Magnetic Resonance Imaging (MRI) Access Control and Safety Procedures in the King's Clinical Research Facility

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Approved by	Elka Giemza, CRF Manager
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Keywords	Magnetic Resonance Imaging (MRI), Access Control, safety, training, emergency, contingency
Supporting references	"MRI Local Rules" –KCH, SLaM, , KCL (DH) Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use (*Medicines and Healthcare Products Regulatory Agency*), March 2015.

Change History

Date	Change details, since approval	Approved by
May 2016	1. Updated related documents and references 2. Amendments to all sections to incorporate the current MHRA safety guidelines and to reflect current Local Rules 3. Additional Appendices for the classification of an MR Authorised Person and for an example of a CRF MRI Safety Screening Questionnaire and MRI Request Form	E.Giemza
May 2018	1. Section 4.3: Updated contact for MR Safety Expert 2. Section 4.6: Updated location for the MR safety training database 3. Section 5.2: Amended to reflect that not all MR personnel are automatically granted access to the MR Controlled Access Area 4. Section 7.1: Amended date for the MRI Local Rules	E.Giemza
August 2020	1. Update of NIHR logo 2. Supporting references: correction to text 3. Section 5.1: New text inserted 4. Section 5.0: numerical order changed as a result 5. Section 5.2: Removal of text for clarification 6. Section 5.5: Addition of text for clarification 7. Section 5.8: Addition of text 8. Section 6.1: Addition of text for clarification 9. Section 6.2 : Addition of text for clarification 10. Section 6.4: Addition of text 11. Section 7.1: Update of information	E.Giemza

Review History		
Date	Review details	Approved by
May 2016	Review of v1.0 conducted by Georgia Bullock, CRF QA Manager, and Karlene Fraser, Clinical MRI Physicist, as per the review date. Changes made as per 'Change History' and re-issued as v2.0.	E. Giemza
May 2018	Review of v2.0 conducted by Georgia Bullock, CRF QA Manager, and Karlene Fraser, Clinical MRI Physicist, as per the review date. Changes made as per 'Change History' and re-issued as v3.0.	E. Giemza
August 2020	Review of v3.0 conducted by Angelina Twumasi, CRF QA Manager, and Karlene Fraser, Clinical MRI Physicist, as per the review date. Changes made as per 'Change History' and re-issued as v4.0.	E.Giemza

1.0 Background

1.1 Magnetic Resonance Imaging (MRI) and Magnetic Resonance Spectroscopy (MRS) are diagnostic and research techniques which do not use X-rays or other ionising

radiation. In the majority of cases, Magnetic Resonance (MR) is considered to be without hazard to the patient. Nevertheless, there are number of potential hazards associated with MRI:

a. Hazards with static magnetic fields (B_0)

b. Hazards with time-varying magnetic field gradients (dB/dt).

c. Hazards with pulsed radiofrequency fields (B_1)

d. Acoustic noise

e. Exposure to MRI during pregnancy

f. Hazards with cryogens

1.2 The King's Clinical Research Facility (CRF) houses a 3.0T GE Discovery MR750 MRI Scanner on the Ground Floor, which is managed and maintained by the Department of Neuroimaging, King's College London (KCL). Studies being conducted within the CRF may require the use of the CRF MRI scanner, and the CRF is responsible for ensuring that robust systems are in place to ensure that anyone wishing to enter the MRI area is appropriately trained, undergoes full safety screening to identify any contraindications which would prevent them entering the area, and has limited access to the MR Controlled Access Area as per the "Local Rules" instructions (see Reference 7.1).

2.0 Purpose

2.1 The purpose of this Standard Operating Procedure (SOP) is to define the safety procedures in place within the CRF to ensure that access to the MRI Controlled Access Area by core CRF staff, users of the CRF (eg: researchers, radiographers, clinicians, nurses and study subjects) and visitors is restricted, safety screening checks are conducted and documented, and all relevant staff attend MRI safety training in accordance with the "Local Rules" guidance.

3.0 Scope

3.1 The CRF consists of the Experimental Medicine Facility (EMF), Clinical Trials Facility (CTF) and the Cell Therapy Unit (CTU). CRF SOPs are applicable across both the

EMF and CTF, the CTU will continue to maintain and control their SOPs to ensure compliance with Good Manufacturing Practice (GMP).

3.2 All staff wishing to access the MR Controlled Access Area on the Ground Floor of the EMF are bound to adhere to the procedures outlined in this SOP.

4.0 Responsibilities

4.1 The organisation responsible for ensuring that the MRI scanner in the CRF is maintained and is operating safely is King's College London (Department of Neuroimaging).

4.2 Each MR system or department has a named MR Responsible Person who has *overall* responsibility for the safe working of the MR system or department, including the updating of operational and safety policies, ensuring adequate training and the maintenance of safety facilities. The current MR Responsible Person for the CRF MRI is Superintendent Radiographer Mark Allin (mark.allin@kcl.ac.uk, Tel: 0203 228 3092 (see MRI Local Rules at Reference 7.1).

4.3 An MR Safety Expert is appointed to provide specialist advice on the scientific and technical issues relating to MR safety and on relevant training requirements for staff. The MR Safety Expert is usually a suitably qualified MR physicist or non-clinical safety officer. The current MR Safety Expert for the CRF MRI Scanner is Marco Borri (marco.borri@nhs.net Tel: 0203 299 9000 x34898) (see MRI Local Rules at Reference 7.1).

4.4 A nominated Consultant Anaesthetist is responsible for anaesthesia services in MRI departments performing anaesthesia. The nominated Consultant Anaesthetist for the CRF MRI Scanner is currently Dr Robin Kumar (robin.kumar@nhs.net, Tel: 0203 299 9000 x33154 (see MRI Local Rules at Reference 7.1).

4.5 The classification of an 'MR Authorised Person' falls into one of three categories: MR Authorised Supervisor, MR Authorised Worker and MR Aware. These persons will have at least received adequate training in MR safety (to the satisfaction of the MR Responsible Person) such that they take responsibility for their own safety within the

MR Controlled Access Area. Further details of each category can be seen in Appendix 8.1.

4.6 MRI Safety Training is held monthly at the Centre for Neuroimaging Sciences (CNS) and is part of the induction to the CRF**.** A list of all MR safety trained individuals is available in the MR safety training database which can be accessed by the CRF Quality Assurance Manager. Confirmation of attendance at an MRI Safety Training session will be verified by the CRF staff member performing the CRF induction (see *CRF-QA-SOP-1: Local Induction Procedure for King's CRF Users* and *CRF-QA-SOP-6: Local Induction Procedure for King's CRF Staff*).

4.7 The CRF Manager is responsible for ensuring that robust access control procedures are in place within the CRF for the MRI Controlled Access Area and that CRF staff and users who wish to enter the area have been appropriately trained, safety screened and are authorised to do so.

5.0 Control of Access and Safety Screening

5.1 For safety reasons it is absolutely vital to control the access of people and equipment into the MRI department. Around the MRI scanner two regions are defined, these are the MR Controlled Access and the MR Environment. The MR Controlled Access Area is concerned with restricting access to the MR Environment which is included within it

5.2 The entire CRF MR Unit is defined as the MR Controlled Access Area and has restricted access by self-locking doors. All entrances to the MR Controlled Access Area must have prominently displayed warning signs. Appendix 8.2 shows the plan of the CRF MRI Unit and the extent of the 0.5mT (5 gauss) fringe field line.

5.3 MR Authorised Persons can have free access to the MR Controlled Access Area. However, all unauthorised persons (including unauthorised staff, patients, research participants, comforters and carers, and visitors) must be appropriately screened by, and seek authority from, an MR Authorised Supervisor before they can first enter the MR Controlled Access Area.

5.4 Under no circumstances can an unauthorised person enter the MR Controlled Access Area when not under the direct supervision of an MR Authorised Person. Any failure to comply with the safety instructions of the supervising MR Authorised Person may be referred to the appropriate employer as a disciplinary issue.

5.5 Within the CRF, the CRF Director, CRF Manager, CRF Quality Assurance (QA) Manager and CRF Facilities Manager act as MR Authorised Supervisors (subject to safety training), and as such may review and screen visitors. All other MRI safety trained CRF staff will be classified as MR Aware and can obtain access to the MR Controlled Access Area but are not permitted to grant access to visitors, (unless officially approved and authorised otherwise by CRF Manager and the MR Responsible Person).

5.6 All unauthorised persons must be at least verbally screened by an MR Authorised Supervisor before entering the MR Controlled Access Area. Persons who fail the screening procedure must NOT enter the MR Controlled Access Area. No unauthorised person will be allowed access to the MR Environment without first completing and signing a safety screening questionnaire to the satisfaction and verification of the MR Authorised Supervisor, who will then countersign.

5.7 There are three types of MR Safety Screening Questionnaire (see Appendix 8.3 for an example) stored at the CRF reception. The appropriate form will be issued by the CRF reception staff to anyone who has not yet completed a screening form and wishes to gain entry into the MR Controlled Access Area. Individuals who have previously completed an MR Safety Screening Questionnaire at the Centre for Neuroimaging Sciences are also required to complete a form at the CRF. These forms are site-specific and must be completed in the CRF for ALL personnel, visitors and study subjects who require access to this area.

5.8 The safety questionnaire for staff and collaborators is a **blue** form. This will usually be completed at the time of MR safety training, but if not, it needs to be completed by a staff member or collaborator the first time they attend the unit. It should then be

authorised by an MR Authorised Supervisor or CRF MR Authorised Supervisor and filed in the 'MRI Access Forms' folder, located in the CRF reception.

5.9 The safety questionnaire used for visitors to the MRI unit is a **yellow** form which needs to be completed by each visitor, authorised by an MR Authorised Supervisor and returned to reception before the visitor (eg: a contractor) to the CRF can enter the MRI unit. It should be held there until the visit has been completed and then shredded/placed in the confidential waste bin. If a CRF MR Authorised Supervisor is the reviewer of the form and sees a potential contraindication which might prevent that visitor entering the MR Controlled Access Area, the form should instead be reviewed and authorised by a CNS MR Authorised Supervisor.

5.10 The MRI Safety Screening Questionnaire for study participants is a double-sided **orange (or peach)** form and is one of two forms that needs to be completed by each participant every time they come for a scan. The front of this form, along with the lower section on the reverse requesting GP details, ***must*** be completed before a participant can be scanned. The upper section on the reverse, relating to the "MRI Picture Library", has not yet been approved by the KCH R&I department, and should ***not*** be completed until further notice. **Reception staff should strike this section through in ink before passing the form to a participant to complete.** Once completed, this form needs to be authorised by an MR Authorised Supervisor (usually the radiographer on duty).

5.11 The second form required by study participants is a white MRI Request Form (see Appendix 8.3) which needs to be completed by the study researcher along with the participant, for **each and every** scan attended. This form will be used for the clinical reporting of incidental findings by a Neuroradiologist, taking into account any known background information or pre-existing medical conditions.

5.12 The research collaborator leading the study needs to be made aware that both the orange and white forms will need to be given to a radiographer prior to the participant entering the MR Controlled Access Area and will be kept to refer to during the scan. Once the scan is complete, both forms will be taken to the Centre for

Neuroimaging Sciences (CNS) to be scanned and uploaded onto CRIS (Computerised Radiological Information System), before being shredded/placed into confidential waste. Currently Michelle Pearce (in the CNS Clinical Admin Office, Room 1.03) will undertake this duty and if necessary can be contacted on 0203 228 3073 or at michellepearce@nhs.net.

6.0 Emergency Procedures & Contingency Plans

6.1 Cardiac Arrest:

In the event of cardiac arrest, any ongoing scan must be aborted immediately. The subject should be removed from the MR Environment at the first opportunity. Under no circumstances should MR Unsafe ferromagnetic resuscitation equipment be brought into the MR Environment. **Please note that the resuscitation trolley in the corridor of the Ground Floor of the CRF and the Airway Trolley in room G11 are MR Unsafe.**

6.2 Major Equipment Failure:

In the event of a major equipment failure, resulting in serious malfunction or electric shock to the patient, the electrical power to the system should be switched off. The patient can then be safely evacuated from the MR Environment. Scanning must not be resumed until a qualified MR service engineer has inspected the system and certified it as safe to use. The MR Safety Expert and MR Responsible Person must be informed of any major equipment failures, and the MR Responsible Person must then inform the MHRA.

Please note: The magnetic field remains ON even after the electrical power has been switched off (by pressing the EMERGENCY OFF button)

6.3 Fire:

KCH fire procedures should be followed as per *CRF-HS-FRM-1: CRF Ground Floor Fire Evacuation Plan.* In addition, the following area-specific rules apply:

6.3.1 On discovering a fire in the MR Controlled Access Area:

6.3.1.1 Raise the alarm by operating the nearest fire alarm call point/shouting "Fire" to warn others.

6.3.1.2 Abort all MR procedures.

6.3.1.3 If you consider it is safe to do so fight the fire using an MR Conditional fire extinguisher. Do not take any MR Unsafe fire extinguishers into the MR Environment.

6.3.1.4 If the fire is in the vicinity of the MR scanner or its associated equipment room and it is safe for you to do so, turn off the electrical power supply to the MRI system.

6.3.1.5 Evacuate the area according to the procedure outlined in the "CRF Ground Floor Evacuation Plan", ensuring that all doors along your escape route are closed.

6.3.1.6 The most senior person should ensure that all patients and staff are accounted for and the location of all patients is known.

6.3.1.7 The MR Safety Expert, MR Responsible Person or the most senior radiographer on duty is designated as the MR Fire Officer and must liaise with the Hospital Fire Officer and the Fire Brigade with regards to the safety of fire crews entering the MRI department.

6.3.1.8 If there is a serious fire which requires additional fire-fighting or breathing apparatus to be brought into the MR Controlled Access Area, the decision to deliberately quench the magnet will need to be taken (see Section 6.4.3).

6.3.2 **Fire Alarms Sounding in MRI Area:**

6.3.2.1 In the event of the alarm sounding continuously: make an immediate check of the whole area to confirm whether a fire has started. If there is a fire, follow the advice on discovering a fire above. If no fire is evident, await a response from the KCH Security Team and the Fire Response Team, advise patients and staff of the situation, remain at work and follow the Security Team's guidance.

6.3.2.2 In event of the alarm sounding intermittently: arrange for a member of staff to leave the area and go to adjacent areas, eg: the corridor outside or an adjacent ward, and determine the cause of the alarm. If no fire or emergency is evident in the adjacent area where the fire alarm is sounding, carry on MR procedures and inform occupants in your area. Reassure the patient. Await further guidance from CRF staff and KCH Security and the Fire Response Team. If the fire is on

the same floor level or adjacent to the MRI Area, complete the scan but do not start any new procedures until further instructions have been given by KCH Security and the Fire Response Team.

6.4 **Magnet Quench:**

In the case of a magnet quench, either deliberate or accidental, the liquid helium in the magnet rapidly boils off as gas and should escape safely to the atmosphere via the quench pipe. It is possible that some gas will escape into the MR Environment and from there into the rest of the MR Controlled Access Area. This is potentially a very dangerous situation because the helium gas is very cold and will cause cold burns if it comes into contact with the skin. Also, helium depletes oxygen and can lead to asphyxiation of anyone who remains in the MR Environment.

6.4.1 **Recognising a Magnet Quench**

A magnet quench may be identified by a loud bang coming from the top of the MRI scanner as the emergency helium valve bursts open. If it is safe to do so, the exit of the quench pipe can be checked for a white plume of escaping helium gas. If helium is escaping into the scanner room in significant quantities it should trigger the audible oxygen level alarm in the control room.

6.4.2 **Emergency Procedure**

In the event of a quench the MR Operator should:

- Abort the scan
- Activate the emergency ventilation
- Evacuate the MR Controlled **Access** Area, informing others present to do so as well
- Shut the doors to the MR scan room and the MR Controlled Access Area

The MR department should remain evacuated until a suitably qualified person or a representative of the scanner manufacturer authorised by the MR Responsible Person has inspected the system.

6.4.3 **Deliberate Magnet Quench**

The decision to initiate a quench should be made by the MR Responsible Person or the MR Safety Expert. In a life-threatening emergency, where none of these people are available, the MR Operator will make the decision.

A deliberate quench may be initiated if there is:

- A serious fire in the Controlled Access Area and the use of fire-fighting equipment that is not MR safe must be used.
- A life-threatening accident involving a ferromagnetic object.

For an incident involving a ferromagnetic object, but where there is no risk to life, it should NOT be necessary to quench the magnet. In this instance, the system should be verified safe by an appropriately qualified person (MR Safety Expert or MR Engineer) before it is used again.

6.4.3.1 **Fire in the MR Environment**

It is especially important to ensure that all fire response personnel are restricted from entering the MR Environment with their equipment until it can be confirmed that the magnetic field has been successfully dissipated. There may still be considerable static magnetic field present despite a quench or partial quench of the magnet.

6.4.3.2 **Life-Threatening Injury**

If a person has been trapped by a ferromagnetic object or if they have an impalement injury by a sharp object, the magnet should be quenched before attempting to remove the person, to prevent further injury. It will be necessary to support the weight of the object when the quench is initiated, again to prevent further injury.

Further ferromagnetic objects should not be brought into the MR Environment. Only MR Authorised Persons, and other appropriately screened and supervised staff, should enter the MR Controlled Access Area.

All incidents must be reported according to local policy. Additionally, the MR Responsible Person and the MR Safety Expert must be informed.

6.5 All incidents must be reported according to the KCH Adverse Incident (AI) Reporting policy. Additionally, the Responsible Person and the MR Safety Expert must be informed.

7.0 Related documents and References

7.1 MRI Local Rules: For all Magnetic Resonance Imaging Departments performing Human Scanning at: King's College Hospital NHS Foundation Trust, South London and Maudsley NHS Foundation Trust, King's College London (Denmark Hill Campus). July 2020.

7.2 Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use. *Medicines and Healthcare Products Regulatory Agency*, March 2015. https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/476931/MRI_guidance_2015_-_4-02d1.pdf

7.3 CRF-HS-POL-1: King's CRF Health and Safety Code of Practice

7.4 CRF-QA-SOP-1: Local Induction Procedure for King's CRF Users

7.5 CRF-QA-SOP-6: Local Induction Procedure for King's CRF Staff

7.6 CRF-HS-FRM-1: CRF Ground Floor Fire Evacuation Plan

8.0 Appendices

8.1 **Table Reformatted from MRI Local Rules**

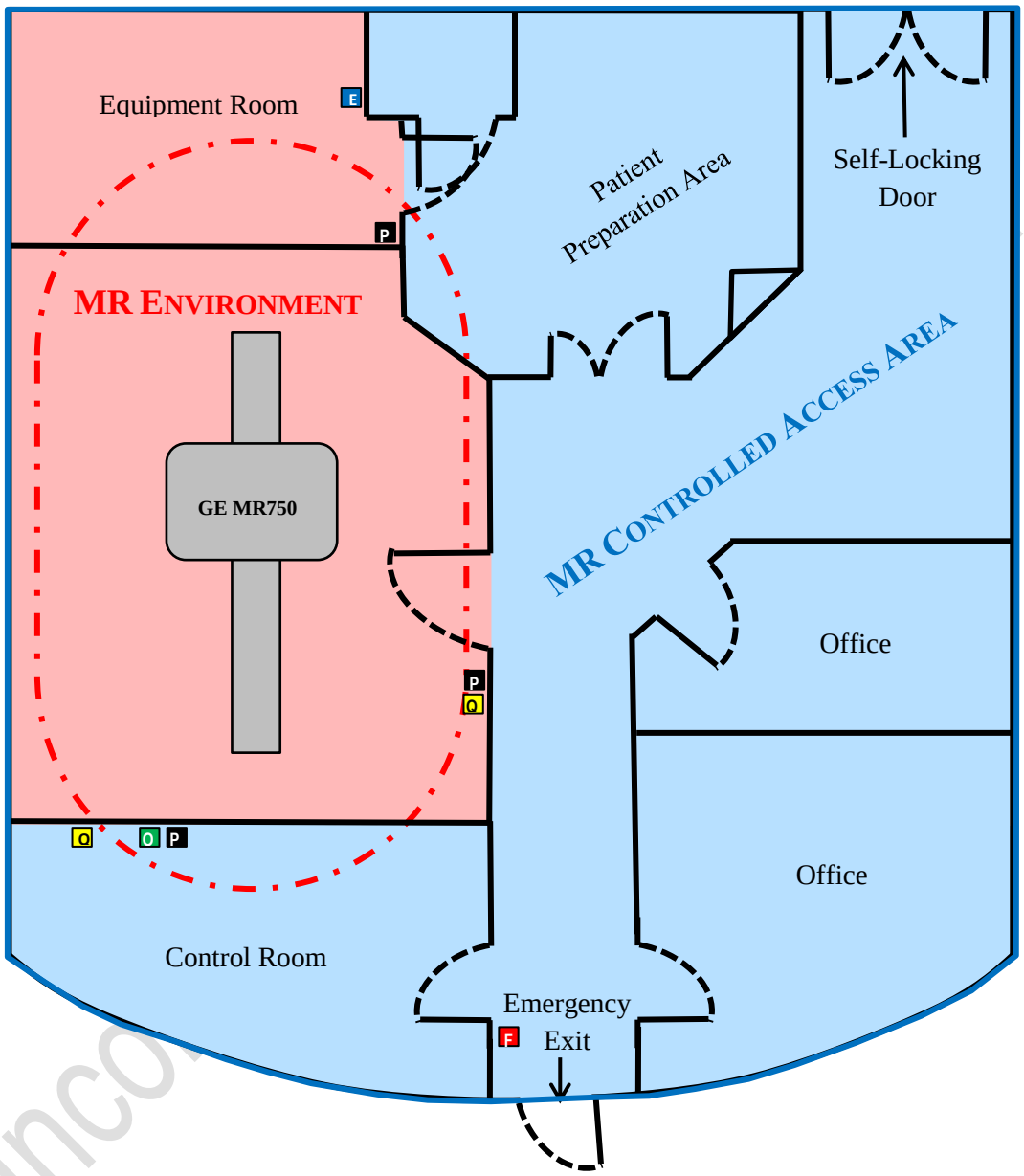
* Authorised Workers can scan research subjects without being supervised only if they have been formally signed off by the MR Responsible Person to be MR Unsupervised Authorised Workers. This status allows an MR Authorised Worker to scan research subjects without being supervised, but only if the subject has been a) consented and b) screened by an Authorised Supervisor for undergoing an MRI scan on an established occasion(s).

Local term	Authorised Supervisor	Authorised Worker	MR Aware
MHRA term	Authorised Person (Supervisor)	Authorised Person (MR Environment)	Authorised Person (Non-MR Environment)
Description	Have received recent training in MR Safety to an appropriate level such that they can take on additional responsibilities including the safety of other people within the MRCAA and MR Environment	Have received adequate training in MR safety such that they take responsibility for their own safety within the MRCAA and MR Environment	Have received adequate training in MR safety such that they take responsibility for their own safety within the MRCAA only
Training requirements	Attended and completed Authorised Supervisor safety training. Read and understood this document, and have signed declaration agreeing to work according to these Local Rules.	Attended basic MR training/ watched MR safety video. Read and understood this document, and have signed declaration agreeing to work according to these Local Rules.	Provided with basic MR safety training, to enable safe presence in MRCAA and instil restriction to the MRE. Sign a limited declaration related to following 'simplified' rules?
Free access to/within MRCAA?	Yes	Yes	Yes
Responsibility for own safety within MRCAA?	Yes	Yes	Yes
Responsibility for safety of others within MRCAA?	Yes	Yes	Yes
Free access to/within MRE?	Yes	Yes	No
Responsibility for own safety within MRE?	Yes	Yes	No
Responsibility for safety of others within MRE?	Yes	No	No
Own Screening	Yes - Annually, or after relevant change	Yes - Annually, or after relevant change	No
Can screen Others	Yes	No	No
Can scan Phantoms & Small Animals if at least:	MR Operator Technical	MR Operator Technical	No
Can scan Healthy Volunteers if at least:	MR Operator Non-Clinical	MR Operator Non-Clinical	No
Can scan Patients if:	MR Operator Clinical	No	No
Duration of Classification:	4 years	3 years	2 years
Classification awarded by:	Responsible Person	Responsible Person	Authorised Supervisor

Typical example:	Radiographers, Physicists, some management	Researchers, Radiology Department Assistants (RDAs)	Researchers, Office staff, some management, radiologists, other clinicians

Table 1. Classifications & definitions for the MR Authorised Person
(Subject to periodic review and updates)

8.2 **Plan of the CRF MRI Unit**



Approximate location of 0.5mT field line	Q Quench Button	E Magnet Room Extractor Fan Manual Override
MR ENVIRONMENT	P Emergency Electrical Power Button	F MR CONDITIONAL Fire Extinguisher
MR CONTROLLED ACCESS AREA	Oxygen Alarm	

8.3 **Example of an MR Safety Screening Questionnaire and Request Form**

King's College Hospital NHS
NHS Foundation Trust

South London and Maudsley NHS
NHS Foundation Trust

KING'S College LONDON

SAFETY QUESTIONNAIRE FOR STAFF / COLLABORATORS

SURNAME..... **FIRST NAMES** .....

D.O.B..... **HOME TEL:** .....

ADDRESS:.....

.....

.....

1. Have you had any Scans or X-rays here before? MRI / CT / X-rays / None

2. Do you have a pacemaker or artificial heart valve fitted? Y/N
   Any other heart or chest operations? Y/N

3. Have you had any operations on your head, ears or spine? Y/N

4. Have you had any operations where metal might have been inserted into your body? Y/N
   If 'Y', please give details .....

5. Have you had any other operations? Y/N
   If 'Y' please give details .....

6. Do you have any foreign metallic bodies in your eyes? Y/N
   Have you done any welding or metalwork? Y/N
   Do you have any shrapnel in your body? Y/N

7. Do you have any of the following:

Dentures, dental plates or bridges	Y/N	False limb, calliper or brace	Y/N
Tattoos / metallic make-up	Y/N	Hearing aid or ear implant	Y/N
Body Piercings	Y/N		

8. Is there any chance you may be pregnant? Y/N

9. When did you attend the MRI Safety / Induction session.....

Please inform one of the radiographers if you later undergo surgery, or the above information becomes inaccurate.

STAFF / COLLABORATOR'S SIGNATURE..... . **DATE** .....

Authorised Signatory .....

South London and Maudsley NHS
NHS Foundation Trust

Centre for Neuroimaging Sciences **MRI REQUEST FORM**

PLEASE USE BLOCK CAPITALS TO COMPLETE THE FORM

Surname ..... **Forenames** ..... Mr/Mrs/Miss/Ms

Address .....

..... Ward.....

.....

NHS number ..... **Hospital number**.....

Sex M / F **Date of Birth**..... **Phone No** .....

GP details.....

Please Circle	
	TRANSPORT
NHS	**O.P.**
PP	**Walking**
RESEARCH	**Chair**

AREA OF MRI: HEAD/MRA/SPINE (cervical/thoracic/lumbar)

Indication:

.....

.....

Relevant Medical History /Additional Information

.....

.....

.....

Check List **(please circle)**

Pacemaker?	Y/N
Vascular Clips?	Y/N
Metal in Eyes?	Y/N
Is Subject **Pregnant?**	Y/N
Is Subject **Claustrophobic?**	Y/N
Does Subject have **impaired Hearing?**	Y/N
Does Subject have **Impaired Eyesight**	Y/N

For further advice on foreign bodies or other MR safety information please contact **Extn 83084** or email **askcns@iop.kcl.ac.uk**

ICD Code (if known).....IQ / NART .....

Age of onset of Current Symptoms.....

Age of onset of First Symptoms.....

Left School with no qualifications ☐

Left School with qualifications ☐

Left School post higher education ☐

Family History of Psychiatric Illness Y☐ N☐ DK☐

Possible Dementia Y☐ N☐ DK☐ MMSE score.....

Past History of Head Trauma Requiring Hospitalisation Y☐ N☐ DK☐

Other disorder (please specify).....

Symptoms (current or most recent episode)

Hallucinations	Y☐ N☐ DK☐	History of Alcohol abuse	Y☐ N☐ DK☐
Delusions	Y☐ N☐ DK☐	History of Drug Abuse	Y☐ N☐ DK☐
Thought disorder	Y☐ N☐ DK☐	Autism spectrum:	
Thought broadcasting	Y☐ N☐ DK☐	Social	Y☐ N☐ DK☐
Withdrawal	Y☐ N☐ DK☐	Repetitive	Y☐ N☐ DK☐
Insertion	Y☐ N☐ DK☐	Communicative Symptoms.....	Y☐ N☐ DK☐
Elevated Mood	Y☐ N☐ DK☐	Learning disability	Y☐ N☐ DK☐
Negative mood	Y☐ N☐ DK☐	Inattentiveness	Y☐ N☐ DK☐
Anxiety/Panic	Y☐ N☐ DK☐	Overactivity	Y☐ N☐ DK☐
PTSD	Y☐ N☐ DK☐	Impulsiveness	Y☐ N☐ DK☐

Research	**Protocol Name**	**Contact Person**	**P.I. on Ethics Approval**	**Project Grant Holder**	**Date**
Clinical	**Hospital/Ward**	**Consultant**	**Contact Telephone Number**	**Directorate**	**Date**

Print Name		**Signature**	

9.0 Approval and sign off

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Position: CRF Director

Signature: Date: