

Informed Consent for Magnetic Resonance Imaging (MRI) with Contrast

Patient's Name _____ Date of Birth ____/____/____

What Is MRI?

Magnetic resonance imaging (MRI) uses a very strong magnet and radio waves to produce images of the body, allowing the doctor to visualize bones, tendons, ligaments, and soft tissues. When appropriate, we inject a special contrast called gadolinium to add valuable information to your examination.

Why Is an MRI Examination Beneficial?

Depending upon the specific type of MRI procedure performed, the doctor will be able to visualize the inside of your ligaments and tendons, revealing partial as well as large muscle tears, sprains, and strains. MRI shows us the inner portions of bone and can reveal tumors or bone bruises, as well as cartilage tears. MRI can also reveal improper blood flow, aneurysms, strokes, tumors, and certain other disorders of the brain. Spinal cord abnormalities and other sources of back pain can also be seen. MRI is one of the most advanced medical imaging methods and is rapidly moving forward in its application and research.

How Do I Prepare for an MRI Examination?

In most instances no special preparation is necessary. There are no food or drink restrictions unless your doctor orders certain rare examinations of your abdomen, and you should continue to take any medications prescribed by your doctor unless otherwise directed. You may not be allowed to wear street clothes or anything metallic, like jewelry, during the examination. The MRI scanner will make a loud "knocking" noise, so hearing protection such as earplugs or headphones will be supplied to you by the center. Examination times commonly range from 20 to 60 minutes and it is important to lie still during the entire examination because movement degrades the quality of the images. Patients who experience severe pain associated with their medical conditions should plan for this, timing their pain medications to achieve optimal pain relief during the time of the examination. We will monitor you throughout the procedure. You can easily communicate with us at any time during the test. Please let us know promptly about any discomfort or distress.

What Are the Risks?

For most people, MRI is one of the safest medical imaging examinations because it involves no harmful radiation. MRI is not painful and there are no known harmful effects to the body. Patients who may be pregnant should always advise their physician and the technologist before the appointment so they can exercise additional caution. Patients with claustrophobia often find MRI examinations unpleasant because of the confining feeling of the equipment. In some cases your doctor may prescribe a sedative to ease this discomfort, or may recommend examination in a less confining MRI system.

The MRI scanner produces a very powerful magnetic field that will attract certain metallic objects that contain even small amounts of iron. The force of this attraction can cause metallic objects to move suddenly and with great force towards the center of the MRI scanner, posing a risk to the patient or anyone in the way of the object. Great care is taken to prevent metallic objects from entering the MRI room, so it is vital that you remove all metallic objects before your examination. Some patients cannot safely undergo MRI examination because of metal in their bodies. Examples of devices or foreign objects that may create a health hazard or other problem during an MRI exam include: pacemaker, implantable cardioverter defibrillator (ICD), neurostimulator, aneurysm clip, metal implant, implanted drug infusion device, or other implants that utilize magnets. Foreign metal objects, especially if in or near the eye, bullets, or shrapnel may also pose a risk and require evaluation. MRI scanners have been known to alter the delivery rate of medication patches, so they must be removed during the examination. Check with the technologist if you have questions or concerns about any implanted object or health condition that could affect the MRI procedure. This is particularly important if you have undergone surgery involving the brain, ear, eye, heart, or blood vessels.

CONTINUED ON BACK

What Are the Alternatives?

In most instances MRI provides a more detailed image of the body than other types of scans. In some cases, depending on individual factors such as your symptoms and the specific condition being investigated, there may be alternatives to having an MRI scan. These include: x-ray, Computed Tomography (CT) scan, Ultrasound, Nuclear Medicine Scan.

What is Gadolinium?

As part of your scheduled MRI examination, you will receive an intravenous injection of gadolinium, a contrast injection that will provide additional diagnostic information for your physician.

Unlike contrast agents used in x-ray studies, MRI contrast agents do not contain iodine and therefore only rarely cause allergic reactions or other problems. If you have a history of kidney failure and are scheduled to undergo a procedure which requires gadolinium, you may be at risk for a rare condition known as Nephrogenic Systemic Fibrosis or Nephrogenic Fibrosing Dermopathy (NSF/NFD). NSF/NSD may result in damage to body organs and possible death.

Although gadolinium has been found to be a very safe contrast agent, there is always the risk of a reaction. These reactions can range from minor ones such as nausea, warmth at the injection site, headache, dizziness, itching, flushing, and hives to more severe reactions such as cardiac arrhythmias, shortness of breath, wheezing, convulsions, unresponsiveness, or even death. These life-threatening reactions are exceedingly rare, occurring in only 0.01% - 0.001% of cases. The medical personnel in charge of your exam are prepared and trained to respond to these types of reactions. At ProScan Imaging we have chosen a contrast agent called Dotarem. This agent has a more stable chemical bond and is considered one of the safer options for Gadolinium contrast available. A very small subset of patients receive Eovist.

What are the Alternatives to Gadolinium?

Alternatives to using intravenous contrast are available. These procedures may be able to provide the necessary diagnostic information. Please ask to speak with the technologist or supervising physician should you have any questions regarding an alternative imaging procedure.

By signing this you agree that you have read this form and/or I have received oral communications of all the information provided in this form. You understand the information, and have had any questions answered regarding this procedure and who will read the exam. In addition, you agree that you 1) have been explained the purpose of the procedure; 2) have been informed of how long the procedure will take; 3) understand the risks, benefits, and complications associated with the procedure; 4) have truthfully informed ProScan of my current medical condition and have complied with any requirements for having this procedure that have been communicated to me; 5) are aware of possible alternatives; and 6) have been given the right to refuse to consent to the procedure.

I have not been pressured to sign this consent and do so voluntarily. I understand that I may contact ProScan at the address and phone number provided if I have any further questions about this form or the procedure. I am at least 18 years of age, of sound mind and not under the influence of alcohol or hallucinogenic drugs. I have no reservations and give my consent to start and complete the exam(s) by my signature and date here.

Patient's and/or Appropriate Agent's Signature

Date

Patient's Name _____ Date of Birth ____/____/____

What is a MRI Enterography?

Magnetic resonance imaging (MRI) is a non-invasive medical scan that uses a magnetic field and pulses of radio wave energy to create images of organs and other structures inside the body. The preparation is similar to that of most other abdominal MRI studies. In many cases MRI shows problems that cannot be seen with an X-ray, ultrasound, or computed tomography (CT) scan. MRI Enterography is a special MRI that produces very detailed images of the small intestines. These detailed images allow a radiologist to better evaluate the presence of certain diseases. It is often used for the evaluation and treatment of patients with Crohn's disease, intestinal inflammation, evaluation and diagnosis of tumors, determine the source of bleeding and other vascular abnormalities, diagnose abscesses, inflammation, fistulas and bowel obstructions. It is particularly useful for those patients who may need to undergo repeated CT scans to evaluate certain diseases, since MRI does not produce radiation.

What are the advantages to MRI Enterography?

MRI is a non-invasive imaging technique that does not involve exposure to ionizing radiation, making it beneficial for younger patients or those who need repeat imaging due to conditions like Crohn's disease. MRI examinations enable the discovery of abnormalities that may be obscured by bone with other imaging modalities and is considered a more reliable examination than x-ray for correctly identifying areas of Crohn's disease involvement. The contrast material used in MRI imaging is less likely to produce an allergic reaction than the iodine-based materials used for conventional x-rays and CT scanning.

What are the Risks?

Although minimal, there is a slight risk of allergic reaction whenever a contrast material or other medication is used during a procedure.

What are the Alternatives?

Alternatives to MRI Enterography include traditional CT imaging, which exposes the patient to radiation, and Video Capsule Endoscopy (VCE), which is an invasive procedure.

How is a MRI Enterography performed?

On the day of the study you may have nothing to eat or drink 4 hours prior to the exam. If you are diabetic or have other medical issues that make fasting an problem, you can have clear liquids sparingly in the 4 hours before your scan. If you must take medications please do so as prescribed with a minimal amount of water or food (clear liquids if possible).

It is necessary to arrive at the imaging facility 1 hour prior to your scheduled exam to drink an oral preparation called Breeza. You will be given two-three (2-3) bottles of Breeza totaling 1000-1500ml. Breeza is flavored beverage for neutral abdominal/pelvic imaging. It has a light citrus flavor and is sugar and gluten free. It is used to allow your esophagus, stomach and intestines to be seen more clearly on the MRI examination.

Your MRI procedure will take approximately 75 minutes. In preparation for the exam the technologist will insert an IV line into your hand or arm to allow for the injection you will receive. You will be placed on the MRI table and positioned to allow for imaging of your abdominal and pelvic area. The technologist will then connect your IV to an injector which will deliver the Gadolinium contrast material during the final portion of the scan. Images of your abdomen will then be acquired. This first portion of the exam will take approximately 20 minutes. The technologist will communicate with you throughout the exam making you aware of the time of each sequence and any necessary breath holds. The technologist will let you know when the contrast injection will be delivered. If you have any concerns or issues please make sure to notify your technologist immediately. After the injection further images of your abdominal and pelvic region will be acquired. This final portion of your exam will last approximately 15-20 minutes. A physician will be on the premises throughout your entire procedure and we will monitor you closely during your scan. You can easily communicate with us during your scan to inform the technologist of any discomfort or concern you may have.

By signing this you agree that you have read this form and/or I have received oral communications of all the information provided in this form. You understand the information, and have had any questions answered regarding this procedure and who will read the exam. In addition, you agree that you 1) have been explained the purpose of the procedure; 2) have been informed of how long the procedure will take; 3) understand the risks, benefits, and complications associated with the procedure; 4) have truthfully informed ProScan of my current medical condition and have complied with any requirements for having this procedure that have been communicated to me; 5) are aware of possible alternatives; and 6) have been given the right to refuse to consent to the procedure.

I have not been pressured to sign this consent and do so voluntarily. I understand that I may contact ProScan at the address and phone number provided if I have any further questions about this form or the procedure. I am at least 18 years of age, of sound mind and not under the influence of alcohol or hallucinogenic drugs. I have no reservations and give my consent to start and complete the exam(s) by my signature and date here.

Signature of Patient or Appropriate Agent

Date



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WARNING! If you have impaired kidney function, require kidney dialysis, or have a personal history of kidney disease, please notify a staff member IMMEDIATELY.

Patient Name _____ Date of Birth ___/___/___

Examination Type _____ Examination Date ___/___/___

Gadolinium Questions:

Yes No Do you have any drug allergies? Please list: _____

- Yes No Are you or could you possibly be pregnant?
- Yes No Are you breast-feeding? Breast milk should be discarded for 72 hours after injection.
- Yes No Have you ever had a previous allergic reaction to MRI contrast?
- Yes No Do you have severe allergies (not minor seasonal allergies)?
- Yes No Do you have asthma?
- Yes No Do you have hemolytic anemia?
- Yes No Do you have sickle cell disease?
- Yes No Do you have, or have you ever had, kidney disease, including kidney cancer, infection or traumatic injury, decreased kidney function, or kidney surgery including removal or transplant?
- Yes No Do you have severe liver disease? Recent liver transplant or currently awaiting transplant?
- Yes No Do you have poorly controlled hypertension? (Greater than 180/110 mmHg)
- Yes No Do you have cardiomyopathy or congestive heart failure?
- Yes No Do you have diabetes? If yes please answer the following:
 - Yes No Are you currently under the care of a physician for your diabetes?
 - Yes No Do you have retinopathy? (eye disease related to your diabetes)
 - Yes No Do you have neuropathy? (Numbness, tingling, burning in extremities)
 - Yes No Do you have heart disease?
 - Yes No Do you have a history of stroke or TIA?
 - Yes No Do you have any lower extremity problems?
(cold feet or legs, infections, sores that won't heal)
- Yes No Are you currently taking any medication containing metformin? These include Metformin (generic), Avandamet, Glucophage, Glucophage XR, Glucovance, Metaglip, Glumetza, Fortamet, Riomet, ACTOPLUS Met, and Janumet.
- Yes No Have you had an MRI or CT in the last 72 hours that involved contrast injection?

Breeza Questions:

- Yes No Do you have any allergies to Citrus fruit?
- Yes No Do you have any known allergies to food or food additives?

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Signature of Patient or Appropriate Agent _____
Date



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HIPAA Acknowledgment & Office Policies

BY SIGNING BELOW, I HEREBY ACKNOWLEDGE AND AGREE TO THE FOLLOWING POLICIES:

RESPONSIBILITY FOR VALUABLES. ProScan does not assume responsibility for securing any and all valuables and personal items belonging to patients or visitors. You are responsible for securing all valuables or personal items prior to your imaging exam.

**I have read and understand the above statements and acknowledge that ProScan and its employees are not liable for the loss or theft of my valuables or personal items.*

CHILDREN IN THE WAITING ROOM. ProScan is not responsible for providing supervision of any child during your imaging exam. You are welcome to bring your child or children if there is another adult accompanying you to supervise your child or children while your imaging exam is being done.

**I have read and understand the above statements and acknowledge that ProScan and its employees will not be responsible for providing childcare for my child or children during my imaging exam.*

CANCELLATION POLICY. If you will not be able to appear for your scheduled appointment, you must notify ProScan 24 hours prior to your appointment time. If you miss or cancel your appointment without giving the appropriate 24-hour notice, ProScan may charge you a \$50.00 cancellation fee.

**I have read and understand the above statements and acknowledge that if I do not provide ProScan with 24 hours prior notice that I cannot keep my scheduled appointment, I may be charged a \$50.00 cancellation fee.*

BY SIGNING THIS DOCUMENT BELOW, I HEREBY ACKNOWLEDGE THAT I HAVE BEEN OFFERED AND/OR HAVE RECEIVED A COPY OF PROSCAN IMAGING AND AFFILIATED ENTITIES NOTICE OF PRIVACY PRACTICES.

I hereby give my consent for ProScan Imaging and Affiliated Entities to release my protected health information to the following individual(s): *(PLEASE PRINT)*

_____	Relationship to Patient _____
_____	Relationship to Patient _____
_____	Relationship to Patient _____

FOR PROSCAN IMAGING USE ONLY – RECEIPT OF NOTICE OF PRIVACY PRACTICES ONLY

Date Acknowledgment Received: _____ Initials: _____

-OR-

Reason Acknowledgment was not obtained: _____

Patient or Legal Representative Signature

Date: _____

Print Name

Relationship/Authority if Legal Representative



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Health History Questionnaire for MRI Examination

Patient Name: _____ Date of Service: ___/___/___

DOB: ___/___/___ Age: _____ Sex: _____ Height: _____ Weight: _____

Yes No Is your visit due to an accident or trauma?

Yes No Have you filed a personal injury claim?

Yes No Was this a work related injury?

Yes No Due to a motor vehicle accident?

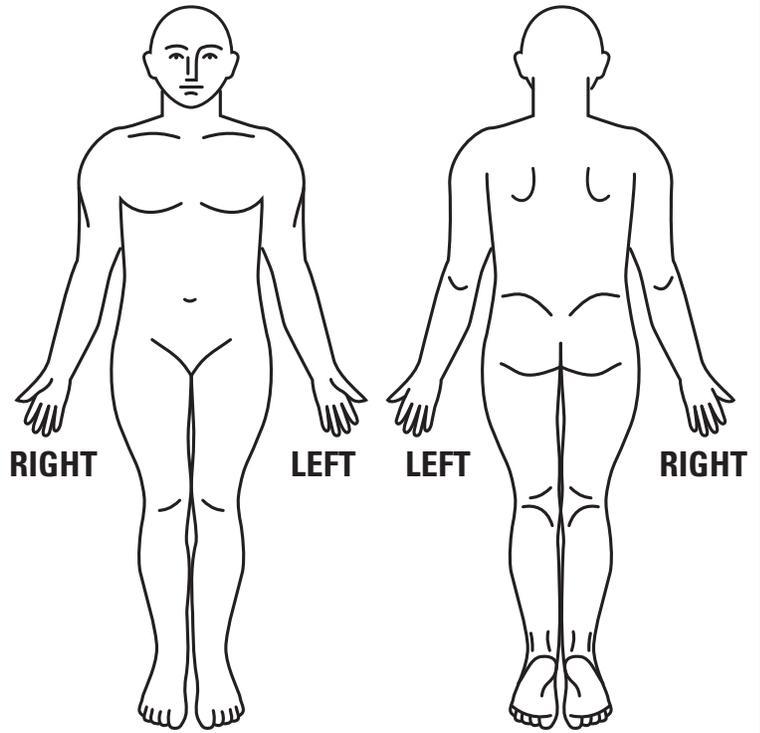
What is the number one symptom you are experiencing? _____

Please describe the nature and date of the injury.

If you are experiencing any pain, please mark with an "x" where the pain is on the illustrations. If you are NOT currently experiencing any pain, please check the box below the illustrations.

Please list all major medical history. Be sure to include all surgeries and drug allergies.

Please list any other MRIs, X-rays, CT scans or Ultrasounds you have had of the area we are imaging today and the date:



NOT CURRENTLY EXPERIENCING PAIN

Tech Notes:

Yes No Contrast Injected?

Time _____ AM/PM Contrast Brand Name _____ Dosage _____

Route Administered _____ Administration site _____

Lot _____ Expiration Date ___/___/___ Reaction? _____

Signature of technologist _____

Signature of Physician Supervising Contrast _____

WARNING! IF YOU HAVE A PACEMAKER, DEFIBRILLATOR OR ANEURYSM CLIP, DO NOT PROCEED WITH YOUR SCAN. PLEASE NOTIFY A STAFF MEMBER IMMEDIATELY.

Patient Name _____ DOB _____ Appt. Date _____

Please indicate if you have any of the following implants or metal inside your body:

- | | | | | | |
|------------------------------|-----------------------------|---|------------------------------|-----------------------------|---|
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | Cardiac Pacemaker | <input type="checkbox"/> Yes | <input type="checkbox"/> No | Cardiac Defibrillator (ICD) |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | Cardiac Loop Recorder (Insertable Cardiac Monitor) | | | |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | Heart Valve prosthesis | <input type="checkbox"/> Yes | <input type="checkbox"/> No | Swan-Ganz or thermodilution catheter |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | Aneurysm Clip | <input type="checkbox"/> Yes | <input type="checkbox"/> No | Metallic stent, filter or coil |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | Vascular Access port and/or catheter | | | |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | Cochlear, otologic or other ear implant | <input type="checkbox"/> Yes | <input type="checkbox"/> No | Intraocular lens, eyelid spring or wire |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | Hearing aids | <input type="checkbox"/> Yes | <input type="checkbox"/> No | Cosmetic colored contact lenses |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | Dentures, partial plates or dental implant | | | |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | Spinal cord stimulator or other neurostimulation system | | | |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | Surgical staples, clips, endoscopic clips or metallic sutures | | | |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | Wire mesh implant | | | |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | Surgically implanted device or prosthesis (penile, eye etc) | | | |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | Insulin or other drug infusion pump | <input type="checkbox"/> Yes | <input type="checkbox"/> No | Radiation seeds or implants |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | Breast or other tissue expander | <input type="checkbox"/> Yes | <input type="checkbox"/> No | Internal electrodes or wires |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | Bone growth or bone fusion stimulator | | | |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | Artificial or prosthetic limb | <input type="checkbox"/> Yes | <input type="checkbox"/> No | Joint replacement (hip, knees etc) |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | Bone/joint pin, screw, nail, wire, plate etc | | | |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | Medication patches of any kind | <input type="checkbox"/> Yes | <input type="checkbox"/> No | IUD, diaphragm or pessary |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | Spinal or intraventricular brain Shunt | | | |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | Body piercings, tattoos or permanent make-up | <input type="checkbox"/> Yes | <input type="checkbox"/> No | Any metallic fragment or foreign body |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | Breast feeding or pregnancy | <input type="checkbox"/> Yes | <input type="checkbox"/> No | Breathing problem or motion disorder |
| <input type="checkbox"/> Yes | <input type="checkbox"/> No | Metallic foreign body in the eye, currently or in the past, for which you previously sought medical attention | | | |

IMPORTANT INSTRUCTIONS! Before entering the MRI environment or MRI system room, you must remove ALL metallic objects, including hearing aids, dentures, partial plates, keys, pagers, cell phones, eyeglasses, hairpins, barrettes, jewelry, body-piercing jewelry, watch, safety pins, paper clips, money clip, credit cards, bank cards, magnetic strip cards, coins, pens, pocket knife, nail clipper, and tools.

Please consult the MRI technologist or radiologist if you have any questions or concerns before you enter the MRI system room.

NOTE: You may be advised or required to wear earplugs or other hearing protection during the MRI procedure to prevent possible problems or hazards related to acoustic noise.

I attest that the above information is correct to the best of my knowledge. I read and understand the contents of this form, and had the opportunity to ask questions regarding the information on this form and the MR procedure that I am about to undergo.

Signature of Person Completing Form: _____ Date ____/____/____
Signature

Form Completed by: Patient Other _____
Print name Relationship to patient

Form Reviewed by: MRI Tech. Rad. _____
 Tech. Assist. Coordinator Signature

I have reviewed this form. All positive responses have been discussed, investigated and cleared. The patient has been coached appropriately and scanned with the SafeScan device.

Signature of Technologist: _____ Date ____/____/____

- Following completion of your MRI scan today, you may continue with your normal daily activities.
- Please make sure that you remain well hydrated for the next 12 hours. Drink an additional 1-2 glasses of water.
- If you are breastfeeding, you should discard you breast milk for the next 72 hours as Gadolinium will be present in the milk for that time period.
- Although it is rare to experience any delayed allergic reactions, please call the center to speak with the supervising physician if you develop a rash or hives. In the event that you have a severe reaction, such as shortness of breath or facial swelling, please call 911.
- If you have any further questions regarding your MRI Enterography procedure, please speak with the technologist.



I read and understand the contents of this form, and had the opportunity to ask questions regarding the information on this form and the procedure I am about to undergo.

Signature of Patient or Appropriate Agent: _____ Date ____/____/____

Signature of Technologist: _____ Date ____/____/____



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