Section II: Contraindications for MRI

There are several types of contraindications that would prevent a subject from having an MRI scan. Metallic implants and foreign bodies as well as the subject's physical condition will be discussed in this section. All subjects are required to remove any clothing that has metal on it. Gowns are provided for the subject to change into. All **subjects and staff members** must empty their pockets of any loose metallic objects (hair pins, safety pins, coins, keys, ID badges, wallets, credit cards, banking cards, lighters, pocket knives, scissors, stethoscopes, hemostats, etc.) before entering the magnet room.

1. Surgical Implants

There are hundreds of metallic implants that can be surgically placed into a person's body for various reasons. Some of these implants are ferrous and may be attracted to the magnetic field. Some may be electronic in nature, in which case, the magnetic field can interrupt the device's normal operations. Worse, by placing an electronic device in the magnetic field, a current may be induced in the conducting wires of the device which could possibly burn the patient. There are many metallic implants that are non-ferrous and may be compatible for MR such as orthopedic screws, rods, and plates. It is suggested that a waiting period of at least six weeks after surgery is necessary for the tissues around the implant to take hold of it to prevent any potential movement of the implant. Although the six week period is generally observed, in some more emergent instances a subject with a non-ferrous implant may be scanned as soon as a day after the implant is in place. There are also some ferrous implants (e.g., heart valves, venous blood clot filters) that are compatible for MR. Typically the waiting period for these implants is six weeks. The bottom line is that the waiting period decision should be left to a Radiologist who is familiar with the implant and its magnetic properties. To prevent injury to the subject, it is extremely important that the scanning investigator be familiar with the difference between compatible and contraindicated implants and devices.

2. Accidental Metallic Foreign Bodies

Occasionally an investigator may have a subject tell them they have been injured by a piece of metal which punctured their body in some way, shape, or form. Common causes of this type of injury are people being shot with bullets, buckshot, pellets, or BB's. Other frequent causes are people who work with grinding, sanding, or cutting metal frequently are exposed to metal slivers flying off of the metal piece they are working with. These metal slivers often fly into the eyes, hands, or face. People who have been involved in wartime activity may have pieces of shrapnel or other metal fragments in their body. Any of these circumstances must be investigated thoroughly to prevent injury to the subject.

3. Checklist of Tested Implants, Devices, and Metallic Foreign Bodies

Located in the MR Facility is a small handbook entitled ***Reference Manual for*** **Magnetic Resonance Safety 2002 Edition .** This book lists hundreds of surgical implants and metallic foreign bodies which have been tested by leading MR safety authorities in magnetic environments for evidence of deflection and torquing of the metallic objects. This book should be used to investigate any questionable implant or foreign body. Additional safety articles are available in the Research Coordinator's office.

4. Procedure to Clear Metallic Implants and Foreign Bodies

The subject should be asked about their surgical or accident history. In addition to this, the investigator should re-question the subject about their history even if the subject has stated that they have not had any surgery. It is not uncommon for a subject to conceal or forget about a procedure or accident which may have happened long ago. Further questioning the subject and explaining to them the importance of their honesty for their own safety can sometimes provide additional information to the investigator.

If you discover the subject has had a surgical implant or an accident involving metal you must find out the following:

1. What was the procedure? What was the nature of the accident?
2. What kind of implant is it? Name of the manufacturer? What does it do? What is it used for?
3. When was the procedure done? What year?
4. Do you know for sure that it is metal?
5. Who was the doctor/surgeon who performed the procedure? Is he or she still in practice?

6. At what hospital was the procedure performed?

7. If it was an accident, did you have any x-rays done at the time and was the metal removed?

Once you have all of the answers to these questions, proceed with the following:

1. Take the information to the MR research technologist or MR Research Coordinator. They have been educated as to what may or may not be scanned and in many instances will be able to assist you.

2. If they do not know of the implant or think the subject may have to be canceled, the PI and a radiologist must be involved at this time for more information. If the subject doesn't know if the implant is metal, the radiologist may suggest x-rays be done to rule out metal. X-rays may not be performed without the permission of the Principal Investigator and the subject.

3. If the radiologist does not know of the implant, you must contact the surgeon who placed the implant and request a copy of the operating room report which should describe the model and name of the implant. This report will be attached to the subject's screening questionnaire for permanent documentation.

4. The final responsibility of canceling or proceeding with the exam lies with the Principal Investigator who should make an informed decision based on the information provided by the MR Research Facility Staff and radiologists.

5. If the subject is cleared, a written permission signed by the Principal Investigator for the subject to undergo the MR exam must be provided to the MR Research Facility. This permission form will be attached to the subject's screening questionnaire for permanent documentation.

*****IMPORTANT NOTE*****

Any person (subject or staff) who has a history of working with metal as an occupation or hobby should have x-rays of their orbits to rule out metallic foreign body before they enter the magnet room. The only case of a patient being blinded by a metal sliver piercing their optic nerve was a former metal worker who did not know that he had a piece of metal in his eye.[2] Typically if metal workers get a sliver of metal in their eye, it is removed in an emergency room by a physician. However, without x-rays, there is no way of knowing if the entire piece of metal was removed. Usually x-rays will be ordered at the time the metal is taken out. If we can obtain a copy of the report from those x-rays, and the subject has not gotten any more metal in their eyes since the x-rays were taken, then we may use the original x-ray report to clear the subject for the MR exam.

5. Emergency Removal of the Subject from the MRI Scanner

If the investigator has placed a subject in the scanner and upon looking at the first set of images notices a metallic artifact present, the investigator must follow the proper procedure for removing the subject from the scanner and the magnet room.

1. Tell the subject you are going to remove them from the magnet. Instruct them to remain perfectly still and to not sit up at any time.

2. Pull the table out of the scanner very slowly.

3. Move a gurney into the magnet room and place it next to the table.

4. Have the subject slide, without sitting up, onto the gurney.

5. Slowly pull the gurney straight away from the magnet without turning the gurney.

6. Once you reach the doorway slowly turn the gurney and move it out through the doorway.

7. Once the subject is safely outside of the room, they may sit up.

** This procedure should also be used if the subject tells you of a contraindicated metallic implant in their body after they have already been placed in the magnet.

6. Pregnant Subjects

It is the policy of the MR Research Facility not to scan any pregnant subjects for research purposes. In the clinical environment, pregnant patients are only scanned in emergency situations. With this in mind, and realizing that research is not done on an emergency basis, pregnant subjects must wait until after they give birth to participate in a research project.

If a subject believes she may be pregnant, it is up to the Principal Investigator decide if the subject should undergo a pregnancy test. If the PI deems a pregnancy test is necessary, all arrangements and financial responsibility will be taken care of by the PI or their designee.

If the pregnancy test is negative and the subject is to undergo the MR, a copy of the pregnancy test report will be needed by the MR staff to attach to the subject's screening questionnaire for permanent documentation.

7. Contrast Agents used in Subjects who are Breastfeeding

In the case where a research subject is breastfeeding her child, the mother must be informed that her milk must be expressed with a breast pump and thrown away for 48 hours following the injection of gadolinium contrast agent.It is important that she be aware of this in order that she may, ahead of time, store enough milk to feed the child during the 48 hours after the contrast injection.

8. Pregnant Staff

It is the policy of the MRI Research Facility that all pregnant staff members be restricted from the magnet room when radiofrequency pulses are on. Any pregnant ancillary staff member (nurses, coordinators, secretaries) who do not need to be in the magnet room should stay out of the room unless there is an emergency with a subject. Pregnant staff members, such as MRI technologists, who must enter the room on a regular basis should only stay in the room as long as necessary i.e., positioning subjects, emergencies, etc.

9. Radiofrequency and Specific Absorption Rate

MR employs radiofrequency (RF) pulses to disturb the alignment of protons in the nucleus of hydrogen molecules in the body. These RF pulses deposit heat into the tissues of the body. This heat deposition is termed Specific Absorption Rate or SAR. SAR is measured in watts per kilogram and is a function of several variables, including: (1) the type of RF pulse used (90 or 180 degrees); (2) the number of RF pulses in a sequence; (3) the pulse width; (4) the TR; (5) the weight of the patient; and (6) the type of coil used.[3] The FDA has developed guidelines to regulate the amount of deposited heat that are within acceptable limits. Currently all manufacturers of MR equipment are required to submit their pulsing sequences to the FDA for SAR review

Conditions in the examination room

Ambient temperature: 21°C, ±3 °C

Relative Humidity: 50% - 70%

Old Specific Absorption Rates (SAR)

Levels insufficient to produce a core temperature increase in excess of 1°C and localized heating to greater than 38°C in the head, 39°C in the trunk, and 40°C in the extremities.

< 3.2 W/kg averaged over the mass of the head

< 1.5 W/kg whole body average for all subjects

< 3.0 W/kg whole body average for subjects with normal functioning thermoregulatory systems

< 8.0 W/kg spatial peak in any one gram of tissue

** It should be noted that subjects with thermoregulatory illnesses such as fever, or diseases in which the patient is unable to sweat, may be compromised by heat deposition in MR. Extreme care should be taken with these subjects to keep them cool during the exam. You should investigate choosing sequences that do not result in high amounts of heat deposition. Also, the eyes are particularly susceptible to heat deposition.

Current Specific Absorption Rates (SAR)

There are three specific absorption rate limits:

Whole-Body SAR Limits

- *Normal mode* - Whole-body SAR = 1.5 W/kg, averaged over any 15-minute period, and SAR = 7.5 W/kg over any 10-minute period. This level is expected to be tolerated by all subjects, regardless of health status.
- *Controlled level 1* - SAR = 4 W/kg, over any 15-minute period, and SAR = 20 W/kg, over any 10-second period. This level of SAR should be tolerated by most healthy individuals; however, because tolerance to raised body temperature is highly variable, medical supervision should be provided.
- *Controlled Level 2* - Any SAR exceeding the maximum for level 1.

Head SAR Limits

- *Normal mode* - Head SAR = 3 W/kg, averaged over any 10-minute period, and SAR = 15 W/kg, over any 10-second period.
- *Controlled Level 2* - Any SAR exceeding the maximum for normal mode.

Local SAR Limits

Local SAR, or hot-spot SAR, is the value of the SAR averaged over the most exposed 1 gram of tissue.

- *Normal mode* - Local SAR = 8 W/kg, averaged over any 5-minute period, and SAR = 40 W/kg, over any 10-second period, anywhere in the head or torso. In addition, the local SAR = 12 W/kg, averaged over any 5-minute period, and SAR = 60 W/kg, over any 10-second period, anywhere in the extremities.
- *Controlled level 2* - Any SAR exceeding the maximum for normal mode.

Slew Rates and Stimulation

On April 21, 1995, CDRH released a draft for public comment which contained revisions to the original MRDD Guidance relating to operation at dB/dt levels beyond the levels of concern listed in that document. A public meeting of the Radiological Devices Panel was held on September 11, 1995 to discuss the proposed revisions, and a final version was issued on October 11, 1995

The original MRDD Guidance had established a level of concern for dB/dt at 20 T/sec for pulse duration over 120 microseconds. As an alternative, a manufacturer could demonstrate that the rate of change of the gradient field was not sufficient to cause peripheral nerve stimulation by an adequate margin of safety. The development of echo planar and similar fast imaging techniques, and the clinical benefits which they provide, caused a re-evaluation of this policy. Evidence was presented that although peripheral nerve stimulation could potentially startle a patient and cause motion which could interfere with image acquisition, the sensation is not harmful. However, painful stimulation should be avoided.

The Guidance Update for dB/dt recommended that manufacturers of equipment which exceeds 20 T/sec conduct volunteer studies to determine if peripheral nerve stimulation is possible with their device. If so, the device should incorporate a warning to the operator below the level at which stimulation begins to occur. Acknowledgment of the warning by the operator should then be necessary to proceed with the scan. Instructions for use should advise the operator to inform the patient when nerve stimulation is possible, and describe the nature of the sensation to the patient. Equipment intended for routine clinical use should be limited so that painful stimulation is not induced.