UNIVERSITY
OF MIAMI
DEPARTMENT of PSYCHOLOGY

SAFETY MANUAL

University of Miami Department of Psychology
MRI Facility

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I. CONTACT INFORMATION FOR SAFETY PERSONNEL

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Scanner Room 305-284-5223

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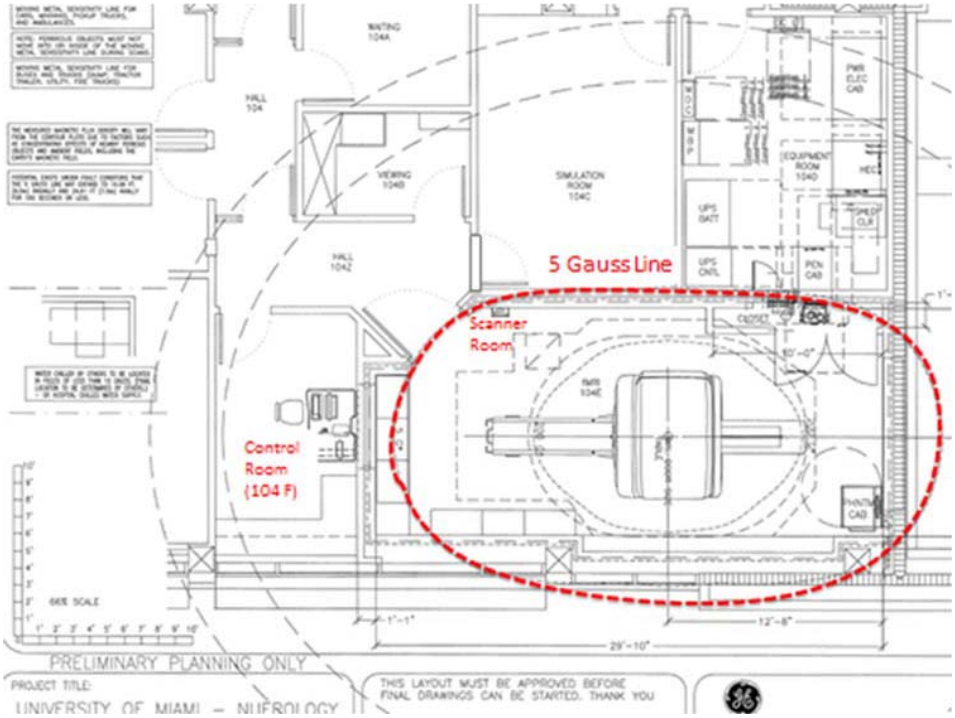
II. DESCRIPTION AND DIAGRAM OF THE MRI FACILITY

During MR scanning the subject is placed in a strong magnetic field. The magnetic field is most commonly generated by a large superconducting magnet. The magnetic field strength, measured in Tesla and Gauss, of whole- body MR magnets can be as high as 8T (1 Tesla = 10,000 Gauss). In comparison, the strength of the earth's magnetic field is approximately 0.5 G. Our facility has a 3T scanner.

A high magnetic field environment exists not only within the bore of the magnet but also around the magnet. The field around the magnet, which is referred to as the fringe (stray) magnetic field, decreases with increasing distance from the center of the magnet. If the magnet is unshielded, the fringe fields of 5-15 G may be present outside the scan room walls. Our facility has a shielded system, containing the magnetic field to the scan room.

It should be noted that the magnetic field is always present (i.e., magnets are always ON). Presence of high static magnetic fields call for extreme caution when working around MR magnets and special precaution are needed to ensure safety.

Figure 1. Diagram of the MR Suite with magnetic field lines. (The 5 Gauss line is indicated in red). This line specifies the perimeter around the MR scanner where the static magnetic field is 5 Gauss or higher. Field strength of 5 Gauss and below is considered "safe" for the general public. Electronic devices and ferromagnetic objects are strictly prohibited inside the 5 Gauss line.



The MRI suite houses a 3T MRI scanner; therefore, the ground floor has several zones that correspond to the safety levels associated with the 3T magnet. Entrance to the different zones is controlled to maintain a secure environment for research participants and staff.

Figure 2. Diagram of the fMRI suite and zone designations.

Zone I is freely accessible by individuals working in the building. No special screening is required to be in Zone I.

Zone II is designated for pre-screening. Zone II includes two separate areas. One area is intended for simulation of the scanning procedures via mock scanner (Room 104C). The second area is intended for research participants reporting for research scans and consists of a waiting area, dressing room and restroom. Zone II is accessed from the reception/waiting area and is controlled by card reader access. Access is granted to personnel after completing the necessary safety training. All individuals participating in a research scan must complete a metal screening form and sign a pregnancy release form in Zone II before undergoing an MR scan.

Zone III includes the control room (104F), a viewing room (104B) and the equipment room (104D). This zone is accessed from Zone II through card reader access. Only key personnel (MR technologist, trained research staff, and the research participant) should have access to this area. Research participants must complete the metal screen, confirm that they are not pregnant and remove all metal from their person prior to entering this zone. In the event that the research participant is a minor, a parent may accompany the child to Zone III but must complete the same procedures (metal screen, etc.). Research staff must complete a metal screen annually during safety training and notify the Facility of any changes prior to entering this area.

Zone IV is the scan room (104E). This zone is accessed through a locked door from Zone III. Only key personnel should enter this room, and this door should remain closed and locked unless

in use. If not already, all metal must be removed from anyone entering this room. No equipment may enter this room unless it is inspected by the safety/technical committee and has an approval sticker. Only the MRI technologist and Principal Investigator that have undergone safety training can have independent access to Zone IV.

No metal objects should be brought by participants, their guardians, or any other visitors into Zones III or IV. Lockers are provided to remove any metal items (e.g., paper clips, bobby pins, USB drives, jewelry, cell phones, credit cards, etc.). A metal wand may be used to confirm any of these items are not brought into the other areas. If an emergency occurs that requires medical attention, individuals should be moved to this area (Zone II) so that medical equipment is not brought into Zones III and IV.

Cards with magnetically encoded strips (e.g., Cane cards, ATM cards, credit cards) will lose all encoded information if brought into the magnetic field. Wallets, briefcases, card holders, etc. should not be brought into Zone III or Zone IV. The facility will not be responsible for replacement of any damaged cards.

III. GENERAL SAFETY CONSIDERATIONS FOR MRI SCANNING

This facility's General Electric MR750 3.0 Tesla MRI scanner has been approved by the Food and Drug Administration (FDA) for human and animal use. It will be used solely for research purposes that will involve human subjects, as well as MRI phantoms (containers filled with gelatinous materials or chemicals).

A. GENERAL SAFETY PROCEDURES IN THE MRI FACILITY

1. All research subjects must be attended at all times while present in the MRI suite.
2. No human research will be performed within the MRI facility without prior IRB approval.
3. All research subjects (or legally authorized representative) must sign an IRB-approved informed consent form before entering the magnet room.
4. All research subjects must be evaluated by the principal investigator, or designee, as to their physical and mental status before entering the MRI suite.
5. All individuals, research subjects, accompanying parents and staff, must undergo screening for metallic objects, using an established questionnaire to determine whether it is safe to enter the magnet room. Those individuals with critically implanted magnetic objects (i.e., aneurysm clips, pacemakers etc.) will not be allowed in the room. All individuals must complete screening forms the day of the scan regardless of previous participation in clinical scans.
6. All research subjects must complete a pregnancy release form before each MRI scan. If there is a question regarding status, subjects will not be scanned. *The exam will be cancelled until a time when the subject can be sure she is not pregnant.*
7. When the MRI scan is in progress, subjects will be given a signaling device (the emergency squeeze ball*)* so that he or she can alert the MRI operator in case of an emergency or discomfort.
8. All subjects will remain in view of the technical personnel while the MRI scan is in progress.
9. When scanning a human subject, another person must be in the control room in addition to the operator.
10. Before scanning a human subject, check the lines of verbal communication with the subject from the workstation.
11. No animals will be scanned at the facility.
12. In case of an emergency, in addition to calling 911, a contact sheet with faculty members to contact will be posted in the Control Room.

B. MRI-SPECIFIC RISKS

There are several risks associated with MRI scanning.

Static Magnetic Fields
In a high magnetic field environment, the attractive forces exerted on ferromagnetic material represents a major potential health hazard. Ferromagnetic structures implanted in the body may experience sufficient force or torque in the scan room to cause movement or dislodgment that could severely injure the subject. Examples of such foreign bodies include certain types of intracranial aneurysm clips, shrapnel, intraorbital metallic structures, insulin pumps, prosthetic limbs, cochlear implants, pacemakers, cardiac or neural defibrillators and other metallic objects on the subjectThe high magnetic field environment may also adversely affect the integrity of magnetically sensitive equipment in or on the subjects. The most common item in this category is the cardiac pacemaker; however, there are other implanted medical devices that may be harmful. Subjects with these devices should not be scanned and should be physically restricted to areas where the magnetic field is less than 5 Gauss.

All subjects should be thoroughly screened for all MR contraindications before taking them into the scan rooms.

Another category of concern is the sudden attraction of ferromagnetic objects into the magnet ('projectile effect'). Individuals could be severely injured and/or equipment could be damaged if hit by objects flying into the magnet. Life threatening situations can occur if a person is pinned against the magnet by a large ferromagnetic object. Wheelchairs, stretchers or ferrous oxygen bottles should not be taken into the scanner room under any circumstances. The scanner table must be brought out of the room for all non-ambulatory wheelchair or stretcher patients and in case of an emergency. Small metal objects (e.g., paper clips, hair pins and coins) should not be brought into the magnet room. These items can damage the equipment and/or have a large effect on the field homogeneity. In order to avoid these situations, **all non-standard equipment (e.g., video projectors, button boxes, IV pumps, etc) must be cleared by the Safety Committee before they can be taken into the scan room**. **All individuals must remove all metallic objects (e.g., jewelry, watches, keys, retainers, glasses, hearing aids, hair accessories) on them before entering the scan room.**

If unsure of the ferromagnetic properties of an object, have the MRI technologist check it with the hand held magnet. ONLY non-ferrous objects may be brought into the scan room once approved.

For some patients, rapid head movement while in the magnetic field may cause dizziness, vertigo, or a metallic taste in their mouth.

<u>Ensuring Safety from Static Magnetic Field Risks</u>
The minimization of risks associated with the static magnetic field of 3.0 Tesla is mainly related to incidental risks (see below). These risks are the same as in other commercially available clinical systems, and like other clinical MRI centers, our facility will incorporate a complete range of procedures, including:

1. Assuring the security of the restricted access area. Entrance doors to the MRI suite will be kept closed at all times. Access to the MRI suite will be tightly controlled, allowing access for only personnel and research subjects who have legitimate reason to be there. Doors to the MRI suite will be securely locked.
2. Entry-ways to the MRI suite will be labeled with clear visible signs warning of the presence of the magnetic field and the exclusion from entry by individuals with implanted metal objects such as prostheses, pins, clips, IUD's, pacemakers, etc.
3. The MRI operator will conduct careful screening of potential subjects before they enter the magnet room (See Appendix).
4. To minimize the potential for dizziness or a metallic taste, it is recommended that the patient remain still while in the region of high static magnetic field.

Switching magnetic field gradients
Peripheral Nerve Stimulation
Changes in the magnetic field (dB/dt) during gradient switching can result in nerve stimulation due to the currents induced in the body. Average peripheral nerve stimulation threshold is ~60 T/s. The time-varying magnetic fields used in MRI can, in some instances, induce stimulation of peripheral nerves, thereby producing sensations such as 'twitching' or 'tingling' during fast imaging sequences such as echo planar and spiral scans. In very rare instances, this nerve stimulation can be painful. Nerve stimulation is particularly likely when subjects are physically positioned in a way that increases the likelihood of inducing stimulation, such as with hands clasped or arms/legs folded. It should be noted that the parameter of interest here, dB/dt (the rate of change in the magnetic field per unit time), is not a function of the strength of the static magnetic field, so evaluating risk in a 3T MRI scanner involves the same considerations as evaluating other MRI systems operating at lower magnetic field strengths (i.e., the same issues apply to all the commercially available, FDA approved scanning systems). Thus, it is the *gradient system only* that needs to be evaluated to determine the risk of producing nerve stimulation.

FDAGuidelines: The FDA Guidance of 1995 was developed specifically to consider the fact that many clinical systems were capable of exceeding levels of dB/dt that could produce nerve stimulation. It was originally considered that a warning level should be implemented to guard against peripheral nerve stimulation, but the FDA finally concluded that: *'... this warning level is not considered critical since there are no harmful effects associated with mild peripheral nerve stimulation'*. The current guidelines therefore include monitoring procedures to help avoid painful peripheral nerve stimulation, and without specific dB/dt limitations.

The gradients used in our 3.0 Tesla MRI system will typically be operated at levels below those considered to be negligible according to FDA guidelines. Our system, like most commercially available, FDA-approved systems, does have the capacity to exceed this level, but it will include the same safeguards that are included in other FDA-approved clinical systems. Furthermore, policies and procedures will be implemented according to FDA guidelines to avoid the possibility of painful peripheral nerve stimulation. Therefore, in all circumstances the system will be operated in a way that poses non-significant risk to the participant.

Peripheral nerve stimulation can be minimized by advising the subject to avoid touching hands together or crossing their legs, using R/L frequency direction in echo planar scans and changing to a low dB/dt scan.

Ensuring Safety from Peripheral Nerve Stimulation

1. All consent forms for studies that might induce peripheral nerve stimulation will provide this information.
2. If the built-in stimulation monitor is bypassed by a user sequence, record of dB/dt value will also be included with the imaging data to help in an analysis of levels of peripheral nerve stimulation possibly perceived by subjects.

3. If the built-in stimulation monitor is bypassed by a user sequence, detailed calculations of the changes in magnetic field over time of which the gradient system is capable will be calculated, and conservative values will be selected as limits that will be used to determine when special additional monitoring is indicated. In these cases, monitoring procedures recommended by the FDA will be used.
4. The gradient switching times and strengths will be monitored together with the routine assessment of all electrical components of the system.
5. All MR operators will receive special training to prevent peripheral nerve stimulation.
6. Before any scanning procedure that might stimulate peripheral nerves, an operator will:
    - Inform the subject that peripheral nerve stimulation may occur
    - Describe the nature of the sensation to the subject
    - Instruct subjects not to clasp their hands, since this may create a conductive loop which will increase the possibility of stimulation
    - Maintain constant verbal contact with the subject
    - Instruct subjects to inform the MR operator if they experience discomfort or pain
    - Terminate the scan if the subject complains of discomfort or pain
    - Complete a report of any incidents involving severe discomfort or pain, including a description of the associated circumstances (imaging parameters, dB/dt value, level of pain, etc.), and submit this report immediately both to the IRB and to the MRI Safety Committee

Acoustic Noise

Vibrations induced by alterations of gradient coil currents (in the static magnetic field) can be heard as the banging noise during scanning. Noise produced during fast scan techniques (e.g., echo planar, spiral, fast-gradient-echo) can be uncomfortably loud. The noise level increases with the field strength.

FDA Guidelines: "The acoustic noise levels associated with the device must be shown to be below the level of concern established by pertinent Federal Regulatory or other recognized standards setting organizations. If the acoustic noise is not below the level of concern, the sponsor must recommend steps to reduce or alleviate the noise perceived by the patient." Current FDA guidelines follow the regulations of the International Electrotechnical Commission (IEC) Standard 601-2-33, which stipulate that for MR equipment used in medicine, hearing protection is required when the system can produce acoustic sound levels above 99 dBA and that the protection should be able to reduce noise levels to below 99 dBA.

The FDA has approved systems for which noise levels have been quantified, ranging up to 105 dB RMS for scanners operating at field strengths of 1.5 Tesla. It is important to note that the static magnetic field strength is only one factor, and not necessarily the most important one, in determining acoustic noise. Among the factors listed above, the design and construction of the gradient coils plays a major role in the noise level that MRI scanning produces. Therefore, noise levels are not necessarily greater when scanning at 3.0 T compared with 1.5 T field strengths. It is nevertheless possible that, in some circumstances, our system could produce noise levels higher than 99 dB, as do many clinical systems operating at lower field strengths.

Summary of Risks: The acoustic noise levels perceived by human subjects when undergoing MRI examination in our 3.0 Tesla magnet constitutes a non-significant risk. Specifically, our system will not be operated in a way that will present more noise to human subjects than is recommended by the FDA.

Ensuring Safety From Acoustic Noise: As suggested by the FDA, we will take steps to reduce or alleviate the noise levels experienced by subjects in this protocol. This will be accomplished by one of two methods:

1. Use of disposable earplugs
2. Use of acoustically shielded headsets

Use of hearing protection is MANDATORY for all subjects.

Tissue Heating

MRI scanning induces some heating of body tissues. The specific absorption rate (SAR) that determines heating is the amount of radiofrequency (RF) energy deposited (typically by a coil or "helmet"-like apparatus placed over the subject's head) per unit volume of tissue per unit time. Therefore, the subject's correct weigh should be entered so the SAR limits can be calculated properly and prevents excessive RF exposure when using manufacturer supplied pulse sequences. RF energy in MRI examinations is not a function of the strength of the static magnetic field. Rather, the Specific Absorption Rate (SAR) for RF radiation is related to the amplitude of RF power, the duration of the RF pulse, the type of RF coil used, the frequency of RF radiation, the resistivity of the tissue, the configuration of the anatomical region being examined, and several other parameters.

FDAGuidelines: "The following are levels of concern at which the reviewer shall exercise appropriate actions to ensure that the safety of the device is substantially equivalent to a predicate device: A) If SAR < 0.4 watts per kilogram (W/kg) whole body; and if SAR < 8.0 W/kg spatial peak in any 1 gram of tissue; and if SAR < 3.2 W/kg averaged over the head: **below level of concern**. Or B) If exposure to radiofrequency magnetic fields is 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: **below level of concern**. The parameter SAR cited above must be shown to fall below either of the two levels of concern by presentation of valid scientific measurement or calculation evidence sufficient to demonstrate that SAR is of no concern."

It should be noted that this guideline is based on the calculation of a system that has no thermoregulatory response, and thus it is a very conservative estimate compared with the temperature change that would be experienced in any living subject. Normal diurnal temperature variations in humans, for example, are about +/-1°C from the normal set point 37°C, and healthy people with normal thermoregulatory responses can easily dissipate any excess (or, in this instance, deposited) heat by increasing their peripheral blood flow or sweat rate. Thus, the heating effect of MRI with the SARs used in accord with these guidelines is extraordinarily unlikely to cause any acute effects in healthy human subjects.

Electrical Burns
RF fields can cause burns by producing electrical currents in conductive loops. When using equipment such as surface coils, ECG or EEG leads, the investigator must be extremely careful not to allow the wire or cable to form a conductive loop with itself or with the subject. Precautions should be taken to avoid the body of the subject from touching the inside of the scanner and subjects should be instructed not to cross arms or legs to avoid creating a conductive loop. Coupling of a transmitting coil to a receive coil may also cause severe burns.
Summary of Risks: Because all experiments performed on the 3.0 Tesla system will comply with FDA guidelines with regard to SAR, and because appropriate RF power safety checks are in place, the criterion for classification of NSR is satisfied.

Ensuring Safety from Tissue Heating Risks
The magnitude of temperature increase during MRI scanning is minimal. Increases are always within FDA guidelines, which include core temperature increases less than 1°C, as well as localized heating to less than 38°C in the head, 39°C in the trunk, and 40 °C in the extremities. Our 3.0 Tesla system has in place a means to monitor RF power levels and ensure that energy deposition is sufficiently low to stay well within these guidelines for temperature increases. First, a "system security" unit is employed to integrate the output of the RF amplifiers. This integration takes into account the amplitudes and duty cycle of the transmitter. If system security detects an output that might exceed the guidelines noted above, it automatically shuts down the entire RF power system. Secondly, all pulse sequences are evaluated, based on calculations and sound scientific measurements, to ensure that SAR remains within FDA-approved guidelines, prior to their use in humans. Any experiment performed on our 3.0 Tesla system will comply with all FDA guidelines with regard to RF power deposition. Proper and routine monitoring of all RF electronics (e.g., coils, transmitters, system security, etc.) will be performed on a regular basis. All pulse sequences will be evaluated (by calculation and by valid scientific measurement) prior to use in humans.

Tattoos, Permanent Cosmetics, and Eye Makeup

Cosmetic tattoos or “permanent cosmetics” are used to reshape, recolor, recreate, or modify eye shadow, eyeliner, eyebrows, lips, beauty marks, and check blush. Permanent cosmetics are also used aesthetically to enhance nipple-areola reconstruction procedures and other applications. Permanent cosmetics and tattoos may cause artifacts and both cosmetic and decorative tattoos may be associated with relatively minor, short-term cutaneous reactions. The frequency and severity of soft tissue reactions or other problems related to MR imaging and cosmetic tattoos is unknown. Tope and Shellock conducted a study in 2002 of 135 study subjects which found that only two individuals reported reactions. One described a sensation of “slight tingling” and the other reported “burning sensation”. Both incidents were transient and did not prevent the MR procedures from being performed. Based on the literature on this topic and these findings, it appears that MR imaging may be performed in subjects with permanent cosmetics without serious soft tissue reactions or adverse effects.

Before undergoing an MR scan, subjects should be asked if he or she had a permanent coloring technique (i.e., tattooing) applied to any part of the body. This included cosmetic applications

such as eyeliner, lip-liner, lip coloring, as well as decorative designs. There is a small documented number of patients (fewer than 10 documented cases) have experienced transient skin irritations, cutaneous swelling, or heating sensations at the site of the permanent coloring in association with MR procedures (review of medical Device Reports, 195 to 2011). Subjects should be informed of the risks associated with the site of the tattoo and be advised to inform the MRI technologist immediately regarding any unusual sensations felt at the site of the tattoo in association with the MRI scan. If the subject is not comfortable continuing, they may refuse to participate at any time.

C. INCIDENTAL RISKS

The physical confinement, isolation, and noise produced by the scanner could cause mild to moderate emotional distress.

Subjects should be educated about specific aspects of the MR scan (e.g., noise, space inside the scanner, and exam duration).

Visibility and temperature conditions will be optimized before the scan.

The research team should maintain physical or verbal contact with the subject throughout the scan. All subjects will be able to communicate directly with the operators and study staff to inform them of any emotional or physical distress during the scanning procedure. If the subject complains of body aches, dizziness or anxiety (including claustrophobia) during the scan and they squeeze the emergency ball, stop the scan and access the situation. If they wish, the scan will be terminated immediately and the subject will be removed from the scanner.

Superconducting system concerns
In superconducting magnets, liquid helium is used to maintain magnet coils in a superconductive state. Safety concerns arise in the event the magnet coil ceases to be superconducting (i.e., quench). During a system quench, liquid helium boils off rapidly and gaseous helium may be released into the scan room. Prolonged exposure to gaseous helium (looks like steam and lighter than air) can result in asphyxiation and frostbite and therefore the subject should be evacuated from the scan room immediately. Secondarily, it might be difficult to open the scan room door because of increased pressure in the scan room. Therefore, all investigators must be familiar with the procedure required during an unexpected quench.

D. PREGNANCY

There are no known adverse effects of MRI on developing fetuses. Most early studies on pregnant animals were negative for teratogenic effects, and a recent survey found no association between working in the MR environment and a number of pregnancy outcome variables. However, given the scarcity of data on the subject and the high susceptibility of the developing fetus to damage in general, we believe it is not worth the risk for pregnant women to participate

as subjects in MR research studies. Pregnant participants will not be scanned. Although there are no known risks associated with MRI during pregnancy, according to facility policy, UM will not scan someone who is pregnant. Therefore, all women of childbearing potential (menstruating or >12 years old) must complete a form stating that they are not pregnant within 24 hours of each MRI scan. Most clinical units allow pregnant employees to enter the scan room, but not to remain in the room while the RF and gradient fields are applied during image acquisition. Pregnant researchers at the Center will regulate their own exposure to the magnets.

E. DATA SAFETY

All MRI data is stored on servers stored in restricted access locations on the campus of Coral Gables. They are maintained by University of Miami administrators and employ triple redundancy for data integrity. Access to the server is granted on the instructions of University of Miami research faculty only.

IV. SAFETY ORGANIZATION WITHIN THE MRI FACILITY

The Imaging Facility is a research-only unit. No clinical studies are undertaken at the Facility. With respect to safety, the Facility's activity falls under the general guidelines of germane institutional policies at the University of Miami, and other relevant policy-making bodies of the state and federal governments.

The final responsibility for safety within the imaging facility rests with the Management Committee, which comprises individuals knowledgeable about experimental procedures in MRI, medicine, neuroscience, physiology, physics, and electronics. In the event that an unsafe condition arises, or if a safety policy has been violated, the Management Committee has the authority and responsibility to revoke approval of the protocol involved until the condition is corrected.

The MRI Physics Manager is experienced and knowledgeable about the operation of the MRI scanner, safety hazards, and safety policies of imaging facility. The Physics Manager has the authority to suspend any activity in the imaging facility that in his judgment violates the safety policies of the Management Committee (or University), or that otherwise constitutes an unsafe condition. He may transfer this authority to a MR technologist approved operator of the facility. The safety-related activities of the facility will be distributed among its members.

1. The Physics Manager will ensure that the safety policies of the Safety/Technical Committee are followed during the execution of approved MRI research protocols.
2. The Physics Manager will maintain a permanent file of incident reports and any corrective actions taken.
3. The MR technologist will coordinate training classes concerning safe conduct of research in the imaging facility and document the test results.
4. The MR technologist will report employee accidents to the university safety department and to the Management Committee.
5. The safety/technical committee will ensure adequate distribution of the manual governing safety within the imaging facility.
6. Remain updated on all new governmental and non-governmental policies and recommendations regarding MRI safety. These can be found at MRIsafety.com and Manual for Magnetic Resonance Safety, Implants and Devices: 2013 Edition by Dr. Frank Shellock.

A qualified MRI technologist will be responsible for performing all MRI procedures.
A qualified MRI research team member will be responsible for performing all study approved procedures.

A qualified MRI research team member must have the following qualifications:

1. Viewed the Ulearn video on MRI safety.

2. Read the MRI safety manual including Appendix Materials
3. Read the MRI Equipment Manual.
4. Complete online MRI safety training.
5. Scored higher than 80% on the safety quiz.
6. Have been approved or certified by the Management Committee.

V. SAFETY INFORMATION

1. EMERGENCY PROCEDURES

A. MEDICAL EMERGENCIES

- Dial 305-284-6666
    - Report whether a child or adult is involved
    - Report that the emergency is in the Neuroscience Annex/MRI facility, room 104.
    - Report the nature of the emergency.
- Send a person to meet the code team at the entrance.
- Remove the subject from the scan room.
    - If the person is unconscious or is non-ambulatory, undock the scan table.
        - ✓ Bring the patient to Home position
        - ✓ Fully step down on the pedal labeled UNDOCK at the foot of the table.
        - ✓ If the undock pedal malfunctions, pull the RED emergency release lever on the magnet enclosure (on the lower right side of the patient transport) straight out to release the transport table.
    - Emergency procedures shall NOT be administered in the magnet room, and NO medical equipment shall be allowed in the magnet room. Instead, the MRI operator or emergency team shall remove the subject immediately from the magnet room and transport her/him to Zone II, where the emergency will be handled by the medical response team.
    - The magnet room door shall be closed upon removal of the subject to avoid entry of any metallic objects into Zone IV.
- If the subject is not breathing and unconscious, perform CPR until the code team relieves you. CPR teaches 30 compressions at a rate of 100 compressions/minute, followed by 2 breaths. The compressions should be at least 2 inches for adults, while the depth should be less for an infant (use two fingers rather than whole hand).
- If not already onsite, the principal investigator shall be contacted and informed of the nature of the emergency.
- All adverse events shall be documented on an incident report. The IRB and the physics manager will be notified immediately via a telephone and within 48 hours in writing.

Figure 3. Fire extinguisher in the MRI Suite.

B. FIRE EMERGENCIES

RACE

Rescue anyone in danger

The MRI operator shall immediately remove the subject from the magnet room and building.

Activate the fire department

Dial 911 and give the following information:

- ✓ Nature of the emergency
- ✓ Your name
- ✓ Phone number
- ✓ Neuroscience Building/MRI facility, Room 104

Remind them that the building contains an MRI scanner and should not use any ferrous metal in Zone III. The MRI operator should put a sign on the door to Zone II that no persons occupy this wing.

The MRI operator and/or research staff assisting with scanning during a fire emergency should greet fire personnel to remind them that the building contains an MRI scanner.

Activate the fire alarm system in the building

Press the emergency stop button that will disable all electrical power to the scan room.

Confine the fire. Close all doors to the area.

Evacuate the building or **Extinguish** the fire

If the fire occurs in the magnet room, the fire shall be extinguished using a non-ferrous fire extinguisher. The fire extinguisher near the outside door of the control room (picture here) is non-ferrous and is the only one that should be used.

C. QUENCH

What is a quench?
During a quench, the magnet loses its super-conductivity. The magnetic field ramps down in a matter of seconds - typically at a rate of approximately 20 seconds. The magnet begins to warm up. Depending on the current fill level, liquid helium boils off at 500 to 1500 liters within a few minutes and expands quickly. The exact amount depends on the fill level as well as the field strength of the magnet. A 3T magnet has a higher boil-off rate than a 1.5 T magnet. One liter of liquid helium translates into approximately 700 liters of gaseous helium. During maximum conditions this means approximately 1000 m3 gas. The purpose of the quench line is to securely exhaust gaseous helium to the outside. In view of these precautions, how does one explain a quench? A quench may be released by pressing the magnet's "emergency shut-down" switch (the one with a red "do not touch" label). Another source for quenching is a helium fill level that decreases to a point where the magnet begins to warm up. In rare instances, a spontaneous quench may be observed that cannot be explained by the presence of obvious external sources.

A quench is accompanied by hissing or whistling noises caused by the quickly escaping stream of cold helium gas. Plumes of white fog sink to the floor mainly from the upper part of the magnet and the vicinity of the quench line due to condensation of both water vapor and air. The stream of gas diminishes in a matter of minutes. Air near the non-insulated components of the magnet and the quench line condenses into liquid air and drips to the floor.

<u>Risks associated with a failing quench line</u>
The possibility of a quench was taken into careful consideration during the design of both the magnet and the helium quench line. In the event of a quench, systems and procedures are in place to insure the safety of personnel. As a result, a quench is completely harmless to personnel. However, it is vital that MRI operators understand the events triggered by a quench, and the necessary precautions in the event of a quench. Neither the magnet nor the MR installation are subject to damage during a quench.

Helium is lighter than air, non-poisonous and non-flammable. However, since it displaces oxygen, the risk of suffocation exists. Cryogenic helium escaping into the ambient air leads to white clouds caused by condensation. These clouds adversely affect visibility.

Persons may be rendered unconscious by the amount of helium entering their respiratory system. Depending on the helium concentration present, a few breaths suffice to result in unconsciousness.

In addition, escaping helium is extremely cold, causing hypothermia and frostbite. The latter results in injuries resembling burns (cryogenic burns) after the skin is exposed to normal temperature levels. Skin contact with cold parts or liquid air may also lead to frostbite.

At no time, should anyone touch the cryogenic parts of the scanner.

Minimization of risks:

The planning as well as the installation of room venting and quench line have to adhere to the planning requirements and be checked by a GE field engineer.

The helium boil-off system as well as the venting system has to be visually inspected daily to determine possible changes. The technologist should check that the helium recycling system is operational.

In particular:

- Constructional changes inside and outside the shielded RF-room
- Inappropriate changes by unauthorized personnel
- Damage to the thermal insulation of the exhaust line
- Damage to the exhaust line
- Obstructed exit, e.g. presence of bird nests (is the protective grid still intact)?
- Damage to protective rain covers (these are regularly required for vertically exiting quench lines. Depending on the design, they are also frequently in place for horizontal exits).
- Was the exhaust to the outside changed after the system was handed over to the customer, endangering third parties through the gas exhausted? This may involve, for example, windows installed at a later date, exits and entrances put in place for heating and air conditioning systems, new buildings or temporarily installed containers.
- Was the heating and air conditioning system or venting of the room changed, e.g. by adding additional venting inlets or outlets in adjacent rooms?
- Were additional MR systems installed?
- Is the same quench line used for additional MR systems?

Since each system is subject to either changes or remodeling of the building during its operating life, the operator needs to be thoroughly familiar with the importance of the quench line and the venting system. For this reason, we recommend visual inspections on a daily basis for constructional changes in the vicinity of the quench line and severe weather-related changes such as wind storms, tropical storms, and hurricanes. In case of questionable system functionality, contact the customer service facility.

In case of a quench, the following may occur:

- **Small leaks**: Smaller amounts of helium gas in small clouds of fog may remain *above* head level. They are exhausted to the outside via the heating and air conditioning system and replaced by fresh air. This situation is not critical as long as the heating and air conditioning system functions as required. White fog-like plumes, consisting of cold air, that sink to the floor do not lead to suffocation. In this case, overpressure is not present. There is no risk of suffocation for either patient or personnel.
  Response**:** The patient can be removed, either immediately or after a few minutes depending on the patient's reaction to the situation. Remove any subject and report leaks to the Physics Manager, MRI technologist, and safety/technical committee. These would

lead to small clouds of fog that clearly remain above head level and are frequently visibly sucked off by the heating and air conditioning system. Leakages are the result of constructional errors that need to be corrected. During normal operation there is no leakage of Helium, the vent kit generally sends the helium to the outside during a quench.

- **The quench line fails in part only:** Partial failure occurs when only part of the helium gas is exhausted to the outside via the integrated venting system. Larger amounts of helium are present and spread *at the level* of a person's head impairing visibility. The heating and air conditioning no longer ensures a quick air exchange. Additionally, the pressure in the room increases. Depending on the size of the leakage, hazardous conditions may be present for the personnel involved.
  Response: Open all doors (the control room door first, and then the RF-room) and evacuate immediately. Depending on the extent of the leak, persons and rescue personnel may be endangered. As a rule, rescue personnel should not work alone, but rather in groups of two or more people.

- **Total failure:** The venting line fails completely, e.g. through blockage or breaks in the line. The entire amount of gas is blown into the examination room. Up to 1000 m^3 gas are blown into the room, which frequently has a volume of less than 100 m^3.In the case of a complete failure, **loss of life is imminent.**

While a quench may cause a certain level of anxiety in patients and operators that have not been instructed sufficiently, it is usually quite harmless.

The following applies in the case of a quench: for safety reasons, personnel should leave the system and its vicinity if evacuations are not necessary.

The operating personnel should be trained in overseeing the evacuation of the MR suite and adjacent rooms.

Personnel should only return to the MR suite after the situation is back to normal, that is, noises have stopped and visibility is no longer obstructed. For safety reasons, all rooms should be thoroughly aired; doors to the outside should be open. Usually the air conditioning system will provide for effective air exchange.

Usually, the strongest gas flow occurs only after several minutes and will subsequently subside. However, the course of gas flow is not fully predictable, since at the time of occurrence the type of error in the quench line is generally not fully known.

Prior to opening the door to the RF-room, all available doors and windows of the control room should be opened to ensure sufficient ventilation. All personnel in the vicinity of the system who is not needed for rescue activities should leave prior to the rescue of a patient in the examination room. When opening the door, possible overpressure in the room should be factored in as follows:

- If the door opens in the direction of the control room, the door may fly open due to overpressure. The operator should be aware of this possibility so that he can avoid injuries caused by the unexpected opening of the door.

- If the door opens in the direction of the RF-room, it may be impossible to open it due to the overpressure in the room. In this case, existing openings (windows or emergency flaps) have to be opened up. The over- pressure may lead to windows or flaps swinging unexpectedly. If there are no emergency openings, the observation window may be smashed in (hazardous situation caused by splinters). We should make sure that the door opens while pulling it away from the RF room/Magnet room.

After opening the door to the examination room, the helium gas may escape to adjacent rooms, endangering the safety of the rescue personnel. It is possible to check the air with an oxygen monitor. A gas mask does not protect against oxygen displacement by the helium gas. An oxygen tank must remain in the facility for emergencies due to escaping helium. In addition to the risk of suffocation there is also the additional risk of hypothermia.

Since the helium gas warms up quickly and spreads downward from the ceiling, a rescue worker standing upright is exposed to greater danger than a patient lying in the magnet.

After the patient has been removed from the examination room, no personnel should remain in the vicinity of the system until the quench has been stopped and ventilation has been ensured.

During a total failure of the quench line in the magnet room, the room will be quickly filled with cryogenic helium gas. After a quench, the usual service procedure goes into effect (contact GE). Customer service has to be notified as quickly as possible to put the system back into operation. You never want to use the quench button, it will render the system out of commission for a long time period. The quench button is located in the Magnet room.

D. EMERGENCY MAGNET RUNDOWN (Quench button).

The device for an **Emergency Magnet Rundown**, pictured below, allows for the rapid reduction of the magnetic field in about two minutes. It will also boil-off cryogens and therefore, unlike the Emergency Off button, this button **WILL PRODUCE A QUENCH**. There is a quench button in the control room to the left of the operator's console, and also one in the scanner room. **Only the MRI physics manager or director of the MRI facility is authorized to trigger the rundown UNLESS A HUMAN LIFE IS AT RISK.**

DO NOT quench the magnet if a piece of furniture or equipment got into the bore. Such objects can be safely removed by calling GEs' service engineer to slowly power down the magnet. The rundown should be triggered to free someone pinned to the magnet or to remove a large ferromagnetic object captured in the magnetic field when injury to the subject is imminent.

After quench, the MRI physics manager must:

1. Use the intercom to alert the patient to stay calm and remain on the table until the operator gains access to the room to offer assistance.
2. Prop open the magnet room door to promote air circulation.
3. Transport the patient out of the room.
4. Evacuate all personnel from the area.
5. Inform the director and call the GE service engineer.

Figure 4. Quench button in the control room.

E. EMERGENCY OFF

The **Emergency Off** button (pictured below) is on the operator's console, and there is also one in the scanner room. It removes ALL electrical power from the MRI console and the patient table, including any power sources from the Uninterrupted Power Supply (UPS) devices. The effect of pushing the Emergency Off button is to turn off the entire MR system EXCEPT for the static magnetic field and the magnet rundown unit (described below). This DOES NOT produce a quench.

The button should be used only to stop a scan during a patient emergency or during a serious equipment fault or hazard, such as fire or water in the vicinity of the MR equipment.

Figure 5. Emergency Off Button in the control room.

F. POWER FAILURE

In the event of a power failure, if an MRI study is in progress, the patient will first be removed from the bore manually. Simply pull the patient table out of the bore. Once patient safety is secured, the MRI operator will return to the MRI suite and properly shutdown all of the computers (which should be receiving power from UPSes), thus preventing corruption of the software on the MRI scanner. The MRI facility and ancillary systems will remain off until Facilities personnel notifies the MRI Physics Manager of adequate power return.

2. SPECIFIC HAZARDS WITHIN THE MRI FACILITY

A. ELECTRICAL HAZARDS

1. The MRI scanner will be evaluated regularly for electrical hazards by the GE Service Engineer, as detailed in the service agreements with the MR system manufacturer
2. All modifications to the equipment will be performed only by the GE Field Engineer and will be properly evaluated in terms of electrical safety
3. Safety tests will be carried out on a regular basis by the GE Field Engineer with regard to radio frequency and magnetic field levels, as detailed in the service agreements with the MR system manufacturers. After safety tests are completed, the service engineer will leave a comprehensive service report relating all results and action taken to restore any faults in MRI system.

B. CRYOGEN HAZARDS

A superconductive magnet in the MRI scanner uses cryogens to supercool the electrical conductor that creates the magnetic field. Temperatures as low as -269°C (-452°F) are achieved to create the proper superconducting environment within the magnet. A quench, which is a sudden boil-off of the entire volume of cryogenic liquid, causes a rapid loss of the static magnetic field.

Cryogens come in large vacuum containers called “Dewars”. Liquid helium is generally used for cooling purposes, although some service procedures also require liquid nitrogen. Nitrogen Dewars weigh from 400 to 500 pounds when full. Helium Dewars weigh from 700 to 800 pounds. In addition to large Dewars, there may be smaller helium gas cylinders present. This helium gas is used to fill the magnet to the correct cryogen levels. The cryogens boil off as they cool the magnet wires and must be replenished periodically by qualified personnel. Contact with the cryogenic liquids or gas could result in severe frostbite, and care is needed when in proximity to these substances. Furthermore, leaking helium or nitrogen gas will displace oxygen from the room. An ambient air oxygen concentration of less than 17% to 18% is not sufficient for human respiration, and therefore a large cryogen leak or quench of the magnet is dangerous to humans and animals in the room.

Safety Procedures:

- All Dewars and gas cylinders must be non-magnetic.
- Dewars should be stored in a well-ventilated area.
- Gas cylinders should be stored upright and secured to the wall with a chain with a metal protective cap in place (if the cylinder falls over or the valve is knocked off, the container may act like a rocket, as a full cylinder has enough power to penetrate walls)
- The valves of Dewars and cylinders should not be tampered.
- Because cylinder caps may be metal, they should be removed before bringing the cylinder into the magnet room.
- If possible, all personnel should stay out of the magnet room when a qualified service engineer is filling cryogens in the magnet. If personnel from the MRI suite must be present, they must wear proper gloves, a face shield, and ear protectors.

- Flammable material must not be brought near the cryogen containers.
- The wearing of protective clothing is essential during all work performed with liquefied cryogens. Such clothing consists of:
    - Safety gloves
    - Work gloves
    - Face shield
    - Laboratory coat or overalls (cotton or linen)
    - Non-magnetic safety shoes

C. FIRE HAZARDS

General Safety Procedures:

1. Necessary equipment (fire extinguishers, etc.) will be stored within the MRI suite to manage all classes of fire. All equipment will be non-magnetic.
2. To protect against the possibility of fire, no flammable liquids in excess of five gallons will be brought into the MRI suite.

Fire with Operators On-Site:

1. The Operator will know all of the fire emergency related procedures, including a patient evacuation plan, and its proper execution. The front entrance, located on the first level, has been assigned as the point of exit for evacuation during a fire.
2. The MRI Physics Manager or MRI technologist or the Research Director of the facility will evaluate the need for an emergency quench of the magnet.
3. In the event of a fire requiring outside response, the MRI physics manager, MRI research committee or the Director will quench the magnet if ferromagnetic equipment must enter the MRI magnet room. They will direct entry and exit to the magnet room until the magnetic field reaches zero.

Fire During Off Hours or No Operators On-Site:

1. Contact the MRI Physics Manager MRI technologist or the Chair of the Technical Committee immediately to receive instructions for firefighting personnel and Security staff as to the means of entry to the MRI suite and to the proper means of quenching the magnet, if necessary. These phone and pager numbers are at the front of this manual.
2. For purposes of access in an emergency, the Public Security Department will have access to the MRI suite.

D. INFECTION CONTROL

1. Hands must be washed between subjects.
2. The MRI table and head rest must be covered using exam paper sheets. Sheets must be discarded after each subject.
3. Disposable headphone covers must be used and discarded after each use.
4. All contaminated products must be discarded in the gray trash bin.
5. The magnet room table and headrest must be wiped with a Sani-wipe at the end of the day.

E. SAFETY PROCEDURES FOR EXPERIMENTS INVOLVING CHILDREN

1. Specific IRB approval and consent form for using infants or children population in MRI scan must be obtained prior to the scans.
2. The child must be accompanied by a parent or an adult representative. The scans must be approved by the parent or the adult representative.
3. More careful consenting and explanation of MRI scans to children shall be done.
4. Accompany the child at all time and do not let him or her move freely in the control room and magnet room.
5. Specifically instruct the child that he/she need to remain motionless for 30 minutes to one hour.
6. If a child is very young and cannot lie still, no scan will be performed.
7. Parents may be in the magnet room during a scan, but they must complete the same screening procedures as a research participant.

F. SAFETY OF UNIVERSITY PERSONNEL

1. University staff will have access to the magnet room within the Facility only under the supervision of the MRI Physics Manager, or a certified MRI operator.
2. In the event of an emergency, the Security Officer will have on file a telephone number for the MRI Physics Manager. Once contacted, the Physics Manager or the Co-director will advise the Security Officer in safe methods to access the facility and the safety procedures to follow once the restricted area is entered.

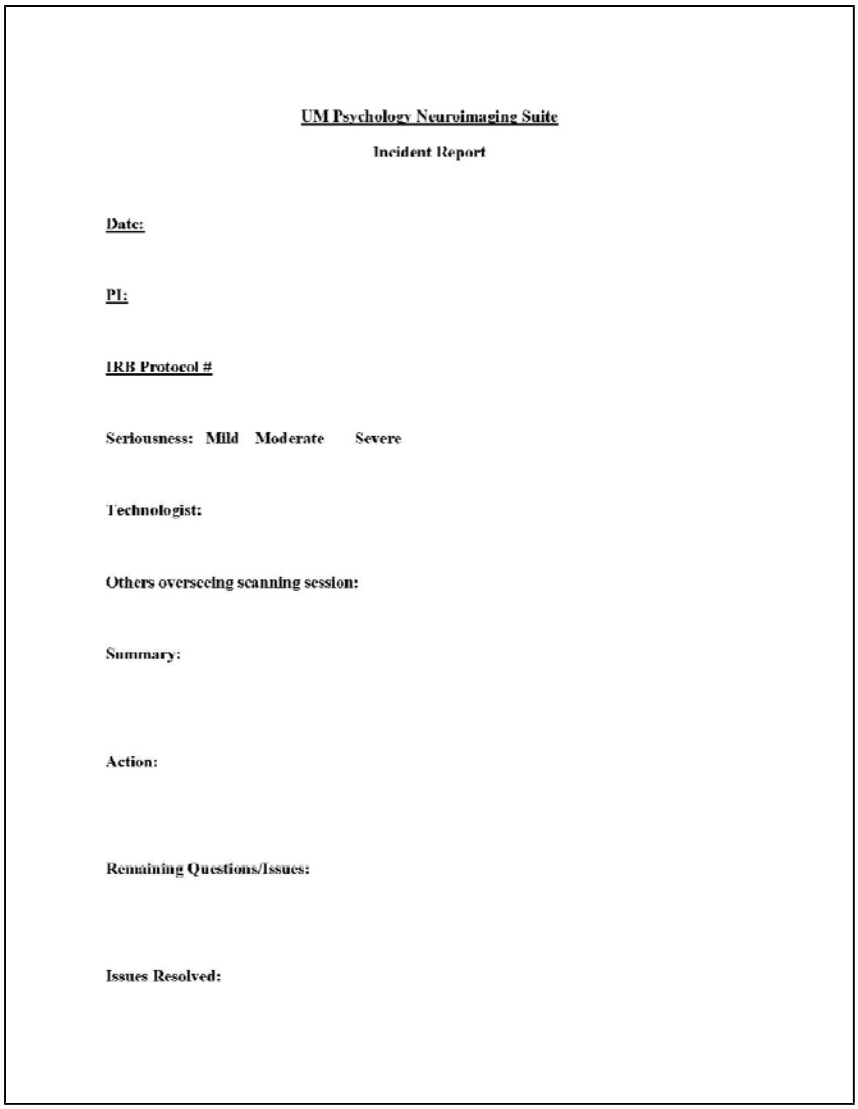
G. INCIDENT REPORTS

It is the duty of the MRI Physics Manager to report all violations of safety procedure and accidents to the Management Committee. The MRI operator will document any the following incidents in writing and immediately submit this report to the Physics Manager.

1. Incidents in which any person was injured.
2. Incidents requiring the emergency quench of the magnet.
3. Incidents involving damage or potential damage to MRI and ancillary equipment.

4. Conditions that constitute a safety hazard.
5. Incidents in which an approved protocol was not followed, causing an unsafe condition.

Figure 6. Incident Report.



UM Psychology Neuroimaging Suite

Incident Report

Date:

PI:

IRB Protocol #

Seriousness: Mild Moderate Severe

Technologist:

Others overseeing scanning session:

Summary:

Action:

Remaining Questions/Issues:

Issues Resolved:

Nothing in the foregoing is to be interpreted as preempting the legal and institutional responsibilities of the University of Miami's Institutional Review Board or regulations of the University of Miami.

VI. GLOSSARY

Cryogen: A superconductive magnet in the MRI scanner uses cryogens to super-cool the electrical conductor that creates the magnetic field.

Exclusion Zone: The magnet room and the MRI suite are considered the exclusion zones. All ferrous equipment must remain outside exclusion zone.

Ferromagnetic vs Ferrous: Ferromagnetic, a substance that is ferromagnetic and has a large positive magnetic susceptibility (e.g. iron). Ferrous items can possess intrinsic magnetic fields and react strongly in an applied magnetic field. (Iron, Nickel, Cobalt).

Peripheral Nerve Stimulation: Sensations such as 'twitching' or 'tingling', usually in an arm or leg. In very rare instances, this nerve stimulation can be painful.

Quench: Quench is the term used to describe a rapid loss of field strength in a superconducting magnet. During a quench, the magnetic current dissipates as heat and causes the liquid Helium to boil off in gaseous form. MRI installations are designed with ventilation systems to handle the rapid boil off of liquid helium

Restricted Access Area: All of MRI Unit except patient waiting area

Security Zone: The Security Zone warning sign will be posted on the entrance to the magnet room to alert personnel to the high magnetic field and warn not to bring ferromagnetic objects into the magnetic room.

Static Magnetic Field: Static magnetic fields are measured in Gauss (G) or Tesla (T), with 10,000 G being equal to 1 T. For comparison's sake, the earth's magnetic field varies from approximately 0.3 to 0.7 G between the equator and the poles, respectively, while a small refrigerator door magnet may be used as strong as 150 G to 250 G. The strengths of the static magnetic fields used in clinical and research MR systems for imaging and/or spectroscopy range 0.012 T to over 10 T (100,000 G). According to the most recent recommendations and guidelines provided by the United States Food and Drug Administration (FDA), clinical MR systems are permitted to function on a routine clinical basis at static magnetic field strengths of up to 4.0 T.

Tissue Heating: MRI scanning induces some heating of body tissues.

Unrestricted Area: The unrestricted area in the MRI suite is the patient waiting room.