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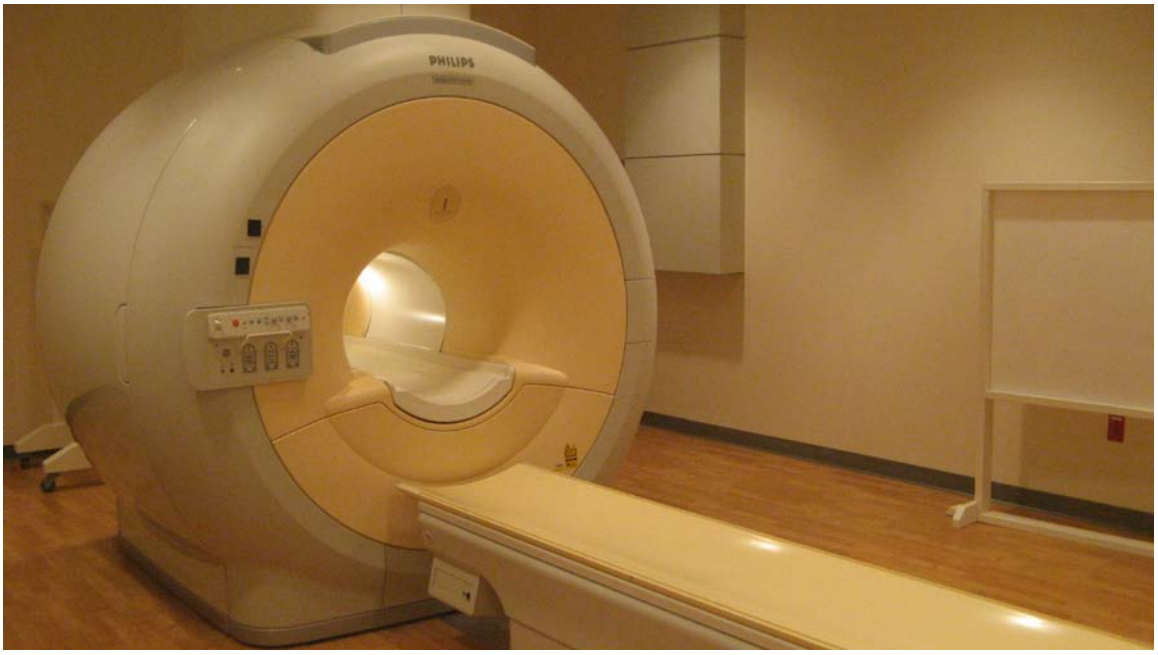
BIRC
BRAIN IMAGING RESEARCH CENTER
A program of the Psychiatric Research Institute at the University of Arkansas for Medical Sciences

# University of Arkansas for Health Sciences

# Brain Imaging Research Center




## Magnetic Resonance Imaging (MRI)

## Policies and Procedures Manual
## Version 3.1

# Brain Imaging Research Center

# MRI Policies and Procedures

## Purpose

The purpose of the MRI Safety Policies and Procedures is to maintain a safe environment, during research procedures, in the magnetic resonance (MR) imaging area of the Brain Imaging Research Center. It has been reported by others, that MR related injuries, fatalities, and equipment damage were the apparent result of failure to follow established safety guidelines. For the purpose of maintaining safe MRI practices, recommendations from the ***ACR Guidance Document for Safe MR Practices: 2007*** and **Joint Commission** (**JCAHO)** policies are used. Because MRI technology continues to progress, this is a living document that will be updated as needed.

## Policies

### Safety Training

- Individuals working within the magnetic environment must complete the required MRI Safety Training prior to conducting or participating in studies.
- All Researchers must renew the MRI Safety Training on an annual basis.

### Standard of Practice at the BIRC

MRI Safety Approval

Researchers

- Only researchers with approved protocols are allowed to schedule MRI scanner time for research studies.
- Researchers using the MRI system for human studies must have an approved IRB protocol prior to scanning human research participants.

Individuals

- Individuals working within the magnetic environment must undergo a mandatory screening interview by the MRI Coordinator for safety risks prior to entering the magnetic field. MRI screening includes the MRI screening form and a handheld scan with the MedNovus SAFESCAN® ferromagnetic detector. This includes individuals who may be accompanying a research participant. THERE ARE NO EXCEPTIONS TO THIS POLICY.
- Two MRI safety trained individuals must be on site when a human research participant is being scanned.
- MRI scanner operators scanning human research participants must have current CPR training.
- At least one MRI safety trained BIRC employee, student or faculty member must be present during human subject scanning.
- Individuals who are or may be pregnant are not allowed to remain in the MR scanner room while the RF and gradients are operating.

Research Participants

- Research participants in MRI studies must undergo a mandatory screening interview by the MRI Coordinator for safety risks prior to entering the magnetic field. MRI screening includes the MRI screening form and a handheld scan with the MedNovus SAFESCAN® ferromagnetic detector*. THERE ARE NO EXCEPTIONS TO THIS POLICY. The BIRC has a zero tolerance policy regarding adverse events. All safety guidelines must be followed by all personnel.
- Research participants in MRI studies must be treated within institutional, local and federal guidelines and regulations (i.e. NIH and FDA policies of Human Subject Research).

# Brain Imaging Research Center

## MRI Policies and Procedures

- Subjects with implants, devices and other objects within or on research participants or other individuals intending on entering the magnetic environment must be investigated by the manufacturer label. This investigation must be documented prior to the individual or research participants entering the scanner magnet room.
- Manufacturer documentation which includes the FDA approval must be obtained to ensure safety of implants, devices or other objects at 3.0T (Reference Manual for Magnetic Resonance Safety, Implants, and Devices: 2011 Edition)
- Research participants must be evaluated for medical status that would indicate a safety risk and/or prevent a successful MRI study. PHI will be pulled from a participant's medical record on a need basis.
- Subjects cannot exceed the Philips 3T weight limit of 330lbs/150kgs.
- The research participant must be given an operator call squeeze ball with instructions for use by the scanner operator.
- Researchers/Coordinators must interview research participants identified during pre-screening as having tattoos and proceed accordingly.
- Researchers/Coordinators must interview research participants identified during pre-screening as having medication patches and contact their physician or exclude the individual from the study. Researchers may not remove medication patches prescribed by physicians.

MRI Scanner Operator

- MRI scanner operators must be trained as evidenced by signed documentation.
- MRI scanner operators who scan research participants must have current CPR documentation.
- MRI scanner operators must personally complete a detailed screening of all participants prior to the MRI scan.
- MRI scanner operators must use the initial Survey scan to assess that the individual in the scanner is safe to be scanned prior to continuation of scanning.
- MRI Scanner operators must also verbally monitor the research participant throughout the procedure.
- MRI scanner operators have the authority to stop MRI procedures that are deemed by them to be unsafe.

Emergency or Illness

- An individual or research participant who becomes ill or injured must be removed, from the magnetic environment, immediately by the researcher or scanner operator.
- If an individual or research participant becomes ill or injured the institutional policies for the scanner location must be followed.
- If there is a Magnet Emergency, the MR Director and the MRI Coordinator must be notified.
- The MRI Coordinator must report any emergency incident to Philips, and if applicable the Researcher/MRI Coordinator must report to the IRB and the study sponsor.

Equipment

- Any equipment to be used within the magnet room must be approved by the MR Director or the MRI Coordinator.

# Brain Imaging Research Center

# MRI Policies and Procedures

## Static Magnetic Field

- Only properly pre-screened individuals are allowed in the magnetic environment of the MR scanner room THERE ARE NO EXCEPTIONS TO THIS POLICY.
- Only equipment and accessories approved by the MR Director and the MRI Coordinator are allowed to enter the magnetic environment of the MR scanner room.
- Any incident or near incident of a projectile accident must be reported to the MR Director and the MRI Coordinator.

## Radio Frequency (RF) Electromagnetic Fields

- Only properly trained individuals should operate devices and monitoring equipment in the magnetic environment.
- RF pulse timing sequences that exceed FDA Specific Absorption Rate (SAR) limits must not be used.
- Only electrically conductive devices, equipment, accessories and materials that have been thoroughly tested by a MRI safety trained BIRC personnel and determined to be safe for MR procedures are allowed.
- Philips recommendations for safe use of all devices must be followed.
- All non-essential electrically conductive materials must be removed from the MR system bore, including unused RF coils, cables and wires prior to scanning.

## Time Varying Magnetic Fields: Gradients

### Potential Nerve Stimulation

- Research participants must be instructed to not clasp their hands or in any other way form a closed loop with their extremities to reduce or avoid peripheral nerve stimulation (PNS).
- Phase and Frequency encoding directions must be selected carefully by the scanner operator to avoid peripheral nerve stimulation.
- Researchers and scanner operator must continuously monitor research participants being scanned in a study and stop scanning immediately if any peripheral nerve stimulation is reported or suspected, and correct the situation before proceeding.
- Individuals who have Vagal Nerve Stimulation (VNS) implants are NOT safe to participate in a functional MRI (fMRI) study due to the rapid gradient switching required for Echo Planar Imaging (EPI) utilized in fMRI.

### Acoustic Noise

- Research participants must be supplied with 2 forms of hearing protection to meet the OSHA guidelines; both the foam ear plugs and a head set system.
- Any researcher or individual who remains in the scanner room during data acquisition must wear hearing protection.
- The intercom and auditory stimulus equipment must be adjusted to not exceed safe dB levels for the research participant.

# Brain Imaging Research Center

## MRI Policies and Procedures

### Infection Control

- The scanning table and any other surfaces that have come in contact with the research participant must be cleaned and the linens changed BEFORE placing another research participant on the scanning table.
- Gloves must be removed and disposed of properly BEFORE touching common areas such as scanner keyboard, log books, light switches, counter surfaces and other objects.
- Surfaces touched with gloves must be cleaned properly before leaving the area.

### Reporting

- Injuries to personnel or a research participant must be reported to the MRI Director, Principal Investigator (PI) and the UAMS Occupational Health and Safety. (UAMS Injury Reporting http://www.uams.edu/safety/Accident.aspx)
- Any incident or near incident of a projectile accident must be reported to the MRI Director and MRI Coordinator by the scanner operator or researcher involved.
- Equipment damage and/or failures must be reported to the scanner operator.
- Facility safety breaches must be reported by the scanner operator to the MRI Director and MRI Coordinator.

# Brain Imaging Research Center

# MRI Policies and Procedures

## Standard Operating Procedures

### Scanning Procedure

The use of Magnetic Resonance Imaging (MRI) presents known safety hazards. Policies and Standard Operating Procedures have been developed so that employees, researchers, students, colleagues, study participants, and associated equipment remain safe in the magnetic environment. All personnel working within the magnetic environment are required to complete MRI safety training. The BIRC has also developed general MRI Use Guidelines and Policies containing additional pertinent information, which can be found at: http://psychiatry.uams.edu/?id=7778&sid=3

BIRC employees and support staff assigned to work in the MRI area(s) are required to adhere to the MRI Safety Policies and Standard Operating Procedures.

Components of the MRI scanner system that present potential risks are:

- The static or main Magnetic field of the system inside the scanner room
- This strong magnetic field is always present.
- The risk of the strong magnetic field increases the closer an object is to the bore or opening of the magnet.
- Objects that are ferromagnetic may become projectiles with the potential to cause serious injury.
- Objects that are ferromagnetic may pin someone against the magnet in a life threatening manner.
- Everyone must be screened for potential contraindication to safety prior to entering the magnetic field.
- All equipment must be evaluated for potential risk prior to being safely placed in the magnetic field.
- The Radio Frequency (RF) that is produced when the MRI scanner is operating
- Research participants must be protected from potential heating and burns.
- The FDA sets limits to the amount of heating or the Specific Absorption Rate (SAR) that is allowed.
- Equipment and accessories must be used properly and safely to prevent heating or burns to the research participant or animal.

The Gradients or Time Varying Magnetic Fields

- Rapidly changing gradient fields used in MRI have the potential to cause peripheral nerve stimulation.
- Gradients produce excessive acoustic noise levels for which hearing protection must be provided and worn.

Ancillary equipment used for experiments

- All equipment placed in the magnetic environment must be considered for heating or any other potential safety risk.

### Safe MRI Practice

To maintain safe laboratory practice, at least two MRI Safety Trained individuals, besides the research participant being scanned, must be in the immediate area at all times. That is, the operator of the scanner

and another individual who has completed MRI safety training. The MRI scanner operator performing studies with research participants must have current cardiopulmonary resuscitation (CPR) training as evidenced by a signed document. For phantom studies, one MRI safety trained individuals should be on site. At least one BIRC employee, student or faculty member must be present for all MRI scanning.

### Safety Training

Safety Training for all MRI Researchers mandated by the MRI Director is a two step process. The online training and quiz are located on the UAMS PRI web-site: http://intranet.uams.edu/staffeducation/E_Learning/PublishedFiles/MR_SafetyAspects/MR_Safety_Aspects_Video_Training.htm.

The second part includes the viewing of Philips training videos at http://netforum.medical.philips.com/Selection/DocumentsSelection.aspx?DocTypeId=20.

**Log-In** is required for the use of Philips Netforum.

A renewal of MRI safety training for research staff is required every two years according to UAMS BIRC guidelines.

### 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.

The researcher must be aware of which objects and devices are safe to move into the static magnetic field.

### MRI Safety Screening

Each individual must be checked for safety or pre-screened prior to entering the magnetic environment of the scanner room. A standardized form is used for evaluating the safety of an individual BEFORE that individual is permitted within the magnetic environment. MRI Safety Screening Training is a segment of the requirement for MRI researchers.

### Equipment Screening and Operation

All equipment used for research MRI studies, including projectors and stimulus producing apparatus, must be tested for MRI safety BEFORE entering the magnetic field. MRI safe equipment is developed for specific magnetic field strengths and MRI system configurations. Routine inspection and maintenance of

equipment must be performed. Broken or malfunctioning equipment must be identified and reported to the MR scanner operator.

### Research Participant Scanning

It is essential that there is constant communication between the research participant within the MRI scanner and the scanner operator. Every research participant is given a contact signal squeeze ball that will alert the scanner operator of a difficulty even when the scanner is running and producing loud noises. During the quiet times of the study the scanner operator should maintain verbal contact with the research participant. A research participant who does not respond verbally requires immediate investigation to ensure the research participant's well being.

### Post MRI Scanning Procedures

The MRI scanner at BIRC is utilized for a number of research studies. It is important that all MRI users ensure the facility and equipment are maintained in good working order. Upon completion of the MRI study the researcher must ensure that all equipment is restored to normal operation. If there is a problem with specific equipment, it must be reported to the MR scanner operator. Report to the MR scanner operator if a supply item is becoming low in quantity especially if the last, or near last of an item is used.

Researchers will ensure that coils, shim files, configuration files, and all computers are returned to standard usage. All accessories and/or devices are to be turned off properly, cords and cables wound, and returned to their designated storage area.

### Radio Frequency (RF) Electromagnetic Fields

MRI research studies are to be conducted so that safety risks from RF, including potential tissue heating and burns to the research participant, are eliminated. 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. ***Note:*** Pulse sequences with 180º refocusing pulses (such as spin-echo EPI and inversion-recovery prepped flow sequences) have much higher RF power deposition (potential heating) than sequences without 180º pulses, such as gradient recalled echo planar imaging, GRE-EPI.

### Time Varying Magnetic Fields: Gradients

Nerve Stimulation

# Brain Imaging Research Center

# MRI Policies and Procedures

The application of momentary magnetic field gradients (dB/dt) can induce current in conductive materials, including nerve or muscle tissue. Research participants should be instructed to report any sensations to the scanner operator so that corrective action can be implemented. The FDA considers the procedure to be of significant risk any time the rate of change of the gradient fields (dB/dt) is sufficient to produce severe discomfort or painful nerve stimulation.

Acoustic Noise

Acoustic noise produced during the MRI scanning procedure is known and documented. Research participants must be provided hearing protection. Individuals remaining in the scanner room while the gradients are operating must wear hearing protection. The FDA follows the OSHA guidelines which limits the permitted decibel level based on the time duration of the exposure.

## Infection Control

All surfaces that have come into contact with a research participant, animal model or any other potential infectious substance must be properly cleaned before the next MRI study is conducted. The prevention of any infectious material of research participant or animal model origin from being transferred in any way to another research participant, animal or individual is the responsibility of all researchers.

Research Participants

For research participants infection control includes cleaning the scanning table, coil, positioning pads, the emergency squeeze ball and any other surfaces that have come in contact with the subject. These surfaces as well as linens must be cleaned or replaced BEFORE placing another research participant on the scanning table. All used linens are to be placed in the appropriate hamper. Any spills or bodily fluids must be cleaned thoroughly with a disinfectant solution or bleach.

## Emergency Safety Procedures

In an emergency, orderly and proper procedures ensure the safety of individuals, researchers and the research participant. The first priority is to remove research participants or individuals from the magnetic environment. Emergency contact information is posted in the MRI scanner console room.

## Medical Emergency

In case of a research participant or other individual with a medical emergency of illness or injury: the individual or research participant must be assisted out of the magnet room. Then a call for assistance per BIRC and UAMS procedure is implemented.

## Emergency Stop

# Brain Imaging Research Center

# MRI Policies and Procedures

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

## Magnet Emergency

- If an individual or research participant is restrained or pinned by a ferrous object to the magnet: Assess if the situation is life threatening, if YES an emergency rundown to quench magnet can be performed by an **authorized** person.
- If an individual or research participant is restrained by a ferrous object to the magnet and is NOT in a life threatening situation, call for assistance to determine the optimal way of releasing the individual or research participant from the magnetic field. If a quench is necessary proceed as above.
- Report the incident as an accident and call for assistance to ensure ferrous object is removed from the field properly.

## 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 extraordinary circumstances resulting in an uncontrolled quench, the oxygen level in the magnet room may significantly decrease possibly making breathing difficult.

## Reporting Requirements

Accidents, Injuries and Incidents

- Any accidents causing injury to an individual or research participant must be reported to the MRI Director or MRI Coordinator by the PI conducting the study. In case of an accident or injury when the principal investigator (PI) is not present, the researcher present must report to the PI. If an accident or injury occurs that is not related to an MRI study, then the scanner operator or individual on site who is responsible should report to the MRI Director.
- Besides reporting to the MRI Director, the accident, injury or incident may need to be reported to the UAMS Institutional Review Board.

Equipment Damage or Failure

Malfunctions of equipment due to breakage or failure may present a safety risk to individuals and research participants. Damage or failure of equipment needs to be addressed immediately so that repairs or replacements can be made. Equipment problems are reported to the scanner operator. The scanner operator will address equipment issues, obtaining assistance if necessary. Failures that prevent normal operation or a safety risk are to be reported to the MRI Director.

# Brain Imaging Research Center

## MRI Policies and Procedures

Facility Safety Breach

A facility safety breach presents a risk to individuals, researchers and research participants. 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 and researchers 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 MRI Director or the MRI Coordinator as soon as reasonably possible.

# Brain Imaging Research Center

# MRI Policies and Procedures

### References:

FDA Guidelines for Magnetic Resonance Equipment Safety
Loren A. Zaremba, Ph.D.
Center for Devices and Radiological Health
Food and Drug Administration

ACR Guidance Document for
Safe MR Practices: 2007

MRI Safety Committee
Medical College of Wisconsin
Milwaukee, Wisconsin 53226

Occupational Safety and Health Administration (OSHA) Guidelines
PART 1910.95 Occupational Safety and Health Standards- Occupational Noise Exposure

Philips Achieva 3.0T TX MultiTransmit technology and Quasar Dual gradients specifications June 2010.

# Brain Imaging Research Center

# MRI Policies and Procedures

## ADDENDUM(S) to MRI Policies and Procedures

**Addendum I**

**BIRC Data Transfer Policy**
**Date of addition: February 21, 2012**

1. At the conclusion of each MRI session, the MRI operator will transfer that session's data from the MRI scanner to the portable harddrive.
2. The MRI operator will document the data transfer to the portable harddrive by listing the subject ID, date of scan, and operator's initials in the Data Transfer Logsheet.
3. Once a week (preferably Fridays), Mr. Shanti Tripathi [or the principle investigator (PI)] will transfer the subjects' data from the portable harddrive to the BIRC server priclus.uams.edu. (Fridays are preferred because online data backup occurs on Sunday morning.) For each session transferred, Mr. Tripathi (or the PI) will document the date of transfer and initial to indicate successful transfer in the Data Transfer Logsheet.
4. Once a month (or more regularly, pending MRI scanner disk space), Mrs. Pallavi Jaivijay will delete transferred data from the MRI scanner. She will first confirm that each session's data (identified by subject ID and scan date) is on the harddrive. She will also confirm that each session's data is listed in the Data Transfer Logsheet as being on the harddrive and uploaded to the server. All of these conditions must be met before the data is deleted. If all conditions are met, Mrs. Jaivijay will delete the data from the scanner and indicate data deletion (by date and initials) in the Data Transfer Logsheet. If all conditions are not met, Dr. Andrew James will be notified as per item 5 below.
5. Any observed deviations from this protocol must be reported immediately to Dr. Andrew James. Reporting these deviations is critical for optimizing the data transfer process and safeguarding data. Dr. James will keep written documentation of deviations from the data transfer process, and may be used to further streamline the process.