INFORMATION FOR VOLUNTEERS

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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.

Thank you for reading this.

Project Title: Genetic Factors Affecting the Neural Coding of Emotional Signals in Humans

What is the purpose of this study?

Previous research has shown that particular areas of the brain are associated with specific individual emotions. This study aims to use functional magnetic resonance imaging (fMRI) to provide a more detailed analysis of these brain systems. The findings will improve our understanding of the way in which our brains process emotional information, and may provide important new information for understanding emotional disorders.

Who is organising the study?

The study is organised by scientists at the Medical Research Council (MRC) Cognition and Brain Sciences Unit (CBU). The scientists are Dr. Andrew Calder, Dr. Luca Passamonti, Dr Michael Ewbank, Dr Elisabeth von dem Hagen and Dr. Sonia Bishop.

Why have I been chosen?

You have been selected for this study based on your initial recruitment to the Cambridge BioResource. When you joined this panel you provided a saliva or blood sample for genetic analysis. The results showed that your ‘genotype’ (genetic make-up) is relevant to the aims of this study. Please note, however, that when you come for testing, the experimenters will not have access to this information. Genetic information is only made available on completion of the study.

What does the study involve?

The genotypes we are interested in are not diagnostic of disease or disorder, so the study is unlikely to have any immediate clinical relevance to you personally. However, different genotypes can affect the brain’s response to different tasks and this will be investigated at the Cognition and Brain Sciences Unit using a brain scanning technique known as functional magnetic resonance imaging (fMRI). More information about what is involved is provided below.

What will you be doing?

You may be asked to perform a number of different tasks, either whilst undergoing fMRI scanning or behavioural testing outside the scanner. The

Volunteer Information Sheet cont.

tasks will be quite simple and will be explained in detail before you go into the scanner. You will have the opportunity to practice and ask any questions you may have before we start. The tasks will vary with the particular question we want to investigate, but in general they will involve looking at pictures of facial expressions or emotional scenes, listening to sounds, or reading emotional sentences. In addition, we may ask you to make decisions about the items (e.g., is the face male or female?) and rate how emotional you find the items. Some of the images may contain material that is unpleasant (e.g., pictures of rotten foods, cockroaches). You will be given a chance to view representative images from this collection, prior to participation in the studies, in order to decide whether or not you would like to take part. The emotional materials have been used in a large number of studies worldwide, in well over one thousand volunteers, and usually present participants with no significant problems. After testing, we may also measure your height and weight, and ask you to fill out some simple questionnaires.

What is MRI scanning?

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 measure brain function using images taken with a magnetic resonance imaging (MRI) 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 that are activated. The scan does not involve any medications, injections or X-rays, and MRI is generally a safe, non-invasive technique.

Like faces, brains come in all shapes and sizes, so there is normal variation in what the scan shows. There is a chance of less than 1:100 that your MR scan may show a significant abnormality of which you are unaware. In the unlikely event that this is the case, you will be offered appropriate counselling and a referral to an appropriate specialist taken in consultation with your General Practitioner. Early detection of any problems has the benefit of starting treatment promptly but, in a small number of cases, may have implications for future employment and insurance.

What does the fMRI scanning procedure involve?

Before your scan, a member of staff will ask you some questions to ensure that you have no metal on or within your body when you enter the scanner’s strong magnetic field. You will then be asked to lie in the scanner and the scanning will start. The scanning can be noisy at times, so we will give you ear plugs as well as headphones to reduce this noise. During some of the scans you will be asked you to perform a simple task by pressing a button in your hand. The testing session will take about 90 minutes, although you will only be in the scanner for up to one hour.

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

The scanner can be loud when it takes images, and you will be given headphones and earplugs to block out some of the sound. Also, the scanner environment is quite confined, and people who are uncomfortable in small or confined spaces may not be able to participate. If this applies to 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 in this study?

We will reimburse you for your time and travel, and you will have made a contribution to our understanding of the relationship between brain and behaviour. You will also be helping to reduce research demands on patients. However, there will be no direct benefits to you in terms of any treatment you might be receiving.

What if new information becomes available?

If the 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 are collected, they will be analysed 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?

The data will be stored on a secure network at the MRC Cognition and Brain Sciences Unit, and only members of the Cognition and Brain Sciences Unit and their collaborators will have access to it.

Will my GP be informed?

Your GP will not be routinely informed of your participation. As discussed, however, there is a chance of less than 1:100 that your MR scan may show a significant abnormality of which you are unaware. In such circumstances, you will be appropriately counselled. You will be referred to the appropriate specialist in consultation with your General Practitioner if that is what you would like.

What will happen to the study results?

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

Are there compensation arrangements if something goes wrong?

In the unlikely event of anything untoward happening, insurance cover for negligent harm will be provided by the Medical Research Council. The Medical Research Council will provide no insurance cover for non-negligent harm, but will give 'sympathetic hearing' to claims.

Will video or audio tapes be used?

The study does not involve recording with video or audio equipment.

Finally, we would like to emphasise that you are able to withdraw from the experiments at any time, without explaining why, and that not taking part would not affect any treatment you might be receiving in any way.

This research study has been approved by the Cambridge Research Ethics Committee.

If you would like further information or would like to discuss any aspect of volunteering for this study, please contact:

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Thank you for taking the time to read this information sheet. Our research depends entirely on the goodwill of potential volunteers such as yourself. If you require any further information, we will be only too happy to be contacted, either to discuss things over the telephone or in person.