# Center for Advanced Magnetic Resonance Development (CAMRD) Guidelines:

**Contrast agent usage for research MRI exams performed in CAMRD**

## Background

Contrast media is a category of pharmaceutical agents used to improve medical imaging. Those typically used for MRI have an extremely low rate of incidents. However, like all pharmaceuticals, they are not completely devoid of risk. Safety measures required by the Duke Institutional Review Board (IRB) must be observed, and any laboratory investigations must be obtained prior to the subject's appointment time and be documented in MaestroCare. Subjects must have a signed ICF which includes the risks of any given agent.

Research guidelines for administration of gadolinium-based agents and for pregnancy testing differ from those used in clinical practice. More detailed information regarding Duke IRB policy on gadolinium administration in research can be found at the following link: https://irb.duhs.duke.edu/sites/default/files/2022-04/gadolinium_risk_policy_9-10-2019.pdf

For detailed information regarding Pregnancy Testing, follow this link: https://irb.duhs.duke.edu/sites/default/files/2022-04/ pregnancy_testing_myers_pregnancy_testing_7-2-2019jw-1.pdf

## Guidelines

### Study Team Responsibilities

1. Place MRI with contrast order in MaestroCare (for documentation of contrast agent administration)
2. Place appropriate peripheral IV for administration of the contrast agent
3. Provide required laboratory values to the CAMRD technologist
4. Obtain signed ICF including approved contrast agent administration language

### Laboratory Requirements for Contrast Agents

1. eGFR > 30 mL/min/1.73m$^2$ within 7 days for all subjects unless otherwise specified in the IRB-approved protocol
2. Beta hcg < 5 mIU/mL within 48 hours unless otherwise specified in the IRB-approved protocol

### CAMRD Technologist Responsibilities

1. Verify lab values and possible allergies
2. Calculate contrast dosage
3. Administer and document contrast agent dose and time in MaestroCare

**Injectable Gadolinium-based Agents Administered in CAMRD**

| | | |
|---|---|---|
| • Vueway | **(**Gadopiclenol) | ACR Group II |
| • Gadavist | (Gadobutrol ) | ACR Group II |
| • Multihance | (Gadobenate dimeglumine ) | ACR Group II |
| • Eovist | (Gadoxetate disodium) | ACR Group III |

Intravenous Gadolinium based agents used in CAMRD are classified as Group II or Group III and are considered to have low association with Nephrogenic Systemic Fibrosis (NSF).

**TABLE 1. ACR Manual Classification of Gadolinium-Based agents Relative to Nephrogenic Systemic Fibrosis**

| |
|---|
| **Group I: Agents associated with the greatest number of NSF cases:** |
| Gadodiamide (Omniscan® – GE Healthcare) |
| Gadopentetate dimeglumine (Magnevist® – Bayer HealthCare Pharmaceuticals) |
| Gadoversetamide (OptiMARK® – Guerbet) |
| **Group II: Agents associated with few, if any, unconfounded cases of NSF:** |
| Gadobenate dimeglumine (MultiHance® – Bracco Diagnostics) |
| Gadobutrol (Gadavist® – Bayer HealthCare Pharmaceuticals; Gadovist in many countries) |
| Gadoterate acid (Dotarem® – Guerbet) |
| Gadoteridol (ProHance® – Bracco Diagnostics) |
| **Group III: Agents for which data remains limited regarding NSF risk, but for which few, if any unconfounded cases of NSF have been reported:** |
| Gadoxetate disodium (Eovist – Bayer HealthCare Pharmaceuticals; Primovist in many countries) |

From 2018 ACR Manual on Contrast Media

**Investigative Agents**

All appropriate safety precautions as determined by the Duke IRB must be observed. A member of the study team must be appointed for administration and documentation of any investigative contrast agents.