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SAFETY MANUAL
&
RULES OF OPERATION



CONTENTS

1. INTRODUCTION.....	3
2. SAFETY OVERVIEW	4
3. OPERATIONAL OVERVIEW	8
4. PROJECT DOCUMENTATION	9
5. ADDITIONAL MATERIAL	9
5.1. DESIGNATION OF THE CONTROLLED AREA	9
5.2. ACCESS, AUTHORISATION AND RESPONSIBILITIES	10
5.3. WELL-BEING OF PARTICIPANTS AND PERSONNEL	11
6. Appendix 1	12
7. Appendix 2	13
8. Appendix 3	14
9. Appendix 4	15
10. Appendix 5	16
11. Appendix 6	18
12. Appendix 7	19
13. Appendix 8	21
14. Appendix 9	24

1. INTRODUCTION

This document governs the use of the magnetic resonance imaging (MRI) scanner installed in the Peninsula MR Research Centre (PMRRC), St Luke's Campus, University of Exeter. It is mainly concerned with MRI-related safety and operational issues, and so should be read in conjunction with national, University and College guidelines that cover more general aspects of safety and procedures. The Director of the Centre has overall responsibility for safety and for revising this document in line with current information and in the light of experiences at the Centre.

The MRI scanner poses a dangerous environment unless operated according to strict safety protocols. SECTION 1 OF THIS DOCUMENT COVERS BASIC SAFETY INFORMATION THAT ALL USERS OF THE CENTRE SHOULD BE FAMILIAR WITH, in order to ensure the safety of themselves, colleagues and participants. All persons who intend to work in the magnet room (staff or students, whatever their affiliations) are first required to study this section and sign a declaration to confirm that this has been done.

Sections 2, 3 and 4 of this document provide information on the Centre's operating procedures that users may find useful.

This document is compiled from a range of currently available literature, the main reference source being the *GUIDELINES FOR MAGNETIC RESONANCE DIAGNOSTIC EQUIPMENT IN CLINICAL USE, WITH PARTICULAR REFERENCE TO SAFETY (MEDICAL DEVICES AGENCY)*, which is available for reference in the Centre. Readers may also wish to consult the Philips safety DVD which is held in the Centre.

2. SAFETY OVERVIEW

- All persons who intend to work in the magnet room (staff or students, whatever their affiliations) are first required to:
 - study this section and sign a declaration to confirm that this has been done;
 - fill in a user safety checklist to identify any contra-indications to working in the Centre; this must be signed by an authorised user.
- The magnet room is potentially a very dangerous environment. Fatal or very serious injury may result from inappropriate actions in such an environment. Major safety considerations include:
 - The imager's magnet is ALWAYS ON. Its magnetic field can adversely affect pacemakers or other implanted devices.
 - The imager's magnet can strongly attract any loose metallic objects in the vicinity, causing them to become dangerous projectiles.
 - Radio-frequency exposure during the imaging procedure can heat tissue, particularly if any metallic implants or objects are in or near the tissue.
- Do not enter the magnet room unless you are confident of your safety and the safety of those around you.
- Do not do anything in the magnet room unless you are confident of your safety and the safety of those around you.
- Other persons who are intended to enter the magnet room (e.g., participants, patients, helpers, observers) are first required to complete a safety checklist (for scanned or non-scanned persons, as appropriate), under the supervision of an authorised user.
- Health and Safety guidelines specify 0.5 mT (5 gauss) as the threshold magnetic field for special precautions to be taken, and require a 'Controlled Area' to be identified. The Controlled Area in the Centre is the magnet room (and a small zone outside the building, secured by fencing).
- Do not forget to remove hairclips and coins etc. from your person before entering the magnet room -- these can easily transform into projectiles.
- Loose metal objects such as tools are in plentiful supply in the laboratory area of the Centre. Great care must be exercised to ensure that these remain within the laboratory.
- Objects such as fire extinguishers and the resuscitation (crash) trolley should NEVER be brought into the magnet room, as their presence is more likely to endanger life than to save it.
- All devices, equipment, implements, etc. must be tested for MRI safety and compatibility, before being allowed into the magnet room, and (where practicable) certified as safe by means of signed and dated label.

- All unidentified metal items must be assumed a safety risk. Metal objects should under no circumstances be taken into the magnet room to test if they are attracted to the magnet.
- Work in the magnet room (imaging, development, etc.) is only allowed under the supervision of one of the authorised users. The person providing supervision is expected to remain within the Centre or its immediate environs. An authorised user can himself/herself work unsupervised.
- The magnet room must be kept locked when not in use. Only authorised users may use the key.
- The machine room must be kept locked except when inspection of the machinery is necessary. Only authorised users may use the key.
- A principal investigator is designated for all projects associated with the Centre. The principal investigator is responsible for ensuring that appropriate project protocols are followed at all times.
- When imaging a participant in normal health who is not a member of a research group associated with the Centre, it is good practice to have two persons on hand -- one to operate the imager and one to cover the needs of the participant.
- When imaging a participant in normal health who is a member of a research group associated with the Centre, the person operating the imager may cover the needs of the participant.
- When imaging a participant or patient with a medical condition, it is good practice to have two persons on hand (even if this condition is long-term and stabilised) -- one to operate the imager and one to cover the needs of the participant/patient.
- The well-being of participants is a major priority – appropriate monitoring should be used, if necessary (according to the judgment of the authorised user).
- The reception area is designed as a waiting room for participants, patients, carers, observers, etc. No one should be left unattended in the reception area for long periods of time. It may be necessary to have someone on hand to cover the needs of persons waiting in the reception area.
- Families and relatives of the participant must wait in the waiting room. (In exceptional circumstances they may be allowed to observe from the control room)
- It may be possible for visitors to observe a study from the control room but this must be agreed with the relevant authorised user, preferably ahead of time.
- In the event of general first aid being required, a notice is posted in a number of locations within the Centre that lists designated first aiders with their respective phone numbers.
- All users should know the location of fire alarms and escape routes.

- Risk-assessment forms must be completed for procedures within the MR Centre that may involve any risk. (Duplicate forms are NOT required if a similar procedure is repeated in a different study.) A copy of each completed form is held in a filing cabinet in the MR Centre.

EMERGENCY PROCEDURES

- In the event of a medical emergency occurring in the controlled area, medical help must be summoned immediately.
 - If possible, the affected person should be removed from the controlled area before treatment commences. The nearest “safe” area is the corridor outside the magnet room.
 - If removal of the affected person is difficult or unsafe, first aid may be administered within the controlled area, but only by a person who has been screened for MRI safety. Do not bring medical devices into the magnet room.
 - If treatment by persons who have not been screened is necessary, the affected person must be removed from the controlled area before such treatment commences.
 - An MRI-safe patient trolley is kept in the examination room at all times.
- To call for an ambulance, dial 9-999 from an internal telephone.
 - Give the following address:
Peninsula MR Research Centre, Peninsula Medical School, Magdalen Road, Exeter
 - Contact Estate Patrol who will make arrangements for personnel and vehicle entry (number from an internal phone 3999, number from a mobile/external phone 263999).
- Emergency shutdown of the magnet (quenching) must only be undertaken by an authorised user, only after due consideration of the relative risks and only in one of the following circumstances:
 - If a participant or other person is in a life-threatening situation resulting directly from the magnetic field, e.g., they are trapped by a metallic object.
 - If the emergency services, e.g., fire service, require access to the controlled area with ferromagnetic equipment.
- Quenching can be manually instigated in an emergency by pressing one of the emergency buttons located either in the magnet room or the control room – the control room is the preferable option. All persons who are able to leave the magnet room must do so before the magnet is quenched. The door to the examination room should be open during quenching.
- If the scanner has NOT been quenched, any emergency services in attendance at the Centre must be informed of the issues presented by the static field.

EVACUATION PROCEDURE IN THE EVENT OF A FIRE OR THE FIRE ALARM SOUNDING

1. Stop all scanning.
2. Remove the participant from the scanner (there is manual override on the patient table, for use in the event of power failure).
3. DO NOT QUENCH the magnet.
4. Do not stop to collect personal belongings.
5. Users should insure that all participants and visitors are included in the evacuation.
6. If at all possible, the door to the magnet room must be secured after it has been evacuated
7. Leave the Centre by the fire exit in the control room (unless this exit has become unsafe, in which case leave via the fire exits from the foyer beyond the reception area), providing any necessary assistance for participants and colleagues to leave the building.
8. Proceed to the designated assembly point: the Magdalen Road car park in front of the Medical School
9. Do not re-enter the building until instructed by the Fire Service or other responsible person.

PROCEDURE IN THE EVENT OF A FIRE AT THE MR CENTRE

1. Immediately operate the nearest fire alarm.
2. Do not tackle the fire, unless you have received fire training to a level commensurate with the severity of the incident.
3. For a fire in the magnet room, if it is possible to tackle this safely with the fire blanket located within the magnet room then do so. If the fire is beyond the scope of the fire blanket, an authorised user must consider an emergency shutdown (quenching -- see EMERGENCY PROCEDURES) so as to allow access by the fire service and/or the use of extinguishers.
4. Do not take fire-fighting equipment into the magnet room
5. If it is safe to do so, electrically isolate the scanner via switches in the plant room
6. Implement the evacuation procedure (see above)
7. Appropriate persons should make themselves available to liaise with the Fire Service, College Safety Officer etc. to inform them of the dangers associated with the magnetic field. They should jointly assess whether it is necessary to enter the magnet room with fire-fighting equipment. If this is deemed necessary, the magnet must first be quenched (if not already quenched).

3. OPERATIONAL OVERVIEW

- All equipment must be returned to its proper place and state. If the area is untidy when you arrive, or if equipment has not been returned to its proper place or default state, notify the Experimental Officer.
- All equipment should be shut down / turned off by the last user of the day. This includes, but is not limited to, the scanner, monitors, stimulus presentation equipment, and monitoring equipment.
- The last user should lock all doors at the end of the day.
- The Experimental Officer is responsible for running an approved quality assurance (QA) scan at least once a week; a QA scan should also be run after any non-standard operation of the scanner.
- Ancillary equipment, e.g. PC, eye tracker, etc., must only be used by competent personnel.
- All equipment (i.e., the scanner and ancillary equipment) must be properly used, serviced and maintained in a good state of repair. If faults occur that prevent normal safe operation of the equipment, the equipment must be taken out of service until repaired and passed fit for use.
- Equipment intended for connection to the scanner must first be checked by an authorised user.
- All equipment malfunctions should be reported to the Experimental Officer. All faults with the Philips System must be (i) reported to Philips Medical Systems at the earliest opportunity (ii) documented in the Faults Book, which is kept in the Control Room, and (iii) reported to the Director of the MR Centre. To minimize inconvenience, faults should also be reported to all users and investigators who are scheduled to use the equipment in the following 48 hours.
- Users are responsible for providing their own supplies unless another arrangement has been agreed.
- Access to the various areas in the Centre is controlled by card locks. The operation of these locks must not be compromised (e.g., by wedging a door open). Note that a card carries information on a magnetic strip, so it will probably become inactive if taken into the magnet room.
- All imaging and other data should be copied to DVD, USB stick or similar. Files may be deleted from the scanner after 1 month. It is the responsibility of the investigator(s) of each individual study to ensure their data is appropriately saved. The Centre will not be responsible for managing and archiving data unless this has been previously agreed. If you have problems with backing up your data, please contact the Experimental Officer.
- All requests for scanner time must be made in advance by using the Centre's on-line scheduling system. Instructions for using the scheduling system, including rules for sharing time between users, are available from the Experimental Officer. If you are unable to make use of a booked session, please contact the Centre so that the session can be made available to others. If you hope to book a session at short notice, please contact the Experimental Officer check for late availability.

4. PROJECT DOCUMENTATION

- Prior to the commencement of each individual study the following documents need to be supplied to the MR Centre, examples are available online (<http://www.ex.ac.uk/pmrrc/booking.shtml>):
 - A completed project form (Appendix 4).
 - The ethics application (in the case of studies involving human participation) and the notification of ethics approval.
- A number of other forms are required to be filled in by each participant (in the case of studies including human participation):
 - Safety checklist form (Appendix 8) – this must be countersigned by an authorised user.
 - Data protection consent form (Appendix 6)
- An information sheet should be provided for each participant, which will vary from study to study, with an example shown in Appendix 5. This information sheet will be required as part of the ethics application, and thus should be included in the copy of the ethics form which is provided to the MR Centre prior to the study.

5. ADDITIONAL MATERIAL

5.1. DESIGNATION OF THE CONTROLLED AREA

- A plan of the MR Centre is shown in Appendix 9. The magnet room is a CONTROLLED AREA WITH RESTRICTED ACCESS. The calculated 0.5 mT (5 Gauss) magnetic field contour is shown on the plan – this falls within the magnet room, except towards the rear of the magnet where it extends beyond the walls of the building into a fenced-off area which forms an addition to the controlled area with access restricted in the same manner as the magnet room. Personnel should avoid unnecessary entry into this fenced-off area for the additional reason that it contains the quench pipe – in the event of the magnet quenching, large quantities of cold helium gas will be discharged into this region leading to the possibility of asphyxiation as well as cold injuries.
- The controlled area is indicated by signs on the door to the magnet room, which is kept locked when the scanner is not in use.

5.2. ACCESS, AUTHORISATION AND RESPONSIBILITIES

- There are five categories of person (and no one else) who can enter the magnet room and/or operate the scanner:
 1. Authorised users, who can operate the scanner unsupervised and work in the magnet room without supervision. Authorised users are approved (see Appendix 1) by the Director of the Centre as having appropriate experience, training and seniority. (Postgraduate students are unlikely to qualify.) They will normally be employees of the University of Exeter or the University of Plymouth. They must sign a declaration (Appendix 3) that they have studied Section 1 of this document. They must complete a user/helper safety checklist (Appendix 7), renewable annually.
 2. Associate users, who can operate the scanner if supervised by an authorised user and work in the magnet room under supervision of an authorised user. Associate users are approved (see Appendix 2) by an authorised user. They must sign a declaration (Appendix 3) that they have studied Section 1 of this document. They must complete a user/helper safety checklist (Appendix 7), renewable annually.
 3. Helpers, who cannot operate the scanner under any circumstances but who may be asked to assist with imaging procedures in the magnet room. They must sign a declaration (Appendix 3) that they have studied Section 1 of this document. They must complete a user/helper checklist, (Appendix 7) renewable annually.
 4. Participants (i.e. experimental subjects), and visitors, who cannot operate the scanner under any circumstances but who may be in the magnet room. These persons must complete a safety checklist on each visit to the Centre. Their well-being is of the highest priority – an appropriate level of supervision should be used (according to the judgment of the authorised user).
 5. Service engineers and other external persons with appropriate professional training, e.g., MRI radiographers, who need to enter the magnet room and/or operate the scanner.
- Authorised users and other persons, with the authority of an authorised user, have free access to parts of the MR Centre that are NOT WITHIN THE CONTROLLED AREA.
- Work in the magnet room is only allowed under the supervision of an authorised user. The person providing supervision is expected to remain within the Centre or its immediate environs. An authorised user can work unsupervised.
- The magnet room must be kept locked when not in use. Only authorised users may use the key. The machine room must be kept locked except when inspection of the machinery is necessary. Only authorised users may use the key.
- Some persons, e.g., University cleaning and maintenance staff, are able to enter the Centre unsupervised in the course of their normal duties. THEY ARE NOT ALLOWED INTO THE

CONTROLLED AREA. Responsibility for cleaning and minor maintenance (e.g., replacing light bulbs) within the controlled area resides with the authorised users.

- The outer door to the MR Centre must be kept closed at all times. Admission is by security card-lock and only authorised persons will have card access. If any of the card-controlled doors are kept ajar for a prolonged period of time this will set off a security alarm.

5.3. WELL-BEING OF PARTICIPANTS AND PERSONNEL

- All participants must be fully consenting adults who have given written informed consent, using an approved form (Appendix 6), or minors who have written consent from their parents/guardians. The authorised user of the scanner is responsible for ensuring that this has been done. The participant must be free to withdraw at any time and this should be explained to them prior to scanning.
- An alarm is available to participants during their examination. The operation of the alarm must be explained to participants before scanning commences.
- If a participant experiences undue discomfort or distress during scanning, the examination must stop.
- Suitable earplugs and/or sound-attenuating earphones must be provided to all participants, except when low-noise MRI sequences are in use. Where participants refuse necessary hearing protection, they must not be scanned. Earplugs must be of a disposable type and discarded after a single use.
- A copy must be maintained of the screening forms of all persons who enter the controlled area. These must be treated as confidential and held in a filing cabinet in the MR Centre.
- Procedures for reporting results to participants, including incidental findings, will vary from project to project. Such procedures must be included in the ethical considerations for the project; participants must be informed of any such procedures in the participant information sheet.
- Procedures for retention of participant data must be included in the ethical considerations for the project; participants must be informed of any such procedures in the participant information sheet.
- The time spent in the magnet by any one person must not exceed 3 hours in any 24-hour period. Other than this, there is no restriction on the frequency with which a person may be scanned.
- The exposure of any one person to the static magnetic field (in or near the magnet) must not exceed an average of 0.2 Tesla, averaged over any 24-hour period. High magnetic fields (maximum 1.5 T) are only experienced within the magnet and just outside the bore, so in practice authorised users and others may work within the MR Centre for an unlimited time, provided they do not remain in or near the magnet for long periods.

APPENDIX 1

PENINSULA MR RESEARCH CENTRE

APPROVAL OF AN AUTHORISED USER

This form must be approved/signed by the Director of the Centre

Name of Authorised User:

Signature:

Date:

APPENDIX 2

PENINSULA MR RESEARCH CENTRE

APPROVAL OF AN ASSOCIATE USER

This form must be approved/signed by an Authorised User of the Centre

Name of Associate User:

Name of Authorised User:

Signature:

Date:

APPENDIX 3

PENINSULA MR RESEARCH CENTRE

DECLARATION BY AN AUTHORISED USER, ASSOCIATE USER OR HELPER

I declare that I have studied Section 1 of the Peninsula MR Research Centre Safety Manual and Rules of Operation.

I can confirm the following:

- 1) I am aware of the procedure in the event of fire and have been shown the location of the nearest fire escapes.
- 2) I am aware of the procedure in the event of medical emergency, and the names and location of the nearest first aiders.
- 3) I understand the safety precautions when entering the scanning room both for the subjects and my own person and will ensure they are adhered to.
- 4) I understand the MRI safety checklist I have filled in and will take responsibility for informing the relevant personnel if there are any changes that may affect my suitability for working within a magnetic environment e.g. subsequent medical procedures or pregnancy.
- 5) I am in receipt of all of the safety and emergency documentation.
- 6) I understand that it is my responsibility, in conjunction with other scanner users, to ensure subject safety.

Signature:

Countersignature:

Name:

Name:

Date:

Date:

APPENDIX 4

PROJECT FORM

Reference Number:

Project Title:

Principal Investigator: *Name:*

School:

Phone:

E-mail:

Other Researchers: *Name:*

School:

Phone:

E-mail:

Name:

School:

Phone:

E-mail:

Funding details:

Project time scale: *Start date:*

Termination Date:

Project type and its objectives:

APPENDIX 5

EXAMPLE INFORMATION SHEET

These notes give some information about an MRI / fMRI study in which you are invited to take part.

fMRI is a method for producing images of the activity in the brain as people carry out various mental tasks. It involves placing the participant inside a large, powerful magnet, which forms part of the brain scanner. When particular regions of the brain are active, they require more oxygen, which comes from red corpuscles in the blood. As a result, the flow of blood increases. This can be detected as changes in the echoes from brief pulses of radio waves. These changes can then be converted by a computer into 3D images. This enables us to determine which parts of the brain are active during different tasks. As far as we know, this procedure poses no direct health risks. However, the Department of Health advises that certain people should NOT be scanned. Because the scanner magnet is very powerful, it can interfere with heart pacemakers and clips or other metal items, which have been implanted into the body by a surgeon, or, with body-piercing items. If you have had surgery, which may have involved the use of metal items, you should NOT take part. Note that only ferromagnetic materials (e.g. steel) are likely to cause significant problems. Thus normal dental amalgam fillings do not prohibit you from being scanned, though a dental plate, which contained metal, would do so, and you would be asked to remove it. You will be asked to remove metal from your pockets (coins, keys), remove articles of clothing which have metal fasteners (belts, bras, etc), as well as most jewellery. Alternative clothing will be provided as necessary. Watches and credit cards should not be taken into the scanner since it can interfere with their operation. You will be asked to complete a questionnaire (the Screening Form), which asks about these and other matters to determine whether it is safe for you to be scanned. You will also be asked to complete a consent form immediately before the scan. To be scanned, you would lie on your back on a narrow bed on runners, on which you would be moved until your head was inside the magnet. This is rather like having your head put inside the drum of a very large front-loading washing machine. The scanning process itself creates intermittent loud noises, and you would wear earplugs or sound-attenuating headphones. We would be able to talk to you while you are in the scanner through an intercom. If you are likely to become very uneasy in this relatively confined space (suffer from claustrophobia), you should NOT take part in the study. If you do take part and this happens, you will be able to alert the experimenters by activating an alarm and will then be removed from the scanner quickly. It is important that you keep your head or part of the body being scanned as still as possible during the scan (unless otherwise instructed) and to help you with this, your head will be partially restrained with padded headrests. We shall ask you to relax your head and keep it still for a period that depends on the experiment but may be more than one hour, which

may require some effort on your part. If this becomes unacceptably difficult or uncomfortable, you may demand to be removed from the scanner. You may be asked to look at a screen through a small mirror (or other optical device) placed just above your eyes and/or be asked to listen to sounds through headphones. You may be asked to make judgements about what you see or asked to perform some other kind of mental task. Details of the specific experiment in which you are invited to participate will either be appended to this sheet or else given to you verbally by the experimenter. Detailed instructions will be given just before the scan, and from time to time during it.

The whole procedure will typically take about 1 hour. You will be able to say that you wish to stop the testing and leave at any time, without giving a reason. This would not affect your relationship with the experimenters in any way. The study will not benefit you directly, and does not form part of any medical diagnosis or treatment. If you agree to participate you will be asked to sign the screening form that accompanies this information sheet, in the presence of the experimenter (or other witness, who should countersign the form giving their name and address, if this is not practical). It is perfectly in order for you to take time to consider whether to participate, or discuss the study with other people, before signing. After signing, you will still have the right to withdraw at any time before or during the experiment, without giving a reason. The images of your brain will be held securely and you will not be identified by name in any publications that might arise from the study. The information in the screening form will also be treated as strictly confidential and the forms will be held securely until eventually destroyed. Further information about the specific study in which you are invited to participate may have been appended overleaf, if the experimenter has felt that this would be helpful. Otherwise, he/she will already have told you about the study and will give full instructions prior to the scan. Please feel free to ask any questions about any aspect of the study or the scanning procedure before completing the screening form.

APPENDIX 6

EXAMPLE CONSENT FORM

The participant should complete the whole of this sheet himself/herself.

Have you read the Information Sheet? Yes No

Have you had the opportunity to ask questions and discuss this study? Yes No

Have you received satisfactory answers to all of your questions? Yes No

Have you received enough information about the study? Yes No

Who has explained the procedure and study to you (write name)?

Do you understand that you are free to withdraw from the study at any time without having to give a reason? Yes No

Do you agree to take part in this study? Yes No

All the personal information we are going to ask you is required to determine whether it is safe and suitable for you to undergo an MRI scan. This information will be kept separately from your scan and once the scan is complete the scan data be referred anonymously. We will not pass on your personal information to third parties.

The consent form you have signed indicates that you have agreed for your scan data to be used for the study you have been recruited for. However, your scan data can form part of a substantial resource that we can draw on in the future, for example for teaching or further scientific studies. We would like to ask you to consider giving additional consent for your data to be used anonymously in this way.

This consent is entirely optional. Answering "No" to the following questions will not affect whether you can take part in the study for which you have been recruited.

I consent for my scan data to be used for education purposes Yes No

I consent for my scan data to be used in further scientific studies Yes No

NAME IN BLOCK LETTERS:

Signed:

Date:

NAME OF RESEARCHER:

Signed:

APPENDIX 7

USER/HELPER SAFETY CHECKLIST

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

Date: _____ Name: _____

Contact Address: _____

Have you had prior surgery or an operation (e.g., arthroscopy, endoscopy, etc.) of any kind?

No Yes If yes, please indicate date and type of surgery

2) Have you had an injury to the eye involving a metallic object (e.g., metallic slivers, foreign body)?

No Yes If yes, please describe

3) Have you ever been injured by a metallic object or foreign body (e.g. shrapnel, bullet etc.)?

No Yes If yes, please describe

4) Are you pregnant, or suspect that you may be pregnant? No Yes

WARNING: Certain implants, devices, or objects may be hazardous to you in the MR environment. Do not enter the scanning room if you have any question or concern regarding an implant, device or object.

Please indicate if you have any of the following

Yes No Anurysm clip(s)

Yes No Cardiac pacemaker

Yes No Implanted cardioverter defibrillator (ICD)

Yes No Electronic implant or device

Yes No Magnetically-activated implant or device

Yes No Neurostimulation system

Yes No Spinal cord stimulator

Yes No Cochlear implant or implanted hearing aid

Yes No Insulin or infusion pump

Yes No Implanted drug infusion pump

Yes No Any type of prosthesis or implant

Important Instructions

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

Please consult a member of staff if you have any questions or concerns before entering the scanner room

Yes No Artificial or prosthetic limb

Yes No Any metallic fragment of foreign body

Yes No Any external or internal metallic object

Yes No Hearing aid

Yes No Other Implant_____

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

Signature of person completing form:_____

Date_____

Form reviewed by: Name:_____

Signature:_____

APPENDIX 8

PARTICIPANT SAFETY CHECKLIST

Name:

Date of Birth:

Weight:

Name of Study/Volunteer Number:

Please check the following list carefully, answering all appropriate questions.

Please do not hesitate to ask staff, if you have any queries regarding these questions.

1. Do you have a pacemaker, artificial heart valve or coronary stent? Yes No

2. Have you ever had major surgery? Yes No

If yes, please give brief details:

3. Do you have any aneurysm clips (clips put around blood vessels during surgery)? Yes No

4. Do you have any implants in your body?

Yes No Joint replacements, pins or wires

Yes No Implanted cardioverter defibrillator (ICD)

Yes No Electronic implant or device

Yes No Magnetically-activated implant or device

Yes No Neurostimulation system

Yes No Spinal cord stimulator

Yes No Insulin or infusion pump

Yes No Implanted drug infusion pump

Yes No Internal electrodes or wires

Yes No Bone growth/bone fusion stimulator

Yes No Any type of prosthesis

Yes No Heart valve prosthesis

Yes No Eyelid spring or wire

Yes No Metallic stent, filter or coil

Yes No Shunt (spinal or intraventricular)

Yes No Vascular access port and/or catheter

Yes No Wire mesh implant

Yes No Bone/joint pin, screw, nail, wire, plate etc.

Yes No Other Implant

5. Do you have an artificial limb, calliper or surgical corset? Yes No

6. Do you have any shrapnel or metal fragments, for example from working in a machine tool shop? Yes No

7. Do you have a cochlear implant? Yes No

8. Do you wear dentures, plate or a hearing aid? Yes No

9. Are you wearing a skin patch (e.g. anti-smoking medication), have any tattoos, body piercing, permanent makeup or coloured contact lenses? Yes No

10. Are you aware of any metal objects present within or about your body, other than those described above? Yes No

11. Are you susceptible to claustrophobia? Yes No

12. Do you suffer from blackout, diabetes, epilepsy or fits? Yes No

For women:

13. Are you pregnant or experiencing a late menstrual period? Yes No

14. Are you taking oral contraceptives or receiving hormonal treatment? Yes No

15. Do you have an intra-uterine contraceptive device fitted? Yes No

16. Are you taking any type of fertility medication or having fertility treatment? Yes No

17. Are you currently breastfeeding? Yes No

Important Instructions

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

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

Signature (Participant/Parent/Guardian)

Date:

MR Centre Staff Signature

RULES FOR ADMINISTRATION OF SCREENING FORMS

General

1. All participants must the screening form before entering the controlled area.
2. Completion of the screening form must be supervised by an authorised user, who must be satisfied that the participant has read the questions carefully and understands their importance.
3. The screening form must be countersigned by an authorised user before the participant enters the controlled area. The form should only be signed if all questions have been answered satisfactorily (see below)
4. If the participant answers “no” to all questions on both screening forms and the authorised person is satisfied that the participant has given the questions due consideration, the participant may be permitted to enter the controlled area.

Initial Screening Form

5. If the participant answers ‘YES’ to any of questions 1, 4, 5 and 7 then the participant **MUST NOT** be allowed into the controlled area. The person supervising the screening should explain the situation clearly, making clear that there is no cause for alarm, and cancel any MRI examination that has been arranged. They should also point out that rejection as a research participant does not necessarily mean that a future MR scan for medical purposes would be unsafe and that they should be guided by the medical personnel concerned if such a need should arise.

If they answer YES to number 6 then the authorised person must ask how long ago and in what capacity the metal filing work took place, for example if it is during school that was a number of years ago with limited exposure the volunteer can still be scanned. However if they currently work with for have recently worked with metal filings in a professional or home improvement capacity then they are deemed unsafe for scanning.

If they answer YES to number 8 then establish whether the hearing aid can be taken off during the scanning session without causing a problem for communication between the researcher and volunteer.

APPENDIX 9

PLAN AND SIDE ELEVATION OF THE MR CENTRE, showing 0.5 mT contour

