SAFETY MANUAL OF FLORIDA STATE UNIVERSITY MAGNETIC RESONANCE IMAGING FACILITY

INTRODUCTION

This document serves as the safety manual of the Florida State University (FSU) Magnetic Resonance Imaging Facility (MRIF). It describes the facilities in the MRIF and their location and how to access these facilities. For researchers wishing to conduct studies at the MRIF, this document outlines the requirements for safety training in order to be permitted access to MRIF. Also described are the procedures to maintain access to the MRIF once access is obtained by a researcher. This document lays out the safety and screening requirements for subjects, in addition to the risks faced by anybody entering the magnet room and the procedures to mitigate those risks. Details of the various procedures to be adopted in case of emergency are laid out in detail.

FACILITIES

The Magnetic Resonance Imaging (MRI) Facility at Florida State University houses a state-of-the-art research dedicated whole-body 3.0T Siemens Prisma scanner. The system is equipped with:

- a high-performance gradient system (80 mT/m @ 200 T/m/s simultaneously, on all three axes) with an advanced cooling system;
- New Tim 4G RF system with 48, 64 or 128 independent channels for faster imaging and higher SNR;
- $50\times50\times50$ cm^3 field of view.

In addition to the body coil, the system is equipped with 8, 32, and 64 channel head coils and a number of flexible surface coils.

SITE ACCESS AND RESTRICTIONS

LOCATION AND CONTACT INFORMATION

The MRIF is located in the in the Suite G0135, Medical School Research Bldg. (#4002), College of Medicine, Florida State University, 1115 West Call St., Tallahassee, FL, 32306-4300. The layout of MRIF is shown in Figure 1.

The reception desk in the MRIF can be contacted by calling 850-644-1889.

The MRI control room can be contacted by calling 850-644-2155.

Hours of Operation

The MRIF is open 8am – 5pm Monday to Friday (University holidays excluded). Typically, scanning only takes places during these hours. Should you need to scan outside these hours, this can only be accomplished by prior arrangement with the MRIF technologist.

Safety Zones

The MRIF is divided into four safety zones as indicated on the floorplan of the facility. These zones are labelled 2-4, and each zone is progressively more restrictive.

Zone 1: The MRIF does not have any zone 1 areas, which are open to the public. All areas in the MRIF are key card controlled.

Zone 2: First access/contact points between MR subjects and MR Staff

This is the area where subjects will be screened, change, experience the mock scanner, and wait to enter the magnet. Subjects and non-MR personnel are not free to move about this area unsupervised. The only exception to this will be cleaning staff and FSU police and fire staff who have had Level 1 MR Safety Training or MR First Responders Safety Training.

Zone 3: Control Room

Only MR personnel and prescreened subjects may enter this zone. MR personnel are staff that have completed the Level 2 MR Safety Training, have an approved annual metal screening form on file, and have a record of annual MR Safety Training on file.

Zone 4: The MR scanner magnet room.

Zone 4 is always located within Zone 3 and the same training and screening requirements apply to both zones.

Signage

Warning signs are posted at all entry points to Zones 2 – 4. Additionally, Zone 4 areas are marked potentially hazardous due to the presence of a strong magnetic field. A sign at the entrance to the magnet room is a red light, stating “The Magnet Is On”.

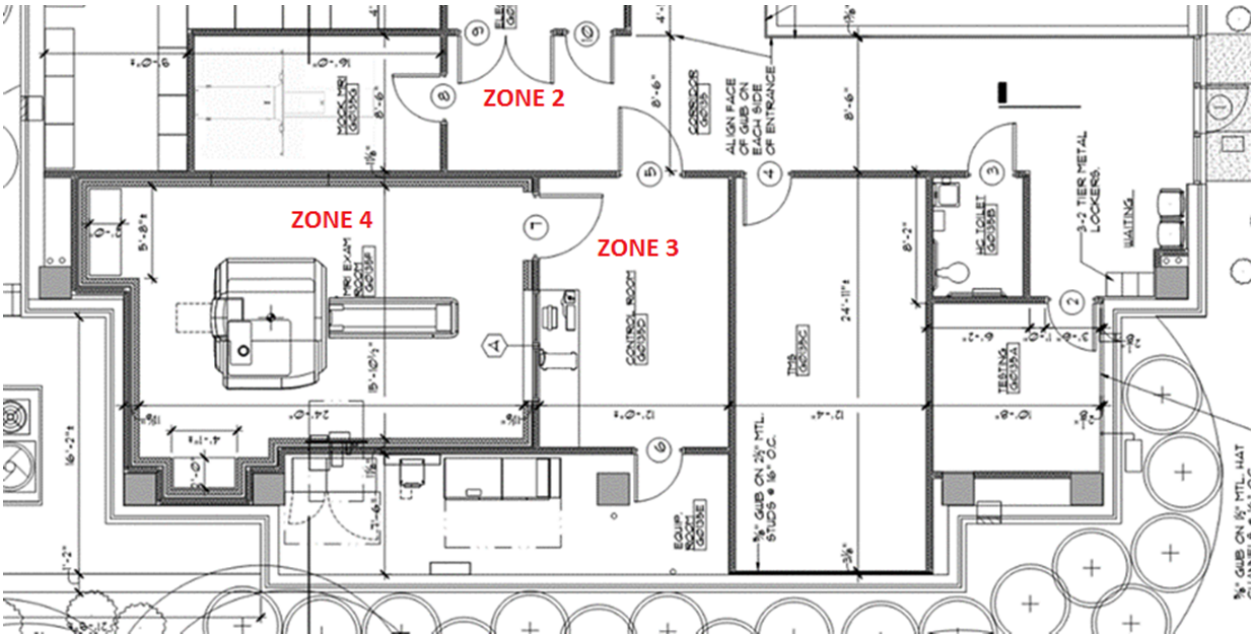

FIGURE 1 MRIF LAYOUT.

Card Access

Access to the MRIF (i.e., Zone 2) is controlled by card key access. Authorization for card key access to the MRIF requires successfully completing safety training and having a metal screening form for control room and scanner access (Zones 3 and 4). Access must be approved by the current MRI Technologist. Access to the 3T MRI scanner control room (G0135F) is by key only. External access doors should never be propped open.

MRIF Personnel Classification and Training Requirements

Designation and Description of MRIF Personnel and Non-MR Personnel

MRI Personnel includes the Scientific Director, Research Support Scientist, MRI Technologist and those who perform other work associated with the MRIF.

MR Safety Training

MRI personnel must attend an in-person MR Safety Training course and pass an annual safety exam to maintain access to the MRIF Project and Calendar System and MRI Facility. MR personnel will receive an email notification that their certifications are going to expire. Courses will be offered on an as needed basis. To schedule in-person safety training, please contact mri-facility@fsu.edu. After attending safety training MRI personnel will be required to take an online quiz and answer a series of multiple-choice questions. A passing grade on the quiz is 90%. Passing the online quiz is a yearly requirement to maintain access to the MRIF. You may attempt the

online quiz at most three times before attendance at an in-person safety training course becomes mandatory. The requirement to take the quiz only applies to researchers. Other personnel, e.g., custodians, facilities, first responders, will be provided with in-person safety training on an annual basis.

Metal Screening

MR personnel must also have an approved metal screening form on file in order to obtain access to the MRIF Project and Calendar System and MRI Facility. This form must be completed annually or sooner, if the individual has surgery or is involved in an accident that may have caused a metal injury.

MR Personnel Levels

A current list of MR Personnel, their levels, and the due date of their next safety training/update must be maintained within the MRIF at all times. Documentation of MR personnel completion of MR safety training and metal screening form will be updated at least annually and must be signed by the MRI Technologist. Records of documentation must be maintained within MRIF.

There are four levels (see below) of MR personnel. It is the responsibility of the MRIF Oversight Committee to determine which MR Personnel/Researcher designations individuals may have.

Level of access to the all zones of the MRIF is granted according to the Level of MRIF Personnel training.

Level 1 Personnel must have an approved metal screening form on file and must have completed in-person MR Safety Training. Level 1 personnel may enter zone 2 unescorted and may consist of ancillary personnel such as police and fire, facility maintenance, and cleaning staff.

Level 2 Personnel must have an approved metal screening form on file, must have attended in-person safety training, and passed a safety exam (renewable annually). Level 2 personnel are oriented to zone restrictions, perform metal screenings and subject experiment preparations. They are allowed in zone 3 unaccompanied, and in zone 4 accompanied by level 3 or 4 personnel, to assist in subject set up and equipment placement as directed by the level 3 or 4 personnel.

Level 3 Personnel (also known as operators) must have an approved metal screening form on file, have attended safety training, and have passed a safety exam (renewable annually). They must have detailed knowledge of current policies and safety procedures at MRIF. Operators are permitted entry to Zone 3 unaccompanied by Level 4 personnel. Operators are permitted access to Zone 4 (the scanner room) unaccompanied by Level 4 personnel. Though the amount of training required to be certified as an operator is at the discretion of the MR Technologist (Level 4), a minimum of 20 hours training is suggested. Only an MR Technologist (Level 4 personnel) can

grant Level 3 status to a prospective operator. This may only occur when the prospective operator has demonstrated proficiency in their ability to operate the scanner to the satisfaction of the MR Technologist (Level 4 personnel). Thereafter, operators are permitted to operate the MRI scanner, including scanning human subjects, unsupervised by Level 4 personnel. When operating the scanner, operators assume all responsibility for ensuring that MRIF policy and safety guidelines are enforced. Operators must ensure the health and safety of all study personnel and research particpants. Operators are responsible for the safe management of all equipment. In all cases, the operator for a study must be recorded in the MRIF project management and reservation system. Should the operator change, the reservation must be edited to reflect such a change.

Only FSU faculty, postdoctoral scholars, full-time research assistants and graduate students are eligible for operator training. Undergraduates are not eligible for operator training.

Once granted, operator status must be maintained. This is accomplished by scanning at least once every 30 days. Operators who do not scan once every 30 days lose their status and must be recertified by scanning with MR Technologist (Level 4 personnel) to ensure their proficiency.

It is the responsibility of the operator of record to ensure that research participants to be scanned must have properly executed IRB-approved consents (and assents, if appropriate). Additionally, operators must assure that screening forms and other documentation required for the incidental finding program are properly filled in. Copies of all documents must be placed in the secure drobox in MRIF.

Level 4 Personnel must have an approved metal screening form on file and must have watched and completed the exam for the MR Training Video, Advanced Safety Training for MRI Healthcare Professionals and current certificate on file. They must be CPR certified and have extensive knowledge in MRI Scanning and Safety, participant screening, and emergency procedures. They must be a board-certified MRI Technologist.

SUBJECT SCREENING AND SAFETY REQUIREMENTS

The purpose of metal screening is to ensure that no one enters Zone 3 (control room) or Zone 4 (magnet room) with ferromagnetic objects, either in their bodies, on their bodies, or as part of any materials or equipment that is being brought into the magnet room. Metal screening of ALL individuals entering these zones is a cornerstone of keeping the MRI environment safe.

SUBJECT METAL SCREENING

Volunteers must fill out a metal screening form each time they participate in an exam.

IMPLANTS AND CONTRAINDICATIONS

Subjects with certain medical conditions or metal eye injury will **NOT** be scanned. Subjects who screen positive for implanted electronic devices will **NOT** be scanned under any circumstances. Examples of such exclusionary devices include but are not limited to pace makers, neuro-stimulators, insulin pumps, intraocular pressure monitoring contact lenses. Subjects with the residual parts of such devices will **NOT** be scanned under any circumstances. Subjects with externally fixed orthopedic hardware will **NOT** be scanned under any circumstances. Subjects with Harrington rods will **NOT** be scanned under any circumstances. Where the MRI Technologist or operator has any doubts about the veracity of the information provided about implants, the ability of the prospective subject or their representative to provide said information, or the compatibility and safety of implants in a prospective subject, the subject will **NOT** be scanned under any circumstances.

Subjects with certain classes of implants, such as cardiac stents, carotid stents, heart valve replacements, knee replacements, internal bone or joint pins or screws **may** be scanned six weeks after device implantation. Some types of birth control devices may also be scanned. The device name, manufacturer, and model number **may** be required to document its MR compatibility and safety. This information may be found on an implant card given to the subject or in their surgical notes. Approval for these implants must be saught from the MRI Technologist **seven calander days** prior to the proposed scan date. In this case, the final decision to scan a subject with implants rests **solely** with the techonologist. Researchers are advised to get as much information about the implant (such as date of implant, device name, manufacturer, and model number) before enrolling the subject in a study. Each subject's particular circumstances will be judged on a case by case basis.

Level 3 or 4 operators may scan subjects with the any of the list of implants below without prior approval.

1. Dental implants (non-magnetic)
2. Hernia mesh
3. Mirena intrauterine device (IUD)
4. Nexplanon implant for birth control
5. Knee replacements as long as there is no external component
6. Intraocular lens implant (for cataract)
7. Dental permanent retainers (may cause distortion)
8. Breast implants - saline or silicone.

Other implants not on the lists above will not be scanned.

A decision to scan a subject with implants made by a level 3 operator can at all times be over ruled by MRIF staff. If the MRIF personnel declines to scan the subject, the subject will **NOT** be scanned under any circumstances.

All implants, regardless of type, must be documented on the MRI screening form. At all times, researchers are welcome to consult with MRIF personnel to determine whether the subject could be eligible for scanning at MRIF.

PREGNANCY

Any female subject who is pregnant may not be scanned or enter the scanner room. Although "there are no known deleterious effects related to the use of MR procedures during pregnancy" (Sawyer-Glover & Shellock, 2000), the FDA guidelines indicate that the effects on the fetus remain to be established (Shellock, SMRI Safety Committee, 1991). Women of child-bearing age will be scanned only if the project was approved by the FSU Institutional Review Board. Age range and gender distribution of subjects should be provided in the IRB application, along with methods to exclude pregnancy (e.g., questionnaire, pregnancy test, gender/age restriction, etc.).

INFORMED CONSENT

All volunteers that undergo an MRI for an experiment or testing must have signed an informed consent and/or assent; minors must be accompanied by their parent or legal guardian. Minors must have their parent or legal guardian fill out the metal screening form and a consent form. Individuals with diminished cognitive capacity may only be scanned if they are accompanied by a care giver duly authorized to act on their behalf.

INJECTABLE CONTRAST AGENTS

No contrast injections will be given at FSU MRIF.

ANESTHESIA AND SEDATION

The scanning of subjects that require anesthesia or sedation is not permitted at FSU MRIF.

EXAM ATTIRE

Since the prevalence of fabrics containing non-detectable metallic microfibers has increased, the risks of burns occurring should subjects wear such items of clothing into the scanner will be explained to the subject by the MRI technologist. Subjects will be given the option of documenting on their metal screening form that they are not wearing such clothing and/or changing into MRIF provided scrubs for the duration of their scan. As a matter of routine study procedure, researchers should inform subjects that the most suitable form of clothing to wear for their scan is made of cotton or cotton/polyester blends. Subjects will not be scanned should

their garments be or become damp or wet. Should this happen during the course of scanning, all scanning must cease immediately and the subject removed from the scanner.

Claustrophobia and anxiety

Individuals undergoing MR imaging will be screened for known claustrophobia and/or anxiety about undergoing imaging. Individuals wishing to undergo MR imaging will first be offered an opportunity to practice in the simulated MR environment (mock scanner). All individuals undergoing imaging are advised that they may speak to the MR Personnel/Researcher throughout the imaging session or squeeze the handheld squeeze ball to indicate that they need attention or wish to be removed from the magnet and subject bed. The MRIF informs subjects that they may terminate the exam at any time they wish.

Intercom System

The MRIF personnel will verbally check on subjects in between sequences, using the intercom to access their comfort and anxiety levels. If a subject is uncomfortable, the scan will be stopped and the subject removed from the scanner to discuss whether or not to terminate the scan.

Squeeze ball

The squeeze ball allows subjects to set off an alarm to gain the attention of the MRI operator. It will be given to all subjects and they will be instructed to use the alarm in the case of any concern or discomfort during the MRI Exam.

Ear Plugs or headphones

Echo planar Imaging (EPI) and other fast gradient sequences commonly used in the MRIF produce high levels of noise ranging from 126 – 131 dB on a 3T system (Foster, Hall, Summerfield, Palmer, & Bowtell, 2000; Hattori, Fukatsu, & Ishigaki, 2007). Anyone to be scanned must be provided with hearing protection that lowers noise to at least 99dB(A) (Siemens Healthcare, 2015a, p. 30). Accompanying personnel in the magnet room must be provided with hearing protection that lowers noise levels to at least 85dB(A) (Siemens Healthcare, 2015a, p. 30).

Mock Scanner

The use of the mock scanner is strongly encouraged with all subjects irrespective of age. This will familiarize subjects with the confines of the scanner environment. In addition to providing an opportunity to train the subject on study-related issues, it affords an opportunity to train subjects on safety and communication procedures. Moreover, the mock scanner provides an opportunity to train subjects to keep as still as possible while in the scanner through the use of movement related feedback. This can significantly increase subject compliance and reduce the amount of data lost due to motion contamination.

Scanning Children

Children may be accompanied by an adult monitor while they are in the scanner. This adult monitor must remain with the child at all times while the child is in the magnet room. All children should be asked whether or not they want to be accompanied by an adult monitor while they are in the scanner as part of routine study procedure. Any child, irrespective of age, who displays signs of anxiety or who requests to be accompanied while they are in the scanner must be accompanied by an adult monitor. If there is any doubt about the ability of a child to follow safety instructions, they must be accompanied by an adult monitor. The monitor may be a researcher (faculty/staff/graduate student) who has completed safety training, is familiar with the use of the squeeze bulb, the use of the motorized scanner bed, and the manual release on the scanner bed. Should the child be more comfortable with a primary care giver as monitor, the care giver must complete a metal screening questionnaire with no contraindications for MR imaging; they may be required to wear appropriate exam attire (see above) and be familiarized with the use of the emergency squeeze bulb. The adult monitor must wear appropriate hearing protection at all times.

In situations where there is more than one child (e.g., a sibling of the child being scanner) in the MRIF, the child must be accompanied by an adult at all times to monitor their activity and ensure their safety.

Researchers must inform parents and/or primary caregivers that only clothing made of cotton or primarily cotton/polyester blends is permissible. This may require the inspection of clothing labels, which may only be done by the MR technologist in the presence of the parent or primary caregiver.

Diminished Capacity

Any subject who exhibits diminished cognitive capacity and may not be able to follow safety instructions must be accompanied by an adult monitor at all times while the subject is in the scanner room. The monitor may be a researcher (faculty/staff/graduate student) who has completed safety training, is familiar with the use of the squeeze bulb, the use of the motorized scanner bed, and the manual release on the scanner bed. Should the subject be more comfortable with a primary care giver as monitor, the care giver must complete a metal screening questionnaire with no contraindications for MR imaging; they may be required to wear appropriate exam attire (see above) and be familiarized with the use of the emergency squeeze bulb. The adult monitor must wear appropriate hearing protection at all times.

Diminished Communication Abilities

Any subject who exhibits diminished ability to communicate, for example through deafness, or an inability to speak must be accompanied by an adult monitor who has the ability to communicate with the research subject. The monitor may be a researcher (faculty/staff/graduate student) who has completed safety training, is familiar with the use of the squeeze bulb, the use of the motorized scanner bed, and the manual release on the scanner bed. Should the adult monitor not be a researcher, they must complete a metal screening questionnaire with no contraindications for MR imaging; they may be required to wear appropriate exam attire (see above) and be familiarized with the use of the emergency squeeze bulb. The adult monitor must wear appropriate hearing protection at all times.

Scanning People with Disabilities

Where subjects who rely on mobility assistive devices (e.g., wheel chairs, walking frames, walking canes) are to be scanned, only assistive devices that are constructed of MR-safe material are permitted in the magnet room. Before arranging to scan such research participants, researchers should contact the MRIF in advance to ensure that appropriate MR-safe mobility assistive devices are available to ensure the safe movement of the research participant in the magnet room. Such research participants should be asked whether or not they want to be accompanied by an adult monitor while they are in the scanner as part of routine study procedure. The monitor may be a researcher (faculty/staff/graduate student) who has completed safety training, is familiar with the use of the squeeze bulb, the use of the motorized scanner bed, and the manual release on the scanner bed. Should the adult monitor not be a researcher, they must complete a metal screening questionnaire with no contraindications for MR imaging; they may be required to wear appropriate exam attire (see above) and be familiarized with the use of the emergency squeeze bulb. The adult monitor must wear appropriate hearing protection at all times.

Principles of Magnetic Resonance Imaging

MRI is a highly flexible technique for producing detailed images of the human body. It works by using properties of the hydrogen nuclei (protons) found in every tissue of the body. Hydrogen nuclei behave like little magnets in that when they are exposed to a magnetic field they tend to line up in the direction of the magnetic field. When the protons are correctly excited they precess or rotate and in so doing give off a measurable signal that can be picked up in a nearby detector coil. The frequency of precession is proportional to the strength of the magnetic field, so by varying the magnetic field strength across the part of the body to be imaged, it is possible to identify signal emanating from different parts of the body based on their frequency.

To give rise to and measure these signals, an MRI scanner consists of three main parts:

1. A large magnetic field. In the case of the MRI scanner housed in MRIF, this is generated by a 3 Tesla superconducting magnet. Except in the cases of quench outlined below, the magnetic field is ***always present even when the power is off***.
2. Gradient coils that are pulsed on and off to produce linear gradients in the magnetic field to facilitate imaging.
3. A radio frequency (RF) transmitter, used to provide excitation to the hydrogen nuclei, and a receiver used to measure the signal emitted by these nuclei as they precess.

The gradient coils and RF transmitter are pulsed on and off over time by passing large electrical currents through them. This gives rise to the term pulse sequence which is used to describe the various ways in which magnetic resonance imaging may occur. Varying the order in which the gradients and RF pulses are applied over time gives rise to the huge number of different magnetic resonance imaging techniques. Since different tissue types may have slightly different properties that affect how they react to the magnetic fields and RF pulses, this also gives rise to the different contrasts between the various tissue types in an image.

One form of MRI imaging is functional MRI (fMRI). This is sensitive to the changes in oxygenation level of blood that accompany neural activation. When different regions of the brain are more active, they are provided with increased amounts of oxygen-rich blood to support neural activity. This inrush of oxygen-rich blood subtly changes the MR signal in the more oxygenated brain tissue in such a way as to make it possible to indirectly map changes in neural activation via blood oxygenation level dependent (BOLD) changes in the MR signal. A typical fMRI experiment consists of the acquisition of multiple while the subject alternates between performance of various task-related conditions. The data is processed offline to identify activation in brain regions that correlates with the various task conditions. A slight modification of this paradigm that removes the task component and images the brain at rest so as to identify resting-state associated patterns of activity has recently become very common.

A typical scanning session consists of at least three scan types:

1. A localizer (aka scout) scan. This consists of a series of images that are acquired in three perpendicular plains. The purpose of this scan is to choose from where the image data should be acquired during the rest of the experiment. This scan typically takes about 1 min to acquire.
2. A high resolution anatomical scan. This is typically used to permit localization of activation of the functional data that will be acquired later (among other uses). This scan usually captures the entire brain with a resolution of, for example, $1mm^3$ per voxel. These scans can take 6 – 8 mins to acquire, though this depends on factors such as voxel dimensions.
3. Rapid dynamic imaging sensitive to the BOLD signal. The most common of these scans is echo planar imaging (EPI) where it is possible to acquire an image of the whole brain in

approximately 2 seconds at a resolution of 3×3×3mm. Though newer imaging methods such as simultaneous multi-slice (SMS) EPI also known as multi-band (MB) EPI permit much finer acquisition resolutions.

In practice, a typical scanning session will consist of at least one localizer scan, at least one high resolution anatomical scan and multiple EPI scans and take approximately one hour or more. Other scans such as diffusion tensor imaging, typically used to map white matter in the brain, may be included as well.

Potential Risks and their Mitigation

Static Magnetic Field

Translational Forces

The most immediate danger of the main magnetic field is projectiles. Both small and large ferromagnetic items introduced into the scanner room pose a serious threat to the health and life of those in the room, as well as the potential to destroy millions of dollars-worth of equipment. All items that are brought into the scanner room for research studies must be checked with the ferromagnetic metal detector in the hallway (zone 2).

The intensity of the static magnetic field around an MR system varies, with respect to the distance from the scanner. This fringe-field of the MR system creates a spatial gradient magnetic field that increases in strength as you move closer to the scanner. The opening of the bore of the magnet is where (accessible) this force is the greatest.

The static magnetic field can affect ferromagnetic and conductive metal within a person's body as well. Vigilant metal screening procedures are vital to a safe MR environment. A ferromagnetic metal detector is provided as a secondary screening source but is not a substitute for a written and verbal metal screening questionnaire. In the research environment, the risk of scanning volunteers with implants strongly outweighs the benefits, and so no volunteer with an implant will be allowed to participate.

The safe fringe field for a person with a pacemaker is at the 5 Gauss line, or just inside the control room door. For this reason, no person with electronic devices either on or in their body may enter the control room (zone 3).

Rotational Forces

Rotational force, or torque, in a static magnetic field is the force exerted on an elongated ferromagnetic object, so that it aligns in the same direction as the static magnetic field. This force is the greatest at isocenter.

Lenz Forces

Lenz's Law states that the current induced in a circuit due to a change or a motion in a magnetic field is so directed as to oppose the change in flux and to exert a mechanical force opposing the motion. A non-ferromagnetic, conductive metal, like aluminum, will experience a pushing force that is the opposite of the scanner's magnetic field.

If you need to introduce a piece of non-ferromagnetic, metal equipment into the scanner room, such as an MR conditional fire extinguisher, or research equipment, move slowly into the scanner room. If you move quickly with a large item, you may "run into" the opposing force.

Biological Effects

Biological effects of the static magnetic field are caused by the static field interacting with fluid in the body. Dizziness and vertigo may be caused by the disruption of the flow potentials in the semicircular canals, which are the gyroscope of the body. This is resolved by moving slowly away from the magnet.

Magnetophosphenes in the eye can cause flashes of light as they move through the magnetic field.

The magneto hydrodynamic effect is a slight change in the cardiac output, caused by blood in the aorta flowing perpendicular to the magnetic field, which alters the conductivity in the heart. For this reason, ECG patterns will be altered in the magnet. This effect is not significant at the 3T field strength level.

Time-varying Magnetic Fields: The Gradient

Gradients in the magnetic field are created by coils of wire inside the magnet. The strength of the gradients is measured in terms of the change in the field strength per unit of distance. The rapid switching of these field gradients can cause peripheral nerve stimulation (PNS) as they induce a voltage in nerve tissue. This stimulation is the greatest at the furthest distance from isocenter within the bore and Echo Planar Imaging (EPI) sequences create the highest amount of PNS.

PNS is not dangerous, however, the FDA limits it when it is sufficient to produce severe discomfort or pain. All subjects are warned of PNS and told to notify researchers by using the alarm bell, if this becomes uncomfortable or painful.

As the gradients are turned on and off during a scan by switching the direction of large currents that flow through the wires inside the scanner, a force is exerted on the wires. The current oscillates at audible frequencies and the greater the current, the greater the sound; in the range of 126 – 131 dB on a 3T system (Foster et al., 2000; Hattori et al., 2007) during EPI sequences. The FDA has recommended that safe audible levels are no more than 99 dB(A) (US Food and Drug

Administration, 2014). Therefore, anyone in the magnet room while it is in operation is required to correctly wear earplugs.

Radiofrequency Fields (RF): Tissue Heating

In contrast to the main static magnetic field, radiofrequency (RF) pulses are only present during scanning. The RF field is greatest at isocenter and is negligible outside of the bore. RF energy is exchanged with the subject in order to create MR images. As these fields pass through the conductive tissues of the body they generate electrical currents that circulate within body tissues. The body tissues are resistive however, so that the circulating current loses energy to the body in the form of heat.

A powerful amplifier (43.2 kW peak power) (Siemens Healthcare, 2015b, p. 9 Technical data) generates this energy and scanner software limits the absorption rate in those being scanned. Entering the correct weight and height of a subject during registration will enable this software to correctly estimate the absorption rate for each sequence.

The effects of RF absorption are the heating of the tissue and the subject's ability to cool, through evaporation, convection, conduction and radiation. If the input is greater than the output you will get tissue heating. This can be expressed in terms of the specific absorption rate (SAR), which is the FDA limit for RF exposure and is primarily set to avoid warming of the subject.

According to the FDA (US Food and Drug Administration, 2014), the recommended SAR level for MR imaging are 4W/kg (whole body), 3.2W/Kg (head). If scanning in normal mode, the whole-body SAR is maintained at 2W/kg and at first level, 4 W/kg (IEC 60601-2-33:2010, 2010).

Each subject's weight must be entered accurately in the scanner control computer as it is an integral component of correct SAR calculation. ***This is a critical safety step***. Any subject whose weight cannot be accurately established cannot be scanner.

High risk subjects

Certain individuals are at much higher risk of problems from SAR. This includes, but is not limited to, subjects with diabetes, obesity, cardiovascular disease, reduced ability to perspire, hypertension, and old age. These subjects may become warm quicker than healthy subjects and may have reduced ability to disperse heat. These subjects will be carefully monitored for heating and comfort and may only be scanned with explicit IRB approval.

Radiofrequency Fields (RF): Metal in the Bore

There is potential for thermal injury from excessive RF power deposited as a result of conductive metal in the bore heating. MR Conditional equipment used in MRI Research must be carefully placed.

In order to avoid creating large loops with conductive material, we will:

- Maintain sufficient distance between any wires or cables and the subject's skin by using padding
- Make sure that cables are run in straight lines to avoid crossing or looping.
- Make sure that cables are run parallel to the magnetic field.
- Make sure that cables from different components, such as ECG, RF and EEG are kept separated.

Radiofrequency Fields (RF): Proximity Burns

Proximity burns are burns where focused RF energy is deposited on areas of skin that are touching the bore of the magnet. To eliminate the possibility of proximity burns, pads will be used to ensure that the subject's tissues do not directly come into contact with the inner bore of the magnet during the MR imaging process.

Pads are provided for this purpose. It is also important that the patient's own tissues do not form large conductive loops.

RF burns can be caused where very small areas of skin-to-skin contact take place, usually medial calves barely touching, lateral thigh where fingers barely touch and also heels barely touching. These areas create large loops in the body and energy focuses through the loop and when skin is barely touching, the elevated energy is deposited in a very small area, as opposed to being dispersed into a large area.

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 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 subjects not to touch their thighs, calves or heels in the MR scanner. To help mitigate the possibility of these burns, we will use scrubs to reduce skin-to-skin contact and use cushions to skin to bore contact.

Tattoos

While all tattoos are not contraindicated, questions regarding the type of tattoo ink used during the screening process is warranted. Many different kinds of metal oxides exist that are used in tattoo ink. Creating a heat sink in the form of an ice pack on tattoos mitigates tissue heating. However, we will not scan volunteers with glow in the dark tattoos, as this is the most reactive ink.

THERMAL CONTROL

The condition of the air within MR Magnet room will affect the rate of cooling of the subject. Subject scanning will be performed when the room temperature is below 72°F/22°C and the relative humidity is between 40% and 60% to ensure excessive heating does not occur (Siemens Healthcare, 2015b, p. 24 Technical Data) Thermostats for the control room and the magnet (or exam) room in addition to a hygrometer are located on the wall to the right as you enter the control room. They are shown in Figure 2.

Blankets will be provided to subjects who are cold. However, the MR Technologist will explain that they should squeeze the alarm bell if they become too warm. The MR Operator will stay in verbal contact with them in between series over the intercom to ensure that they are not becoming too warm.

FIGURE 2 HYGROMETER (LEFT) AND THERMOSTATS (RIGHT).

Devices

Any behavioral, physiological or other equipment to be brought into the magnet room must be screened for MR compatibility. The device must bear a tag indicating its compatibility. If deemed MR compatible, any subsequent modifications to the device necessitate rescreening of the device. All such devices must be brought into and be positioned in the magnet room **BEFORE** the subject is allowed to enter the magnet room. To arrange screening of a device for MR compatibility, please email mri-facility@fsu.edu.

Simultaneous fMRI and EEG

The MRIF is equipped with an MRI compatible EEG system from Brain Products. The system consists of (among other items) MR-conditional in-bore amplifiers, and MR-conditional 64-channel EEG caps. The EEG system is only certified by the manufacturer to be compatible with certain types of MRI scans, specifically, GRE-EPI, MPRAGE, and localizers. When performing simultaneous MRI-EEG measurement, only MRI scans that are compatible with the EEG system according to the manufacturer are permitted.

Incident Reporting

It is the responsibility of all MRI personnel to report all near-events and adverse events to the MRI Technologist, even if there is no injury to personnel or damage to equipment. All such incidents must be logged using the form provided at here.

Visitors

Visitors are not permitted in the magnet room. Visitors may only enter the control room if they have completed a metal screening questionnaire and their screening questionnaire indicated no contraindications for MR imaging.

Contact with Bodily Fluids

Universal Precautions begin with the assumption that all human research participants can harbor potentially infectious agents. Where contact with bodily fluids is possible, Universal Precautions as documented in the FSU College of Medicine Faculty Handbook (Collins, 2016) and in the FSU Safety Manual must be followed. A brief summary of universal precautions can be found in the appendix of this document.

The MRIF does not provide personal protective equipment (PEP) or sharps disposal. It is the responsibility of individual PIs to provide any necessary PEP and sharps disposal containers required by their research project. Disposal of all PEP and sharps, and where necessary bodily fluids, must be performed in accordance with applicable environment health and safety

guidelines. It is the responsibility of individual PIs to ensure that members of their research staff receive appropriate training in the collection, management and disposal of bodily fluids.

In the event of a bodily fluid spill if you are not trained or need assistance, FSU Environmental Health and Safety can be contacted at 850-644-5374, 850-644-6895, or FSUPD after hours at 850-644-1234.

More information can be found in the FSU Safety Manual.

EMERGENCY PROCEDURES

Emergency procedures are posted in the control room of the MRIF. They will be reviewed and updated annually by the Safety Committee and must be incorporated into Safety Training for all MRIF Researchers and MR personnel.

The major risk in the facility is related to individuals entering the MRI facility who are unfamiliar with the MRI environment and its hazards. MR Personnel/Researchers working in the facility will be constantly vigilant of who is entering the control room and magnet room. Especially in emergency situations, MR Personnel/Researchers will ensure that no one without proper training or screening enters the Magnet Room of MRIF and that those individuals who do enter have removed all ferrous material from their persons.

Two MR personnel are required when performing an experiment.

During imaging activities involving research participants, there will be at least two MR Personnel/Researchers present whenever a participant is in the Magnet Room. This policy is in place to facilitate expeditious responses to emergencies.

EMERGENCY TRAINING

ALL personnel who use MRIF must have up-to-date safety training as specified in the requirements for MR personnel. This includes basic safety training for personnel and researchers who use facilities at MRIF. These individuals must also be fully aware of the current procedures for both medical emergencies and facility emergencies.

FIRST AID KIT

MRIF is equipped with a First Aid kit, which is located in the control room. ***Note that the First Aid Kit itself and its contents are not MR-safe. The kit must not be brought into the magnet room.***

FIRE EXTINGUISHER

As part of the Zone 3 and Zone 4 restrictions, MRIF has readily accessible, clearly marked, MR-conditional fire extinguisher available. Additionally, there is a smoke detector system and a sprinkler system that will be automatically activated in case of smoke or fire, respectively. The fire evacuation plan is posted above the fire extinguisher and in the Safety Training presentation.

Emergency Procedures (as posted beside scanner console).

*****In Case of Emergency, Call 911*****

Physical Location:

Suite G0135, Medical School Research Bldg. (#4002)
College of Medicine
Florida State University
1115 West Call St.
Tallahassee, FL 32306-4300

FIRE EMERGENCY

If there is a fire or an equipment failure such as sparking wires or signs of smoke.

1. Stop the scanner
2. Press the **Emergency Power Off** (**EPO) button** (shown in Figure 3)
3. Remove the subject from the area
4. Alert 911
5. Extinguish (only if safe)
6. CLOSE SCANNER ROOM DOOR.
7. Ensure all MR Personnel are out of the building and accounted for at the assigned meeting location. (See the Fire Evacuation Plan located above fire extinguisher).
8. Wait for EMS to arrive.

MEDICAL EMERGENCY

In case of a medical emergency

1. Stop the scanner
2. Remove subject from the scanner room
3. Call 911
4. CLOSE THE SCANNER ROOM DOOR
5. Provide immediate care to subject
6. Wait for EMS to arrive.

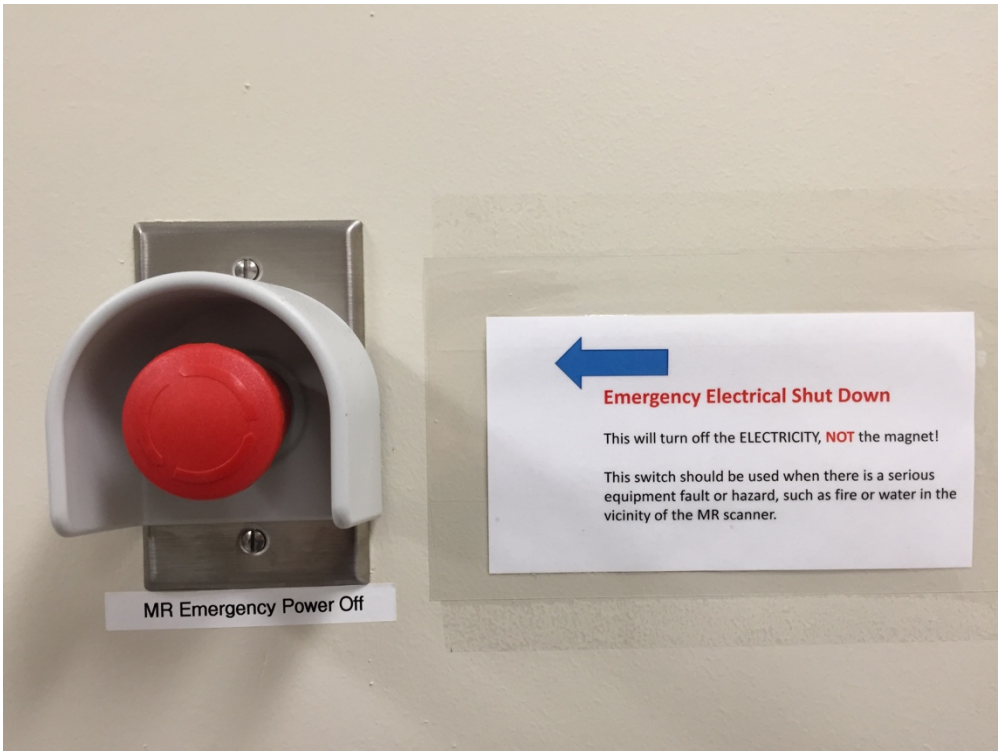

FIGURE 3 THE EMERGENCY POWER OFF BUTTON IN THE CONTROL ROOM.

MRI MAGNET

A quench is when the cryogens (liquid helium) are rapidly released, or "boiled off" from the magnet through a vent into the outside air. A quench can occur spontaneously but usually occurs when the cryogens are being topped off. A quench can be done manually in the case of an emergency. This will render the MRI Scanner inoperable and it is very expensive to ramp up (refill the cryogens and recalibrate) the magnet.

There are **ONLY 2** situations requiring a quench:

1. If there is a fire in the magnet room that cannot be put our using a non-magnetic fire extinguisher and requires the assistance of the fire department.
2. If any individual is pinned to the magnet, trapped or in a life-threatening situation by a non-removable ferrous object.

EMERGENCY QUENCH PROCEDURE

1. Evacuate the magnet room but leave the door open.
2. Depress one of the **Magnet Stop buttons**. One is inside the magnet room and one is in the control room. The magnet stop button in the control room is shown in Figure 4.
3. An alarm will sound and the Magnet Stop button will light up.
4. Do not touch the helium ducts in the magnet room.

5. Police, fire, and other emergency personnel should be restricted from entering the room with their axes, oxygen tanks, etc., until it can be confirmed that the magnetic field has dissipated.

NOTE: In the absence of a major emergency, facility users should ***never*** quench the magnet by themselves.

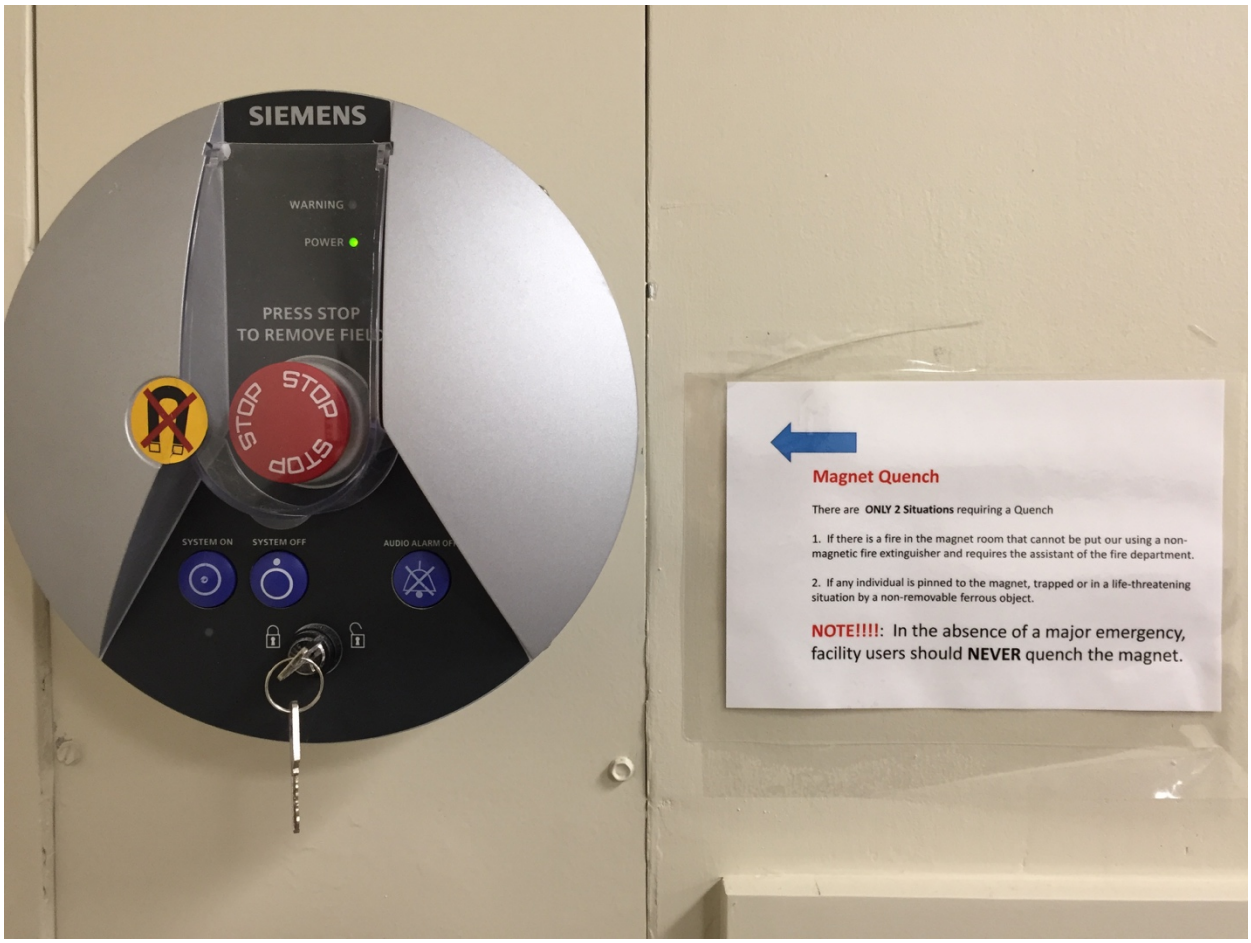

FIGURE 4 THE EMERGENCY MAGNET QUENCH/STOP BUTTON IN THE CONTROL ROOM.

SPONTANEOUS QUENCH PROCEDURE

A sudden appearance of white clouds or fog around or above the MRI scanner indicates that cryogenic gases have vented partially or completely in the magnet room.

1. In the event of a spontaneous system quench, it is imperative that all personnel, research participants, and subjects be evacuated from the magnet room, as quickly and safely as is feasible.
2. If anyone is in the magnet room while a quench occurs, OPEN the magnet room door immediately for ventilation or the participant has the potential to suffocate. If you cannot open the door, break the window to vent the room.

3. Do not touch the helium ducts in the magnet room.
4. Staff should turn of power to the scanner using the **EPO** button (shown in Figure 3).
5. There may also still be a considerable residual static magnetic field despite a quench or partial quench of the magnet.
6. Site access should be immediately restricted until the arrival of Siemens equipment service personnel.

EMERGENCY ELECTRICAL SHUT DOWN

An emergency electrical shut down is different from a quench because it only turns the power off. It does **NOT** turn the magnet off.

Emergency electrical shut down procedure

1. There are three electrical power off buttons, one inside the magnet room, one is in the control room (shown in Figure 3) and one is in the equipment room. Make sure that it is the power shutdown button but be careful NOT to inadvertently depress the quench button. You can tell the difference because the electrical power off buttons are uncovered; the quench buttons are covered (as shown in Figure 4).
2. Press the Table stop button.
3. Manually release the table bed and remove the volunteer from the scanner.

POWER OUTAGE PROCEDURES

If the power goes out while a subject is in the scanner, use the manual table release to remove them from the magnet.

MAGNET ROOM DOOR FAILURE

In the event of a power failure or a failure of the pneumatic system in the magnet room door, it may be necessary to press the emergency door open button. Buttons are located in the magnet room and in the control room. The buttons are next to the door and clearly labeled as in Figure 5.

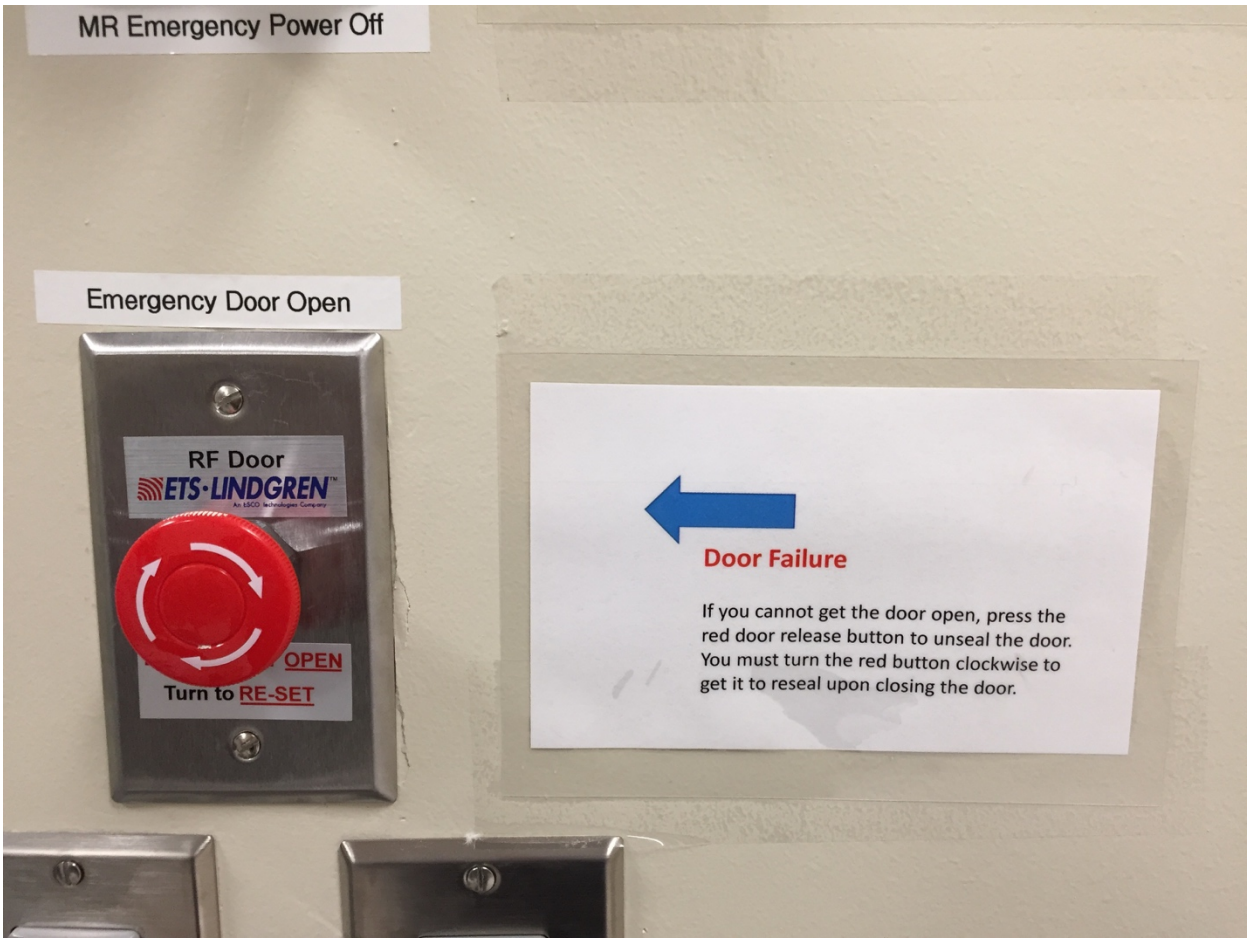

FIGURE 5 EMERGENCY MAGNET ROOM DOOR OPEN BUTTON IN THE CONTROL ROOM.

FIRE EVACUATION ROUTE

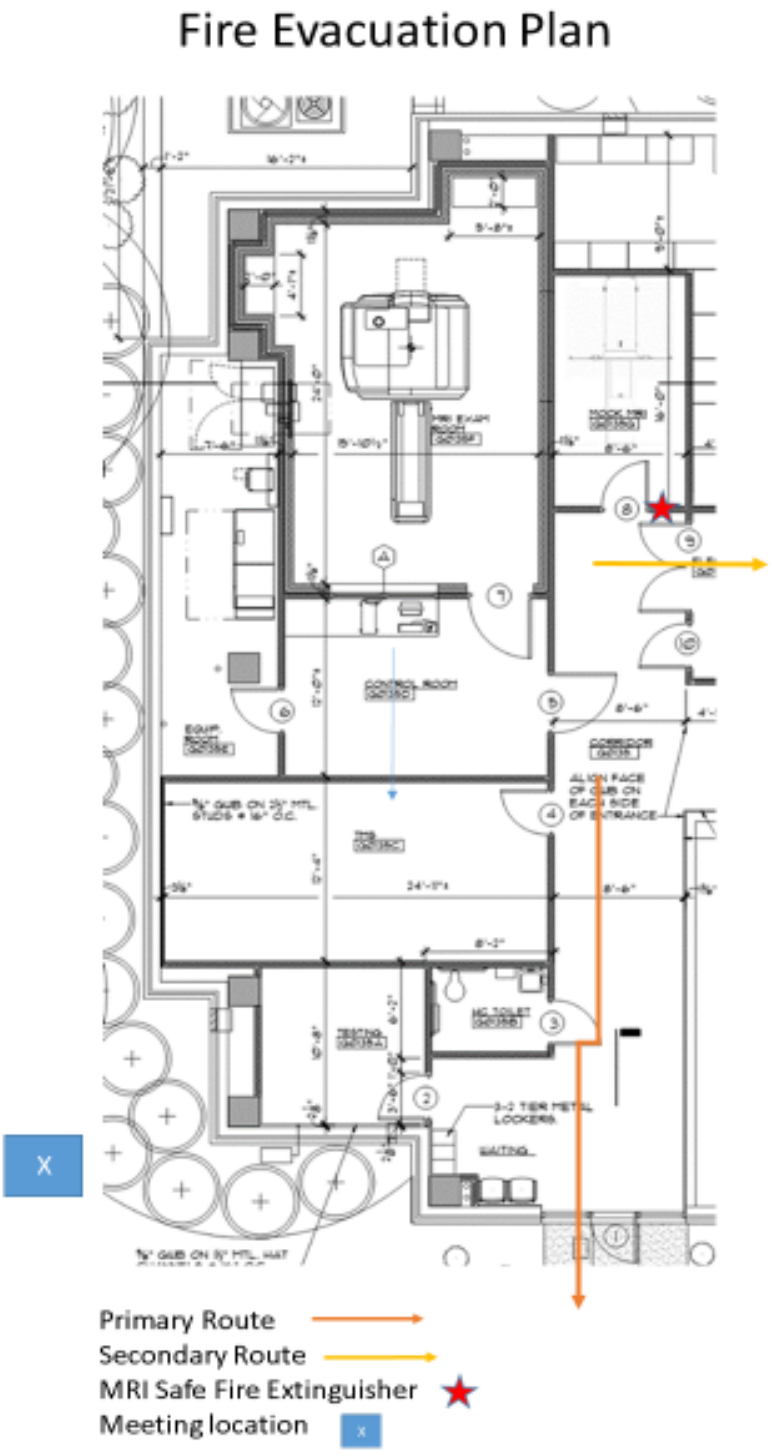

FIGURE 6 EVACUATION ROUTES.

APPENDIX

The following description of Universal Precautions is take from the FSU College of Medicine Faculty Handbook p. 87.

When providing patient care, regardless of the real or perceived communicable disease status of the patient, all students and staff should follow standard universal precautions:

- Wash hands before and after patient contact, according to hospital policy, even if gloves are used
- Wear gloves when exposure to blood, body fluids, excretions or secretions is likely.
- Use gloves appropriately according to aseptic and/or sterile techniques and change gloves between patients.
- Wear gowns/aprons when soiling of clothing with blood or body fluids is likely.
- Wear masks, face shields and eye protection when aerosolization of blood or body fluids may occur.
- Dispose of sharps in designated rigid sharp containers. Never recap by hand.
- Dispose of waste saturated with blood or body fluids in designated red-bag trash containers.

See also the FSU Safety Manual section on universal precautions.

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