

Participant Information for the study:

Sample only

IMPORTANT: This is only a sample information sheet. Information sheets may be slightly different for each study. It is important that you read and understand the particular information sheet that is given to you *before* you participate in the study.

You are invited to participate in a Research Project that is explained below. Thank you for taking the time to read this information. The statement is 3 pages long. Please make sure you have all the pages.

This project follows the guidelines of the National Health and Medical Research Council Statement on Human Experimentation, including approval by a properly constituted ethics committee.

What is the Research Project about?

The project aims to determine (1) what parts of the brain are active when we perform a variety of tasks and 2) how these brain regions detect and interpret these tasks. We will use two methods to study these aspects of brain function, namely (1) functional MRI brain scanning and (2) MR spectroscopy of the brain. Functional MRI is a type of brain imaging which provides pictures of brain function, rather than brain structure, and is currently used by doctors at the hospital to localise language and limb movement parts of the brain prior to surgery. We will use this technique to find the parts of the brain that activate in response to the task and whether chemical abnormality occurs in those parts of the brain. MR spectroscopy measures the chemicals in the brain.

Who are the Researchers?

The researchers are scientists and neurologists from the Brain Research Institute, and the Austin & Repatriation Medical Centre, who have expertise in epilepsy, brain imaging and brain physiology. They are

Why am I being asked to be in this research project?

We would like the opportunity to study your brain response to tasks using functional MRI and MR spectroscopy, which can be used to study areas which can be affected by epilepsy.

What do I need to do to be in this research project?

If you choose to participate in this research project, you will need to have one visit to the Brain Research Institute, located at the Austin Repatriation Medical Centre, in Heidelberg. The visit will consist of an MRI scanning session, followed by an out-of-scanner task, and a questionnaire regarding your experience inside the scanner.

Functional MRI is similar to previous MRI scans that you may have had, although we may need to keep your head still with a strap across your forehead. You will lie in the MRI scanner and will be asked to perform some tasks. The tasks which you may be asked to perform are listed in the following section. **You will be in the MRI scanner for about 40 to 70 minutes.**

What tasks shall I be required to perform in the scanner?

You will be asked to perform one or more tasks while you are in the MRI scanner. The specific details of the tasks will be carefully explained to you, and you will have the opportunity to become familiar with the tasks in the MRI scanner. The tasks will be selected from the following categories: Motor / Movement (e.g. finger movement), Sensory / Touch (e.g. have your fingers lightly brushed), Visual

(e.g. look at a moving pattern on a video screen), Memory (e.g. try to remember a list of words), Language (e.g. think of words beginning with a given letter), Emotion (e.g. think of a happy place), Cognitive (e.g. “what is five plus seven?”) or a combination of the above (e.g. “Choose the word that best describes this picture?”).

Is there likely to be a benefit to me?

Participants in this study are perfectly healthy volunteers. This study is not designed to be used for screening or diagnosis. Some subjects find participation in functional MRI studies and the opportunity to visualise their own brain afterwards an interesting experience.

What happens if something abnormal is found in my scans?

As part of your study we will obtain a limited number of pictures of your brain. Our research studies are designed to improve our knowledge of the brain. They are not designed for diagnostic or clinical purposes. After your scan, a specialist will examine these pictures (this will not be done on the day of your study).

Minor changes are sometimes found in completely healthy people. You should be aware that because our pictures are taken for a specific research purpose, not all abnormalities that might be detected by other MR scans are necessarily seen. On extremely rare occasions, we might find an abnormality that is significant and which should be investigated further. If we find such a significant abnormality in your brain, we will contact the researcher directly involved in your study. It is then their responsibility to follow up these findings with you.

Although a significant abnormality is extremely unlikely, you should be aware that if such an abnormality is detected and you are informed, then this knowledge may have consequences for you. Please take the time to consider carefully what it would mean to you if we told you of an abnormality in your brain which might, or might not, affect you later in life. Knowledge of an abnormality may affect your ability to work in certain professions, obtain life or health insurance and other facets of daily living. If you do not want to know, then it is better not to participate.

Is there likely to be a benefit to others in the future?

We anticipate that this research will provide important information about the network involved in language processing. Such knowledge is of critical importance, for example in the diagnosis of language disorders, and in pre-operative evaluation of patients where surgery may jeopardise language function.

What are the possible risks and side effects for me?

There are no known risks from the MRI scanning except for dangers associated with metal implants. Bringing metal into the scanner can be dangerous because of the very strong magnetic field. **You must not bring any metal into the MRI scanner.** If you have metal implants, you may not be able to participate. Prior to going into the MRI scanner, you will be screened by the MRI technologist to make sure that you can safely be put into the scanner. The MRI scanner is noisy, so you will wear special headphones to reduce the noise. There is no harmful radiation and no need for injections with MRI scanning.

What are the possible discomforts?

The MRI scanner is shaped like a tunnel and is a bit tight for space. It also makes a loud hammering sound. You will wear headphones to lessen the scanner noise. You may also occasionally feel warmth. Foam cushioning and Velcro straps are used to keep your head relatively still during scanning. While the cushions and straps are restraining, they should not be uncomfortable. We will be

able to see and communicate with you during the scanning. If you are becoming uncomfortable or having difficulty concentrating during the session, we can stop the scanning and if desired, continue at another time. You can also request that the scanning be stopped at any time by pushing on a button.

What are the likely things that could be an inconvenience for me?

The possible inconveniences to you relate mostly to the time that the test takes. We will try to perform the MRI study at a time of convenience. Parking is available very close to the scanner.

What will be done to make sure the information is confidential?

We will not use your name to identify the test results. Instead, we will use a numeric code to identify participants in our study. We will store all test results in a locked area and on CD-ROMs. We hope to publish the results of our study in a scientific journal and will display any MRI scans with no references to the identity of individuals. The records dealing with your participation will be kept under safe storage for 7 years after completion, and these records may be inspected for purposes of data audit by authorised persons within the institution (eg; Ethics Committee) or outside (eg: sponsors or regulatory bodies).

Will I be informed of the results when the research project is finished?

We will attempt to show you the results of the MRI scans after they are processed. If you wish to know the results of the research project once it has been completed, we would be happy to send you a letter explaining our overall findings.

Participation is voluntary. You can withdraw from this research project at any time. No explanation is needed.

You may like to discuss your participation in this research project with your family and with your doctor. You can ask for further information before deciding if you will take part. You are welcome to have a family member or a friend with you while the project is explained to you.

The name and phone number of the person to contact for more information or in an emergency:

Dr Telephone

Further information about the Brain Research Institute and for an overview of the research projects undertaken here, visit our website, at www.brain.org.au

If you wish to contact someone about this study, you may contact:

Head of study (researcher): ..., Phone (03) ...

Director of BRI: Graeme Jackson, Phone (03) 9496-4076

Chairman of ... Human Research Ethics Committee (independent of study):
..., Phone: (03) ...

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