INFORMED CONSENT FOR MRI (With or Without Contrast Injection)

Patient Name: _____

I, the undersigned, being either the patient named above or legally authorized representative of the patient named above, do hereby consent to the performance of medical diagnostic and imaging procedures at Health Images on the terms and conditions more fully set out below. I understand that I have the right to be informed about the diagnostic imaging procedure being used so that I may make the decision whether or not to undergo the procedure.

1. **Consent to Imaging Procedure:** Your attending physician believes it beneficial for you to undergo a diagnostic imaging procedure known as magnetic resonance imaging (MRI) to obtain additional information that may aid in diagnosing and treating your medical condition. It has been explained to me that MRI does not use x-rays or radiation. Instead a magnetic field and radio waves are used to create an image of internal body structures. MRI is a painless procedure that only requires that you lie quietly on a padded table that gently glides you into the magnet. While the scanner is performing your scan, you will hear some humming and thumping sounds. These are normal and should not worry you. In some cases, a contrast agent may be injected into your vein in order to give a clearer image of the area being examined. The MRI study may be conducted without the injection of contrast, but the images may not be as helpful to the radiologist and your physician. Inform the technologist if you wish to refuse the contrast injection.

2. Because of the magnetic field and radio frequencies, people with a heart pacemaker, brain aneurysm clips, and some implanted metallic or electrical devices should not have an MRI. It is important that you inform the technologist if you have any of these metallic appliances. Please inform the technologist if you are pregnant or think that you may be pregnant.

3. **Potential Risks:** Anytime an injection is given there is the potential for bruising or swelling at the injection site. Occasionally, minor allergic reactions occur in the form of itching, sneezing, hives, swelling of the eyes, wheezing or nausea. These symptoms may require treatment with medication we have at hand. Rarely, a more serious reaction will occur. A radiologist will evaluate the situation and determine if additional medical treatment is necessary. Even though it is rare, medical statistics indicated that a fatality might occur from the injection of contrast. If you have had a reaction to a sickle cell anemia or kidney disorder, are pregnant or breast-feeding, you MUST inform the technologist.

No reference to gadolinium risks

4. Blood Laboratory results may be needed before we can perform this exam. If we are unable to obtain lab results from your physician that are no greater than 6 weeks old, the Blood Lab testing will be performed at our center before your examination.

5. The benefit of this exam is to assist your physician with making a diagnosis. There may be other imaging alternatives, however your physician believes the MRI to be the best diagnostic test for you, after evaluating your symptoms and medical condition.

By my signature below, I hereby certify that I have fully read this consent, had it explained to me or have had it read to me. I have been given an opportunity to ask questions about my condition, alternative forms of treatment, and the procedures to be used, and the risks and hazards involved. I understand its contents and have sufficient information to give this informed consent.

_____ **Date** _____ **Time** _____

Patient/Parent/Legal Guardian Signature

_____ **Date** _____ **Time** _____

Witness Signature

Gadolinium contrast material

Not applicable to this exam ☐

_____ CC of Magnevist With a _____ at _____ X _____

In _____ Lot _____ Expiration Date _____

Site Location _____ By _____

Contrast Reaction Yes No Physician Covering Contrast _____

Explain: _____

CONSENT FOR ADMINISTRATION OF GADOLINIUM BASED MRI CONTRAST AGENT

A. CONTRAST ENHANCED MRI

Your physician has determined that a contrast enhanced Magnetic Resonance Imaging (MRI) study is needed to help diagnose a medical condition. The MRI contrast agent helps to distinguish abnormal tissue from normal. The Food and Drug Administration has issued an advisory concerning a rare disease called Nephrogenic Systemic Fibrosis (NSF) that is linked with the use of MRI contrast agents. This disease has only occurred in people with severe kidney disease or in patients with any kidney disease associated with liver failure or recent liver transplantation. Your tests indicate that you have significant kidney disease which means you may be at increased risk of developing NSF following MRI contrast.

You will be given an agent (Multihance, Prohance or Eovist) that has had no definite previous reported association with NSF. Your risk of getting NSF is therefore believed to be extremely low risk and the added benefit of you receiving a contrast enhanced MRI is believed to be important for your medical management.

If you are on dialysis, we will discuss your risk of NSF with your nephrologist (kidney) doctor and an additional dialysis session may be prearranged.

B. NEPHROGENIC SYSTEMIC FIBROSIS (NSF): BACKGROUND

NSF causes hardening and thickening (fibrosis) of the skin, muscles, and blood vessels throughout the body. Patients with NSF describe swelling and tightening of the skin, especially the arms and legs. The condition may develop over a period of days to several weeks. Sometimes the skin thickening makes it difficult to move the joints. Severely affected patients may be unable to walk and occasionally this condition has resulted in death.

The first case of NSF was reported in 1997. The disease is rare, with only between 250 and 400 cases reported after that and all linked to use of an MRI contrast agent in patients with significant kidney disease. Kidney failure can allow the contrast agent to stay longer in the blood giving it more time to break up and settle out in the tissues of the body. Nearly all cases of NSF have occurred with use of 2 brands of MRI contrast that are not used at the University of Virginia. After recognition of this condition and its risk factors, its occurrence is now extremely rare.

Risks of MRI Contrast:

• Allergic reaction. Some people experience temporary itching after receiving MRI contrast. Less than one person in 300,000 will experience a severe allergic reaction which requires treatment.

(CONTINUED ON NEXT PAGE)

• Contrast infiltration. Contrast that is injected outside of the vein into other tissues can cause localized pain and swelling. Treatment generally consists of hot or cold packs and elevation of the affected arm. Infiltrations most often resolve over time.

•Temporary metallic taste in the mouth, tingling in the arm, nausea, or headache occurs in less than 1 in 100 people

• Nephrogenic Systemic Fibrosis. A rare fibrosing condition involving the skin and organs that has occurred in patients with severe renal failure. As discussed above, you may be at increased risk for this condition because you have kidney disease. Your exact risk is not precisely known but is thought to be extremely low.

An MRI without a contrast agent may be an alternative. If you would like to speak to a physician regarding this, to discuss these risks, to ask questions or if you wish to reschedule your examination, please inform the MRI technologist.

C. PATIENT OR LEGAL REPRESENTATIVE SIGNATURE:

By signing below I state that I am 18 years of age or older, or otherwise authorized to consent. I have read or have had explained to me the contents of this form and I agree to receive the care, treatment or services listed on this consent. I have had a chance to ask questions and all of my questions have been answered.

SIGNATURE OF PATIENT OR LEGAL REPRESENTATIVE	PRINTED NAME	DATE	TIME

IF SIGNED BY PERSON OTHER THAN THE ADULT PATIENT, CHECK RELATIONSHIP TO PATIENT:

☐ 1. Agent Named in Advance Directive ☐ 4. Adult Child ☐ 7. Other Blood Relative
☐ 2. Guardian ☐ 5. Parent ☐ 8. Other* _____
☐ 3. Husband/Wife ☐ 6. Adult Brother/Sister

FOR MINOR PATIENTS:

☐ 1. Parents ☐ 2. Guardian or Legal Custodian ☐ 3. Authorized person for child in out-of-home placement

*** Requires review and appointment by Ethics Consult Service.**

D. PHYSICIAN STATEMENT/SIGNATURE & WITNESS SIGNATURE:

I have explained the procedure(s) stated on this form, including the possible risks, complications, alternative treatments (including non-treatment) and anticipated results to the patient and/or his/her representative. The patient and/or their representative has communicated to me that they understand the contents of this form.

SIGNATURE OF PHYSICIAN OR DESIGNEE OBTAINING CONSENT	PRINTED NAME	PIC #	DATE	TIME

SIGNATURE OF WITNESS (OPTIONAL)	PRINTED NAME	DATE	TIME

E. INTERPRETER ATTESTATION

Interpretation has been provided by

SIGNATURE OF INTERPRETER/CYRACOM ID #	PRINTED NAME	DATE	TIME