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Magnetic Resonance Safety Policy of UCSF

1. MRI Safety Committee

- The University of California, San Francisco Medical Center (UCSF) will maintain MR Safety Polices and Procedures, which are to be established, maintained, and routinely reviewed by the University's MRI Safety Committee.
- The policies and procedures shall be reviewed and updated regularly and in all cases at least annually. Introduction of any significant changes in MRI system hardware or software that will significantly change the safety parameters in the MR imaging environment (e.g. adding faster/stronger gradient capabilities, higher RF duty cycle sequences), will be reviewed by the MRSC prior to implementation. In this review process, national and international standards and recommendations should be taken into consideration prior to establishing our own local guidelines, policies, and procedures.
- It is the responsibility of the MRI Safety Committee to ensure that the MRI safety guidelines are established and maintained on a current basis, and is appropriate for the various MR systems operated by the University. It is the responsibility of the UCSF administration to ensure that the policies and procedures that are established by the MRI Safety Committee are implemented and adhered to at all time by all UCSF personnel.
- Procedures should be in place to ensure that all adverse MRI safety events, that occur in the MR site is reported to the Chair of the MRI Safety Committee in written form (incident report) within a 24 hour period. All incidents and adverse effects will be discussed at a quarterly meeting of the MRI Safety Committee. A serious adverse event will result in an immediate session of the MRI Safety Committee.
- The MRI Safety Committee is responsible for the development of a MRI Safety training program for the hospital staff personnel.

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2. Potential Hazards and Risks in a MRI Environment

- Magnetic field risk: The static magnetic field of the MRI system is exceptionally strong, A 1.5 T magnet generates a magnetic that is approximately 21,000 greater than the earth's natural field. In such an environment ferromagnetic metal objects can become airborne as projectiles. Small objects such as paper clips and hairpins have a terminal velocity of 40mph when pulled into a 1.5 T magnet and therefore pose a serious risk to the patient and anyone else in the scan room. The force with which projectiles are pulled toward a magnetic field is proportional to the mass of the object and distance from the magnet. Even surgical tools such as hemostats, scissors and clamps, although made of a material known as surgical stainless steel, are strongly attracted to the main magnetic field. Oxygen tanks, gurneys, floor buffing machines, and construction tools are highly magnetic and should never be brought into the scan room. However there are non-ferrous oxygen tanks and gurneys available, which are MRI compatible. Sand bags must also be inspected since some are filled, not with sand, but with steel shot which is highly magnetic. Consumer products such as pagers, cell phones, cameras and analog watches may be damaged by the magnetic field. Pacemakers may be reprogrammed or turned off by the magnetic field. The magnet field erases credit cards with magnetic strips.
  Patients with ferrous intra-cranial vascular clips may be at risk due to the possible movement of the clip. See Contraindications for MRI in Section 12.
- Radio-frequency (RF) field risk: The radio-frequency field may induce currents in wires that are adjacent or on the patient, causing skin burns. It may induce currents in intracardiac leads, resulting in inadvertent cardiac pacing. Prolonged imaging may cause the patient's core body temperature to rise. In practice, significant patient heating is only encountered in infants.
- Cryogen risk: During a planned or accidental shutdown of the magnetic field, quench, the liquid Helium in the magnet turns into gas and may escape into the scan room displacing the oxygen in the room leading to asphyxia.
- Biological effects due to the static magnetic field: For the static magnetic fields currently used in MRI up to 2 Tesla, there are no known biological effects. The majority of studies show no effects on cell growth and

morphology. Data accumulated by the National Institute for Occupational Safety, the World Health Organization, and the US State Department show no increased risk for leukemia or other cancer.
Some reversible biological effects have been observed on human subjects exposed to 2.0 T and above. These effects include fatigue, headaches, hypotension and irritability.

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3. MRI Environment. Static magnetic field issues: Access restriction

- Magnetic field distribution (Fringe Field): The stray magnetic field outside the bore of the magnet is known as the fringe field and this is a 3 dimensional field measured in Gauss. MRI systems are shielded to confine the fringe field within the scan room. Magnetic fields, which are less than 5 Gauss, are inconsequential to MRI safety. In most systems the 5 Gauss field is confine within the scan room and therefore its fringe field does not affect any area external to the magnet room.
  The 30 Gauss field demarcates the point where projectile hazards become significant and only MRI compatible equipment can safely enter this region.
  Each MRI system has its own unique fringe field due to varying magnetic design, shielding characteristics, and field inhomogeniaty, and therefore each site must be supplied with a schematic, which clearly defines the fringe field of the magnet. The schematic must demarcate the 30 Gauss line and 5 Gauss line.
- This section summarizes the different zones of a UCSF MR suite and points out specific safety issues, which are of greatest concern.
  The MRI site is to be divided into 2 zones:
  - **Unrestricted Zone:** Uncontrolled, and freely accessible to the general public. This area is typically outside of the MRI environment itself, and is the area through which patients, health care personnel, and other employees of the MRI site access the MRI environment.
  - **Restricted Zone:** This area is the region in which free access by unscreened personnel and/or equipment can result in serious injury or death as a result of interactions between the individuals/equipment and the MRI scanner's particular environment, including but not limited to its static and time varying magnetic fields. The 5 Gauss field designates where the **Restricted Zone** begins. The distance of the 5 Gauss field from the iso-center of the magnet will vary, depending on the characteristics of the magnet. The Restricted Zone should be clearly marked and demarcated as being potentially hazardous, and physically restricted from general public access. All access to the Restricted Zone is to be strictly controlled and supervised by MRI personnel. The magnet room will be locked when unattended.
    As part of the **Restricted Zone** site restriction and equipment testing and clearing responsibilities, all MRI sites must have access to a hand magnet for screening purposes (>=1000 gauss). This will enable the staff to test external and even some superficial internal devices or implants for the presence of grossly detectable ferromagnetic attractive force.
    Only MR compatible equipment approved by the MR Safety Committee may be brought into the Restricted Zone.
- Signage: Standardized signs visualizing a magnetic field and the restriction of ferromagnetic objects should be placed at the entrance of the **Unrestricted and Restricted Zones**. These signs should be large, direct and eye catching.

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4. Screening: Patient/Non-MRI Personnel/MRI Personnel

- Patient screening: Patients entering an MRI suite for a diagnostic exam are screened for contraindications such as pacemakers, metal foreign bodies in the eyes, cranial aneurysm clips, etc. A standard hospital approved MRI screening form is to be filled out prior to a patient entering the Restricted Zone. It will be the responsibility of the MRI technologist to review the MRI screening form prior to allowing a patient into the Restricted Zone. All contraindications are to be brought to the attention of the MRI radiologist in-charge of the case.
  All Non-MRI Personnel (e.g., patients, volunteers, varied site employees and professionals) with implanted cardiac pacemakers, auto-defibrillators, diaphragmatic pacemakers, and/or other electromechanically activated devices on whose function the Non-MR Personnel is dependent should be precluded from the Restricted Zone.
  Patients with history foreign bodies in the eyes will require a negative CT scan of the orbits prior to being admitted to the Restricted Zone.
  Patients with a cranial aneurysm clip will require a written report from the referring physician stating the name of the clip and the date of placement prior to being admitted to the Restricted Zone.
  Individuals undergoing an MRI procedure must remove all readily removable metallic personal belongings and devices on or in them (e.g., watches, jewelry, body piercing if removable, contraceptive diaphragms), metallic drug delivery patches, and clothing items which may contain, metallic fasteners, hooks, zippers, loose metallic components, metallic threads, etc. It is therefore advisable to require that the patient/research subject wear a site-supplied gown.

- MRI Personnel screening: All MRI Personnel are to undergo an MRI screening process as part of their employment interview process to ensure their own safety in the MRI environment. A signed hospital approved screening form will be kept on file for every MRI Personnel. For their own protection and for the protection of the ancillary staff all MRI Personnel must immediately report to their supervisor any trauma, procedure, or surgery that they experience
  Which a ferromagnetic metallic object/device that may have been introduced within or on them. This will permit an appropriate screening to be performed upon the employee to determine the safety of permitting those MRI Personnel into the environment.
- Ancillary Staff screening: Screening procedure is the same as Patient screening.

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5. Staff Training Program

- MR-Personnel training: It is key that all personnel working in the
  MR environment be fully briefed on MR safety. The program will include the following:
  - A comprehensive information packet on MR safety.
  - A video on MR safety.
  - A written competency test on MR safety, which is to be done annually as part of the Radiology Department Safety review.
- All new medical center employees are to attend the New Employee Orientation program provided by the medical center, which includes MR safety as part of the program. Ancillary Staff training: Most accidents that occur in a MR static magnetic field environment are due to a lack of knowledge of MR safety by the ancillary staff of the hospital (e.g. physicians, nurses, housekeeping, anesthesia technologist, etc.). It is vital that all hospital employees that may come in contact with the magnetic field be informed about MR safety in the following manner:
- Introduction to MR safety during the New Employee orientation course sponsored by the hospital. This is to include written information and watching a 15-minute video on MR safety.
- Participate in the annual hospital safety review course sponsored by the hospital and completion of the written safety review exam.

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6. Cardiac, Respiratory Arrest or other medical emergency

As in any medical facility, the MR suite should be equipped with emergency medical supplies on a crash cart. These emergency supplies should be located in the **Unrestricted Zone**. Many of these supplies can be dangerous in the **Restricted Zone**. For this reason, in any medical emergency, all patients should be removed from the scan room to a predetermined magnetically safe location in the **Unrestricted Zone** before resuscitation begins. **Restricted Zone access must be maintained during resuscitations and other emergent situations**. See MRI Code Blue Protocol.

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7. Magnet Quench

Quenching is the process whereby there is a sudden loss of absolute zero of temperature in the magnet coils, so that they cease to be super conducting and become resistive, thus eliminating the magnetic field. This results in helium escaping from the cryogen bath extremely rapidly. It may happen accidentally or can be manually instigated in the case of an emergency. Quenching may cause severe and irreparable damage to the super conducting coils, and so a manual quench should only be performed in extreme cases when the physician and service engineer are involved in the decision to quench. A fire in the scan room may also be a cause to quench the magnet, so the fire fighting personnel can safely enter the room (see MRI Code Red Protocol). All systems should have helium-venting equipment, which removes the helium to the outside environment in the event of a quench. However if this fails, helium will vent into the room and replace the oxygen. For this reason all scan rooms should contain an oxygen monitor that sounds an alarm if the oxygen falls below a certain level. Under these circumstances immediate evacuation of the patient and personnel is necessary. It is noted that if the scan room door is closed when a quench occurs and helium escapes into the scan room, the depletion of oxygen causes a critical increase in pressure in the room compared with the control area. This produces high pressure in the scan room, which may prevent opening of the door. If this should happen, the glass partition between the scan and control rooms should be broken to release the pressure. The scan room door can then be opened as usual and the patient evacuated. In such a case the patient should be immediately evacuated and evaluated for asphyxia, hypothermia and ruptured eardrums.

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8. Acoustic Noise

As current is passed through the gradient coils during image acquisition, a significant amount of acoustic noise is created. Although these levels are anticipated to be well below the OSHA standards whereby a hearing loss

prevention program must be started (80 dB over 8 hours or half the exposure time for each additional 5 dB exposure), it can cause some reversible and irreversible effects, These effects include communication interference, patient annoyance, transient hearing loss and in patients who are susceptible to hearing impairment, permanent hearing loss. It is recommended that all patients are provided with earplugs or head phones.

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9. Radio frequency and gradient fields related issues (thermal)

In contrast to the main magnetic field, RF and gradients are only present during scanning. RF energy (64 MHz- between AM and FM radio) is exchanged with the patient in order to create MR images. A relatively powerful amplifier (25kW) generates this energy and software controls limit the specific absorption rate in the patient. The effects of RF absorption are the heating of the tissue and the patient's ability to dissipate excess heat. This can be expressed in terms of SAR, which is the FDA limit for RF exposure and is primarily set to avoid warming of the patient. The recommended SAR level for imaging in the US is 0.4W/kg (whole body), 3.2W/Kg (head) and 8 W/kg (small volume). The RF field is focused within the bore of the magnet and is negligible external to it.

While software limits RF exposure to safe levels, looped conductors (e.g. wires) within the bore of the magnet can focus these RF fields, producing elevated energy deposition. These concerns are greatest on high field scanners and have been known to cause substantial burns. Accordingly, looped conductors within the bore must be avoided at all cost.

Care should be taken to ensure that the patient's tissue do not directly come into contact with the inner bore of the magnet during the MR imaging process. Pads and other such insulating devices are provided for this purpose. It is also important that the patient's own tissues do not form large conductive loops. Therefore, care should be taken to ensure that the patient's arms and legs not be positioned in such a way as to form a large caliber loop within the bore. For this reason it is preferable to instruct patients not to cross their arms or legs in the MR scanner.

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10. Pregnant Patients

As yet, there are no known biological effects of MRI on fetuses. However, there are a number of mechanisms that could potentially cause adverse effects as a result of the interaction of electromagnetic fields with developing fetuses. Cells undergoing division, which occurs during the first trimester of pregnancy are more susceptible to these effects.

The FDA states "If the information to be gained by MR would have required more invasive testing, MRI is acceptable. In light of the high risk potential for pregnant patients in general, delay of the MR exam until after the first trimester is preferable. The American College of Gynecology and Obstetrics recommends that pregnant patients should be reviewed on a case-to-case basis, and the risk-benefit ratio needs to be made by the physicians involved.

It should be noted that numerous fetuses have undergone MRI without any abnormalities at birth, or after 4 years of childhood development. Gadolinium enhancement is at present best avoided when examining a pregnant patient. For more info, see Patient Pregnancies and MRI.

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11. Pregnant Employees

MR is too new to make an informed decision on magnetic safety for pregnant employee. Each person must make their own decision to stay in MR or if possible rotate back to the radiology department.

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12. Contraindications for MRI

All persons coming in contact with the magnetic field should be appropriately screened for contraindications. A useful reference for determining MR compatibility is Shellock's Pocket Guide to MR Procedures and Metallic Objects. An online reference is www.mrisafety.com.

The following devices are absolutely contraindicated for MR imaging because they are magnetically, electrically, mechanically activated or affected:

- Pacemakers
- Neurostimulators
- Cochlear implants
- Bone Growth stimulators
- Implant able drug-infusion pumps

- Implant able cardiac defibrillators
- Implant able pediatric sternum device
- Metallic foreign body in the eye

- Pacemakers for MRI. Even field strengths as low as 5 Gauss are sufficient to cause deflection, programming changes, and closure of the reed switch, which converts a pacemaker to an asynchronous mode. In addition, patients who have had their pacemaker removed may have pacer wires left within the body, which could act as an antenna, and (by induced currents) cause cardiac fibrillation.
- Neurostimulators: The are two types of neurostimulatorss:
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    - Passive receivers: neurostimulators that receive RF energy that is magnetically coupled from an external device by means of a coil placed over the implanted device.
    - Hermetically encased pulsed generators: neurostimulators that contain a battery and are programmed by an external device to produce the various stimulus parameters.
- Because of the specific design and intended function of neurostimulators, the electromagnetic fields used for MR procedures may produce problems with the operation of these devices. Malfunction of a neurostimulator that results from exposure to the electromagnetic fields of an MR system may cause discomfort or pain to the patient.
- Cochlear implants: Some types of cochlear implants employ a relatively strong cobalt samarium magnet used in conjunction with an external magnet to align and retain a radio frequency transmitter coil. Other types of cochlear implants are electronically activated. Consequently, MR procedures are strictly contraindicated in patients with these types of implants because of the possibility of injuring the patient and/or damaging or altering the function of the cochlear implants.
- Bone growth stimulators: These devices usually have an external electronic component that attaches to electrodes implanted in areas of fractured bones and are used to enhance and facilitate the rate of bone healing. Similar to neurostimulators, patients with bone growth stimulators should not undergo MR procedures until data are available to support that there are no hazards associated with the presence of these devices in patients during the operation of MR systems. Currently there is no neurostimulator or bone growth stimulator that has received from the FDA the designation of being "MR-compatible".
- Implant able drug infusion pump: A drug infusion pump is used for automatic delivery of antineoplastic agents, morphine, or narcotics. The infusion pump has ferromagnetic components, a magnetic switch, and is programmed by telemetry. The presence of these features in a device is usually considered reasons for the device being designated as contraindicated for patients undergoing MR procedures.
- Implant able cardiac defibrillators: Implant able cardiac defibrillators are used to treat patients with sustained ventricular arrhythmias that are refractory to antiarrhythmic pharmacological treatment. These devices use an external magnet to test the battery charger and to activate and deactivate the system. Deactivation of an implant able cardiac defibrillator is accomplished by holding a magnet over the device for approximately 30 seconds. Obviously, magnetic fields of MR systems would have a similar effect on implant able cardiac defibrillators and, therefore, patients with these devices should avoid exposure to MR systems. In addition, because implant able cardiac defibrillators also have electrodes that are placed in the myocardium, patients should not undergo MR procedures because of burns and other risk related to the presence of these conductive materials.
- There is a new implanted device system utilized for pediatric patients that is contraindicated for MRI. Dr Michael Harrison, pediatric surgery UCSF, has informed the MRI Safety Committee that they are currently running a phase 2 research procedure, The Magnetic Mini-Mover procedure. This research procedure utilizes the following products, “Magnimplant” and “Magnatract”in a combined system to correct for pectus excavatum or sunken chest deformity, in pediatric patients. As part of the system “Magnimplant” is an internal magnet that is surgically placed behind the sternum, and “Magnatract” is an external brace with a magnet implanted. The devices combine to exert a defined magnetic force to the chest wall.
  Per Dr. Harrison: “The device is made for us by Texcel and stays in 18-30 months.” “It is implanted on the sternum through a small subxiphoid incision which will always be visible, so this would be the best marker in an unconscious patient.” “The patients are teen and preteen and they and their parents have verbal and written warnings about MRI. In addition the patients wear (or at least are given) a medi alert bracelet saying no MRI.”
  This device system is totally contraindicated for MRI at any field strength.
  We should specifically ask the parents of pediatric patients if this magnet device has been implanted in the sternum of their child. It seems that currently they are doing it on older kids, but they plan to do it in patients as young as 1 year old in the future. It also seems that these devices may remain implanted for years, although studies are still ongoing to determine the best clinical usage. For more information concerning the research procedure, utilize the following links: http://pedsurg.ucsf.edu/conditions--treatments/magnetic-mini-mover-procedure.aspx#a3, or http://clinicaltrials.gov/ct2/show/NCT00466206, or contact the principle investigator, Dr. Michael Harrison, Professor of Surgery, Pediatrics.
- Intra-ocular ferrous foreign bodies: Intra-ocular metal foreign bodies are a cause of major concern in MR

safety. It is not uncommon for patients who have worked with sheet metal to have metal fragments or slivers located in and around the eye. Since the magnetic field exerts a force on ferromagnetic objects, a metal fragment in the eye could move or be displaced and cause injury to eye or surrounding tissue.

The following are relative contraindications for MR imaging:

- Intra-cranial vascular clips
- Penile implants
- Shrapnel
- Halo
- Coronary stents
- Pregnancy

- Intra-cranial vascular clips: Some intra-cranial aneurysm clips are absolute contraindications in MR imaging. The surgical management of intra-cranial aneurysms and arteriovenous malformations by the application of aneurysm clips is a well-established procedure. The presence of an aneurysm clip in a patient referred for a MR procedure represents a situation that requires the utmost consideration because of the associated risks.
  Certain types of intra-cranial aneurysm clips (e.g., those made from martensitic stainless steels such as 17-7PH or 405 stainless steel) are prone to torque in a MR produced magnetic field. The displacement of these clips may damage the vessel, resulting in hemorrhage, and or death. Intra-cranial clips made of a material known as titanium are now commonly used, and have proved safe for MR.
  To minimize the possibility of inadvertently imaging a patient with a magnetically active metallic implant, implanting physicians must provide patients with information about the type and identity of their particular implants, and suggest, where appropriate, that the patients carry an alert card or wear a medical alert bracelet, or necklace identifying them as having such an implant. In addition, physicians who order MR procedures must carefully screen patients and inform the MR imaging facility of any metallic implants the patient may have and provide written documentation stating the name and model number of the clips.
- Penile implants: Some penile implants evaluated for ferromagnetic qualities had substantial deflection forces measured when exposed to a 1.5 Tesla magnetic field. Although it is unlikely that a penile implant would severely injure a patient undergoing an MR procedure because of the manner in which it is used, it would undoubtedly be uncomfortable. For this reason, subjecting a patient with one of these implants to an MR procedure is inadvisable.
- Shrapnel: Most pellets and bullets tested for MR compatibility are composed of no ferromagnetic materials. Ammunition that proved to be ferromagnetic tended to be manufactured in foreign countries and or used for military applications. Because pellets, bullets, and shrapnel may be contaminated with ferromagnetic materials, the risk versus benefit of performing an MR procedure in a patient should be carefully considered as well as whether or not the metallic object is located near a vital anatomic structure.
- Halo: Halo vests pose several risk factors which include deflection and subsequent dislodging of the halo, heating due to RF absorption, electrical current induction within the halo rings, electrical arcing and severe art factual consequences which could render the imaging acquisition useless. Non-ferrous and non-conductive halo vests, which are MR compatible, are commercially available.
- Coronary stents within 6 weeks of implantation: Various types of intra-vascular stents have been evaluated for safety with MR systems. Several of these stents have demonstrated magnetic field interactions associated with exposures to MR systems. Fortunately, these particular devices typically become incorporated securely into the vessel wall within 6 weeks after their introduction.
- Pregnancy: See Pregnant Patients and Pregnant employees in section 10 and section 11 respectively.

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