MRC Cognition and Brain Sciences Unit

UNIVERSITY OF CAMBRIDGE

MRI FACILITY

Standard Operating Procedures

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1 Introduction

This documentation is intended to provide a basic review of safety issues in magnetic resonance imaging (MRI) and how these affect the day-to-day practice of performing MRI scans at the MRC Cognition and Brain Sciences Unit (CBU).

It is based on the recommendations of the Medicines and Healthcare products Regulatory Agency (MHRA) [8], the National Radiological Protection Board (NRPB)/Health Protection Agency (HPA) and now Public Health England (PHE), the International Electrotechnical Commission (IEC), the International Commission on Non-Ionising Radiation Protection (ICNIRP), and the Siemens Magnetom Prisma^{fit} Operating Instructions.

2 MR Hazards and Safety Procedures

2.1 Static Magnetic Field

Safety issues to consider with a strong static field, B0, are projectile effects, implantable medical device safety and compatibility, peripheral equipment compatibility, and biological effects.

2.1.1 Projectile Risk

The projectile risk applies to devices which have magnetic components. These can be passive devices such as keys and coins or active devices such as infusion pumps. Magnetic objects experience a strong attracting force in the fringe field of the magnet. Therefore, even small magnetic objects such as coins can turn into dangerous projectiles which may cause serious injury to people. The force on an object depends on the strength of the change in magnetic field (the magnetic field gradient). The potential hazard of the projectile effect of ferromagnetic material in a strong magnetic field is therefore a serious concern in MR units.

CBU Health and Safety procedures

- Only authorised personnel will have free access to the Magnet Room (cf. 3.3). Authorisation of personnel includes a training course during which the projectile hazard is discussed in detail.
- All other persons must be screened for ferromagnetic objects (cf. 3.7 and Appendix D).

2.1.2 Implantable Medical Devices

The strong static magnetic field can affect implantable medical devices in exposed people (staff, patient or volunteer). Any ferromagnetic component within an implantable medical device may experience both an attractive force (i.e. the device will try to move to the isocentre) and a torque force (i.e. the device will try to turn to line up with field lines). Both of these effects can cause tissue damage and/or damage to the implantable medical device. Examples of implantable medical devices are stents, clips, prostheses, pacemakers and neuro-stimulators.

CBU Health and Safety procedures

- A test of the 0.5 mT (5 Gauss) contour was undertaken independent of the manufacturer, confirming that the 0.5 mT is contained within the Controlled Area.
- Only Responsible Personnel have free access to the Controlled Area.
- Authorisation of personnel includes both screening and a training procedure during which the potential hazards of implantable medical devices are discussed in detail.
- All other persons must be screened for implantable medical devices (cf. 3.7 and Appendix D).

2.1.3 **Monitoring Equipment**

The static field can affect monitoring equipment that has ferromagnetic components. Firstly, the function of the equipment could be affected.

Secondly, all equipment with ferromagnetic components has the potential to be a projectile hazard.

CBU Health and Safety procedures

- Monitoring and other peripheral equipment which is taken into the Magnet Room must be MR Safe or MR Conditional (cf. 3.5).
- Only Authorised Personnel are allowed to take monitoring and other peripheral equipment into the Magnet Room. Authorisation of personnel includes a training course during which the potential hazards of monitoring equipment are discussed in detail.

2.1.4 **Biological Effects**

The principal interactions of a static magnetic field, B0, with the body and its functions are the creation of electrical potentials and resulting currents generated by body movements (a 'dynamo effect') and the possible displacement of naturally generated currents within the body by B0 (a 'motor effect').

There is very little evidence to suggest any adverse biological effects of static magnetic fields. A change in the T wave on an ECG trace may be observed in the magnet but this is due to a change in the charge distribution in the blood, not to any blood flow changes or cardiac rhythm changes. No noticeable effects on nerve conduction have been found at field of 3T. Some subjects and workers report nausea or a metallic taste in the mouth when in the field but this seems to be more associated with head movements in a magnetic field than due to the field itself and seems to be worse if working in the bore 'face down'. It is therefore advisable to push subjects slowly into the field and to take care when working in the magnet bore.

CBU Health and Safety procedures

- All participants will be informed about possible biological effects (cf. Volunteer Information Sheet, Appendix C)
- Continuous physiological monitoring (e.g. pulse) will be performed during scanning when necessary
- Supervision of participants will be provided by a Qualified MRI Operator.

A two-way intercom will be used for communication between a participant in the scanner and the Scanner Operator (cf. Appendix I). As an additional measure of precaution, an emergency squeeze bulb will be provided.

2.1.5 **Exposure Limits for Volunteers**

The primary source of information for exposure limits for patients and volunteers in the UK is the 2008 HPA report [8], the 2010 IEC standard [2] and the ICNIRP 2004 and 2009 [1]. All three organisations recommend an approach based on the restriction levels shown in the table below.

	Normal mode	Controlled mode	Research/ Experimental mode	Movement dB/dt limit
HPA	≤ 4T	4 – 8T	> 8T	$1Ts^{-1}$
IEC 2010	≤ 3T	3 – 4T	> 4T	$3Ts^{-1}$
ICNIRP 2009	≤ 4T	4 – 8T	> 8T	$1Ts^{-1}$

At the CBU we define the operating modes as follows:

Normal mode: Routine scans (Siemens sequences and Work in Progress or third party sequences imported from partner sites part of a C2P agreement) in normal volunteers. No physiological monitoring required.

Controlled mode: Routine scans in normal volunteers with MR conditional implants (or Patients w/o MR conditional) implants or with psychological considerations like anxiety. Pulse monitoring necessary.

Research/Experimental mode: Scans using in-house developed sequences (sequences that are completely redesigned particularly the RF and gradients) for the purpose of testing. Should be validated on phantoms (with real-time temperature monitoring) before using in participants. Pulse monitoring and specific ethical approval necessary.

We mostly run in Normal mode but enter Controlled mode when scanning patients.

CBU Health and Safety procedures:

- Continuous physiological monitoring (e.g. pulse) will be performed during scanning when necessary
- Supervision of participants will be provided by a Qualified MRI Operator

In an Emergency:

In order to offer life-saving treatment as soon as possible after an incident, the CBU has purchased two resuscitation kits and have trained members of staff in how to use them. One of these kits is permanently based in the Imaging Facility; the other is situated in the 'Elbow' at the top of the South Wing of the main building.

- There are first aiders on site (members of staff trained in how to use the resuscitation kits). In an emergency there is one internal telephone number (888) that calls all first aiders simultaneously. This ensures that help is provided at the scene as quickly as possible. The Radiographers are trained in Basic Life Support as part of the 'First Aid at work' course, updated every year. First Aiders have attended a 'First Aid at Work' course which is renewed every three years. Radiographers attend also AED training which is updated every year.

- We have a comprehensive first aid kit (including a burns kit) based in the kitchen of the imaging facility. The first Aid equipment in the MRI Unit is inspected every month and the box contains a list of contents. There is also a poster showing all the First Aiders trained and the internal emergency number.

- It is CBU policy that all casualties will be treated outside of the Controlled Area, in the reception area of the Imaging Facility, unless the nature of the emergency prevents this (in which case the casualty will be taken outside of the facility). All CBU first aiders will have automatic access to the reception area (after completion of the appropriate authorization procedure).

- The patient table can be removed from the Magnet Room to aid the emergency removal of a participant. All staff who obtain authorization to enter the Controlled Area will undergo manual handling training as part of the authorization procedure.

CBU Policy on administering First Aid in the Controlled Area:

The CBU policy is that no first aid is to be administered in the Controlled Area. Casualties are to be removed to a 'safe' area – Imaging Reception in the first instance.

However, in an incident where for some reason it is **absolutely impossible to remove a casualty from the Controlled area** the Qualified MRI Operator or Responsible Person present must make a decision about what action is to take place.

As complete units, the first aid kits are MRI Unsafe. However, bandages and dressings are MRI Safe and could be taken into the Controlled Zone and the Magnet Room. In no circumstances must scissors, tweezers or safety pins accompany these items - bandages and dressings would need to be used in their entirety and secured with a reef knot.

Similarly, the Laerdal face mask and/or Blue Dot resuscitation face mask are both MRI Safe and could be used in the Controlled Zone and the Magnet Room in an incident where there was no choice but to resuscitate in these areas. **In no circumstances is a defibrillator or oxygen cylinder to be taken into the Magnet Room.**

2.1.6 Occupational Exposure Limits

The occupationally exposed population consists of adults who are generally exposed under known conditions and are trained to be aware of the potential risk and to take appropriate precautions. At the CBU, this will include authorised personnel only, as only these members of staff will have access to the Controlled Area (cf. Appendix A).

Occupational exposure is covered in the UK by the Health and Safety Executive (HSE) following the EU [4] Directive 2013/35/EU [4] and, internationally, by the ICNIRP [1]. The regulations generally require employers to ensure that worker exposure to EMFs does not exceed certain exposure limit values (ELVs). However, under Regulation 4(3) (b), this requirement does not apply to "the development, testing, installation, use and maintenance of, or research related to, magnetic resonance imaging equipment for patients in the health sector". The HSE published a Certificate of Exemption available from: http://www.hse.gov.uk/radiation/nonionising/emf-exemption-certificate.pdf that includes "the use of magnetic resonance imaging equipment other than for patients in the health sector". There are two conditions set out in the CEMFAW Regulations for these exemptions:

- (i) the exposure of employees to EMFs is as low as is reasonably practicable and
- (ii) employees are protected against any health effects and safety risks related to that exposure.

To satisfy condition (i) a risk assessment has been carried out and attached in Appendix M The organisation of the MRI department, the SOPs, appropriate staff training, incorporation of safety considerations into the design of the MRI unit and control of access to the MRI suite including robust screening procedures and labelling of equipment assure the compliance with condition (ii).

EMFs at different frequencies affect the human body indifferent ways, causing sensory and health effects; see table below. Indirect effects can also happen; indirect effects are caused by the presence of an object in an EMF which may become the cause of a health and safety hazard. One example would be the risk of injury from ferromagnetic objects in a large static magnetic field being attracted to the magnets and hitting anyone in the way. Table 1 provides examples of effects which may be produced by work activities and equipment in the different frequency ranges; in most cases, it will only be the highest power instances that may lead to effects being experienced.

Examples of possible effects of EMFs in relation to MRI

Field and frequency range	Effects	MRI equipment
Static electric and static magnetic fields 0–1 Hz	**Indirect effects:** Uncontrolled attraction of ferromagnetic objects, i.e. the risk of injury from objects in a large static magnetic field being attracted to magnets in the workplace and hitting anyone in the way **Sensory effects**: Nausea, vertigo, metallic taste in the mouth, flickering sensations (magnetophosphenes) in peripheral vision **Health effects:** Micro shocks	Main magnet
Low frequency magnetic and electric fields: 1 Hz–10 MHz	**Indirect effects:** Interference with active or passive implanted or body-worn medical devices, electric shocks **Sensory effects**: Nausea, vertigo, metallic taste in the mouth, flickering sensations (magnetophosphenes) **Health effects:** Nerve stimulation, effects on the central and peripheral nervous system of the body: tingling, muscle contraction, heart arrhythmia	Switched gradient fields

High frequency fields: 100 kHz–300 GHz	**Indirect effects:** Interference with active or passive implanted or body-worn medical devices **Health effects:** Thermal stress, heating effects leading to a rise in core body temperature or localised limb heating (eg knees or ankles) Contact with charged conducting bodies can lead to RF shock or deep tissue burns	RF coils

CBU health and safety procedures

Magnetic field measurements were performed in the Control Room, the Magnet Room as well as in the Technical Room for a detailed risk assessment. The 2T field contour was demonstrated to be contained within the magnet bore. Authorised personnel will therefore not be exposed to magnetic field strength greater than 2T during normal operating procedures. The estimated average exposure for different groups of Authorised Personnel are summarised in the table below (cf. Appendix G for details of the risk assessment). In each case, the estimated exposure values (averaged over 24 hours) are well below 200 mT (0.2 T).

Category of Authorised Personnel	**Average field strength over 24h**	
	Typical	Worst case
Qualified MRI Operator	8.3 mT	52.4 mT
Authorised Researcher (Level 1)	8.3 mT	52.4 mT
Authorised Researcher (Level 2)	81.6 mT	177 mT
Authorised Technician	3.6 mT	13.3 mT

Authorised personnel will be informed about the aforementioned recommendations during the MR safety training course which is part of the CBU MRI Authorisation Procedure (cf. 3.3).

2.1.7 Exposure Limits for General Public

The general public comprises individuals of all ages and of varying health status, and may include particularly susceptible groups or individuals. Moreover, individual members of the public cannot reasonably be expected to take precautions to minimise or avoid exposure.

The table below summarises the basic restrictions for general public exposure to static magnetic fields as recommended by the ICNIRP [1].

General Public	**ICNIRP 98 upper limit (mT)**
Without pacemakers	400
With pacemakers	0.5

CBU Health and Safety procedures

- A measurement of the 0.5 mT (5 Gauss) contour was undertaken confirming that the 0.5 mT is contained within the Controlled Area.
- Access to the Controlled Area will be possible for authorised personnel only.

Members of the general public who wish to access the Controlled Area (e.g. visitors) must be screened like volunteers (cf. 3.7 and Appendix D).

2.2 Time-varying Magnetic Field Gradients (dB/dt)

The safety concerns with the time-varying magnetic field gradients are biological effects such as peripheral nerve and muscle stimulation, and acoustic noise generated by gradient switching. The latter is discussed in a separate section (cf. 2.3).

In MR, three orthogonal magnetic field gradients are switched on and off to select the region of diagnostic interest and to spatially encode the MR signals. As a general guide, the faster the imaging or spectroscopy sequence, the greater the rate of change of the gradient fields used and the resultant current density induced in the tissue.

2.2.1 Biological Effects

Time-varying magnetic fields induce electric currents that could be sufficiently large in tissues to interfere with the normal function of nerve cells and muscle fibres. A well-established example of this is the sensation of flashes of light, ‘the magnetic phosphenes', caused by induced electric currents stimulating the retina. However, this effect has not been shown to be hazardous.

Peripheral nerve stimulation can occur in the body when exposed to high switching magnetic fields (both strong and fast). This manifests itself as a twitching or sensation in the region concerned and can in extreme cases cause pain or injury. Our system is safe guarded by a gradient supervisor unit that will disable the gradient system when the switching rate exceeds a set maximum. The gradient supervisor unit is calibrated, tested, and maintained by the manufacturer.

CBU Health and Safety procedures

- All participants will be informed about possible biological effects (cf. Volunteer Information Sheet, Appendix C).
- Continuous physiological monitoring (e.g. pulse) will be performed during scanning in Controlled Mode
- Supervision of volunteers will be provided by a Qualified MRI Operator

A two-way intercom will be used for communication between volunteer in the scanner and the Scanner Operator. As an additional measure of precaution, an emergency squeeze bulb will be provided.

2.2.2 Exposure Limits for Volunteers

The IEC provides a very comprehensive explanation on the restrictions for time-varying magnetic field gradients to be incorporated in MR scanners (IEC 60601-2-33) [2]; it is too detailed to present in full here. Fundamentally, the IEC states that the system must not have gradient output that exceeds the limit for peripheral nerve stimulation (PNS). This will protect against cardiac fibrillation. The PNS threshold may be determined from numerical modelling or from human studies. For the controlled mode of operation (cf. 2.1.5) the IEC recommends that the gradient system shall operate at a level that does not exceed 100% of the directly determined mean threshold PNS.

CBU Health and Safety procedures

- The time varying magnetic field produced by the gradient system (dB/dt) is automatically calculated for each imaging sequence by the scanner operating system and the Scanner Operator is warned if the critical threshold for PNS is exceeded.
- dB/dt is continuously monitored during scanning by an independent hardware component (gradient supervisor unit) which will inform the Scanner Operator about the current level and disable the gradient unit if the critical threshold for PNS is exceeded.

Manufacturer's statement of conformity with IEC 60601-2-33 (cf. Appendix H: Statement of conformity).

2.2.3 Occupational Exposure Limits

The occupational exposure to time-varying magnetic field gradients must satisfy the two conditions set out in the HSE Certificate of Exemption. The risk assessment done at CBU covers all occupational exposure.

CBU Health and Safety procedures

Given the nature of the MRI studies performed at the CBU, the presence of personnel in the Magnet Room during a scan is not anticipated. Personnel will therefore not be exposed to time-varying magnetic fields during the normal use of the equipment.

2.2.4 Exposure Limits for General Public

The corresponding exposure limits for general public exposure to time-varying magnetic fields are summarised in the table below.

Frequency range	Magnetic flux density (T)
0 – 8 Hz	$4\times10^{-2} / f^2$
8 – 25 Hz	$5\times10^{-3} / f$
25 – 50 Hz	2×10^{-4}
50 -400 Hz	2×10^{-4}
400 Hz – 3 kHz	$8\times10^{-2} / f$
3 kHz – 10 MHz	2.7×10^{-5}

The MHRA understands that it is difficult for an MR unit to measure these parameters but recommend that sites ask for confirmation from the manufacturer that staff will not be exposed to levels above these during the normal use of equipment.

CBU Health and Safety procedures

Members of the general public will not be allowed in the Magnet Room during a scan and will therefore not be exposed to time-varying magnetic fields during the normal use of the equipment. However, there are certain situations when children need to be accompanied during the scan by one parent or carer. They are advised to keep a safe distance from the bore of the magnet, and usually sit on the chair next to the door.

2.3 Acoustic Noise

2.3.1 Hazards

A characteristic of the switching gradient fields is the production of acoustic noise. When the alternating low-frequency currents flow through the gradient coils, which are immersed in the high static magnetic field B_0, forces are exerted on the gradient coils that move like a loudspeaker coil and generate sound waves. The level of this acoustic noise at the location of the patient or volunteer can reach an unacceptable and even dangerous level [5].

CBU Health and Safety procedures

- Earplugs, ear defenders, or other means of hearing protection will be used when scanning a participant
- Adequate staff training in the use of ear protection.

2.3.2 Exposure Limits for Participants

The Control of Noise at Work Regulations 2005 are to ensure that all hearing is protected from excessive noise. As the scanner is capable of generating noise levels in use which are greater than the lower daily exposure level 80dB (A weighted), suitable hearing protection must be used with all participants. Extra care must be taken with young age participants.

CBU Health and Safety procedures

- Standard head phones and hearing protection recommended by the manufacturer will be used.
- Staff will be trained in the selection and fitting of hearing protection.

For all other equipment (e.g. head phones obtained from suppliers other than the manufacturer) a risk assessment will be performed. To this end, information about the maximum sound pressure level produced by the scanner will be obtained from the manufacturer and the type of hearing protection will be chosen to ensure that the noise level at the eardrum is less than the above figure taking into account the frequency spectrum of the MR system in use.

2.3.3 Occupational Exposure Limits

The Noise at Work Regulations 2005 requires that employers must make hearing protection freely available to employees when noise exposure exceeds 80 dBA. The regulations also state hearing protection must be worn by all employees when noise exposure exceeds 85 dBA. The type of hearing protection must be chosen to ensure that the noise level at the eardrum is less than the above figure. Note that these limits do not vary with age.

CBU Health and Safety procedures

Given the nature of the MRI studies performed at the CBU, the presence of personnel in the Magnet Room during a scan is not anticipated. However, should someone be within the magnet room during a scan, other than the participant, suitable hearing protection will be provided and must be worn. The maximum sound pressure level outside the Magnet Room is well below 80dBA during the normal use of the equipment, as confirmed by acoustic noise measurements.

2.3.4 Exposure Limits for General Public

CBU Health and Safety procedures

Members of the general public will not normally be allowed in the Magnet Room during a scan. In situations when the presence of additional people is necessary in the Magnet Room i.e. parent/carer accompanying participant, they will receive noise reduction earplugs and ear defenders. The maximum sound pressure level outside the Magnet Room is well below 80dBA during the normal use of the equipment, as confirmed by acoustic noise measurements.

2.5 Radiofrequency Magnetic Fields (B_1)

The main safety issues for radiofrequency (RF) fields used in MR are thermal heating leading to heat stress, and induced current burns and/or contact burns.

Absorption of energy from radiofrequency fields used in MR results in the increased oscillation of molecules and the generation of heat. If this occurs in human tissue, a compensatory dilation of blood vessels results in an increase in blood flow and the removal of the excess heat, which is dissipated mainly through the skin.

Limbs will disperse thermal energy more rapidly than internal parts of the abdomen. The electromagnetic and thermal characteristics of different organs and parts of organs will differ. The eyes are an example of organs that have very little blood flow. In fact, the lens of the eye has none, and therefore takes time to disperse thermal energy. The testes are organs separated from the main volume of the body and regarded as heat sensitive. Normally their temperature is a few degrees below body temperature. A rise of 1°C is in general very acceptable to a normal healthy body. The actual temperature rise at any time will depend on the balance between the energy absorbed and the energy transferred from the region of the body concerned. The ambient temperature and humidity will play a major role in the rate of dissipation. The lower the ambient temperature and the lower the humidity, the greater the transfer.

2.5.1 Heat Stress

Heat stress is of particular concern for some patients, such as those suffering from hypertension, or pregnant women, or those on drugs such as diuretics or vasodilators that may compromise these responses. Other potentially vulnerable groups include those with neurodegenerative disease, and nerve damage from medical conditions such as diabetes, or old age.

One fundamental issue is excessive cardiovascular strain resulting from thermoregulatory responses to body temperatures raised over a short period of time by more than 0.5°C in vulnerable people. The temperature rise is a function of the Specific Absorption Rate (SAR), health factors and medication.

CBU Health and Safety procedures

- Pregnant women will not be scanned at our unit.
- Potentially vulnerable people (e.g, on hypertensive drugs) must be monitored closely, including pulse rate.

2.5.2 Induced Current Burns

There have been reports of burns that have occurred when the arms or the legs have been positioned in such a way as to create a conductive loop pathway [6]. The RF burns have occurred where the arms or thighs meet.

CBU Health and Safety procedures

- Adequate positioning of volunteers to avoid conductive loops (cf. 3.7.3).
- Scanning of participants will be conducted or supervised by a Qualified MRI Operator.

2.5.3 Contact Burns

Contact burns are the most often reported adverse incident in MR A review of burns in MR is given in [7]. The radiofrequency field will induce currents in conductors and can raise their temperature significantly.

Examples of causes are: contact with metal in clothing, coils, coil leads, ECG connectors and oxygen monitor probes. Part three of these guidelines discusses how to screen and set up patients to avoid this hazard.

CBU Health and Safety procedures

- Burns to volunteers and patients from contact with such metallic objects must be avoided by the careful positioning and set up within the bore of the magnet (cf. 3.7.3).
- Scanning of participants will be conducted or supervised by a Qualified MRI Operator

  A burns kit and a roll of cling film have been incorporated into the first aid kit.

2.5.4 **Exposure Limits for Volunteers**

The IEC standard information on specific absorption rate (SAR) limits and monitoring is too detailed to list here. It is recommended that sites make themselves familiar with the SAR limits used by their system from both the IEC standard [2] and the manufacturer's user manual.

The IEC SAR limits are set assuming moderate environmental conditions of relative humidity i.e. < 60%, and ambient temperature < 24°C. The MHRA recommends that the MR unit ensures that these environmental conditions are monitored.

The MHRA also recommends that a clear statement should be obtained from the supplier of the maximum operating values for all exposure types that the equipment will provide in normal operation, and the maximum values that could occur in a fault condition.

CBU Health and Safety procedures

- Environmental conditions (ambient temperature, relative humidity) are controlled by an air conditioning system.
- The specific absorption rate (SAR) is automatically calculated for each imaging sequence by the scanner operating system. A scan cannot be started if it exceeds the SAR limit.
- The SAR is continuously monitored during a scan by an independent hardware component (radiofrequency supervisor unit). The radiofrequency supervisor unit immediately stops a scan if the SAR limit is exceeded.
- As SAR calculations depend on the body weight, the participant's weight must be determined before the scan and the correct value must typed in during the setup of the scan.

Manufacturer's statement of conformity with IEC 60601-2-33 (cf. Appendix H: Statement of conformity).

2.5.5 **Occupational Exposure Limits**

CBU Health and Safety procedures

Given the nature of the MRI studies performed at the CBU, the presence of personnel in the Magnet Room during a scan is not anticipated. Personnel will therefore not be exposed to radiofrequency magnetic fields during the normal use of the equipment.

2.5.6 **Exposure Limits for General Public**

CBU Health and Safety procedures

Members of the general public will not be normally allowed in the Magnet Room during a scan and will therefore not be exposed to RF magnetic fields during the normal use of the equipment. In situations

when the presence of additional people is necessary in the Magnet Room i.e. parent/carer accompanying participant they will sit in locations that are far from the RF source to minimise exposure.

2.6 Cryogens

There should be no hazards from cryogens provided adequate attention has been paid to the provision of venting directly to the outside of the building of all potential sources of helium and nitrogen following normal boil-off or in the event of a pressure release valve bursting. However, for completeness and as a warning, reference is made to some of the potential hazards.

The hazards in the use of low temperature liquefied gases for MR systems are:

- Asphyxiation in oxygen-deficient atmospheres.
- Cold burns, frostbite and hypothermia from the intense cold.
- Over-pressurisation from the large volume expansion of the liquid following evaporation.

2.6.1 Asphyxiation

Nitrogen and helium may produce local oxygen deficient atmospheres, which will produce asphyxia if breathed. Atmospheres containing less than 18% oxygen are potentially dangerous and entry into atmospheres containing less than 20% oxygen is not recommended. Atmospheres containing less than 10% oxygen can result in brain damage and death.

Asphyxia due to oxygen deficiency is often rapid with no prior warning and the victim may not be aware of the asphyxia. Typical symptoms are:

- Rapid breathing and gasping for breath
- Rapid fatigue
- Nausea
- Vomiting
- Collapse or inability to move
- Unusual behaviour

2.6.2 Cold Burns, Frostbite and Hypothermia

Liquid helium and nitrogen or even their cold gases can damage the skin producing an effect similar to a heat burn. Unprotected parts of the skin that come into contact with uninsulated items of cold equipment may also stick fast to skin, the flesh being torn on removal.

The cold vapours from liquefied gases may cause frostbite given prolonged or severe exposure to unprotected parts. A symptom is local pain but sometimes no pain is felt or it is short-lived.

Transient exposure to very cold gas produces discomfort in breathing and can provoke an attack of asthma in susceptible people.

2.6.3 Handling Cryogens

<u>CBU Health and Safety procedures</u>

- Training authorised by cryogen suppliers must be undertaken before personnel operate and replenish the cryogens.

- Maintenance of cryogenic plant must have been authorised by the appropriate senior site engineer, physicist or technician to ensure that it is safe to carry out such work, and those involved must be accompanied by a Responsible Person while in the Controlled Area.

- Pipes or metalwork that are not insulated must not be touched by unprotected parts of the body.

- In the event of unusual venting, immediately inform an authorised cryogenic operator or the site engineer, physicist or technician.

No unauthorised person, at any time, should operate or tamper with cryogenics, valves, etc.

2.7 Other Potential Hazards

2.7.1 Laser Light Localizer

The laser light localizer on the magnet facilitates correct patient positioning. It contains two Class II lasers. Direct exposure of the eyes to the laser beam may result in injury of the eye (cornea).

CBU Health and Safety procedures

- Strictly adhere to the operating procedures provided by Siemens
- Inform patients of this risk and ask them to keep their eyes closed during the positioning procedure.
- Check that the laser light localizer appears in the form of crosshairs on the patient table. If the laser light localizer takes the form of a spot, switch the laser light localizer off and notify Siemens Service.

Have the laser light localizer checked regularly by Siemens Service.

2.7.2 MR Phantoms

When measurement phantoms are used as intended within the scope of quality measurement of RF coils, there is no physical contact with measurement phantom fluids. The fluids are sealed in the measurement phantoms.

Phantoms are filled with water-based nickel sulphate solutions or oil. Other components may include sodium chloride, sodium phosphate buffers, as well as lactates, acetates, or dye.

If phantom fluid has escaped, aerosols containing nickel may form in the event of a fire or atomization caused by strong air currents. Carcinogenic effects cannot be ruled out if these aerosols are absorbed by the body.

CBU Health and Safety procedures

- Do not use damaged phantoms.
- Avoid skin contact with phantom fluid.
- Wear protective clothing when handling a damaged phantom (gloves, work coat, and goggles).
- Wear a mask with a filter for inorganic vapours if aerosols are formed.
- Change contaminated clothing immediately.
- Do not eat, drink, or smoke.
- Ensure that phantom fluid does not enter the waste water.

Dispose of phantom fluid in compliance with local and national regulations.

3 Management of the MRI Facility

3.1 Responsibility and Organisation

3.1.1 Key Personnel

CBU Director
MRC Cognition and Brain Sciences Unit

Responsibility: General management of health and safety related issues at the Cognition and Brain Sciences Unit. Chair of the Unit Management Committee (UMC) which has overall responsibility for Unit policy and management.

CBU Deputy Director: Neuroimaging
MRC Cognition and Brain Sciences Unit

Responsibility: Implementation, supervision and maintenance of health and safety procedures related to neuroimaging at CBU. Chair of the Imaging Management Committee (IMC) which has overall responsibility for general neuroimaging policy and management at the CBU, within the framework laid down by the Director and the UMC.

CBU Head of MRI
MRC Cognition and Brain Sciences Unit

Responsibility: Implementation, supervision and maintenance of health and safety procedures related to MRI. Chair of the MRI Management Committee which has responsibility for the implementation, supervision and maintenance of health and safety procedures specific to the CBU MRI Facility.

CBU Health and Safety Coordinator
MRC Cognition and Brain Sciences Unit

Responsibility: Implementation, supervision and maintenance of general health and safety procedures at the CBU as required by *the UK Health and Safety at Work etc Act 1974*.

Senior Radiographer
MRC Cognition and Brain Sciences Unit

Responsibility: Day to day management of the radiography team at the CBU Imaging Facility. Implementation, monitoring and maintenance of health and safety procedures related to MRI, including training of MRI Qualified Operators.

Medical Monitor
MRC Cognition and Brain Sciences Unit

Responsibility: For referring an adult for further clinical investigation in the event that a scan is flagged as abnormal (eg. an abnormality is noticed in a brain scan by a radiographer).

Paediatric Medical Monitor
Consultant Paediatric Neurologist

Responsibility: For referring a child for further clinical investigation in the event that a scan is flagged as abnormal (eg. an abnormality is noticed in a brain scan by a radiographer).
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Facility Administrator

Responsibility: Overall responsibility for administration of the CBU Imaging Facility within the wider Unit administrative framework. Note mri.admin@mrc-cbu.cam.ac.uk is accessed by both MRI Admin and Radiographers.

3.1.2 External MR Safety Advisor

3.1.3 MRI Management Committee

The MRI Management Committee shall consist of

- The Head of MRI (chair)
- The Facility Administrator
- Senior Radiographer

The committee will review and update local MRI Facility issues, including health and safety policy.

Any changes or crucial updates to policy that are needed in between these meetings can be made via Chairman's action.

3.1.4 Access for Personnel

The MR scanner and the related equipment are contained within a designated Controlled Area (cf. Appendix A). Access to the Controlled Area shall be given only to authorised personnel (please see section 3.3.3 for categories of authorised personnel). Only Responsible Users and Qualified MRI Operators will have free access to the Controlled Area.

Unauthorised personnel shall have access only if accompanied by a Responsible Person or Qualified MRI Operator who will take on the full responsibility for the presence of the unauthorised person or persons for the duration of their presence in the Controlled Area.

The Head of MRI shall formally approve certification of a member of staff as an authorised person when the member of staff has satisfactorily completed training in their responsibilities and the safety requirements of MR equipment.

The MRI Unit shall maintain a list of all authorised personnel together with full details of their training and certification with ready access available to the Responsible Persons and the Qualified MRI Operators .

3.2 Controlled Access Area

3.2.1 Definition of Controlled Access Area

The controlled access area includes all accessible areas where the magnetic field exceeds 0.5 mT (5 Gauss). The extent of the Controlled Access Area is outlined on the MR site plan (cf. Appendix A). The Controlled Access Area consists of three zones:

- Zone 1: Magnet Room, Control Room, office
- Zone 2: Technical Room
- Zone 3: Plant Room

3.2.2 Access to Controlled Area

Access to the Controlled Area is provided by self-locking doors. The devices for operating the locks are:

- Zone 1: plastic card keys (plus Magnet Room by key)
- Zone 2: key
- Zone 3: key

Keys for the Magnet room, Zones 2 and 3 are kept in a numbered safe in the Control Room. Only Responsible persons have access to this safe and they are responsible for keeping this code confidential. Disclosure of this code is permitted in an emergency after which the code must be changed.

3.2.3 **Warning signs**

Following the standard procedures and recommendations of the manufacturer (Siemens Medical, Erlangen, Germany) the following warning signs are in use.

 Strong Magnetic Field	 Radio Frequency Field
 Wear hearing protection	 Laser light
 No entry to persons with implants which may be affected by electromagnetic fields, e.g. cardiac pacemakers, defibrillators, hearing aids, insulin pumps, drug pumps	 No entry to persons with implants made of metal or other metal objects in the body
 No entry with mechanical watches, electronic data carriers such as pocket calculators, digital watches, etc.	 No entry with fire extinguishers made of ferrous metal
 No entry with metallic parts of any kind	 No entry with data carriers such as credit cards, identification cards with magnet strips, magnetic tapes, etc.
 No open fire. Smoking prohibited	

3.3 Access Control

Entry to the MRI building is controlled by access card. Access privileges will be upgraded to include the MRI Facility upon completion of the relevant training courses. Those completing the relevant training and without a Unit card will be assigned a temporary one whilst they carry out their research at the CBU.

3.3.1 Access for Personnel

The selection and certification of a person for authorisation rests with the Head of MRI and must be endorsed by the Assistant Director - Neuroimaging.

An individual shall only be granted access after satisfactory completion of the local MRI Authorisation Procedure. This includes:

- A lecture about MRI safety
- Watching a MRI safety video (provided by Siemens)
- A tour of the MRI suite including a practical demonstration of the magnetic field strength
- A tutorial and practical demonstrations of emergency procedures

All personnel must have satisfactorily passed the screening for MRI suitability (cf. Appendix D). Repeat screening shall take place when necessary and appropriate records shall be maintained. All personnel must satisfy themselves that they conform at all times, to the requirements of the screening for MRI suitability.

3.3.2 Responsibilities of Authorised Personnel

- On entering the Controlled Area, all personnel must at all times comply with the CBU Standard Operating Procedures.
- All unauthorised personnel, which will include visitors, patients and unauthorised staff, shall have access only if accompanied by a Responsible Person or a Qualified MRI Operator.
- The Responsible Person/ Qualified MRI Operator will take on the full responsibility for the presence of the unauthorised person or persons for the duration of their presence in the Controlled Area.
- All authorised personnel who act as volunteers for scanning must conform to the appropriate requirements referred to in the sections about volunteer management (cf. 3.6 and 3.7).
- Responsible personnel can screen workmen, cleaners, engineers and other visitors for entry to the Magnet Room but not volunteers or patients for scanning.
- Only a Qualified MRI Operator can screen volunteers and patients for scanning.

Lost or mislaid cards must be reported to the Facility Administrator immediately so that all access privileges on the card can be suspended.

3.3.3 Special Categories of Authorised Personnel

Certified User – A person, who has completed the appropriate CBU training programme, is familiar with the building and CBU procedures and is granted limited access to the building during research hours only. This person is not permitted to allow unauthorised persons into the Controlled Area.

Responsible User - A person, who has completed the appropriate CBU training programme, is familiar with the building and CBU procedures and has received additional training on screening visitors/workmen (not participants) and attending the building in an emergency. This person has 24/7 access to the building (including Control Room key safe) in order to assist the emergency services if required.

Radiographer – A clinically trained radiographer, who has been trained to run the scanner, and who is familiar with the MR suite and the relevant CBU procedures. This person is granted free access during the MRI Facility Opening Hours and is permitted to screen participants and other staff/visitors requiring access to the site.

Qualified MRI Operator – A Radiographer, or a Responsible User who has also been trained to run the scanner and who is familiar with the MR suite and the relevant CBU procedures. The procedures and requirements for a Responsible User becoming a Qualified MRI Operator are stated in a separate document "**Qualified MRI Operator Training at the CBU**".

NB: an authorised person is any of the above

3.3.4 Required Staffing Levels for Scanning

For **scanning volunteers during CBU Opening Hours** of the CBU (cf. Appendix I), the minimum requirement is one Qualified MRI Operator and at least one other authorised person.

For **scanning volunteers outside CBU Opening Hours** of the CBU (cf. Appendix I) the minimum requirement is one Qualified MRI Operator and at least two other authorised persons.

For **scanning phantoms** the minimum requirement is one Qualified MRI Operator provided that this person does not enter the Magnet Room. Otherwise, at least one other authorised person must be present.

3.4 Categories of Exposed Persons

3.4.1 Participants

It is not anticipated that any MRI for diagnostic purposes will be performed at the MRC Cognition and Brain Sciences Unit. Most studies will be on healthy control participants who are volunteers and will have been pre-screened for any neurological illnesses as well as any history of head injury, psychiatric disturbance or substance abuse.

However, increasingly more studies are recruiting 'stable' patients; that is, participants who have a neurological history, but who do not require ongoing medical attention and for whom MRI poses no significant risks over and above those that apply to a normal healthy participant. Possible groups include stable ex-stroke patients, mild Parkinson's disease and early stage Alzheimer's Disease.

The scanning of healthy volunteers would require prior approval from Cambridge Psychology Research Ethics Committee (CPREC) or Local Research Ethics Committee (LREC). These studies would involve standard cognitive neuroscience paradigms which have been used previously on similar volunteers outside the scanner, and will be undertaken within the guidelines laid out by the Standard Operating Procedures.

Scanning studies involving patients or drugs would require prior approval from the Local Research Ethics Committee (LREC). These studies would be undertaken within the guidelines laid out by the Standard Operating Procedures.

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All participants must be screened before exposure (cf. 3.7 and Appendix D).

Only Qualified MRI Operators are allowed to scan participants.

Written informed consent must be obtained from all participants.

3.4.2 Staff

Only Responsible Persons shall have free access to the Controlled Area. Unauthorised staff shall be subject to the procedures for the general public (see below).

3.4.3 General Public

All unauthorised personnel, including unauthorised staff and the general public, must be screened for a wide range of factors (cf. 3.7 and Appendix A) and seek authority to enter the Controlled Area.

3.4.4 Cleaning and Maintenance Staff

Cleaning and maintenance staff (e.g. estates and engineering staff) requiring access to the Controlled Area may only do so as unauthorised personnel and must undergo screening (cf. 3.7 and Appendix D). They may only gain access to the Controlled Area under direct supervision of a Radiographer or Responsible Person. A request for access needs to be made through the Facility Administrator and requires approval of the Head of MRI. All items required to be used in the Magnet Room must be demonstrated to be MR Safe. Cleaning equipment to be used in the Magnet Room must be clearly labelled and stored appropriately.

3.5 Control of Equipment

3.5.1 Equipment Policy

All equipment taken into the Magnet Room must be MR Safe or MR Conditional.

MR Safe	'An item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically nonconductive, nonmetallic, and nonmagnetic'	
MR Conditional	'An item with demonstrated safety in the MR environment within defined conditions. At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field and the radiofrequency fields. Additional conditions, including specific configurations of the item, may be required.'	
MR Unsafe	'An item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.'	

Only equipment may be taken into the Magnet Room if:

classified as MR Safe or MR Conditional by the manufacturer

- labelled MR Safe or MR Conditional by an Authorised member of staff, following adequate testing. Testing and labelling must be approved by the Head of MRI, and a written record must be kept.

A re-examination of each device's MR safety will be required whenever changes are made to the MR environment or device.

3.5.2 Responsibility for Entry

Control of equipment entering the Magnet Room on a day-to-day basis is the responsibility of the Qualified MRI Operator (cf. 3.3) responsible for the examination at the time. Only equipment that is known to be MR Safe or Conditional should be taken into the Magnet Room.

3.6 Volunteer Management: General Considerations

3.6.1 Volunteers

The means of volunteer recruitment must be approved by the relevant Research Ethics Committee (REC).

In addition to screening onsite before the scan (see 3.6.2 below), it is recommended that volunteers are pre-screened before attending the MRC CBU, to save time and prevent a potential volunteer being sent home because not suitable. Some recommended questions are given in **Appendix L**. These questions can be asked over the phone, though researchers might want to consider posting a version and getting a signed response before booking the scan, to have a record of responses (in case a volunteer complains about being sent home) – though ethical approval will be needed for this. Note that the answers to these questions can include personal information, so anything written down that includes PID should be stored safely in accord with the ethics approval and the CBU's data protection policies.

Members of staff are permitted to be scanned under the supervision of the Qualified MRI Operator.

The term volunteer shall include:

- Healthy members of the public volunteering for a MR study.
- 'Stable patients' volunteering for a MR study.

3.6.2 Pre-requisites for MR Examination

For all MR examinations of volunteers the following prerequisites must be fulfilled:

- Ethical approval for scanning volunteers must be obtained from the relevant Research Ethics Committee prior to the MR examination.
- Written MR information must be made available to all volunteers before they consent to scanning, as defined in the study protocol approved by the research ethics committee.
- Written informed consent must be obtained before examination (Appendix E).
- All volunteers must be screened before exposure (Appendix D)

The following additional considerations will apply to the MR examination of volunteers under the age of 18 years:

- Ethical approval for scanning volunteers must be obtained from the relevant Research Ethics Committee prior to the MR examination.
- Written MR information must be made available to the participant and their parent/legal guardian before they consent to scanning, as defined in the study protocol approved by the research ethics committee.
- A demonstration and introduction session should be made available for the participants and their parent/legal guardian prior to the scanning session, and the details of such a "desensitisation" process must be approved by the Imaging Management Committee.
- A parent/legal guardian must accompany the participant at all times (except in the MRI room itself); they cannot be supervising other dependents.
- Participants under 16 must give informed verbal assent, and signed informed consent must be obtained from the parent/guardian before the examination (using relevant form in Appendix E).
- The MRI Screening Form (parent/guardian form) (Appendix D) must be completed before the examination in the presence of the participant and signed by their parent/legal guardian.
- Participants aged 16 and over may be exempt from the above need for parental/guardian participation in the study and in the consent/screening process, where the relevant Research Ethics Committee approves such exemptions within the study protocol. In this case, such participants would complete the Adult forms (Appendix D and E), giving their own signed, consent.
- A parent/legal guardian will need to complete a visitor's screening form (Appendix D), and they will also need full screening if they accompany the participant in the MRI room during the scan

3.6.3 Medications

Medications taken by volunteers can be divided into three categories:

1. Those taken for a medical condition that might affect volunteer's safety in the scanner, e.g., anti-epilepsy drugs. Volunteers should have declared such medical conditions during screening, but if medications indicate such a condition, then radiographers should investigate further whether there will be risk to the volunteer, and not begin scanning if unsure.
2. Those taken that might affect volunteer's comfort in the scanner, e.g, anti-anxiety (anxiolytic) drugs. The eligibility of volunteers taking such medication should be approved by the relevant REC, and should include close monitoring of physiological signals like pulse and breathing rate.
3. Those that pose no risk to the volunteer, but might affect data quality, e.g, affect the neurovascular coupling for fMRI, such as caffeine. This is the responsibility of the researcher to decide eligibility.

3.6.4 Responsibility for Volunteers whilst in the Controlled Area

The Qualified MRI Operator will remain responsible for the safety, health and well-being of the volunteer throughout the period that the volunteer is within the Controlled Area.

3.6.5 MRC Indemnity Arrangements for Volunteers

Studies sponsored by the MRC:

The MRC provides indemnity where it is the Sponsor or has entered into a written agreement to provide indemnity for all or part of a study:

Negligent Harm. This will be covered by the MRC for MRC sponsored studies involving a member of the CBU.

Non-negligent Harm. The MRC does not provide cover for non-negligent harm. However, it takes a sympathetic view of non-negligent claims.

A copy of the MRC's indemnity policy statement can be obtained by emailing mri.admin@mrc-cbu.cam.ac.uk.

Studies not sponsored by the MRC:

Where the MRC is not the sponsor, then the researcher must provide written confirmation of any insurance or indemnity arrangements made in line with the terms and conditions agreed with their parent organisation. The insurance or indemnity arrangements must be as defined in the LREC/CPREC approval for the study.

Medical Doctors:

Medical doctors are advised to arrange adequate personal insurance against claims for negligent and non-negligent harm. They are advised that even non-remunerated research may be regarded as private practice (non-NHS practice) by some medical insurers.

3.6.6 Pregnant Women

There is currently no convincing evidence that electromagnetic fields that would be experienced in the normal operating mode can cause any detrimental effect to the well-being of the foetus, however a precautionary approach is recommended.

We therefore exclude all women who are or may be pregnant as a general measure of precaution.

3.6.7 Implanted Medical Devices

Implanted medical devices fall into two main categories:

- Active implanted medical devices - such as pacemakers, defibrillators, neurostimulators, cochlear implants and drug pumps, where functionality is dependent upon an energy source such as electrical, mechanical or pneumatic power.

- Non-active implanted medical devices - which are passive in that they require no power source for their function, for example hip/knee joint replacements, heart valves, aneurysm clips, coronary stents and breast implants.

Active implanted medical devices can contain metallic components which render the device incompatible with MR in that MR may be unsafe and therefore contraindicated by the implant manufacturer or may cause artefacts which can affect image quality.

Some non-active implanted medical devices are inherently not MR safe, and would prevent scanning under all circumstances like aneurysm clips

Some non-active medical devices are not associated with significant MR risks and may be scanned, including

- Knee and hip replacements
- Bone fixation plates
- Dental implants

Some non-active implanted medical devices may have an unknown risk. As a precautionary measure, further specific information would be required about the MR safety of a particular device prior to scanning. If sufficient information and advice from the manufacturer can be obtained about MR safety at 3T, it would be permitted to scan the person. Examples include: Vascular stents, cardiac valves.

Some non-active devices may be MR safe but nonetheless unsuitable for MR in view of the large interference with the MR signal. Examples in this category include

- Jaw or maxillary reconstruction metalwork
- Metallic shoulder prostheses

3.6.8 Metallic Foreign Bodies

The presence of metallic objects such as bullets, pellets, shrapnel, or other types of metallic fragments, in particular ferromagnetic objects, is a particular hazard both external and internal to the body. This is of particular relevance to volunteers who are or have been involved in the manufacture of metal products. The embedded metal fragments will heat up and may move or become dislodged. The potential for injury is greater if the object is near soft tissue structures and/or significant vessels e.g. aorta or carotid artery.

We therefore exclude all volunteers with such metallic foreign bodies as a general measure of precaution.

3.6.9 Indwelling Catheters

Although indwelling catheters are unlikely to contain ferromagnetic material, **we exclude all volunteers with indwelling catheters unless specific advice is obtained from the manufacturer about the safety of the device at 3T.**

3.6.10 Spectacles and Hearing Aids

Metallic orthoses such as spectacles and hearing aids must be removed before scanning. MR safe spectacles are provided that match as much as possible the volunteer's prescription.

3.6.11 Transdermal Patches

A transdermal patch is a medicated adhesive pad that is placed on the skin to deliver a time-release dose of medication through the skin into the bloodstream.

Burns have been reported to the MHRA associated with transdermal patches due to the presence of come metallic backing.

Transdermal patches containing metal must be removed. A list of known MR unsafe patches is displayed in the MR control room

3.6.12 Tattoos, Makeup

Tattoos may contain iron oxide or other metallic substances that are conductive. As with any conductive material in MR there is the risk of heating due to RF energy deposition. There is no evidence to predict tattoo behaviour in MR but considering the worst case scenario i.e. burns due to tattoo on face **CBU will not scan volunteers with tattoo on the face. During scanning, patients should be asked to report any discomfort immediately.**

Volunteers may be asked to remove any makeup as some products contain large amounts of paramagnetic substances that affect the image quality

3.6.13 Body Piercings

Metallic body piercings might heat up and may move or become dislodged, which may lead to injury. Also, they could cause artifacts on the MR images.

All body piercings must therefore be removed before the volunteer enters the Controlled Area.

3.7 Volunteer Management: Scanning

3.7.1 Preparation

Identification: The Qualified MRI Operator must ensure that the volunteer is correctly identified.

Volunteer weight and height: It is important that a current weight and height measurement is available at the time of scanning in order for the MR equipment to calculate the SAR levels to which the volunteer will be exposed. If the current weight and height is not known, the volunteer must be weighed and height measured before scanning.

Reassurance and explanation: A suitably trained person should describe the examination to the volunteer, explaining the sights, sounds and experiences to be anticipated, and predicting the likely length of examination.

3.7.2 Screening

Before booking in volunteers for an examination they will obtain an information sheet that covers major safety questions such as pacemakers, implants, and pregnancy. Participants under 18 will be offered a demonstration and familiarisation session prior to the scanning session.

Before booking in volunteers for an examination, volunteers will be pre-screened in order to prevent an inappropriate examination being booked. The pre-screening interview will cover major safety questions such as pacemakers, aneurysm clips, electronic implants and pregnancy.

On arrival in the unit volunteers will be asked to complete a screening form (cf. Appendix D). A Qualified MRI Operator will then review the screening form with the volunteer.

The screening form must be signed by the volunteer (or parent/legal guardian) and the Qualified MRI Operator. The parent/legal guardian will be asked to complete a screening form. A Qualified MRI Operator will then prepare the volunteer for the MR examination. This includes the removal of all unsafe items from the volunteers body/clothes (e.g. watches, credit cards, jewellery, hairpins, body piercings, hearing aids, spectacles, etc). The volunteers will be asked to store these items in one of the lockers provided.

Before entering the Controlled Area, the Qualified MRI Operator must ensure that the volunteer to be scanned has completed the screening form and that he/she has no unsafe items on him/her. The use of a hand-held metal detector will facilitate this procedure.

3.7.3 Positioning

Two issues are important here: volunteer comfort and volunteer safety. Time taken to ensure that the volunteer is comfortable will lead to greater volunteer compliance with the scan. With regard to volunteer safety, the prevention of burns is the major concern. Poor positioning of the volunteer and associated cables, leads and sensors, have been the cause of many burns reported to the MHRA.

To avoid burns caused by RF heating [*ECRI. Safety concerns in the MR environment: unique environment, unique risks. Health Devices 30(12), 2001, p. 422-444.*]:

- Ensure that insulation is placed between the cable and the volunteer if contact cannot be avoided.
- Do not loop conductive cables or allow cables to cross one another.
- Do not pass cables diagonally across the patient.

- Ensure that cables run parallel to the bore of the magnet and as close to the centre of the bore as possible.
- Ensure that cables do not touch the bore of the magnet.
- Ensure that cables exit the bore of the magnet as close to the centre as possible.
- Ensure that the volunteer's skin does not touch the bore of the magnet.
- Use insulation such as MR compatible foam pads if necessary.
- Ensure that no conductive loops form with any parts of the volunteer's body i.e. avoid skin-to-skin contact. Foam pads can be placed between the thighs, between the arm or hand and the trunk and between the ankles to avoid the formation of any conductive loops.
- Ensure that sensors are placed outside the scanning area whenever possible, as well as away from RF coils.
- Ensure that regular checks for damage are made on all coils, cables and leads for damage and do not use if damage is seen.
- Use only high impedance leads; fibre optic leads are preferred.
- Ensure that the volunteer is instructed to inform staff immediately if they feel any warming.
- Ensure that the sites of all sensors are regularly checked for any evidence of heating if the volunteer is unconscious or for any reason unresponsive.

Ensure that you are familiar with and follow the manufacturer's instructions at all times. This includes using only the monitoring equipment, ECG wires, leads, electrodes and accessories recommended by the MR system manufacturer.

3.7.4 Hearing Protection

The time-varying magnetic field gradients used in MRI may produce loud noise within the magnet interior. Volunteers should be clearly warned of this. With fast imaging sequences (such as EPI) the noise level may exceed 85 dBA.

All volunteers being scanned must therefore wear suitable hearing protection (e.g. non-metallic earplugs and/or ear defenders). **Staff and others remaining in the Magnet Room during an examination, must also wear suitable hearing protection.**

3.7.5 Comfort

Adequate lighting and ventilation in the magnet interior are important. Care should be taken if pillows, blankets or covers are used to ensure that they are MR compatible and that heat loss is not inhibited. At all times during scanning the volunteer should be in a position to make contact with the operator and give warning of any discomfort or concern.

3.7.6 Communication

For communication between the volunteer and the person who is scanning, a two-way intercom is available. Recorded music or narrative of the volunteer's choice can be made available during structural brain scans and during the set-up period.

3.7.7 Panic Alarm

An alarm / panic button will be provided at all times. The device will be given to all volunteers with an explanation of its intended use. This has to be tested before scanning of each volunteer.

3.7.8 Volunteer Monitoring

Pulse monitoring is necessary when scanning in the Control or Research Mode.

Visual and audio contact with the subject should be maintained throughout the scanning session.

The Qualified MRI Operator must not leave the Control Room whilst a volunteer is being scanned unless it is to enter the Magnet Room.

3.7.9 Maximum Time in the Scanner

There is no guidance on the duration of MRI sessions so currently there is no limit providing the SAR limits are not reached.

3.8 Data Management

Currently, there is evidence to support the view that, provided the recommendations referring to the exposure limits (cf. 2.1.5, 2.2.2, 2.3.2, 2.4.4) are followed by all those associated with MR diagnostic equipment and its operation, the risk of short or long term deleterious effects is very low.

However, it is in the interest of the individual and the population as a whole, that records are maintained of all MR scans of all volunteers.

3.8.1 Minimum Data Required

The following is regarded as the minimum scan data that should be retained:

- Equipment reference including update status and static magnetic field intensity.
- The subject's name or reference, sex and age.
- Date of scan.
- The approximate time spent in the magnet.

This information should be held with a copy of the patient/volunteer consent form, including a signed statement showing confirmation of full explanation given and medical screening conducted.

3.8.2 Scan Logs

Scan logs are in electronic form via the subject data management system provided by the manufacturer.

All volumes of the scan log, all the volunteers' records should be held in safe keeping for a period that ensures compliance with the current guidance from the Department of Health and the Medical Research Council. It should be in a form from which full details can be retrieved within this period if required.

3.8.3 Data Protection and Confidentiality

Access to Personally-Identifiable Data (PID) will be restricted to members of the research team, as defined by their ethical approval, and to the CBU radiographers and CBU panel management team (for members of our volunteer panel, as approved by separate ethics). All PID will be stored securely and in line with CBU Data Protection policy (http://intranet.mrc-cbu.cam.ac.uk/administration/data-protection/) and the University of Cambridge's policies (e.g, GDPR: https://www.information-compliance.admin.cam.ac.uk/data-protection/general-data-protection-regulation). The MRC and University of Cambridge comply with the requirements of the EU General Data Protection Regulations 2016 and the Data Protection Act 2018 with regard to the collection, storage, processing and disclosure of personal information and is committed to upholding the Acts core Data Protection Principles.

If participants give their consent (e.g, as on standard CBU Consent Form), then their anonymised data may be shared with other researchers. In the case of MRI images that include the face, though this is not currently regarded as PID, it is recommended that the face is removed before sharing.

3.8.4 Abnormal (Incidental) Findings

The Cognition and Brain Sciences Unit is a cognitive neuroscience research unit and does not provide any diagnostic services and seeks to avoid harm from implicit but unproven public-health screening. This policy will be clearly stated on the volunteer information sheet.

Even though we do not provide a diagnostic service, as stated for participants in our information sheets, we have a Duty-of-Care. This Duty-of-Care includes the need to act on potentially serious problems that are noticed during the course of volunteers' participation in a study, but also the need to avoid harm directly (eg distress, anxiety, mental well-being) or indirectly (by invasive further investigations; or by loss of employment and financial well-being) as a result of a false-positive findings. Therefore, if a potential abnormality is noticed on a brain scan (e.g, by a radiographer during acquisition or by a researcher during analysis), this will be brought to the attention of the CBU Medical Monitor, who is responsible for acting on this information. Formal review of every scan by a radiologist, or review of every scan by a radiographer trained for diagnostic reporting, is not warranted.

It may be necessary to exclude such participants from the study for scientific but not medical reasons, in which case the reasons for the exclusion will not be fed back to the researcher. The Medical Monitor will determine whether referring the individual for further clinical evaluation is appropriate, either directly in the event of life-threatening abnormalities, or via the General Practitioner. If the incidental finding is from an individual under 18 years of age, the findings will be referred to the Paediatric Medical Monitor. Note that, if a volunteer later contacts a researcher to ask about possible abnormal findings, the researcher should only take their contact details, and then tell the Medical Monitor and Radiographers, one of whom will contact the volunteer. A researcher should not try to give any medical or quasi-diagnostic feedback to the volunteer.

3.9 Staff Training

To avoid accidents, it is essential that all personnel associated with MR equipment be adequately trained.

The training of all appropriate categories of staff in terms of their normal duties and those in the event of an emergency is essential before installation and for all new staff subsequent to installation. Regular reviews of the training status as well as updates and refresher courses for all staff will be required during the operating life of the MR diagnostic unit.

A particular area of concern is that of an emergency which can relate to the safety of the person scanned and the staff, or of an environmental emergency such as a fire. Careful consideration must be given to setting up the correct form of training for the specialist staff who may be involved in any form of emergency which needs their entry into the Controlled Area and the necessary liaison with the appropriate groups both within and outside the establishment.

The MRI Management Committee (cf. 3.1) will ensure that the necessary responsibilities are established and carried out. Furthermore, it will review and update the unit's health and safety policy at regular intervals.

3.10 Accident/Incident Reporting and Investigation

All accidents and near misses, however minor, must be reported to the relevant line manager and recorded (*see Appendix J).*

All accidents and near misses will be investigated by the relevant line manager to establish the root cause and introduce management action to prevent a recurrence.

All notifiable accidents, dangerous occurrences and cases of occupational related ill health, as defined by The Reporting of Injuries, Diseases and Dangerous Occurrences Regulation 1995, must be reported to the Safety Co-ordinator who will ensure the Director, the local Health and Safety Executive Office and the Health and Safety Section at Head Office are informed.

3.11 Booking policy

All MRI projects must be approved by the Imaging Management Committee (IMC), and then booked through the MRI Facility Administrator. Procedures for this process are on the CBU WIKI and in the Minutes of the IMC.

- Pilots are charged and will be used to review the slot time requirements for the rest of the project
- Users are charged for the total slot time rather than the total EPI time
- Cancellations must be given at least 10 working days notice.
- Cancellation of an entire project of slots will require at least 4 weeks notice.
- Any cancellations with less than notice than above will be charged unless special circumstances are allowed by the IMC (for example patients who cannot be replaced at short notice).
- It is the researcher's responsibility to pre-screen volunteers for the suitability for the scan. If the volunteer or patient cannot participate due to reasons that should have been revealed in the screening of the volunteer / patient, e.g. piercings, claustrophobia, then the slot will be charged. Other exceptional considerations, such as head movement, will be treated on a case by case basis by the IMC.
- If for any reason the volunteer / patient or researcher is late for the scan slot, the Qualified MRI Operator will have the right to terminate the session.
- If a fault is found with CBU equipment causing the data to be invalid, then a slot will not be charged.

4 Emergency Procedures

4.1 General Considerations

An emergency can relate to the well-being of patients and volunteers being scanned, to an environmental emergency such as a fire or a threat to a member of staff. Careful consideration must be given to setting up the correct form of training for the specialist staff involved in any form of emergency which needs their entry into the Controlled Area, and the necessary liaison with the appropriate groups both within and outside the establishment.

Caution In an emergency access to the Controlled Area must be subject to the direct supervision of an adequately trained and Responsible Person.

Caution Consideration will need to be given to the provision of the necessary supervision and control should an emergency such as a fire occur out of hours.

Caution No ferromagnetic material of any kind must enter the Magnet Room. All personnel must be adequately screened for ferromagnetic material being carried on their person, hairgrips, key rings, scissors, knives, etc., beyond the 0.5m T (5 gauss) static magnetic field level. There can be only one exception to this rule, which is if the magnet has been de-energised (quenched) before the entry of unauthorised personnel.

4.2 Emergency Switches

4.2.1 Location

There are three different types of emergency shutdown switches: the **Magnet Quench** switch, the **Power Stop** switch, and the **Patient Table Stop** switch. The location of these switches is shown on the floor plan in Appendix B.

4.2.2 Magnet Quench Switch

There are two Magnet Quench switches, one in the Control Room, the other one in the Magnet Room (cf. Appendix B).

The Magnet Quench switch is used to de-energise (quench) the magnet.

This will quickly reduces the field strength of the magnet to a low level. As a result, magnetic field energy is converted into heat energy. The helium coolant boils off abruptly and is released through an exhaust line. This generates a considerable amount of noise (hissing, etc.) because large amounts of helium gas are released into the open.

Lowering the magnetic field strength to 20 mT takes less than 20 seconds.

The rapid release of the magnet's stored energy, is moderately violent, and may cause permanent damage to the magnet. It WILL cause weeks of downtime and the loss of about £10,000 of helium.

A deliberate Magnet Quench may only be initiated if there is:

- An uncontrollable fire in the Magnet Room which requires the use of ferromagnetic fire-fighting equipment.
- A life-threatening accident involving a ferromagnetic object.

4.2.3 Power Stop Button

There are three Power Stop switches, located in the Control Room, the Magnet Room, and the Technical Room (cf. Appendix B).

The Power Stop switch is used to for an emergency shutdown of the complete MR system (except the magnet). This will immediately cut electrical power to all components of the MRI system except the magnet.

One of the Power Stop buttons must be pressed if there is

- A fire or
- An electricity-based accident

4.2.4 Patient Table Stop Button

There are three Table Stop buttons: two are located on the control units on the right and left side of the patient table at the magnet, and one on top of the patient intercom in the Control Room (cf. Appendix B).

The Patient Table Stop button is used for stopping the motor-powered movement of the patient table in case of emergency.

Push the Patient Table Stop button in case of accident or risk of injury due to table movements. The Patient Table Stop symbol will appear on the table display. The brakes are released and the patient table may be moved horizontally by hand.

4.3 Location of Rescue Equipment

A Heartstart FRx AED will be based in the kitchen of the Imaging Facility, along with a comprehensive first aid kit (including a burns kit) and a first aid blanket. The kitchen door carries appropriate signage.

A second Heartstart FRx along with an oxygen cylinder will be based in the 'Elbow' at the top end of the south wing of the main CBU building. In an emergency within the Imaging Facility the second AED, along with the oxygen cylinder, will be brought to the Reception Area by one of the first aiders.

Most CBU first aid staff will have had training in using the AED equipment. They are summoned, on the internal telephone network by an 888 call.

A St John's Ambulance plastic carry sheet will be permanently on the wall in the Magnet Room to aid the emergency removal of a casualty.

4.4 Evacuation and Access Routes

4.4.1. Evacuation of the MR Building, Escape Routes.

In the event of the fire alarms sounding the member of staff in charge of the building at that time (e.g. Head of MRI, Radiographer, Qualified MRI Operator, Responsible Person) will:

- ensure everyone in the scanner building evacuates by a fire escape and makes their way to an assembly point, where they must remain until instructed otherwise.
- check all rooms (including technical and plant) are empty of people.
- collect the AED, first aid kit and first aid blanket if safe to do so.
- make their way to the main entrance of the CBU in the front car park and report to the head fire officer attending.

Fire extinguishers should not be the first defence in tackling fires, always evacuate first if possible and only if a person's life is in imminent danger use fire extinguishers to fight a fire.

4.4.2. Access Routes for Rescue Vehicles

Turn left into the MRC site from Chaucer Road, once in the front car park keep left and follow the access road through the black gates and down the full length of the South Wing. At the bottom turn right and the scanner building is directly in front (cf. Appendix F for plan showing evacuation and access routes).

4.5 Medical Emergencies

4.5.1 General Consideration

In the event of a medical emmergency (e.g. cardiac arrest), the scan should be terminated immediately. The patient/volunteer should be removed from the Magnet Room at the first opportunity. Under no circumstances should ferromagnetic resuscitation equipment be brought into the Magnet Room.

4.5.2 Emergency Procedures – Medical Emergencies

Qualified MRI Operator

- Terminate scan
- Remove volunteer from bore of the magnet
- Check condition of volunteer/patient and make an assessment as to whether urgent additional help is needed.
- Escort the volunteer to the 'safe area' (MRI reception) and stay with them.

IF THIS IS AN EMERGENCY AND URGENT HELP IS NEEDED:

- Qualified MRI Operator and other Certified User to remove the volunteer from the Magnet room to the 'safe area' (MRI Reception) using the MRI compatible trolley if required.

- Call 888 from internal phone to summon CBU first aiders to the Imaging Facility **(during Unit working hours only)**

- Call 999 **out of working hours or when an ambulance is needed.**

Report our location

- Imaging Facility
  MRC Cognition and Brain Sciences Unit

Report what has happened
Details of the medical emergency (e.g. suspected cardiac arrest)
Details of the patient (e.g. female approx 25 years old)

- **DURING UNIT WORKING HOURS**: inform Reception on 100 and ask them to send somebody outside to wait for the ambulance and direct it where to go.
- **OUTSIDE OF UNIT WORKING HOURS:** a person should be dispatched to the front car park to direct the ambulance.

Report incident
Inform at least one of the following persons:
– Head of MRI
– Assistant Director Neuro-imaging
– Director

4.6 Major Equipment Failure

4.6.1 General Consideration

In the event of a major equipment failure, resulting in serious malfunction or electric shock, the electrical power to the MR system should be switched off by pressing the Power Stop buttons (cf. 4.2.3 and Appendix B). The patient/volunteer can then be safely evacuated. Scanning may not be resumed before a qualified Siemens Service Engineer has inspected the system and certified it for safe use. The Head of MRI must be informed immediately of any such failures.

4.6.2 Emergency Procedures – Major Equipment Failure

Qualified MRI Operator

- Press one of the Power Stop buttons.
- Remove patient from bore of the magnet.
- Speak to the volunteer and make an assessment of their condition

In case of a medical emergency

- Call 888 to summon CBU first aiders to the Imaging Facility **(during Unit working hours only).**
- Call 999 **out of working hours or when an ambulance is needed.**

Report our location

- Imaging Facility
  MRC Cognition and Brain Sciences Unit

Report what has happened

Details of the medical emergency (e.g. suspected cardiac arrest)
Details of the patient (e.g. female approx 25 years old)

- **DURING UNIT WORKING HOURS:** inform Reception on 100 and ask them to send somebody outside to wait for the ambulance and direct it where to go.
- **OUTSIDE OF UNIT WORKING HOURS**: a person should be dispatched to the front car park to direct the ambulance

Report incident

Inform at least one of the following persons
– Head of MRI
– Assistant Director Neuro-imaging
– Director

4.7 Magnet Quench

4.7.1 General Consideration

During a quench, the super-conductivity of the magnet is suspended. The liquid helium boils off during this process and is released via the exhaust vent line. The energy of the magnetic field is converted into heat.

A quench may be triggered by:

- the Magnet Quench switch.
- an accident (earthquake, fire, etc.)

A magnet quench generates a considerable amount of noise (hissing, etc.) because large amounts of helium gas are released into the open.

Warning: Frostbite may be caused by touching the exhaust vent line. Keep clear of the exhaust vent lines.

In the event of the magnet quenching, the MR unit should be evacuated until a suitably qualified person or a representative of the supplier authorised by the Responsible Person has inspected the system.

If the oxygen alarm is activated call 999 and report that we have a depletion of oxygen due to helium and consequently there is an acute risk of asphyxiation. Do not enter the Magnet Room.

4.7.2 Emergency Procedures – Magnet Quench

- Terminate the scan
- Remove patient/volunteer immediately using the MRI Compatible Trolley if needed.

Evacuate

- **Evacuate the MR Facility (shouting "Evacuate Quench")**

- All occupants must immediately make their way the fire assembly point in the rear garden.
- Staff with volunteers/patients/visitors should escort them to the assembly point.
- The Senior Radiographer or their deputy (other Radiographer, Qualified MRI Operator or Responsible Person) will be responsible for collecting the AED and first aid equipment on route if safe to do so and checking that all of the rooms are empty on their way out.
- Assemble at the meeting point in the rear garden and do not re-enter the building until it has been declared safe by a suitably qualified person.
- When reasonable to do so report the incident to at least one of the following: Head of MRI, Assistant Director Neuro-imaging, Director

In case of a medical emergency

- Call 888 to summon CBU first aid staff to the Imaging Facility **(during Unit working hours only).**
- Call 999 **out of working hours or when an ambulance is needed.**

Report our location

- Imaging Facility
  MRC Cognition and Brain Sciences Unit

- **DURING UNIT WORKING HOURS:** inform Reception on 100 and ask them to send somebody outside to wait for the ambulance and direct it where to go.
  OUTSIDE OF UNIT WORKING HOURS: a person should be dispatched to the front car park to direct the ambulance

Report what has happened
Details of the medical emergency (e.g. suspected cardiac arrest)
Details of the patient (e.g. female approx 25 years old)

4.8 Deliberate Magnet Quench

4.8.1 General Consideration

A deliberate magnet quench may only be initiated if there is

- An uncontrollable fire in the Magnet Room which requires the use of ferromagnetic fire-fighting equipment

- A life-threatening accident involving a ferromagnetic object

4.8.2 Emergency Procedures – Deliberate magnet Quench

Check

- The decision to initiate the quench should be made by the Head of MRI or his deputy. In a life-threatening situation where none of these persons are available, the responsible Qualified MRI Operator or Responsible Person will make the decision.

- In the event of a person being trapped by a ferromagnetic object, it will be necessary to support the object when the quench is initiated. Do not bring any further ferromagnetic objects into the Magnet Room. Only authorised staff should enter the Magnet Room.

- If a person has an impalement injury by a sharp object, the magnet should be quenched before attempting to remove the patient to prevent further injury. (Do not attempt to remove the impaled object as this can lead to profuse blood loss).

Evacuation

- All occupants must immediately make their way the fire assembly point in the rear garden.
- Staff with volunteers/patients/visitors should escort them to the assembly point.
- The Senior Radiographer or their deputy (other Radiographer, Qualified MRI Operator or Responsible Person) will be responsible for collecting the AED and first aid equipment on route if safe to do so and checking that all of the rooms are empty on their way out.
- Assemble at the meeting point in the rear garden and do not re-enter the building until it has been declared safe by a suitably qualified person.
- When reasonable to do so report the incident to at least one of the following: Head of MRI, Assistant Director Neuro-imaging, Director

Quench

To initiate a magnet quench, life the flap on the Magnet Stop Switch (cf. 4.2.2 and Appendix B) and press it. Hold it down for 10 seconds and release. The magnet will quench.

4.9 Fire

4.9.1 General Considerations

All fire alarms in the main Unit and the MRI Facility are automatically linked to the Fire Station. Breaking the glass at one of the alarm points will result in the fire brigade being directed to the Unit.

In the event of fire, the fire has to be extinguished with methods appropriate to the surroundings. Fire fighters have to be able to take appropriate actions immediately. For this purpose, the fire department has to be familiar with the MR system and its location.

Before initial start-up of the MR system, the fire department must be informed about the MR system and the structural conditions on site.

The following devices/materials may be used for fire-fighting:

- Non-magnetic CO2 extinguisher
- Self-contained, anti-magnetic compressed air respiratory apparatus (or hose connection)
- Airtight chemical protective suit

Warning: Heating up/ignition of synthetic blankets due to radio frequency during the measurement! Use only blankets made of linen, cotton or paper.

The magnet must be quenched if the emergency services wish to enter the Magnet Room with ferromagnetic equipment (cf. 4.8). Warning notices must be provided. In exceptional cases it may not be necessary to quench the magnetic field if it is not necessary to enter the Magnet Room.

4.9.2 Emergency Procedures (Fire)

ON DISCOVERING A FIRE:

- On discovering a fire in the MRI Facility, raise the fire alarm by breaking the glass on one of the fire alarm points.
- Terminate all MR procedures
- Press the Power Stop button
- **Evacuate (**see *Evacuation* below)

ON HEARING THE FIRE ALARM:

- Terminate all MR procedures
- Press the Power Stop button
- **Evacuate** (see *Evacuation* below)

Evacuation

- All occupants must immediately make their way the fire assembly point in the rear garden.
- Staff with volunteers/patients/visitors should escort them to the assembly point.
- The Senior Radiographer or their deputy will be responsible for collecting the AED and first aid equipment on route if safe to do so and checking that all of the rooms are empty on their way out. They will need to report to the senior fire officer attending.
- Assemble at the meeting point in the rear garden and do not re-enter the building until it has been declared safe by a suitably qualified person.
- When reasonable to do so report the incident to at least one of the following: Head of MRI, Assistant Director Neuro-imaging, Director

In the event of a fire within the Magnet Room

- Only fire extinguishers clearly marked as non-ferromagnetic (MR Safe) may be brought into the Magnet Room.

- In the event of a serious fire in the Magnet Room that requires additional fire-fighting equipment to be brought into Magnet Room, the magnet must be quenched (cf. 4.8)

Fire equipment may be brought into the Magnet Room only after is has been verified that the magnetic field is no longer present.

4.10 Emergency Contact Numbers

In an emergency outside of working hours, assistance is available from Scanner One, the on-call emergency service co-ordinated by Authorised Personnel. This service provides a line of communication with an authorised user out of hours and will if necessary arrange for a Responsible Person to be on site to help resolve a problem, meet an engineer or meet the emergency services.

Scanner One (xxxxxxxxxxxxxx).
University of Cambridge Security Office (xxxxxxxxxx)

In an emergency occurring outside of working hours, and in addition to calling 999, the above number needs to be called in order to ensure qualified persons are arranged to be on hand to assist the emergency services.

Please note that University Maintenance,University Security or Hyline Security, the Police and the Fire-brigade **WILL NOT enter the Imaging Facility** until a member of staff is on the scene. This needs to be a Responsible Person.

5 References

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[6]
Knopp MV, Essig M, Debus J et al. Unusual burns of the lower extremities caused by a closed conducting loop in a patient at MR imaging. Radiology 200(2), 1996, p. 572-575.

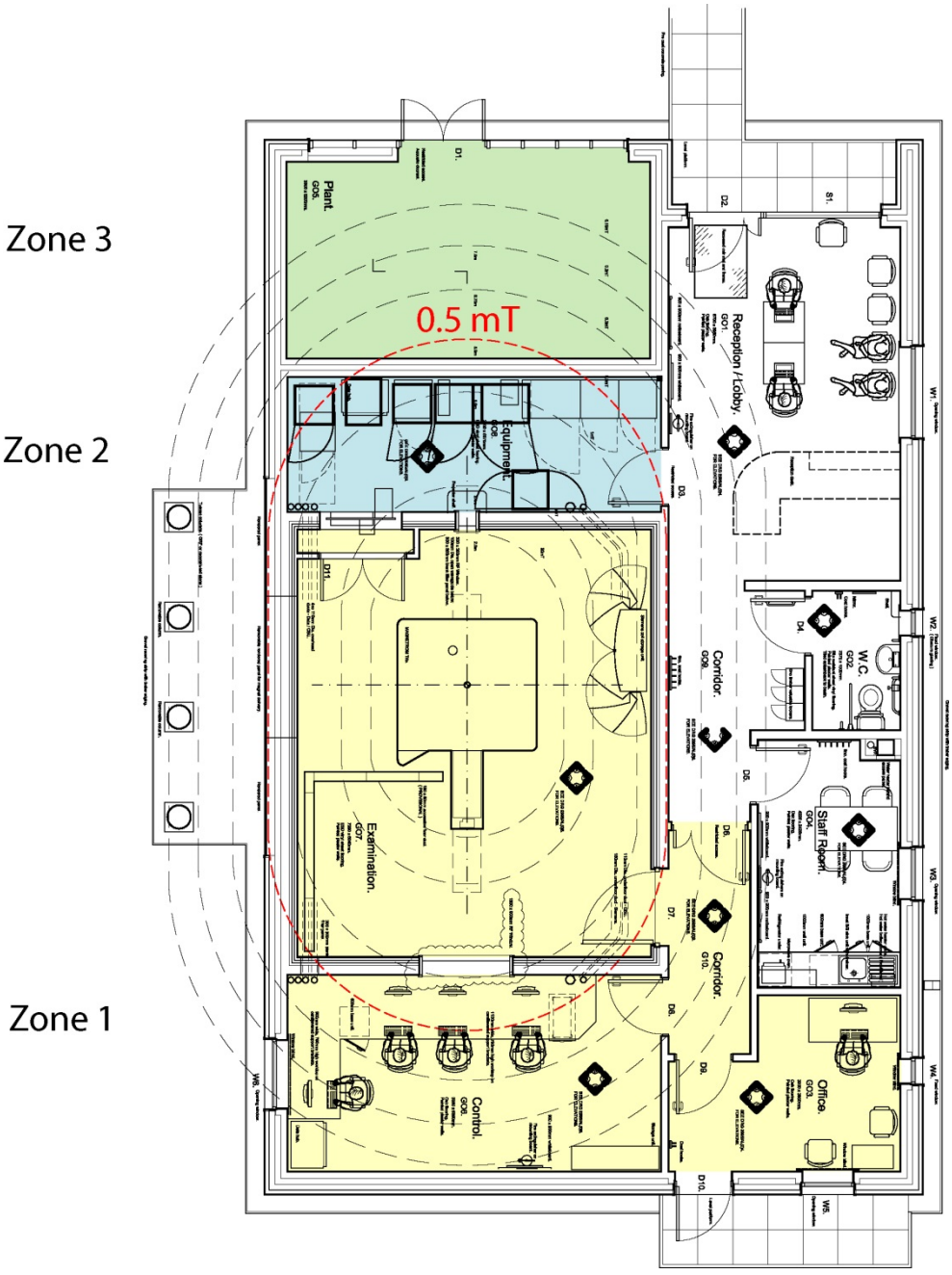
[7]
Dempsey MF, Condon B and Hadley DM. Investigation of the factors responsible for burns during MRI. Journal of Magnetic Resonance Imaging 13(4), 2001, p. 627-631.

[8] MHRA Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use, 2015 v4.2

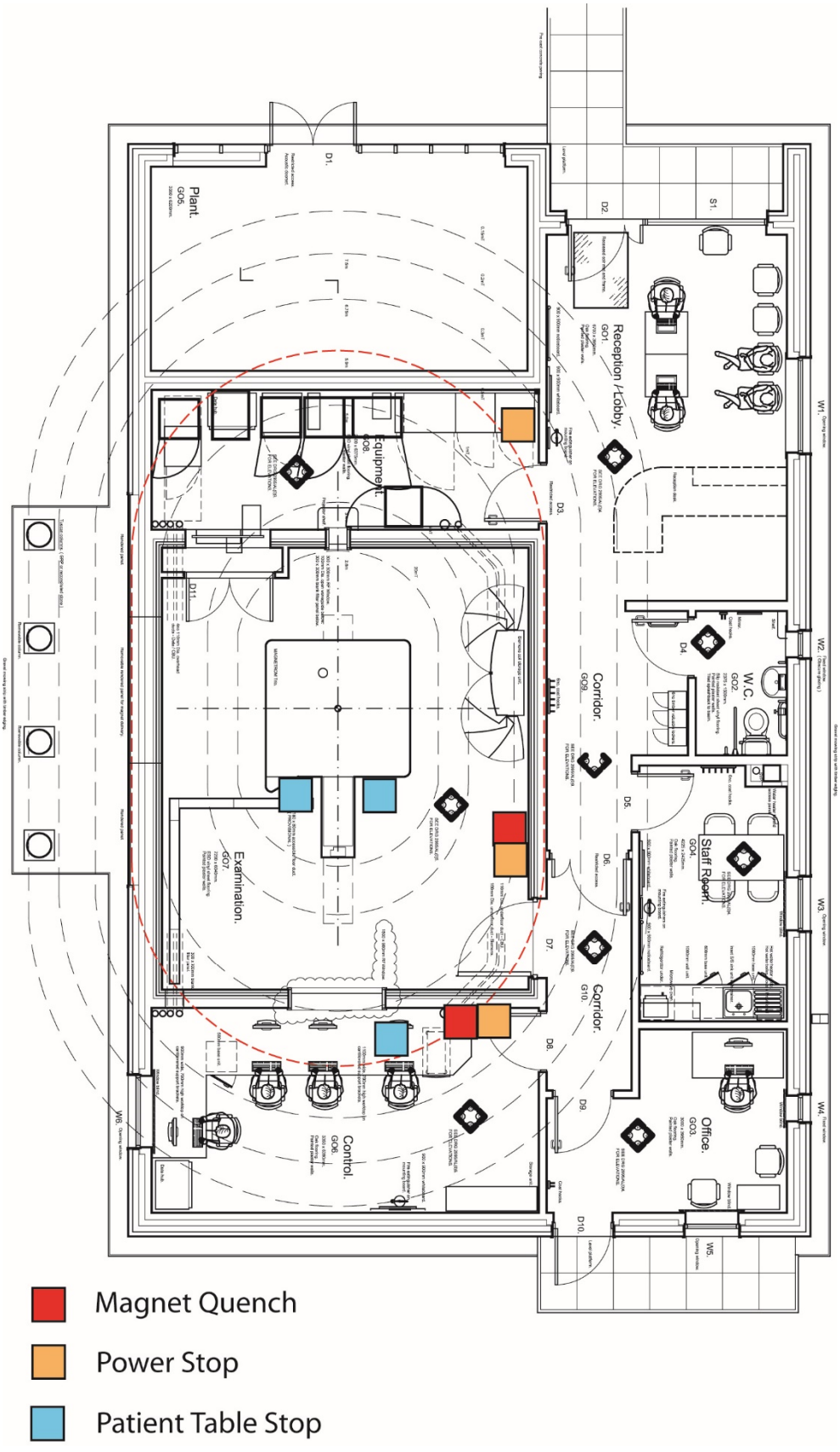
[9] Health Protection Agency. Protection of Patients and Volunteers Undergoing MRI Procedures. Documents of the Health Protection Agency Radiation, Chemical and Environmental Hazards August 2008. RCE-7

6 Appendix

Appendix A: Controlled Access Area

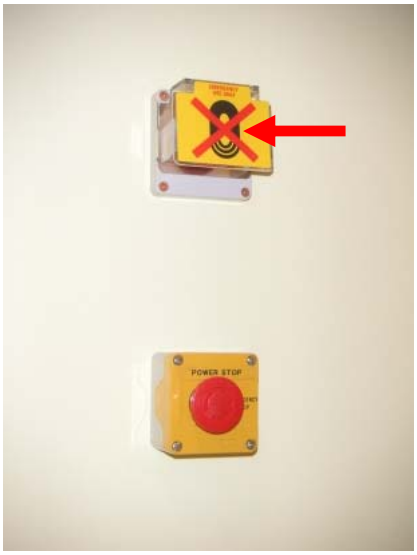


Appendix B: Emergency switches



Magnet Quench

Control Room



Magnet Room

Power Stop

Control Room

Magnet Room

Appendix C: Volunteer Information Sheet

MRC Cognition and Brain Sciences Unit

[Ethics code and PI]

UNIVERSITY OF CAMBRIDGE

Version and date

Study Title

Adult Volunteer Panel Study Participant Information Sheet

Principal Investigator: xxxxx
Researcher(s): xxxxx
Study Title: xxxxx
PRE/NRES Code: xxxxx

Researchers, please adapt this form for your study.
Black text should not be altered.
Adapt sections in blue for your study (remember to also change the page header information).
Red text indicates guidance on completion and should be removed together with this box before producing the final form.

You are being invited to take part in a research study. Before you decide whether or not to participate it is important that you understand why the research is being done, what it will involve and how the information collected from you is stored and used. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?

The aim of this study is to better understand how our brains support our ability to see words and objects.

Who is organising and sponsoring this research?

The study is organised by [PI], and is sponsored by [the University of Cambridge], this means that [the University of Cambridge] takes responsibility for the study.

Has the study been approved?

This study has been reviewed and approved by an independent group of people [insert approving ethics committee] who have a duty to protect research volunteers' safety, rights, wellbeing and dignity.

Why have I been invited to take part?

You have been asked to participate either because you responded to an advertisement or because you previously volunteered to be a member of the Volunteer Panel at the Cognition & Brain Sciences Unit.

Do I have to take part?

It is up to you whether or not to take part. Before deciding you should read this information sheet and ask about anything that is not clear. If you decide to take part we will ask you to sign a form indicating that you have agreed (consent form). However, even after you have signed that form you can withdraw from the study without having to give us a reason.

You should be aware, however, that we aim to anonymise our results (separate and remove your personally identifying information) as soon as possible after data collection to protect your privacy. If you decide to withdraw some time after your participation it may therefore not be possible to identify and remove your specific results.

What will I be asked to do in the study?

Taking part requires you to visit the Cognition & Brain Sciences Unit for a session of up to 2 hours. You will be asked to do one or more computerised tasks that test your memory or perception (e.g. how you see or hear things). You may also be asked to perform these tasks within a brain scanner: either an MRI scanner or an MEG scanner, possibly with additional EEG recording (see below for the details of these techniques). The Researcher will explain which of these scans, if any, will take place during a given visit. The tasks you will be invited to do look at how we perceive different aspects of the way in which information is presented to us. For

example, you might be shown a series of letters on a computer screen, and asked to decide whether it is a word or not. All of the tasks will be explained in detail before you start and you will have the opportunity to practice them and ask any questions you may have. These tasks are not usually a test of how your abilities compare with those of others but rather how people in general perceive the world. Sometimes there is no 'correct' answer, we just want to know what you can see or hear.

This section should include the **time commitment**, **number of separate sessions required** and **sufficient detail on what participants will be asked to do for them to make an informed decision**. If, for valid inference, some information will be withheld from participants until the task is complete this should be mentioned and informed consent taken on that basis (e.g. *"because we do not want to influence your results there are some details about this experiment that we cannot tell you until the end. You should only proceed if you are happy with this. Please note that this study has been reviewed by an ethics committee, an independent group of people with a responsibility to protect research participants' wellbeing and dignity.")* The general nature of the questions participants may be asked (e.g. on 'eating habits') should be included. If you will be asking questions (e.g. on self-harm or plans to hurt others) that could lead to disclosure of Personally Identifiable Information to a GP, child protection agency etc. **the possibility and nature of these questions should be covered in this section in order to gain fully informed consent**.

Will video or audio recordings be made?

The study does not involve video or audio recording. If video or audio recordings will be made, potential participants should be told how, and for how long, these are stored, what will happen to recordings after transcription has taken place and who will have access.

Will I be paid for taking part or have my expenses paid?

To thank you for your contribution to this study we give you £X for each hour of your time, and reimburse your travel expenses, up to a limit that you can discuss with the researcher.

The following sections are to be included if relevant to the current study. If you are using MRI, MEG or EEG this should have been previously outlined in the "What will I be asked to do in the study?" section. If you are using a different technique (e.g. TDCS) a similar section should be included here giving participants enough information to make an informed choice.

What is an MRI scan?

MRI stands for "magnetic resonance imaging." MRI uses a strong magnetic field to give us a 3D picture of your brain and allows us to see changes in the activity of different parts of your brain as you do tasks. MRI is a non-invasive technique (all the scanning equipment is outside of the body) that is used routinely in modern medicine. It has no known side effects. It does not involve injections or x-rays. Because of the strong magnetic field a qualified MRI operator will ask you to remove all metal belongings (which we will store safely) and check that you have no metal within your body. You remain clothed throughout and metal that is part of your clothes (jeans rivets etc.) is normally unproblematic. If the operator does not think it is safe we will not continue. They will also ask you questions to ensure that you will be comfortable in the scanner. If you are very uncomfortable in small, confined spaces you may not wish to participate. If it is safe and you are happy to proceed, during the session you will lie comfortably on a hospital-style bed with your head inside the MRI scanner whilst the scans are taken. It is a bit noisy and you will be asked to wear ear-plugs. You will be provided with a hand-held alarm that you can squeeze if you become uncomfortable or distressed at any time. This will alert the operator who will remove you from the scanner immediately. To collect good information it is important that you keep your head as still as possible when in the scanner. Scans typically last 30 to 60 minutes.

This section must be included if MRI is used What if the MRI scan suggests something unusual about my brain?

We do not run diagnostic scans, but if something abnormal is detected (that was not already on your records), you will be appropriately counselled and referred to an appropriate specialist in consultation with your GP, if that is what you would like. There can be benefits of detecting problems in terms of starting treatment earlier than would otherwise be the case but, very occasionally, findings may have implications for future employment and insurance.

What is an MEG scan?

MEG stands for "magnetoencephalography", which gives us recordings of the electrical activity from your brain as you do tasks. MEG has been used routinely in research for 20 years and has no known side effects. MEG is non-invasive (all the scanning equipment is outside of the body) and does not involve any injections or X-rays. You remain clothed throughout. MEG measures very weak magnetic fields produced by the brain's activity, so before the scan, a qualified MEG operator will ask you to remove all metal belongings (which we will store safely). A small number of electrodes will also be placed on your head, to record your head position and eye movements. This preparation period will take 15 to 45 minutes. After that be asked to sit underneath the MEG helmet that covers most of your head but not your face. MEG scans are not noisy and you will be able to talk

with the Operator at any point if you wish to stop. It is important that you keep your head as still as possible. The scan will typically last 30 to 60 minutes. Our MEG scans produce useful research information but not diagnostic information about health issues.

What is an EEG scan?

EEG stands for "electroencephalography", which gives us recordings of the electrical activity from your brain as you do tasks. It has been safely and routinely used in research and hospitals for over 50 years and has no known side effects. EEG is non-invasive (all of the scanning equipment is outside of the body), does not involve any injections or X-rays and you remain clothed throughout. An elasticated cap is placed over the top of your head (not over your face). It has soft silicone (rubber like material) tips that rest gently against the skin on top of your head. To make these 'electrodes' they are then filled with salt-water (like seawater) paste. Once filled, they conduct the very weak electrical signals generated by the brain's activity that are then recorded by a computer. Getting a good, comfortable fit of the cap and then filling/testing the tips takes about 45 minutes during which you can relax, chat, watch a movie etc. Wearing the cap and the feel of the salt water against the skin is unusual to begin with but people often get used to it and stop noticing that its there after a while. Once everything is in place you will be asked to do the task that will usually take 30 to 60 minutes. When the task is finished the cap is removed and you can wash any remaining paste completely out of your hair. We have the necessary facilities (basin, hand-shower, towels, shampoo) near to the testing room. Sometimes, EEG will be recorded at the same time as MEG (see above). EEG scans are not noisy and you will be able to talk with the Operator at any point if you wish to stop. Whilst EEG is widely used in hospitals our use does not provide diagnostic information.

What are the possible risks/side effects of taking part?

There are no obvious risks from the computer tasks that you will be asked to complete. If you become tired or uncomfortable during any of the tasks please let us know and we can take a break or end the session. Remember you can withdraw from the study at any time without needing to give us a reason.

[If relevant] With the appropriate safety checks in place MRI, MEG and EEG are safe, non-invasive imaging techniques, with no known side effects.

What happens to my personally identifiable information?

You have provided us with two types of information. *Personally identifiable information* includes your name, address and date of birth – information from which you could be identified and that we use to contact you, calculate your age and so on. Anonymised research data includes information like the buttons you pushed on a computer task, information from a brain scan and your answers on a questionnaire; in other words, once it is no longer connected to your Personally Identifiable Information, information from which it would not be possible, or would be very difficult, to identify you personally.

We separate your Personally Identifiable Information from your Anonymised Research Data and treat these two types of information very differently.

The University of Cambridge Data Protection Officer is the Data Controller for any Personally Identifiable Information that you have given us. Contact details: The Old Schools, Trinity Lane, Cambridge CB2 1TN data.protection@admin.cam.ac.uk.

Electronic Personally Identifiable Information is either entered directly into a secure area of our computer system or transferred there as soon as possible after collection. Personally Identifiable Information on paper records is kept in a locked filing cabinet within a secured building. Personally identifiable information is treated with strict confidentiality and in line with Data Protection Act 1998, which regulates the collection, storage, processing and disclosure of such information. This information is held very securely and only for as long as is necessary (e.g. for contacting you and for the management of the research).

You should specify here where, for how long and for what purpose personally identifying information (PID) will be held *by your study team* (e.g. for the purposes of contacting participants). You do not need to specify how long it will be held by the panel as this is dealt with in a separate information sheet. **It is a general expectation that, whilst you need to retain PID, it will be held in the CBU safe haven computing area and/or in a locked filing cabinet but that it will be deleted/destroyed as soon as possible.** It is acceptable, indeed advisable, to keep panel ID numbers in your data (these are not PID because they can only be linked back to individuals via the Panel).

In deciding for how long *your study team* need to retain PID you need to consider the risks presented by your study. Remember, the Panel will retain the participants' PID and have a record of their involvement in your study for as long as those individuals continue to be Panel members. `If your study is low risk e.g. routine behavioural assessment, the risks to privacy of keeping PID separate from the Panel may outweigh the risk of a participant leaving the panel and being uncontactable. However, if your study has potential risks or may be perceived as having potential risks (e.g. transcranial stimulation, requiring repeated unusual movements) you may wish to specify a retention period over which, even if an individual leaves the panel, you could nevertheless

contact them or verify their involvement and the procedures that were in place. **The most important thing is to specify here in this information sheet where and for how long PID will be retained outside of the Panel and who will have access to it. You need to gain participants explicit consent for that retention. You then need to put in place steps to ensure the deletion of those PID at the end of the interval (e.g. even if you have left the CBU).**

All studies using MRI should include the following section in addition to any other statement about retention of PID

If you have taken part in a brain scanning study, the scanner operator will have been through a safety-screening sheet with you. This is an important record that safety procedures were followed. This sheet includes your name, address and date of birth and the name and address of your General Practitioner (GP). The scanner operators keep a secure copy of this sheet for 10 years in case of safety audit, even if you stop participating in studies here. After 10 years this record will be deleted.

If you have questions about how long and for what reasons your Personally Identifiable Information is held, please ask the researcher.

What happens to my anonymised research data?

Your *anonymised* research data, typically combined with similar information from other volunteers, will be used for scientific research. The results are presented in scientific papers and talks, in teaching and in explaining our science to health professionals, school groups and the public in general. We take great care to ensure that individuals cannot be identified from our research outputs.

Undertaking scientific studies is expensive and relies on the generous contribution of time from volunteers. To make the most of your *anonymised* research data we plan to look after it for the long term and may use it to answer research questions beyond those for which it was originally collected. This may include combining *anonymised* research data from this study with *anonymised* data from other studies in the CBU in which you have been involved (e.g. brain scanning studies) and with the *anonymised* answers that you gave when you joined the Panel. In addition to our own analyses, we agree with the principle that research data, often collected with public money, are a public good, produced in the public interest, which should be made openly available with as few restrictions as possible in a timely and responsible manner. Many of the bodies that fund our research insist that we follow this principle. In line with this we may also share *anonymised* research data with other researchers in the UK and around the world and may make anonymised research data available as “Open Data”. Open data can be downloaded free of charge by anyone interested in the research or who wishes to repeat or conduct new analyses. This allows others to check our results and helps avoid research duplication. If research data is made Open we have no control over how that information is used.

We are very aware that, sometimes, anonymised research data could be used to identify an individual (for example, questionnaire responses about life events could identify a particular person to someone who knows him or her or who had read a newspaper story of similar events). In such cases we take great care to reduce the chances of this individual being identified by omitting critical details or not sharing even anonymised data with anyone outside of the original research team.

The following section need only be included if you are asking relevant questions. If you are, ensure that you collect the relevant information (e.g. GP details) at the outset of the session and that researchers are trained in precisely what to do should such a disclosure occur.

Are there any circumstances in which you would divulge my Personally Identifiable Information to anyone outside of the research team?

We have a duty of care to volunteers and the general public. If you give us information that indicates a real risk of harm to yourself or another person we have a responsibility to share that information with relevant services. You should only consent to taking part if you understand this possibility.

Can I get access to my results from the study?

It is important that, as researchers, we minimise potential harm to volunteers in our studies. We often use new techniques and interpreting research data can be complicated and has the potential to cause undue concern. For this reason we do not divulge individual results (with the exception of abnormalities detected on MRI scans, see above). If you have concerns about your performance please discuss these with the researcher.

If there are plans to feedback general results from the study e.g. via email or newsletter, this should be mentioned here. Note: **Never send mass emails to participants in a way that each can see others’ email addresses.**

Are there compensation arrangements if something goes wrong?

The study has insurance to deal with any claim in the very unlikely event of anything going wrong that causes harm.

What should I do if I have a complaint about the study?

We are keen that volunteers feel informed and well treated when they take part in our research. If you have a complaint about this study please contact the Principle Investigator listed at the end of this information sheet in the first instance. If you are not happy with the response, please contact the Director of the Cognition and Brain Sciences Unit (director@mrc-cbu.cam.ac.uk). Further steps can be taken through the University of Cambridge if necessary.

Thank you for considering taking part in this study. Our research depends entirely on the goodwill of potential volunteers such as you. If you require any further information, we will be pleased to help you in any way we can.

Further information and contact details

If you require more information, please contact:

Dr XXXX

MRC Cognition & Brain Sciences Unit

15 Chaucer Road, Cambridge. CB2 7EF Tel: 01223 xxxx

Email: XXXX@mrc-cbu.cam.ac.uk

Appendix D: Screening forms

- **Subject**

3.0 MRI SCREENING FORM

MRC Cognition and Brain Sciences Unit
15, Chaucer Road, Cambridge CB2 2EF Tel: 01223 355294

MRC Cognition and Brain Sciences Unit

Subject ID:..... Scan I.D. ..... MRI number..... VOLUNTEER

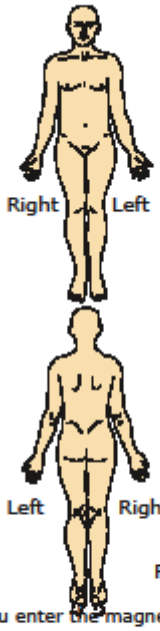
Date: ...../...../..... Principal Investigator/Lab:.....

Last Name:..... First Name:..... Height:..... Weight:.....
Birthdate:...../...../..... Email Address:.....
Address:..... City:.....
Post Code:..... Phone:(Home) ..... (Work) .....
GP's Name & address:.....
.....

1. Have you ever had surgery or other invasive procedures? ☐ Yes ☐ No
Type and Date:.....
Type and Date:.....
2. Have you had any previous MRI studies? Please detail:..... ☐ Yes ☐ No
..... Date:...../...../.....
..... Date:...../...../.....
Facility Name & Location.....
3. Have you ever worked as a machinist, metal worker, or in any profession or hobby grinding metal? ☐ Yes ☐ No
4. Have you had an injury to the eye involving a metallic object (e.g., metallic slivers, shavings, foreign body)? ☐ Yes ☐ No
5. Are you pregnant, experiencing a late menstrual period, or having fertility treatments? ☐ Yes ☐ No
6. Are you currently taking or have recently taken any medication? ☐ Yes ☐ No
Please List:.....
7. Do you have drug allergies or have you had an allergic reaction? ☐ Yes ☐ No
Please List:

Some of the following items may be hazardous to your safety or may interfere with the MRI exam. Please check the correct answer for each of the following. If you checked yes, please give more information. E.g. Type of material? How long ago? Use the diagram to indicate where on your body?

	Yes	No
Cardiac pacemaker	☐	☐
IUD or diaphragm	☐	☐
Aneurysm clip or brain clip	☐	☐
Carotid artery vascular clamp	☐	☐
Neurostimulator	☐	☐
Insulin or infusion pump	☐	☐
Implanted drug infusion device	☐	☐
Spinal fusion stimulator	☐	☐
Harrington rods (spinal rod)	☐	☐
Aortic clips	☐	☐
Internal pacing wires	☐	☐
Venous umbrella	☐	☐
Artificial heart valve/prosthesis	☐	☐
Artificial limb or joint	☐	☐
Ear tubes	☐	☐
Wig, toupee, or hair implants	☐	☐
Body piercing(s)	☐	☐
Metal or wire mesh implants	☐	☐
Pessary or bladder ring	☐	☐
Swan-Ganz catheter	☐	☐
Claustrophobia	☐	☐
Body Tattoo / Art	☐	☐



	Yes	No
Shrapnel, buckshot, or bullets	☐	☐
Implant held in place by a magnet	☐	☐
Shunt (spinal or intraventricular)	☐	☐
Tattooed eyeliner or eyebrows	☐	☐
Transdermal delivery patch (nicoderm)	☐	☐
Metal fragments(eye, head, ear, skin)	☐	☐
Facelift or other cosmetic surgery	☐	☐
Implanted cardiac defibrillator	☐	☐
Cochlear, otologic, or ear implant	☐	☐
Stents, filters, coils for blocked arteries	☐	☐
Electrodes (on body, head or brain)	☐	☐
Wire sutures or surgical staples	☐	☐
Prosthesis (eye/orbital, penile, etc.)	☐	☐
Metal rods in bones; joint replacements	☐	☐
Bone/joint pin, screw, nail, wire, plate	☐	☐
Asthma or breathing disorders	☐	☐
Seizures or motion disorders	☐	☐
Vascular access port or catheters	☐	☐
Other implants in body or head	☐	☐
Hearing aid (Remove before entry)	☐	☐
Dentures (Remove before entry)	☐	☐
Fixed Metal dental work (brace / retainer)	☐	☐

Please remove **all metallic objects** before you enter the magnet room including: keys, hair pins, barrettes, jewellery, watch, safety pins, paperclips, money clip, credit cards, coins, pens, belt, metal buttons, pocket knife, & clothing with metal in the material. **Earplugs are required during the MRI examination.**

Your Signature..... Date:...../...../.....

PTO

- **Parent/Guardian on behalf of Volunteer**

MRC Cognition and Brain Sciences Unit
15, Chaucer Road, Cambridge CB2 7EF Tel: 01223 355294

MRC Cognition and Brain Sciences Unit

PARENT/GUARDIAN

Subject ID: ..... Scan I.D. .....

Project Reference No. ..... Date: ...../...../.....

Principal Investigator/Lab: .....

VOLUNTEER DETAILS

Last Name: ..... First Name: .....

Height: ..... Weight: ..... Birthdate: ...../...../.....

Email Address: .....

Address: ..... City: .....

Post Code: ..... Phone:(Home) ..... (Work) .....

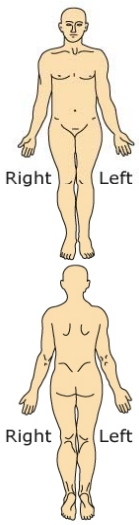
GP's Name & address: .....

.....

1. Has the volunteer ever had surgery or other invasive procedures? ☐ Yes ☐ No
   Type and Date: .....
   Type and Date: .....
2. Has the volunteer ever had any previous MRI studies? Please detail: ..... ☐ Yes ☐ No
   ..... Date: ...../...../.....
   ..... Date: ...../...../.....
   Facility Name & Location .....
3. Has the volunteer ever worked as a machinist, metal worker, or in any profession or hobby grinding metal? ☐ Yes ☐ No
4. Has the volunteer ever had an injury to the eye involving a metallic object (e.g., metallic slivers, shavings, foreign body)? ☐ Yes ☐ No
5. Is the volunteer pregnant, experiencing a late menstrual period, or having fertility treatments? ☐ Yes ☐ No
6. Is the volunteer currently taking or have recently taken any medication? ☐ Yes ☐ No
   Please List: .....
7. Does the volunteer have drug allergies or has had an allergic reaction? ☐ Yes ☐ No
   Please List:

Some of the following items may be hazardous to the volunteer's safety or may interfere with the MRI exam. Please check the correct answer for each of the following. If the answer is yes, please give more information. E.g. Type of material? How long ago? Use the diagram to indicate where on the volunteer's body?

	Yes	No
Cardiac pacemaker	☐	☐
IUD or diaphragm	☐	☐
Aneurysm clip or brain clip	☐	☐
Carotid artery vascular clamp	☐	☐
Neurostimulator	☐	☐
Insulin or infusion pump	☐	☐
Implanted drug infusion device	☐	☐
Spinal fusion stimulator	☐	☐
Harrington rods (spinal rod)	☐	☐
Aortic clips	☐	☐
Internal pacing wires	☐	☐
Venous umbrella	☐	☐
Artificial heart valve/prosthesis	☐	☐
Artificial limb or joint	☐	☐
Ear tubes	☐	☐
Wig, toupee, or hair implants	☐	☐
Body piercing(s)	☐	☐
Metal or wire mesh implants	☐	☐
Pessary or bladder ring	☐	☐
Swan-Ganz catheter	☐	☐
Claustrophobia	☐	☐



	Yes	No
Shrapnel, buckshot, or bullets	☐	☐
Implant held in place by a magnet	☐	☐
Shunt (spinal or intraventricular)	☐	☐
Tattooed eyeliner or eyebrows	☐	☐
Transdermal delivery patch (nicoderm)	☐	☐
Metal fragments(eye, head, ear, skin)	☐	☐
Facelift or other cosmetic surgery	☐	☐
Implanted cardiac defibrillator	☐	☐
Cochlear, otologic, or ear implant	☐	☐
Stents, filters, coils for blocked arteries	☐	☐
Electrodes (on body, head or brain)	☐	☐
Wire sutures or surgical staples	☐	☐
Prosthesis (eye/orbital, penile, etc.)	☐	☐
Metal rods in bones; joint replacements	☐	☐
Bone/joint pin, screw, nail, wire, plate	☐	☐
Asthma or breathing disorders	☐	☐
Seizures or motion disorders	☐	☐
Vascular access port or catheters	☐	☐
Other implants in body or head	☐	☐
Hearing aid (Remove before entry)	☐	☐
Dentures (Remove before entry)	☐	☐

The volunteer must remove **all metallic objects** before they enter the magnet room including: keys, hair pins, barrettes, jewellery, watch, safety pins, paperclips, money clip, credit cards, coins, pens, belt, metal buttons, pocket knife, & clothing with metal in the material. **Earplugs are required during the MRI examination.**

Signature ..... Date: ...../...../.....

Relationship to volunteer .....

Authorised staff name..... Authorised staff signature.....

-
-
- **Visitor/Staff**

MRC Cognition and Brain Sciences Unit
15, Chaucer Road, Cambridge CB2 7EF Tel: 01223 355294

MRC Cognition and Brain Sciences Unit

VISITOR/STAFF

Job Title:.....

Date: ...../...../..... Purpose of Entry:.....

Last Name:..... First Name:.....

Email Address:.....

Address:..... City:.....

Post Code:..... Phone:(Home)..... (Work).....

1. Have you ever had surgery or other invasive procedures? ☐ Yes ☐ No
Type and Date:.....
Type and Date:.....

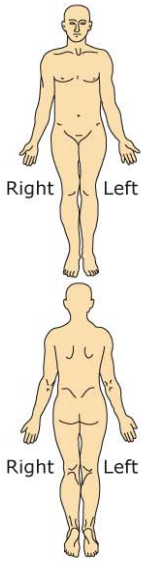
2. Have you ever worked as a machinist, metal worker, or in any profession or hobby grinding metal? ☐ Yes ☐ No

3. Have you had an injury to the eye involving a metallic object (e.g., metallic slivers, shavings, foreign body)? ☐ Yes ☐ No

4. Are you pregnant, experiencing a late menstrual period, or having fertility treatments? ☐ Yes ☐ No

Some of the following items may be hazardous to your safety. Please check the correct answer for each of the following. If you checked yes, please give more information. E.g. Type of material? How long ago? Use the diagram to indicate where on your body?

	Yes	No
Cardiac pacemaker	☐	☐
Aneurysm clip or brain clip	☐	☐
Carotid artery vascular clamp	☐	☐
Neurostimulator	☐	☐
Insulin or infusion pump	☐	☐
Implanted drug infusion device	☐	☐
Spinal fusion stimulator	☐	☐
Harrington rods (spinal rod)	☐	☐
Aortic clips	☐	☐
Internal pacing wires	☐	☐
Venous umbrella	☐	☐
Artificial heart valve/prosthesis	☐	☐
Artificial limb or joint	☐	☐
Ear tubes	☐	☐
Wig, toupee, or hair implants	☐	☐
Body piercing(s)	☐	☐
Metal or wire mesh implants	☐	☐
Pessary or bladder ring	☐	☐
Swan-Ganz catheter	☐	☐



	Yes	No
Shrapnel, buckshot, or bullets	☐	☐
Implant held in place by a magnet	☐	☐
Shunt (spinal or intraventricular)	☐	☐
Transdermal delivery patch (nicoderm)	☐	☐
Metal fragments(eye, head, ear, skin)	☐	☐
Facelift or other cosmetic surgery	☐	☐
Implanted cardiac defibrillator	☐	☐
Cochlear, otologic, or ear implant	☐	☐
Stents, filters, coils for blocked arteries	☐	☐
Electrodes (on body, head or brain)	☐	☐
Wire sutures or surgical staples	☐	☐
Prosthesis (eye/orbital, penile, etc.)	☐	☐
Metal rods in bones; joint replacements	☐	☐
Bone/joint pin, screw, nail, wire, plate	☐	☐
Vascular access port or catheters	☐	☐
Other implants in body or head	☐	☐
Hearing aid (Remove before entry)	☐	☐

Please remove **all metallic objects** before you enter the magnet room including: keys, hair pins, barrettes, jewellery, watch, safety pins, paperclips, money clip, credit cards, coins, pens, belt, metal buttons, pocket knife, & clothing with metal in the material.

Your Signature..... Date: ...../...../.....

Authorised staff name..... Authorised staff signature.....

Appendix E: Consent Forms

MRC Cognition and Brain Sciences Unit

UNIVERSITY OF CAMBRIDGE

CBU ADULT VOLUNTEER PANEL STUDY CONSENT FORM

Ethics Title:
Study Title:
Principal Investigator: **PRE/NRES Code**
Researcher(s): **Study/Project**

Agreement to continued membership of the CBU Adult Volunteer Panel

The MRC Cognition and Brain Sciences Unit (CBU) is part of the University of Cambridge (from July 1st 2017). The University of Cambridge have the responsibility for safeguarding research data and personal information.

Please initial to indicate that you have read each point

1. I agree to my continued membership of the CBU Adult Volunteer Panel and understand that this means the University of Cambridge holding my personally identifiable information (e.g. my name and address) that I provided when I registered as a volunteer with the MRC Cognition and Brain Sciences Unit Adult Volunteer Panel. This includes information given before the CBU became part of the University of Cambridge. ☐
2. I understand that the CBU Volunteer Panel uses a commercial web interface (sona-systems.com) to communicate with volunteers and that, whilst I remain a member of the Panel, my personal information is therefore held on computer servers belonging to this company in Canada and the Netherlands. These are compliant with EU law on data protection. I agree to this. ☐
3. I understand that, should I no longer wish to be a member of the Panel, or I cannot be contacted 5 years after my last participation, all personally identifiable information held about me will be deleted from the Panel and the Sona-systems website. ☐
4. I confirm that I have had an opportunity to read the CBU Adult Volunteer Panel Information sheet and the CBU Human Subject Privacy Policy, had the opportunity to consider this information, ask any questions and had these questions answered satisfactorily. ☐

Agreement to participate in this study:

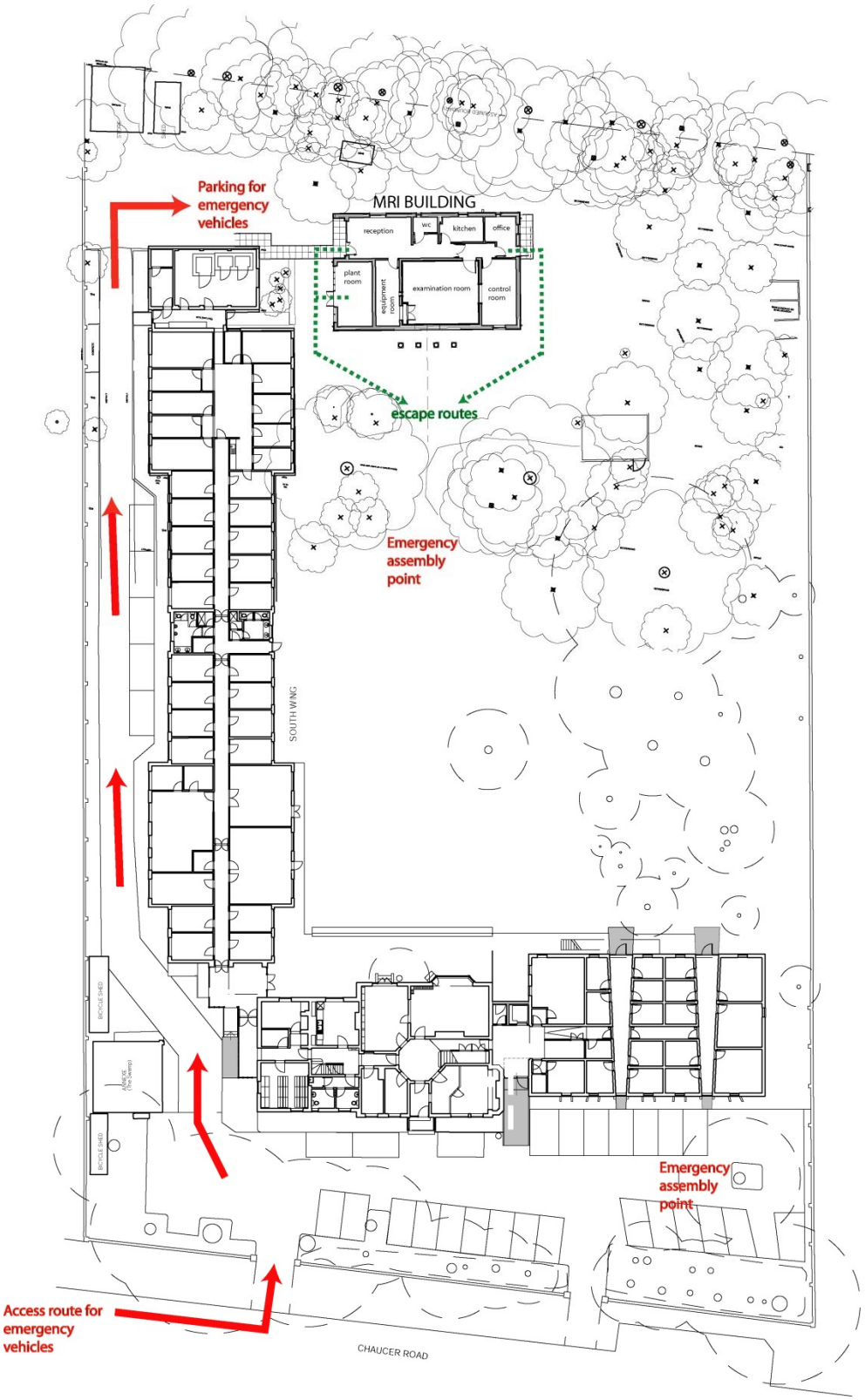
5. I confirm that the nature of the above named study has been explained to me and that I have agreed to take part. ☐
6. I confirm that I have read the participant information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐
7. I understand that my participation in the above study is voluntary and that I am free to withdraw at any time without giving a reason. ☐
8. I understand that my personally identifiable information, such as my name, address and date of birth are treated as highly confidential by the research team and kept in a secure computing area and/or in a locked filing cabinet. I have read and understood for how long these details will be kept by the researchers running this study. ☐
9. [IF RELEVANT] I understand that MRI radiographers will complete a safety screening sheet that will include my name, address and date of birth. I understand that this is retained by the radiographers separately from my research data for 10 years in case of safety audit. I agree to this. ☐
10. [IF RELEVANT] I understand that the CBU has a duty of care to volunteers and the general public that, in exceptional circumstances, places limits on its duty of confidentiality to research participants. I understand and agree to this. ☐
11. I agree that my *anonymised* research data from this study will be kept in the long-term, may be combined with data from other CBU studies to answer new research questions, may be shared with other researchers or may be made 'Open' without new consent being sought from me. ☐
12. I agree to the CBU panel manager receiving the scores from measures I have completed in this study and making these available to other researchers within the CBU for the purposes of inviting particular participants (e.g. fluent French speakers) to take part in specific studies. ☐

To indicate your agreement with points 1-12 above, please sign below.

Panel id: Name of Participant:

Signature: ..... Date: .....

Appendix F: Evacuation and access routes



Appendix G:
Risk assessment of magnetic field exposure

The aim of this risk assessment was to estimate the magnetic field exposure averaged over a period of 24 hours. This analysis was based on typical tasks performed by different categories of Authorised Personnel, taking into account the location of the area where each task is performed, as well as the corresponding field strengths and duration of the exposure. To this end, the maximum magnetic field was measured in six reference areas (A1-A6, cf. Fig. G-1) located within the Controlled Area. The results of this analysis are summarised in Table G-1.

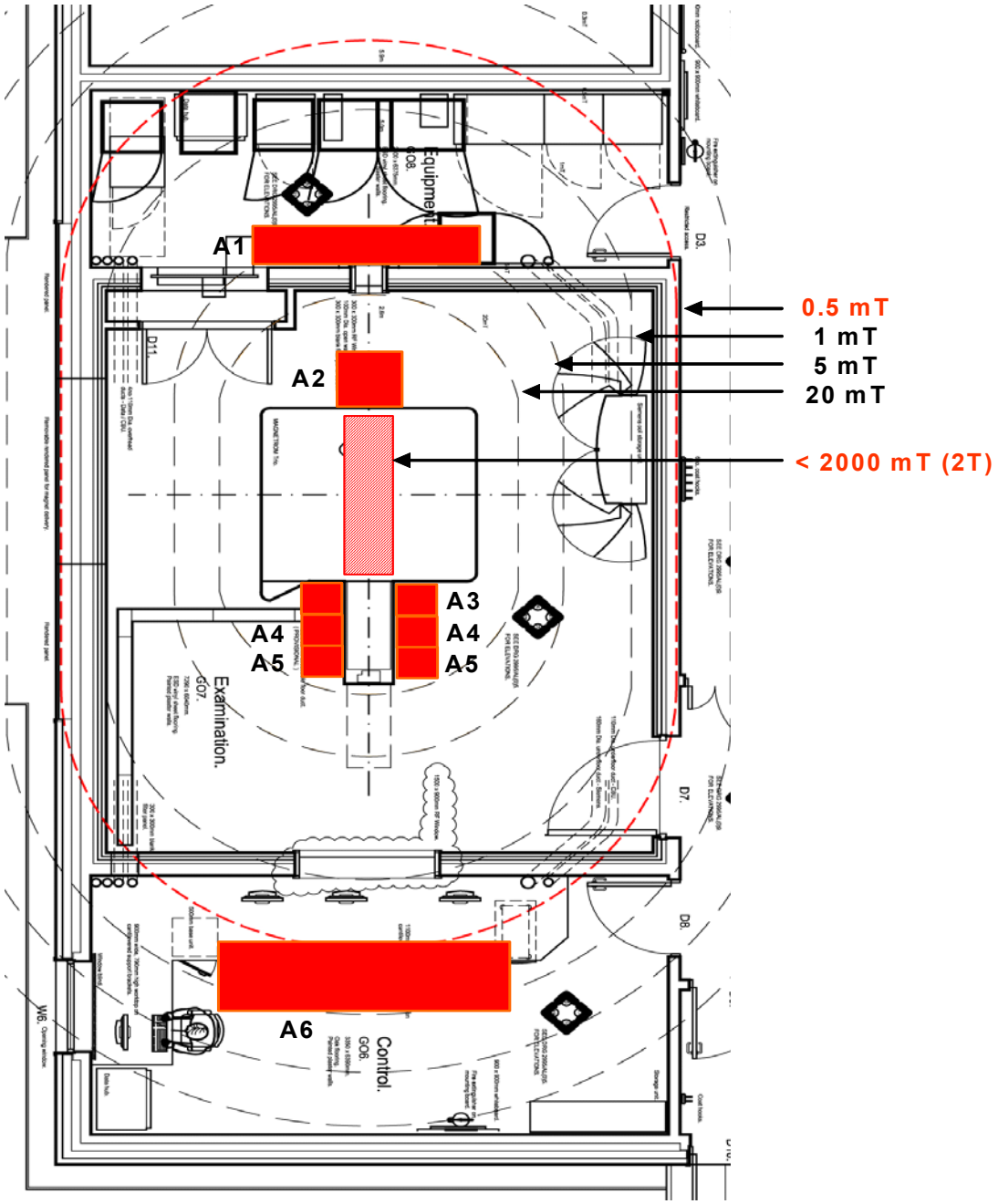


Fig. G-1. *Location of the reference areas*

Table G-1. *Magnetic field exposure during typical tasks*

Area	**Max. Field Strength**[1)]	**Typical Tasks**	**Who**	**Duration**[2)] Typical	**Duration**[2)] Worst case
A1	8.0 mT	Adjustment of projector Maintenance of projector	R, AR1, AR2 T	5 min 30 min	15 min 8 h
A2	1000 mT	Adjustment of screen Maintenance work on screen	R, AR1, AR2, T	5 min	15 min
A3	500 mT	Positioning and preparation of participants or phantoms Interaction with participant	R, AR1 AR2	- 3 h	2 h 8 h
A4	110 mT	Positioning and preparation of participants or phantoms Interaction with participant	R, AR1 AR2	1 h 2.5 h	- -
A5	40 mT	Positioning and preparation of participants or phantoms Interaction with participant	R, AR1 AR2	- 2.5h	- -
A6	0.5 mT	Scanning; Control of ancillary equipment; Data Analysis Maintenance work	R, AR1 T	8 h 30 min	10 h 8 h

[1)] Measured using a calibrated Gaussmeter
[2)] Per day
R = Radiographer or Qualified MRI Operator
AR1 = Authorised Researcher (Level 1)
AR2 = Authorised Researcher (Level 2)
AT = Authorised Technician

The magnetic field exposure averaged over a period of 24 hours was calculated for different categories of Authorised Personnel using the reference values listed in Table G-1 for both typical and worst case conditions (cf. Table G-2). The analysis was base on the following assumptions:

Radiographer or Qualified MRI Operator. Positioning and preparation of participants or phantoms is done in area A4. This takes 5-10 min per subject, which gives about 1h for 8 subjects per day. The worst case condition assumes this task being performed in area A3 located close to the magnet bore (total exposure time: 2h).

Authorised Researcher (Level 1): Typically stays within the Control Room, but assists with adjusting the projector or the screen. The worst case condition assumes an Authorised Researcher additionally helping with positioning and preparation of participants or phantoms in area A3 (total exposure time: 2h).

Authorised Researcher (Level 2): This refers to researchers who are present in the Magnet Room during the entire scanning session. The maximum period of time is limited to 8h per 24h interval. Typically the researcher would move in areas A3-A5. The worst case assumption is that the researcher stays in area A3 all the time.

Authorised Technician. The average magnetic field exposure was calculated for maintenance work in areas A1, A2 and A6, carried out under both typical and worst case conditions.

Table G-2. *Average magnetic field exposure*

Category of Authorised Personnel	**Average field strength over 24h**	
	Typical	Worst case
Radiographer or Qualified MRI Operator	8.3 mT	52.4 mT
Authorised Researcher (Level 1)	8.3 mT	52.4 mT
Authorised Researcher (Level 2)	81.6 mT	177 mT
Authorised Technician	3.6 mT	13.3 mT

Appendix H: Statement of conformity

(NB: The document show here is the previous version for the **MAGNETOM Trio** system. The current version for the Siemens **TIM Trio** system will be provided in due course by Siemens.

SIEMENS

CONFORMITY with Standards and Regulations for MR Systems

Manufacturer	Siemens Aktiengesellschaft Medical Solutions
Division	Magnetic Resonance (MR)
Address	Henkestraße 127, D-91052 Erlangen, Germany
Medical device	**MAGNETOM Trio**

The following standards and regulations were observed during the developing process for the MR-Systems MAGNETOM Espree for the technical requirements of each system.

IEC 60601-1	Medical electrical equipment: General requirements for safety
IEC 60601-1-1	Safety requirements for medical electrical systems
IEC 60601-1-2	Electromagnetic compatibility, requirements and tests
IEC 60601-1-4	Programmable electrical medical systems
IEC 60601-2-33	Particular requirements for the safety of magnetic resonance equipment for medical diagnosis
EN 30993 - 1	Biological evaluation of medical devices: Part 1Guidance on selection of tests
EN 30993 – 5	Part 5 Tests for cytotoxicity: in vitro methods
EN 30993 – 10	Part 10: Tests for irritation and sensitization.
IEC 60825-1	Safety of laser products - Part 1: Equipment classification requirements and user's guide

Place and date: Erlangen, 2005-06-10

Name: V. Schmidt, MR Global Regulatory Support

Signature: V. Schmidt

7401446-QCE-NOR-01.doc 1/1 Version 01

Appendix I: Definition of Terms

Authorised Person	A person who has free access to the Controlled Area. The selection and certification of a person for authorisation rests with the Head of MRI and must be endorsed by the Assistant Director Neuro-imaging. Certification of an individual shall only be authorised after satisfactory completion of the local MRI Authorisation Procedure.
Controlled Area	The controlled area includes all accessible areas where the magnetic field exceeds 0.5 mT (5 Gauss). The extent of the Controlled Area is outlined on the MR site plan (cf. Appendix A).
Control Room	The location of the MR control console and all computers used for stimulation and monitoring control. The Control Room is part of the Controlled Area.
Equipment Room	The room housing the Siemens MRI hardware and ancillary equipment. The Equipment Room is part of the Controlled Area and only accsessible via a key lock.
Magnet Room	The magnet room is the radiofrequency shielded room that contains the 3 Tesla superconductive magnet, as well as ancillary MR Compatible equipment required for scanning. The Magnet Room is part of the Controlled Area.
MR Environment	The three dimensional volume of space surrounding the MR magnet that contains both the Faraday shielded volume and the 0.50 mT field contour (5 Gauss (G) line). This volume is the region in which an item might pose a hazard from exposure to the electromagnetic fields produced by the MR equipment and accessories.
MR Conditional	An item with demonstrated safety in the MR environment within defined conditions. At a minimum, address the conditions of the static magnetic field, the switched gradient magnetic field and the radiofrequency fields. Additional conditions, including specific configurations of the item, may be required
MR Safe	An item that poses no known hazards resulting from exposure to any MR environment. MR Safe items are composed of materials that are electrically nonconductive, non-metallic, and nonmagnetic
Plant Room	The room that contains the main air conditioning unit for the MR building. The Plant Room is only accessible from outside the MR building via a key lock. The Plant Room is part of the Controlled Area.
CBU Opening Hours	The official Opening Hours of the CBU are: Mon-Thu 9:00-17:30 and Fri 9:00-16:30
MRI Facility Opening Hours	The official Opening Hours of the MRI Facility are: Mon-Fri 8:00-20:00 and Sat 08:00-18:00.
Radiographer	A clinically-trained radiographer, HCPC registered, who has been trained to run the scanner, and who is familiar with the MR suite and the relevant procedures.
Qualified MRI Operator	A person who is either a Radiographer or has been trained to operate the scanner (see Section 3.3.3).

Appendix J: Near Miss Form

NEAR MISS REPORT Ref No.....

Name .....

MRC Staff ☐ Employee Number.....
Other Staff ☐
Student ☐
Visitor/Member of public ☐
Contractor/Engineer ☐

Occupation.....

Date/ Time of Incident ..... Location .....

Date/Time reported to Safety Co-ordinator .....

Report Completed by.....

Description/Details of incident

Signature Date

Appendix K: RECEIPT

Please read the declaration below, initial and sign the form.
Please return <u>this signed page only</u> to MRI Administrator at CBU.

Initial	
☐	I have received and understand the Standard Operating Procedures.
☐	I undertake to follow the procedures recommended to prevent damage to property, injury or ill health to myself and others.
☐	I have attended the MRI Training Stage One (Video and Safety Presentation) and the MRI Training Stage Two (Practical Session - Screening & Site Tour).

SIGNED: _____

NAME:
(PLEASE PRINT) _____

UNIT/DEPARTMENT/
UNIVERSITY _____

DATE: _____

Appendix L: Recommended Pre-Screening

Structured phone interview for screening Panel volunteers and other volunteers for fMRI

[[Experimenters should thoroughly familiarise themselves with this sheet, especially the notes sections under each question, before ringing up potential volunteers for the first time. If there are any doubts over the suitability of a volunteer, experimenters should clarify the situation with a radiographer]]

Name of volunteer …… Date ……..

Introduction and brief explanation
1. Introduce yourself, and describe why you are phoning. As an introduction to MRI, you might like to say something similar to: "As you may know, MRI is an acronym for 'Magnetic Resonance Imaging'. MRI can be used to examine both brain structure and the 'brain at work'. It is safe and non-invasive, and allows us to examine how different parts of the brain may be involved in language, hearing, vision, movement, memory, thought and emotion."

2. [Assuming volunteer is interested in taking part following intro] Have you taken part in a research MRI scan before, either here at the CBU or at the Wolfson Brain Imaging Centre. YES/NO
[[If YES, proceed to section B, otherwise go to section A]]

SECTION A (if new):

General

3. Are you right handed? YES/NO
[[Most studies scan only right handers to keep the data as homogeneous as possible, though decision up to researcher]]

4. How old are you?
[[Volunteers have to be at least 18. (We do scan children, but only with parental consent, and for advice about talking to parents, please consult an experienced researcher.)]]

5. What is your approximate height?

6. What is your approximate weight?
[[Potential volunteers with very high weight/size may feel unduly uncomfortable in the scanner, and should therefore be excluded]]

Study Specific

7. Ask any experiment specific questions here.
[[E.g. Do they need to be native English speaker, have normal hearing, or not taken part in similar study before?]]

Claustrophobia

8. Volunteers lie on a bed that slides, so that the head and much of the body is inside a tunnel; in the large magnet. People who don't like small spaces might find this uncomfortable - would this be a problem for you? YES/NO
[[Lying in the MRI scanner involves one's whole body being enclosed in a relatively narrow tube. Claustrophobia would make it difficult for the volunteer to remain comfortable during this. Significant claustrophobia could be grounds for dismissing the volunteer from suitability for fMRI.]]

Vision

9. [Only if visual component] Will you need glasses to look at a computer screen in the scanner? YES/NO

[[If YES, suggest that volunteer wears contact lenses instead, if they have them. If they require glasses, but don't have contact lenses, explain that a non-metallic glasses substitute will be provided, but that it would help if the volunteer brought with their latest glasses prescription.]]

Lying still

10. Volunteers are typically in the scanner for an hour, during which time they have to lie fairly still on their back on the scanner bed. Would this be a problem for you, for instance due to back problems? YES/NO
[[Given that volunteers might have to lie on their backs without moving their heads constantly in the fMRI scanner for over an hour, any bladder, neck or back problems might make it very uncomfortable for the volunteer. They might also exacerbate existing neck problems. Also, volunteers need to be able to move independently, and get on/off a bed on their own, unless you have special help for them.]]

Metal

11. Because MRI requires volunteers to be in a strong magnetic field, we have to be very careful to ask about metal in the body, since these metallic bits could move or heat up, causing discomfort or damage. Do you have any metal implants, not including normal fillings? YES/NO
[[Any ferromagnetic metal in the volunteer's body could potentially do serious damage to that volunteer if s/he goes into the MRI scanner, so it is important to make sure there is absolutely nothing in the volunteer's body of this sort (except for dental fillings --- although if there are many fillings, this might cause an artefact in a non-brain area of the scan, but won't be dangerous for the volunteer). Any implants may contain metal, even if the volunteer believes they are made from another material. Check with radiographer if not clear. If the volunteer has ever worked with metal, such as welding, or any job where metal shards might have flown into the volunteer's skin or eyes, then this could be a problem. If the volunteer has worn eye and other protection, this may still mean there are some shards under finger-nails, etc. If in doubt, then it is possible to have an x-ray of the danger area of the body before MRI scanning, to make sure things are safe. Ask the radiographers for the feasibility of this. Obviously for an fMRI scan, exclusion on metal grounds means exclusion from all studies and this information needs to be passed on to the panel manager.]]

12. Do you have a pacemaker? YES/NO

13. Have you ever broken a bone that required a pin or plate or something similar to be put in? YES/NO

14. Do you have any piercings? YES/NO

If YES, are they removable?

15. Do you have any extensive experience of metalworking, or any accidents involving metal (splinters in the eye, for example?) YES/NO

General health
[[A volunteer who is not healthy may make scanning a problem (e.g. severe asthmatic). Any problems with health may underlie other considerations (see metal notes above and other notes in this section). Of course, health exclusion criteria are a judgement call (except when metal implants are an issue), but careful consideration should be given before scanning anyone with a history of convulsions/epilepsy (except febrile convulsions, which are quite common in infancy and have no known long-term neurological consequences), loss of consciousness of more than a couple of hours, or psychoactive medication. Migraine is only a factor if very frequent, i.e. more than one per week, or accompanied by visual loss or hemiparesis, which is very rare.]]

16. I need to ask you some questions about your general health. Have you ever been in hospital or had an operation? YES/NO

If so, why?
[[Pay particular attention to: convulsions, head injury, ischaemia/stroke, cardiac/respiratory problems, operations in which there is ANY chance of a metal clip/pin/plate/ having been inserted]]

17. Have you ever even been knocked out? If so, for how long?
[[There is no evidence that loss of consciousness for a few minutes necessarily causes detectable brain damage. If they have lost consciousness for several hours at any point and have been admitted to hospital for more than overnight observation (which used to be quite common with concussion), then it is worth considering excluding them. Any more serious brain injury than concussion normally excludes a participant from any study of healthy participants. Remember that volunteers might not think of combat sports, such as boxing, kick-boxing, martial arts, etc. as causing brain injury, but in any sport where there are repeated blows to the head are probably grounds for exclusion, for similar reasons.]]

18. Have you ever had an MR scan on any part of your body? YES/NO
[[Again to check for implants, primarily. Also, may reveal head injury or implant considerations, as well as revealing other problems. E.g. any physical disability will cause difficulties in getting in the scanner.]]

19. Are you on any medication currently, not including (if female) the contraceptive pill? YES/NO
If yes, what? (And what is it for?)

[[If volunteer is currently on psychiatric medication such as anti-depressants, neuroleptics, tranquillisers, or anything else, then it is probably best to exclude them, although final judgement rests with the experimenter and depends on the study questions and the ethical approval. If they are no longer on such medication but have been in the past, then whether or not to exclude them would depend on the why they were taking the medication, how long they took it for, and how long ago this was. You should also be aware that some medications can affect data quality, e.g., by affecting the neurovascular coupling in fMRI. If unsure, ask a more experienced experimenter or the radiographers.]]

Rules to explain to volunteer

There are some other things you should know:

(if female): we do not scan women if they are pregnant, or trying to become pregnant.

(again, if female) If you have a contraceptive coil, you cannot be scanned for at least 6 weeks after insertion.

(again, if female) If you have a coil we need to know the make / type, as not all coils are MRI compatible.

We do not scan people under the influence of alcohol. [[You may also want to discourage high levels of caffeine prior to scanning]]

We do not recommend that you are scanned with a hangover.
[[Make sure the volunteer doesn't have a hangover at the time of the scan, which would make things unpleasant for him/her and, probably, interfere with task performance. Alcoholism or other substance abuse would be a clear reason for exclusion for a study of healthy volunteers.]]

The scanner makes a banging noise when it is working, and this can be loud. You will be given earplugs, which will block some of the noise, and headphones.

SECTION B (if scanned before):

20. When were you last scanned?
[[We discourage volunteers from being scanned on more than one study per week, unless necessary, eg part of a study design]]

B2) Have you had any operations or accidents since?
[[If YES, then carefully ask questions 16 to 19]]

B3) Ask any experiment specific questions here
[[E.g. Do they need to be native English speaker, right handed, have good hearing, or not taken part in similar study before?]]

[END OF QUESTIONNAIRE]

Appendix M: Occupational exposure to electromagnetic fields (EMF)

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RISK ASSESSMENT RECORD FORM

Section 1: Administrative Details

Name of Assessor:	Job Title:	Date of Assessment:
Gary Chandler	Lab Manager	01/06/2017

Section 2: Activity/Task

Activity /Task
Provision of MRI testing at the CBSU

Risk:
Occupational exposure to electromagnetic fields (EMF)

Area affected:
MRI Building

MRC Cognition and Brain Sciences Unit

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Source of Risk (Background):
Three types of electromagnetic field are employed in MRI, and each is associated with physiological effects.

- Exposure to strong static magnetic fields, particularly when there is rapid motion of the head, is associated with transient sensory effects such as vertigo, nausea, and a metallic taste. These effects resolve once the movement stops or the affected person is removed from the field. There are no known longer-term health consequences. These effects can only occur if an individual is very close to the magnet.
- Exposure to the switched magnetic field gradients used in MRI can result in peripheral nerve stimulation, which at sufficiently high levels of exposure can result in intolerable pain. This can only occur if an individual is inside the scanner or very close to the bore of the magnet (wthin 0.5-1 m) while imaging is taking place
- Exposure to RF magnetic fields can result in excessive tissue heating. In practical terms, this can only occur if an individual is inside the scanner during imaging.

The Control of Electromagnetic Fields at Work Regulations 2016 [1] place an obligation on employers to assess occupational EMF exposure, perform risk assessments, put appropriate control measures in place, and provide workers with appropriate information and training.

The Regulations contain exposure limit values (ELVs) for occupational exposure to EMFs, but the development, testing, installation, use and maintenance of, or research related to, MRI equipment for patients in the health sector is exempted from these ELVs, subject to certain conditions. The HSE has also exempted certain MRI activities that do not fall within this definition.

The conditions that apply to the exemptions are as follows.

- The exposure of employees is reduced to the lowest level reasonably practicable*; and
- Employees are protected against the health effects and safety risks arising from their exposure to electromagnetic fields.

There is copious evidence (e.g. Capstick et al 2008) [2] to show that MR workers can exceed the ELVs for time varying magnetic fields when they move around in the vicinity of the MR scanner and if they are close to the scanner (within 0.5-1.0 m) while images are being acquired. There may be exceptional circumstances in which the limits for exposure to RF fields may be exceeded.

*Since the transient physiological effects encountered in MRI only occur above a particular exposure threshold (although this threshold may vary somewhat between individuals), there is no need for further

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reduction of exposure below that level. Thus ALARP effectively only applies at exposure levels at which effects may occur, which only arise within approximately 0.5-1 m from the scanner.

Supporting Evidence:
Published data on hazards and EMF exposure (e.g. [2]) in MRI. MHRA guidelines on safe use of MRI [3]. HSE guidance on The Control of Electromagnetic Fields at Work Regulations 2016.

Factors the risk contains: *(if for COSHH include route of exposure, length of exposure time and exposure limits)*
Electromagnetic fields.

Potential Consequence if risk is realised:
- Transient physiological effects.

Section 3: Current Control Measures

The employees at particular risk where the ALs and ELVs can be exceeded are the MRI Radiographers and trained operators.
The CBSU MRI SOPs are in place and are followed
To minimise where the ELVs are exceeded MR staff only remain in the scanner room where absolutely necessary and only approach with 1 metre of the scanner when needed to prepare the volunteer, testing or essential cleaning.
MRi staff are screened for anything that might put them at a higher risk from exposure to EMFs such as being pregnant or those with medical implanted devices. MRI staff are protected against the health effects and safety risks posed, by their training and the sharing of information about the risk and how to avoid them.
The indirect effect of ferromagnetic materials becoming projectiles in the vicinity of the static field are also covered in the SOPs with careful screening and thorough testing of any equipment used in the MRI room.
Where an employee reports experiencing a health effect and that employee is believed to have been exposed to EMFs exceeding any ELV, health surveillance and any medical examinations would be provided as appropriate.
The MRI equipment is fully maintained and updated by the manufacturer and we will consider the availability of alternative equipment or equipment designed to reduce the level of exposure as they become available where practicable. The manufacturer, Siemens, has produced a statement of Conformity with IEC 6060601-2-33 for the safe use of its equipment within current guidelines
The system is safe guarded by a gradient supervisor unit that will disable the gradient system when the switching rate exceeds a set maximum.
The gradient supervisor unit is calibrated, tested, and maintained by the manufacturer.
The time varying magnetic field produced by the gradient system (dB/dt) is automatically calculated for each imaging sequence by the scanner operating system and the Scanner Operator is warned if the critical threshold for peripheral nerve stimulation PNS is exceeded.
dB/dt is continuously monitored during scanning by an independent hardware component (gradient supervisor unit) which will inform the Scanner Operator about the current level and disable the gradient unit if the critical threshold for PNS is exceeded.

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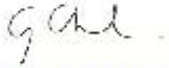
Section 8: Review
Risk Owner: Gary Chandler 
Planned Review Date: 01/06/2018 reviewed no change Next Review Date 01/06/2019
Reference
[1] The Control of Electromagnetic Fields at Work Regulations 2016. [2] Capstick M, McRobbie D, Hand J, Christ A, Kühn S, Hansson Mild K, Cabot E, Li Y, Melzer A, Papadaki A, Prüssmann K, Quest R, Rea M, Ryf S, Oberle M, Kuster N. An investigation into occupational exposure to electromagnetic fields for personnel working with and around medical magnetic resonance imaging equipment. Employment, Social Affairs and Equal Opportunities DG, European Commission, 2008. Available at: http://www.itis.ethz.ch/assets/Downloads/PapersReports/Reports/VT2007017FinalReportv04.pdf. [3] D. Grainger, "Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use," Medicines and Healthcare Products Regulatory Agency, Mar. 2015.