Guidelines for MR scanner operator training for non-radiographers

Victorian Biomedical Imaging Capability (VBIC)

www.vbic.org.au

EXECUTIVE SUMMARY

- Human MRI research is an emerging field within Victoria and requires research guidelines and operational models for MRI research facilities outside the hospital context.
- The Victorian Biomedical Imaging Capability (VBIC) has developed common procedural guidelines on the implementation of MR scanner operator training for non-radiographers.
- VBIC recognises that MR scanner operation requires adequate and appropriate training in order to ensure overall safety of staff and participants within an MR environment.
- MR scanner operator training is one of the key overall objectives for increasing Biomedical Imaging research capability, capacity, quality and competitiveness within Victoria.

This white paper is a result of working negotiations of VBIC consortium representatives throughout the time period of March 2011 – May 2013. This paper was presented and approved by the VBIC Coordination Committee on 7 June 2013.

Table of Contents

1 Disclaimer

The information contained in this document is a guide only and no VBIC or non-VBIC site is compelled to implement this guide. The VBIC Coordination Committee takes no responsibility for the success, failure, competence or capability resulting from the implementation of suggestions made in this document. All imaging facilities should review this information in the context of their own quality control, quality assurance, training and risk management strategies. Those seeking to implement this guide are advised to check their organisation's legal and insurance regulations (see Section 8, page 8).

2 Introduction

Currently, accredited radiographers undertake the vast majority of Magnetic Resonance Imaging (MRI) research scans of human volunteers, because MRI research on human volunteers in Australia was, up until now, primarily confined to the hospital environment. As MRI research of human volunteers is becoming more widespread, an increasing need for MR scanner availability has emerged over the last few years, with MRI research facilities emerging outside the hospital context.

Although MR scanner operation by accredited radiographers, as per clinical guidelines, has been a suitable arrangement in the past, the opportunities for improved MR physicist training and the increasingly specialised nature of research MRI protocols necessitate a reconsideration of the practice of radiographer-only operation in MRI research facilities.

The Victorian Biomedical Imaging Capability (VBIC) plays a significant role in advancing imaging research in Victoria. Due to the number of research-focused MR scanners funded by VBIC or supported through VBIC-funded staff, it is appropriate that VBIC leads the activities to document a well-considered and suitable approach, which will help mitigate the risks associated with MR scanner operation by non-radiographers while maximising opportunities to enhance MR physicist training and development. Ultimately, this will produce better-trained researchers and perhaps lead to improved research outcomes.

The existence of MR scanners purely used for research purposes provides a unique opportunity to enhance the training of researchers, MR physicists in particular. Furthermore, research and clinical scanning protocols are diverging and are growing in complexity such that MRI research requires an increasing amount of hands-on experience as well as knowledge of the physics and computational capabilities of the MR scanner. These two factors are driving the development of this protocol.

2.1 Definitions

Word/Term	Definition
Phantom	Specifically designed objects that can be scanned, and provide a known MRI

	outcome. In many cases they are used to evaluate, analyse or tune the performance of the MR scanner. They can also be used as an educational tool.
Healthy participant	Any person who has volunteered to participate in an MRI scan and does not have a known clinical condition of specific research interest.
Research participant	Any person who has volunteered to participate in an MRI scan and also has a known clinical condition of specific research interest.
Clinical patient	A person referred with an MRI Request Form for an MRI scan for medical reasons
MRI	Magnetic Resonance Imaging
MRI principal	Executive manager of the MRI facility
MRI operator trainee	A person engaged in undertaking the MR scanner operator training schedule
MRI certified operator	A person who has successfully complete the MR scanner operator training schedule
MR Safe (adapted from US FDA)	The device or implant is completely non-magnetic, non-electrically conductive, and non-RF reactive, eliminating all of the primary potential threats during an MRI procedure.
MR Conditional (adapted from US FDA)	A device or implant that may contain magnetic, electrically conductive or RF-reactive components that is safe for operations in proximity to the MR scanner, provided the conditions for safe operation are defined and observed (such as 'tested safe to 1.5 teslas' or 'safe in magnetic fields below 500 gauss in strength').
MR Unsafe (adapted from US FDA)	This category is reserved for objects that are significantly ferromagnetic and pose a clear and direct threat to persons and equipment within the magnet room. Any "unknown" object is automatically assigned to this category unless safety can be proven.

3 The need for non-radiographer MR scanner operators

Key drivers for non-radiographer scanner operation

1. Enhanced training opportunities – the existence of MR scanners only used for research provides unique training opportunities for MR researchers (MR physicists in particular).
2. Specialisation of research imaging protocols – increasingly research and clinical imaging protocols are quite different with differing intended outcomes.

3.1 Enhanced training opportunities

In the past, researchers conducted their activities on clinical scanners after-hours or in quiet periods. As a clinical environment, the MR scanner can only be operated by suitably qualified personnel – namely radiographers.

However, through infrastructure development and enhancement initiatives such as the formation of VBIC and the National Imaging Facility, there are an increasing number of MR scanners located in research facilities and only used for research purposes. For very specific participant cohorts, i.e. healthy participants, and under controlled circumstances (i.e. adherence to appropriate participant screening protocols) there is an opportunity to provide enhanced training and experience to MR physicists, and thus improve research capability, capacity and quality in Victoria.

3.2 Specialisation of research imaging protocols

As MRI research has grown, the scanning protocols used in research and clinical settings have diverged. We are now at a point where a large amount of research scanning involves protocols that may not be familiar to radiographers, as they are not used in clinical practice (a good example is functional brain imaging). Thus, physicists and other non-health professionals working on the development of MR equipment and/or MRI protocols need a different set of expertise compared to health professionals, including experience in the application of scanning methodology to healthy participants in order to evaluate their research efforts.

4 Non-radiographer scanner operation

Researcher performance of research scans on MR consoles is not a new practice overseas or in Australia. Within the UK, and Europe more broadly, this has been common practice since the 1990s, and relates to a number of scope of practice changes for radiographers. Within Australia, researchers have been operating MR scanners at the University of Queensland since the early 1990s, when the first and only program of its type in Australia was implemented.

Case study – University of Queensland

Since the early 1990s (reportedly from 1992), the University of Queensland has trained researchers to operate MR scanners for human volunteers under very specific circumstances. Their credentialing process involves an in-house training program. Although no formal review has been undertaken, there have been no adverse incidents reported from the University of Queensland program. Appropriate training and supervision (by a radiographer) has been used to ensure safety[1]. Despite the extended history of University of Queensland researchers operating MR scanners, this approach has not been taken up across the biomedical imaging research community.

5 VBIC's MR scanner operator training

As owners and operators of a number of MR scanners and associated peripheral equipment, VBIC has the opportunity to establish new operational models for biomedical imaging research. Currently, radiographers operate the vast majority of MR scanners as per clinical guidelines, regardless of the subject being scanned (i.e. clinical patient, research participant or healthy participant) or the location of the scanner (dedicated research facility or clinical setting).

Of course, researchers must be appropriately trained and supervised before being allowed to operate an MR scanner. The requirements for a standardised training and certification process for researchers to be approved to operate an MR scanner for scanning healthy participants are outlined below.

VBIC proposes an *MR scanner operator training* program for MRI research facilities for certifying researchers to operate MR scanners under specific conditions. By implementing this training, VBIC Nodes will be able to offer a richer research training experience to PhD students and post-doctoral staff of their facility. This could create increased demand for PhD and post-doctoral places as well as a improve MRI research capability, capacity and quality in Victoria.

5.1 Description

The *MR scanner operator training* builds on the basic MRI safety training that must already be in place at MRI research facilities (see Appendix 1). The training will provide an MRI certified operator the additional knowledge necessary for independent operation of the MR scanner, including safe handling of subjects and MR-related research equipment.

The training will be available to advanced graduate students (i.e. higher degree research students undertaking a Masters or PhD), post-doctoral research fellows, faculty and certain other individuals at the discretion of the MRI principal. Undergraduate students will not be permitted to become certified to operate the MR scanner.

[1] Ian Brereton, Personal Communication

Prerequisites

- Undergraduate science, biomedical science or similar degree*
- Completion of MRI safety training as outlined in the VBIC MRI safety guidelines (see Appendix 1)

**Note: If this prerequisite cannot be met, it will be up to the MRI principal to judge if the applicant qualifies to start the training.*

Assessment

A full description of the training specifications and record logbook, developed by VBIC, is attached as Appendix 2. The training is considered complete once an accredited MR radiographer signed off on all training units, and the trainee and the MRI principal have co-signed the final check. At their discretion, the MRI principal may determine further training is required. This may include a confidential discussion between the MRI principal and the MR radiographer.

Following successful completion of training, the MRI certified operator will need to maintain their training, particularly as it relates to health and safety requirements of the facility. Further specific training, maintenance of currency and re-credentialing (e.g. after a prolonged period of not scanning) is at the discretion of the MRI principal and the MR radiographer.

6 Scope of practice and risk assessment

The objective is to ensure the safe operation of the MRI research facility, while ensuring it is utilised to its fullest extent. To ensure safety is maintained, the scope of practice of an MRI certified operator will be limited to a very narrow and defined set of circumstances. Specifically:

- All scanning protocols are developed and optimised in consultation with a radiographer and/or radiologist, at the discretion of the MRI principal, prior to the MRI study. During the study, any MRI related queries must be directed to a certified MR radiographer (this may be done over the phone). This will help ensure researchers and study participants are protected from adverse scanner events.

- All participants (and their carers or visitors) whishing to enter the magnet room must first pass an MR safety screening process as outlined in the MRI safety guidelines (see Appendix 1). If an implanted device or a change in circumstances (for example pregnancy) is identified at the final screening step performed by an MRI certified operator, the scan should be postponed until positively identification in writing for each new item is obtained which confirms that the participant is safe to be scanned. There should be no exceptions to this guideline.

- Under no circumstances does the qualification of a person as an MRI certified operator allow them to scan clinical patients or research participants. The scope of practice of MRI certified operators is limited to

healthy participants for their own research study only[2]. That is, MRI certified operators cannot perform scans for other researchers or projects they are not involved in. Limiting the MRI certified operator's scope of practice will help ensure the safety of study participants and the researchers.

Appendix 3 provides a risk matrix on common risks related to normal MR scanner operation and the additional mitigation strategies for non-radiographer scanner operation.

7 Outcomes

Upon completion of the training, the MRI certified operator will have acquired:

- Knowledge of quality control theory and site-specific procedures
- Knowledge of best practice in MR radiography and MR technology applications
- Specialised knowledge of advanced MRI techniques

Upon successful completion of the *MR scanner operator training*, MRI certified operators are granted access to all areas of the specific MRI facility they have been certified as an operator in (i.e. the certification only covers one MRI site). MRI certified operators are responsible for the safety of research personnel, normal volunteers and visitors, while operating the scanner(s).

8 Implementation

In order to implement these guidelines, the following procedure is suggested:

1. Notify VBIC administration you are implementing the guidelines.
2. Provide the guidelines to the local OHS authority to approve their use at the MRI research facility.
3. Notify the relevant Human Research Ethics Committee chairperson that the site has adopted the guidelines and provide a copy of the guidelines if requested.
4. Notify the organisation's insurer and ensure policy covers non-radiographers scanning healthy participants.

9 Appendices

Appendix 1: VBIC MRI safety guidelines

Appendix 2: MR scanner operator training – Record of training

Appendix 3: Risk matrix non-radiographer MR scanner operation

[2] Note that it is important that MRI certified operators should not perform scans on all healthy participants that are *controls* within the research study that also involves research participants as it could create a scanning bias within the study.

MRI safety guidelines

Victorian Biomedical Imaging Capability (VBIC)

www.vbic.org.au

Table of Contents

Version: 1
Approved by: VBIC Node Directors
Date of approval: 7 Jun 2013

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: _____/_____/_____

MR scanner operator training - Record of Training

Name of trainee:

MRI research facility:

Training Unit	Description	Date	Name, position and signature	
MRF induction and MR safety training	MRF induction and MR safety session			
	MR safety screening form (conducted by the MRF radiographer)			
MRI safety policies and procedures	Participant handling and preparation procedures			
	Pre scanning checks			
MR facility and equipment orientation	Overview of facility management, scope and configuration			
	Orientation to MRI equipment room, oxygen connections, vacuum valve and immobilization pillows			
Life support training	Certification in Basic Cardiac Life Support (training provided by the MRF home institution)			
MRI operator training	Overview of scanning procedures (provided by the MRF)			

	Overview of the MRI scanner start-up and shutdown procedures (must be completed with the MRF radiographer)			
	Overview of MRF incidental finding protocol and procedure (provided by the MRF)			
	MRI console operation: • 10 hours shadowing accredited radiographer. • 20 hours of supervised scanning of phantoms or ex-vivo samples • 20 hours supervised MRI sessions*. (Logbook, as provided on the following pages, must be attached to this record document)			

**If the MRI study involves a large number of participants at least 5 participants of the study are scanned under supervision of the MRF radiographer. As such, MRI operator trainee assists in positioning, planning and implementing scans specific to his/her study.*

Final check

Evidence of completion of all training listed above needs to be provided to the MRF radiographer. All evidence should be included in the final record of training. The MRF and the trainee should keep a copy of the record of training. The MRI principal signs below to indicate they have cited all relevant evidence. The trainee signs below indicating all evidence is true and correct.

Signature of trainee: Date:_____ / _____ / _____

Signature of MRI principal: Date:_____ / _____ / _____

1.1 MRI console operation – Logbook training session

1.1.1 10 hours shadowing accredited radiographer

Hour (s)	Start time	End time	Date	MRI protocol/case type	Signature radiographer

Note: A minimum of 5 different types of cases must be performed. The MRF radiographer must sign off each session.

1.1.2 20 hours supervised MRI sessions – phantoms or ex vivo samples

Hour(s)	Start time	End Time	Date	MRI protocol/case type	Signature radiographer

Hour(s)	Start time	End Time	Date	MRI protocol/case type	Signature radiographer

1.1.3 20 hours supervised MRI sessions – human research subjects

Hour(s)	Start time	End Time	Date	MRI protocol/case type	Signature radiographer

Risk matrix non-radiographer MR scanner operation

Risk	Events expected if risk occurs	Current actions (radiographer operated)	Likelihood (1-5)	Impact (1-5)	Risk exposure (1-25)	Strategy	Additional mitigation strategies implemented - non-radiographer operator
Exposure to excessive noise	Prolonged exposure to high levels of acoustic noise can cause permanent hearing loss and tinnitus.	Noise cancelling headphones and earplugs are provided to all participants and any individuals in the MR scanning room whilst the scanner is operating.	2	2	4	Mitigate	Researcher is advised of the requirement for two levels of hearing protection in the training program. Additional staff member to be present at all times
3T MRI brain effects	Movement of the head in or near the entrance of the MR management bored can induce dizziness.	Ensure that the participants' head is not moved quickly through the MR magnet bore. Advise the participant to remain lying on the trolley when they emerge from the bore, rather than sitting up straight away. All MR personnel receiving MR safety training will be informed of the Lorentz phenomenon and instructed to move their head slowly when near the entrance of the MR magnet bore.	2	1	2	Mitigate	Researcher is advised to inform participants to remain lying on the trolley until they are advised to sit up. Researchers will be advised to move head slowly when near the entrance of the bore. Additional staff member to be present at all times.
RF body heating	Exposure to RF electromagnetic fields (EMF) can induce heating of biological tissues (quantified as SAR in units of W/kg).	Participants with impaired thermoregulatory ability as a result of age, disease or the use of medications are in the nominated group for handling with caution, and scanning times will be kept as short as practicable. To minimise the risk of RF burns, MR personnel will advise and monitor the participant to ensure that they do not position their limbs in a way that will create conductive body loops (though this risk is already low if only RF head coils are used). Furthermore, coil leads, ECG leads and oxygen monitor probes, in particular, must be MR SAFE OR MR CONDITIONAL and insulation shall be placed between the individual's skin and these types of items.	2	1	2	Mitigate	Researcher to be trained regarding the creation of conductive body loops. Additional staff member to be present at all times.

Risk	Events expected if risk occurs	Current actions (radiographer operated)	Likelihood (1-5)	Impact (1-5)	Risk exposure (1-25)	Strategy	Additional mitigation strategies implemented - non-radiographer operator
Gradient field neural effects	Exposure to switched gradient field occurs when the scanner is collecting images	Software and hardware components exist in the scanner to control the exposure of the patient to gradient fields. Before a sequence is commenced, the scanner system performs a calculation to ensure the EMF exposure levels are acceptable.	2	1	2	Mitigate	Researcher must not override the function calculating and notifying the operator of exposure levels, in the absence of a radiographer. Additional staff member to be present at all times.
3T missile magnets	Ferromagnetic items may be drawn into the scanner at high speeds, resulting in impact with people or equipment.	MR personnel are responsible for screening themselves for metal objects and implants, as instructed in their MR safety training. All non-MR personnel entering the scanner room must first pass an MR safety screening process conducted by the radiographer. The screening process shall include completion of a "screening form" to indicate if wearing or carrying any ferromagnetic objects. Just prior to entry, these persons will also be verbally questioned and visually inspected by the radiologist for the presence of ferromagnetic objects on their person. Any equipment purchased for the MR scanning room must be confirmed as MRI safe. The entrance to the console room shall be marked with appropriate signage indicating the presence of a strong magnetic field.	1	5	5	Mitigate	Training to be updated 6 monthly. Additional staff member to be present at all times. This staff member will also oversee and vigilantly screen the participant.
Metal implants	MR scanning of a participant with a passive or active metallic implant can exert a strong attractive force on a ferromagnetic object inside the participant's body.	All non-MR persons entering the scanner room shall be screened for the presence of implants, to establish whether they have any implanted devices or materials, whose operation, position or temperature could be affected by the magnetic field, e.g. pacemakers, aneurysm clips, stents, clips, shunts, wires or joint replacements.	1	5	5	Mitigate	Researchers will be required to screen participants and have a secondary screening performed by an additional staff member. Researcher shall be made aware in their training that in some cases persons may not disclose implants inside them, either from forgetting, not being mentally

Risk	Events expected if risk occurs	Current actions (radiographer operated)	Likelihood (1-5)	Impact (1-5)	Risk exposure (1-25)	Strategy	Additional mitigation strategies implemented - non-radiographer operator
		This includes the completion of a "screening form", which is reviewed by the radiographer. The radiographer determines whether it is safe for the individual to enter the scanner or scanner room, and signs the form accordingly. Where concern may be raised the person administering the questionnaire will consult with another senior radiographer, or the MBI Clinical Head					competent, or being deliberately misleading. In all cases, the researcher conducting the screen will be vigilant for any sign of an implant, including body scars and detailed and repeated questioning of the participant's medical history, and of participant associates where appropriate. In the event that a metal implant of any kind is identified, or suspected, the individual will not be scanned by the researcher, but a radiographer will re-screen the individual and undertake the scan if they deem it appropriate.
Cardiac arrest during scan	Participant goes into cardiac arrest whilst undergoing MR scan	Participants with a known heart condition are monitored during scanning by appropriately qualified medical personnel.	1	5	5	Mitigate	Participants with a known heart condition shall not be screened by non-radiographer operators. Resuscitation equipment is available for use by appropriately trained and certified resuscitation staff in the building. All non-radiographer operators will be required to undertake first aid training (level?)
Participants with a mental health condition	MR scanning of a participant with a diagnosis of a mental health condition may cause significant anxiety for the participant. In severe circumstances, psychological distress may lead to a panic attack.	The radiographer is alert to detecting participant distress at the earliest possible time, to discover the source of the distress, and then to provide appropriate intervention.	1	3	3	Avoid/ mitigate	If anxiety / claustrophobia / panic attacks have been demonstrated by the participant in the past, the individual will only be screened by a radiographer.

Risk	Events expected if risk occurs	Current actions (radiographer operated)	Likelihood (1-5)	Impact (1-5)	Risk exposure (1-25)	Strategy	Additional mitigation strategies implemented - non-radiographer operator
Pregnant women	Exposure of the fetus to acoustic noise, low frequency gradient coil magnetic fields and RF heating from the MR scanner. There is no clear evidence that exposure to static or low frequency magnetic fields can adversely affect pregnancy outcome (ICNIRP Procedures published in Health Physics 2004;87(2):197-216).	Pregnant women shall be precluded from MR scans unless specific ethics approval is granted.	2	1	2	Avoid	Researchers will not be allowed to scan pregnant women, or those who suspect they are pregnant.
Young children	Implant and missile hazards, as children may not disclose as reliably as adults. Premature removal from the scanner and movement artefacts may result.	Children are provided with training sessions in the "mock" MR scanner, prior to the actual scan being performed. Children are not sedated for studies on this site.	3	1	3	Avoid	Researchers will not be allowed to scan children under 10 years of age.
MRI contrast agents	Adverse reactions to intravenous injection of contrast agent	Contrast agents will not be used	5	3	15	Avoid	Contrast agents will not be used
Lone working	A staff member suffering an accident while alone in the MRI facility (e.g. being struck by a magnetic missile) may be unable to summon assistance	A minimum of two MR personnel shall always be present in the MR facility during scanning operations after hours.			0	Avoid	Researchers will not be allowed to work alone. A minimum of two personnel shall always be present in the MR facility during scanning operations conducted by non-radiographer operators
Injury in	Participants or scan	Keep scan room clear of obstacles that could	1	3	3	Mitigate	Scan room will be kept clear of

Risk	Events expected if risk occurs	Current actions (radiographer operated)	Likelihood (1-5)	Impact (1-5)	Risk exposure (1-25)	Strategy	Additional mitigation strategies implemented - non-radiographer operator
scanner	operators could be injured while in the scan room (not related to magnetic missile) and may need assistance	cause injury. Ensure a minimum of two MR personnel shall always be present in the MRI facility during scanning operations after hours.					obstacles that could cause injury. Researchers will not be allowed to work alone. A minimum of two personnel shall always be present in the MRi facility during scanning operations conducted by non-radiographer operators
Loss of skills	Adverse outcomes for researcher or research subjects.	Radiographer maintains suitable level of practice through continuing professional development, continual safety training and refresher courses.	2	5	10	Mitigate	Researchers are required to maintain their MR safety training. The MRI principal and the radiographer will maintain a regular dialogue on researcher skill. Certification will be removed if scanner practices are deemed unsafe. On a case-by-case basis re-training may or may not be recommended.