

Ethical guidelines for staff and students in the Department of Psychology who plan to use magnetic resonance imaging (e.g., fMRI) with human participants (especially those who plan to do so using the facilities at the Academic Unit of Radiology in Sheffield)

Magnetic Resonance Imaging (MRI) can provide anatomical, functional, and physiological information regarding the human brain. fMRI is a particular type of MRI / neuroimaging technique that measures the vascular response to brain activity by detecting changes associated with blood flow and oxygenation in the presence of a strong magnetic field, switching magnetic field gradients, and pulsed radiofrequency waves.

While the technique is widely used (in medicine, as well as increasingly by psychologists in research studies) and is safe provided that contra-indications are avoided (as detailed below), the use of MRI requires the consideration of a number of additional ethical issues. For example, should the participant be told if their scan shows any incidental finding whether it has any significance on their health or not? If there are findings on the scans that may affect the participant's health, should their GP be told? Should participants be offered an image as an incentive for taking part? A brief overview of these issues is provided below.

Researchers in the Department of Psychology who are considering the use of MRI in their research should consider these issues and also consult additional guidance, as required.

Contraindications

As stated above, MRI is considered to be a safe procedure. However, because of the strong static and time varying electromagnetic fields involved, certain conditions (e.g., the presence of metal in the body) can introduce potential risks for the participants. Therefore, potential participants need to be carefully screened to ensure that they would answer 'No' to each of the following example questions. These will also be checked by the radiographers conducting the scan, but identifying and excluding potential participants with these conditions prior to recruitment will prevent valuable scanning time and associated resources from being wasted.

- *Do you have a pacemaker or artificial heart valve?*
- *Have you had any brain operations (e.g., insertion of aneurysm clips or metal plates)?*
- *Have you had any recent surgery to your head or body (within the last two months)?*
- *Do you have any joint replacements or metal implants (e.g., screws)?*
- *Have you EVER had metal in your eyes (e.g., from a lathe in a machine shop)?*
- *Do you have any shrapnel from a war injury or previous gunshot injury?*
- *Do you wear a false limb, calliper or brace?*
- *Do you wear dentures, or a dental plate?*
- *Have you ever suffered from epilepsy or blackouts?*
- *Do you have any ear implants e.g. cochlear?*
- *Do you have any non-removable rings attached to your body?*
- *Is there any chance that you might be pregnant?*

Information and informed consent

As with any procedure, it is important that participants are informed as to the potential disadvantages and risks to taking part – in particular, that (i) certain conditions (e.g., having a pacemaker, or being pregnant) preclude participation and (ii) the scanner is a noisy and confined environment. With this in mind, the information sheet should include a statement along the following lines:

This type of scanning is considered to be safe. It does not involve exposure to ionising radiation; neither does it involve any injections. However, because the scanner is quite noisy and a rather confined environment, some people may find the experience unusual. There is an intercom by which you can speak to us and we can bring you out of the scanner at any time if you wish. Fully trained staff from the Academic Unit of Radiology will be present at all times.

What if the scan shows a potential abnormality?

All brain scans conducted for research purposes at the Royal Hallamshire Hospital are routinely looked at by a consultant neuroradiologist. The issue of whether such information should be disclosed to the participant or not has raised considerable debate (see, for example, the references at the end of this section). The view of the Ethics Committee in the Department of Psychology (DESC, shared by colleagues at the University of Sheffield – see, e.g., Hoggard et al., 2009) is that participants who have scans – even for research purposes – should be informed if those scans indicate a potential abnormality. It should be noted, however, that abnormal findings may make some future financial arrangements more difficult, such as obtaining life insurance. With this in mind, the information sheet should make it clear to participants that, by agreeing to take part, they consent to being told if their scan shows any potential abnormality. However, they should also be encouraged to recognise that the scan is not intended to be diagnostic. For example:

The scan that you will receive in this study is designed to answer our research questions. The scan is not a substitute for one that a medical doctor would order and it may not show problems that could be identified by a scan conducted for medical purposes. However, if an abnormality is detected then we will contact you and arrange to meet you and explain what we have seen. We will also contact your GP. It is important, therefore, that if you do not wish to know about any potential abnormality that you may have (or you do not wish your GP to know), then you should not volunteer to take part in this research project.

A template for a letter that might be sent to participants whose scans are flagged as indicating a potential abnormality is appended to the end of this document (Appendix A). Researchers should, therefore, obtain the name and address of participants' GP, along with contact details for the participant (typically, a phone number, email address, and postal address). Given the sensitivity of these issues, researchers might also think carefully about the implications of recruiting participants who are known to them (e.g., friends and family).

Anon (2005). How volunteering for an MRI scan changed my life. *Nature*, 434, 18.

Check, E. (2005). Brain-scan ethics come under the spotlight. *Nature*, 433, 185.

Hoggard, N., Darwent, G., Capener, D., Wilkinson, I. D., & Griffiths, P. D. (2009). The high incidence and bioethics of findings on magnetic resonance brain imaging of normal volunteers for neuroscience research. *Journal of Medical Ethics*, 35, 194–199.

Olson, S. (2005). Brain scans raise privacy concerns. *Science*, 307, 1548-1550.

Pickard, J. D. (2005). Guidelines reduce the risk of brain-scan shock. *Nature*, 435, 17.

Wardlaw, J. M., Davies, H., Booth, T. C., Laurie, G., Compston, A., Freeman, C., ... Jackson, A. (2015). Acting on incidental findings in research imaging. *British Medical Journal*, 351, h5190.

Site file and approval from the Academic Unit of Radiology

Research by members of the Department of Psychology at the University of Sheffield using MRI is relatively unique in that the lead researcher (i.e., the PI) and associated ethical approval procedure may both be separate to the MRI unit run by the Academic Unit of Radiology. Each new study that involves using MRI with human participants should follow the standard operating procedure for the administration of research undertaken in the Academic Unit of Radiology at the University of Sheffield (see Appendix B).

This will involve creating a site file containing a copy of the protocol, information sheet, consent form, and all regulatory approvals. This information should be approved by the associated senior academic within the Academic Unit of Radiology (Professor ID Wilkinson) prior to commencement of the study and stored in the Academic Unit of Radiology (within the scan control area, while the study is 'live'). Please note that during the inception of a project involving MRI, it is important to discuss the proposed design, scanning needs, and requisite resources with Prof Wilkinson.

Prior to commencement of MR scanning a referral card (see Appendix C) and MR Screening Form (see Appendix D) with the participant's demographics i.e. name, date of birth, address and GP details would need to be completed and taken to the Academic Unit of Radiology prior to MR scanning. This would prevent valuable scanning time and associated resources from being wasted if for any reason the participant had to be excluded from MR scanning.

The Ethics Committee in the Department of Psychology (DESC) have agreed that the standard operating procedures described in Appendix B represent a 'minimum standard' for studies using MRI with human participants. DESC have also agreed that all applications for research involving MRI will be reviewed by at least one person who is familiar with these procedures.

It is expected that project PIs / supervisors will be physically present for all MR scanning sessions and that students / non-members of staff will only be designated as competent and capable of running sessions following discussion with, and the agreement of, Professor Wilkinson.

Can participants be offered an image (e.g., of their brain) as an incentive for taking part in the research?

The Academic Unit of Radiology do not routinely provide copies of scans conducted for research purposes and there is a strong steer that participants should **not** be offered an image (e.g., of their brain) as an incentive for taking part in the research; not least because this may influence who volunteers to take part in the research (e.g., participants who are worried about having frequent headaches may be more likely to volunteer)

If researchers in the Department of Psychology have further queries about applying for approval for projects involving MRI, then they can contact Dr Tom Farrow (t.f.farrow@sheffield.ac.uk).

Thomas Webb, March 2017 (with thanks to Leanne Armstrong, Nigel Hoggard, Tom Farrow, Richard Rowe, Iain Wilkinson, and Stuart Wilson)

Appendix A: Template for a letter that might be sent to participants whose scans are flagged as indicating a potential abnormality

Date

Address

Dear XXXX

You kindly agreed to volunteer for a MRI scan at the Academic Unit of Radiology in the University of Sheffield. As you were made aware before having the scan, part of our operational policy agreed with the University Research Ethics Committee (UREC) is to review the scans of people who volunteer for research studies using this technique.

Although this imaging has been done only for research purposes and not clinical reasons, we feedback any findings that might be useful for the person to know. With this in mind, I wondered if it would be possible to arrange an appointment for you to look at the scans with me and discuss the findings? When we meet we can discuss whether any further action is necessary, such as sending out a letter to your GP.

Please telephone XXXX or email XXXX to arrange an appointment. If we do not hear from you within two weeks of the date of this letter, then we will phone you to check that you have received it.

Yours sincerely

XXXX

Appendix B: Standard operating procedure for the administration of research undertaken in the Academic Unit of Radiology at the University of Sheffield

1. All staff involved in research in the Academic Unit of Radiology must comply with and be trained in Good Clinical Practice (GCP) Regulations and Guidelines. Certification and training can be found via the following website: <https://learn.nihr.ac.uk/>
2. A site file must be created for every research study being conducted in the Academic Unit of Radiology. The site file must include a copy of the following documents:
 1. Protocol, including the scientific rationale for the research along with the methodology
 2. Participant Information Sheet
 3. Consent Form
 4. All regulatory approvals which may include:
 - Research Ethics Approval (REC)
 - Medicines and Healthcare Products Regulatory Agency (MHRA)
 - Healthy Research Authority (HRA)
 - University Ethics Approval
 - Sponsor Approval
3. The Unit Administrator of the Academic Unit of Radiology (Mark Skevington, m.skevington@sheffield.ac.uk) must be made aware of any research study being conducted in the Academic Unit of Radiology.
4. Participants must give written consent prior to any research being conducted as per GCP regulations.
5. Participants must be made aware that MR imaging will be reviewed by a radiologist and potentially that an incidental finding could be detected; in which case, they may be contacted to discuss the scan.

Radiologist – Head and musculoskeletal: Dr Nigel Hoggard
Chest: Dr Andrew Swift

Appendix D: Academic Unit of Radiology, MRI screening form

THE UNIVERSITY OF SHEFFIELD ACADEMIC DEPARTMENT OF RADIOLOGY
Magnetic Resonance Imaging Unit at the Royal Hallamshire Hospital
PATIENT & VOLUNTEER SCREENING FORM

Please complete this form prior to having your scan. Please circle the appropriate answer.

Surname _____

First name(s) _____

Date of birth _____

Address _____

Home / Mobile tel _____ Work tel _____

Have you ever had any surgery to your heart or chest e.g. cardiac pacemaker, replacement valves, stents or filters inserted? Yes No

Have you ever had any operations to your brain, e.g., aneurysm clips or shunts inserted? Yes No

Have you EVER had any metal fragments in your eyes? Yes No

Are you, or could you be, pregnant? Yes No

Do you have an electronic or breast implant in your body? Yes No

Have you had any surgery of any type in the last 2 months? Yes No

YOU MUST RING THE UNIT IF YOU HAVE ANSWERED YES TO ANY OF THE ABOVE QUESTIONS. FAILURE TO DO SO MAY MEAN THAT YOU CANNOT BE SCANNED, TELEPHONE NO. 0114 271 8684

Do you suffer from any heart disease or rhythm disorder? Yes No

Do you have any hearing problems, e.g., tinnitus? Yes No

Do you have any kidney problems? Yes No

Do you wear any removable metal dental work? Yes No

Do you suffer from epilepsy or diabetes? Yes No

Do you have any allergies? Yes No

Do you have any metallic objects in your body, e.g. metal fragments or surgical clips? Yes No

If so, please specify _____

Please remove all credit cards and loose metallic objects, e.g., watches, wallets, keys, money, glasses, jewellery (Including body piercing), hearing aids, hair clips and skin patches.

Lockers for your valuables are provided in the waiting area.

How much do you weigh? _____

If you have read and understood the above restrictions, then please sign below

Signature _____ Date _____
or signature of consenting adult

Name of GP: _____

Address of surgery: _____

