**IRB NUMBER: 206338091714**

LOYOLA UNIVERSITY CHICAGO
HEALTH SCIENCES DIVISION
MAYWOOD, ILLINOIS
DEPARTMENT OF RADIOLOGY

INFORMED CONSENT

Participant's Name: _____

Medical Record Number: _____

**PROJECT TITLE:** Evaluation of Gadoterate in Patients with Renal Dysfunction

## THE APPROVAL FOR THIS PROJECT EXPIRES ON 08/15/2019.

You are being asked to consider enrolling the patient in a research study. The patient is too ill to give consent right now. When the word "you" appears in this consent form, it refers to the ill person.

You can only consent for the patient if you are the patient's guardian, spouse, parent or you hold the power of attorney for healthcare.

If the patient regains his or her ability to make decisions, he or she will be informed about the study and asked for a decision about continued participation.

### Participant Information

**PRINCIPLES CONCERNING RESEARCH:** You are being asked to take part in a research project. It is important that you read and understand the principles that apply to all individuals who agree to participate in the research project described below:

1. Taking part in the research is entirely voluntary.

2. We do not know if you will benefit from taking part in the research but the knowledge obtained may help others.

3. You may withdraw from the study at any time without anyone objecting and without penalty or loss of any benefits to which you are otherwise entitled.

4. If during your participation in the research project new information becomes available which would affect your being in the research project, your doctor will discuss this new information with you and will help you make a decision about your continuing in the research.

The purpose of the research, how it is to be done, and what your part in the research will be is described below. Also described are the risks, inconveniences, discomforts and other important information which you need to make a decision about whether or not you wish to participate. You are urged to discuss any questions you have about this research with the staff members.

**PURPOSE OF RESEARCH:** You are being asked to participate in this study because your doctor has ordered an MRI for you and you have decreased kidney function. An MRI would normally be performed with intravenous contrast material (a dye injected into your vein) in order to improve the accuracy of the result of the MRI findings.

Because your kidney function is decreased, we usually do not give the patients the contrast in the vein. This is because the contrast has been shown to cause kidney damage in some cases. We are testing a contrast agent called Gadoterate in patients with decreased kidney function. Gadoterate is approved by the Food and Drug Administration and is commercially-available. Similar to other Gadolinium contrast agents, it is routinely avoided in patients with decreased kidney function.

The other problem that can occur in patients with decreased kidney function who receive gadolinium contrast agents is called Nephrogenic Systemic Fibrosis (NSF). This problem is rare and is caused by the gadolinium. NSF is rare and serious. In this disorder scar tissue forms in the skin, joints, eyes and internal organs. It can be debilitating and fatal. There is no established treatment for this disease.

This purpose of this study is to study the safety and benefit of using Gadoterate in patients with decreased kidney function.

This research is sponsored by Guerbet Pharmaceuticals, the manufacturer of Gadoterate.

Approximately 280 people will participate in this research.

**DESCRIPTION AND EXPLANATION OF PROCEDURES:** If you agree to participate in this study, you must read this consent and sign. Your medical records will be reviewed to determine if you are eligible to participate.

You can choose to be in one of two groups. Once you have read and discussed this consent with the study doctor, please place your initials next to the group you choose:

_____ **Treatment Group:** You choose to receive Gadoterate contrast as a part of your MRI.

_____ **Control Group:** You choose NOT to receive Gadoterate. In this case you will have your MRI scan but without administration of the Gadoterate contrast. If you have already had your MRI without contrast, you will also be placed in this group.

If you are in the Treatment Group OR the Control Group, we will draw a small amount of blood (about one teaspoonful for each blood draw listed) and perform routine lab work to establish your current kidney function level. If you have already had your MRI without contrast, this blood sample has already been drawn as part of your routine lab work and you will not need to have this sample drawn. If you are in the Treatment Group you will then receive a standard dose of intravenous Gadoterate as part of your MRI exam. In either group, in 48-72 hours you will return to the research site for another blood-draw to examine your kidney function.

If you are in the Control Group' or the Treatment Group, you will be asked to answer a brief questionnaire regarding certain possible skin conditions already present at the time of your MRI. Then, at 6 weeks, 3 months, and 6 months-time, you will be contacted by a member of the study staff and asked a list of questions to make sure there are no subsequent long term skin changes described in the questionnaire.

In addition, you will be asked to allow review of your medical chart during the course of the study (1-2 years) and up to one year after. The investigators will be analyzing future diagnoses, exam results, pathology reports, and healthcare costs associated with your medical course.

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

**RISKS/DISCOMFORTS:** There may be other side effects or risks that are not known at this time.

The major risks that may occur if you participate in the treatment group of the study are:

- Acute kidney injury, with the possibility of dialysis being required
- Nephrogenic Systemic Fibrosis (NSF) – a rare progressive disease characterized by scar tissue forming in the skin and internal organs
- Severe allergic reaction (difficulty breathing, hives, swelling) – a potential complication of any intravenous contrast material.

In addition, less-severe nonspecific reactions have been reported:

- Headache
- Nausea
- Pain at the injection-site

**Other Risks:** If you are in the Treatment Group, you will need to provide blood during each of your study visits. Risks associated with drawing blood include the following: pain, bruising, fainting, and feeling lightheaded.

Patients in the Control Group will not experience problems because they are participating in the research project.

**REPRODUCTIVE AND SEXUAL ACTIVITY INFORMATION:** The intervention in this study could affect a developing baby. Therefore, you cannot participate in this research project if you are pregnant or breast feeding.

If you are a woman of childbearing potential, a pregnancy test will be done to make certain that you are not pregnant before beginning the study.

Despite that fact that Gadolinium may remain in the body for a period beyond administration, there is no current recommendation to employ a method for pregnancy-prevention following a Gadolinium MRI exam.

**BENEFITS:** We do not know if you will benefit from participating in this study. The information we learn may help others.

The benefits of intravenous contrast during an MRI exam are improved study quality. This may lead to an improved ability to diagnose your condition.

**ALTERNATIVE TREATMENTS:** You do not have to participate in this research project to receive care and treatment at Loyola University Medical Center.

**FINANCIAL INFORMATION:** Some health plans will not pay the costs for people taking part in studies. Check with your health plan or insurance company to find out what they will pay for. Taking part in this study may or may not cost your insurance company more than the cost of getting treatment without being in this study. Depending on your health insurance, there may be a co-payment for the standard visits. You will be responsible for any usual out-of-pocket expenses such as co pays, coinsurance or deductibles.

Costs for procedures not included in the standard care will be covered by the research study.

Neither you nor your insurance provider will be billed for any procedures that are performed exclusively for this research study. Those procedures that are being performed for research purposes only include use of Gadoterate and bloodwork drawn specifically to have the MRI performed and blood work after the MRI related to the study. The MRI and any other care related to your condition is considered routine care and you or your 3rd party payor would be responsible for this test. You will be responsible for any additional costs to diagnose or treat your condition if you have a side effect of gadoterate used in your scan.

You will receive a payment of $25 after you complete the research-related blood draw visit at 48-72 hours after your MRI. You will also receive a parking sticker for this visit. This money is meant to assist you in paying any travel expenses, lost wages from work, child care, etc. that you may have as a result of taking part in this study. You will receive this payment in the form of a check that will be mailed to you about 3 weeks after you have completed the visit. You will receive the parking sticker at the time of your visit.

Your participation in this research study may contribute to the development of commercial products from which Guerbet Pharmaceuticals or others may receive economic benefit. There is

no provision in place to provide you with compensation for any patent or discoveries arising from this research.

If you receive payment for participating in this research, personal information about you, including your name, address, and Social Security number, will be released to the Loyola University Chicago Accounting Office for the purpose of recording the payment and for tax reporting to the United States Internal Revenue Service (IRS). You will need to complete a W-9 form. This form will be provided to you. If you choose not to complete the W-9, you will not receive reimbursement.

**RESEARCH RELATED INJURY:** In the event that you are injured or have side effects as a result of participating in this research project, your doctor will take the necessary steps to treat the problem. There are no funds available from Loyola University Medical Center, Loyola University Health System or Loyola University Chicago to pay for the cost of care of the problem. You will be financially responsible for the cost of care of any problems. By signing this form, you are not giving up any legal rights to seek to obtain compensation of injury.

**INFORMATION COLLECTED AND WHAT WILL HAPPEN TO IT:** In order to meet the goals of the research study (see Purpose of Research section of this consent), we will collect information on you, your test results, and how you do from you and your Loyola University Medical Center (LUMC) medical records. The information will be collected by Dr. Ari Goldberg, the study physician(s), the research nurses, data administrators and secretaries.

Information about you will be provided to Loyola University Chicago; Guerbet Pharmaceuticals, the research sponsor; data collection and study verification agencies; and/or government regulatory agencies such as the Food and Drug Administration.

In this way, we will learn about the safety and effectiveness of using Gadoterate contrast in patients with low kidney function.

The information we will collect and send includes:

_X___ MEDICAL RECORD (including, but not limited to, history and physical exam notes, progress notes, consultation reports, laboratory test results, AND/OR operative reports)

_X___ BLOOD SAMPLES

We will collect and provide this information about you for at least 1 year, but not more than 3 years, following your MRI exam.

Once the information is disclosed outside of LUMC, it may no longer be protected by federal privacy laws.

It is possible that the sponsor, Guerbet Pharmaceuticals , research nurses, data collection and/or study verification agencies, data administrators or staff, other designees for the sponsor, or the Food and Drug Administration will come to LUMC and view the medical record (see above for description of content) and the research records. They may take notes or copy pages of the

medical record. This is done to verify the accuracy of the information LUMC is sending to them.

The results of this research study may be published in a journal for the purpose of advancing medical knowledge. You will not be identified by name or by any other identifying information in any publication or report about this research.

Consent for LUMC to use and disclose your medical information is required in order for you to participate in the study.

**WITHDRAWAL OF CONSENT:** Your consent to use and disclose your medical information for the purpose of this research study is completely voluntary. You can withdraw your consent for LUMC to use and disclose your information and your consent to participate in this study at any time without affecting your ability to receive care and treatment at LUMC unrelated to the research study. Withdrawal means that all study procedures and follow-up will stop and we will not send any more information about you to the sponsor of this research or its designees. However, information already used and disclosed to the research sponsor prior to the time of your withdrawal from this study may continue to be used and disclosed by LUMC and the sponsor.

For your safety, we may ask that you return to clinic see a dermatologist if our follow-up interviews or blood draw indicate that you might be experiencing symptoms of NSF. If you withdraw from the study, you will need to contact your physician(s) to discuss what other options may be available.

If you withdraw from the study, we will ask that you sign the form attached to this consent and send it to Dr. Ari Goldberg or give it to the study staff. Your withdrawal from the study will not have any effect on any actions by LUMC taken before the attached form is received by LUMC.

Your study doctor, the Institutional Review Board, the regulatory authorities, or the sponsor, Guerbet Pharmaceuticals, may terminate the study at any time with or without your consent.

**CONSENT**

I have fully explained to _____ the nature and purpose of the above-described procedure and the risks that are involved in its performance. I have answered and will answer all questions to the best of my ability. I may be reached at 708-216-2229.

_____Date:____/_____/____
Signature

Dr. Ari Goldberg, the principal investigator for this study, or his associates will be available to answer any questions you may have. Dr. Ari Goldberg can be reached at: 708-216-2229 or through the page operator at 708-216-8000.

If you ever feel that you have been injured by participating in this study or if you have any questions concerning your rights as a research participant, you may contact either Kenneth Micetich, MD, Chair of the Institutional Review Board for the Protection of Human Subjects-Loyola University Chicago Health Sciences Division, at 708-216-2633 or the Director of the Human Research Subjects Protection Program at 708-216-4608.

Although you have the right to revoke this authorization, you accept that such revocation will not apply to any uses and disclosures of your information that are described in the Loyola University Health System Notice of Privacy Practices or otherwise allowable under any Federal or State laws.

You will receive a signed copy of this informed consent document.

You have been fully informed of the above-described research program with its possible benefits and risks. Your signature below indicates that you are willing to participate in this research study and agree to the use and disclosure of information about you as described above. You do not give up any of your legal rights by signing this consent document.

_____Date:____/_____/____
Signature: Participant

_____Date:____/_____/____
Signature: Witness

**Consent for Continued Participation:**

At the time that you became ill, you were not able to make a decision about participating in a research project. The person making medical decisions on your behalf during your illness agreed for you to be in this research study. Now that you are again able to make decisions, you can choose whether or not to remain a participant.

If you decide to stay in the study, you will be asked to review and sign the full consent form for this research.

If you decide to end your participation, your personal and medical information gathered since the start of the research project may still be used for this research.

Please check below to indicate your decision:

_____ I wish to stay in the study

_____ I wish to end my participation in the study

_____ _____

Signature of Participant Date

_____ _____

Signature of Person Obtaining Consent Date

_____ _____

Signature of Witness Date

**PROJECT TITLE:** Evaluation of Gadoterate in Patients with Renal Dysfunction

REVOCATION OF AUTHORIZATION TO
RELEASE PROTECTED HEALTH INFORMATION (PHI)

I, _____, hereby revoke my consent to participate in the study titled, "Evaluation of Gadoterate in Patients with Renal Dysfunction ", at Loyola University Medical Center ("LUMC"). I also revoke my consent to release information I provided to LUMC that allowed LUMC to use and disclose my medical information to Guerbet Pharmaceuticals as outlined on the consent form, which I signed on ____/_____/____ (INSERT DATE CONSENT WAS SIGNED ORIGINALLY). I understand that this revocation does not apply to any action LUMC has taken in reliance on the consent I signed earlier.

_____Date:____/_____/____
Signature: Participant

**Please return this form to:**

**Dr. Ari Goldberg**
**Loyola University Medical Center**
**2160 South First Avenue**
**Maywood, Illinois 60153**