

**Royal Holloway,
University of London**

Magnetic Resonance Imaging Unit

RULES OF OPERATION

September 2017

This version was approved by the Policy Committee as at October 2015 and amended as at September 2017.

It supersedes all previous versions, copies of which should be destroyed.

Contents

1. Introduction
2. Designation of the Controlled Area
3. Working Procedures: General Rules
4. Working Procedures: MRI-specific Rules
5. Emergency Procedures
6. Reporting of Faults
7. Record Keeping

APPENDICES

Appendix 1 Plan of MRI unit indicating controlled area

Appendix 2 Personnel and responsibilities

Appendix 3 Screening forms and their interpretation

Appendix 4 Consent form

Appendix 5 Emergency Procedures and quench

Appendix 6 Fire Procedures

Appendix 7: CUBIC Guidelines for scanning children

Appendix 8: List of Authorized Personnel

1. INTRODUCTION

This document governs the use of the magnetic resonance (MR) scanner installed on the campus of Royal Holloway, University of London and jointly owned by Royal Holloway, the University of Roehampton, the University of Surrey and Brunel University.

Although there are no known adverse effects to humans from the static or time-varying electromagnetic fields used in MR scanning, there is a need for caution for a number of reasons:

- The static field can cause pacemakers or other implanted devices to malfunction and cause other metal implants or shards to move.
- The static magnetic field can cause loose ferro-magnetic articles to become projectile causing injury or death to persons near or in the magnet bore.
- The static field can cause damage to personal possessions such as analogue watches and credit cards.
- The gradient field can cause peripheral nerve stimulation.
- Radiofrequency (RF) exposure can heat tissue, particularly if any metallic implants or objects are present.

The MRI scanner therefore can pose a dangerous environment unless operated according to strict safety protocols.

This document outlines the rules that MR scanner users MUST adhere to, in order to ensure the safety of themselves, colleagues and participants. It has been drawn up by the Management Committee and approved by the Policy Committee as constituted by the Memorandum of Agreement among the four universities dated October 2002, amended by the ovation agreement of October 2009 when the University of Roehampton took over the role of University of Reading, and amended by the novation agreement of Nov 2015 and an amendment agreement of April 2017. ALL users of the scanner, whatever their affiliations, MUST adhere strictly to its provisions.

This document is compiled from all the currently available safety literature, the main reference source being the Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use (November 2014; URL: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/419352/Safety_guidelines_for_magnetic_resonance_imaging_equipment_in_clinical_use.pdf) provided by the Medicines and Healthcare Products Regulatory Agency (MHRA).

PERSONNEL AND RESPONSIBILITIES

As with all Health and Safety directives, all personnel have a responsibility to behave sensibly and ensure the well-being of themselves, their colleagues, participants in MRI examinations and any other visitors. Some personnel (*THE AUTHORISED PERSONNEL / AUTHORISED PERSON*) have additional responsibilities; these people are identified in Appendix 2.

2. DESIGNATION OF THE CONTROLLED AREA

- 2.1 A plan of the MRI unit is shown in Appendix 1. Within the unit there exists a **Controlled Area** which totally encloses the 0.5 mT (5 Gauss) magnetic field contour. The extent of the controlled area is shown in Appendix 1.
- 2.2 Access to the controlled area is through the Preparation Room, which is entered via a door with a security-coded lock to prevent unauthorised access.
- 2.3 All unauthorised personnel including unauthorised staff and visitors must be screened and must be supervised by an authorised person at all times whilst within the controlled area (see Sections 3 and 4). All objects and equipment must similarly be screened.

3. WORKING PROCEDURES: GENERAL RULES

- 3.1 No person or object must enter the controlled area without screening by an authorised person to ensure that entry is safe.
- 3.2 These rules are in addition to and can be seen as an extension of the Health and Safety at Work etc Act. 1974 This clearly lays down the mandatory responsibilities and statutory

requirements of the employer, employees and visitors who have access to the place of work. All the terms of the Act must be adhered to, including that persons must behave in a responsible and considerate manner in order not to endanger themselves or others and to maintain a good working atmosphere.

- 3.3 Equipment must only be used by trained and competent personnel.
- 3.4 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. ALL faults must be reported and a record kept. The procedure for the reporting and documentation of faults must be followed (see Section 6).
- 3.5 Working areas and exits should be kept clean, tidy and free from obstruction.
- 3.6 Should the use of equipment produce an accident, near miss or hazardous situation, operation must cease immediately until the cause is investigated and the hazard is removed.
- 3.7 An Accident/Incident Report Form must be completed without delay following any accident or hazardous situation. Copies of this form are kept in the Control Room. The incident should also be reported immediately to the MRI Safety Officer (see Appendix 2).
- 3.8 In the event of an emergency such as fire, local procedures must be followed (see Section 5 and Appendix 6). All personnel should know the location of fire alarms and escape routes.

4. WORKING PROCEDURES: MRI-SPECIFIC RULES

4.1 Control of access

- 4.1.1 Authorised Personnel (defined in Appendix 2), and other persons with the authority of the MRI Safety Officer (see Appendix 2), have free access to parts of the MRI Unit that are NOT WITHIN THE CONTROLLED AREA. Screening is not necessary in order to enter the outer rooms of the Unit.
- 4.1.2 No person may enter the controlled area unless at least TWO able-bodied adults, both of whom have been screened in the previous 12 months and have removed all metal items from their clothing, and at least one of whom is an Authorised Person, are present in the MRI Unit. No person may be placed inside the scanner unless at least TWO AUTHORISED PERSONS, at least one of whom is an employee of one of the four universities and at least one of whom has full (as opposed to probationary; see Appendix 2) status, are present in the MRI Unit. The boundaries of the MRI Unit are defined on the plan in Appendix 1. NO person, whatever their status, may enter the controlled area when alone in the MRI Unit except for retrieving or preparing equipment, or for running phantom scans. Entering the controlled area alone requires special permission by the MRI Safety Officer and the MRI Director, and will only be granted to a limited number of experienced Authorised Persons who need to enter the controlled area frequently. Children under 18 years of age are not typically permitted to enter the controlled area except to have a scan.
- 4.1.3 Authorised Personnel must be trained in MR safety to a level prescribed by the MRI Safety Officer. They must be screened (using the initial screening form) at least on a yearly basis, with records of screening kept securely in the MRI unit. Any person who is not an Authorised Person but who assists an Authorised Person in order to permit entry to the Controlled Area (see 4.1.2) must first receive basic training in safety as prescribed by the MRI Safety Officer.
- 4.1.4 Unauthorised Personnel and objects DO NOT have free access to the controlled area. **This includes domestic services; responsibility for cleaning the controlled area resides with the authorised personnel.**
- 4.1.5 All people and objects must be “screened” (see Section 4.2) by authorised personnel before access to the controlled area is permitted. Screening people requires the written questionnaires shown in Appendix 3 to be completed and to show no contra-indications for access.
- 4.1.6 The outer door to the MRI unit must be kept closed at all times – even when the area is being supervised by an authorised person. Admission is by security code only. Only authorised

persons will have access to this code. The code must not be divulged to others and any inadvertent disclosure must be reported to the MRI Safety Officer, who will then change the code.

- 4.1.7 When the MRI unit is not in use, the following doors must be kept locked:

- Unit outer door
- Examination room door
- Preparation Room door
- Equipment room door

These doors are identified in Appendix 1.

4.2 Screening

- 4.2.1 Only Authorised Personnel are permitted to “screen” participants and other visitors. The person must understand, complete and sign two written questionnaires (see Appendix 3). The authorised person must then decide if access is safe for the participant, using the rules and guidelines in Appendix 3.

- 4.2.2 ALL persons must undergo primary screening before access to the controlled area is permitted. Primary screening must exclude the presence of the following from the controlled area:

Any person fitted with a cardiac pacemaker.

- 4.2.3 All persons and objects must undergo secondary screening before access to the controlled area is permitted. Secondary screening must exclude the following from the controlled area:

Aneurysm clips of any type

Occlusive clips or pins

Heart valve replacements and cochlear implants

Mechanical/Electrical/Magnetically operated devices

People with metallic splinters in the eye or other remaining metal from injury

Catheters and intra-venous devices

Persons under 6 years of age

Pregnant women

Mechanical watches, credit cards, magnetic tapes, other magnetic recording media.

All loose ferro-magnetic objects about a person such as dentures, hairgrips, hearing aids, jewellery (except wedding ring), keys, money, pens, scissors, spectacles and tools

All other ferro-magnetic objects including gas cylinders, trolleys and computer equipment, but with the exception of certain small items of equipment (e.g. photometers and other optical equipment) which may be taken into the controlled area for specific purposes provided that express permission is granted by the MRI Safety Officer, that the MRI Safety Officer is present in the controlled area and that no persons other than authorised personnel are present in the controlled area at the time

- 4.2.4 Persons to be given an MRI examination must undergo additional screening, to identify the following:

(a) People suffering from epilepsy or thermoregulatory problems

(b) People with implants or prostheses that are known to be made of non-ferro-magnetic materials and are not specifically excluded in 4.2.3 above

(c) People with intra-uterine contraceptive devices in place

(d) People suffering from diabetes.

Such people are not excluded from entering the controlled area without being scanned. For (a) and (b), they may only be scanned after appropriate medical consultation and approval. For (c), they may only be scanned if there is written evidence available (e.g. in the form of the official website of the company) documenting that the device in question is safe to be used inside a 3T scanner. For (d), Authorized Personnel needs to clarify whether their diabetes is

well controlled, whether they experienced any metabolic problems, and whether they had skipped any meals on the date of the scan. Furthermore, Authorized Personnel needs to ask for the presence of an insulin pump, which would be a contraindication. Any medical recommendations for supervision during scanning must be implemented if the scan proceeds.

- 4.2.5 For proper prediction of SAR level, participants need to indicate their approximate weight and height. When scanning children, weight and height should be verified by Authorized Personnel prior to scanning.

4.3 MRI Examination

- 4.3.1 Only participants who have been approved by an authorised person are permitted to be scanned.
- 4.3.2 Only Authorised Personnel who are trained are permitted to operate the equipment.
- 4.3.3 The person operating the equipment on any given occasion is personally responsible for ensuring that the participant has been properly screened, even if the examination has been arranged and approved by another authorised person.
- 4.3.4 Adult participants must be fully consenting and must have given written informed consent, using the approved form (Appendix 4). For children under the age of 18, the consent of a parent or guardian must be obtained in addition to that of the child (for CUBIC Guidelines for scanning children, including template information and consent forms, see Appendix 7). The person operating the scanner is personally responsible for ensuring that this has been done. The participant must be free to withdraw such consent and to withdraw from the experiment at any time.
- 4.3.5 The purpose and nature of the examination should be explained to the participant, who must be given the opportunity to ask questions.
- 4.3.6 Contrast agents must not be administered and no other invasive procedure may be performed.
- 4.3.7 A record must be maintained of all persons who are scanned (see Section 7).
- 4.3.8 A record must be maintained of the screening forms for all persons entering the controlled area. These must be treated as confidential and held in a locked cabinet in the MRI Unit.
- 4.3.9 An alarm buzzer must be available to participants during their examination. The operation of the alarm must be explained to participants before scanning commences and the alarm should be tested regularly.
- 4.3.10 The Operator must check every few minutes (normally via the intercom) that the participant is comfortable.
- 4.3.11 If a participant experiences undue discomfort or distress during scanning, the examination must stop.
- 4.3.12 Suitable earplugs or sound-attenuating earphones must be provided to all participants. For children, special earplugs, and, if the head size allows this, ear muffs or sound-attenuating headphones need to be used. Where participants refuse to wear the hearing protection provided, they must not be scanned. Earplugs must be of disposable type and discarded after a single use. Where earphones are used these should be adequately maintained and inspected on a regular basis. Any damage to the earphones should be reported immediately to the MRI Safety Officer.
- 4.3.13 Persons must not be examined during servicing or be in position in the scanner during switch on/off of the magnet (except in emergency).
- 4.3.14 Only equipment that is safe and designed for the purpose may be connected to the MR scanner or used within the controlled area (see also Appendix 3).

- 4.3.15 If a participant who is unable to position him/herself on the bed unaided is to be scanned, assistance should be given but only by prior arrangement with the MRI Safety Officer and only by staff who are trained in such procedures.

4.4 Result of examination

- 4.4.1 Scanning of human participants should be performed for research purposes only, using volunteers who are either healthy or have a known, previously documented neurological abnormality which does not present a contraindication for MRI.

- 4.4.2 In the event that a scan reveals a suspected abnormality that was unknown to the authorised person in charge of the scan and which they suspect might require treatment, the following procedure must be adopted.

- (i) So as to avoid distress to participants arising from false alarms, staff *must not disclose their concerns to the participant*.
- (ii) The authorised person involved must, without delay, report his/her concerns to the MRI Safety Officer and supply a high-quality print displaying the suspected abnormality.
- (iii) The MRI Safety Officer should, as a matter of urgency, write to the participant's General Practitioner (whose name must be supplied by the participant prior to scanning; see Section 7 and Appendix 3), enclosing the print and describing the cause for concern. The letter should state whether or not the person expressing concern is medically qualified. It should also state that the participant concerned has not been informed and that the decision as to whether the participant should be informed, and the task of informing, are referred to the GP.
- (iv) In the interests of participant confidentiality, the authorised person concerned should not discuss the situation with colleagues or other participants.

- 4.4.3 Assuming that there is no suspicion of abnormality, staff are encouraged, but not required, to offer to provide the participant with a sample image obtained during the examination, either electronically or in printed form as the participant prefers.

4.5 Exposure limits

- 4.5.1 The time spent in the magnet by any one person must not exceed 90 minutes in any 24-hour period. Other than this, there is no restriction on the frequency with which a screened person may be scanned.

- 4.5.2 The exposure of any one person to the static magnetic field must not exceed an average of 0.2 Tesla, averaged over any 24-hour period. In practice, this means that operators and others may work within the MR Unit but outside the controlled area for unlimited periods, provided that they enter the controlled area only occasionally and for short periods, to supervise volunteers. An operator standing by the bore opening will experience a field of the order of 0.5T.

5. EMERGENCY PROCEDURES

Current emergency procedures are described in Appendix 5 and Appendix 6.

- 5.1 Should any part of the system fail that may endanger participants, staff or equipment, the examination must stop and the participant must be removed from the scanner. If there is a risk of damage to the equipment, an authorised person must then electrically isolate the equipment by pressing one of the red 'stop' buttons in the Control Room and Examination Room. No further scanning is permitted to take place until the fault has been corrected.

- 5.2 Emergency shutdown of the magnet (quenching) must only be undertaken by authorised personnel, only after due consideration of the relative risks and only in one of the following circumstances (see also Appendix 5):

- (i) if a participant or other person is in a life-threatening situation resulting directly from the magnetic field. If the endangered person is in the scanner, the magnet should be quenched before the person is removed from the scanner.

(ii) if the emergency services, e.g. fire service, require access to the controlled area with ferromagnetic equipment. In this event, the participant must be removed from the scanner before the magnet is quenched.

NOTE: The magnet MUST be quenched before the emergency services may have access to the controlled area.

- 5.3 In the event of a medical emergency occurring in the controlled area, medical help must be summoned immediately (see Appendix 5). If possible, the affected person should be removed from the controlled area before treatment commences. If this is difficult or unsafe, first aid may be administered within the controlled area, but only by a person who is qualified in first aid, has been screened within the past 12 months and has removed any loose metal objects from their person. If treatment by medical or paramedical staff who have not been screened is necessary, the affected person must be removed from the controlled area before such treatment commences. An MR-safe patient trolley is kept in the examination room at all times. If the affected person is unable to walk, even with assistance, he/she should be moved onto the trolley and wheeled out of the controlled area. This must be done by authorised persons, all of whom have been trained in this procedure.
- 5.4 In the event of a fire, the fire procedure (see Appendix 6) must be followed. If evacuation is required, all participants and visitors must be removed from the scanner area, taking due care of the magnetic field. All doors must be secured on leaving especially those that govern access to the controlled area. Note that the fire alarm does not automatically unlock doors to the controlled area.

6 REPORTING OF FAULTS

- 6.1 ALL faults must be (i) reported to the MRI Safety Officer (see Appendix 2) at the earliest opportunity and (ii) documented in the Faults Book, which is kept in the Control Room.
- 6.2 If faults occur that prevent normal safe operation of the equipment, it must be taken out of service until repaired and passed fit for use.
- 6.3 Should the use of equipment produce an accident, near miss or hazardous situation, operation must cease immediately until the cause is investigated and the hazard is removed.
- 6.4 To minimize inconvenience, faults should also be reported to all other authorised users who may be intending to use the equipment in the following 48 hours.
- 6.5 In the event of a fault that prevents normal safe operation:
- The MRI Safety Officer must be informed
 - The fault must be recorded in the Incident Book
 - The room must be signed out of use
 - A “Do not use” sign must be fixed to the equipment
 - The equipment must be signed over to the engineer and then signed back by the engineer once repaired and tested. Only then may it be signed back into use for scanning.

7. RECORD KEEPING

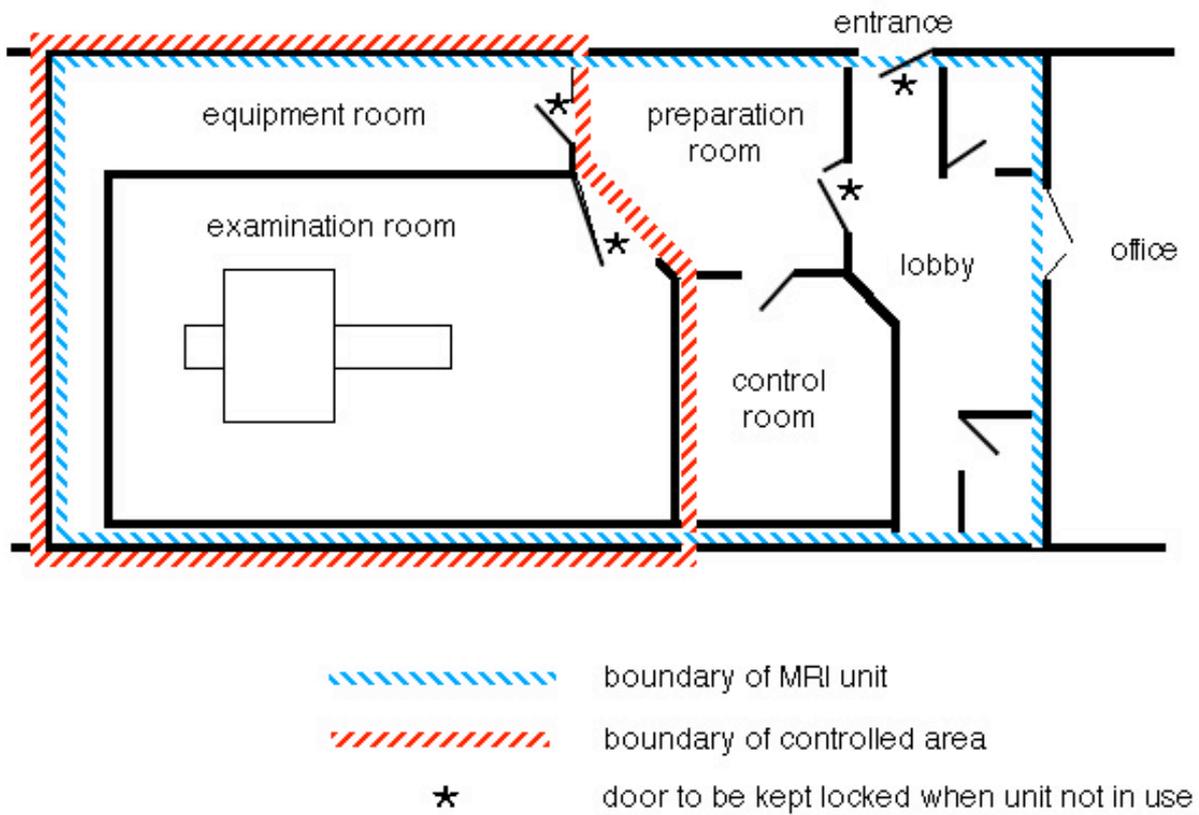
For each person scanned the following information must be recorded and retained for 10 years:

- Name, sex and age
- Date of scan
- The name and address of the person’s general practitioner (GP)
- Region of body scanned and type of coil used
- Approximate time spent in the magnet
- Scan data including sequence type, TR, number of slices, number of volumes (for EPI); for anatomical scans/ diffusion/ spectroscopy: duration of the scan

The two screening forms and the consent form must also be retained for 10 years.

All information should initially be held in a locked filing cabinet in the control room. It may be removed after not less than one year for safe keeping elsewhere at the discretion of the MRI Safety Officer.

APPENDIX 1 – PLAN OF MRI UNIT INDICATING CONTROLLED AREA



APPENDIX 2 – PERSONNEL AND RESPONSIBILITIES

MRI SAFETY OFFICER

This person is responsible for ensuring that the rules and procedures set out in this document are adhered to at all times. He/she also carries responsibility for keeping abreast of any new legislation or external guidelines that may be relevant to internal procedures.

The MRI Safety Officer is the MRI Operations Officer at the Department of Psychology, Royal Holloway. In times of absence, he may appoint a deputy who must previously have been approved by the Management Committee.

AUTHORISED PERSONNEL

The terms “Authorised personnel” and “Authorised person” are used interchangeably. These are essential staff who are conversant with, and are able to put into practice all the rules and emergency practices outlined in this document. These personnel have access to the Controlled Area (subject to the rules in section 4.1). They are responsible for screening participants and other visitors to ensure that it is safe for them to enter the controlled area, and they must supervise all non-authorised people at all times when in the controlled area. Records of screening are kept by the MRI Safety Officer and held in the Control Room.

Authorised person status is granted by the Management Committee. This Committee will maintain a list of current authorised users at all times and will immediately inform the MRI Safety Officer of any alterations to it. Before Authorised Person status can be conferred, a person must undergo the following training and testing:

- (i) Training in the operation of the scanner
- (ii) Training in First Aid (to the level of ‘Emergency First Aid at Work’)
- (iii) Basic fire training (internal programme; content to be determined by the Royal Holloway Safety Officer)
- (iv) Training in removing an unconscious participant from the controlled area
- (v) Viewing the current Siemens safety video
- (vi) Attendance at a safety lecture given by a suitably qualified person approved by the Management Committee (or viewing a video recording of such a lecture)
- (vii) Reading the Safety Guidelines for Magnetic Resonance Imaging Equipment in Clinical Use (November 2014) provided by the MHRA
- (viii) Studying all relevant risk assessment forms (provided by the MRI Safety Officer)
- (ix) Thoroughly reading the local *Rules of Operation* and successfully completing a written test, to be administered by the MRI Safety Officer, covering the rules and procedures covered in this document,

These requirements apply to all persons, including members of the Management Committee.

Persons who satisfy all the above requirements but have little or no practical experience will initially be given Probationary Authorised Person Status. Such persons will automatically become full Authorised Persons when they have been present at 10 scans and have operated the scanner on at least 5 of those occasions.

Authorised persons must be screened at least yearly. They must also be trained in the use of any new equipment, software or procedures that may be introduced from time to time. Authorised persons need to attend refresher courses once their First Aid Training certificate expires.

The current list of authorised personnel, together with their qualifications, training and experience, will be made available on request to all relevant university ethics committees.

EQUIPMENT MANUFACTURERS

Trained service personnel or representatives of the equipment manufacturers can operate the equipment for quality control testing, servicing and demonstration purposes. Such people may be admitted to the controlled area by authorised personnel on production of identification (and normally by arrangement with the MRI Safety Officer).

APPENDIX 3 – SCREENING FORMS AND THEIR INTERPRETATION

There are two screening forms and an information form. The purpose of the initial screening form is to identify and eliminate at-risk individuals without the need for them to go to the MR unit. The purpose of the second screening form is to ensure that scanning is safe at the time of the scan. The purpose of the information form is to provide volunteers with information about the procedure.

The information form must be given to the participant at the time of, or prior to, initial screening. The participant should be encouraged to read it before deciding to participate or completing the initial screening form. Authorised persons carrying out screening may add project-specific information to the information form but must not remove any information. They may also add additional project-specific questions to the initial screening form, but may not remove any items.

The initial screening form can be completed at any time prior to the scan, at any convenient location. Wherever possible it should be completed in the presence of an authorised person as defined in Appendix 2, who should ensure that the questions are fully understood and that considered answers are given, and should witness the participant's signature. For children under the age of 18, an authorized person should assist the child and a parent or guardian in filling out the initial screening form (for details, see Appendix 7). Where it is not convenient to complete the form in the presence of an authorised person, the participant's signature should be witnessed by another adult who should countersign and add his/her name and address. In this case an authorised person should subsequently establish by conversation with the participant that adequate attention to the questions has been paid. He/she should verbally go over the questions in the initial screening form taking particular care to check that the participant has no pacemaker, artificial heart valve, cochlear implant or any other ferromagnetic metal implant.

The second screening form must be completed in the MR Unit immediately prior to scanning. For children under the age of 18, an authorized person should assist the child and a parent or guardian in filling out the second screening form (for details, see Appendix 7). The participant's completed initial screening form must be available for inspection by the participant when completing the second screening form. The authorised person who will operate the scanner must then certify, by signing the second screening form, that all necessary checks have been made.

In addition, a consent form must be signed by all participants before scanning (see Appendix 4). For children under the age of 18, the consent needs to be signed both by the child and a parent or a legal guardian (for details, see Appendix 7). For children that do not yet know how to sign, they may provide their consent by drawing a smiley. Only one parent or the legal guardian needs to sign the consent. However, if the other parent explicitly expressed disagreement for the child to be scanned, the child should not be scanned. The consent can be signed at any time after the initial screening has been completed. The signature must be witnessed by another adult, who should be either Authorised Person, or a scientific colleague informed about the details of the particular study, and should add his/her address if not an authorised person. As well as witnessing the signature, this person is responsible for ensuring that the participant fully understands the consent form and has had adequate opportunity to ask questions.

All three forms must be lodged in the MR unit before scanning takes place.

Exceptions:

- (i) If the person to be scanned is an authorised person who has been scanned on a previous occasion, the second screening form need not be completed.
- (ii) For persons who will enter the controlled area but will not be placed inside the magnet, the initial screening form must be completed in accordance with the rules; however the second screening form and consent form need not be completed.

For participants who are scanned more than once, the answers to the questions on the two screening forms must be confirmed on each occasion, either be countersigning the original screening forms or by completing fresh forms. The consent form must be completed in relation to each scan.

Copies of the information form and the two screening forms follow.

INFORMATION FORM - ADULTS

These notes give some information about an (f)MRI 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.

MRI is a method for producing images of the grey and white matter of the brain. This is made possible due to the fact that regions containing grey or white matter have different effects on the echoes from brief pulses of radio waves, which we can visualize as 3D images.

DTI is a method for visualizing anatomical connections between different brain regions. This is made possible due to the fact that water molecules tend to move along a major direction in areas that are part of a fibre bundle, whereas they tend to move in random directions outside such fibre bundles. This difference can be visualized in 3D images.

MRS is a method for measuring the amount of certain metabolites (e.g. GABA) in a specific region of the brain. This is made possible by the fact that different metabolites have different effects on the echoes from brief pulses of radio waves, and these differences can be measured.

In a typical experiment, you may be scanned with just one or a combination of the methods described above. In some research projects, other body parts such as the lower leg, knee, thigh or ankle may be scanned. The researcher will be able to provide you with more details about these scans. In those cases, the body part being scanned will be put in the centre of the scanner, so your head might be just outside.

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 Initial Screening Form) which asks about these and other matters to determine whether it is safe for you to be scanned. In addition, you are asked to give the name and address of your Family Doctor. This is because there is a very small chance that the scan could reveal something which required investigation by a doctor. If that happened, we would seek advice from a specialist, using anonymised data, whether or not a follow-up is suggested, and if so, contact your doctor directly. By signing the consent form, you authorise us to do this. You will also be asked to complete a second, shorter, screening 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 ear-plugs 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 as still as possible during the scan, 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, plus another 15 minutes to discuss with you the purposes of the study and answer any questions about it which you may raise. 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 initial 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. We may share your data with carefully chosen research colleagues, or with big databases such as the UK Data Archive, but the information we share will never contain your name or address. The information in the two screening forms 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 initial screening form.

INITIAL SCREENING FORM

NAME OF PARTICIPANT Sex: M / F

Date of birth..... Approximate weight in kg..... Approximate height in cm.....

Please read the following questions CAREFULLY and provide answers. For a very small number of individuals, being scanned can endanger comfort, health or even life. The purpose of these questions is to make sure that you are not such a person.

You have the right to withdraw from the screening and subsequent scanning if you find the questions unacceptably intrusive. The information you provide will be treated as strictly confidential and will be held in secure conditions.

Delete as appropriate

- | | |
|--|--------|
| 1. Have you been fitted with a pacemaker or artificial heart valve? | YES/NO |
| 2. Have you any aneurysm clips, shunts or stents in your body or a cochlear implant? | YES/NO |
| 3. Have you ever had any metal fragments in your eyes? | YES/NO |
| 4. Have you ever had any metal fragments, e.g. shrapnel in any other part of your body? | YES/NO |
| 5. Have you any surgically implanted metal in any part of your body, other than dental fillings and crowns (e.g. joint replacement or bone reconstruction) | YES/NO |
| 6. Have you ever had any surgery that might have involved metal implants of which you are not aware? | YES/NO |
| 7. Do you wear a denture plate or brace with metal in it? | YES/NO |
| 8. Do you wear a hearing aid? | YES/NO |
| 9. Do you use drug patches attached to your skin? | YES/NO |
| 10. Have you ever suffered from any of: epilepsy, diabetes or thermoregulatory problems? | YES/NO |
| 11. Have you ever suffered from any heart disease? | YES/NO |
| 12. Is there any possibility that you might be pregnant? | YES/NO |
| 13. Have you been sterilised using clips? | YES/NO |
| 14. Do you have a contraceptive coil (IUD) or other contraceptive implants installed? If yes, please provide details: _____ | YES/NO |
| 15. Are you currently breast-feeding an infant? | YES/NO |

Please enter below the name and address of your UK doctor (general practitioner).

I have read and understood the questions above and have answered them correctly.

SIGNED..... DATE.....
(for children under 18 years: signature by a parent or guardian)

In the presence of (name)(signature)

Address of witness, if not the experimenter:

SECOND SCREENING FORM

This form should be completed and signed immediately before your scan, after removal of any jewellery or other metal objects and (if required by the operator) changing your clothes.

NAME OF PARTICIPANT

Date of birth.....

Sex: M / F

Please read the following questions CAREFULLY and provide answers. For a very small number of individuals, being scanned can endanger comfort, health or even life. The purpose of these questions is to make sure that you are not such a person.

You have the right to withdraw from the screening and subsequent scanning if you find the questions unacceptably intrusive. The information you provide will be treated as strictly confidential and will be held in secure conditions.

BEFORE YOU ARE TAKEN THROUGH FOR YOUR SCAN IT IS ESSENTIAL THAT YOU REMOVE **ALL METAL OBJECTS** INCLUDING:-WATCHES, PENS, LOOSE CHANGE, KEYS, HAIR CLIPS, ALL JEWELLERY, METALLIC COSMETICS, CHEQUE/CASH POINT CARDS.

Delete as appropriate

- 1. Are you wearing or carrying any metal items such as those listed above? YES/NO
- 2. Have your answers to any of the questions in the initial screening form changed?
(The initial screening form must be shown to you before you answer this question.) YES/NO
- Specifically, please confirm:
- 3. Have you been fitted with a pacemaker, artificial heart valve or cochlear implant? YES/NO
- 4. Are you wearing a drug patch attached to your skin? YES/NO
- 5. Is there any possibility that you might be pregnant? YES/NO

I have read and understood the questions above and have answered them correctly.

SIGNATURE..... DATE.....
(for children under 18 years: signature by a parent or guardian)

FOR STAFF USE:

I certify that the initial screening form and the consent form have been completed by the person named above and I have attached them to this form. The volunteer has been given the standard information sheet about MRI experiments, together with any necessary study-specific information, and has been given an opportunity to ask questions. I am satisfied that the volunteer is adequately informed and understands the content of the consent form. I have taken adequate steps to ensure that the volunteer has no ferro-magnetic metal in or on his/her person and I am satisfied that the scan can proceed.

SIGNATURE..... NAME (print)

APPENDIX 3 continued

RULES FOR ADMINISTRATION OF SCREENING FORMS

GENERAL

1. All participants must complete both the initial and second screening forms before entering the controlled area.
2. Completion of the screening forms must be supervised by an authorised person (see Appendix 2) who must be satisfied that the participant has read the questions carefully and understands their importance.
3. The second screening form must be countersigned by an authorised person before the participant enters the controlled area. The form should only be signed if all questions have been answered satisfactorily (see below), the participant's UK GP details have been added and the participant has signed both screening forms and the consent form. The only exception to providing name and address of the UK GP details are collaborators from abroad. In such cases, instead of providing the participant's UK GP details, the participant needs to confirm in writing that he/ she is going to undertake the responsibility of contacting his/ her GP in the unlikely case of an incidental finding.
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, 2, 3, 4, 8, 11, 12, 13 and 15 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.
6. If the participant answers 'yes' to any of questions 5, 6, 7, 10 and 14, the person must not be scanned unless medical advice is first taken and any medical supervision that may be recommended is implemented. In such cases, explicit permission to proceed must be obtained from the MR Safety Officer before scanning. The following specific rules apply in such cases:
 - (Q.6) A person who has had surgery that clearly did not involve implantation of metal (e.g. tonsillectomy) may be scanned. Persons who have had any surgery where the use of metal implants cannot be ruled out must not enter the controlled area unless it is first established that the implant contains no ferromagnetic material. They must not be scanned unless medical advice has been taken and any medical supervision that has been recommended is provided. Scanning may proceed only if the answer to question 6 has become "no" and the initial screening form has been re-administered and the answers reflect this.
 - (Q.7) A person wearing a dental plate or brace may enter the controlled area but must remove the device before being scanned. If it is not readily removable, the person should not be asked to remove it and scanning must not proceed.
 - (Q.10) A person suffering from thermo-regulatory problems, or epilepsy may enter the controlled area but must not be scanned without medical supervision. A person suffering from diabetes may enter the controlled area but must not be scanned without additional screening from Authorized Personnel as described under 4.2.4.
 - (Q.14) A woman with an intra-uterine contraceptive device may enter the controlled area but must not be scanned unless the type of IUD or contraceptive implant is known to be MR safe (examples: Mirena, Nova T-380, Implanon).

If there is ANY DOUBT as to whether it is safe to proceed, the participant **MUST NOT** be allowed to enter the controlled area.

7. If a participant has answered 'yes' to a question but is subsequently permitted to enter the controlled area, the facts and the basis of the decision must be documented and attached to the filed screening forms. Any material statements made by the participant should be made in writing on the screening form.

SECOND SCREENING FORM

8. If the participant answers 'yes' to question 1 then he/she should be asked to remove the item(s) in question, if that is practical, and then amend the answer and initial the change, or complete a fresh second screening form.
9. If the participant answers 'yes' to question 2, the initial screening form must be completed afresh and any affirmative answers acted upon in accordance with the rules above.
10. If the participant answers 'yes' to question 3, they must not be allowed into the controlled area.
11. A person answering 'yes' to question 5 must not be scanned, but may be allowed into the controlled area for other purposes (e.g. a pregnant authorised person may enter to supervise volunteers, but has the right to refuse to do so).

APPENDIX 4 – CONSENT FORM

ROYAL HOLLOWAY, UNIVERSITY OF LONDON - MAGNETIC RESONANCE IMAGING UNIT

CONSENT FORM

NAME OF PARTICIPANT.....

Please read the following statement carefully and then add your signature. If you have any questions, please ask the person who gave you this form. You are under no pressure to give your consent and you are free to withdraw from the MRI examination at any time.

I agree to participate in an MRI examination conducted for research purposes

by (name of researcher)

on(name of project).

- I understand that the examination is not part of any medical treatment.
- I have completed two screening forms and I have been given an opportunity to discuss any issues arising from them.
- The nature of the examination has been explained to me and I have had an opportunity to ask questions about it.
- I consent to a specialist and my UK general practitioner being contacted in the unlikely event that the scan reveals any suspected abnormality.

Signature

(for children under 18 years: signature by child and a parent or guardian)

Date.....

WITNESS:

Statement by a witness, who must be either an authorised person or a scientific collaborator who is familiar with the experimental procedure and is able to answer questions about it.

I certify that the above participant signed this form in my presence. I am satisfied that the participant fully understands the statement made and I certify that he/she had adequate opportunity to ask questions about the procedure before signing.

Signature.....

Date.....

Name

Address of witness (if not an Authorised Person):

APPENDIX 5 – EMERGENCY PROCEDURES AND QUENCH

QUENCHING refers to the loss of absolute zero in the magnet coils. If the temperature rises, the coils cease to be superconducting and become resistive. Heat is then generated, resulting in boil-off of helium, and the field strength falls sharply. Quenching can be manually instigated in an emergency. Re-establishing the static field after quenching is an expensive, specialist procedure. In addition, the magnet may be permanently damaged.

Procedure in the event of a person being in a life-threatening situation due to the magnetic field

1. Manually quench the magnet by pressing one of the emergency buttons located in the control room and the examination room. The DOOR to the examination room should be OPEN during quenching. Manually quenching may be performed only by an Authorised Person who must first have given due consideration to the relative risks (see Note below).
2. Dial 444 and call for an ambulance.
3. Do not attempt to remove the participant from the scanner.

Procedure in the event of a person being in a life-threatening situation that does not involve the magnetic field

1. Dial 444 and call for an ambulance
2. Unless there is an injury that requires the person to be kept still, remove the person from the Controlled Area

NOTE: Quenching the magnet carries its own risks. Quenching involves the release of large amounts of energy, which can cause a significant rise in temperature in the magnet. Cryogens are vented to the outside air but there is a risk of release into the scanner room, which can cause changes in air pressure or even asphyxiation. A careful balancing of risks must be made as to whether quenching is appropriate. Quenching should only be performed if the situation is judged to be life-threatening AND it is judged that the presence of the magnetic field poses a bigger risk than the quenching procedure itself. Such situations are extremely rare and quenching should be regarded as a last resort.

APPENDIX 6 – FIRE PROCEDURES

Procedures in the event of a fire involving the MRI unit

If you discover a fire:

- 1 Immediately operate the nearest fire alarm. This is located just inside the main entrance door to the MRI unit
- 2 Implement the evacuation procedure (see below).

DO NOT tackle the fire, unless you have received fire training to a level commensurate with the severity of the incident.

DO NOT take fire-fighting equipment into the Controlled Area unless it is known to be MR-safe.

Evacuation procedure:

1. Stop all scanning.
- 2 Remove participant from the scanner.
- 3 Electrically isolate the scanner by pressing either of the two unprotected red buttons located on the walls of the control room and the examination room. DO NOT QUENCH the magnet.
- 4 Do not stop to collect personal belongings.
- 5 Leave the Unit and building by the nearest convenient exit.
- 6 Secure all doors after leaving.
- 7 Do not re-enter the building until instructed by the Fire Brigade or a responsible officer of the College.
- 8 Proceed to the designated Assembly point 15 (situated between Queens building and Queens Annex building). Authorized personnel from partner universities must familiarize with the assembly point.
- 9 The MRI Safety Officer or an Authorised Person must be available to liaise with the Fire Brigade and College Safety Officer. They should jointly assess whether it is necessary to enter the Controlled Area with fire-fighting equipment. If this is deemed necessary, the magnet must first be quenched by the MRI Safety Officer or an Authorised Person.

APPENDIX 7 – CUBIC GUIDELINES FOR SCANNING CHILDREN

CUBIC RESEARCH INVOLVING CHILDREN & YOUNG PEOPLE - Guidelines (adopted from the Kings' College guidelines) -

Summary: This document is intended to provide guidance to researchers who wish to undertake research with children and/or young people as participants at CUBIC. Research involving children and young people is subject to the same ethical and governance requirements as any other research project involving human participants. However, the inclusion of children and young people as participants can also raise specific ethical issues, risks and governance requirements. It is these issues that this document addresses.

Key principles:

Research involving children and young people (CYP, i.e. individuals under the age of 18) should only be conducted where:

1. The research is responsive to the needs and/or priorities of this population or community and there is a reasonable likelihood that this population or community stands to benefit from the results of the research;
2. The research might not equally well be carried out with adults;
3. The study methods are appropriate for CYP; and
4. The circumstances in which the research is conducted provide for the physical, emotional and psychological safety of the child.
5. All research needs to be carried out following the 'Guidelines for minimum standards of ethical approval in psychological research' provided by the British Psychological Society.

Recruitment documents (Information Sheets, consent forms, handouts, posters etc):

When creating recruitment documents, such as Information Sheets, it is key that these documents are tailored specifically towards the different participant groups at which they are aimed. Careful attention needs to be given by researchers to devising ways of enabling CYP to access the information required for consent. This should take account of factors such as level of reading ability and attention span. The use of visual imagery (such as cartoon characters), spaced out text rather than long paragraphs, and generally simplified wording on the documents to be seen by CYP, can be very helpful in this regard. The primary aim is to keep such documents as clear and concise as possible to ensure the child is fully informed and understanding of what the project will involve. There are various reading age tests/tools available online where you can check the readability of the documents you intend to use during a study.

It should usually be the case that separately worded Information Sheets and consent forms are used for parents and for child participants (for examples, see Appendices 1-3). This is because in most cases the child is the participant, while the parent is not. As such, the wording on the different documents should reflect this.

Note that an authorized person should ask the child – where appropriate – about pregnancy and the existence of piercings in the absence of the parent or legal guardian.

Methods of obtaining consent:

For research involving CYP *written* consent should be taken through the use of a physical consent form (one for a parent to give consent for the child to take part and one for the child themselves to give consent to take part).

Safeguarding requirements:

When undertaking research with CYP there may be specific safeguarding requirements and governance responsibilities that the researcher will need to take into account.

Child protection issues/limits to confidentiality:

Researchers have a legal and moral duty to respect the rights of participants for their participation and data to remain confidential. However, there are some circumstances where a disclosure might be made by a participant, or evidence may come to light of a child protection issue. In such circumstances, the researcher may have a legal, professional or moral duty to breach the confidentiality of participants and inform a third party outside of the researcher team, such as a relevant authority (e.g. the Children's services department of the local authority/social services, a school/educational establishment, the police etc). It is crucial that all such possibilities are considered by the researcher prior to the project taking place, with appropriate procedures put in place. Parents and CYP should be made aware on the Information Sheet that there may be limits to confidentiality, and that certain situations would mean that the researcher has a duty to inform a relevant authority outside of the research team. An example of wording which may be used is as follows: 'Everything you say will be treated as confidential, unless I am worried that there is a risk of harm to you or another young person, in which case I will inform your teacher/ social worker' (or adapted for younger children).

DBS checks:

Researchers running experiments with children at CUBIC need to provide evidence of DBS checks to the MRI Safety Officer prior to scanning. It is the researchers responsibility to provide evidence of these documents. No scanning can go ahead without a DBS being provided.

During the experiment

It is recommended that parents should wait for their children outside the MR control room. This is to avoid the risk of spotting abnormalities. Parents should be allowed inside the control room at the beginning of the experiment and during longer breaks between scans to have a chance to talk to their children via the intercom.

After the experiment

It is recommended that images are mailed to the parent (e.g. in form of a DVD) rather than being given to them right after the scan, arguing that we need some time to process the images first. This is to prevent us from having to explain why they cannot have their images in case we spotted some abnormalities.

[Add CUBIC and/or University logos]

Having an fMRI Scan at CUBIC – Information for Participants Under 18

Hello and welcome to CUBIC MRI centre here at Royal Holloway University. You are here because you have kindly agreed to take part in a study about the human brain, and will be having a brain scan as part of that.



Having a brain scan

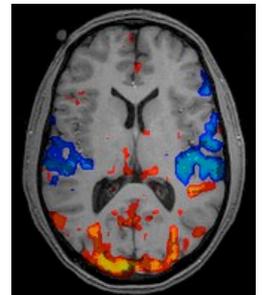
We will be using a technique called magnetic resonance imaging (MRI) to take pictures of your brain while you are lying in an MRI scanner. The scanner will look a lot like the one in this picture.



There are two main types of scan we will be using today.

Structural MRI scans allow us to look at what the brain looks like, as you can see in this picture. During a structural scan, you will be asked to lie very still and possibly watch some videos while the scan takes place.

Functional MRI scans allow us to look at which parts of the brain are being used when you're doing or thinking particular things. For example, this picture shows the parts of the brain that are active while watching and listening to a music video. During a functional scan, we will ask you to play simple computer games while in the scanner. You will have the chance to practice this beforehand.



Safety first!

The most important thing to tell you is that these scans are very safe. You will not feel anything while the scan is being taken, and there are no side effects. However, the scanner uses powerful magnets to create the pictures and so it is important that no metal is taken into the scanning room. A researcher will take you through some screening forms to make sure you are metal-free. To be on the safe side we also say that pregnant women and people with certain health conditions should not take part, so you may be asked some health questions as well.

What is it like in the scanner?

As you can see from the picture above, the scanner looks a bit like a washing machine! You lie on the bed and this is then moved into position so that your head is inside the scanner. Most people are happy to lie in the scanner, but if you are *claustrophobic*, meaning you do not like being in small spaces, then you may decide not to be scanned. ***You can of course stop taking part at any time, for any reason, and you do not need to tell us why.***

While you're in the scanner you will talk to the researcher through an intercom system, and they will check on you regularly to make sure all is well. You will also be given a buzzer to press if you need to get their attention quickly.

When the scanner is running it will be **very noisy**, so we will give you some earplugs and headphones which you must wear in order to protect your ears.

Another important thing to mention is that it takes a few minutes to collect each brain scan. If you move during the scan the pictures can be ruined or come out very fuzzy, so it's very important that you **stay as still as possible** while you're in the scanner.

What will happen to my data?

We are interested in learning about how the human brain works and how it develops when you're a child or teenager. Your brain scan will be combined with others and used by the research scientists to answer these questions. Once scientists have found out something interesting, we often share our findings with other people in talks and written reports, and sometimes our findings will be in the news. However, we will keep your individual data safe and will never give out your name or contact details

without you and your parents' agreement. We may share your data with other researchers doing similar projects, and with big databases such as the UK Data Archive, but the information we share will never contain your name or address.

Very rarely we might see something on your brain scan that we think should be checked by a doctor. We have asked your parents to give us your GP's details in case this is necessary. However, it is very unlikely.

Everything you say will be treated as confidential, unless we are worried that there is a risk of harm to you or another young person, in which case we will inform Surrey Children's Services (<http://www.surreycc.gov.uk/social-care-and-health/contacting-social-care/contact-childrens-services>).

Get a picture of your brain

You may be curious to see what your brain looks like. If you decide to take part in the study, we will send some pictures of your brain. You'll receive this a few days after taking part.

Keeping your contact details for future research

If you are willing for us to do so, we would also like to keep your contact details on file for the next five years in case future opportunities to participate in research occur. Your contact information will be kept confidential. Please tick the relevant box on the consent form if you are happy for us to do this.

[Include contact details of researchers, and ethics info for particular study]

INFORMATION FORM - PARENTS

These notes give some information about an (f)MRI study in which your child/ ward is 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.

MRI is a method for producing images of the grey and white matter of the brain. This is made possible due to the fact that regions containing grey or white matter have different effects on the echoes from brief pulses of radio waves, which we can visualize as 3D images.

DTI is a method for visualizing anatomical connections between different brain regions. This is made possible due to the fact that water molecules tend to move along a major direction in areas that are part of a fibre bundle, whereas they tend to move in random directions outside such fibre bundles. This difference can be visualized in 3D images.

MRS is a method for measuring the amount of certain metabolites (e.g. GABA) in a specific region of the brain. This is made possible by the fact that different metabolites have different effects on the echoes from brief pulses of radio waves, and these differences can be measured.

In a typical experiment, your child/ ward may be scanned with just one or a combination of the methods described above. In some research projects, other body parts such as the lower leg, knee, thigh or ankle may be scanned. The researcher will be able to provide you with more details about these scans. In those cases, the body part being scanned will be put in the centre of the scanner, so the head might be just outside.

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 your child/ ward has had surgery which may have involved the use of metal items it should NOT take part. Note that only ferro-magnetic materials (e.g. steel) are likely to cause significant problems. Thus normal dental amalgam fillings do not prohibit your child/ ward from being scanned, though a dental plate which contained metal would do so, and your child/ ward would be asked to remove it. Your child/ ward will be asked to remove metal from his/ her 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. Together with your child/ ward you will be asked to complete a questionnaire (the Initial Screening Form) which asks about these and other matters to determine whether it is safe for your child/ ward to be scanned. In addition, you are asked to give the name and address of your child's/ ward's Family Doctor. This is because there is a very small chance that the scan could reveal something which required investigation by a doctor. If that happened, we would seek advice from a specialist, using anonymised data, whether or not a follow-up is suggested, and if so, contact your child's/ ward's doctor directly. By signing the consent form, you and your child/ ward authorise us to do this. You and your child/ ward will also be asked to complete a second, shorter, screening form immediately before the scan. Finally, we might be asking your child some confidential health questions in your absence as it is very important that your child/ ward feels able to answer honestly.

To be scanned, your child/ ward would lie on your back on a narrow bed on runners, on which your child/ ward 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 your child/ ward would wear ear-plugs and, where suitable, ear muffs or sound-attenuating headphones. We would be able to talk to your child/ ward while being inside the scanner through an intercom. If your child/ ward is likely to become very uneasy in this relatively confined space (suffer from claustrophobia), your child/ ward should NOT take part in the

study. If your child/ ward does take part and this happens, he/she will be able to alert the experimenters by activating an alarm and will then be removed from the scanner quickly. It is important that your child/ ward keeps its head as still as possible during the scan, and to help him/ her with this, the head will be partially restrained with padded headrests. We shall ask your child/ ward 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 child's/ ward's part. If this becomes unacceptably difficult or uncomfortable, your child/ ward may demand to be removed from the scanner.

Your child/ ward may be asked to look at a screen through a small mirror (or other optical device) placed just above his/ her eyes and/or be asked to listen to sounds through headphones. Your child/ ward may be asked to make judgements about what he/ she sees or asked to perform some other kind of mental task. Details of the specific experiment in which your child/ ward is invited to participate will either be appended to this sheet or else given to you and your child/ ward 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, plus another 15 minutes to discuss with you and your child/ ward the purposes of the study and answer any questions about it which you and your child/ ward may raise. Your child/ ward will be able to say that he/ she wishes to stop the testing and leave at any time, without giving a reason. This would not affect your relationship or the relationship of your child/ ward with the experimenters in any way. The study will not benefit you or your child/ ward directly, and does not form part of any medical diagnosis or treatment. If you and your child/ ward agree that your he/she participates you and your child/ ward will be asked to sign the initial 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 and your child/ ward to take time to consider whether to participate, or discuss the study with other people, before signing. After signing, you and your child/ ward will still have the right to withdraw at any time before or during the experiment, without giving a reason.

The images of your child's/ ward's brain will be held securely and your child/ ward will not be identified by name in any publications that might arise from the study. We may share your data with carefully chosen research colleagues, or with big databases such as the UK Data Archive, but the information we share will never contain your name or address, or the name or address of your child/ ward.

The information in the two screening forms will also be treated as strictly confidential and the forms will be held securely until eventually destroyed.

Everything your child will say will be treated as confidential, unless we are worried that there is a risk of harm (e.g. suspicion of physical abuse) to your child/ ward or another young person, in which case we will inform Surrey Children's Services (<http://www.surreycc.gov.uk/social-care-and-health/contacting-social-care/contact-childrens-services>).

Further information about the specific study in which your child/ ward 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 initial screening form.

CUBIC Consent Form for Participants Under 18

Study-specific information

Please tick appropriate box:

Yes, I would like to take part in this study

No, I do not want to take part in this study

If Yes, please complete the following:

Delete as appropriate

1. I have read the Information Sheet about having a brain scan, or someone has read it to me. YES/NO

2. I understand that I do not have to take part in this study if I do not want to. YES/NO

3. I understand that I can leave a session at any time without giving a reason and without any adverse consequences. YES/NO

4. I have completed two screening forms accurately. YES/NO

5. I have had the opportunity to ask any questions I wish to ask about the study. YES/NO

6. I have access to the names and telephone numbers of the research team in case I have any questions in the future. YES/NO

7. I understand that this scan is not medical treatment. A specialist and my GP can be contacted in the unlikely event that the scan reveals something that should be followed up by a doctor. YES/NO

8. I am happy for the research team to store my data. They will not give out my name, but my data can be stored on a national database and shared with other researchers. YES/NO

Signature
(Children can write their name or draw a smiley)

Date.....

WITNESS:

Statement by a witness, who must be either an authorised person or a scientific collaborator who is familiar with the experimental procedure and is able to answer questions about it.

I certify that the above participant signed this form in my presence. I am satisfied that the participant fully understands the statement made and I certify that he/she had adequate opportunity to ask questions about the procedure before signing.

Signature.....

Date.....

Name

Address of witness (if not an Authorised Person):

ROYAL HOLLOWAY, UNIVERSITY OF LONDON - MAGNETIC RESONANCE IMAGING
UNIT

CONSENT FORM FOR PARENTS/ GUARDIANS

NAME OF PARTICIPANT

DATE OF BIRTH PARTICIPANT:

Please read the following statement carefully and then add your signature. If you have any questions, please ask the person who gave you this form. You are under no pressure to give your consent and you and your child are free to withdraw from the MRI examination at any time.

I (PRINT NAME OF PARENT/ GUARDIAN HERE) agree for my child (PRINT NAME OF CHILD HERE) to participate in an MRI examination conducted for research purposes
by (name of researcher)
on(name of project).

- I understand that the examination is not part of any medical treatment.
- We have completed two screening forms, and we were given an opportunity to discuss any issues arising from them.
- The nature of the examination has been explained to me and my child, and we have had an opportunity to ask questions about it.
- I consent to a specialist and my child's UK general practitioner being contacted in the unlikely event that the scan reveals any suspected abnormality.

Signature

Date.....

WITNESS:

Statement by a witness, who must be either an authorised person or a scientific collaborator who is familiar with the experimental procedure and is able to answer questions about it.

I certify that the above parent/ guardian signed this form in my presence. I am satisfied that the parent/ guardian fully understands the statement made and I certify that he/she had adequate opportunity to ask questions about the procedure before signing.

Signature.....

Date.....

Name

Address of witness (if not an Authorised Person):

Schedule 3: Principles for Allocation of Scanner Time between the Parties

1. Ownership of time to be divided in the proportions of the capital shares (see Section 3). Three time categories, together covering all available time:
 - (i) working days, 8am-8pm
 - (ii) weekends and public holidays, 8am-8pm
 - (iii) nights (8pm-8am)
2. Time in each category separately to be divided in the capital-share proportions. Management Committee to manage allocation of dates and times to maximum mutual convenience.
3. Each Party's time allocation to be managed independently by that Party. Each Party to be free to use its time as it wishes (i.e. use by its own scientists charged to its grants, by its own scientists whose research is funded by the institution, by outside collaborators and by outside paying customers, in whatever proportions it wishes). All income from charges to be retained by the Party in question; each paying outside user to be the customer of the Party owning the time used, not the consortium.
4. Transfer of time between Parties
 - (i) Flexible arrangements for transfer of unused time between Parties should be superimposed on the fixed time ownership divisions. Each Party should have the right to use the facility at any time, if it is not being used by the owner of the time in question.
 - (ii) Such use should normally be by arrangement. Parties to co-operate in identifying unused time well in advance and granting approval for its use by others; Management Committee to determine detailed arrangements and to review the equity of actual usage periodically.
 - (iii) When one Party uses spare time owned by another Party and makes a charge, either to a research grant or to an external customer, the income should be divided in equal shares between the owner of the time and the Party securing the income.
5. Detailed records of Scanner use will be kept centrally (see Section 4) and used as a basis for any transfer of funds between Parties arising from this arrangement.
6. Time is allocated on the following basis:

Monday: Surrey
Tues: RHUL
Weds: Roehampton
Thurs: RHUL
Friday: Brunel

This relates to prime time, which is weekdays 8am-8pm. At night and weekends, anybody can use the scanner any time. The schedule was decided by the Management Committee and can be varied by that committee at any time.

Schedule 4: The Policy Committee

A Policy Committee will be established with the powers and duties, terms of reference and working arrangements as set out below.

Membership

One representative at the level of Vice Chancellor or Vice Principal from each of the participating universities.

The Chair will be appointed annually by the Policy Committee from among its members.

Terms of Reference

Subject to the terms of the Contract for Continued Operation of a 3-Tesla Scanner, the Policy Committee shall determine policy for the effective use of the Scanner, ensure that the policy is implemented and monitor its effectiveness. Specifically, the Policy Committee will:

- (i) determine charging rates for the Scanner, on the recommendation of the Management Committee;
- (ii) approve changes to Schedule 2, on the recommendation of the Management Committee;
- (iii) seek to resolve any disputes arising out of the working of the Agreement, or the use of the Scanner, if such disputes cannot be satisfactorily resolved by the Management Committee;
- (iv) seek to agree to the transfer by any of the Parties of its share to another institution, at the request of a Party.

Working Arrangements

- (i) The Policy Committee will meet at least once in each academic year.
- (ii) A member of staff from the Party responsible for chairing the Policy Committee will be appointed secretary and will take minutes of all Policy Committee meetings.
- (iii) Any member of the Policy Committee may nominate a deputy to attend any meeting in his/her unavoidable absence.
- (iv) Subject to the provisions of this Schedule, the Policy Committee may otherwise determine its own rules of procedure.

Schedule 5: The Management Committee

A Management Committee will be established with the powers and duties, terms of reference and working arrangements as set out below.

The Management Committee will report to the Policy Committee.

Membership

One member, nominated by the Principal or Deputy Principal of Royal Holloway

One member, nominated by the Vice-Chancellor of each of the other Parties.

One of the members nominated by the Principal of Royal Holloway shall chair the Management Committee.

Terms of Reference

Subject to the terms of the Contract for the Continuing Operation of a 3-Tesla Scanner, and the Policy Committee, to which the Management Committee reports, the Management Committee will:

- (v) consider and recommend charging rates for the Scanner to the Policy Committee;
- (vi) approve and revise from time to time the list of trained users of the Scanner, in accordance with the criteria in Schedule 2;
- (vii) review and amend, as appropriate, the principles for the allocation of time on the Scanner;
- (viii) review Schedule 2 and make recommendations, as necessary, to the Policy Committee;
- (ix) exclude, if this is felt to be necessary, in the academic interests of all the Parties, any external research contracts or customers from using the Scanner;
- (x) consider proposed agreements with third parties which may restrict the use of the Scanner, or the publication of results obtained from work on the Scanner;
- (xi) monitor day-to-day management of the Scanner by receiving and assessing reports from the Director of MRI, the Department of Psychology at Royal Holloway;
- (xii) seek to resolve any disputes arising out of the working of the Agreement, or the use of the Scanner;
- (xiii) undertake a review of the working of the Agreement at regular intervals and the use of the Scanner three years after the date of the installation of the Scanner, and produce a written report, including recommendations.

Working Arrangements

- (v) The Management Committee will meet at least once in each academic year.
- (vi) The Chair will arrange for a secretary to be appointed to the Management Committee; the secretary will take minutes of all Management Committee meetings.
- (vii) Any member of the Management Committee may nominate a deputy to attend any meeting in his/her unavoidable absence.

Subject to the provisions of this Schedule and the Policy Committee, the Management Committee may otherwise determine its own rules of procedure.