MRI SAFETY POLICY

REFERENCES: Magnetic Resonance, Bioeffects, Safety and Subject Management, Shellock, Kanal. Lippincott, 1996. Injuries Associated with MR Imaging: Survey of Safety Records and Methods Used to Screen Subjects for Metallic Foreign Bodies before Imaging. AJR 1994. The AAPM/RSNA Physics Tutorial for Residents: MR Imaging Safety Considerations, Price. Radiographics 1999. ACR Guidance Document for Safe MR Practices, AJR, 2007. ACR Guidance Document on MR Safe Practices: 2013, JMRI, 2013.

INDEX TO MRI SAFETY POLICY AND PROCEDURE

Purpose: This is a Magnetic Resonance (MR) Imaging safety policy for Behavioral Sciences Imaging Center (BSIC), located on the ground floor of the Brain and Behavioral Sciences Building (BBSB). The document details the safety procedures and training requirements for Principle Investigators (PI) and research staff who will perform and supervise MR examinations as the part of the research protocols. MR is an ever changing, evolving technology. There are potential risks in the MR environment, not only for the research participants but also for the facility support staff, researchers, and others who find themselves only occasionally or rarely in the magnetic fields of MR scanners, such as security, housekeeping personnel, firefighters, police, etc. This manual has been developed to help guide the MR staff regarding these issues.

It is the intent of the MRI Safety Manual to:

- Protect and educate all subjects/subjects, direct and ancillary personal about the possible risks, associated with the MR Facility including but not limited to static, time-varying magnetic fields and radio frequency (RF) pulses.
- Ensure compliance with the most up to date MR safety information provided by the Joint Commission and the American College of Radiology (ACR).
- Prove helpful as the field of MRI and research using MRI continues to evolve and mature.

This policy delineates protocol for the following safety areas:

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

The MRI Physicist and the Director of BSIC has overall authority and responsibility for safety policy where MRI is performed.

1 Section I: Personnel Designations, Screening, and Training

Personnel are placed in one of four categories to clarify who will have access to the MRI site and who has decision-making responsibility in ambiguous cases. Every person entering the MRI scanner room must be screened to determine personal risk for entering the MR environment. The method of screening will vary as described below. MRI safety training will vary with each individual's level of security clearance. All training will be through online learning modules with online examinations. The following are the personnel categories and screening/training requirements:

- **Non-MR personnel**
  1. **Includes**:
     - i. Subjects and research personnel that is not trained in MRI safety
     - ii. **Housekeeping and BBSB staff who do not directly work on MRI projects**
     - iii. Visitors
     - iv. Family/escorts of subjects
     - v. Vendor representatives
     - vi. Inspectors and surveyors (e.g., Fire, JCAHO and DOH)
  2. **Screening** (using the MRI Safety Screening Form)
     - i. MUST be screened each time they enter Zones III or IV.
     - ii. MUST be screened by at least one Level II MR personnel face-to-face with written documentation of screening
     - iii. All screening forms should be scanned and stored in the file associated with the relevant protoocl.
  3. **Training**
     - i. Not required
- **Level I MR personnel:** All research staff working in the MR environment with access to controlled areas
  1. **Includes**
     - i. ALL Research Personnel working with subjects.
     - ii. ALL MRI staff
     - iii. Reception, transport, **security and housekeeping** who have access to BSIC
  2. **Screening**
     - i. Psychiatry/BSIC/UTH Research Staff: **ALL** staff who escort participants into the Zones III and IV must be screened before first access. Documentation is kept on file.
       - – Any subsequent injury or medical procedure must be reported by

the associate immediately because this may affect their personal safety when entering MRI.

3. **Training**: Completion of the current online Basic MRI Safety training module.

- **Level II MR personnel:**
  1. **Includes:** MR users requiring additional training regarding time varying magnetic fields, cable and other equipment management, etc.
     i. ALL PIs who use or supervise MRI exams
     ii. ALL research staff who supervise MRI exams
  2. **Screening:** As for Level I Personnel
  3. **Training:** Completion of the current online Advanced MRI Safety training module will be required for new employees before they can work in the MR environment.
- **Level III MR personnel:** These individuals have decision-making power in ambiguous cases.
  1. **Includes:** The Center Director, the Clinical MRI physicist, and specifically designated PI.
  2. **Screening:** As for Level II
  3. **Training:** By the MRI physicist with extensive knowledge of and experience with MRI

2 Section II: MRI Site Access Restrictions (The format is mixed up, need to be edited)

I. The MRI site is classified into four regions:

Zone I Outside of the MRI site e.g. lobby area of the BBSB .

1. Unrestricted access.

[PHOTO]

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

1. This includes BSIC areas where subjects are greeted, registered, and screened.

Zone III Secure area immediately to the MRI scanner room.
Only Level I or higher MRI personnel may enter unaccompanied.

1. Secured by key or card access system.

3 Only Level I or higher personnel may hold cards coded to open these doors.

Zone IV The MRI scanner room.

1. Secured by key access system with “glass-break” emergency release.

2. Only Level II or higher MRI personnel may enter unaccompanied.

Zone	Activity	Personnel Designation
I	Non-MRI activities	Non-MR Personnel
II	Limited access control Participant Interviews Clinical Screening Metal Screening Participant Gowning Animal Transfer Area Ferrous Quarantine Storage Medical staging (emergency response)	Those officially supporting or participating in operation of the MR Facility.
III	Strict Access Control Screened prior to entry Situational Awareness MR Conditional/Safe devices only 5-gauss line	Level II or higher unescorted Only MR personnel can provide escort to others in Zones III and IV.
IV	Strict Access Control Screened prior to entry Harmful aspects of magnetic field Cryogen hazards MR Conditional/Safe devices only Infection Control Practices	Level II or higher unescorted.

II. Signs

1. Warning signs are posted at all entrances to Zones II, III, and IV.
2. A red sign is posted at all entrances to Zone IV. It reads "Magnet On"
3. All areas with magnetic field stronger than 5 Gauss are signed.
4. Emergency contact phone number is posted for first responders to contact before they enter the BSIC during an after-hours emergency.

3 Section III: Implants

Any special circumstance not covered below must be evaluated and approved in writing by physician before allowing the subject or other individual to enter Zone IV.

Unsafe Implants, which MAY NOT ENTER ZONES III or IV

1. Any Pacemakers/Defibrillators – **MAY NOT ENTER ZONES III or IV.**
2. Spinal stimulators, neurostimulators – **MAY NOT ENTER ZONES III or IV.**
3. Cochlear implants – **MAY NOT ENTER ZONE IV.**
4. Infusion pumps –must consult MRI physicist.
5. Aneurysm Clips: **MAY NOT ENTER ZONES III or IV.** See Appendix B.

Conditionally Safe Implants: Some implants that contain ferromagnetic components may be safe following a period during which biointegration of the implant occurs. A six-week interval should be allowed to pass following implantation of such a device prior to entering Zone III. **Devices that may generally be considered safe following this six-week interval include, but are not necessarily limited to:**

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

Safe Implants:

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

Section IV: Equipment

1. The MRI scanner will be maintained to ensure its optimal imaging performance and safety by the BSIC team including the technologists, the MRI or site manager, the MRI engineers, and the MRI physicist. A Quality Control Program will be in place, which exceeds standards set forth by SIEMENS and American College of Radiology.
2. ONLY MR safe equipment or MR Conditional equipment (provided that all conditions are met), may be brought into the MR scanner room (Zone IV). If a ferromagnetic device must be used within Zone IV, it must be installed or secured in place by qualified personnel as designated by the Center Director. Such a device must be installed before any subject or research subject is allowed to enter the room. No such unsecured device may be introduced into Zone IV while a subject or research subject is within Zone IV.
3. Medical device (e.g., ventilator, implant) safety must be based on the manufacturer's FDA-approved usage, not on local testing of devices. Only in exceptional circumstances would a medical device be tested on site.
4. Testing:

   a. Implants: NO on-site testing for MR compatibility is permitted. Only the manufacturer's statement of safety will be relied upon.

   Equipment: A strong hand magnet (>0.1 Tesla) can be used to test new equipment. b. Testing of equipment with a hand magnet must ONLY be performed by personnel appropriately trained and credentialed to know how to perform testing and how to interpret the results of testing. These personnel include Level II MR personnel. The hand magnet itself is a significant safety hazard, which could lead to equipment damage, serious injury or death if it were inadvertently brought near the magnetic field. Therefore, the magnet is kept secured and is not available in the MRI suite (Zones III and IV).

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

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

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

   f. Use of equipment in Zone III and Zone IV.
      - MR safe equipment – MRI safe models of basic medical equipment can be used and kept in MRI-controlled Zones (III and IV) (for example, stethoscope, sphygmomanometer, scissors, ambu bag and mask, physiologic monitoring equipment, basic tools).
      - Only MR Conditional fire extinguishers may be brought into and kept within Zones III and IV.
      - MR Conditional equipment – All MRI conditional equipment located in Zone III and

Zone IV that is not permanently fixed must be listed in a log, specifying the device and the associated conditions for safe use. This log will be available as an online electronic file on the department's MRI safety webpage.

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

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

b. Subject transport equipment:

Only MR safe stretchers, wheelchairs, cribs, etc. are to be used within Zones III and IV. Oxygen/Gas cylinders are prohibited within Zones III and IV unless attached to the anesthesia machine.

Inspections – BSIC team will conduct monthly inspections to include the following:

a. Check for labeling of all equipment in Zones III and IV.
b. Removal of prohibited, unnecessary or unsafe equipment from Zones III and IV.
c. Check for potential fire hazards in Zone IV, and remove all unnecessary power cords, wires, linens, foam pads, and devices from the MRI scanner room.
d. Testing of anesthesia equipment, including carts and tanks.
e. Testing of the access security system, including emergency door releases.
f. Critical assessment for cleanliness, including inspection of the MRI equipment and electronic rooms, must be completed throughout the MRI suite. Subject positioning devices should be assessed for wear and cleanliness and discarded if found imperfect.

g. Projectile Incident Response Plan

Extreme caution must be exercised when attempting to remove a ferromagnetic object from the magnetic field, to minimize the possibility of second injuries or further equipment damage. See "**Removal of ferromagnetic objects that enter the room"** below**.** When in doubt, consult the MR Physicist and Center Director.
If the projectile is small (e.g., pens, paperclips, keyrings) and there is no risk of human injury or equipment damage, the object may be removed by Level II MR personnel.
When a large object is stuck against the magnet, follow the procedure in "**Removal of ferromagnetic objects that enter the room."**

a. Quench the magnet ONLY if the object held against the MRI scanner poses an

imminent threat of injury or death, such as if a subject or staff member is pinned between the object and the magnet. Note that quench is a dangerous procedure, and essential precautions must be taken before and after quenching the magnet. See: "**Quench and Cryogen Handling**".

b. Any incident or near-miss incident involving a projectile MUST be reported.

Section V: Gradient and Radiofrequency Hazards

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

1. **Nerve or muscle stimulation:**

   a. Clinical MRI equipment performs within FDA-specified safety limitations that generally preclude the induction of sufficient current within tissue to cause direct nerve or muscle stimulation. Some high-duty cycle applications, such as EPI and SSFSE, may nonetheless cause nerve or muscle stimulation, especially at 3.0 Tesla. This stimulation is not hazardous but may be uncomfortable. If a subject complains of twitching or pain during a high-duty cycle acquisition (especially echo-planar imaging (EPI)), the scan should be stopped immediately. The remainder of the examination may proceed, provided the subject is comfortable. The incident should be reported to MRI physicist.

   b. Research pulse sequences (not FDA approved) may pose a higher nerve or muscle stimulation risk. Before commencing any such imaging pulse sequence, the subject must be instructed to report any sensation suggestive of nerve/muscle stimulation, such as twitching, tingling, or electric shocks. If these symptoms are reported by the subject, the scan must be stopped, and the incident should be reported to MRI physicist.

2. **Induction of current in metallic details:** High duty cycle MR imaging pulse sequences can induce a current within metallic foreign bodies. Long metallic objects such as wires, braids, brain electrodes, etc. can conduct significant current when subjected to a high level of dB/dt. The presence of a looped conductor increases the likelihood and magnitude of induced current.

   Precautions should be taken in subjects with **any potential items containing such loops**

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

   Preventing Burns:

   Pulse sequences may deposit power more efficiently in metallic objects within or outside the subject, leading to serious burns. The following precautions should be taken:

   a. All metal must be removed from the subject. This includes, but is not limited to **underwire bras**, jewelry, transdermal drug delivery patches and external orthopedic braces or prostheses. The subject may be required to remove **ALL** personal clothing and change into clothing provided by the BSIC facility. Note that fabrics, particularly in undergarments, may contain

unsuspected metallic components, which can lead to serious burns

c. **Non-removable conductive items:** Tattoos and permanent makeup as well as implanted metallic items, such as orthopedic hardware, may undergo significant heating.
    i. The subject must be informed of this possibility and asked to report any suggestive symptoms. The technologist must communicate verbally with the subject throughout the examination to ascertain symptoms of heating.
    ii. Dry cold packs may be applied to any such superficial, non-removable conductive material, such as tattoos or subcutaneous implants (e.g., infusion pumps), to function as a heat sink and minimize tissue heating.

d. All unnecessary coils, cables, wires, and monitoring leads must be removed from the MR scanner prior to scanning. Any necessary external wires or cables including the cables connecting the RF coil to the scanner should be carefully managed with attention to the following:
    i. The wires/cables must be **insulated** from the subject using sheets, sponges or other means. The wires/cables must not touch the subject's skin.
    ii. The wires/cables must NOT form any loops.
    iii. The wires/cables must be placed as far from the inner walls of the MRI bore as possible.
    iv. The subject should be positioned so that they are not in contact with the inner walls of the MRI bore.

e. More extensive caution and use of cold packs should be employed in subjects such as young children.

f. The staff positioning the subject in the MRI scanner should ensure that no large loops are formed with the subject's tissue. **Arms and legs should be uncrossed**.

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

Burn Care

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

a. The scan MUST be stopped immediately.

b. Apply cold compresses or ice to affected or reddened areas.

c. For severe burns, contact the medical team or take the subject to the emergency room for further examination and treatment.

d. The incident must be reported to the site manager/supervisor by the MRI technologist with detailed subject information and specific imaging parameters including the coil(s) used, how they were connected and specified in software. The incident must be reviewed by the Center Director and the MRI physicist to determine and address the cause of the injury.All MRI burn

incidents MUST be reported.

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

Section VI: Pregnancy hazards

1. Subjects: While MRI is not known to have any adverse effect on the fetus but comprehensive controlled long-term studies have not been conducted. As a result, we endeavor to avoid MR imaging of a pregnant women if at all feasible. Women of childbearing age will be assumed to be pregnant **unless they** have had a recent negative pregnancy test or within 7 days of a menstrual period, have undergone surgical sterilization or attest that they consistently use birth control with every sexual intercourse.
   Precautions:
   a. Screen subjects before enrolling them into the protocol.
   b. Ensure that subject does not get pregnant during the protocol.
2. MRI Staff: MRI staff may work during pregnancy even within the MR scanner room (Zone IV). However, any worker who *may be* pregnant must NOT remain within the room during scanning.
3. Others: May not enter the MR scanner room (Zone IV) if they *may be* pregnant as described above.

Section VII: Contrast Agent Usage

The BSIC does not offer routine administration of contrast agents. All protocols that require contrast agent must arrange for qualified personnel to perform contrast administration.

Section VIII: COVID Precautions and Emergency Situations

1. **COVID Precautions**

COVID guidance. High level of COVID in Houston metropolitan area will trigger a change in policy on scanning, MR room cleaning and disinfecting protocols are quite varied and are subject to change with the unique clinical circumstances of that particular site (e.g., availability of PPE, emergent need for immediate access to not yet disinfected MR scanner.). General guidelines include cleaning protocol with COVID approved disinfecting agents following a clockwise, linear, top to bottom pattern of cleaning all visible surfaces. However, these will be tempered by local guidelines and policies and especially the specific clinical needs of the patients and site, and are likely to change over time.

MR exams for subjects utilizing face masks

1. Research subject use of face masks while in the MR environment is anticipated to provide some level of protection from COVID-19 for these individuals, MR staff, and subsequent subjects at that location. MRI facilities are recommended to provide face masks that are known to be MR Safe for patients and research subjects. A recent FDA Safety Communication reports burns to a patient's face, consistent with the shape of the mask that occurred during a 3T neck exam.

2. In addition to a bendable metal strip that permits conforming around the nose in many surgical masks, some manufacturer's masks incorporate metallic fibers and/or metallic nanoparticles in an effort to enhance antimicrobial properties, and these would be expected to pose a risk in MRI.

3. If there is a metal strip in the surgical mask, patients should be fitted with known MR Safe masks or respirators, prior to coming to the research imaging. Alternatively, when this is not possible, metallic components from a face mask should be removed prior to, or when necessary, upon the patient's arrival at the MR suite. Tape may be applied across the bridge of the nose section of the mask after removing the metal strip if the site feels that this would be sufficient for adequate transmission control and to maintain the intended function of the mask. If the patient has a tracheostomy, a face mask without metallic component should also be placed over the tracheostomy.

4. MRI examinations with metal containing masks is strongly discouraged.

5. Personal Protective Equipment (PPE) worn by MR Technologists and other healthcare personnel entering Zone IV

    a. Powered air-purifying respirators (PAPR) should not be brought into Zone IV due to the potential risks of adverse interactions with ferromagnetic components of the PAPR system.

    b. As PPE worn by healthcare personnel are not expected to be exposed to the time varying RF or gradient magnetic fields of the MR imaging environment, the only MR-related safety concern is that of potentially ferromagnetic components of the PPE (e.g., staples, metallic band inserts, etc.) and possible translational and rotational forces that the static magnetic field and the static magnetic field gradient may exert upon them. For such equipment, potential risks can be mitigated by ensuring that no ferromagnetic components are present in the PPE or by removing such components and replacing them with tape (if possible to do so without adversely affecting their intended isolation functionality).

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

field present despite a quench or partial quench of the magnet.

3.

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

4. **Cryogen Handling and Quench Situations**

1. Only trained service personnel may handle cryogens. During cryogen fills, Zone IV and Zone III must be evacuated of all, but trained service personnel

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

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

5. **Unplanned Magnet Quench (not deliberately initiated by MR personnel)**

In the event of a magnet quench it is imperative that all personnel/subjects/subjects be evacuated from the Zone IV as quickly and as safely feasible.

1. Stop all scanning and open the scan room door immediately. If the door to the scan room is closed the pressure may build up making it impossible to open the door. In this event, it may become necessary to break the glass window to allow the gasses to escape and the pressure to lessen so that the scan room door may be opened.
2. The access to the scan room should be immediately restricted to all individuals until the arrival of the MR equipment service personnel.
3. Do not rely upon the oxygen sensors in the room to warn of low oxygen levels in the room. This technology is now considered by industry experts not to be sufficiently reliable to allow for continued operations during situations of power outage, etc.
4. It is especially important to ensure that all police and fire response personnel are restricted from entering the MR scan room with their equipment (axes, air tanks, guns, etc.) until it can be confirmed that the magnetic field has been successfully dissipated, as there may still be considerable static magnetic field present despite a quench or partial quench of the magnet.
5. Execute the emergency contact process in the MRI Facility SOP.

6. **Emergency Magnet Quench**

Users of the MRI facility should only quench the magnet in the event that the magnetic field itself poses

an **immediate risk to life or major property**. Two such circumstances are:

a. A metal object is lodged in the scanner in a way that poses an immediate serious threat to a person (e.g., the person is pinned to the magnet by a metal object that is causing internal injuries).
b. Fire personnel determine that there is ***no other alternative*** to entering the room with axes or other heavy gear when fighting a fire.

If the absence of a major emergency, facility users should **never quench the magnet by themselves**, even if they are convinced that a magnet quench will ultimately be necessary (e.g., if a large object has been drawn into the magnet but poses no immediate risk to a person).

Quench Procedure

1. Follow the steps in the (Please put this back if you are sure we will have this set up).
2. When the magnet is quenched, the helium in the scanner boils off. Although the helium should vent out of the room to outside vent, **make sure the door to Zone IV is wide open before quenching the magnet**. If possible, exit all persons from Zone IV before quenching the magnet to minimize the chance of asphyxiation in the event that the helium is improperly vented.
3. If emergency medical assistance is needed, dial 911 and request medical assistance as detailed elsewhere in this manual.
4. The helium vent ducts become dangerously cold during a quench. Do not touch them.
5. Execute the emergency contact process in the MRI Facility SOP.
6. The quench procedure will interrupt continued research in the MRI Facility for an indeterminant amount of time.

7. **Fire Emergencies**

a. Call 911 immediately
b. If smoke or fire is coming from the scanner, equipment room or console, perform an emergency electrical shutdown as described elsewhere in this manual.
c. If you are scanning and smoke or fire is NOT coming from the scanner, equipment room or console, stop the scan and release the bed. If time permits, initiate a routine electrical shutdown.
d. If you determine that it is necessary or appropriate to attempt to extinguish a fire in Zone IV yourself (e.g., if your subject is on fire), use an MR safe/compatible fire extinguishers in the MR Facility. **NEVER BRING A STANDARD RED FIRE EXTINGUISHER FROM ELSEWHERE IN THE BUILDING INTO ZONE IV.**
e. Remove the subject from the scanner and escort the subject out of the building.
f. Do not return to the building until advised by fire personnel that it is safe to do so.
g. Execute the emergency contact process in the MRI Facility SOP.

8. **Non-Fire Facility Emergencies**

The following non-fire, non-medical emergencies, may warrant a shutdown of the equipment:

- Unscheduled Power Shutdowns
- Magnet Quench (catastrophic boil-off of helium)
- Water Leaks
- Foreign Metal Objects in the Magnet
  a. Perform a routine electrical shutdown, or if circumstances such as a rapid flooding threaten to

reach the equipment before a routine shutdown could be completed, perform an emergency electrical shutdown. Both shutdown procedures are described elsewhere in this manual.

b. Remove the subject from the scanner
c. If appropriate, evacuate the building and do not return until advised that it is safe to do so.

9. **Fire Alarms**

When an unscheduled fire alarm sounds:

1. Remove the subject from the scanner and escort the subject out of the building.
2. Do not return to the building until advised by fire personnel that it is safe to do so.
3. Execute the emergency contact process in the MRI Facility

10. Emergency Electrical Shutdown

The following events should prompt an emergency electrical shutdown:

- You see smoke or fire coming from the scanner, equipment room or console.
- Flooding has carried or is threatening to carry water into electrical equipment

Electrical shutdowns do not turn off the magnetic field—the magnet is ALWAYS ON unless the magnet has been quenched.

a. Locate and press one of the large red electrical shutdown buttons in Zone IV or Zone III. **Make sure that it is the electrical shutdown button, not the quench button.** The electrical shutdown buttons are all uncovered, and there is no writing on the button itself.
b. Electrical shutdown immediately stops all power to the scanner, the scanner equipment and the console computers. It does not turn off the lights. Also, power to the simulation equipment will not be interrupted, so be aware that electrical or fire hazards may still be present.
c. In the case of fire or medical emergency, call 911.
d. Remove subject from Zone IV.
e. Execute the emergency contact process in the MRI Facility SOP.
f. Circumstances that justify an emergency electrical shutdown do not typically justify quenching the magnet. Do not quench the magnet unless there is a specific reason to do so (possible reasons for quenching the magnet are discussed elsewhere in this manual).
g. It will take an indeterminant amount of time to restore the scanner to operational status.

11. Routine Electrical Shutdown

A routine electrical shutdown may be necessary if a situation is developing that might predispose the equipment to electrical damage or that might soon warrant an emergency electrical shutdown. **Electrical shutdowns do not turn off the magnetic field—the magnet is always on unless the magnet is quenched.** A routine electrical shutdown requires 3-5 minutes to complete. **If an emergency electrical shutdown becomes warranted at any time, follow the emergency electrical shutdown procedure described elsewhere in this manual**, even if a routine electrical shutdown has already been initiated. Situations that would warrant a routine electrical shutdown include:

- Receiving notice that an electrical outage in the building is likely
- Development of a minor water leak that is not expected to flood electrical equipment before a routine shutdown can be completed

- Alarms sounding indicating that the magnet has quenched or that helium is unacceptably low (a routine warning message on the console that the helium needs to be refilled and instructing you to call service is not an alarm and does not warrant an electrical shutdown).
- Error messages from the scanner console indicating that correction of a problem requires rebooting the equipment.
- Failure of the scanner bed to respond to its controls

Per the manufacturer's updated recommendations, a routine electrical shutdown should NOT be routinely performed at the end of the day. The scanner should be left in operational status.

a. Follow the MRI Facility SOP for procedures on performing a routine electrical shutdown.
b. Reenergize the equipment in accordance with the SOP when appropriate.

Appendix A: Precautions: External Potentially Ferromagnetic Objects

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

site-provided gowns. Note that these individuals must remove all metal (e.g. jewelry), even if not ferromagnetic, in order to prevent thermal injury.

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

Appendix B: Aneurysm Clips. BSIC Policy Is to Exclude ALL Subjects with Aneurism Clips from the Protocol.

1. Placing a subject who has been implanted with a ferromagnetic aneurysm clip into the strong magnetic field of an MR imager **leads to devastating injury** and death due to intracranial hemorrhage. Due to the potential for severe injury, no subjects can be enrolled in the research protocols that use BSIC MRI scanner.

Appendix D: Screening Form

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

LEVEL 1 SCREENING:

The screening form (available at www.txbrain.org) must be reviewed by Level I or II MR personal to identify any positive responses to the screening questions. Any of these "yes" responses must be communicated to the MR technologist. The screener must sign in the Level I screening box on the screening form.

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

1. The technologist must review the screening form in the presence of the subject and verbally confirm the subject's responses to the screening questions. The technologist then

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

Appendix E: Subject Comfort and Psychological Care

General Precautions:

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

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

Every subject must be given the emergency call bell button and shown how to use it if they need to contact the technologist urgently.

Subjects who indicate that they are uncomfortable or claustrophobic:

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

Appendix G: Definitions

MR Safe: A designation indicating that the object or device is safe in all MR environments, without conditions. It is reserved for nonmetallic, nonconducting, and nonmagnetic objects that pose no known hazards in any MR environment.

MR Conditional: A designation indicating that the object or device may be safely used in the MR environment, provided the conditions for safe use are met. Decisions based on published MR Conditional or safety claims should recognize that all such claims apply to specifically tested static field and spatial gradient field strengths and only apply to the precise model, make, and identification of the tested object. For example, "MR Conditional having been tested to be safe at 3 T at spatial gradient strengths of 1130 G/cm or less and normal operating mode."

MR Unsafe: A designation indicating that the object or device is known to present safety

risks in the MR environment. These are primarily ferromagnetic objects.

Level I MRI Personnel - Level I MR Personnel are individuals who have had MRI safety training as approved by the BSIC.

Level II MRI Personnel - Level II MR Personnel have completed all requisite MRI safety and user training established by the MRISC. Level II users may operate the scanner without supervision, supervise Level I personnel, escort non-MRI personnel within Zones III and IV, and administer the MRI safety screening to study participants.

Zone I - General facility area freely accessible to the public. This area is typically outside the MR environment.

Zone II - Limited Access: This is the Zone located between the public uncontrolled Zone I and the strictly controlled Zone III. This area has limited access available to research subjects and MRI staff personnel who have been safety trained or safety screened by Level 2 MR personnel. It is in Zone II that the answers to MRI screening questions, medical histories, medical insurance questions, etc. are typically obtained.

Zone III - The MR scanner (Zone IV) itself is located adjacent to this space. Zone III can be defined as regions from which potentially hazardous energies (related to the MR imaging process) may be accessed. Zone III regions should be physically restricted from general public access by, for example, key locks, passkey locking systems, or any other reliable, physically restricting method. Only MR personnel shall be provided free access, such as the access keys or passkeys, to Zone III. Individuals that have undergone safety screening will be allowed access to this area only when accompanied by appropriate MR personnel.

Zone IV - Is the room housing the MR scanner itself. Zone IV should also be demarcated and clearly marked as being potentially hazardous due to the presence of very strong magnetic fields. Zone IV, by definition, will always be located within Zone III as it is the MR magnet and its associated magnetic field which generates the existence of Zone III. Only research subjects, researchers, and FAU personnel accompanied by Level II MR personnel who have undergone safety screening or safety training will be admitted to this Zone.

MRI Physicist

Char of the Department