Administration of Gadolinium Based MR Contrast Agents to Patients with Kidney Disease

I, (Name of Patient) _____ , have been asked to carefully read all of the information contained in this consent form.

I, understand that I am being given information about Gadolinium Based Magnetic Resonance Contrast Agents (GBMCA or contrast agent), their risks and alternatives to help me make an informed decision whether to voluntarily and freely undergo the procedure. The information in this consent form, in addition to discussions with my physicians and other health care providers and any other written material they may provide, is intended to give me the information I need to make my decision.

My physician(s) has determined that a Magnetic Resonance Imaging (MRI) study is needed to help diagnose a medical condition. Alternative testing for diagnosis may include ultrasound, computerized axial tomography (CT scan) and/or angiography. However, this testing may not be as sensitive as MRI. Additionally, the administration of an iodine-based contrast agent for studies such as CT scanning or conventional angiography might be associated with certain risks, including possible damage, temporary or permanent, to the kidneys, especially in patients with kidney disease.

People who have kidney disease who are given a gadolinium based MR contrast agent may have a very small risk of developing a disease called, Nephrogenic Systemic Fibrosis (NSF). To date this disease has only been found in patients with kidney disease, and the vast majority if not all of those have severe or end stage renal disease. Doctors have been listing people who have NSF in a database (http://www.icnfdr.org). It was recently discovered that almost all people with NSF had severe or end stage kidney disease and had been given one or more gadolinium based magnetic resonance contrast agents a few days or months before getting NSF.

NSF is often associated with thickening and tightening of the skin (usually involving the arms and/or legs but occasionally also the trunk) and scarring. The scarring may involve other parts of the body including the diaphragm, heart, lungs, and muscles. There is no reliable cure, although some reports exist of partial responses to treatment. The disease may rarely continue to get worse and can even cause death.

The United States Food and Drug Administration has approved five gadolinium based magnetic resonance contrast agents. Most of the cases of NSF have to date been reported to have been associated with a prior administration of one of these agents. About 3% - 5% of patients with severe or end stage kidney disease who get this one particular brand (Omniscan) seems to develop NSF. I understand I will not receive this agent.

Doctors think that the risk of NSF with the other four agents is lower, but the risks of developing NSF after having received any of these four gadolinium based MR contrast agents is unclear and may well vary significantly even among these four agents. Studies are ongoing and no one knows the exact risk. The risk seems to increase with the amount of gadolinium based contrast administered. The standard dose administered for the planned MRI study would have been _____ ml. This dose has been lowered in my case to _____ ml. because I have been identified as having either temporary or permanent decreased kidney function and/or may have an increased risk of NSF.

597196

(05/12/11)

CATHOLIC HEALTH INITIATIVES

Franciscan Health System

St. Joseph Medical Center, Tacoma, WA
St. Francis Hospital, Federal Way, WA
St. Clare Hospital, Lakewood, WA
St. Elizabeth Hospital, Enumclaw, WA
St. Anthony Hospital, Gig Harbor, WA

CONSENT FOR ADMINISTRATION
OF GANDOLINIUM BASED MR CONTRAST AGENTS
DIAGNOSTIC IMAGING

Administration of Gadolinium Based MR Contrast Agents to Patients with Kidney Disease

If I am currently receiving hemodialysis I understand hemodialysis will be/has been arranged to occur as soon as possible after the study. My nephrologist will determine whether or not an additional hemodialysis session is needed.

Additional rare risks associated with administration of these gadolinium based MR contrast agents may include:

1. **Allergic reaction.** Large, hive-like swellings in the mouth or throat, confusion, dizziness, head ache, difficulty breathing, lack of breathing or severe allergic reaction may occur in a few patients. If any of these symptoms occur additional medical treatment may be necessary.
2. **Contrast infiltration.** The movement of contrast outside of the vein into other tissues. Treatment generally exists of hot or cold packs and elevation of the extremity. Infiltrations most often resolve over time.

I understand Dr. _____ is available to answer any questions I may have about the information provided in this form.

MY SIGNATURE BELOW ACKNOWLEDGES THAT:

1. **I have read (or had read to me), understand and agree to the statements set forth in this consent form.**
2. **All blanks requiring completion were filled in before I signed.**
3. **No guarantees or assurances concerning the results of the procedure have been made.**
4. **I am signing this consent form voluntarily. I am not signing due to coercion or any other influence.**
5. **Dr. _____ has discussed and explained the reasons and the anticipated benefits for me to receive an Intravenous gadolinium based contrast agent for this procedrue. My physician has discussed available alternative procedures, although not recommended, including non-treatment and the possible consequences of not having this procedure. I have had the opportunity to ask questions and they have been answered to my satisfaction.**
6. **I agree to the administration of gadolinium based contrast agent for the completion of a MRI and/or MRA study.**

Signature of Patient or Person Legally Authorized to Consent for the Patient	**Date**	**Time**
Witness	**Date**	**Time**

CATHOLIC HEALTH INITIATIVES
Franciscan Health System
St. Joseph Medical Center, Tacoma, WA
St. Francis Hospital, Federal Way, WA
St. Clare Hospital, Lakewood, WA
St. Elizabeth Hospital, Enumclaw, WA
St. Anthony Hospital, Gig Harbor, WA

CONSENT FOR ADMINISTRATION
OF GANDOLINIUM BASED MR CONTRAST AGENTS
DIAGNOSTIC IMAGING

597196 (05/12/11)