UM Center for Brain Imaging Research (CBIR)

MR Safety Manual

www.mdbrain.org

SAFETY TRAINING

Access to the imaging center:

MR Operator: This individual has passed MRI safety and equipment training to ensure the safety of those who are present during activities in the MRI center. He or she can review and approve or disapprove for participant metal screening. They receive in-depth equipment training and knowledge of emergency procedures and are approved for independent operation of the 3T MRI system by the Center MR physicist.

User: Researchers and research team staff who have passed safety and basic equipment training. They are trained on safety during research-related activities within the MRI center. Those researchers involved with human participants will also have completed the human subject-training regimen (CITI). Approved MRI users can enter the MR suite unescorted, but cannot escort participants or visitors into the magnet room without the explicit approval of an MR operator. All users should complete annual refresher training on MR safety.

Research Participant: These are individuals who have enrolled and who have provided informed, written consent to participate in approved research protocols involving MRI, and have passed the initial MR metal screen conducted by the research team. A research participant must complete a MR metal screen on the day of MRI, with the form signed off by a MR Operator before entering the scanner room.

Visitor: These individuals who are not a research participants or MRI-users. These visitors may have access to the facility on a pre–approved basis. MR metal screen has to be filled out and approved by MR Operator.

TRAINING REQUIREMENTS

MRI Safety Training:

All personnel planning to enter the fMRI suite for the purposes of conducting research must complete Basic MRI Safety Training.

Basic MRI Safety training will be done on-site by staff and consists of a presentation that includes viewing of a Siemens safety video. This format will give individuals a chance to ask questions and get answers to any concerns that they might have.

Initial training also includes a familiarization with the facility.

Once initial training is complete, annual refresher courses may be done entirely on-line. The Center's physicist will maintain a log of currency in safety training for all MRI users.

Individuals seeking to become MRI-Operators must complete an Advanced Safety Training course. This is a more detailed coverage of safety procedures, human subject screening procedures and emergency procedures.

Emergency Procedures Training: MRI-Operators will receive instruction the Center's physicist in procedures related to emergency situations involving medical emergencies or those presenting an immediate threat to human life or to the facility infrastructure. This training is recommended, but not required for users.

MRI system operations:
MRI operator will conduct MRI system operation and related training. Operation of the MRI system will be conferred by the Physicist and the Director upon the determination of competency. The training will involve onsite observation and supervised practice in the operational procedures of the MRI system, and safety and emergency protocols. Anyone certified to operate the MRI system must also have received Emergency Procedures Training. Additional ad hoc training may occur due to newly developed safety guidelines.

TRAINING PROGRAM CONTENTS

Basic Safety Training

• Watch MR safety video
• Site specific orientation
• Emergency evacuation plan
• De-metaling
• Hearing protection

Emergency procedures

• Location and use of Emergency Power Shutdown buttons
• Location and use of Magnet Stop buttons
Any other problems not related to scanner….Water/pipes/electricity
• Medical Emergency procedure
• Quench procedure

Scanner Operations Training

• Human subject screening procedures
• Human subject preparation
Squeeze ball
• Patient table controls
• Minimum 6 hours of shadowing personnel performing magnet operations
• System start-up and shut-down procedure
• Routine scanning

• New human subject registration
• Protocol selection
• Prescription
• Measurement (scanning)
• Data archival and retrieval
• Logging
• Human subject monitoring (intercom) system
• Oxygen sensor location
• Coil handling and storage
• Linens storage and use
• Knowledge to access data on cryogen levels
• Knowledge of SAR and stimulation warnings
• Phantom placement and scanning
• Orientation for non-Research Personnel
• Basic familiarity with the hazards associated with the magnetic field, missile effect
• Location and meaning of magnetic field
• Instruction to attend to and obey all posted signs

EMERGENCY PROCEDURES

MEDICAL EMERGENCIES

• In case of emergency, the MRI-operator will instruct the second individual, who is required to be present for all human studies, to dial extension 7555 (Spring Grove Emergency) to report the nature of the emergency along with the location to the response team.

• 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 human subject immediately from the magnet room and transport her/him to the waiting area or nursing room, where the emergency will be handled by the medical response team.

• The magnet room door shall be closed upon removal of the human subject to avoid entry of any metallic objects.

• 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 and provided to the principal investigator, who decides when to file with the IRB according to the respective IRB protocol. The center Director and Physicist should be notified immediately via telephone.

FIRE EMERGENCIES

If an electrical fire were to occur in any of fMRI Suites (including control, magnet, equipment room, waiting room or offices), one nonferrous water mist fire extinguisher is located within magnet room to contain the fire. Personnel are not required to fight fires and should evacuate the building immediately in the event of a fire.

• The MRI operator shall immediately remove the human subject from the magnet room. All personnel should evacuate the building according to the building evacuation plan, in a calm manner.

• Disconnect electrical power to the MRI system by pressing the emergency SHUTDOWN button.
• If the fire occurs in the magnet room, the fire shall be extinguished using a non-ferrous fire extinguisher (the fire extinguisher near the control room is non-ferrous).

• If the fire is not extinguished after emptying the available extinguisher, or jeopardizes the safety of personnel, the magnetic field must be removed by pressing the MAGNET STOP button on the Emergency Rundown Unit.

• All personnel, including firefighters, must be screened for entry into magnet room until magnetic field area is less than 5 Gauss.

• All doors shall be closed to contain the fire.

• Extension7555 (Spring Grove Emergency) or 911 shall be dialed identifying the type and location of fire.

• Do not reenter the building until granted permission by the Fire Department.

QUENCH

The MRI magnet is maintained at high field strength by means of super-cooling its conductive loops of wire with liquid helium, which is at an extremely low temperature – close to absolute zero. In certain circumstances, this helium may be rapidly vented off, warming the magnet and causing it to quickly lose its magnetic field either intentionally or unintentionally. This is known as a "quench." A quench may be released by pressing the magnet's "Emergency RUNDOWN" switch (the one with a red "do not touch" label). This is referred to a "controlled quench". Another source for quenching is a helium fill level that decreases to a point (about 30%) where the magnet begins to warm up. This is known as an "uncontrolled quench". In rare instances, a spontaneous quench may be observed that cannot be explained by the presence of obvious external sources.

Intentional or Controlled Quench:
A controlled **quench** should only be initiated by authorized personnel in the event of a potentially life-threatening emergency, such as an individual in respiratory distress being pinned to the magnet by a metallic object. A quench of the magnet is extremely expensive and has the potential to damage the equipment. An intentional quench is performed in an extreme emergency to rapidly run the magnetic field to zero. A quench of the magnet should only be performed when:

a) A person is pinned to the magnet and is unable to free themselves without harm.

b) There is a fire in the MRI scanner, equipment, or console room.

c) There is a fire in another area that is a threat to the MRI Suite

In non-life threatening situations, such as a piece of equipment being pinned against the magnet, no one should initiate a quench. If a metal object traps a human

subject in the magnet bore so that removal is not possible without quenching the magnet, or if it is determined that a potentially life-threatening situation exists, the operator or his designee should press one of the two Magnet Rundown buttons.

a) The magnetic field will dissipate in approximately one minute.

b) Use the intercom to ***alert the human subject to stay calm and remain on the table*** until the operator gains access to the room to offer assistance.

c) If the quench was initiated because of a medical emergency, the procedures listed above under **Medical Emergencies should be followed**.

d) After ensuring that the magnet and equipment rooms are secure and that all individuals have exited these areas, ***inform the Director, the Physicist, and notify Siemens of quench.***

e) Secure magnet room door. The MR operator is responsible for ensuring that no one enters the magnet room without proper screening for MRI safety. Note that even in the event of a quench, a significant magnetic field may remain for some period of time.

f) After a quench, the usual service procedure goes into effect (please refer to the Siemens System Manual located in the cabinet in the control room). Siemens Customer Service is to put the system back into operation as quickly as possible.

g) MR operation to file an incident report for record reviewed and commented by physicist and/or director. If a research participant is involved inside the magnet room during the event, regardless of cause and outcome, the research team should file reportable new information (RNI) or other appropriate report through the respective IRB protocol.

Uncontrolled Quench (or spontaneous quench):
It is possible, but highly unlikely, that a spontaneous quench of a magnet could be caused by an accident (electrical malfunction, earthquake, etc.). If a spontaneous quench occurs, remove the human subject immediately, following the same procedure as a user-induced quench.

EMERGENCY SHUTDOWN

The **Emergency SHUTDOWN** button is located on the wall in the MRI magnet room and on the operator's console. It removes ALL electrical power from the MRI console, the console computers and the patient table, including any power sources from the Uninterrupted Power Supply (UPS) devices.

Pushing the **Emergency SHUTDOWN** button turns off the entire MRI system EXCEPT for the static magnetic field and the MAGNET RUNDOWN unit (described below).

Pushing the **Emergency SHUTDOWN** DOES NOT PRODUCE A QUENCH. It does not turn off the lights. Also, power to the stimulation equipment will not be interrupted, so be aware that electrical or fire hazards may still be present.

The button should be used ONLY TO STOP A SCAN DURING A HUMAN SUBJECT EMERGENCY or DURING A SERIOUS EQUIPMENT FAULT OR HAZARD, such as fire or water in the vicinity of the MR equipment.

EMERGENCY MAGNET RUNDOWN

The device for an **Emergency Rundown** allows for the rapid reduction of the magnetic field in about two minutes. It will also boil-off cryogens and therefore, unlike the **Emergency SHUTDOWN** button, this button **WILL PRODUCE A QUENCH**. The button is located inside the magnet room on the left wall adjacent to the door. **Only the MRI Physicist or Director of the Imaging Center is authorized to trigger the rundown UNLESS A HUMAN LIFE IS AT RISK (i.e. do not quench the magnet if a piece of furniture or equipment got into the bore. Such objects can be safely removed by calling a Siemens' service engineer who will 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 human subject is imminent.

PROCEDURE FOR POWER FAILURE

There is no back-up power to the scanner. In the event of a power failure, if an MRI study is in progress, enter the magnet room and remove the human subject from the bore manually. Simply pull the patient table out of the bore. Once human subject safety is secured and escorted out of the magnet room, the MRI operator will return to the magnet room and control room and properly shut down all of the computers (including those receiving power from UPS), thus preventing corruption of the software on the MRI scanner. When power returns, the system should self-start.

GENERAL SAFETY PROCEDURES IN THE IMAGING CENTER

a) All individuals must undergo screening for metallic objects (which may include items with a magnetic strips like bank /credit cards) and complete the appropriate screening

form as part of the inclusion/exclusion checklist during the consent process, and signed off by the principal investigator or his/her designee.

b) All research participants and visiting staff who do not use the scanner room on regular basis must complete metal screen form on the day of entering the magnet room and receive approval by the MR operator before entering.

c) All individuals with critically implanted magnetic objects (i.e., aneurysm clips, pacemakers etc.) will not be allowed in the room.

d) All human subjects must be supervised at all times while in the MRI suite. All human subjects will remain in view of the technical personnel via direct eye contact while the MRI scan is in progress.

e) No human research will be performed within CBIR without prior approval of the UMB IRB. Investigators and research and MRI staff must ensure that each participant has signed an IRB-approved informed consent form before entering the magnet room.

f) When the MRI scan is in progress, human subjects will be given a signaling device to hold so that he or she can alert the MR Operator of any discomfort or in case of an emergency.

g) When scanning a research participant, another person must be in the control room in addition to the operator.

MRI-SPECIFIC RISKS

The risks of MRI scanning can be classified into one of four categories; those associated with a) Acoustic Noise Levels, b) Gradient or Time-varying Magnetic Fields, c) Radiofrequency (RF) Magnetic Fields, and d) Static Magnetic Fields. Following the established safety procedures, none by themselves should be above minimal risk for research protocols.

a) Acoustic Noise

The acoustic noise associated with MRI imaging is related to the mechanical movement of the gradient coils during the scanning process.

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 human subject." 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 dB and that the protection should be able to reduce noise levels to below 99 dB.

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. Our system could produce higher noise levels.

Ensuring Safety from Acoustic Noise: We take steps to reduce the noise levels experienced by human subjects, accomplished by one of two methods: use of disposable earplugs and/or acoustically shielded headsets

b) Peripheral Nerve Stimulation
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'. In very rare instances, this nerve stimulation can be painful. Nerve stimulation is particularly likely when human subjects are physically positioned in a way that increases the likelihood of inducing stimulation, such as with hands clasped or arms 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.

FDA Guidelines: 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.

Summary of Risks: 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.

Ensuring Safety from Peripheral Nerve Stimulation

i. All consent forms for studies that might induce peripheral nerve stimulation will provide this information.

ii. 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 human subjects.

iii. 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.

iv. Before any scanning procedure that might stimulate peripheral nerves, an operator will inform the human subject that peripheral nerve stimulation may occur. Describe the nature of the sensation to the human subject. Instruct human subjects not to clasp their hands, since this may create a conductive loop which will increase the possibility of stimulation. Instruct human subjects to inform the MR operator if they experience discomfort or pain. Terminate the scan if the human subject complains of more than mild discomfort or pain.

v. 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 provide this to the study PI for submitting to the IRB and also report to a MRI Safety Officer immediately.

c) Tissue Heating

MRI scanning induces some heating of body tissues. This 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 human subject’s head) per unit volume of tissue per unit time. 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.

FDA Guidelines: "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℃ and localized heating to greater than 38℃ in the head, 39℃ in the trunk and 40℃ 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 human 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.

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.

d) Static Magnetic Fields

The possible risks of static magnetic fields have received much attention in the lay press, but scientific consensus on these risks has yet to be fully reached. The FDA has deemed that systems operating at 8.0 Tesla or less do not pose a significant risk. Moreover, experience with thousands of clinical studies over the past decade, and with multiple human investigations carried out at higher field strengths over this period, have not revealed risks of exposure to higher static magnetic fields. The most significant risk associated with static magnetic fields is that ferromagnetic objects, such as aneurysm clips or heart valves, can interact with the magnetic field of an MRI scanner, causing the device to malfunction or to move, and injuring the human subject.

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

FDA Guidelines: “Studies conducted at 8T or less are not considered significant risk" (FDA Center for Devices and Radiological Health, memorandum 7-14-03).

Summary of Risks: This category of risk applies to work conducted around superconducting magnets of any kind (including standard clinical diagnostic MRI units). It is not unique to our 3.0 Tesla facility. The MRI facility will maintain a safety policy to safeguard human subjects and staff members from these incidental risks. Systems with static magnetic field less than 8 Tesla have been considered to represent a non-significant risk (NSR) by the FDA. The static magnetic field of our system (3.0 Tesla) is therefore to be classified as posing NSR to human subjects.

Ensuring Safety from Static Magnetic Field Risks 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:

i. Assure the security of the restricted access area. Entrance doors to the MRI room should be kept closed at all times. Access to the MRI suite will be tightly controlled, allowing access for only personnel and human subjects who have legitimate reason to be there.

ii. 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.

iii. The MRI operator will conduct careful screening of potential human subjects before they enter the magnet room.

e) Incidental Risks
The physical confinement and isolation produced by the scanner could cause distress, although in our extensive past experience, human subjects generally tolerated the procedures well. All human subjects will be able to communicate directly with the operators to inform them of any emotional or physical distress during the scanning procedure. If they wish, the scan will be terminated immediately and the human subject will be removed from the scanner.

f) Ensuring Documents Safety
Training Records: maintains safety and compliance training records for all personnel and users. The Imaging Center Manager and the MR operator manage these records and maintain documentation of proficiency testing and copies of certification for MRI Operators.

Screening Forms: The initial safety screening forms for human subjects are kept on file by the PI overseeing the study. A copy of the screen form or a newly filled out form on the day of scanning will be signed off and kept on file by the MRI operator.

Pregnant subjects – Pregnant will be excluded from participating in MRI protocols.

Consent Forms: Signed consent forms for each human subject involved in a study are maintained by the PI in accordance with IRB requirements.

Data: The naming convention for all imaging studies will not contain any personal identifying information. The imaging files contain a NID and the date and time of the scan. It is the jurisdiction and responsibility of the PI to keep their human subject volunteer information protected and confidential. PIs will retain copies of their own volunteer's signed informed consents and assents, MRI prescreening, and any other documentation related to participation in their study. Once imaging data has been shared with the PI, it becomes their jurisdiction and responsibility to maintain and use the data in a confidential and appropriate manner.

Administrative Data Logs: The following logs are kept by the MRI Operator and Imaging Center Manager:

i. Quality assurance data.
ii. Weekly temperature and humidity readings for the scanner and equipment rooms.
iii. Weekly cryogen readings.
iv. Scanner and equipment room filter change dates.
v. Scanner communication log with Siemens for maintenance and scanner errors.
vi. IP addresses, port numbers, application entry titles.

Usage Logs: Accurate records regarding use of the scanner are required for proper billing and reporting to federal funding agencies. When using the scanner, MRI Operators must record the following information

i. Date.
ii. NID and subject name
iii. Protocol ID or nickname.
iv. PI
v. Start and end time of scanner use.

SPECIFIC HAZARDS WITHIN THE IMAGING CENTER

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.

Critically, 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 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), and non-magnetic safety shoes

FIRE HAZARDS

Fire with Operators On-Site:
a) The MR Operator needs to know all of the fire emergency related procedures, including a human subject evacuation plan, and its proper execution.
b) If the situation is life-threatening, the MR Operator can quench the magnet.
c) In the event of a fire requiring outside response, the magnet can be quenched if ferromagnetic equipment must enter the MRI magnet room. MR Operator will control entry to the magnet room until the magnetic field is less than 5 Gauss.

Fire During Off Hours or No Operators On-Site:
a) Contact the Director, the Deputy Director, the Imaging Center Manager, or a MR operator immediately. These phone and cell numbers are at the front of this manual. Contact numbers for emergencies will also be posted in central location for quick reference.
b) Once contacted, they will instruct fire-fighting 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.

INFECTION CONTROL PROCEDURES FOR HUMAN STUDIES

a) Frequent hand washing.
b) The MRI table and head rest must be covered using exam paper sheets or linen. Sheets must be discarded or linens must be changed after each human subject.
c) All contaminated products must be discarded in proper bin.
d) The magnet room table and headrest must be wiped with a disinfectant wipe at the end of the day

SAFETY PROCEDURES INVOLVING CONTRAST AGENTS

IRB approval, consent form indicating for use, recommended dose levels, warnings, and contraindications, which are identified on the product inserts. Contrast agents can only be administered by a physician or a nurse under the direction of a specific physician.

SAFETY PROCEDURES INVOLVING CHILDREN SUBJECTS

a) Specific IRB approval and consent form, and if age 12-18, an assent form.
b) The child must be accompanied by a parent or an adult representative.
c) More careful consenting and explanation of MRI scans will be performed when subjects are children.
d) Children must be accompanied at all time and will not be allowed to move freely in the control room and magnet room.

SAFETY OF SECURITY PERSONNEL

a) Security staff will have access to the magnet room within the Center only under the supervision of the staff.
b) In the event of an emergency, the Security Officer will have on file a telephone number for the Center's Director, Deputy Director, MRI Physics Manager, or one of our emergency contact faculty. 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

INCIDENT REPORTS

It is the duty of any imaging center staff to report all violations of safety procedure and/or accidents. The MRI Operator will document any of the following incidents in writing. This includes:
a) Incidents in which any person was injured.
b) Incidents requiring the emergency quench of the magnet.
c) Incidents involving damage or potential damage to MRI and ancillary equipment.
d) Conditions that constitute a safety hazard.
e) Incidents in which an approved protocol was not followed, therefore causing an unsafe condition.

SUMMARY OF SOME KEY SAFETY GUIDELINES

1. Certification

• The physicist is responsible to train and certify all console operators as qualified MR Operator, including safety courses.
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• Research users who are not operators, but are essential to the running of a research study may enter the magnet room, if they have successfully completed the required safety training (including any refreshing course).

2. Human Subject Policies

• Safety of the research volunteers is EVERYONE’s responsibility. Everyone in the MRI suite, including imaging center staff, NRP staff, any research PI and project staff has the responsibility to ensure safety of our participants.

• The MR Operator running the console has the authority to enforce safety standards. If he/she runs a human subject, the operation must be supervised by at least one Center staff.

• No one may enter MRI suite without approval and supervision from a research staff or an imaging center staff. In the absence of a research staff, a participant should in

principle wait at the Tawes Building Lobby. A participant should be accompanied by a research staff at the MRI suite.

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• No one may enter magnet room without the supervision of a MR operator or a trained staff member.

• Anybody working within the magnetic environment must be screened for metal safety risks prior to entering the magnetic field. This includes individuals who may be accompanying a human subject. For research participants, the screening must be approved prior to each time a subject enters magnet room.

• Individuals who screen positive for implanted or attached medical devices must not be allowed into the magnet room unless prior approval is obtained from a MR Safety Officers, who reserve the right to request for more medical information before a decision is made. Only after the device is identified, documentation of its MR compatibility and safety is secured, will they be permitted into magneto room.

• The Center staff must review and/or test the safety of any behavioral or physiological devices entering the magnet room. Tested devices must be positioned in the scan room BEFORE any human subjects are in the vicinity of the magnet or positioned on magnet table.

• Special care will be given to positioning of any wires attached to the device. Wires must not touch the research subject. Wires should be kept straight and not contain loops.

• Visitors are not permitted inside the magnet room without permission of a MR Safety Officer. All visitors must be supervised by staff.

3. Emergencies

Medical Emergency: In case of a human subject with a medical emergency including illness or injury: 1) The human subject must be assisted out of the magnet room. 2) Operator dials 7555 or 9-1-1 for assistance.

Emergency Stop: If there is an emergency such as an equipment failure that could cause injury; sparking of equipment or a fire, the MR operator or research staff must immediately perform an Emergency SHUTDOWN.

Magnet Emergency: If a human subject is restrained or pinned by a ferrous object to the magnet:

a) Assess if the situation is life threatening. If YES, an MAGNET RUNDOWN to quench magnet can be performed by an authorized personnel.

b) If a human subject is restrained by a ferrous object to the magnet and is NOT in a life threatening situation, call Siemens engineer for assistance to determine the optimal way of releasing the human subject from the magnetic field. If a quench is necessary proceed as above.

c) Report the incident as an accident after procedure.

Emergency Quench: A quench includes the rapid release of cryogens and results in the loss or significant decrease of the magnetic field. A quench should ONLY be performed by authorized personnel in dire emergency that involves a serious personal injury or life threatening situation.

Note: In the event of extraordinary circumstances (such as an earthquake or explosion) that result in an uncontrolled quench, the oxygen level in the magnet room may significantly decrease possibly making breathing difficult.

4. Peripheral Nerve Stimulation and other Sensory Effects

• If the human subject complains of pain or discomfort, including headache stop the scan immediately. If the pain is not due to a biomechanical cause (awkward placement of body, poor placement of neck or head supports, etc.) terminate the study. If the discomfort is due to a biomechanical cause, the study may continue if the cause is corrected.

• If the human subject complains of tingling, a light touch sensation, or muscle twitching stop the scan and access the extent of discomfort. If the discomfort cannot be minimized, the study must be terminated.

• Users should report complaints of unexplained discomfort or pain to protocol PI and should follow IRB procedure of the protocol. A MR safety officer should be notified.

• When giving informed consent and, again, prior to entry into the magnet room, human subjects will be informed that they should report to the scan operator and the research staff any excessive warmth, visual flashes, dots, scintillations, or tactile sensations during an MR study.

5. Acoustic Noise

• All individuals entering the magnet bore must be provided adequate sound protection. Earplugs and headphones can attain this standard (< 99 db of audible noise).

• When earplugs are used to provide sound protection, only center-approved earplugs should be used.

• Dispose of earplugs after each subject is scanned.

6. Radio Frequency Fields

• Each person's weight must be entered into the appropriate program field before starting a scanning session. This is a critical safety rule.

• The human subject fan should be ON at all times to maintain adequate airflow through the bore.

• The MR Operator should inquire whether the subject is too warm or cold periodically during the study.

• Use non-conducting pads when needed. Position the subject's hands to the side and ensure that legs are not crossed.

• When using surface coils place a sheet or pillowcase between the coil and the human subject's skin.

• Removable eye makeup must be washed off prior to a scan.

• Human subjects with permanent eyeliner or other metallic ink tattoos may be scanned only after they sign the informed consent document associated with a specific, approved IRB protocol. Such subjects must be informed of the risk of skin irritation. Maintain close communication with these subjects during the course of the scan.

7. Training Requirements

MRI Safety Training: All personnel requiring access to the MRI suite for research and/or other activities must complete MRI safety training appropriate to their role in the work.

Human Subjects Training: All researchers having a protocol that involves human subjects are required to have completed the CITI training.

Emergency Procedures Training: For all protocols involving human subjects, at least two staff, who have completed MRI emergency procedures training and are capable of handling the MRI emergency, must be present during each MRI data acquisition session.

8. MR SAFETY ZONES

The MRI suite is divided into three safety zones

1) Unrestricted areas for safety issues. However, all users must follow the human subject rules described above. These areas include waiting area, bathrooms, and changing rooms.
2) Restricted Area (Potentially hazardous zone). All visitors and human subjects must be escorted by staff to enter this zone: offices, hallways, nursing room, equipment room, and control room.

3) Magnet Room. All persons, including researchers, users, human subjects and special visitors must complete screening and sign an appropriate screening form, and signed off my a MR operator. Nobody is permitted unless supervised by a MR operator or a trained certified staff member.