

Pilot Study of Spectroscopic MRI-Guided, Dose-Escalated Radiation Therapy for Newly-Diagnosed Glioblastoma

NCT03137888

Informed consent date: March 13, 2019



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
Consent to be a Research Subject / HIPAA Authorization

Title: Rad3383-17 Pilot study of spectroscopic MRI-guided, dose-escalated radiation therapy for newly-diagnosed glioblastoma

Principal Investigator/Sponsor: Hui-Kuo G. Shu, MD, PhD

Study-Supporter: National Cancer Institute (NCI)

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.

Why is this research being done?

You are asked to participate in this research because you have a gliosarcoma or glioblastoma (GBM) of the brain. This research uses a type of MRI scan that detects your brain's natural metabolism, an imaging technique called Spectroscopic magnetic resonance imaging (sMRI). This sMRI scan can map areas of high tumor metabolism without using any injection of contrast agent. There is a significant difference in metabolism between normal brain tissues and brain tumors, which can show where the extent of tumor is in your brain beyond the current clinical MRI scans. The purpose of this study is to determine if higher dose localized radiotherapy [75 Gray (Gy), as compared to 60 Gy currently used as standard of care] guided by sMRI can improve patient outcome. It will also be investigated how this type of treatment affects mood, function and quality-of-life compared to standard therapy. Researchers do not yet know whether this will improve tumor control. There may be risks associated with an increased dose of radiation treatment.

The current standard care starts with removing as much of it as can be safely removed. Radiotherapy and temozolomide chemotherapy are used to treat the remaining tumor. This treatment usually does not control the

tumor for the long term. This study seeks to identify the most active areas of the tumor based on the sMRI and increases the dose of radiation therapy to those areas in hopes of improving tumor control.

Radiotherapy is given for approximately 30 sessions over about 6 weeks. The radiation is aimed at the areas of the brain where there is likely to be tumor after surgery. Standard diagnostic MRI scan with contrast agent is used to target the radiation. Standard MRI shows areas where the shape of the brain is altered and areas where the brain is disturbed or injured. The targeting of radiation is also guided by your doctor's knowledge of the likely pattern of extension of the tumor.

Your doctors will target radiation using the location of metabolically active tumors in addition to the standard abnormalities normally targeted based on standard diagnostic MRI. These areas of biochemical abnormalities will receive extra radiation beyond the standard dose. We do not know whether this is safe or will improve your tumor control outcome.

Patients getting standard therapy are treated with radiation to a dose of 60 Gy to the highest risk regions and a lower dose (45-54 Gy) to lower risk regions. Even with this therapy, the tumor will generally regrow within the area that got 60 Gy of radiotherapy treatment. Higher radiation doses may result in better control. This has been tested in studies before. Increasing the dose of radiation based on standard diagnostic MRI was safe but did not improve outcome.

This research is being done to ultimately determine whether giving additional radiation to these areas of high tumor metabolism will improve results of treatment. We will test whether targeting radiation this way is safe. Tumor outcome will be monitored. You will also have tests of mood, neurocognitive function and quality-of-life to monitor the benefit of more aggressive treatment from the aspect of patients' quality-of-life.

How many people will be in this study?

Up to 52 people will take part in this study, with 25 expected to take part at Emory.

What will I be asked to do (procedures)?

If you agree to be in this study, we will ask you to do the following things:

Before the research starts (screening):

After signing this consent form, you will be asked to have some screening tests or procedures to find out if you can be in the research study. These tests and procedures are part of regular cancer care and are routinely done even if it turns out that you do not take part in the research study. If you have had some of these tests or procedures recently, they may not have to be repeated.

- A medical history (questions about your health, current medications, and any allergies) will be taken.
- A physical examination including height and weight will be performed.
- Your performance status or how your disease affects your daily activities will be assessed.
- An assessment of your tumor will be made by MRI (magnetic resonance imaging).
- A pregnancy test for women of childbearing potential will be obtained.

If these tests show that you are eligible to participate in the research study, you will begin the study treatment. If you do not meet the eligibility criteria, you will not be able to participate in this research study.

After the screening procedures confirm that you are eligible to participate in the research study:

You will have the following tests and procedures:**Radiation therapy:**

You will have radiation therapy (RT) about 5 days/week for about 6 weeks. The treatment involves a higher dose to a selective volume based on sMRI [75 Gray (Gy), as compared to 60 Gy currently used as standard of care] guided by sMR.

Medications during radiation therapy:**Temozolomide (TMZ) chemotherapy (standard care)**

TMZ chemotherapy will be given as a pill by mouth. It is started on the first day of radiation. It will be given daily (7 days/week) for the duration of RT (about 6 weeks). The dose of TMZ that is used in this phase of treatment will be based on your height and weight. TMZ must be taken at least one hour before or two hours after eating. Prior to receiving TMZ, you will be given a medicine to prevent nausea.

Rest period:

Following radiation treatments, there will be a four-week break in which you will not take any study medications.

Adjuvant Phase which is the treatment given after radiotherapy is done (standard care)

After the 4-week rest period, you will re-start Temozolomide chemotherapy – dose, duration, and number of cycles will be determined by your doctor. This is standard therapy for your type of tumor.

Spectroscopic MRS (sMRI) scans (research activity):

sMRI scan will be performed on a normal MRI machine **without** intravenous contrast. These studies will take less than an hour and may be done with or separate from normal diagnostic MRIs. These are extra scans that happen because you are participating in this study.

The timing for the two sMRI scans is as follows:

- 1) Within 2 weeks before the start of RT/TMZ (for RT planning)
- 2) Two weeks after the start of RT/TMZ (during the third week of treatment)

It is possible that the sMRI scan will not function properly due to technical reasons or that it will identify an area within your brain of high tumor metabolism that is too large to safely treat with the increased dose of radiation. If this happens, you will be removed from the study and treated as per standard of care or considered for an alternative research protocol.

Neurocognitive, mood, and quality-of-life studies (research activities):

We want to know how your life has been affected by your brain tumor and its treatment. Your memory and thinking ability (neurocognitive function), mood (depression survey), and general sense of well-being (quality-of-life) will be evaluated by a tests and questionnaires. These will be done in your doctor's office. It takes about 40 minutes to complete these tests and questionnaires.

The timing of these tests is as follows:

- 1) Within 14 days before to the day of starting therapy (may be performed anytime on first day of therapy),
- 2) 10 weeks after starting therapy (4 weeks after completion of RT/TMZ)

- 3) Every 6 months thereafter. Tests are repeated until either tumor progression or 2 years without progression after completion of RT/TMZ.

This information may help doctors better understand what effects this treatment has on patients and may eventually help patients and doctors decide which treatment to use for these brain tumors. As always, we will do our best to make sure that your personal information will be kept private.

MRI scans (standard care):

A diagnostic MRI scan with and without intravenous contrast will be done 1-2 weeks before the start of therapy if the immediate post-operative MRI scan was done > 28 days from registration. This is for RT treatment planning and establishment of a pre-treatment baseline.

About 10 weeks after the start of therapy, you will have another diagnostic MRI scan with and without intravenous contrast. This is to look at the status of your tumor. The follow-up diagnostic MRI scans will be ordered by your doctor according to the standard care schedule of your type of tumor.

Physical exams (standard care):

Physical exams will be performed every other week during RT/TMZ treatment.

How long will you be in the study?

You will be in the study for 2 years. We will monitor the records of your long term outcome after this. The treatment with radiation and chemotherapy lasts for six weeks. One month after this, chemotherapy will start again according to your doctor's instruction as standard care therapy for your type of tumor.

What are the possible risks and discomforts?

Risks and Discomforts

There are risks to taking part in any research study.

Please notify your doctor if any of the following occur:

- A fever of 100.5 F or above.
This could be a sign of an infection. If you have a low white blood cell count, this can be serious, life-threatening or fatal. You may have to take antibiotics or be admitted to the hospital.
- Low energy or shortness of breath.
This could be a sign of anemia (not enough red blood cells). If this becomes severe, you may need to come into the clinic or hospital to have a transfusion of red blood cells.

This study changes the way radiation is aimed. More radiation will also be given to some areas of your brain. This may increase the risks and side effects related to the radiation therapy. Ask your doctors about how these risks apply to you. Your doctors will discuss any extra risks in your situation.

Risks of Radiation Therapy:

Likely (events occurring greater than 20% of the time):

- Tiredness
- Hair loss

- *Redness or irritation of your skin*
- *Dry skin*

Less Likely (events occurring less than or equal to 20% of the time):

- *Headaches*
- *Worsening of your current symptoms*
- *Swelling of your brain requiring steroids*
- *Ear pain or discomfort*
- *Decreased Hearing*

Rare but serious (events occurring less than 2-3% of the time):

- *Seizures.*
- *Coma.*
- *Lower white blood cell and platelet counts raising the risk of infection and bleeding.*
- *Radiation therapy at these dose levels also may cause damage to normal brain, but this is rare.*
- *Specific effects depend upon the location of the area(s) of damage but may be a decrease in judgment, memory, emotions, vision, hearing, sensation, or ability to control movement.*
- *Another brain tumor or cancer caused by radiation*

Risk associated with temozolomide (standard care)

Likely risks of TMZ (events occurring more than 20% of the time):

- *Feeling sick to your stomach (nausea).*
- *Throwing up (vomiting).*
- *Decreased appetite (anorexia).*
- *Difficulty in passing stools (constipation).*
- *Headache.*
- *Fatigue.*
- *Fever (pyrexia).*

Less likely risks of TMZ (events occurring less than or equal to 20% of the time):

- *Fall in the white blood cell counts that leads to a higher risk of infection (neutropenia).*
- *Fall in the platelet count leading to a higher risk of bleeding (thrombocytopenia).*
- *Fall in the red blood cell count leading to anemia (feeling tired and low energy) (anemia).*
- *A low number of a particular white blood cell, which is important to the immune system (lymphopenia).*
- *Sores in the mouth (stomatitis).*
- *Loose stools (diarrhea).*
- *Pain in the belly (abdomen).*
- *Change in liver function tests (tests that show how the liver is working).*
- *Rash (psoriasis).*
- *Itchiness (pruritis).*
- *Lack of interest in or ability to carry out daily activities.*

- *Weakness (asthenia).*
- *Dizziness.*
- *Anxiety.*
- *Depression.*
- *Memory loss.*
- *Muscle pain (myalgia).*
- *Joint pain (arthralgia).*
- *Tingling or burning in your arms or legs.*
- *Shortness of breath (dyspnea).*
- *Cough.*
- *Swelling in your arms or legs (edema).*
- *Increased need to pass urine.*

Rare but serious risks of TMZ (events occurring less than 2-3% of the time):

- *Problem with the bone marrow that causes decreased production of red cells, white cells, or platelets that can sometimes turn into blood cancer called Myelodysplastic syndrome.*
- *Convulsions.*
- *Weakness on one side of your body (hemiparesis).*
- *Abnormal coordination.*
- *Inability to move an arm or leg (paralysis).*
- *Severe skin reaction.*
- *Fever, chills, swelling of body, shortness of breath (allergic reaction).*
- *Re-activation of hepatitis infection (if you have previously been diagnosed with Hepatitis-A type of infection in the liver).*
- *A blood disorder in which the body's bone marrow does not make enough new blood cells (Aplastic Anemia).*
- *Inflammation in the lungs (pneumonitis).*
- *Change in kidney function tests (tests that show the kidneys are working).*
- *Later development of secondary leukemia, lymphoma or other cancers.*
- *Liver damage which may cause yellowing of eyes and skin, swelling and may result in liver failure.*

Risks and side effects related to spectroscopic MRI (research activity)

Less Likely:

- Some people who are claustrophobic (have a fear of enclosed places) might feel anxiety or nervousness during MR scan.
- Increased discomfort from the noise that the MRI instrument makes
- This will involve up to an extra hour in the MRI scanner each time spectroscopy is done.

Risks and side effects of study questionnaires (research activity)

Less Likely:

- You may get tired or bored when we are asking you questions or you are completing questionnaires. You do not have to answer any question you do not want to answer.

For more information about risks and side effects, ask your study doctor.

Risks and side effects related to radiation

- In addition to radiation therapy you may receive additional radiation from procedures to evaluate your condition. The principal risk associated with a radiation dose is the possibility of developing a radiation-induced cancer later in life. However, the additional risk of radiation-induced cancer from these diagnostic procedures is low compared to the risks from the radiation therapy.

Are there risks related to pregnancy?

You should not become pregnant or father a baby while on this study because the radiation and chemotherapy in the standard care of your tumor type can affect an embryo or fetus.

Women should not breastfeed a baby while on this study.

It is important you understand that you need to use birth control while on this study. Check with your study doctor about what kind of birth control methods to use and how long to use them. Some methods might not be approved for use in this study.

The treatments used in the standard care (TMZ) of your tumor type may make you unable to have children in the future.

Women will need to have pregnancy testing prior to enrolling in the study.

Additional risks

The sMRI results and copies of your MRI scans will be shared with researchers outside of Emory, after all identifying information will be removed from these data. Despite significant precautions that will be taken to maintain confidentiality for study subjects, there remains a small possible risk for breach of confidentiality.

It is possible that we will discover that you have a medical issue that is unrelated to the purpose of this sMRI study. If we believe that the information is of urgent medical importance, we will share this information with you. You should not assume that if you are not contacted, that you do not have any medical issue might be related to a disease.

There may be side effects and discomforts that are not yet known.

Will I benefit directly from the study?

You may or may not benefit from being a part of this study. Your brain tumor may improve while you are in this study but you may feel worse (headache and pressure) with more aggressive treatment that could cause significant tumor cell death with accompanying brain swelling triggered by cancer death with accompanying edema. This study is designed to learn whether or not more aggressive radiation therapy is beneficial for patients with your type of brain tumor. Especially for treating brain tumor patients, the balance between aggressive treatment and preserving quality of life is critically important to see the real benefit in patients with your type of brain tumor. The change in the amount of radiation and how it is aimed may have increased risks. We do not know if it improves the outcome.

If you take part in this study, you may help others in the future based on information gained by this study.

Will I be compensated for my time and effort?

You will not be compensated for your time and effort.

What are my other options?

If you decide not to join this study, other options are available. You do not have to join this study to get treatment.

Your other choices may include:

- Getting treatment or care for your cancer without being in a study
- Taking part in another investigational study
- Getting no treatment
- Getting comfort care, also called palliative care. This type of care helps reduce pain, tiredness, appetite problems and other problems caused by the cancer. It does not treat the cancer directly, but instead tries to improve how you feel. Comfort care tries to keep you as active and comfortable as long as possible.

Talk to your doctor about your choices before you decide if you will take part in this study.

Why might we take you out of the study early?

You may be taken out of the study if:

- Staying in the study would be harmful.
- You need treatment not allowed in the study.
- You fail to follow instructions.
- You become pregnant.
- The study is cancelled.
- There may be other reasons to take you out of the study that we do not know at this time.

If you are taken out of the study early, the study team may use your health information that it has already collected if the information is needed for this study or any follow-up activities.

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

Your samples and health information will be stored and shared with other researchers. The samples and information will be available for any research question, such as research to understand what causes certain diseases (for example heart disease, cancer, or psychiatric disorders), development of new scientific methods, or the study of where different groups of people may have come from.

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 activities (spectroscopic MRI and neurocognition tests)

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 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. Hui-Kuo Shu 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.

Cost

The study sponsor will pay for certain items and services that you may receive if you take part in this study. These study-related costs provided by the study sponsor will include but are not limited to the following:

- 1) spectroscopic MRI scans,
- 2) administration of neurocognitive/quality-of-life/mood tests and assessments.

As indicated above, spectroscopic MRI scans will be provided to you free of charge for this study. However, diagnostic MRI studies are part of the standard-of-care assessment and follow-up for patients with your type of tumor. Therefore, the cost of these diagnostic MRIs will be billed as part of the normal management of your type of tumor.

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.

Generally, insurance companies will not pay for items and services that are required just for a research 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.

Withdrawal from the Study

- You can agree to be in the study now and change your mind later.
- If you wish to stop, please tell us right away.
- Leaving this study early will not stop you from getting regular medical care.

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.

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.
- 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.Hui-Kuo Shu 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: [Office for Human Research Protections; Food and Drug Administration].
 - Public health agencies.
 - Research monitors and reviewer.
 - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

Expiration of Your Authorization

Your PHI will be used until this research study ends.

Revoking Your Authorization

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

Dr. Hui-Kuo Shu
Winship Cancer Institute, Emory University
1365 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.

Contact Information

Contact Dr. Hui-Kuo Shu 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 and Authorization

TO BE FILLED OUT BY SUBJECT ONLY

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

Name of Subject

Signature of Subject (18 or older and able to consent)

Date

:____ **am/pm**
Time (please circle)

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)