

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

If this procedure is being performed in Indiana, the following person has witnessed the signing of this form:

Witness's Signature

Date

What Is Breast MRI?

Breast MRI is an extremely sensitive tool for detecting the presence of breast cancer and evaluating the extent of the cancer. Breast MRI is most commonly used in high-risk women when the findings of an x-ray mammogram are inconclusive because of dense breast tissue, or when there is a suspected abnormality that requires further evaluation. High-risk women include those with a personal history of breast cancer or those with a very strong family history of breast cancer (such as mother or sister diagnosed with the disease). Breast MRI scans work by using a contrast medium to demonstrate the new blood vessels that feed tumors and to characterize the nature of the tumor as either potentially malignant or probably benign. Breast MRI is not used to screen the general population for breast cancer and is not a replacement for x-ray mammograms.

Advantages and Limitations

Breast MRI can often detect tiny cancers of only 3 to 5 millimeters in diameter (the size of a pea) and can detect cancer even when mammograms or physical examinations are normal. Even though the examination is very useful, tumors smaller than 3 millimeters can be missed and (rarely) certain large tumors that do not absorb the contrast very well may not be detected. Some forms of noninvasive breast cancer, called ductal carcinoma in situ (DCIS) or lobular cancer in situ (LCIS), may not be detected by breast MRI and yet may be detectable on an x-ray mammogram. Therefore, x-ray mammograms are performed in conjunction with the breast MRI and remain very important for diagnosis. Ultrasound may also be performed after the MRI to check areas of concern seen on the examination.

What Are the Risks?

There tends to be a higher "false positive" rate associated with breast MRI than with x-ray mammography. This means that some benign breast disorders may look like cancer on the MRI, requiring further testing or biopsy to exclude the presence of cancer.

What Are the Alternatives?

Breast MRI is a very specialized scan and provides information that is generally not obtained by other imaging methods like mammography or ultrasound. In some cases, depending on your individual factors, your physician may recommend proceeding directly to biopsy instead of a breast MRI.

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

If this procedure is being performed in Indiana, the following person has witnessed the signing of this form:

Witness's Signature

Date

Date of Service: ___/___/___ Referring MD: _____

Patient Name: _____

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

INDICATIONS FOR MRI (symptoms or diagnosis): _____

History of Breast Conditions. Do you or have you had:

Yes No A palpable mass in your breast? (a lump that can be felt)

Yes No Previous breast biopsy and/or breast surgery? Right breast Left breast

Describe: _____

Where: _____ Date: ___/___/___ Non-malignant (benign) Malignant (cancer)

Yes No Surgical clips? Where: _____ Date: ___/___/___

Yes No Injury to breast? Where: _____ Date: ___/___/___

Yes No Grandmother, mother, or sister with a history of breast cancer? If yes, who? _____

Yes No **Are you on Hormones?** If yes, please list: _____

Yes No **Pregnant?**

Yes No **Breast feeding?**

Yes No **Implants?** If yes, what kind: Silicone Saline Combination

Yes No **Menopausal?** If no, date last menstrual period began: ___/___/___

OTHER BREAST EXAMINATIONS PERFORMED – LIST ALL THAT APPLY

FACILITY WHERE PERFORMED (Hospital, Clinic, Physicians Office)

DATE OF PROCEDURE

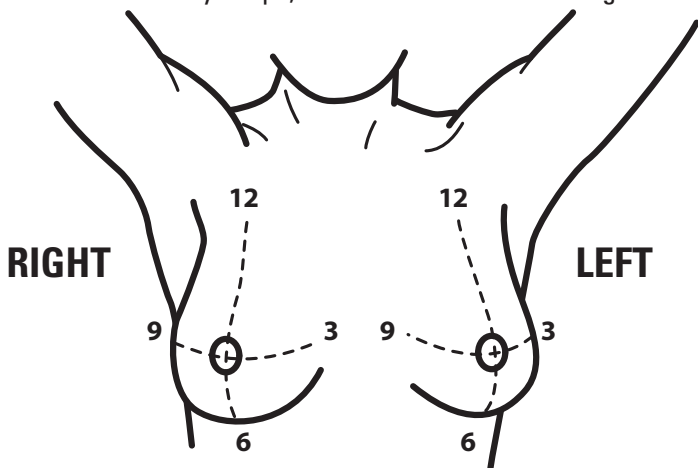
Mammogram _____ /___/___

CT Scan _____ /___/___

Breast MRI _____ /___/___

Ultrasound _____ /___/___

Please MARK any lumps, lesions or scars on the diagram:



Additional Notes:

TECHNOLOGIST CHECK ONE:

All prior reports and images are uploaded into POL2

The reports/images we do not have onsite have been requested and details are entered in notes section of POL2

Technologist's Signature: _____ Date: ___/___/___



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: _____

_____ Date: _____
Patient or Legal Representative Signature

_____ Relationship/Authority if Legal Representative
Print Name

If this procedure is being performed in Indiana, the following person has witnessed the signing of this form:

Witness's Signature _____ Date ____/____/____



This page intentionally left blank

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?

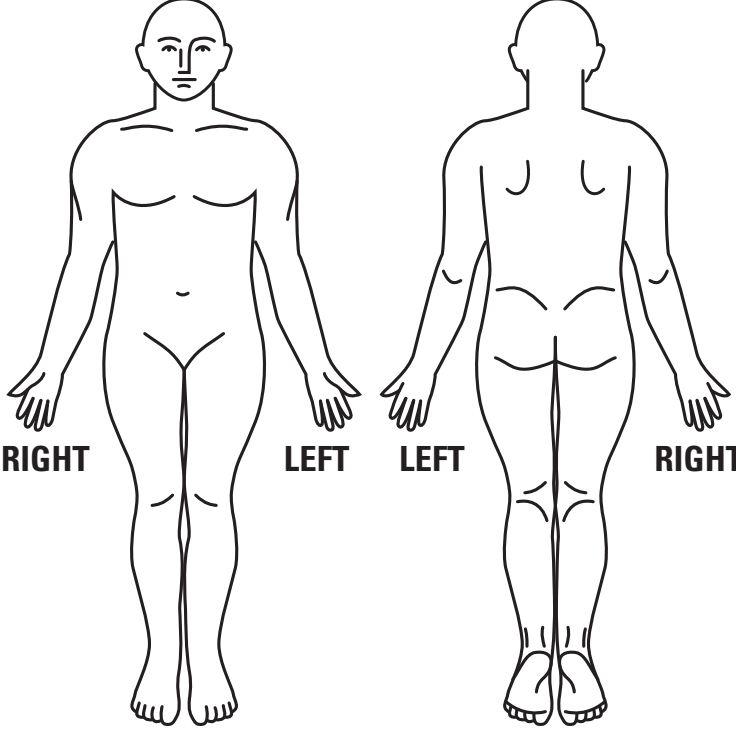
What is the number one symptom you are experiencing? _____

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 _____

Signature of Witness _____

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 ____/____/____

If this procedure is being performed in Indiana, the following person has witnessed the signing of this form:

Witness's Signature: _____ Date ____/____/____

Health History Questionnaire for Patients Receiving Dotarem

Patient Name _____ Date of Birth ___/___/___

Examination Type _____ Examination Date ___/___/___

Yes No **Are you or could you possibly be pregnant?**

Yes No **Are you breast-feeding?**

If yes, please initial to indicate you were provided education prior to your contrast enhanced exam about breast feeding after your contrast enhanced exam is completed. Initial Here: _____

Yes No **Have you ever had a previous allergic reaction to MRI contrast?**

Yes No **Are you currently being treated for NSF (Nephrogenic Systemic Fibrosis)**

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 **If yes, are you currently receiving dialysis treatment?**

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?**

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

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

Signature of MR Technologist: _____ Date ___/___/___

If this procedure is being performed in Indiana, the following person has witnessed the signing of this form:

Witness's Signature: _____ Date ___/___/___



This page intentionally left blank

Post-Procedure Instructions for Gadolinium

- 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. This is especially important if you had an examination of the renal arteries or the breasts.
- If you are breast feeding please refer to the breast feeding instruction letter you were given prior to your MRI exam.
- 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 examination, please speak with the technologist.



Supervising Physician: _____ Phone: _____

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 MRI Technologist: _____ Date: ___/___/___

If this procedure is being performed in Indiana, the following person has witnessed the signing of this form:

Witness's Signature: _____ Date: ___/___/___



This page intentionally left blank