Informed Consent Form

RAD4391-18: Diagnostic Accuracy of Dynamic Susceptibility Contrast (DSC) Perfusion MRI to Determine Radiation Necrosis versus Tumor Progression in Brain Metastases Treated with Stereotactic Radiosurgery

NCT Number: NCT03680144

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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 45 people who are being studied, at Emory and elsewhere.

Why is this study being done?

This study is being done to answer the question: Is an advanced MRI sequence (i.e. perfusion MRI) able to accurately determine whether radiographic changes after radiation treatment are due to tumor progression or treatment side effect. . You are being asked to be in this research study because you will be treated with radiation 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 participate for a period of 1 year from completion of radiation therapy. The researchers will ask you to do the following: obtain a Brain MRI before your radiation therapy during which an optional perfusion MRI sequence may be obtained. None of these procedures will be paid for by the study.

How is this study going to help you?

If you are in the study, you will be helping the researchers answer the study question.

What are the risks or discomforts I should know about before making a decision?

The study will take time. The drug/device/procedure 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 [an additional MRI sequence obtained at the time of routine imaging MRIs: Added minutes (~5) to total imaging study time], 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
Regardless of whether you decide or not to enter this study, you will still receive the same standard-of-care treatment for your condition.

Costs
All of the medicines and radiation on this study are what you would normally get if you were not on the study. There should not be additional costs. There is more information in the cost section below. 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 of the 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 | WINSHIP CANCER INSTITUTE
A Cancer Center Designated by the National Cancer Institute

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

Title: RAD4391-18: Diagnostic accuracy of dynamic susceptibility contrast (DSC) perfusion MRI to determine radiation necrosis versus tumor progression in brain metastases treated with stereotactic radiosurgery

IRB #: 00102506

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Study-Supporter: Winship Cancer Institute of Emory University

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

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

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

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This Web site will not include information that can identify you. At most the Web site will include a summary of the results. You can search this Web site at any time.

What is the purpose of this study?
The purpose of this study is to assess whether an advanced MRI sequence (i.e. perfusion MRI) is able to accurately determine whether radiographic changes after radiation treatment are due to tumor progression or treatment side effect. There will be about 45 people taking part in this study.

What will I be asked to do?

If you do not already have a brain MRI that is usable for radiation therapy treatment planning, you will be asked to obtain a Brain MRI before your radiation therapy during which an optional perfusion MRI sequence may be obtained. In addition, during your routine follow-up MRI imaging scans you will also obtain this perfusion MRI sequence (required in follow-up). This sequence will add approximately 5 minutes to each MRI scan. Per the normal standard of care, patients will continue to be scanned routinely every 3 months indefinitely. However, for this study, patients will be followed for a period of 1 year from completion of radiation therapy. Patients can choose to opt out of the study at any time.

Who owns my study information and samples?

If you join this study, you will be donating the imaging data acquired during the DSC-perfusion MRIs. There are no tissue samples or other study information required. If you withdraw from the study, data that were already collected may be still be used for this study. You will not receive any compensation if your information is used to make a new product. If you withdraw from the study, data 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 procedures that are not known at this time.
The most common risks and discomforts expected in this study are: Added minutes (~5) to total imaging study time.

The less common risks and discomforts expected in this study are: None

Rare but possible risks include:

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. This study is designed to learn more about MRI imaging to discern post-treatment radiographic changes in brain metastases after radiation therapy. 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?

Regardless of whether you decide or not to enter this study, you will still receive the same standard-of-care treatment for your condition.

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 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.

Medical Record

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

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

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

The results of some study tests and procedures will be used only for research purposes and will *not* be placed in your medical record. For this study, those items include: None

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

In Case of Injury

If you believe you have become ill or injured from this research, you should contact Dr. Hui-Kuo Shu at telephone number [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 and Saint Joseph's will help you to get medical treatment. Neither Emory, Saint Joseph's nor the sponsor have set aside money to pay for this 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.

For Emory and Saint Joseph's, the only exception is if it is proven that your injury or illness is directly caused by the negligence of an Emory or Saint Joseph's 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.

If you believe you have become ill or injured from this study, you should contact Dr. Hui-Kuo Shu at telephone number [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 and Saint Joseph's will help you to get medical treatment. Emory and Saint Joseph's has not set aside any money to pay you if you are injured as a result of being in this study. 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. "Negligence" is the failure to follow a standard duty of care. If you get ill or injured as the direct result of the study drug [or device, as appropriate] or a study procedure, the sponsor will pay the costs for your medical treatment of the illness or injury. The sponsor will not pay for co-payments or co-insurance that your insurer says you must pay. Also, the sponsor will not pay for illness or injury:

(a) from medical conditions you had before you started the study;
(b) from the natural progression of your disease or condition;
(c) from your failure to follow the study plan; or
(d) that is directly caused by the negligence of an Emory or Saint Joseph's employee.

If you have Medicare or Medicaid: the sponsor may need information about your identity and your study treatment to give to the government agencies that run these programs.

Your insurance will be billed for any costs of medical treatment that the sponsor does not pay. Your insurer may be told that you are in a research study.

You will have to pay for any treatment costs that are not paid for by your insurance or the sponsor.

If you believe you have become ill or injured from this research, you should contact Dr. Hui-Kuo Shu at telephone number [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 and Saint Joseph's will help you get medical treatment. Emory and Saint Joseph's has not set aside any money to pay you if you are injured as a result of being in this study. 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. "Negligence" is the failure to follow a standard duty of care.

If you get ill or injured as the direct result of the study drug [or device, as appropriate] or a study procedure, then, depending on what insurance you may have, the sponsor may pay for some of all of the costs of your medical treatment for the illness or injury. If you are uninsured, or if you have Medicare or Medicaid, the sponsor will pay for the costs of your medical treatment for the illness or injury. If you have Medicare or Medicaid, the sponsor may need information about your identity and your study treatment to give to the government agencies that run these programs.

If you have private insurance, Emory and Saint Joseph's will look at your claims for these costs to determine if they can be sent to your insurance for payment. Your insurer may be told that you are in a research study and given information about your treatment. The sponsor will pay for the costs that are not paid by your insurance provider.

The sponsor will not pay for co-payments or co-insurance that Medicare, Medicaid or your private insurer says you must pay. Also, the sponsor will not pay for illness or injury:

(a) from medical conditions you had before you started the study;

(b) from the natural progression of your disease or condition;
(c) from your failure to follow the study plan; or
(d) that is directly caused by the negligence of an Emory and Saint Joseph's employee.

You will have to pay for any treatment costs that are not paid for by the sponsor or by any insurance you may have.

Costs
The sponsor will not pay for any items or services associated with the study.
The study sponsor does not plan to pay for any items or services that you may receive if you take part in this study.

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

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

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

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

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

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

Authorization to Use and Disclose Protected Health Information

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

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.

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. 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 and Saint Joseph's Hospital may use and disclose your PHI to get payment for study related treatment and to run normal business operations.
- The Principal Investigator and research staff will share your PHI with other people and groups to help conduct the study or to provide oversight for the study.
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- The following people and groups will use your PHI to make sure the research is done correctly and safely:
    - Emory and Saint Joseph's Hospital offices that are part of the Human Research Participant Protection Program and those that are involved in study administration and billing. These include the Emory IRB, the Emory Research and Compliance Offices, and the Emory Office for Clinical Research.
    - Public health agencies.
    - Research monitors and reviewer.
    - Accreditation agencies.
- Sometimes a Principal Investigator or other researcher moves to a different institution. If this happens, your PHI may be shared with that new institution and their oversight offices. PHI will be shared securely and under a legal agreement to ensure it continues to be used under the terms of this consent and HIPAA authorization.

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

Revoking Your Authorization
If you sign this form, at any time later you may revoke (take back) your permission to use your information. If you want to do this, you must contact the study team at: Attn: Hui-Kuo Shu, MD, PhD, 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 [redacted]:

- if you have any questions about this study or your part in it,
- if you have questions, or concerns 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 complaints about the research or an issue you rather discuss with someone outside the research team.

You may also let the IRB know about your experience as a research participant through our Research Participant Survey at **https://tinyurl.com/ycewgkke.**

TO BE FILLED OUT BY SUBJECT ONLY

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

_____
Name of Subject

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

TO BE FILLED OUT BY STUDY TEAM ONLY

_____
Name of Person Conducting Informed Consent Discussion

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