Exeter MR Research Centre

SAFETY MANUAL & RULES OF OPERATION

APRIL 2018

This policy is intended to provide staff and students working at the Exeter MR Research Centre with an overview of the safety issues involved in working at the centre and the operating procedures that need to be followed to minimise risk to themselves and others.

Date of next review: April 2019

Contents

1	Intr	Introduction		
	1.1	Doc	ument scope	4
	1.2	Role	es and responsibilities	4
	1.2	1	Director	4
	1.2	2	MR safety officer	4
	1.2	3	MR safety expert	4
	1.2	4	Users	4
2 Controlled areas and major hazards		d areas and major hazards	4	
	2.1	The	MR environment	4
	2.2	Maj	or hazards	4
3	Use	rs of	the MR centre	6
	3.1	Autl	norised personnel	6
	3.1.	1	Authorised user	6
	3.1.	2	Associate user	6
	3.1.3		Training and approval of authorised personnel	6
	3.2	Non	-authorised personnel	6
	3.2.1		Participants	6
	3.2.	2	Visitors	6
	3.3	Oth	er personnel	6
	3.3.	1	MR service engineers	6
	3.3.	2	Other staff	7
4	Acc	ess to	the EMRRC and controlled areas	7
	4.1	Acce	ess to the EMRRC	7
	4.2	Acce	ess to controlled areas	7
	4.3	Ente	ring the MR environment	7
5	Оре	eratio	nal overview	7
	5.1	Scar	nner operation	7
	5.2	Qua	lity assurance	7
	5.3	Risk	assessments	8
	5.4	Equ	ipment	3

.5	Faults		
.6	Incidents		
Proj	ect procedures		
.1	Principal investigator		
.2	Prior to commending a project9		
.3	Booking		
.4	MR screening participants9		
.5	Ethical issues		
.6	Scanning participants		
.7	Staff required for scanning participants		
.8	People accompanying participants11		
.9	Data11		
Eme	rgency procedures		
.1	First aid and medical emergencies11		
.2	Oxygen alarm sounding11		
.3	Evacuation in the event of a fire or fire alarm12		
.4	Fire		
.5	Quenching the magnet in an emergency13		
Refe	rences		
Appendix 1 (Authorised personnel approval)			
10 Appendix 2 (user and visitor safety checklist)			
1 Appendix 3 (Participant safety checklist)1			
	.1 .2 .3 .4 .5 .6 .7 .8 .9 Eme .1 .2 .3 .4 .5 Refe App		

Introduction

1.1 Document scope

This document governs the use of the magnetic resonance imaging (MRI) equipment installed in the Exeter MR Research Centre (EMRRC), St Luke's Campus, University of Exeter. It is mainly concerned with MRI-related safety and operational issues, and so should be read in conjunction with national, University, and College guidelines that cover more general aspects of safety and procedures.

1.2 Roles and responsibilities

1.2.1 Director

The Director (Dr Judith Meakin, University of Exeter) has overall responsibility for safety at the EMRRC and for revising this document in line with current information and in the light of experiences at the Centre.

1.2.2 MR safety officer

The MR safety officer (Dr Abdelmalek Benattayallah, University of Exeter) is responsible for ensuring the day-to-day safety at the EMRRC. They are also responsible for liaising with the University of Exeter Medical School (UEMS) H&S committee, training users, and maintaining records.

1.2.3 MR safety expert

The MR expert (Ron Hartley-Davies: r.hartley-davies@bristol.ac.uk and Jonathon Delve: Jonathon.Delve@UHBristol.nhs.uk) is responsible for providing advice to the Director and MR Officer on the safe operation of the EMRRC.

1.2.4 Users

Responsible for the safety of themselves and others as outlined in section 3.

2 Controlled areas and major hazards

2.1 The MR environment

A plan of the EMMRC is shown in Figure 1; it comprises the scanner (magnet) room, control room, machine room, laboratory, reception, and external plant. A region, termed the MR environment, is defined as being within the 0.5 mT magnetic field contour (Figure 1). The areas that include the MR environment are indicated by signs (on the door to the MR scanner room and on the two entrances to the external plant). Access to these areas is controlled as described in section 4.

2.2 Major hazards

The scanner involves the use of a strong static magnetic field, time varying magnetic fields, and radiofrequency magnetic fields. These all pose hazards and fatal or very serious injury may result from inappropriate actions in the MR environment.

Major MR safety considerations include:

- The magnet is ALWAYS ON;
- Its magnetic field can adversely affect pacemakers or other implanted devices;
- The magnet can strongly attract any loose metallic objects in its vicinity, causing them to become dangerous projectiles;
- Radio-frequency exposure during the imaging procedure can heat tissue, particularly if any metallic implants or objects are in or near the tissue.

An additional risk within the external plant is that it contains the quench pipe. In the event of the magnet quenching, large quantities of cold helium gas will be discharged out of the quench pipe leading to the possibility of asphyxiation as well as cold injuries.

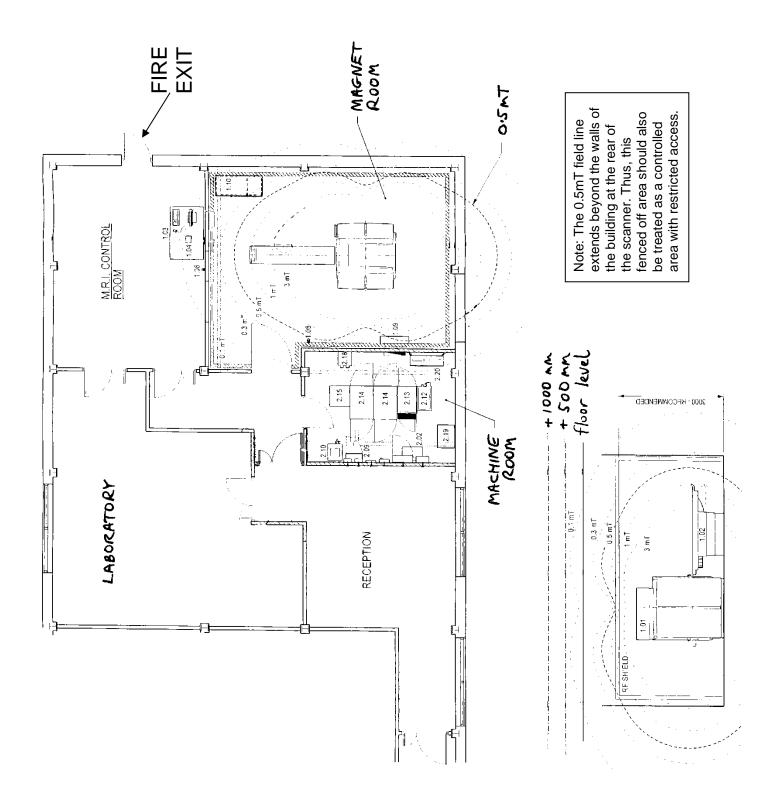


Figure 1. Plan and side elevation of the MR Centre showing the 0.5 mT magnetic field contour.

3 Users of the MR centre

3.1 Authorised personnel

3.1.1 Authorised user

Authorised users are allowed to work unsupervised in the EMRRC and the MR environment. They are responsible for supervising all associate users, participants and visitors whilst they are at the EMRRC. They are responsible for their own health and safety and that of those they are supervising. If an Authorised user is working alone, they must take note of the Lone Working Risk Assessment.

3.1.2 Associate user

Associate users are allowed free access to work unsupervised in the EMRRC and are allowed to enter and work in the MR environment if supervised by an Authorised user. They are responsible for their own health and safety. If an Associate user is working alone, they must take note of the Lone Working Risk Assessment.

3.1.3 Training and approval of authorised personnel

All users (Authorised users and Associate users) must have current approval to work in the EMRRC. This approval consists of having completed an appropriate level of training together with an approval form (Appendix 1) and safety screening form (Appendix 2). Both forms must have been checked and signed by the Director or another existing Authorised user.

The training of Authorised and Associate users will depend on the prior experience of the individual but must include, as a minimum, information on what to do in an emergency. Users who will be working at the EMRRC over a regular period must also complete the UEMS general laboratory induction.

Approval of an Authorised user lasts for a maximum of 12 months and must be renewed if the user wishes to continue working at the centre. Records of users and the expiry date of their approval will be kept on an electronic database at the EMRRC. Approval forms and safety screening forms will be retained at the EMRRC for three years.

3.2 Non-authorised personnel

3.2.1 Participants

Participants are allowed into the EMRRC under the supervision of an Authorised user or Associate. They are allowed into the MR environment under the supervision of an Authorised or Associate user but must have first completed a safety screening form (Appendix 3) that has been checked and signed by an Authorised user who must be satisfied that the participant has read and understood the questions on the form

3.2.2 Visitors

Visitors are allowed into the EMRRC under the supervision of an Authorised or Associate user. They are allowed into the MR environment under the supervision of an Authorised of Associate user but must have first completed a safety screening form (Appendix 2) that has been checked and signed by an Authorised user who must be satisfied that the visitor has read and understood the questions on the form.

3.3 Other personnel

3.3.1 MR service engineers

MR service engineers are allowed to work unsupervised in the MR environment with the agreement of an Authorised user.

3.3.2 Other staff

Other staff internal and external to the University (e.g. campus services, security, fire offices) may require access to the EMRRC and the MR environment. Access must be agreed with an Authorised user and safety screening forms (Appendix 2) completed as required and signed before the staff enter the MR environment.

4 Access to the EMRRC and controlled areas

4.1 Access to the EMRRC

- Access into to the EMRRC, and between areas in the EMRRC, is controlled by card locks that are operated by University of Exeter staff or student cards.
- The operation of these locks must not be compromised (e.g. by wedging a door open).
- Only Authorised users and Associate users will have their cards activated to allow them access to the EMRRC.
- The list of users who have swipe card access will be maintained by the MR safety officer.

4.2 Access to controlled areas

- Access to the MR environment (MR scanner room and External plant) is controlled by key locks.
- These areas are kept locked when not in use and only Authorised users may use the keys.
- At the end of a scanning session it is the responsibility of the Authorised user present at the session to ensure all doors are locked, keys returned to the key store and the facility left in a safe operating state.

4.3 Entering the MR environment

- Metal objects can easily transform into dangerous projectiles when taken into the MR environment and care must be taken to ensure that objects are not taken into the MR environment unless it is known that it is safe to do so.
- All unidentified metal items must be assumed a safety risk and must not be taken into the MR environment until they have been checked and approved by an Authorised user.
- All devices, equipment, implements, etc. must be tested for MRI safety and compatibility, before being allowed into the magnet room, and (where practicable) certified as safe by means of signed and dated label.
- Everyone must check that they have removed all metal items from their person (e.g. hairclips, coins, keys etc.) before entering the MR environment. Authorised users are responsible for checking with the user or participant that they have done this.

5 Operational overview

5.1 Scanner operation

- Authorised users and MR service engineers may operate the scanner unsupervised.
- Associate users may be allowed, at the discretion of the Authorised user who is supervising them, to operate the MR scanner.
- The scanner should not be operated on University Closure days (since there will not be sufficient help available in the event of an emergency).

5.2 Quality assurance

• The MR safety officer will run a quality assurance (QA) scan at least once a week; a QA scan should also be run after any non-standard operation of the scanner.

5.3 Risk assessments

- General risk assessments have been performed for many operational aspects of the EMRRC and can be found at http://gentres.oveter.ac.uk/pmrrg/publication/EMPRC_rick_assessment_acus.pdf
 - http://centres.exeter.ac.uk/pmrrc/publication/EMRRC_risk_assessment_2015.pdf
- A lone working risk assessment for the centre can also be found at <u>http://centres.exeter.ac.uk/pmrrc/publication/EMRRC_Lone_Working_Risk_Assessme_nt_20016.pdf</u>.
- When new equipment or procedures are introduced, a risk assessment must be performed before the equipment or procedure is used.

5.4 Equipment

- All equipment (i.e. the scanner and ancillary equipment) must be properly used, serviced and maintained in a good state of repair. If faults occur that prevent normal safe operation of the equipment, the equipment must be taken out of service until repaired and passed fit for use.
- Equipment intended for connection to the scanner must first be checked by an Authorised user.
- Ancillary equipment, e.g. PC, eye tracker, etc., must only be used by competent personnel.
- All equipment should be returned to its proper place and state after use.
- All equipment should be shut down / turned off and returned to its proper place by the last user of the day. This includes, but is not limited to, the scanner, monitors, stimulus presentation equipment, and monitoring equipment.
- Users are responsible for providing their own supplies (i.e. earplugs, gloves, contrast agent) unless another arrangement has been agreed.

5.5 Faults

- All equipment malfunctions must be reported to the MR safety officer and should be documented in the online Incident Log
 (http://gontrog.outor.ac.uk/pmpro/goguro/incident_form_php)
- (<u>http://centres.exeter.ac.uk/pmrrc/secure/incident_form.php</u>). All faults with the Philips System (i.e. MR scanner equipment) should also be reported
- All faults with the Philips System (i.e. MR scanner equipment) should also be reported to Philips Medical Systems at the earliest opportunity.
- To minimize inconvenience, faults should also be reported to all users and investigators who are scheduled to use the equipment in the following 48 hours.

5.6 Incidents

- All safety incidents must be reported to the MR safety officer and Director and documented in the online Incident Log (http://centres.exeter.ac.uk/pmrrc/secure/incident_form.php).
- The MR safety officer is responsible for reporting incidents through the relevant University H&S committee.
- Some safety incidents should also be reported Medicines and Healthcare Products Regulatory Agency (MHRA, 2015); the MR safety officer is responsible for assessing whether this is necessary and filing the report.

6 Project procedures

6.1 Principal investigator

A principle investigator must be designated for all projects running at the EMRRC. The principal investigator is responsible for ensuring that the project procedures detailed in this section are followed.

6.2 Prior to commending a project

- Prior to the commencement of a new project, an online Project form must be submitted (<u>http://centres.exeter.ac.uk/pmrrc/captcha/captcha-page.php</u>).
- The risks involved in performing the project need to be assessed, and new risk assessments produced, in collaboration with the MR safety officer, if required.
- Studies involving human participants also need to supply the following:
 - Ethics application and the notification of ethical approval.
 - Participant information sheet and consent form.
- The MR safety officer will allocate a project number that can be used to make scanner bookings. The following prefixes will be used (SS: Sport and Healthcare Science; PS: Psychology; PMS: Medical School; PH: Physics).

6.3 Booking

- All requests for scanner time must be made in advance by using the EMRRC on-line booking system.
- Instructions for using the booking system are available from the MR safety officer.
- Rules concerning the amount of time that may be booked in advance are on the EMRRC website.
- If users are unable to make use of a booked session, they must contact the EMRRC so that the session can be made available to others.
- If users wish to book a session at short notice, they should contact the MR safety officer or Authorised user to check for late availability.

6.4 MR screening participants

- For studies involving human participants a safety screening form (Appendix 3) must be filled in by every participant before they are scanned.
- For studies where participants are scanned on multiple occasions within the same study, the safety screening form filled in on the first visit may be checked by the participants and resigned to confirm that nothing has changed since the previous visit.
- Screening forms must be approved and countersigned by an Authorised user before the participant is allowed in the MR environment.
- If the individual answers "NO" to all questions on both screening forms and the Authorised User is satisfied that the participant has given the questions due consideration, the form may be countersigned by the Authorised User and the participant may be permitted to enter the controlled area.
- If the individual answers 'YES' to any of questions pertaining to implants/devices within the body then the manufacturer/model must be obtained to confirm whether scanning is safe to undertake. Initially this can be assessed via the MRI safety list at: http://www.mrisafety.com/TheList search.asp. However, if the implant/device is not listed, then the manufacturer must be contacted directly to confirm the safety status before any scanning can take place. If it is not possible to scan a participant due to the implant/device the reason should be explained and it should be emphasized that even though they cannot be scanned as a research participant this does not necessarily mean that a future MR scan for medical purposes would be unsafe and this will be guided by the medical personnel concerned if such a need should arise.
- Authorised User is responsible for assessing implant safety before signing the screening form and allowing the participant in the MR environment.
- A copy must be maintained of the screening forms of all participants who are scanned and retained in a filing cabinet in the MR Centre for 5 years. Participants should be informed as part of the consenting process that this data will be retained.

6.5 Ethical issues

- All participants must be fully consenting adults who have given written informed consent, or minors who have written consent from their parents/guardians.
- The investigator is responsible for providing a copy of the signed consent form for the Authorised user to ensure that consent has been obtained.
- Copies of the consent forms will be retained at the MR centre in a filing cabinet for 5 years.
- Procedures for reporting results to participants, including incidental findings, will vary from project to project. Such procedures must be included in the ethical considerations for the project; participants must be informed of any such procedures in the participant information sheet.
- Procedures for retention of participant data must be included in the ethical considerations for the project; participants must be informed of any such procedures in the participant information sheet.

6.6 Scanning participants

- An alarm is available to participants during their examination. The operation of the alarm must be explained to participants before scanning commences.
- The well-being of participants is a major priority appropriate monitoring should be used, if necessary (according to the judgment of the Authorised User).
- If a participant experiences undue discomfort or distress during scanning, the examination must stop. The participant must be free to withdraw at any time and this should be explained to them prior to scanning
- Suitable earplugs and/or sound-attenuating earphones must be provided to all participants, except when low-noise MRI sequences are in use. Where participants refuse necessary hearing protection, they must not be scanned. Earplugs must be of a disposable type and discarded after a single use.
- The time spent in the magnet by any one person must not exceed 3 hours in any 24-hour period. Other than this, there is no restriction on the frequency with which a person may be scanned.
- The exposure of any one person to the static magnetic field (in or near the magnet) must not exceed an average of 0.2 Tesla, averaged over any 24-hour period. High magnetic fields (maximum 1.5 T) are only experienced within the magnet and just outside the bore, so in practice Authorised users and others may work within the EMRRC for an unlimited time, provided they do not remain in or near the magnet for long periods.

6.7 Staff required for scanning participants

- When imaging a participant in normal health who is not a member of a research group associated with the EMRRC, it is good practice to have two persons on hand: one to operate the scanner and one to cover the needs of the participant.
- When imaging a participant in normal health who is a member of a research group associated with the EMRRC, the person operating the scanner may cover the needs of the participant.
- When imaging a participant or patient with a medical condition, it is good practice to have two persons on hand (even if this condition is long-term and stabilised): one to operate the scanner and one to cover the needs of the participant/patient.
- When scanning a participant or patient who is receiving an infusion (e.g. contrast agent) medical staff (e.g. a nurse or doctor) should also be present.

6.8 People accompanying participants

- The reception area is designed as a waiting room for participants, patients, carers, observers, etc. No one should be left unattended in the reception area for long periods of time. It may be necessary to have someone on hand to cover the needs of persons waiting in the reception area.
- Families and relatives of the participant must wait in the waiting room; in exceptional circumstances they may be allowed to observe from the control room.
- It may be possible for visitors to observe a study from the control room but this must be agreed with the relevant Authorised user, preferably ahead of time.

6.9 Data

- All imaging and other data should be copied to DVD, USB stick or similar.
- Files may be deleted from the scanner after 1 month. It is the responsibility of the principle investigator of each individual study to ensure their data is appropriately saved.
- The EMRRC will not be responsible for managing and archiving data unless this has been previously agreed.
- If users have difficulties with obtaining and storing their data, they should contact the MR safety officer.

7 Emergency procedures

7.1 First aid and medical emergencies

- In the event of first aid being required, a first aider should be called. Notices in the reception area and control room list the local first aiders and their respective phone numbers.
- In the event of a significant injury or medical emergency occurring in the EMRRC
 - Phone for an ambulance immediately on (9)999;
 - Call a first aider;
 - Contact Estate Patrol on their general number 3999 (01392 723999 from a mobile/external phone) or their emergency number 2222 (01392 722222 from a mobile/external phone).
- The address to give the emergency services is Exeter MR Research Centre, University of Exeter Medical School, Magdalen Road, Exeter.
- If the affected individual is within the MR environment they should, if possible, be removed from the MR environment before treatment commences.
- If removal of the affected individual is difficult or unsafe, treatment may be administered within the MR environment, but only by a person who has been screened for MR safety.
- If treatment by persons who have not been screened, or who have been deemed as unsuitable for entering the MR environment, is necessary, the affected individual must be removed from the MR environment before such treatment commences.
- An MRI-safe patient trolley is kept in the Magnet room at all times; no other medical devices or equipment may be taken into the MR environment.
- If the scanner has NOT been quenched (see section 7.5), any emergency services in attendance must be informed of the issues presented by the static field.

7.2 Oxygen alarm sounding

• The oxygen monitor has two alarms: the first indicates that oxygen levels are lower than they should be, the second indicates that oxygen levels are dangerously low.

- In the event of the alarm sounding scanning should be stopped, the participant removed, and the door to the Scanner room left open.
- The incident should be reported to the MR Safety Officer and recorded using the online Incident log.
- The MR Safety Officer should investigate the reason for the alarm sounding and scanning should not be recommenced until it is deemed safe.
- If the second alarm sounds and there is no one in the Scanner room, personnel should not enter the Scanner room until it has been assessed as safe.

7.3 Evacuation in the event of a fire or fire alarm

- Stop all scanning.
- Remove the participant from the scanner (there is manual override on the patient table, for use in the event of power failure).
- Close and lock the door to the scanner room, if possible.
- Check all rooms in the EMRRC to ensure that all users, participants and visitors are included in the evacuation.
- Exit the EMRRC via the fire exit in the control room. If this exit has become unsafe, leave via the fire exits from the foyer beyond the reception area.
- Do not stop to collect personal belongings.
- Proceed to the designated assembly point: the Magdalen Road car park in front of the Medical School
- Do not re-enter the building until instructed by the Fire Service or other responsible person.

7.4 Fire

- On discovering a fire:
 - Immediately operate the nearest fire alarm.
 - Phone for the Fire Service on (9)999
 - Contact Estate Patrol on their general number 3999 (01392 723999 from a mobile/external phone) or their emergency number 2222 (01392 722222 from a mobile/external phone).
 - Implement the evacuation procedure (see 7.3).
- The address to give the emergency services is Exeter MR Research Centre, University of Exeter Medical School, Magdalen Road, Exeter.
- Users should only tackle the fire if they have received fire training to a level commensurate with the severity of the incident.
 - For a fire in the scanner room a MRI safe fire extinguisher, located in the vestibule outside the Scanner room must be used; no other fire extinguishers may be used.
 - For a file outside the scanner room, other fire extinguishers may be used.
- If the fire is beyond the scope of a fire extinguisher, an Authorised user must consider an emergency shutdown (see section 7.5) so as to allow access by the fire service and/or the use of extinguishers.
- Appropriate persons should make themselves available to liaise with the Fire Service, Estate Patrol etc. to inform them of the dangers associated with the magnetic field. They should jointly assess whether it is necessary to enter the magnet room with fire-fighting equipment. If this is deemed necessary, the magnet must first be quenched (if not already quenched).

7.5 Quenching the magnet in an emergency

- Emergency shutdown of the magnet (quenching) must only be undertaken by an Authorised user who has considered the relative risks of the situation and is in one of the following circumstances:
 - An individual requiring medical treatment is in a life-threatening situation resulting directly from the magnetic field, e.g., they are trapped by a metallic object.
 - The emergency services require access to the MR environment with ferromagnetic equipment.
- Quenching can be manually instigated in an emergency by pressing one of the emergency buttons located either in the magnet room or the control room (the control room is the preferable option).
- All persons who are able to leave the magnet room must do so before the magnet is quenched. The door to the examination room should be open during quenching.

8 References

MHRA, 2015. Safety guidelines for Magnetic Resonance Imaging equipment in clinical use, v4.2 ed. Medicines and Healthcare Products Regulatory Agency.

9 Appendix 1 (Authorised personnel approval)

Type of user (Authorised or Associate)

Name:

Expiry date

I have read the 'Safety Manual and Rules of Operation' document dated ______ and understand its contents.

I have undertaken an induction and am aware of the procedures to follow in an emergency.

I understand the major hazards posed by the EMRRC and am aware of the precautions that need to be taken to ensure the safety of myself and others I am responsible for.

I have completed a safety screening form and understand that I am responsible for informing the MR safety officer if there are any changes that may affect my suitability for working within a magnetic environment.

Approver

Name:

Signature:

Date:

10 Appendix 2 (user and visitor safety checklist)

Magnetic environment screening form for Non-scanned Individuals

The MR system has a very strong magnetic field that may be hazardous to individuals entering the MR environment if they have certain metallic, electronic, magnetic or mechanical implants, devices or objects. Therefore all individuals are required to fill out this form before entering the scanner room. Be advised, the magnet is **always ON**.

Date: Name:					
Contact Address:					
1. Have you had prior surgery or an operation (e.g., arthroscop	py, endoscopy, etc.) of any kind? \Box No \Box Yes				
If yes, please indicate date and type of surgery:					
2. Have you had an injury to the eye involving a metallic obje	ect (e.g., slivers, foreign body)? 🛛 🗖 No 🗖 Yes				
If yes, please describe:					
3. Have you ever been injured by a metallic object or foreign l	body (e.g. shrapnel, bullet etc.)? 🛛 🗖 No 🗖 Yes				
If yes, please describe:					
4. Are you pregnant, or suspect that you may be pregnant?	□ No □ Yes				
WARNING: Certain implants, devices, or objects may be hazardous to you in the MR environment. Do not enter the scanning room if you have any question or concern regarding an implant, device or object.					
5. Please indicate if you have any of the following:					
\square No \square Yes Anurvsm clip(s)					
🗆 No 🗖 Yes Cardiac pacemaker	<u>Important Instructions</u>				
\square No \square Yes Implanted cardioverter defibrillator (ICD)					
\square No \square Yes Electronic implant or device	Remove all metallic objects before				
\square No \square Yes Magnetically-activated implant or device	entering the scanner room including				
\square No \square Yes Neurostimulation system	hearing aids, mobile phone, keys,				
\square No \square Yes Spinal cord stimulator	glasses, hair pins, jewellery,				
□ No □ Yes Cochlear implant or implanted hearing aid watches, safety pins, paperclips,					
□ No □ Yes Insulin or infusion pump credit cards, magnetic strip cards,					
□ No □ Yes Implanted drug infusion pump coins, pens, pocket knives, nail clippers, steel-toed boots/shoes and					
□ No □ Yes Any type of prosthesis or implant all tools. Loose metallic objects are					
□ No □ Yes Artificial or prosthetic limb especially prohibited within the MR					
□ No □ Yes Anv metallic fragment of foreign body					
□ No □ Yes Anv external or internal metallic object					
□ No □ Yes Hearing aid					
\square No \square Yes Other implant					

I confirm the above information is correct to the best of my knowledge. I have read and understood the entire contents of this form and have had the opportunity to discuss its contents to my satisfaction.

Signature (person completing the form):..... Reviewed by:..... Signature:.....

For repeated visits only:

Signature (person completing the form):	Reviewed by:	. Signature:
Signature (person completing the form):	Reviewed by:	. Signature:
Signature (person completing the form):	Reviewed by:	. Signature:
Signature (person completing the form):	Reviewed by:	. Signature:
Signature (person completing the form):	Reviewed by:	. Signature:
Signature (person completing the form):	Reviewed by:	. Signature:
Signature (person completing the form):	Reviewed by:	. Signature:
Signature (person completing the form):	Reviewed by:	. Signature:
Signature (person completing the form):	Reviewed by:	. Signature:
Signature (person completing the form):	Reviewed by:	. Signature:
Signature (person completing the form):	Reviewed by:	. Signature:
Signature (person completing the form):	Reviewed by:	. Signature:

11 Appendix 3 (Participant safety checklist)

Participant Safety Checklist

Name:	Date of Birth: Study Name/Volunteer Number: .	
Please check the following list carefully, answering Please do not hesitate to ask staff, if you have any a		
1.Do you have a pacemaker, artificial heart valv	ve or coronary stent?	Yes No
2.Have you ever had major surgery? If yes, please give brief details:		Yes No
3.Do you have any aneurysm clips (clips put are	ound blood vessels during surgery)?	Yes No
4.Do you have any implants in your body?		
Yes No Joint replacements, pins or w	ires	
Yes No Implanted cardioverter defibi	rillator (ICD)	
Yes No Electronic implant or device		
Yes No Magnetically-activated impla	nt or device	
Yes No Neurostimulation system		
Yes No Spinal cord stimulator		
Yes No Insulin or infusion pump		
Yes No Implanted drug infusion pump	p	
Yes No Internal electrodes or wires		
Yes No Bone growth/bone fusion stin	nulator	
Yes No Any type of prosthesis		
Yes No Heart valve prosthesis		
Yes No Eyelid spring or wire		
Yes No Metallic stent, filter or coil		
Yes No Shunt (spinal or intraventricul	lar)	
Yes No Vascular access port and/or ca	atheter	
Yes No Wire mesh implant		
Yes No Bone/joint pin, screw, nail, w	ire, plate etc.	
Yes No Other Implant		
5.Do you have an artificial limb, calliper or sur	gical corset?	Yes No

	6.Do you have any shrapnel or metal fragments, for example from working in a mach	ine tool shop? Yes No		
	7.Do you have a cochlear implant?	Yes No		
	8.Do you wear dentures, plate or a hearing aid?	Yes No		
	9. Are you wearing a skin patch (e.g. anti-smoking medication), have any tattoos, body permanent makeup or coloured contact lenses?	y piercing, Yes No		
	10. Are you aware of any metal objects present within or about your body, other than above?	those described Yes No		
	11.Are you susceptible to claustrophobia?	Yes No		
	12.Do you suffer from blackout, diabetes, epilepsy or fits?	Yes No		
For women:				
	13.Are you pregnant or experiencing a late menstrual period?	Yes No		
	14.Do you have an intra-uterine contraceptive device fitted?	Yes No		
	15. Are you taking any type of fertility medication or having fertility treatment?	Yes No		

Important Instructions

Remove all metallic objects before entering the scanner room including hearing aids, mobile phones, keys, glasses, hair pins, jewellery, watches, safety pins, paperclips, credit cards, magnetic strip cards, coins, pens, pocket knives, nail clippers, steel-toed boots/shoes and all tools. Loose metallic objects are especially prohibited within the MR environment.

I have understood the above questions and have marked the answers correctly.

Signature (Participant/Parer	Date	 MR Centre Staff Signature
For repeated Signature (Participant/Parer	 Date	 MR Centre Staff Signature
Signature (Participant/Parer	Date	 MR Centre Staff Signature
Signature (Participant/Parer	Date	 MR Centre Staff Signature