

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 by 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 gray 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.