Informed Consent Form

A Phase 1 / 2 Study of Visudyne (liposomal verteporfin) in Persons with Recurrent High Grade EGFR-mutated Glioblastoma

NCT Number: NCT04590664

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

You Are Being Asked to Be in a Research Study

Concise presentation of key concepts

You are being asked to be in a research study. A research study is designed to answer a scientific question. If you agree to be in the study you will be one of 24 people who are being studied, at Emory.

Why is this study being done?

This study is being done to answer the question if a commercial drug (called Visudyne), used to treat other diseases (certain eye diseases), could slow down or reverse the growth of your recurrent glioblastoma. We also want to know what doses of this drug are tolerable. We intend to test doses higher than those used to treat eye diseases.

You are being asked to be in this research study because you have been diagnosed with a glioblastoma that overexpresses a molecule called EGFR and that continues to grow after treatment with standard therapy.

Do you have to be in the study?

It is your decision to be part of this research study. You do not have to be in it. Your choice will not affect your access to medical care for your condition. Before you make your decision, you should take time to learn about the study.

What do I have to do if I choose to participate in this study?

If you are eligible and want to be part of the study, you will be participating until your tumor progresses, or you get sick from the treatment or choose to stop. You will get an infusion of drug every week through a port-a-cath device (a device used to draw blood and give treatments). An MRI will be obtained after you complete the first 42 days (6 weeks). If your tumor has not grown, the cycles will be repeated (weekly, now 5 out of 6 weeks) until the tumor grows, or you get sick from the treatment or you choose to stop. While in the study, the researchers will ask you to do the following: physical examination, taking measurement of your vital signs, blood samples drawn and appropriate imaging scans, MRIs. You will also have to have a port-a-cath placed which is a minor surgery.

How is this study going to help you?
If you are in the study, you will be helping the researchers answer the study question. Given this is an investigational treatment, there is no guarantee that the study treatment will help you if you choose to participate in this study. We hope the study treatment will stop your tumor from growing.

What are the risks or discomforts I should know about before making a decision?
The study will take time. The drug that is being tested may not work any better than regular care, and may even cause harm. All studies have some risks. Some risks are relatively small, like being bored or losing time. Some are more serious – for this study, these include: light sensitivity [sunlight or bright lights (like those at the dentist or a sports event) can burn your skin or eyes after Visudyne; Allergic reaction to the drug, Infusion site irritation], loss of privacy, and breach of confidentiality. A full list of expected risks, their frequency and severity are in the "What are the possible risks and discomforts?" section of this document.

Alternatives to Joining This Study
If you decide not to enter this study, there is care available to you outside of this research study. Your doctor will discuss alternative options with you. You do not have to be in this study to be treated for your cancer.

Alternative FDA-approved treatments for recurrent GBM include the Novo-TTF device, bevacizumab, and Gliadel chemotherapy wafers (placed after a second surgery). These are not experimental treatments. If you enroll on this study instead of receiving one of these proven treatments, you will forego any benefit these proven treatments might give you.

Costs
Your insurance will pay for things that are normal for care of a person with GBM, like doctor visits and MRI. The study will pay for things that are not covered by your medical insurance like the study drug. If you do not have a port-a-cath and need one for the study, the study will pay for that.

The study team can help you work out how much you might have to pay. There is more information in the cost section below.

What Should I Do Next?
Read this form, or have it read to you. Make sure the study doctor or study staff explains the study to you. Ask questions (e.g., about exact time commitment, about unfamiliar

words, more details on specific procedures, etc.) Make sure you understand which parts are research and which are standard care that you would have even if you did not join the study. Take time to consider this, and talk about it with your family and friends.

Emory University
Consent to be a Research Subject / HIPAA Authorization

Title: A Phase 1 / 2 study of Visudyne (liposomal verteporfin) in persons with recurrent high grade EGFR-mutated glioblastoma

Principal Investigator: William Read, MD

Sponsor-Investigator: William Read, MD

Study-Supporter: Bausch and Lomb and Ivy Foundation

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?

You have been diagnosed with a glioblastoma that overexpresses a molecule called EGFR. Your tumor has recurred. We are doing this study because this type of tumor is almost never cured with surgery, radiation, or chemotherapy. We need better treatments.

We are going to use a medicine called Visudyne (liposomal verteporfin) to treat persons with EGFR-positive glioblastoma (GBM).

Visudyne is currently on the market to treat certain eye diseases. This is done in combination with laser light. Many people have been treated with Visudyne for eye diseases.

No-one has ever tried to stop a brain tumor with Visudyne. Research suggests Visudyne given alone can damage or suppress GBM cells, but that has never been tried in people with GBM, only in the lab on cells and mice. Also, weekly doses of Visudyne is something new, and on this study we

will gradually use higher doses of Visudyne than people have ever received (although animals did get high doses and if they stayed out of the light they did OK). The use of Visudyne to treat brain tumors is investigational.

If it works, we could use Visudyne treatments to stop the growth of recurrent glioblastoma.

We don't know how much Visudyne it will take to stop a GBM from growing, or if it will work at all. We also don't know if high doses of Visudyne will make people sick. On this study we will be giving Visudyne every week, and we will be trying higher and higher doses to see what works and to see if people get sick from the high doses.

The first 3 people on this study will get a normal dose – the same as we used in the surgery study and double what people get for eye treatment. Those people will get a treatment every week. People on the study after those first 3 will get higher doses.

Bausch and Lomb is the company that makes Visudyne and they have agreed to give us their drug to use for this study. They are not paying us to do the study and they are not giving us any money. A foundation called the Ivy Foundation gave us money to do the study. The Ivy Foundation supports research into glioblastoma treatment.

What will I be asked to do?

This study asks you to do several things. Most of them would be done as standard of care if you were not on this study. After you sign this Informed Consent form and before starting treatment, you will be asked to:

- Review your health history and document how you feel
- Conduct a physical exam including measurement of your height, weight, blood pressure, temperature, breathing rate, heart rate and performance status (which measures the degree of your ability to complete daily activities such as dressing and eating).
- You will have a complete neurological exam to test your motor skills, sensation, reflexes and coordination.
- Have baseline testing of your organ function (by collecting blood and urine samples). If you are a woman of child-bearing potential, you will be asked to have a pregnancy test.
- Have a magnetic resonance imaging (MRI: which is a method of obtaining pictures of internal soft bodily tissue through the use of powerful magnets and radio waves) to see your tumor.
- Go over your past and current medications.
- Ask you for blood tests for research purposes. This will be before and after the first dose and it could be as much as 42 ml of blood. That is 1.4 ounces.
- Because Visudyne can potentially damage veins and you will be getting a dose each week, you will be asked to get a port-a-cath placed. That is an outpatient surgery.
- If you are already taking bevcizumab (Avastin) for treatment of GBM you may continue on that medicine.

Prior to each treatment you will have laboratory tests (blood and/or urine) and an evaluation including physical exam by your treating physician. This will be 5-10 ml of blood to make sure blood counts and organs are OK.

Once on treatment, you will receive Visudyne by vein every week for the first six weeks, and then every week for 5 out of 6 week after. It will take about an hour to get the infusion. You will have MRI done every 6 weeks to see if your tumor has continued to grow, or stopped, or shrunk.

You will get the same dose of Visduyne that you started with each time. As this study goes along, new participants will get a higher dose than the previous participants. Your dose will not change unless you get sick from it, in which case it could decrease.

YOU MUST STAY OUT OF BRIGHT LIGHT WHILE ON THIS STUDY! This is the main side effect we are worried about in this study. Visudyne makes your cells sensitive to light. Normal room light should not cause any issues, but sunlight or bright lights like at the dentist could cause damage. People who get Visudyne for eye treatment can get unexpectedly sunburned. At higher doses people might become even more sensitive to light. You will be asked to bring a hat and sunglasses and wear long sleeves / long pants for each visit.

About 3 tablespoons of blood will be drawn from one of your veins for laboratory tests (such as standard blood counts including a count of your platelets, and blood chemistries). These laboratory tests will be done weekly. If you are pregnant you will not be allowed to participate in this study.

Participants in the first part of this study will be asked to stay longer after their infusion has finished for extra blood draws. We will study how fast Visudyne is cleared from the body.

Visudyne is a vesicant, which means it can cause irritation of the skin and tissue if it leaks out of an IV. For this reason everyone participating on this study will have a port-a-cath placed. A port-a-cath makes the infusion of vesicant drugs safer. Instead of an IV in the arm, we will use the portacath for blood draws and infusions.

During the study, physical exams, and neurologic exams will be repeated. Routine blood tests will be done. Your blood counts will be checked each time you come for a Visudyne infusion. Participants on this study will have previously resected tumor specimens analyzed to help researchers understand your response or nonresponse to Visduyne treatment.

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. You will receive it as an infusion in the Phase 1 unit at Emory University. 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 study doctor or study nurse. You may also call the pharmacy at [redacted] if you have questions about the medicine.

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.

What are the possible risks and discomforts?
There may be side effects from the study drug or procedures that are not known at this time.

While on the study, you could experience the following side effects.

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

Light sensitivity. This is the number one side effect of concern. Visudyne greatly increases light sensitivity. Sunlight or bright lights (like those at the dentist or a sports event) can damage your skin or eyes after Visudyne. In animal studies, when animals got sick after big doses of Visudyne they got burns on the skin if they were in bright light. It is all kinds of light, not just ultraviolet and so sunscreen does not help. On this study you need to stay out of the sun and bright lights. Regular lights like a lighted room are ok.

We will ask you to wear a hat, long sleeves and long pants, and sunglasses to each visit. We will provide sunglasses in case someone forgets. You need to stay out of the sun.

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

Allergic reaction. Visudyne is made up in liposomes which are like microscopic drops of oil. About 1 in 10 people are sensitive to those. Sensitivity happens during infusion – some people get flushed, or itchy or have back pain. We will give medicine (dexamethasone, diphenhydramine, famotidine) before the infusion to try to decrease the chance of reaction. If you have a mild reaction that can be treated by giving the infusion more slowly.

In the animal studies, some pigs that were under anaesthesia and got Visudyne died from allergic reactions. If they were not under anaesthesia none died and if they got medicine first none had allergic reactions. This did not happen to other kinds of animals like mice. But this means allergic reactions could be serious.

Infusion site irritation. Visudyne is a vesicant drug. If it leaks out of the IV under the skin it can be irritating. For this reason we require everyone on this study to get a port-a-cath, which is a safer way to give vesicant drugs.

Most side effects described for Visudyune have to do with eyes, because that is the normal use for Visudyne. Most people who get Visudyne get it with laser treatment of the eyes.

Rare but possible risks include:

Animals who got Visudyne at very high doses did not get sick, except for light sensitivity. Some animals had slightly lower red blood or platelet counts. There may be side effects in humans we don't know about. That is part of why we are doing the study.

We require you to get a port-a-cath on this study if you don't already have one. Sometimes port-a-caths get infected and have to be removed.

If you are a woman: to protect against possible side effects of the study drug, women who are 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 for 8 weeks after study participation. 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 8 weeks after the last dose. You and the study doctor should agree on a method of birth control to use throughout the study and for 8 weeks after study participation.

Other side effects due to **blood drawing** may include: pain, bruising, bleeding or other discomfort at the blood drawing site. Anemia (low red blood cells), fainting or infection at the blood drawing site may occur (very unlikely). Your physician will discuss these with you.

In addition to these risks, there is always the risk of very uncommon or previously **unknown side effects**. This study may also have risks to you that cannot be determined at this time.

You will be told of any risks that may be discovered while you are part of this study.

Reproductive risks: Use of Visudyne may impair your ability to reproduce due to degenerative changes in the ovaries, uterus or testes. The period that this effect may last is not known. The exact defects that may occur in human fetuses is unknown. Because of this risk of birth defects due to exposure of an unborn child to Visudyne, you should not be on this study if you and your partner are planning to have a baby during this study and for two months after coming off of the study. A barrier method of birth control (i.e. condom) must be used during the study and for eight (8) weeks after your last dose of study drug. You should not nurse a baby while on this study. Ask about counseling and more information about preventing pregnancy.

Financial risks: Visudyune will be covered by the study. Things are required by the study will also be covered by the study, for example the port-a-cath placement. Other medical care will be charged to your insurance – this includes MRI and doctor visits.

MRI's: If you are considering this study you have probably had an MRI before. MRI uses a large magnet instead of X-rays to take pictures of the inside of your body. People who have metal in their bodies (pacemakers, metallic cardiac valves, implanted infusion pumps or any other metallic pieces such as bullets or shrapnel fragments, neurostimulators, certain clips or staples from prior surgery) may not receive a MRI. The magnetic field used in MRI scanning may harm such people or cause problems with devices such as pacemakers. Part or all of the body will be passed into a long, narrow

tube (scanner), which is open at both ends. The scanner has an intercom which will allow you to talk to the doctors and staff during the procedures. The machine will produce a loud knocking noise. This is normal. You will be given earplugs to protect your ears. In addition, you may feel light vibrations throughout your body.

Some people, especially those who have a tendency to feel uncomfortable in small or closed spaces, may feel "closed in" and become anxious while in the scanner. If you feel ill or anxious during scanning, doctors and the MRI staff will help you or the scanning will be stopped.

For the standard brain MRIs you will receive a contrast agent through the vein using a small needle. A small amount of people develop temporary reactions during the dye administration, including nausea, headache, hot flashes, and heart palpitations. These symptoms usually go away on their own within minutes. The most common side effects of the MRI contrast agent (Magnevist or similar gadolinium chelate) are local warmth/pain at injection site, nausea and/or vomiting. A smaller group of people are actually allergic to the dye and may develop a rash, hives, difficulty breathing, and in extreme cases, the patient may stop breathing, the heart may stop, and the patient may die. These effects are rare and are usually temporary and can be treated if they occur. Serious allergic reactions are very rare but may occur and may be life threatening (a rare event occuring in <1% of individuals). Death resulting from allergic reaction is rare. Be sure to tell your study doctor if you have allergies of any kind, such as hay fever, iodine allergy, eczema, hives or food allergies. You will be closely monitored during the procedure, and if any allergic reaction develops, you will be treated immediately.

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?

This study is not designed to benefit you directly although we hope that it will. Your condition may improve while you are in this study but it may not, and it may get worse. This study is designed to learn more about brain tumors and the use of liposomal verteporfin (Visudyne) as chemotherapy. The study results may be used to help others in the future.

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 study doctor will discuss these with you. You do not have to be in this study to be treated for your disease.

Instead of being in this study, other options are:

- Chemotherapy of another type
- Other forms of radiation

- Other forms of surgery
- Other experimental therapy
- No further anti-cancer therapy and comfort care only

Please talk to your regular doctor about these options. You may continue to get care from your physician even if you do not take part in the study.

If your disease becomes worse, or should you have severe side effects, this therapy will be stopped and other treatments will be discussed.

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 (data that has been stripped of all information that can identify you), 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.

Your data and specimens from this study may be useful for other research being done by investigators at Emory or elsewhere. To help further science, we may provide your deidentified data and/or specimens to other researchers. If we do, we will not include any information that could identify you. If your data or specimens are labeled with your study ID, we will not allow the other investigators to link that ID to your identifiable information.

We will use your sample and data only for research. We will not sell them.

In general, we will not give you any individual results from the study of the samples you give us. If we find something of urgent medical importance to you, we will inform you, although we expect that this will be a very rare occurrence.

Medical Record
If you have been an Emory Healthcare patient before, then you already have an Emory Healthcare medical record. If you have never been an Emory Healthcare patient, you do not have one. An

Emory Healthcare medical record will be made for you if an Emory 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 medical record you have now or any time during the study.

Emory Healthcare 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 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: research blood collection.

Tests and procedures done at non-Emory places may not become part of your Emory 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 believe you have become ill or injured from this research, you should contact Dr. William Read at [redacted]. You should also let any health care provider who treats you know that you are in a research study.

If you get ill or injured from being in the study, Emory will help you to get medical treatment. Emory will not pay for your medical treatment. Your insurer will be billed for your treatment costs. If you do not have insurance, or if your insurance does not pay, then you will have to pay these costs.

Emory have not, however, set aside any money to pay you if you are injured as a result of being in this study or to pay for this medical treatment. For Emory, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory employee. “Negligence” is the failure to follow a standard duty of care. You do not give up any legal rights you may have by being in this study, including any right to bring a claim for negligence.

Costs

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

Visudyne, the study drug, will be provided to you free of charge for this study by the drug manufacturers as long as you participate.

You will have to pay for some of the items or services that are part of this study. Emory will not pay for your regular medical care. If you have insurance, Emory will submit claims to your insurance for items and services that are part of this study. 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. You or your insurance company will be responsible for the cost of medications you might take at home such as medications for nausea. 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.

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.

The study doctor also has the right to stop your participation in this study without your consent if:

- He believes 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.

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. If you do not sign this form, 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.
- 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. William Read 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 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.

  - Study-Supporters: Bausch and Lomb and their authorized agents and Ivy Foundation
- 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:

William Read, MD
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 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.

<u>Contact Information</u>
Contact Dr. William Read 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, and any optional studies you initialed above. 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

Signature of Subject (18 or older and able to consent)	**Date**	**____:____ am / pm Time (please circle)**
Signature of Legally Authorized Representative	**Date**	**____:____ am / pm Time (please circle)**

Authority of Legally Authorized Representative or Relationship to Subject

TO BE FILLED OUT BY STUDY TEAM ONLY

Name of Person Conducting Informed Consent Discussion

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