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RADIOLOGY POLICY AND PROCEDURE

SUBJECT: MRI SAFETY

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Purpose: To ensure safety in the MRI environment

Magnetic resonance imaging (MRI) requires a unique set of high-level safety precautions in order to safely administer this essential diagnostic modality. This policy delineates protocol for the following safety areas:

1. Static magnetic field hazards related to projectiles
2. Medical device hazards
3. Time-varying magnetic field hazards including tissue heating and acoustic noise
4. Pregnancy-related hazards
5. MRI contrast material-related hazards
6. Patient comfort, psychological care and claustrophobia
7. Cryogen hazards

The Medical Director for MRI Services has overall authority and responsibility for safety policy at ALL sites where MRI is performed.

Section I: Personnel Designations, Screening and Training

- Personnel are placed in one of four categories in order to clarify who will have access to the MRI site and who has decision making responsibility in ambiguous cases.
- Every person entering the MRI scanner room must be screened to determine personal risk for entering the MR environment. The method of screening will vary as described below.
- MRI safety training will vary with each individual's level of security clearance. All training will be through online learning modules with online examinations and must be renewed annually. The following are the personnel categories and screening/training requirements:
- **Non-MR personnel**
 1. **Includes:**
 - i. Patients and research subjects
 - ii. Radiology staff not working with MRI
 - iii. General hospital staff including physicians, nurses, PAs, anesthesia technologists
 - iv. Housekeeping and maintenance staff
 - v. Visitors
 - vi. Family/escorts of patients
 - vii. Vendor representatives
 - viii. Inspectors and surveyors (e.g., JCAHO and DOH)

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2. **Screening** (using the MRI Safety Screening Form, see Appendix D)
 - i. **MUST** be screened each time they enter Zone IV.
 - ii. **MUST** be screened by at least one Level II MR personnel face-to-face with written documentation of screening
 - iii. All screening forms are scanned and stored in PACS, associated with the relevant exam.
 3. **Training**
 - i. Not required
- **Level I MR personnel:** All staff working in the MR environment with access to controlled areas
 1. **Includes**
 - i. ALL Radiology attending physicians, nurses and PAs.
 - ii. ALL MRI staff
 - Reception, transport, housekeeping associates who work in MRI
 2. **Screening**
 - i. Radiology Associates: ALL are screened at time of employment. Documentation is kept in the associate's personnel file.
 - Any subsequent injury or medical procedure must be reported by the associate immediately because this may affect their personal safety when entering MRI.
 - ii. Non-Radiology Associates: Screening is performed by the associate's department and kept in the associate's personnel file.
 - Any subsequent injury or medical procedure must be reported by the associate immediately because this may affect their personal safety when entering MRI.
 3. **Training:** Completion of the current online Basic MRI Safety training module annually including successful completion of the online examination.
 - **Level II MR personnel:**
 1. **Includes:** MR users requiring additional training regarding time varying magnetic fields, cable and other equipment management, contrast agents, etc.
 - i. ALL Radiology attending physicians who protocol or supervise MRI exams
 - ii. ALL Radiology in-training physicians
 - iii. ALL Anesthesiology and other staff who administer sedation or anesthesia

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- in MRI.
 - iv. MR technologists
 - v. MR supervisors
 - vi. MR nurses & PAs
 - 2. **Screening:** As for Level I Personnel
 - 3. **Training:** Completion of the current online Advanced MRI Safety training module including successful completion of the online examinations. Each associate must also complete a Specialized MRI Safety training module corresponding to their specific clinical role. New employees will be required to complete training before they can work in the MR environment.
- **Level III MR personnel:** These individuals have decision-making power in ambiguous cases.
 1. **Includes:** The Medical Director for MRI Services, the Clinical MRI physicist, and specifically designated attending radiologists.
 2. **Screening:** As for Level II
 3. **Training:** Radiologists and the MRI physicist with extensive knowledge of and experience with MRI and those who have completed further training under the Medical Director for MRI Services.

Section II: MRI Site Access Restrictions

- I. The MRI site is classified into four regions:

Zone I Outside of the MRI site.

1. Unrestricted access.

Zone II The unsecured, interface area between the publicly accessible, uncontrolled Zone I and the strictly controlled Zones III and IV.

1. Patients are greeted, registered, and screened in Zone II, but access to Zone II is not restricted..

Zone III Secure areas immediately adjacent to the MRI scanner room. “If you can walk over and touch the door to the scanner room, you are within Zone III”

1. Only Level I or higher MRI personnel may enter unaccompanied.
2. Secured by card access system.
3. Only Level I or higher personnel may hold cards coded to open these doors.
4. Doors to have automatic closing and locking devices.

Zone IV The MRI scanner room.

1. Secured by card access system with “glass-break” emergency release connected to the MMC Security Department

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2. Only Level II or higher MRI personnel may enter unaccompanied.
3. Doors to have automatic closing and locking devices.

II. Signs

1. Warning signs are posted in English and Spanish at all entrances to Zones III, and IV.
2. A red, lighted sign, with power failure backup, is posted at all entrances to Zone IV. It reads “Magnet On” and is always illuminated.
3. All areas with magnetic field stronger than 5 gauss are signed.
4. All outpatient facilities post an emergency contact phone number for first responders to contact before they enter the building during an after-hours emergency.

Section III: Implants

Any special circumstance not covered below must be evaluated and approved in writing by a level III MR physician prior to allowing the patient or other individual to enter Zone IV.

Unsafe Implants, which MAY NOT ENTER ZONE IV

1. Unapproved Pacemakers/Defibrillators – **MAY NOT ENTER ZONE IV.**
2. MR Conditional Pacemakers: See Appendix C.
3. Spinal stimulators, neurostimulators – **MAY NOT ENTER ZONE IV.**
4. Cochlear implants – **MAY NOT ENTER ZONE IV.** Infusion pumps – must consult a Level II MR physician.
5. Aneurysm Clips: See Appendix B.

Conditionally Safe Implants: Some implants that contain ferromagnetic components may be safe following a period during which biointegration of the implant occurs. A six-week interval should be allowed to pass following implantation of such a device prior to entering Zone III.

Devices that may generally be considered safe following this six-week interval include, but are not necessarily limited to:

1. MR Conditional Vena Cava Filters
2. MR Conditional Prosthetic Heart Valves
3. MR Conditional Vascular and Other Stents
4. Penile Implants that are not already classified as MR Safe

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Safe Implants:

1. Manufacturer assurance: A patient implanted with any medical device warranted by the manufacturer, with FDA approval, to be SAFE for MRI may be scanned EVEN IMMEDIATELY FOLLOWING IMPLANTATION. Confirmation of the safety of the device MUST be confirmed by consulting the manufacturer (package insert, website, telephone support or other means) or Level II or III MR personnel knowledgeable about the specific device.
2. Orthopedic Hardware: Safe immediately after implantation, even if partially ferromagnetic. Precautions to prevent thermal injury should be taken as described below.
3. Skin Staples: Safe, even within the immediate postoperative period. Precautions to prevent thermal injury should be taken as described below.

Section IV: Equipment

1. The MRI scanner will be maintained to ensure its optimal imaging performance and safety by the radiological team including the radiological technologists, the MRI or site manager, the MRI engineers, and the MRI physicist. A Quality Control Program will be in place, which exceeds standards set forth by the American College of Radiology.
2. ONLY MR safe equipment or MR Conditional equipment (provided that all conditions are met), may be brought into the MR scanner room (Zone IV). If a ferromagnetic device must be used within Zone IV, it must be installed or secured in place by qualified personnel as designated by the Medical Director for MRI Services. The installation of such a device must be completed before any patient or research subject is allowed to enter the room. No such unsecured device may be introduced into Zone IV while a patient or research subject is within Zone IV.
3. Medical device (e.g., ventilator, implant) safety must be based on manufacturer's FDA approved usage, not on local testing of devices. Only in exceptional circumstances would a medical device be tested on site.
4. Testing:
 - a. Implants: NO on-site testing for MR compatibility is permitted. Only the manufacturer's statement of safety will be relied upon.
 - b. Equipment: A strong hand magnet (>0.1 Tesla) can be used to test new equipment. Testing of equipment with a hand magnet must ONLY be performed by personnel appropriately trained and credentialed to know how to perform testing and how to interpret the results of testing. These personnel include Level

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III MR personnel. The hand magnet itself is a significant safety hazard, which could lead to equipment damage, serious injury or death if it were inadvertently brought near the magnetic field. Therefore, the magnet is kept secured and is not available in the MRI suite (Zones III and IV).

c. If a device/equipment leaves MRI suite for repair/service, it must be tested/verified again for MR safety and labeled appropriately before it is introduced in the MR suite.

d. If the MR safety of an object is unclear or in dispute, Level III MR personnel must make the determination as to safety. If there is any doubt as to safety, err on the side of caution.

5. Signage – Within Zones III and IV, ALL equipment, regardless of size, must be labeled “MR Safe”, “MR Unsafe” or “MR Conditional” using ASTM approved symbols. Equipment that is permanently fixed in place is exempt from this requirement.

6. Use of equipment in Zone III and Zone IV.

a. MR safe equipment – MRI safe models of basic medical equipment can be used and kept in MRI controlled Zones (III and IV) (for example, stethoscope, sphygmomanometer, scissors, ambu bag and mask, physiologic monitoring equipment).

b. Only MR Conditional fire extinguishers may be brought into and kept within Zones III and IV.

c. MR Conditional equipment – All MRI conditional equipment located in Zone III and Zone IV that is not permanently fixed in place must be listed in a log, which specifies the device and the associated conditions for safe use. This log will be available as an online electronic file within the department MRI safety webpage.

d. Ventilators, anesthesia machines, physiological monitors, power injectors and infusion pumps:

Only devices manufacturer-certified and FDA-approved for MRI may be used and only within the conditions specified by the manufacturer. Certain devices may be certified with specific field strength (“gauss line”) restrictions. Such devices may only be used after (1) the safe use zone has been measured by the MRI physicist, (2) the floor path of acceptable field strength is permanently marked on the floor and (3) the Medical Director has approved the safe use plan. Such field-strength limited devices must always be tethered to a permanently installed wall anchor at a location outside of the marked path when in the MR scanner room. The purpose of this tether is to maintain the device in a safe position, not to restrain the device

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if drawn by the magnetic field. The location and device must be marked using standard signage.

e. Patient transport equipment:

Only MR safe stretchers, wheelchairs, cribs, etc. are to be used within Zones III and IV. Patients are to be transferred to an MR safe transport device OUTSIDE of the secure entrance to Zone III. Transport personnel are to remove the non-MR safe transport equipment.

f. Oxygen/Gas cylinders are prohibited within Zones III and IV. Patients requiring oxygen therapy must be connected to wall oxygen and all cylinders must be left OUTSIDE Zone III. The only exception allowed is for emergency backup tanks for anesthesia machines. These tanks must be tested as a part of monthly inspections and labeled MRI Safe.

Inspections – Each site must conduct monthly inspections to include the following:

- a. Check for labeling of all equipment in Zones III and IV.
- b. Removal of prohibited, unnecessary or unsafe equipment from Zones III and IV.
- c. Check for potential fire hazards in Zone IV, and remove all unnecessary power cords, wires, linens, foam pads, and devices out of the MRI scanner room.
- d. Testing of anesthesia equipment including carts and tanks.
- e. Testing of the card access security system, including emergency door releases and the response time from hospital security as applicable.
- f. Audit of 10 MRI Screening Forms for completeness including technologist certification and signature.
- g. Audit of 10 clinical MRI exams for protocol adherence.
- h. Critical assessment for cleanliness throughout the MRI suite. This must include inspection of the MRI equipment/electronics rooms. Patient positioning devices should be assessed for wear and cleanliness and discarded if found imperfect.

7. Projectile Incident Response Plan

Extreme caution must be exercised when attempting to remove a ferromagnetic object from the magnetic field, in order to minimize the possibility of second injuries or further equipment damage. See **“Removal of ferromagnetic objects that enter the room”** below. When in doubt consult the MR Physicist and

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Medical Director.

If the projectile is small (e.g., pens, paperclips, key-rings) and there is certainly no risk of human injury or equipment damage, the object may be removed by Level II MR personnel. However, all medical equipment involved in an incident has to be assessed before it can be used for patient care.

a. When a large object is stuck against the magnet, follow the procedure as in **“Removal of ferromagnetic objects that enter the room”**.

b. Quench the magnet only when the object held against the MRI scanner poses an imminent threat to of injury or death, such as if a patient or staff member is pinned between the object and the magnet. Note that quench is a potentially dangerous procedure and essential precautions must be taken before and after quenching the magnet. See: **“Quench and Cryogen Handling”**.

c. Any incident or near-miss incident involving a projectile MUST be reported using the Departmental Occurrence Reporting System and the Midas reporting system.

Removal of ferromagnetic objects that enter the room:

In the event that a ferromagnetic object is brought into Zone IV and is stuck against the scanner, the Medical Director for MRI Services, the MRI physicist, or an on-site Level III MR Personnel must be notified immediately. MRI service technicians should be called to remove the device. Imprudent attempts to remove a device may result in severe injury or death.

Quench the magnet only when the object held against the MRI scanner poses an imminent threat to of injury or death, such as if a patient or staff member is pinned between the object and the magnet. Note that quench is a potentially dangerous procedure and essential precautions must be taken before and after quenching the magnet. See: **“Quench and Cryogen Handling”**.

Section V: Gradient and Radiofrequency Hazards

Background: Two types of time-varying magnetic fields are employed in MR imaging: Gradient magnetic fields (GMF) and radiofrequency magnetic fields (RF). Each has specific hazards and, therefore requires specific safety precautions. The primary hazard of GMF is the induction of current (1) in the patient leading to nerve stimulation or (2) in a conductor leading to electrical current within tissue. The predominant hazard of RF is (3) tissue heating leading to discomfort or burns. Additionally, both GMF and RF produce potentially hazardous levels of acoustic noise.

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1. **Nerve or muscle stimulation:**
 - a. Clinical MRI equipment performs within FDA specified safety limitations that generally preclude the induction of sufficient current within tissue to cause direct nerve or muscle stimulation. Some high duty cycle applications, such as EPI and SSFSE may nonetheless cause nerve or muscle stimulation, especially at higher static magnetic field (e.g., 3.0 Tesla). This stimulation is not hazardous, but may be uncomfortable. If a patient complains of twitching or pain during a high duty cycle acquisition (especially echo-planar imaging (EPI)), the scan should be stopped immediately. The remainder of the examination may proceed, provided that the patient is comfortable. The incident should be reported using the Departmental MRI incident reporting system.
 - b. Research pulse sequences (not FDA approved) may pose a higher risk of nerve or muscle stimulation. Prior to commencing any such imaging pulse sequence, the subject must be instructed to report any sensation suggestive of nerve/muscle stimulation such as twitching, tingling or electric shocks. If these symptoms are reported by the patient the scan must be stopped and the incident should be reported using the Departmental MRI incident reporting system.

2. **Induction of current in metallic implants:** High duty cycle MR imaging pulse sequences can induce current within metallic foreign bodies. Long metallic objects such as wires, pacemaker leads (even if no longer in use and not attached to a pulse generator), brain electrodes, etc. can conduct significant current when subjected to a high level of dB/dt. The presence of a looped conductor increases the likelihood and magnitude of induced current.
Precautions should be taken in patients with **electrodes implanted in sensitive tissues** including, but not limited to heart, brain and spinal cord.
Do not image with high dB/dt pulse sequences (especially EPI) unless there is a compelling medical necessity that will impact treatment AND a level III MR physician has made a careful review and judgment of risk benefit. The assessment and determination must be documented in a PACS note.

3. **Tissue Heating:** Clinical MRI equipment performs within FDA limits for tissue heating. Any research sequence must be ascertained to meet the FDA guidelines as determined by a qualified physicist approved by the Medical Director for MRI Services.

Preventing Burns:

Pulse sequences may deposit power more efficiently in metallic objects within or outside

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the patient, leading to serious burns. The following precautions should be taken:

- a. All metal must be removed from the patient. This includes, but is not limited to jewelry, transdermal drug delivery patches and external orthopedic braces or prostheses.

The patient is required to remove **ALL** personal clothing and change into clothing provided by the MRI facility. Note that fabrics, particularly in undergarments, may contain unsuspected metallic components, which can lead to serious

- c. **Non-removable conductive items:** Tattoos and permanent makeup as well as implanted metallic items, such as orthopedic hardware, may undergo significant heating.

- i. The patient must be informed of this possibility and asked to report any suggestive symptoms. The technologist must communicate verbally with the patient throughout the examination to ascertain symptoms of heating.

- ii. Dry cold packs may be applied to any such superficial, non-removable conductive material, such as tattoos or subcutaneous implants (e.g., infusion pumps), to function as a heat sink and minimize tissue heating.

- d. All unnecessary coils, cables, wires, and monitoring leads must be removed from the MR scanner prior to scanning. Any necessary external wires or cables including the cables connecting the RF coil to the scanner should be carefully managed with attention to the following:

- i. The wires/cables must be **insulated** from the patient using sheets, sponges or other means. The wires/cables must not touch the patient's skin.

- ii. The wires/cables must NOT form any loops.

- iii. The wires/cables must be placed as far from the inner walls of the MRI bore as possible.

- iv. The patient should be positioned so that they are not in contact with the inner walls of the MRI bore.

- e. More extensive caution and use of cold packs should be employed in unconscious or poorly responsive patients including young children. It is advisable to avoid MRI altogether in such patients to minimize risk of burns.

- f. The staff positioning the patient in the MRI scanner should ensure that no large loops are formed with the patient's tissue. Arms and legs should not be crossed.

- g. The technologist **MUST** communicate with the patient between scans and monitor patient feedback during scans. The scan should be stopped immediately if the patient complains of discomfort due to heating, tingling or electric-like shocks. Correct the situation before proceeding.

Burn Care:

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If the patient complains about severe heating or burning during MRI, the following procedures should be taken:

- a. The scan **MUST** be stopped immediately.
- b. Apply cold compresses or ice to affected or reddened areas.
- c. For severe burns, contact the medical team (for inpatients) or take the patient to the emergency room (outpatients) for further examination and treatment.
- d. The incident must be reported to the site manager/supervisor by the MRI technologist with detailed patient information and specific imaging parameters including the coil(s) used, how they were connected and specified in software. The incident must be reviewed by the Medical Director for MRI Services and the MRI physicist to determine and address the cause of the injury.
- e. All MRI burn incidents **MUST** be reported using the Departmental Occurrence Reporting System. Severe incidents **MUST** also be reported with the MIDAS System in compliance with MMC policy.

4. **Acoustic noise:**

- a. All patients must be provided hearing protection (earplugs and/or headphones).
- b. All non-patients **MUST USE** hearing protection if they are in the scanner room during imaging.
- c. All research subjects **MUST USE** hearing protection during all scans.
- d. The scanner room door must remain closed during imaging.

Section VI: Pregnancy hazards

1. Patients: While MRI is not known to have any adverse effect on the fetus, comprehensive controlled long-term studies have not been conducted. As a result, we endeavor to avoid MR imaging of a pregnant women if at all feasible. Women of childbearing age will be assumed to be pregnant **unless they** are within 7 days of a menstrual period, have undergone surgical sterilization or attest that they consistently use birth control with every sexual intercourse.

Precautions:

- a. Postpone the examination until after pregnancy, if at all possible.
- b. Determine if the results of MRI will alter management *while the patient is still pregnant*.
- c. Determine if the diagnostic information required could be obtained from another imaging modality that does not employ ionizing radiation.
- d. If the above criteria have been satisfied, a Level II MR Physician must confirm medical necessity.

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2. MRI Staff: MRI staff may work during pregnancy even within the MR scanner room (Zone IV). However, any worker who *may be* pregnant must NOT remain within the room during scanning.
3. Others: May not enter the MR scanner room (Zone IV) if they *may be* pregnant as described above.

Section VII: Contrast Agent Usage

Refer to Policy M14-Administration of Gadolinium Contrast in MRI

Section VIII: Emergency Situations

1. Medical Emergencies: In the event of a medical emergency involving a patient in the MR scanner room (Zone IV), the patient IS REMOVED FROM THE ROOM as BLS is initiated. Further resuscitation may continue in Zone III. Access restriction to Zone IV **MUST** be maintained during resuscitation and other emergent situations for the protection of the patient and all involved.

NO UNSAFE EQUIPMENT IS TO BE BROUGHT INTO THE MR SCANNER ROOM – INCLUDING CRASH CARTS, DEFIBRILLATORS, LARYNGOSCOPES, ETC.

2. Fire/Police Emergencies: In the event of a fire within the MR Scanner room (Zone IV) or a large fire in the vicinity of the magnet, leading to excessively high room temperature, immediate quench of the magnet should be undertaken to avoid magnet explosion. Only MR Conditional fire extinguishers may be used within the MR suite. If fire or police personnel need to enter the MR scanner room, MR personnel who have completed MRI Emergency Training must be consulted regarding quenching the magnet. The MRI technologist and/or radiological staff-on-duty must ensure that non-MR personnel including police, firefighters, and security are restricted from entering the MRI scan room with their equipment (axes, air canisters, weapons, etc.) during emergencies, until it can be confirmed that the magnet is not at field, as there may still be considerable static magnetic field present despite a quench or partial quench of the magnet.

NO EQUIPMENT, INCLUDING FIREARMS, AXES, AIR TANKS, HOSES, ETC., MAY BE BROUGHT INTO THE MR SCANNER ROOM WHILE THE MAGNET IS AT FIELD.

3. Cryogen Handling and Quench Situations

1. Only trained service personnel may handle cryogens. During cryogen fills,

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- Zone IV and Zone III must be evacuated of all, but trained service personnel
2. Each MR scanner room will be equipped with an audible oxygen alarm. If the alarm sounds, the patient and all others must be evacuated from Zone III and IV and the MR service team, hospital security, MR Physicist and Medical Director for MRI Services must be notified immediately.
 3. In the event of a spontaneous quench, the MR scanner room (Zone IV) and adjoining rooms (Zone III and Zone II) must be evacuated immediately. All doors and windows in the MRI facility should be opened. The MR service team, MR Physicist, hospital security and Office of the Medical Director for MRI Services must be notified immediately.

If cryogenics leak into the room (may appear as clouds of smoke):

1. The patient should be evacuated from the room as rapidly as is safe, to prevent asphyxiation.
2. Staff entering the room to evacuate the patient should be careful to maintain orientation in the room; keep the exit door in sight.
3. Cryogen condensate (on the floor and horizontal surfaces) is extremely cold and may cause thermal injury (frostbite) on contact.
4. If pressure within the room prevents opening the door:
 - a. The window to the control room should be broken
 - b. Ventilate adjacent areas as they may also rapidly fill with cryogen vapor
5. Secure the MR suite and maintain restricted access after evacuation.
Communicate with first responders regarding the safety status of the magnet and the MRI suite. Evaluation of the status by the MR Service Engineer or the MRI Physicist may be needed.

Appendix A: Precautions: External Potentially Ferromagnetic Objects

1. Personnel must remove all potentially ferromagnetic objects prior to entering Zone IV unless they are known to be non-ferromagnetic.
 - a. Gold, sterling silver, copper, brass and aluminum are non-ferromagnetic.
 - b. Any alloy or plated object should be considered ferromagnetic.
 - c. Stainless steel should not be assumed to be non-ferromagnetic and must be tested.
2. ANYONE wishing to enter the MR scanner room must comply with this policy. This includes, but is not limited to: Patients, technologists, nurses, physicians, maintenance staff and housekeeping staff.
3. ALL individuals who will be subjected to MR scanning must remove ALL external potentially conductive or ferromagnetic objects including ALL clothing and change into

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- site-provided gowns. Note that these individuals must remove all metal (e.g. jewelry), even if not ferromagnetic, in order to prevent thermal injury.
4. The following is a PARTIAL list of items that may be dangerous:
Watches, jewelry, pagers, cell phones, pens (even if only the spring or point is metal), paperclips, staples, body piercings [if removable], contraceptive diaphragms, metallic drug delivery patches, cosmetics containing metallic particles [such as eye make-up], and clothing items that may contain metallic fasteners, hooks, zippers, loose metallic components, or metallic fabric, logos or threads.
 5. All ambulatory patients must be screened by FerrAlert solo (typically available in Zone II at the entrance to Zone III) to detect any remaining ferromagnetic materials **AFTER** changing and **BEFORE** entering Zone IV. Any objects detected must be removed, and the patient screened again until no such materials can be detected.
 6. Hypodermic needles may NOT be brought into Zone IV. IV catheters should be placed in Zone II or Zone III and only plastic injection ports should be used in Zone IV.

Appendix B: Aneurysm Clips

1. Placing a patient who has been implanted with a ferromagnetic aneurysm clip into the strong magnetic field of an MR imager may lead to devastating injury and death due to intracranial hemorrhage. Due to the potential for severe injury, the non-ferromagnetic nature of the clip must be definitely established and documented before a patient implanted with such a clip can be placed in the magnetic field of the MRI scanner.
2. Given the demands of proper testing and the potential for severe injury, the following policy is to be adhered to at Montefiore Medical Center and its affiliated sites.
 - a. The manufacturer's FDA approved statement is the **ONLY** criterion for determining if an aneurysm clip is MR Conditional. **NOTE** that aneurysm clips are approved as MR Conditional and **NOT** MR Safe.
 - b. Clips are only considered safe for imaging at field strength equal to or less than the manufacturer's recommendation as well as in compliance with any additional conditions of the approval.
 - c. The exact type of clip implanted in the patient must be documented in writing. Acceptable documentation must reference the exact manufacturer and model of clip (the lot or serial number of an individual clip is generally NOT required) and may include:
 - i. Letter from the implanting surgeon or referring physician
 - ii. Operative note
 - iii. Implant ID card containing the patient's name
 - d. A copy of the written documentation must be scanned and stored in PACS.

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- e. Patients who have undergone MRI without adverse outcome are NOT to be considered safe for MRI without documentation as above.
- f. If images from a prior MRI scan are available, the artifact created by the clip may be assessed to determine if the patient may safely undergo MRI. This determination must be made by a Level III MR Physician and be documented in PACS.

Appendix C: MRI Conditional Pacemakers

1. Pacemakers and MRI

- a. Pacemakers in MRI can lead to patient fatality.
 - o Likely cause is triggering of pacemaker during the repolarization phase (R on T) leading to a fatal arrhythmia.
- b. NO pacemakers are MRI SAFE (NOT: )
- c. The FDA has approved 2 devices manufactured by Medtronic for use in MRI. These are termed “SureScan[®]” systems and are MR **CONDITIONAL** ().
 - o Revo[®] MR
 - o Advisa[®] MR
 - o **Mandatory conditions discussed below**
- d. **ALL** other pacemakers and all ICDs should be treated as MRI UNSAFE ()

2. MRI Conditional Pacemakers: What are the conditions/restrictions?

- a. Only approved under SPECIFIC CONDITIONS:
 - i. Complete SureScan[®] system
Approved IPG
 - 1. MUST verify on CXR (~).
 - 2. Confirm by checking medical record AND the patient’s implant card.
 - Approved leads
 - 1. Verify on CXR (~).
 - 2. NOTE: some approved leads do NOT bear the ~ symbol and cannot be confirmed by CXR.
 - 3. Confirm by checking medical record AND implant card
- b. Device must be programmed to a SureScan[®] mode PRIOR TO ENTERING Zone III.
- c. Continuous heart rate monitoring during the scan is mandatory.

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- i. A qualified cardiology clinician must continuously monitor the patient in person.
 - ii. This individual must be qualified to rescue the patient.
 - iii. Crash cart with defibrillator must be available in Zone III.
3. **Scheduling MRI for patients with MRI Conditional Pacemakers**
 - a. Handled on a case-by-case basis.
 - b. Requests for scheduling of MRI conditional pacemaker patients for MRI will be referred to the MRI Manager who will coordinate the exam requirements.
 - i. Order entry systems (POE and EMR) will still block orders for patients with pacemakers.
 - ii. The MMC Call Center will not schedule MRI for patients with pacemakers of any type.
 - c. Required for scheduling:
 - i. Completed “Cardiology Clearance Form”.
 - ii. Initial completion of the “MRI Conditional Pacemaker Checklist”
 1. Section 1 should be completed.
 2. Remainder will be completed on the day of the procedure.
 - iii. The exam will be scheduled on a 1.5 Tesla MRI scanner at the Moses Campus, in coordination with the Cardiology Clinician who will program the pacemaker and monitor the patient.

Appendix D: Screening Form

ALL segments of the screening form must be completed and signed by the patient or their guardian. Minors who are under 18 years old may not sign the screening form and it must be completed under the supervision of a parent or knowledgeable guardian.

LEVEL 1 SCREENING:

The screening form must be reviewed by Level I or II MR personal to identify any positive responses to the screening questions. Any of these “yes” responses must be communicated to the MR technologist. The screener must sign in the Level I screening box on the screening form.

LEVEL 2 SCREENING – TO BE PERFORMED ONLY BY THE MR TECHNOLOGIST:

1. The technologist must review the screening form in the presence of the patient and verbally confirm the patient’s responses to the screening questions. The technologist then marks their determination as to the safety of the patient for MRI on the screening form.
2. If further clarification is required from the Radiologist, the technologist must complete

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the applicable section.

3. A legible, printed technologist's name and signature must be completed; initials are NOT sufficient.
4. If the patient can communicate, but is unable to write, the technologist may fill in the answers and document in writing on the form how/why they did so.
5. The screening form must be completed as described above prior to the patient entering Zone IV.
6. The technologist who scans the patient (as indicated in RIS) is the person who will be held responsible for any lapse in policy adherence and its consequences.
7. If a family member or any person other than the patient or physician supplies patient information, documentation occurs in the form of that person's signature; relationship to the patient is also indicated on the form.
8. Every completed Safety Screening Form must be scanned into PACS and thereby becomes part of the medical record.
9. Prior to placing any patient into the MR scanner, the patient's prior Radiology exams AND reports MUST be reviewed in PACS and RIS by the technologist to detect pacemakers, intracranial aneurysm clips, metallic foreign bodies or other potential hazards. The MR technologist must visually review the most recent prior chest radiograph, if any is available on PACS.

Appendix E: Patient Comfort and Psychological Care

General Precautions:

Patients' experiences in the MRI environment may be discomfort, stress and anxiety provoking for many reasons. These may include concern over an unknown diagnosis, claustrophobia, long scan times, physical discomfort due to the relatively hard table top, confining coils and immobilization devices and cold. Statistics indicate that about 10% and up to 20% of the general population is claustrophobic to some degree.

Patient comfort will be assured before, during and after the MRI examination by inquiring whether the patient is comfortable or at ease. Blankets, pillows, padding and cushions should be employed to ensure and patient ease and comfort. The MRI bore ventilation fan level should be optimized based on patient feedback. In addition, music or video should be provided to reduce the patient's stress level. Patients should never be kept in the scanner while technical concerns are evaluated.

Every patient must be given the emergency call bell button and shown how to use it if they need

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to contact the technologist urgently.

Patients who indicate that they are uncomfortable or claustrophobic:

1. Patient comfort **MUST** always guide the procedure. The patient must never be asked to remain in the magnet when experiencing discomfort or distress.
2. Patients who express concern about claustrophobia should be informed of options at scanning sites and scanner types as well as sedation/anesthesia, which require their physician's recommendation..
3. Claustrophobic patients should be offered additional care during MRI to improve their comfort and ease. These techniques may include the use of feet first positioning to keep the head and face out of the bore, prone positioning, mirrors or prism glasses, blindfold or "eye pillow", audio and video entertainment, and accompaniment by a family member during the MR procedure.
4. The MRI Operator should terminate the scan if the patient experiences any symptoms of claustrophobia, significant anxiety or panic attack. These may include diaphoresis, tachycardia, perceived dyspnea or "suffocation", chest tightness and faintness or lightheadedness.
5. The patient's concern must be taken seriously and at face value. If a patient asks to stop the exam, leave the scanner, or uses the emergency call bell, they must be immediately assessed and removed if they h.

Appendix F: Special patient cases

[E.g., patients unable to comply with screening and without accompanying personnel able to provide relevant information]

Postpone the examination if medically acceptable. If not,

1. Head, neck, chest and abdominal radiography and/or CT and/or review of similar recent studies is **REQUIRED** and must be reviewed by a Level II or III MR physician **BEFORE** the scan may proceed. This review is **to exclude potentially lethal metallic foreign bodies (e.g., aneurysm clips) and medical devices (e.g. pacemakers).**
2. **Review of prior radiographic/CT studies (in PACS) is required prior to each MRI exam, to detect interval placement of a potentially dangerous implant.**
3. Level II or III MR personnel should physically examine (e.g., to detect a pacemaker) the patient to determine if additional precautions or radiographic studies are required.

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4. The indication for the MR study and the outcome of the radiographic examinations must be documented in a PACS note.

Approved: E. Stephen Amis, Jr., M.D., Chairman
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Qi Peng, Ph.D., MRI Physicist