complications), the information can be obtained from your peripheral blood. Bone marrow to confirm remission.
• Review all current and past medications and treatments for your disease.
• Assess your quality of life (a questionnaire to be filled out)

Based on the results from the Screening visit and if your study doctor finds that you still qualify for this study, you will begin therapy.

Since the initial treatment of AML (induction) is considered standard of care, meaning that we use a regimen that is commonly used at Emory, which is not experimental. That phase will consist of 1-2 cycles of chemotherapy, the first cycle includes cytarabine and an anthracycline (either daunorubicin, idarubicin, or mitoxantrone). The second cycle is optional at your docotr's recommendation and uses only cytarabine. A bone marrow biopsy is obtained between days 14 and 21 from the start of the first cycle of chemotherapy (+/- 3 days) to assess response to chemotherapy. A second bone marrow biopsy is repeated after the blood counts have recovered to document remission. The evaluations that are done during induction are done according to standard of care, and include blood work to measure organ function, including kidney and liver function tests, blood counts, and clotting factor measurements as needed. Part of the standard treatment of AML includes antibiotics, IV fluids, and transfusion support.

After the induction chemotherapy, if you are in remission based on the bone marrow exam, you will start the experimental part of this study, which is consolidation and maintenance with OMA. During consolidation, you will receive OMA by subcutaneous injections, twice each day, 12 hours apart, on days 1 – 10 of the treatment cycle. No drug is administered on days 11 – 28 of the treatment cycle. You will receive 3 cycles of consolidation with OMA. The injections will be administered either at home or at Emory/Winship Cancer Institute.

Bone marrow biopsies will be obtained monthly during consolidation to make sure that you are still in remission.

If you are still in remission at the end of consolidation, you will receive maintenance therapy with OMA twice daily by subcutaneous injection for 5 consecutive days of each 28 day cycle. You will receive up to 6 cycles of maintenance therapy with OMA. You will be assessed in the clinic on a monthly basis and will have bone marrow biopsies every 3 months during maintenance therapy with OMA. The injections will be administered either at Emory/Winship Cancer Institute or at home.

Evaluations During Induction

Test	Baseline
Research Samples: Peripheral blood (20mL), Bone Marrow Aspirate (10mL)*	X
Comordity Score	X
Quality of life Questionnaire	X

Evaluations During Consolidation

Week	1	2	3	4	5	6	7	8	9	10	11	12
Day	1											
H&P	X	X	X	X	X	X	X	X	X	X	X	X
Medication review	X	X	X	X	X	X	X	X	X	X	X	X
Physical exam	X	X	X	X	X	X	X	X	X	X	X	X

ECOG PS	X	X	X	X	X	X	X	X	X	X	X	X
CBC with diff.	X	X	X	X	X	X	X	X	X	X	X	X
CP Comp	X	X	X	X	X	X	X	X	X	X	X	X
Research samples: Peripheral blood (20mL) and Bone marrow aspirate (10mL)	X			X				X				X
Bone marrow aspirate[1]	X	X		X				X				X
Quality of life questionnaire	X			X				X				X
Comordity Score	X											

1. Bone marrow aspirate (biopsy if indicated based on suspicion of relapse) performed monthly during consolidation to document continuous remission. Molecular tests and cytogenetics obtained as clinically indicated. Research samples are obtained monthly during consolidation.

Evaluations During Maintenance

Week	1	4	8	12	16	20	24
Day	1						
H&P	X	X	X	X	X	X	X
Medication review	X	X	X	X	X	X	X
Physical exam	X	X	X	X	X	X	X
ECOG PS	X	X	X	X	X	X	X
CBC with diff. [1]	X	X	X	X	X	X	X
CP Comp	X	X	X	X	X	X	X
Research samples: Peripheral blood (20mL) and Bone marrow aspirate (10mL)	X			X			X
Bone marrow aspirate[2]	X			X			X
Quality of life questionnaire	X			X			X

1. CBC with differential will be collected weekly during maintenance and if counts remain stable (no neutropenia or significant thrombocytopenia), can decrease frequency to every other week.
2. Bone marrow aspirate (biopsy if indicated) performed every 3 months during maintenance. Molecular tests and cytogenetics obtained as clinically indicated. Research samples are obtained every 3 months during maintenance.

Other experimental drugs will not be allowed while you take part in this study. However, you will receive appropriate medications for the treatment of adverse events and/or illnesses that arise during the study or are required for your medical care.

If the AML relapse returns at any time during the study, you will be removed from the study and will be offered other therapy if available.

Note: Blood studies and/or bone marrow aspirations may be obtained more frequently or at intervals other than those specified above, during induction, consolidation, and maintenance phase of treatment, if required for your medical care and treatment.

What does your participation require you to do?

For this study to be successful, it is important that you co-operate fully with your study doctor and follow his/her instructions precisely. By signing this consent form, you agree to follow your study doctor's instructions, attend all study-related visits and perform all study specific assessments. You

should not take part in any other therapeutic research project. This is to protect you from such things as interaction of research drugs or similar hazards.

While participating in this study, you should avoid exposure to the sun or solarium visits for up to 3 days following treatment.
Do not take any other prescription or over-the counter medications or remedies from the pharmacy, health food store or supermarket unless the doctor conducting the study has approved them.

HOW LONG WILL I BE IN THE STUDY?

Your active participation in the study will end 1 month after the last dose of maintenance therapy is completed. After that, we will track your progress by calling your doctor or you to assess the status of the AML and collect information about any further therapies that you may be receiving.

You may be taken off the study without your consent for the following reasons:

- If you develop side effects that are considered dangerous
- If you refuse to have tests that are needed to see if this treatment is safe and effective
- If the physician in charge of the study decides that it is in your best medical interest
- If you need additional treatment not allowed in this study
- Pregnancy
- The AML returns/relapses.
- The study is cancelled

Your decision to take part in this study is voluntary and you may withdraw at any time without penalty or loss of benefits to which you are otherwise entitled.

If you should decide to stop taking part in the study, you should tell the study doctor. The study doctor can also discontinue your participation in this trial without your consent if he/she feels that it is in your best interest or if there are administrative reasons. If you should withdraw voluntarily from the study or are asked by your personal/another doctor to leave the study, you must notify your study doctor. You may be asked questions about your experience with the study drug. You also will be asked to cooperate by having end of study laboratory tests, tumor assessments, and physical exam performed.

WHAT ARE THE RISKS OF THE STUDY?

OMA

At each visit, your doctor will ask you about any unusual symptoms. You will be closely monitored for any side effects and should report any changes in the way you feel to your doctor. The side effects of OMA may be a minor inconvenience or could be severe enough to be life-threatening or fatal.

The side effects of OMA are categorized as follows:

Most Common	**Common**	**Uncommon**
What it means: This type of side effect may occur in 15-30% of patients. This means that 15 to 30	**What it means:** This type of side effect may occur in 2-5% of patients. This means that 2 to 5 patients	**What it means:** This type of side effect does not occur very often, but can occur in less than 1% of patients. This means that less than

patients out of 100 might get this.	out of 100 might get this.	1 patient out of 100 might get this.

Most Common OMA Side Effects:

Most common side effects are those that have occurred in 15 to 30% of patients who have received OMA:

- Low white blood cell counts, which are needed to prevent infection
- If you experience low white blood cell counts, you may be at increased risk of infections
- Low platelet counts, which are needed to prevent bleeding
- If you develop low platelet counts, you may experience bleeding
- Low blood pressure
- Fast heart rate
- Irregular heart beat
- Diarrhea
- Vomiting

Common OMA Side Effects:

Common side effects are those that Have occurred in 2-5% of patients who have received OMA:

- Chills
- Depression (sadness)
- Tiredness
- Irritation
- Confusion
- Abnormal taste
- Metallic or bitter taste
- Skin lesions
- Rash
- Hair loss
- Skin redness
- Fluid retention with weight gain
- Inflammation of the mucous membrane (for example, membranes lining the nose and mouth)

- High blood sugar level
- Increased blood levels of kidney function tests and liver enzymes
- General aches and pains, sometimes requiring treatment with pain medications

Uncommon OMA Side Effects:

When OMA was administered by rapid infusion into the vein at single OMA doses higher than are being used in this study, the following uncommon side effects occurred in less than 2% of patients who had received OMA:

These risks have not been observed to date, with the subcutaneous route of administration of OMA, which is being used in the current study.

- Fever
- Fatal changes in heart rhythm
- Heart failure

Risks Related to Bone marrow biopsy and aspiration:

Most Common Side Effects	Common Side Effects	Uncommon Side Effects
• Pain at the time the marrow procedure is done	• Infection and bruising at the aspiration site	• Allergic reaction to the numbing medicine • Hitting a nerve

The blood tests and bone marrow tests done at each visit are standard medical tests. The risks of taking blood may include fainting, pain (like a pin prick when the needle is inserted into your arm) and/or bruising. Rarely, there may be a small blood clot or infection at the site of the needle puncture. This problem usually resolves by itself.

The bone marrow test is performed by using a needle to obtain a small sample of bone marrow from the pelvic bone. You may experience pain, bleeding and/or bruising from the bone marrow aspiration. You may faint and/or develop an infection with redness and irritation at the site where bone marrow is removed. The blood pressure cuff may also cause discomfort or bruising to the upper arm. In order to make the procedure more comfortable, you will get a local anesthetic to numb the area. A mild sedative may also be given to you. While you are sedated, you will be able to respond to commands. Details of the procedure and any possible problems will be explained in a separate informed consent form.

Since the study drug OMA is investigational, there may be risks with the use of it that are not known. If your disease worsens, the side effects become intolerable, or new scientific developments occur indicating that this treatment is no longer in your best interest, treatment will be stopped and other alternatives will be discussed with you by your study doctor.

There may be side effects from the leukemia itself coming back, including death from leukemia related complications.

Risk to the Unborn Child and Fertility (Men and Women):
Both men and women will be included in this study. To prevent the possible occurrence of any unknown effect of OMA on an unborn fetus, women who are pregnant may not take part in this study. Mothers should not breast-feed during the study. Women of childbearing potential must have a negative pregnancy test before receiving study drug. The following are considered effective birth control: oral contraceptive pill, condom, diaphragm plus spermicide, abstinence, patient or partner surgically sterile, patient or partner more than 2 years post-menopausal, or injectable or implantable agent/device. You may qualify for the study if you are at least 2 years post-menopausal, surgically sterile (have undergone a hysterectomy or a bilateral tubal ligation), or have a vasectomized partner.

If you or your partner becomes pregnant even while taking precautions you must inform the study doctor immediately.

If you may be pregnant you should not take part in this study because of possible effects of chemotherapy exposure on your unborn child. There are currently no studies that show an increase in the risk of genetic mutation in the next generation of offspring.

ARE THERE BENEFITS TO TAKING PART IN THE STUDY?

During your participation in this study, your doctor will closely follow your condition. It is possible that there may be no benefit to you from your participation in this study, and that you may experience only the discomfort related to the possible additional side effects. However, you may benefit from the treatment if the progression of your disease is stopped or slowed. The information gained from this study may also help other cancer patients.

WHAT OTHER OPTIONS ARE THERE?

Other treatments have been used to treat AML. Instead of taking part in this study, you may choose to receive another type of treatment. While there is no standard regimen for your type of cancer, the following are options available to you:

- You may choose to be treated with the standard Emory regimen but not as part of this study.
- You may choose to be treated with other chemotherapeutic agents.
- You may take part in other research studies for the treatment of your cancer.
- After obtaining remission, you may choose to receive other drugs for consolidation and maintenance, such as cytarabine alone for consolidation or hypomethylating agent therapy.
- You may choose not to receive OMA consolidation and maintenance.

These alternatives will be explained to you by your doctor, as well as the risks and benefits of alternative (other) courses of therapy. The study doctor will answer any questions you have about these other treatments. You do not need to take part in this study to receive treatment for your condition.

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.

COMPENSATION

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

CONFIDENTIALITY

Certain offices and people other than the researchers may look at your medical charts and study records. Government agencies and Emory employees overseeing proper study conduct may look at your study records. These offices include: Food and Drug Administration, Teva Pharmaceuticals, Emory 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. Study sponsors may also look at your study records. Emory will keep any research records we create private to the extent we are required to do so by law. A study number rather than your name will be used on study records wherever possible. Your name and other facts that might point to you will not appear when we present this study or publish its results.

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

Research Information Will Go Into the Medical Record:
If you are or have been an Emory Healthcare patient, you have an Emory Healthcare medical record. If you are not and have never been an Emory Healthcare patient, you do not have one. Please note that an Emory Healthcare medical record **will** be created if you have any services or procedures done by an Emory provider or facility for this study.

If you agree to be in this study, a copy of the consent form and HIPAA patient form that you sign **will** be placed in your Emory Healthcare medical record. Emory Healthcare may create study information about you that can help Emory Healthcare take care of you. For example, the results of study tests or procedures. These useful study results will be placed in your Emory Healthcare medical record. Anyone who has access to your medical record 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. On the other hand, some state and federal laws and rules may not protect the research information from disclosure.

Emory does not control results from tests and procedures done at other places, so these results would not be placed in your Emory Healthcare medical record. They will not likely be available to Emory Healthcare to help take care of you. Emory also does not have control over any other medical records that you may have with other healthcare providers. Emory will not send any test or procedure results from the study to these providers. If you decide to be in this study, it is up to you to let them know.

IN CASE OF INJURY

If you get ill or injured from being in the study, Emory would help you to get medical treatment. Emory 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 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. Arellano at telephone number 404-778-1900. You should also let any health care provider who treats you know that you are in a research study.

WHAT ARE THE COSTS?

Teva Pharmaceutical will pay for certain items and services that you may receive if you take part in this study. Teva Pharmaceutical will provide the study drug, Omacetaxine (OMA), for free during the 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 will submit claims to your insurance for items and services that the sponsor does not cover. Emory 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 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 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.

First, whether or not you have health insurance.

If you do have health insurance:

1. The insurance may or may not pay for clinical trials.
2. If the insurance pays for clinical trials, the amount paid will be different depending on the insurance coverage you have.

3. You will have to pay for any co-payments, deductibles or co-insurance amounts that your insurance coverage requires. Emory and Teva Pharmaceutical will not pay for these.
4. If you do have insurance, you should contact the insurance provider and tell them you want to be in this clinical trial. Ask them what they will pay for and what they will not pay for.

If you do not have insurance, Emory 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 withdraw from the study. 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 and sponsor also have the right to stop you from taking part in this study without your consent if:

- They believe it is in your best interest;
- You were to object to any future changes that may be made in the study plan;
- or for any other reason.

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 may use and disclose your PHI to get payment for study related treatment and to run normal business operations. c
- 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.
- Martha Arellano, MD 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 research team and the Sponsor 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 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: Food and Drug Administration
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
    - Teva Pharmaceuticals, the manufacturers of Omacetaxine, and their authorized agents

- 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 and any required record-keeping period..

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:

Martha Arellano, MD • 1365-C Clifton Road, NE • Suite 1152 • 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 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. Arellano at 404-778-1900:

- 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 404-712-0720 or 877-503-9797 or irb@emory.edu:

- 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

If you agree to take part in this study, please print your name and sign below. By signing this consent form, you will not give up any of your legal rights. We will give you a copy of the signed consent, 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)

_____ _____ ____:____ am / pm
Signature of Legally Authorized Representative with authority for research decisions Date Time (please circle)

_____
Authority of Legally Authorized Representative or Relationship to Subject