# MRI safety guidelines

## Victorian Biomedical Imaging Capability (VBIC)

www.vbic.org.au

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# 1 Introduction

## 1.1 Purpose

The use of Magnetic Resonance Imaging (MRI) presents known safety hazards. It is crucial to establish policies and procedures to prevent incidents from occurring. VBIC has developed this guide of general MRI safety information for MRI research facilities.

The purpose of the VBIC MRI Safety Guidelines is to provide a resource for continued safe MRI practices within the VBIC community. This document does not constitute an MRI safety policy or procedure; rather it contains guidelines for the major topics that should be addressed in MRI safety policies and procedures for MRI research facilities. Note that where changes are made to the MR scanner (e.g. as part of research activities), the relevant safety guidelines should be reviewed and updated. Indeed, these guidelines do not take into consideration safety requirements of modified MR scanners.

The information herein has been derived from RANZCR and ACR recommendations to prevent accidents and injuries in the MR environment.

## 1.2 VBIC node with a MRI research facility

- It is the responsibility of the relevant facility Management Committee to ensure that MRI safety policies and procedures are established and are appropriate for the various MR systems operated at that facility.
- MRI safety policies and procedures will be reviewed and updated regularly and in all cases at least annually.
- Any and all adverse events, MRI safety incidents or 'near incidents' are reported to the facility's Management Committee and used in continuous quality improvement efforts.
- Where possible, adverse events, MRI safety incidents or 'near incidents' should be reported to the VBIC Coordination Committee for use across VBIC for continuous quality improvement.

NOTE*: Introduction of any significant changes in MR system hardware or software that will significantly change the safety parameters in the MR imaging environment has to be reviewed prior to implementation. In this review process, national and international standards and recommendations should be taken into consideration prior to establishing own local guidelines, policies, and procedures.*

## 1.3 Definitions

**Management Committee:** group of people responsible for the operations of the MRI research facility. It may include researchers, administrators and/or radiographers.

**MR personnel:** Individuals who have passed MR safety training to ensure safety within the MRI research facility.

**Non-MR personnel:** any individual or group who has not within the previous 12 months undergone the designated MR safety training as defined by the VBIC node Management Committee.

**Study participant:** A study participant is a human subject who is placed into the MR scanner for research purposes. The study participant must complete and sign a MR screening form (prior to the MRI scan).

# 2 MR environment

## 2.1 MRI research facility design: Access restriction and zoning

Each MRI research facility must supply a schematic floor plan, which clearly defines the magnetic field distribution (Fringe field) with demarcation of the 30 Gauss line and 5 Gauss line for each MR scanner available at the facility.

The schematic floor plan must include indication of the four safety zones as described by the RANZCR (2007) and the ACR Guidance Document for Safe MR Practices (2013):

- Zone 1: the general public area outside the MR environment. This is the area through which study participants and MR personnel access the MR environment.
- Zone 2: the area between Zone 1 (Public Access) and the strictly controlled Zone 3 (Control Room) and Zone 4 (Magnet Room).
- Zone 3: the Control Room. All access to Zone 3 is to be strictly restricted, with access to regions within it controlled by, and entirely under the supervision of, MR personnel. This zone is restricted from general public access by a reliable restricting method that can differentiate between MR personnel and non-MR personnel.
- Zone 4: the Magnet Room. This area is synonymous with the MR scanner magnet room itself. Zone 4, by definition, will always be located within Zone 3. Every individual must be screened for potential contraindication to MRI safety PRIOR to entering the Magnet Room. All equipment must be evaluated for potential safety risk PRIOR to being safety placed in the Magnet Room. The Magnet Room door is always locked when unattended. The MR scanner operator must be able to directly observe and control via line of sight the entrances or access to Zone 4 from their normal positions when stationed at their desks in the Control Room.

Note*: All MRI systems should have helium-venting equipment, which removes the helium to the outside environment in the event of a quench. All magnet rooms should contain an oxygen monitor that sounds an alarm if the oxygen falls below a certain level.*

## 2.2 Staff training program

The node Management Committee is responsible for the development of a MR Safety training program for staff. The program should include the following:

- A comprehensive information packet on MR safety
- A video on MR safety
- A written competency test (questionnaire or quiz) on MR safety
- A tour of the MRI research facility

It is required that all MR personnel complete MR safety training prior to obtaining access to the MR environment.

Documentation signed by MR staff indicating that they are familiar with the MR safety policies procedures has to be kept in the Control Room.

Safety training must be renewed annually by all MR personnel and visiting MR researchers if they plan to continue to perform MRI research studies at one of the VBIC MRI research facilities.

## 2.3 Standard of practice

At least two MR safety trained individuals must be present for all MRI scanning during normal work hours, i.e. Monday to Friday from 9am to 5pm.

After normal hours, weekends and holidays a minimum of two MR safety trained individuals besides the study participant being scanned must be present. For animal studies a minimum of two MR safety trained individuals should be on site at all times animals are scanned.

## 2.4 Emergency procedures

Orderly and proper emergency procedures ensure the safety of individuals, researchers and study participants. MR safety documentation should include procedures for at least the following emergencies:

- Magnet quench procedure. This section should include when it is appropriate to quench the magnet and who is responsible for quenching the magnet
- Power failure procedure
- Emergency off procedure
- Medical Emergencies
- Fire and evacuation procedure. Clearly state in this section that fire in the magnet room can only be tackled using non-magnetic materials.
- Security and personal threat

Note*: Actions concerning alarms or emergencies related to the MR equipment should only be taken by the responsible MR radiographer or senior MR staff unless the emergency itself renders such action impossible.*

## 2.5 Potential hazards and risks in a MR environment

All users of MR scanner systems should be aware of the safety hazards for using MRI. Therefore, it is important that MR safety policies contain information and risk assessment on at least the following topics:

- Strong static magnetic field
- Time-Varying fields (Gradient magnetic fields) – Noise protection
- Radiofrequency field:
    - Study participants and animals must be protected from potential heating and burns. Care should be taken to ensure that the study participant's tissue do not directly come into contact with the inner bore of the magnet during the MR imaging process. Pads and other such insulating devices are provided for this purpose. It is also important that the study participant 's own tissues do not form large conductive loops. Therefore, care should be taken to ensure that the arms and legs not be positioned in such a way as to form a large caliber loop within the bore. For this reason it is preferable to instruct study participants not to cross their arms or legs in the MR scanner.

- Equipment and accessories must be used properly and safely to prevent heating or burns to the study participant or animal.
- It is necessary to limit the amount of heating and the Specific Absorption Rate (SAR). VBIC nodes are advised to follow the recommendations of the RANZCR (2007) and/or the European HPA (2010)

# 3 Screening procedure

## 3.1 MR personnel screening

All MR personnel are to undergo an MR screening process as part of their facility induction process to ensure their own safety in the MR environment. A signed screening form must be kept on file for every MR personnel. For their own protection and for the protection of the ancillary staff all MR personnel must immediately report to their supervisor any trauma, procedure, or surgery that they experience, and if applicable, which ferromagnetic metallic object/device that may have been introduced within or on them. This will permit an appropriate screening to be performed upon the employee to determine the safety of permitting those MR personnel into the MR environment.

Pregnant employees are advised not to remain in the MR scanner room while the RF and gradients are operating.

## 3.2 Study participant screening

It is mandatory for every study participant to undergo comprehensive screening in preparation for the MRI study. This involves the use of a MR screening form to document the screening procedure, a review of the information on the screening form by a radiographer, and an oral interview to verify the information and allow discussion of any questions or concerns the study participant may have. All sections of the MR screening form must be completed, and include the date and signature of the reviewer and study participant.

The following steps should be included in the screening procedure:

1. Initial screening by the MR researcher recruiting the participant. The aim is to identify any reason why the scan could not proceed safely. However, researchers do not need to resolve the issue; that is the role of the MR Radiographer, see step 2.
2. Review of screening form by a certified MR radiographer before the booking of the scan. This includes investigation of potential implants, devices or other items identified by the researcher that could prevent the scan from proceeding safely. Each implant, device or other item should be reviewed and it status (MR Safe, MR Conditional or MR Unsafe) identified in writing and agreed to (i.e. relevant personnel sign the appropriate forms, see Appendix 1).
3. Final screening by the MR operator on the day of the scan. This is an oral assessment, often performed as a conversation between the participant and MR operator, to identify any items missed in the initial screen or changes to circumstances since the initial screen. If a new item or a change in circumstances (for example pregnancy) is identified at the final screening step, positively identification in writing for each item (see step 2) must be obtained before scanning the participant.

## 3.3 Persons other than study participants (e.g. companion, cleaners, security)

Persons other than study participants may be screened only once, providing the screening MR staff member is a certified MR radiographer.

## 3.4 Screening forms

Each individual must complete a written MR safety screening questionnaire before their introduction to Zone 4. No empty responses will be accepted. Each facility should develop their own MR screening forms. To assist with this, the screening forms used at three VBIC nodes (Austin, Clayton and Hawthorn) and other relevant resources are available on the VBIC website (vbic.org.au). As an overarching principle, every identified implant or foreign body has to be positively identified in writing as MR Unsafe or, alternatively, MR safe or MR Conditional in the MR environment (see step 2 of the screening procedure in section 3.2) before permitting the individual into the Magnet Room.

The following provides some justification for the inclusion of some of the questions in the screening forms used by VBIC nodes.

1. General information: this information is necessary to be able to contact the participant or his/her GP should the need arise
2. Questionnaire
   2.1. Questions to confirm any possible contraindications. As best as possible/practicable adolescents should be questioned separate from parents or guardians to ensure accurate responses to all questions (e.g. relating to piercings and/or pregnancy).
      - Have you ever had surgery or an operation? A history of surgery or operative procedures must be investigated to ensure there are no metal or implanted devices within the body, which could risk the safety of the study participant, scanner operator or other individual. Identification of all devices or implants must be made to ensure the safety of the study participant and to avoid damage to any device. Metallic objects may cause distortion of data even if they are determined to be MR safe.
      - Have you had a MRI scan before? A participant who has had previous MRI studies either clinically or for research will be potentially more comfortable with the study. If the participant has been rejected for a prior MRI study, this may indicate a safety incompatibility.
      - Have you ever had an injury to the eye involving a metallic object (e.g. metallic slivers, shavings, shrapnel, foreign body)? Any injury to the eye must be investigated. Serious injury to the individual may occur if there is ferrous material in or near the eye. It is recommended that adolescents be questioned separate from parents or guardians to have accurate information about possible foreign bodies in or near the eye. Participants with history of foreign bodies in the eye will require a negative X-ray or CT scan of the orbits prior to being admitted to the restricted zone.
      - Have you ever worked with metal (grinding, fabricating, etc.) or had an injury involving a metallic object e.g. (metallic slivers, shavings, shrapnel, foreign body)? Similarly to metallic objects in the eye, serious injury to the individual may occur if there is ferrous material in or near major organs of the body. It is recommended that adolescents be questioned separate from parents

or guardians to have accurate information about possible foreign bodies. Participants with a history of foreign bodies may require a negative CT scan or an X-ray of the orbits prior to being admitted to the restricted zone.

- Do you have a history of seizure disorder or epilepsy? A study participant with a history of seizure disorder is a warning that the scan operator and/or safety monitor carefully observe and communicate with the participant for any change in behavior or sudden body contractions.
- For female participants: Are you pregnant or suspect you are pregnant? In some instances, pregnant participants may be excluded from research MRI studies. If a study participant suspects pregnancy, the MRI scan should be postponed until the participant is able to confirm her pregnancy status (i.e. via a blood test). Once the pregnancy status is known, the safety of the scan can be considered in conjunction with the relevant health professionals (e.g. GP, obstetrician, radiologist and/or radiographer.

2.2. Questions to confirm any possible contraindications

- All types of implants or foreign bodies must be approved by a MR radiographer even if a medical doctor approves the implanted device "safe for MRI scanning". The MR researcher must notify the MR scanner operator of a participant's implanted device prior to scheduling for further evaluation of a participant's compatibility to be scanned. If an implanted device is identified at the final screen, the scan should not go ahead until the device is determined to be safe. The MR scanner operator should also notify the researcher for record-keeping purposes.
- In order to approve the scanning of an individual with an implanted device (i.e. that the device is deemed *MR-Safe* or *MR-Conditional)* an additional form (see Appendix 1) must be filled in for each procedure/incident/device identified through the safety screening form.

3. Consent form on incidental findings: an incidental finding is described as an abnormality on the MR images of the study participant that is observed by the MR scanner operator. The screening form must contain a section on incidental findings and how they will be handled.
4. Signature and date: The last section of the MR screening form must have the printed name and signature of the individual that is completing the form and the safety trained individual that is reviewing the MR screening form. The individual(s) that complete the form and review the form must both enter the date. The MR screening form is a medical-legal document and is invalid if printed name, signatures, or date are not included.

NOTE: *Screening forms for MR personnel should be essentially identical to the participant screening form, as such, a specific guidance is not provided here.*

## 3.5 Use of contrast agents

The ACR guidelines on gadolinium contrast agents (2012) will serve as the standard of practice when administering gadolinium contrast agent for clinical trial participants or study participants requiring gadolinium.

## 3.6 Use of sedation and analgesia

The ACR Guidance Document for Safe MR Practices (2013) will serve as the standard of practice when sedation or analgesia is required

# 4 Appendix 1

Safety form to document implants or foreign bodies

**MRI SAFETY - FORM 3 MRI safety information**

THE FLOREY INSTITUTE OF NEUROSCIENCE & MENTAL HEALTH

- ***To be completed by MRI team***
- **Please indicate safety information available for each procedure / incident listed by the researcher**

**Name of patient: _____ DOB: _____/_____/_____**

**Safety Form Reference number:** ???-????????-??

**(Initials/DOB/Instance number e.g. JL-12051982-01)**

**Procedure number: _____**

Procedure: _____

Hospital: _____

Surgeon: _____ Date of procedure: _____

Implant name: _____ Manufacturer: _____

Details of implant: _____

Copy of item label attached: Yes/ No

Relevant documentation attached: Yes/ No

Safe @ 3T according to Shellock's MRI safety reference manual: Yes/ No

Safe @ 3T according to manufacturer's information: Yes/ No

**Further details:** _____

_____

_____

Based on the information provided please identify if it is **unlikely** the participant will experience any adverse effects during his/her 3T Research scan. Yes/ No

- **If YES, please advise the researcher to proceed with the booking request. Please note: The researcher and participant will be informed that if the participant feels any discomfort during the scan – the scan will stopped.**
- **If NO, please advise the researcher that based on the information provided we cannot confirm that this participant is safe to be scanned at 3T.**

**Name: _____ Signed_____ Date: _____/_____/_____**

**Name: _____ Signed_____ Date: _____/_____/_____**