SPECIALTY IMAGING CENTER
NORTHRIDGE

MRI GADOLINIUM CONSENT / FDA EVALUATION ALERT

Patient Name: _____ D.O.B._____

Your doctor has asked us to perform an MRI examination with contrast material called Gadolinium. During this test, a Gadolinium-contrast agent is injected into a vein resulting in diagnostic information and distinguishing neighboring tissue.

The Federal Drug Administration (FDA) is currently evaluating important safety information about Gadolinium-containing contrast agents and a disease known as Nephrogenic Systemic Fibrosis or Nephrogenic Fibrosing Dermopathy (NSF / NFD) that can occur in **patients with kidney failure**. New reports have identified a possible link between NSF / NFD and exposure to Gadolinium containing contrast agents used for Magnetic Resonance Imaging, in patients with advanced renal failure.

NSF / NFD causes fibrosis of the skin and connective tissues throughout the body. Patients develop skin thickening that may prevent bending and extending joints, resulting in decreased mobility in joints. In addition, patients may experience fibrosis that spreads to other parts of the body such as the diaphragm, muscles in the thigh and lower abdomen, and the interior areas of lung vessels. The clinical course of NSF / NFD is progressive and may be fatal.

After having been informed and having the opportunity to ask questions in regards to this procedure, I am aware of the possible risks of Gadolinium as a result of this MRI exam and consent to this study.

It is recommended that prior to elective Gadolinium Based MR Contrast Agent (GBMCA) administration, a recent (e.g., last 6 weeks) Glomerula Filtration Rate (GFR) assessment be reviewed for patients with a history of:

1. Renal disease (including solitary kidney, renal transplant, renal tumor)
2. Age > 60
3. History of Hypertension
4. History of Diabetes
5. History of severe hepatic disease/liver transplant/pending liver transplant. For patients in this category only, it is recommended that patient's GFR assessment be nearly contemporaneous with the MR examination for which the GBMCA is to be administered.

Patient/Guardian Signature: _____ Date: _____

Witness Signature: _____ Date: _____