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UTMB MRI SAFETY MANUAL

SECTION ONE - GENERAL INFORMATION

PURPOSE:

- To establish the policies and procedures to maintain safe clinical and laboratory practice involving magnetic resonance imaging (MRI) devices at UTMB facilities.

- To implement a MRI safety program that models the recommendations given by ACR Guidance Document for Safe MR Practices: 2007 that are applicable to UTMB.

SCOPE:

- This manual establishes requirements that are applicable to all persons who receive, possess, acquire, transfer or use MRI devices in either clinical or laboratory settings at UTMB facilities; or who operate UTMB owned MRI devices at temporary sites for limited time periods.

- The contents of this manual have been developed by the UTMB Radiation Safety Program.

- In situations where there is a conflict with the policies and procedures contained in this manual and those contained in local policies and procedures, such as “UTMB Nursing Practice Standards”, those contained in this manual shall take precedence.

PROHIBITIONS:

- MRI devices shall not be used in any manner that creates a threat or danger to UTMB faculty, staff, patients and/or the general public.

- Exposure of an individual for training, demonstration or other non-healing arts purposes is prohibited unless under the direct supervision of a MRI practitioner of healing arts.

  - Exposure of an individual for the purpose of healing arts screening is prohibited without a written doctor’s order or any other proper language.

  - Exposure of an individual for the purpose of research on humans is prohibited unless prior authorization is received from the institutional review board (IRB).
SECTION ONE: GENERAL INFORMATION (CONTINUED)

DEFINITIONS:

- **Individuals**: Within this document, individuals are employees, staff, PIs or other personnel who are working and/or conducting studies in the MRI environment.

- **Medical Event**: Any adverse patient health effect that is a result of failure or misuse of laser safety equipment.

- **MRI Environment**: The MRI environment is that area within the scanner room where the magnetic field strength exceeds 3 gauss.

- **MRI Practitioner of the healing arts (practitioner)**: a person licensed to practice the healing arts by either the Texas State Board of Medical Examiners as a physician; the Texas State Board of Dental Examiners; the Texas Board of Chiropractic Examiners; the Texas Board of Nursing; the American Osteopathic Association or the Texas State Board of Podiatry Examiners. A practitioner’s use of a MRI device is limited to his/her scope of professional practice as determined by the appropriate licensing agency.

- **MRI Device Operator**: The MRI scanner operator is an individual who is an UTMB employee, has completed the MRI safety training and is specially trained in the operation of one or more of the MRI scanners. There are two levels of device operators:
  
  - Individuals who are allowed to operate the device for phantom and/or animal studies
  
  - Individuals who are allowed to operate the device for patients and/or research participant studies

- **Patient**: A patient is a human subject who is placed into the bore of the MRI device for clinical purposes. The patient must be treated and cared for within all institutional and federal guidelines and regulations.

- **Research Participant**: is a human subject who is placed into the bore of the MRI device for research purposes. The research participant must be treated and cared for within all institutional and federal guidelines and regulations.

- **Technical Staff**: Non-faculty who have met certain training and experience requirements as set forth in this manual and whose MRI use is under the general supervision of an MRI Practitioner.
SECTION ONE: GENERAL INFORMATION (CONTINUED)

RESPONSIBILITIES OF MRI PRACTITIONER:

- Notify the UTMB Radiation Safety Office (RSO) of any acquisition, transfer or disposal of a MRI device.

- Ensure that MRI devices are properly maintained, aligned, calibrated and repaired by qualified persons.
  
  o MRI Practitioner shall not allow non-UTMB employees to provide such services without first obtaining a copy of documents indicating that the vendor/person is qualified to provide MRI services. A copy of these documents shall be sent to the Radiation Safety Office.

- Conduct an annual inventory of all MRI devices in their possession.

- Ensure that only appropriately trained and authorized individuals use the MRI devices.

- Maintain a current list of individuals authorized to use the MRI devices.

- Ensure all individuals who work with or in the vicinity of MRI devices shall be knowledgeable about the devices in their work area and the potential health hazards associated with the use of these devices.

TRAINING/QUALIFICATIONS:

- All individuals (Technical and Non-Technical staff) shall have MRI safety training applicable to their job functions for the hazards encountered working within all zones of the MRI environment.

- All individuals (Technical and Non-Technical staff) shall complete an applicable job function MRI safety training refresher course annually.

- Documentation of training shall be in a manner approved by the Radiation Safety Office.

- Exemptions from attending UTMB MRI training classes (this exemption does not apply to annual refresher training):
  
  o Individuals who have documentation of comparable training received prior to arriving at UTMB.
SECTION ONE: GENERAL INFORMATION (CONTINUED)

- Individuals who have documentation of comparable training received outside of UTMB.
- Faculty members whose training and experience history has been accepted by the Radiation Safety Office in the course of becoming an MRI Practitioner.
- Individuals who have been granted exemption by the Radiation Safety Office

- Documentation of hands-on training shall be signed by the preceptor or vendor.
- Non Technical Staff shall have MRI safety training applicable to their job function for the hazards encountered working within all zones of the MRI environment

STATIC MAGNETIC FIELD:

The most common breaches of MRI safety occur due to an object being attracted to the Static Magnetic Field. An individual may be struck, injured or trapped against the magnet by the object. Equipment may be damaged by slamming into the magnet or being struck by another object that is accelerating rapidly due to the strong attraction of the magnetic field.

- **Field Strength**
  - The strength of the static field is regulated by the federal government. As of July 14, 2003 the U.S. Department of Health and Human Services (DHHS) Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH) determined that there is a significant risk scanning adults, children, and infants older than one month at a main static field greater than 8 T. The limit for neonates and infants younger than one month is 4 T. Currently the maximum magnetic field strength for clinical use and research use at UTMB is 3.0T and 18.8T respectively.

- **Projectile Effect**
  - Items that are ferromagnetic have the potential of becoming projectiles when brought into the magnetic field.
SECTION ONE: GENERAL INFORMATION (CONTINUED)

- Projectiles have the potential of causing serious injury including death, to anyone who may be in the path of the object as it accelerates toward the magnet. Projectiles may cause an individual to be pinned to the magnet. Equipment may be irreparably damaged by becoming a projectile or by being struck by one.

- **Torsion and Translation Forces**

  - Ferromagnetic objects or devices, including those within the human body will be attracted to the magnet.

**EQUIPMENT SCREENING:**

All equipment used for research studies or patient MRI scans, including projectors and stimulus producing apparatus, must be tested for MRI safety BEFORE entering Zone IV. Individuals are cautioned to NEVER take equipment into the magnet room without prior testing for magnetic attraction.

- **MRI Safety Label Terminology**

  - **MR Safe**: An item that poses no known hazards in all MRI environments. Items include non-conducting, nonmetallic, nonmagnetic items such as a plastic container or a cotton sheet. An item may be determined to be *MR Safe* by providing a scientifically based rationale rather than test data. The *MR Safe* icon consists of the letters ‘MR’ in green in a white square with a green border or the letters ‘MR’ in white within a green square.

  - **MR Compatible**: A device shall be considered *MR Compatible* if it is MR safe and has been demonstrated, when used in the MRI environment, to neither significantly affect the quality of the acquired data nor have its operations affected by the MR system. The MRI conditions in which the device was tested should be specified in conjunction with the term *MR Safe*, since a device which is safe under one set of conditions may not be found to be so under more extreme MR conditions.
SECTION ONE: GENERAL INFORMATION (CONTINUED)

- **MR Conditional**: An item that has been demonstrated to pose no known hazards in a specified MRI environment with specified conditions of use. For *MR Conditional* items, the labeling includes results of testing sufficient to characterize the behavior of the item in the MRI environment. Any parameter that affects the safety of the item should be listed, and any condition that is known to produce an unsafe condition must be described. The *MR Conditional* icon consists of the letters ‘MR’ in black inside a yellow triangle with a black border.

![MR Conditional Icon]

- **MR Unsafe**: An item that is known to pose hazards in all MRI environments. This includes magnetic items such as a pair of ferromagnetic scissors. The *MR Unsafe* icon consists of the letters ‘MR’ in black on a white field inside a red circle with a diagonal red band.

![MR Unsafe Icon]

**EMERGENCY PROCEDURES**:  

- **Written emergency procedures**
  - Written emergency procedures, applicable to the specific MRI device in use, should be made available in the areas where MRI devices are used.
  - All MRI users shall familiarize themselves with these emergency procedures.

- **Medical attention**
  - MRI Practitioners and/or Technical Staff shall immediately seek appropriate medical attention for any individual injured within the MRI environment.
  - The emergency team must report outside the appropriate MRI scanner room to begin treatment for the patient.
SECTION ONE: GENERAL INFORMATION (CONTINUED)

- Crash carts and other emergency equipment containing ferromagnetic material **must not** be brought into the scanning room.

- An MRI safe approved stretcher or dockable scanning table must be available at all times near the MRI scanning room.

- **Emergency Stop**
  
  o If there is an emergency such as an equipment failure that could cause injury; sparking of equipment or a fire, the scanner operator or designee should immediately perform an emergency stop.

- **Magnet Emergency**
  
  o If it is necessary to drain (quench) the magnetic field immediately (e.g. in the case of fire, or a person pinned to the magnet), pull the emergency magnet shut-off switch located on the magnet safety panel. Pulling the emergency switch quenches the magnet and causes the field to collapse within approximately 10 seconds. This should only be done in a severe emergency.

  o Report the incident as an accident and call for assistance to ensure ferrous object is removed from the field properly.

- **Notification of injury or death**
  
  o Any UTMB faculty, staff or student who becomes aware of an incident resulting in the injury or death of an individual caused by a MRI device shall immediately notify the Radiation Safety Office at (409) 772-2279 during normal working hours or EHS on call person through the UTMB hospital operator.

- **Notification of anomalous events (near misses)**
  
  o Any UTMB faculty, staff or student who becomes aware of an event that **could have** resulted in the injury or death of an individual caused by a MRI device shall notify the Radiation Safety Office within 24 hours of becoming aware of the event.
SECTION TWO – CLINICAL USE OF MRI DEVICES

ZONING:

- **Zone I**
  - Open to general public access,
  - This is generally the reception and waiting area for the MRI suite.
  - Purpose of this zone is to channel patients, research participant and technical staff to the prescreening area (Zone II)
  - Negligible MRI hazards

- **Zone II**
  - This is the first interaction site for patients, research participants, visitors, and others with the technical staff in the MRI suite.
  - The purpose of this zone is to restrict further public access to the suite, provide direct supervision of patients, research participant and visitors by the technical staff, and provide an opportunity to prescreen all patients, research participants and visitors.
  - All ferromagnetic objects must be collected and secured within Zone II.
  - Individuals should verify that all transport equipment is MRI-safe by viewing MRI safety label or by testing for magnetic attraction.

- **Zone III**
  - Zone III is the entry zone to the MRI scanning room
  - Without exception, only the MRI Practitioner and certified technical staff should be allowed free access between Zones III and IV.
  - All technical staff must be prescreened upon employment prior entering Zone III to make sure no unscreened individuals are allowed access to Zone IV.
  - Coded and locked entries are employed to prevent access by unscreened individuals.
SECTION TWO: CLINICAL USE OF MRI DEVICES (CONTINUED)

- **Zone IV**
  
  - Only those personnel required so that the patient can complete the exam will be allowed in the MRI scanning room during the procedure. Family members should remain in the waiting area unless the patient requires their presence for exam completion.
  
  - Code red situations will require the use of MRI-safe fire extinguishers and restriction of public first responders from Zone IV, until MRI safe conditions can be established or first responders verified as MRI safe.
  
  - In a code red situation in Zone IV, first responders **do not** have free access to either Zone III or IV.
  
  - Prior to any incident, local fire and police department personnel should be educated on the hazards of the MRI suite in emergency situations.
  
  - The entrance to this room is visually marked by signage on the normally closed room doors and on the floor indicating that the MRI machine is always on and the area is restricted.

**MRI SAFETY PRE SCREENING:**

Each person must be checked for safety or pre-screened prior to entering the magnetic environment of the scanner room. An important aspect of protecting people from MRI system-related accidents and injuries involves an understanding of the risks associated with the various implants, devices, and accessories which may be present within or adjacent to the person.

- **Individuals**
  
  - All individuals, including clinical, researchers, employees and students, who work within the magnetic environment, must be trained according to UTMB policy and screened for personal safety prior to entering the magnetic field.
  
  - In addition, individuals who have responsibility to recruit subjects, and / or screen subjects for MRI scans are required to complete the MRI Safety Training program.
SECTION TWO: CLINICAL USE OF MRI DEVICES (CONTINUED)

- Any individual who has a need to enter the magnet room (i.e. facility maintenance employees, site visitors) must be screened on a case by case basis.

- **Patients**
  - Preliminary screening of patients for MRI procedures should take place during the scheduling process. Such screening helps to prevent scheduling of patients who may be at risk for safe MR imaging.
  - At the facility, it is mandatory for every MRI patient to undergo comprehensive screening in preparation for the MRI study prior to entering Zone IV (see appendix).
  - It should be noted that having undergone a previous MRI procedure without incident does not guarantee a safe subsequent MRI examination.
  - Family members of patients whose presence is required for exam completion are held to the same screening requirements as patients.
  - Pregnancy – Women who are or may be pregnant may be scanned by MRI after determining that the medical benefits outweigh any theoretical minimal risk to the fetus by referring physician and radiologist.

- **Implants and devices**
  Implants and devices are evolving rapidly and must be thoroughly investigated if potential patients or individuals who will enter the magnetic environment indicate their presence. Implants tested to 1.5T may not be compatible at 3.0T. Any implants for 3.0T imaging must be determined to be acceptable specifically to 3.0T. The maximum magnetic field strength currently used for patients at UTMB is 3.0T. If the individual knows or has documentation as to the specific manufacturer and type of device, then the following steps are implemented:

  - Look up the item by the manufacturer in the current *Reference Manual for Magnetic Resonance Safety, Implants, and Devices* by Frank G. Shellock, Ph.D. or on the web site: [http://www.mrisafety.com](http://www.mrisafety.com)
  - If the device or object is not listed there or has not been tested at the field that the patient is subjected to, then contact the manufacturer for the following information and written documentation:
SECTION TWO: CLINICAL USE OF MRI DEVICES (CONTINUED)

- Have the manufacturer fax the text that states the device is MRI safe and at which magnetic field strength(s), and conditions, it is safe.

- The text sent should include the FDA date stamp that verifies the device is MRI safe at 3.0T or the specific conditions which must be adhered to for the field strength the individual will be entering.

- **Claustrophobia Screening**
  - Statistics indicate that about 10% and up to 20% of the general population is claustrophobic to some degree. In many cases patients who think they are claustrophobic are able to go through an MRI study with some reassurance.

- **Medical Status Screening**
  - Patients must be evaluated for medical status or issues that may prevent them from lying flat or holding still for long periods of time. Patients who are dependent on continuous medication via external or internal devices should be excluded from MRI scans.

- **Magnetic field-related issues and Screening**
  - Magnetic field-related translational attraction and torque are known to present hazards to individuals and patients with certain implants or devices.

**RADIO FREQUENCY (RF) ELECTROMAGNETIC FIELDS:**

Safety risks from RF include potential tissue heating and burns to the patients. RF may damage electronic or implanted medical devices. Equipment that is not RF shielded may be damaged or may cause spurious signals when operated in the magnetic field. Conducting materials within the RF field may result in a concentration of electrical currents sufficient to cause excessive heating and tissue damage. Therefore, all conducting material not in use should be removed from the magnet bore.

Cables, wires and other accessories should be inspected regularly by the scanner operators and researchers to ensure insulation, connectors and other components are intact and functioning safely. Researchers aware of malfunctioning or broken equipment should report the item to the scanner operator.
SECTION TWO: CLINICAL USE OF MRI DEVICES (CONTINUED)

- **Tissue Heating and Burns**
  - Dental hardware
    - Most dental hardware is generally safe in the MRI environment although some orthodontic components may be ferromagnetic.
  - Tattoos
    - RF heating of tattooed tissue has been reported especially with use of iron oxide containing inks. The patient should be informed of the potential for heating or burns and instructed to alert the scanner operator immediately if warming occurs.
  - Transdermal Medication Patches
    - These devices most often contain a metallic layer which has been reported to cause heating of tissue during scanning and producing a burn on the patient. It is essential that any patient wearing a transdermal patch that has a metallic component be identified during the pre-screening process, prior to undergoing MRI.
  - Coils
    - Coils are the devices that transmit and receive the RF signals and can be produced in a variety of configurations. The individual must have some basic knowledge of coil technology to properly conduct the MRI scan. Safety issues can occur as follows:
      - Transmitting RF energy through a receive-only coil may damage or ruin the device.
      - Transmitting more RF power than the coil was designed to manage, can damage or ruin the device.
      - Twisting, looping or crossing cables may cause current to be induced, resulting in damaging the coil, abnormal heating or potential arcing.
SECTION TWO: CLINICAL USE OF MRI DEVICES (CONTINUED)

REPORTING REQUIREMENTS - SAFETY:

Mandatory MRI safety training is required for individuals who work within the magnetic environment. Any events or occurrences that may compromise the safety of the individuals or patients working in or near the magnetic environment need to be reported and addressed.

- **Accidents, Injuries and Incidents**
  - Any accidents causing injury to an individual or patient must be reported to the RSO by the individual conducting the scan.

- **Equipment Damage or Failure**
  - Malfunctions of equipment due to breakage or failure may present a safety risk to individuals and patients. Damage or failure of equipment needs to be addressed immediately so that repairs or replacements can be made. Equipment problems should be reported as soon as reasonably possible to the scanner operator.

- **Facility Safety Breach**
  - A facility safety breach presents a risk to individuals, researchers and patients. Examples of a facility safety breach are failed access points allowing non-trained or non-escorted individuals into the magnetic environment.

  - Open access to the magnetic environment must be addressed immediately to prevent serious injury to individuals or equipment. Other potential safety breaches include: flooding, electrical hazards and obvious structural faults. Individuals should report any breaches to the scanner operator on duty. The scanner operator should report the safety breach to the appropriate facility officer and to the RSO as soon as reasonably possible.
SECTION THREE – ADDENDUM (PEARLAND IMAGING FACILITY)

This addendum is specific to the Pearland Imaging Facility due to the unique configuration of a shared control room for both CT and MRI technicians. The control room which is designated as Zone III is the entry point to both the MRI suite as well as the CT suite. The dual use of the control room coupled with strict adherence to the Zone III recommendations would not be prudent and is not necessary for patients only undergoing CT exams.

MRI SAFETY PRE SCREENING:

- **Patients**
  - At the facility, it is mandatory for every MRI patient to undergo comprehensive screening in preparation for the MRI study (prior to entering Zone IV).

MRI SAFETY PROCEDURES:

- **MRI Technical Staff**
  - Following pre-screening, all MRI patients will be escorted to the MRI suite by the MRI Practitioner, certified MRI technical staff or MRI device operator.
  - Upon entering or exiting the MRI suite the MRI Practitioner, certified MRI technical staff or MRI device operator will always close the MRI suite door behind him/her.

- **CT Technical Staff**
  - CT patients will be accompanied by CT technical staff at all times.
SECTION FOUR – APPENDIX

MRI PATIENT QUESTIONNAIRE (FRONT):

MRI PATIENT SAFETY QUESTIONNAIRE

Patient name __________________________
MRN ______________________
Weight: ___________  DOB: ___________
Type of Exam __________________________________________________

Have you had prior surgery or an operation of any kind? ☐ No ☐ Yes
If yes, please indicate the date and type of surgery:
Date _____/_____/____ Type of surgery _______________________________________________
Date _____/_____/____ Type of surgery _______________________________________________

Have you experienced any problem related to a previous MRI examination or MR procedure? ☐ No ☐ Yes
If yes, please describe: ________________________________________________________

Have you had an injury to the eye involving a metallic object or fragment (e.g., metallic slivers, shavings, foreign body, etc.)? ☐ No ☐ Yes
If yes, please describe: ________________________________________________________

Have you ever been injured by a metallic object or foreign body (e.g., BB, bullet, shrapnel, etc.)? ☐ No ☐ Yes
If yes, please describe: ________________________________________________________

For female patients:

Date of last menstrual period: _____/_____/____ Post menopausal? ☐ No ☐ Yes
Are you pregnant or experiencing a late menstrual period? ☐ No ☐ Yes
Are you taking oral contraceptives or receiving hormonal treatment? ☐ No ☐ Yes
Are you currently breastfeeding? ☐ No ☐ Yes

MRI, Division of Radiology, University of Texas Medical Branch
SECTION FOUR: APPENDIX (CONTINUED)

MRI PATIENT QUESTIONNAIRE (BACK):

WARNING: Certain implants, devices, or objects may be hazardous to you and/or may interfere with the MR procedure. Do not enter the MR system room or MR environment if you have any question or concern regarding an implant, device, or object. Consult the MRI Technologist or Radiologist BEFORE entering the MR system room.

The MR system magnet is ALWAYS on.

Please indicate if you have any of the following:

- Yes  
- No

- Aneurysm clip(s)
- Cardiac pacemaker
- Implanted cardioverter defibrillator (ICD)
- Electronic implant or device
- Magnetically-activated implant or device
- Neurostimulation system
- Spinal cord stimulator
- Internal electrodes or wires
- Bone growth/bone fusion stimulator
- Cochlear, otologic, or other ear implant
- Insulin or other infusion pump
- Implanted drug infusion device
- Any type of prosthesis (eye, penile, etc.)
- Heart valve prosthesis
- Eyelid spring or wire
- Artificial or prosthetic limb
- Metallic stent, filter, or coil
- Shunt (spinal or intraventricular)
- Vascular access port and/or catheter
- Radiation seeds or implants
- Swan-Ganz or thermodilution catheter
- Medication patch (Nicotine, Nitroglycerine)
- Any metallic fragment or foreign body
- Wire mesh implant
- Tissue expander (e.g., breast)
- Surgical staples, clips, or metallic sutures
- Joint replacement (hip, knee, etc.)
- Bone/joint pin, screw, nail, wire, plate, etc.
- IUD, diaphragm, or pessary
- Dentures or partial plates
- Tattoo or permanent makeup
- Body piercing jewelry
- Hearing aid

(Remove before entering MR system room)

- Yes  
- No

- Other implant _______________________
- Breathing problem or motion disorder
- Claustrophobia

I attest that the above information is correct to the best of my knowledge. I read and understand the contents of this form and had the opportunity to ask questions regarding the information on this form and regarding the MR procedure that I am about to undergo.

Signature: ___________________________________________ Date ______________________

Form Completed By:   __ Patient      __ Relative     __ Nurse     __MD

Relationship to patient         Technologist signature