Medical University of South Carolina
CONSENT TO BE A RESEARCH SUBJECT

Dotarem® for Myocardial Perfusion Cardiovascular Magnetic Resonance

Concise Summary

You are being asked to volunteer for a research study. You are being asked to take part in this study because you are scheduled to undergo a contrast-enhanced stress myocardial perfusion magnetic resonance imaging (MRI) scan due to your doctor's concern that you may have restricted blood flow to your heart. The contrast used in these scans is a liquid that is injected in to you to provide brighter, clearer images.

The purpose of this study is to compare two types of contrast that patients receive during this scan. Both contrasts are used in standard of care procedures, and the one administered for your scan will be randomly selected. That means, if you agree to participate, one of the two contrasts will be chosen by chance, like the flipping of a coin. Your participation in the study will last a total of 50 minutes, and all procedures are the same as the clinically indicated scan. You will have an intravenous (IV) port placed in you, and you will be exposed to gadolinium contrast that could potentially cause adverse effects, like an allergic reaction or added stress on kidney function. Furthermore, any metal within your body could cause bodily harm during the procedure.

Although there are no direct benefits from participating in the research study today, the results that we obtain from your scan could possibly lead to improved and more reliable detection of heart defects, and ultimately provide better patient management.

If you are interested in learning more about this study, please continue reading below.

A. PURPOSE OF THE RESEARCH

The overall goal of this study is to compare a gadoterate meglumine (Dotarem®, Guerbet, USA) enhanced myocardium to gadobutrol (Gadavist, Bayer, USA) enhanced myocardium during rest and stress perfusion cardiovascular magnetic resonance (CMR), and see which contrast agent produces better images. Both contrasts being used in this research study are clinically approved for standard of care procedures. We will carefully review the quality of the images produced by the magnetic resonance scanner. Taking part in this study will not affect or change how you are treated; the decision for your treatment is between you and your doctor. The study is sponsored by Guerbet. The investigator in charge of this study at MUSC is Dr. U. Joseph Schoepf. This study will only be conducted at MUSC and will include a total of 90 volunteers.

Please read this consent form carefully and take your time making your decision. As I discuss this consent form with you, please ask me to explain any words or information that you do not clearly understand.

B. PROCEDURES

If you agree to be in this study, the following will happen:

1. On the day of your scheduled visit, the research staff will explain the study and answer all study related questions you may have prior to signing of MUSC IRB approved documents. Copies of study related documents will be given to you.
2. A nurse will go over your medical history and may take a small blood sample (approximately 1 teaspoon or 5 mLs) for a kidney function test to see if you can safely receive intravenous (IV) contrast. This is part of the normal clinical workup for your clinically indicated scan and will not be affected by research. If you are female and could be pregnant, a urine pregnancy test will be performed to rule out pregnancy. This is required for the study but is also necessary for you to receive your clinical contrast-enhanced CMR scan. These tests will be billed to you or your insurance.
3. If these test results show that you are eligible for study participation you will be prepared for your CMR scan.
4. You will have a contrast-enhanced stress myocardial perfusion magnetic resonance imaging scan of your heart. One of the two types of contrast will be randomly selected and loaded into the machine's injector. For the CMR exam, you will lie down on a narrow bed which will then be placed in a tunnel that is 6 feet by 22 inches wide and open at each end. You will lie there quietly for about twenty minutes, during which time you will hear a loud noise. The MRI technologist will inform you of when the contrast will be administered. You may feel warm during this procedure.
5. You will be discharged.

C. DURATION

Today's appointment will last at least 50 minutes. Preparation for the study will take about 20 minutes. The MR scan will require approximately 30 minutes of your time.

D. RISKS AND DISCOMFORTS

Magnetic Resonance Imaging (MRI):
Because the MRI machine acts like a large magnet, it could move iron-containing objects in the MRI room during your examination which could in the process possibly harm you. Precautions have been taken to prevent such an event from happening; loose metal objects, like pocket knives or key chains, are not allowed in the MRI room. If you have a piece of metal in your body, such as a fragment in your eye, aneurysm clips, ear implants, spinal nerve stimulators, or a pacemaker, you will not be allowed into the MRI room and cannot have an MRI.
Having an MRI may mean some added discomfort to you. In particular, you may be bothered by feelings of discomfort in tight spaces and by the loud banging noise during the study. Temporary hearing loss has been reported from the loud noise. This is why you will be asked to wear earplugs. At times during the test, you may be asked not to swallow for a while, which can be uncomfortable.
If your clothes contain metal, you will be asked to get changed into a hospital robe.

Vein puncture
You could experience bruising, pain, and rare incidence of infection at the vein puncture site. This is like a blood

test. This puncture is used to inject the contrast agents. Care will be taken to avoid these possible risks. Skin or vein irritation, fainting, blood clot formation, bleeding at the injection site, or an infection could also occur.

Adverse reactions caused by gadolinium contrast agent
Gadolinium contrast agent will be administered as part of the clinical protocol, independently from the research component of the study. The research protocol will not increase the risk of contrast related adverse reactions in any of the research aims. There is a small risk that you will have an allergic reaction to contrast medium. In this event, the attending physician supervising the MRI acquisition in the study will administer appropriate care. In patients with pre-existing renal dysfunction, gadolinium-based contrast material may cause further deterioration in renal function.

Risks from Contrast Agent Extravasation
Although extremely rare, it is possible that an IV needle is not properly located within the vein or can become dislodged when you lie down on the examination table. When contrast material is injected, it may then leak into the surrounding tissue. This can be painful; however, a contrast media extravasation is usually noticed early on by the personnel monitoring the procedure. However, even if a full dose of contrast material is injected in the tissue surrounding a vein, permanent damage is extremely unlikely. In addition, in our department we use the latest automated contrast media injector generation, which also comprises of an automated extravasation detection device attached to the arm of the patient. Since the implementation of this device we have not experienced any major extravasation of contrast material.

Loss of Confidentiality
Any time information is collected there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed. We will protect your records by keeping all your materials in locked file cabinets or secure password-protected computer files only accessible by research staff.

Randomization
There are potential risks associated with randomizing the contrasts that you will receive. Both contrasts are clinically approved and used in standard of care procedures; however, you could potentially experience adverse reactions to one type of contrast but not the other.

Unknown Risks
The research scans may have unknown side effects. The researchers will let you know if they learn anything that might change your mind about participating in the study.

E. MEDICAL RECORDS

If you are an MUSC patient, you have an MUSC medical record. If you have never been an MUSC patient, a MUSC medical record will be created for the purposes of this study. Results of research tests or procedures

will be included in your MUSC medical record. All information within your medical record can be viewed by individuals authorized to access the record. We will make every effort to keep all research information confidential in the medical record that identify you to the extent allowed by law.

F. BENEFITS

There will be no direct benefit to you from participating in this study. However, it is hoped that the information gained from the study will help in the treatment of future patients with conditions like yours, and will help the researcher learn more about the quality of images produce using different contrasts.

G. COSTS

There will be no additional costs to you as a result of being in this study. However, routine medical care for your scan (care you would have received whether or not you were in this study), including the contrast agent, will be charged to you or your insurance company. You may wish to contact your insurance company to discuss this further. It is possible that your insurance company will refuse to pay for the costs associated with study participation, in which case you will be held financially responsible. Please ask Dr. U. Joseph Schoepf if you would like to know more about which tests and studies are being done solely for research purposes.

H. PAYMENT TO PARTICIPANTS

You will not be paid for participating in this study.

I. ALTERNATIVES

The alternative is not to participate in this study. You will still receive your clinically indicated CMR scan ordered by your doctor.

J. DATA SHARING

Information about you (including your identifiable private information and/or any identifiable bio specimens) may have all of your identifiers removed and used for future research studies or distributed to other researchers for future research without additional informed consent from you or your legally authorized representative.

K. DISCLOSURE OF RESULTS

The results of the procedures you will undergo as part of the research study will be a part of your standard of care. That means that the images will be available in your patient chart. Therefore, the results of the study procedures can be made readily available to you upon request from you physician.

L. AUTHORIZATION TO USE AND DISCLOSE (RELEASE) MEDICAL INFORMATION

As part of this research study, your study doctor and his/her research team will keep records of your participation in this study.

The health information MUSC may use or disclose (release) for this research study includes information in your medical record, results of physical exams, medical history, lab tests or certain health information indicating or relating to your condition.

Your study doctor and his/her research team will use and disclose (release) your health information to conduct this study. The health information listed above may be used by and/or disclosed (released) to the following, as applicable:

- The sponsor of the study including its agents such as data repositories or contract research organizations monitoring the study;
- Other institutions and investigators participating in the study;
- Data Safety Monitoring Boards;
- Accrediting agencies;
- Clinical staff not involved in the study whom may become involved if it is relevant;
- Parents of minor children if less than 16 years old. Parents of children 16 years old or older require authorization from the child; or
- Health insurer or payer in order to secure payment for covered treatment;
- Federal and state agencies and MUSC committees having authority over the study such as:

    - The Institutional Review Board (IRB) overseeing this study; Committees with quality improvement responsibilities; Office of Human Research Protections; Food and Drug Administration; National Institutes of Health or Other governmental offices, such as a public health agency or as required by law.

Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them. You do not have to sign this consent form. If you choose not to sign, it will not affect your treatment, payment or enrollment in any health plan or affect your eligibility for benefits. However, you will not be allowed to be a participant in this research study.

You will be given a copy of this consent form. Your authorization will expire at the conclusion of this study or, if you are participating in a study designed for the development of a drug or device, your authorization will remain in effect until the drug or device is approved by the FDA or until the company's application to study the drug/device is withdrawn. You have the right to withdraw your agreement at any time. You can do this by giving written notice to your study doctor. If you withdraw your agreement, you will not be allowed to continue participation in this research study. However, the information that has already been collected will still be used and released as described above. You have the right to review your health information that is

created during your participation in this study. After the study is completed, you may request this information.

Your health information will be used or disclosed when required by law. Your health information may be shared with a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury or disability and for conducting public health surveillance, investigations or interventions. No publication or public presentation about the research study will reveal your identity without another signed authorization from you.

If you have questions or concerns about this Authorization or your privacy rights, please contact MUSC's Privacy Officer at (843) 792-8740.

Regulations require that you be given a copy of the MUSC Notice of Privacy Practices (NPP) describing the practices of MUSC regarding your health information. One can be found at the end of this form.

The images that are generated from the scans that you undergo today will be available on your electronic medical record. Analysis of these images will be completed for the purposes of this research study; however, these images could also be analyzed for future, undesignated research. All of your patient health information will be removed from the images and they will be anonymized in our records.

M. SIGNIFICANT NEW FINDINGS

If there are significant new findings during the course of the study, you will be notified.

N. STUDENT PARTICIPATION

Your participation or discontinuance will not constitute an element of your academic performance, nor will it be a part of your academic record at this Institution.

O. EMPLOYEE PARTICIPATION

Your participation or discontinuance will not constitute an element of your job performance or evaluation, nor will it be a part of your personnel record at this Institution.

P. SPONSOR COMMITMENT

In the event of a study related injury, MUSC will provide medical treatment to you. MUSC will bill your insurance company, however should the insurance company deny coverage or if insurance is not available, you will be responsible for payment of services.

Results of this research will be used for the purposes described in this study. This information may be published, but you will not be identified. Information that is obtained concerning this research that can be identified with

you will remain confidential to the extent possible within State and Federal law. The sponsor and the Food and Drug Administration (FDA) will receive copies of the research records. The investigators associated with this study, employees of the sponsor, the FDA, and the MUSC Institutional Review Board for Human Research will have access to identifying information. All records in South Carolina are subject to subpoena by a court of law.

In the event of a study related injury, you should immediately go to the emergency room of the Medical University Hospital, or in case of an emergency go to the nearest hospital, and tell the physician on call that you are in a research study. They will call your study doctor who will make arrangements for your treatment. If the study sponsor does not pay for your treatment, the Medical University Hospital and the physicians who render treatment to you will bill your insurance company. If your insurance company denies coverage or insurance is not available, you will be responsible for payment for all services rendered to you.

Your participation in this study is voluntary. You may refuse to take part in or stop taking part in this study at any time. You should call the investigator in charge of this study if you decide to do this. The data collected on you to this point remains part of the study database and may not be removed. Your decision not to take part in the study will not affect your current or future medical care or any benefits to which you are entitled.

The investigators and/or the sponsor may stop your participation in this study at any time if they decide it is in your best interest. They may also do this if you do not follow the investigator's instructions.

Volunteers Statement

I have been given a chance to ask questions about this research study. These questions have been answered to my satisfaction. If I have any more questions about my participation in this study or study related injury, I may contact Dr. U. Joseph Schoepf, MD at (843)-876-4214. I may contact the Medical University of SC Patient and Family Care Liaison (843) 792-5555 concerning medical treatment.

If I have any questions, problems, or concerns, desire further information or wish to offer input, I may contact the Medical University of SC Institutional Review Board for Human Research IRB Manager or the Office of Research Integrity Director at (843) 792-4148. This includes any questions about my rights as a research subject in this study.

I agree to participate in this study. I have been given a copy of this form for my own records.

Signature of Person Obtaining Consent Date	*Name of Participant
	Signature of Participant Date

NOTICE OF PRIVACY PRACTICES

MUSC Organized Health Care Arrangement (OHCA)

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESSS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

The Medical University of South Carolina and its affiliates (including but not limited to the Medical University Hospital Authority, MUSC Physicians, and MUSC Physicians Primary Care) participate in a clinically integrated health care setting. As a result of this clinical integration, these organizations function as an Organized Health Care Arrangement (OHCA) as defined by the Health Insurance Portability and Accountability Act (HIPAA). For purposes of this notice, the members of the MUSC OHCA are collectively referred to in this document as "MUSC." W**e collect or receive this information about your past, present or future health condition to provide health care to you, to receive payment for this health care, or to operate the hospital and/or clinics.**

HOW WE MAY USE AND RELEASE YOUR PROTECTED HEALTH INFORMATION (PHI)

A. The following uses do NOT require your authorization, except where required by SC law:

1. For treatment. Your PHI may be discussed by caregivers to determine your plan of care. For example, the physicians, nurses, medical students and other health care personnel may share PHI in order to coordinate the services you may need.

2. To obtain payment. We may use and disclose PHI to obtain payment for our services from you, an insurance company or a third party. For example, we may use the information to send a claim to your insurance company.

3. For health care operations. We may use and disclose PHI for hospital and/or clinic operations. For example, we may use the information to review our treatment and services and to evaluate the performance of our staff in caring for you.

4. For public health activities. We report to public health authorities, as required by law, information regarding births, deaths, various diseases, reactions to medications and medical products.

5. Victims of abuse, neglect, domestic violence. Your PHI may be released, as required by law, to the South Carolina Department of Social Services when cases of abuse and neglect are suspected.

6. Health oversight activities. We will release information for federal or state audits, civil, administrative or criminal investigations, inspections, licensure or disciplinary actions, as required by law.

7. Judicial and administrative proceedings. Your PHI may be released in response to a subpoena or court order.

8. Law enforcement or national security purposes. Your PHI may be released as part of an investigation by law enforcement.

9. Uses and disclosures about patients who have died. We provide coroners, medical examiners and funeral directors necessary information related to an individual's death.

10. For purposes of organ donation. As required by law, we will notify organ procurement organizations to assist them in organ, eye or tissue donation and transplants.

11. Research. We may use your PHI if the Institutional Review Board (IRB) for research reviews, approves and establishes safeguards to ensure privacy.

12. To avoid harm. In order to avoid a serious threat to the health or safety of a person or the public, we may release limited information to law enforcement personnel or persons able to prevent or lessen such harm.

13. For workers compensation purposes. We may release your PHI to comply with workers compensation laws.

14. Marketing. We may send you information on the latest treatment, support groups and other resources affecting your health.

15. Fundraising activities. We may use your PHI to communicate with you to raise funds to support health care services and educational programs we provide to the community. You have the right to opt out of receiving fundraising communications with each solicitation.

16. Appointment reminders and health-related benefits and services. We may contact you with a reminder that you have an appointment.

B. You may object to the following uses of PHI:

1. Hospital directories. Unless you object, we may include your name, location, general condition and religious affiliation in our patient directory for use by clergy and visitors who ask for you by name.

2. Information shared with family, friends or others. Unless you object, we may release your PHI to a family member, friend, or other person involved with your care or the payment for your care.

3. **Health plan.** You have the right to request that we not disclose certain PHI to your health plan for health services or items when you pay for those services or items in full.

C. Your prior written authorization is required (to release your PHI) in the following situations:

You may revoke your authorization by submitting a written notice to the privacy contact identified below. If we have a written authorization to release your PHI, it may occur before we receive your revocation

1. Any uses or disclosures beyond treatment, payment or healthcare operations and not specified in parts A & B above.

2. Psychotherapy notes.

3. Any circumstance where we seek to sell your information.

WHAT RIGHTS YOU HAVE REGARDING YOUR PHI

Although your health record is the physical property of MUSC, the information belongs to you, and you have the following rights with respect to your PHI:

A. The Right to Request Limits on How We Use and Release Your PHI. You have the right to ask that we limit how we use and release your PHI. We will consider your request, but we are not always legally required to accept it. If we accept your request, we will put any limits in writing and abide by them except in emergency situations. Your request must be in writing and state (1) the information you want to limit; (2) whether you want to limit our use, disclosure or both; (3) to whom you want the limits to apply, for example, disclosures to your spouse; and (4) an expiration date.

B. The Right to Choose How We Communicate PHI with You. You have the right to request that we communicate with you about PHI in a certain way or at a certain location (for example, sending information to your work address rather than your home address). You must make your request in writing and specify how and where you wish to be contacted. We will accommodate reasonable requests.

C. The Right to See and Get Copies of Your PHI. You have the right to inspect and receive a copy of your PHI (including an electronic copy), which is contained in a designated record set that may be used to make decisions about your care. You must submit your request in writing. If you request a copy of this information, we may charge a fee for copying, mailing or other costs associated with your request. We may deny your request to inspect and receive a copy in certain very limited circumstances. If you are denied access to PHI, you may request that the denial be reviewed.

D. The Right to Get a List of Instances of When and to Whom We Have Disclosed Your PHI. This list may not include uses such as those made for treatment, payment, or health care operations, directly to you, to your family, or in our facility directory as described above in this Notice of Privacy Practices. This list also may not include uses for which a signed authorization has been received or disclosures made more than six years prior to the date of your request.

E. The Right to Amend Your PHI. If you believe there is a mistake in your PHI or that a piece of important information is missing, you have the right to request that we amend the existing information or add the missing information. You must provide the request and your reason for the request in writing. We may deny your request in writing if the PHI is correct and complete or if it originated in another facility's record.

F. The Right to Receive a Paper or Electronic Copy of This Notice: You may ask us to give you a copy of this Notice at any time. For the above requests (and to receive forms) please contact: Health Information Services (Medical Records), Attention: Release of Information / 169 Ashley Avenue / MSC 369 / Charleston, SC 29425. The phone number is (843) 792-3881.

G. The Right to Revoke an Authorization. If you choose to sign an authorization to release your PHI, you can later revoke that authorization in writing. This revocation will stop any future release of your health information except as allowed or required by law.

H. The Right to be Notified of a Breach. If there is a breach of your unsecured PHI, we will notify you of the breach in writing.

HEALTH INFORMATION EXCHANGES

MUSC, along with other health care providers belongs to health information exchanges. These information exchanges are used in the diagnosis and treatment of patients. As a member of these exchanges, MUSC shares certain patient health information with other health care providers. Should you require treatment at another location that is a part of one of these exchanges, that provider may gather historical health information to assist with your treatment. You have the option of saying that this cannot be done. If you choose not to take part in these alliances, please contact the MUSC Privacy Office at 792-4037.

HOW TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you think your privacy rights may have been violated, or you disagree with a decision we made about access to your PHI, you may file a complaint with the office listed in the next section of this Notice. **Please be assured that you will not be penalized and there will be no retaliation for voicing a concern or filing a complaint. We are committed to the delivery of quality health care in a confidential and private environment.**

PERSON TO CONTACT FOR INFORMATION ABOUT THIS NOTICE OR TO COMPLAIN ABOUT OUR PRIVACY PRACTICES

If you have any questions about this Notice or any complaints about our privacy practices please call the Privacy Officer (843) 792-4037, the Privacy Hotline (800) 296-0269, or contact in writing: HIPAA Privacy Officer / 169 Ashley Avenue /

MSC 332 / Charleston SC 29425. You also may send a written complaint to the Office of Civil Rights. The address will be provided at your request.

CHANGES TO THIS NOTCE

We reserve the right to change the terms of this Notice at any time. We also reserve the right to make the revised or changed Notice effective for existing as well as future PHI. This Notice will always contain the effective date. You may view this notice and any revisions to it at: http://www.musc.edu/privacy.

EFFECTIVE DATE OF THIS NOTICE

This Notice went into effect on April 14, 2003.
Revised September 2013.