

INFORMATION SHEET – VOLUNTEERS

PROJECT TITLE: **project title here**
Ethics Code: **ethics code here**

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

What is the purpose of this study?

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Why have I been chosen?

You have been chosen because you are a member of the CBSU Volunteer Panel, or because you answered an advert asking for volunteers to participate in research studies using functional magnetic resonance imaging (fMRI).

Who is organizing this study?

The study is organized by a researcher working at the Medical Research Council Cognition and Brain Sciences Unit (MRC CBSU), Cambridge. Your Principle Researcher is:

Principle Researcher Name + (CBSU direct dial number)

What does the procedure involve?

Before your scan a member of staff will ask you some questions to ensure that you have no metal within you before you enter the strong magnetic field. You will then be asked to lie in the scanner and the scanning will start. The scanning can be noisy and so we shall give you ear plugs as well as headphones to reduce this noise. It may not be appropriate for you to be scanned if you are very claustrophobic. During some of the scans we will ask you to perform simple tasks. Replace this entire red section with details of the tasks specific to your project. For example: These tasks will involve remembering items, such as digits or objects, or simple task rules. You will also have to make simple decisions by pressing a button on a button box in your right hand, or by telling us what those decisions are.

You will have ample time before scanning to practice the tasks to ensure you are comfortable with them. The tasks we will be using have been used at the MRC CBSU and usually present volunteers with no significant problems. The scanning session will take about one and a half hours, although you will not actually be scanned for more than 45 minutes of this time.

What is the device involved?

We can learn a great deal about how the brain works by looking at the blood flow to different parts of the brain whilst the brain performs different tasks. We need to obtain this information in both health and disease. We measure brain function using images taken with a magnetic resonance imaging scanner. This scanner uses a strong magnetic field to create detailed images of brain structure and function. By taking a series of images whilst you perform a task we can build up a picture of the brain areas activated by this type of function. The scan does not involve any injections or X-rays.

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

The scanner can be loud when it takes images, and you will be given earplugs and ear defenders to block out some of the sound. Also, the MR environment is quite confined, and people who are uncomfortable in small or confined spaces may not be able to participate. If this should be you, remember that you may withdraw from the study at any time without explaining why. Otherwise MRI is generally thought to be a safe, non-invasive imaging technique. There are no known risks or side effects.

What are the possible benefits of taking part?

We will reimburse you for your time and contribute towards the cost of your travel, and you will have the pleasure of knowing that you have made a contribution to our understanding of the relationship between brain and behaviour. If you wish you can take away a picture of your brain on the day of your scan. There will be no other direct benefits from being involved in the study.

What if new information becomes available?

If any new information pertains specifically to the health of the volunteer, the volunteer will be informed. Otherwise, new information will be disseminated through traditional scientific channels (journal articles, conference presentations).

What happens at the end of the study?

When data from several volunteers is collected, it will be analyzed and written up for publication in a scientific journal. The results may also be presented at scientific meetings, or in talks at academic institutions. Results will always be presented in such a way that data from individual volunteers cannot be identified.

Confidentiality – who will have access to the data?

Members of the Cognition and Brain Sciences Unit (CBSU) and members of the research group will have access to personally identifiable data, such as names and addresses, which are held securely on our servers. The retention of this personally identifiable data is necessary for the management of our volunteer panels, payments to volunteers and for procedures in the case of unusual findings of potential relevance to participants' health. Data are presented in scientific publications, talks etc. in such a way that individual participants cannot be identified (group averages and averaged brain images are typically used). Research data are expensive to collect for the tax payers and charities supporting the research, and may have considerable scientific value beyond the questions for which they were originally collected. New analyses may therefore be conducted by the original CBSU research team or by other CBSU researchers. In addition, there is an increasing emphasis on 'Open Science' and some scientific journals are now making deposition of Open Data – i.e. data that can be accessed by anyone – condition of publication. Therefore anonymised data may also be shared with other researchers around the world. We take steps to ensure that data analysed outside the CBSU are stripped of any personally identifiable information that could link them to an individual, including in the case of brain imaging data ensuring that facial features cannot be reconstructed. This means that your identity will never be disclosed to anyone else, unless we first seek written permission from you.

The MRC complies with the requirements of the Data Protection Act 1998 with regard to the collection, storage, processing and disclosure of personal information and is committed to upholding the Acts core Data Protection Principles. All enquiries concerning access to data held by the Cognition and Brain Sciences Unit should be addressed to the Freedom of Information Liaison Officer at the Unit in the first instance.

What happens if my scan shows something unusual? Will my GP be informed?

Your GP will not be routinely informed if your participation in this study has been as a normal volunteer. This is not a diagnostic scan but if something abnormal is detected you will be appropriately counselled and referred to an appropriate specialist in consultation with your General Practitioner if that is what you would like. Such early detection of an abnormality has the benefit of starting treatment early but, in a small number of cases, may have implications for future employment and insurance.

What will happen to the study results?

They will be kept securely for a minimum of 10 years and possibly indefinitely in the CBSU data archive in accordance with good research practice.

Are there compensation arrangements if something goes wrong?

In the very unlikely event of anything untoward happening, the MRC covers all volunteers against negligent harm.

Will video/audio tapes be used?

There is no routine video or audio recording during scanning sessions at the CBSU. In an instance where recording equipment is planned to be used you will be informed in advance and your consent will be sought.

Can I withdraw from the study?

You may withdraw from the study at any time without explaining why.

Who has approved this study?

This research study has been approved by the [Addenbrookes NHS Trust](#) Local Research Ethics Committee.

Thank you for considering taking part in this study. If you require any further information, we will be pleased to help you in any way we can.

[Your full contact details here](#)
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