DIAGNOSTIC IMAGING CENTERS, P.A.

**INFORMED CONSENT FOR MRI WITH IV CONTRAST**

Name:_____ DOB:_____ MRN: _____ Date:_____

Referring Physician: _____ Procedure(s): _____

## Consent for Gadolinium-based IV Contrast

Some patients undergoing an MRI scan may require an intravenous (IV) dye (contrast) known as Gadolinium. There are many benefits of using IV contrast for an MRI. It improves accuracy, assists in diagnosing abnormalities and may help direct your treatment. As with all drugs or medications, there are risks; however the benefits usually outweigh the small chance of side effects or reactions. The decision to give you IV contrast is not taken lightly and is carefully made by your referring doctor and/or our radiologist. Most injections of IV contrast occur without any issues.

A rare, but possible side effect from IV contrast injections is extravasation. Extravasation means that the contrast material went outside the blood vessel and has gone into the surrounding tissue. Extravasation may result in a stinging or burning sensation, and/or tightness or swelling at the injection site.

Minor contrast reactions are the most common, but happen in less than 0.05% of cases. Symptoms may include headache, sneezing, nausea, vomiting, hives and swelling and usually resolve rapidly. Occasionally medications may be required to help treat these symptoms if they persist.

Rarely, a severe reaction can happen. This may include a rapid or slow heart rate, low blood pressure, an asthma attack (bronchospasm) or complete circulatory arrest/shock. Such reactions require urgent medical treatment, which our offices are prepared to handle.

If you have ANY symptoms that concern you, please tell your technologist promptly.

Patients with reduced kidney (renal) function or kidney failure should not undergo an injection of gadolinium unless this has been cleared by a specialist in this field (renal physician) in order to avoid a potentially life threatening condition known as NSF (Nephrogenic Systemic Fibrosis).

Patients who have had a contrast reaction to the contrast used in CT, IVP, and angiographic examinations are at a 3.7 times increased risk of an adverse reaction. Otherwise, there is no way of predicting who will be allergic to contrast until the dye is given. A patient who becomes allergic will usually develop their symptoms within 10 minutes.

It has been shown that gadolinium agents can be retained in areas of the body, such as the brain, or in bone. The importance of this is unclear, and no disease process has been associated, even in cases where deposits have been found. The lowest retention has been shown with the type of agents (macrocyclic) used at all of our clinics.

If after reading this information you are not willing to undergo a study with IV contrast, the test may still be done without it; however in certain cases this will limit the amount of information we can get from the test.

**The risks associated with the use of gadolinium-based contrast has been explained to me, and I have been given the opportunity to address my questions or concerns.**

❑ **I have received the Gadolinium-Based Contrast Agents (GBCA) Medication Guide.**

❑ I ***CONSENT*** to the administration of a gadolinium based contrast for the completion of a MRI and/or MRA Study.

❑ I ***DECLINE*** to have the MRI and/or MRA with contrast.

×_____ _____

Patient Signature Date

×_____ _____

Witness Signature Date

## Medication Guide

**GADAVIST**
**(gad-a-vist)**
(gadobutrol)
Injection for intravenous use

**What is Gadavist?**

- Gadavist is a prescription medicine called a gadolinium-based contrast agent (GBCA). Gadavist, like other GBCAs, is used with a magnetic resonance imaging (MRI) scanner.
- An MRI exam with a GBCA, including Gadavist, helps your doctor to see if there are any problems better than an MRI exam without a GBCA.
- Your doctor has reviewed your medical records and has determined that you would benefit from using a GBCA with your MRI exam.

**What is the most important information I should know about Gadavist?**

- Gadavist contains a metal called gadolinium. Small amounts of gadolinium can stay in your body including the brain, bones, skin and other parts of your body for a long time (several months to years).
- It is not known how gadolinium may affect you, but so far, studies have not found harmful effects in patients with normal kidneys.
- Rarely, patients have reported pains, tiredness, and skin, muscle or bone ailments for a long time, but these symptoms have not been directly linked to gadolinium.
- There are different GBCAs that can be used for your MRI exam. The amount of gadolinium that stays in the body is different for different gadolinium medicines. Gadolinium stays in the body more after Omniscan or Optimark than after Eovist, Magnevist, or MultiHance. Gadolinium stays in the body the least after Dotarem, Gadavist, or ProHance.
- People who get many doses of gadolinium medicines, women who are pregnant and young children may be at increased risk from gadolinium staying in the body.
- Some people with kidney problems who get gadolinium medicines can develop a condition with severe thickening of the skin, muscles and other organs in the body (nephrogenic systemic fibrosis). Your healthcare provider should screen you to see how well your kidneys are working before you receive Gadavist.

**Do not receive Gadavist if you** have had a severe allergic reaction to Gadavist.

**Before receiving Gadavist, tell your healthcare provider about all your medical conditions, including if you:**

- have had any MRI procedures in the past where you received a GBCA. Your healthcare provider may ask you for more information including the dates of these MRI procedures.
- are pregnant,or plan to become pregnant. It is not known if Gadavist can harm your unborn baby. Talk to your healthcare provider about the possible risks to an unborn baby if a GBCA such as Gadavist is received during pregnancy.
- have kidney problems, diabetes, or high blood pressure.
- have had an allergic reaction to dyes (contrast agents) including GBCAs

**What are the possible side effects of Gadavist?**

- **See "What is the most important information I should know about Gadavist?"**
- **Allergic reactions. Gadavist can cause allergic reactions that can sometimes be serious. Your healthcare provider will monitor you closely for symptoms of an allergic reaction.**

**The most common side effects of Gadavist include: headache, nausea, and dizziness.**
These are not all the possible side effects of Gadavist.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

**General information about the safe and effective use of Gadavist.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. You can ask your healthcare provider for information about Gadavist that is written for health professionals.

**What are the ingredients in Gadavist?**
Active ingredient: gadobutrol
Inactive ingredients: calcobutrol sodium, trometamol, hydrochloric acid (for pH adjustment) and water for injection

Manufactured for Bayer HealthCare Pharmaceuticals Inc.

Manufactured in Germany
 For more information, go to www.gadavist.com or call 1-888-842-2937.
This Medication Guide has been approved by the U.S. Food and Drug Administration. Rev. 4/2018 Reference ID: 4254603