



## Participant Information Sheet

### Royal Adelaide Hospital

Department of Neurology  
Clinical Neurophysiology  
Stroke Unit

5th Floor  
Emergency Block  
North Terrace  
Adelaide SA 5000

Tel 08 8222 5289  
Fax 08 8222 2984  
Outpatient Bookings  
08 8222 2172

Email  
RAH.Neurology@health.sa.gov.au  
www.health.sa.gov.au

**Head of Department**  
Prof PD Thompson

**Consultants**  
Dr M Kiley  
A/Professor TE Kimber  
Dr CS Kneebone  
Dr J Ravindran  
A/Professor JA Terniott  
Professor PD Thompson  
Dr T Kleinig

**Research Nurse**  
Lynda Adams

**Clinical Neurophysiology**  
(EEG, EMG, Evoked Potentials)  
Tel 08 8222 5299

**Senior Clinical Scientist**  
Ms J Le Mottée

**Epilepsy Research using the Internet; an International Pilot Study**  
**Collection of information about seizures and treatment via the Internet**  
**Principal Investigator: Dr Michelle Kiley,**

You are invited to take part in a research study about epilepsy and seizures. In this study, information will be collected over the Internet, and stored in a secure international database which can be accessed via the internet only by approved investigators. Please take your time to think about it and decide whether you wish to take part. You do not have to give permission, and if you choose not to, it will not affect the management of your seizures at all.

### Why are you being asked? – What is it all about?

There are many drugs which are available to treat patients with seizures or epilepsy. All of these drugs have been shown to be effective in reducing the likelihood of seizures, though they do not prevent all seizures in all patients. Indeed, some drugs seem to have very little effect in some patients.

Unfortunately, doctors often cannot predict which drug will work best for a particular person.

We hope to undertake studies to learn more about which of the various anti-epileptic drugs work best in different sorts of seizures. We think this can be done by using the Internet to gather information and coordinate drug studies.

At this stage, the major focus of our research is to check whether patients can be registered and followed via the Internet. We are now undertaking an International Pilot Study to check if this is a realistic goal; once we have demonstrated this approach works, we will be able to arrange studies in which drugs are directly compared with one another.

### What happens during the study?

If you give permission, we will ask your doctor to fill in a form via the Internet to tell us:

- what sort of seizures you have
- how often your seizures occur
- what investigations (scans and EEGs) you have had
- what drugs you are using or have already used
- when your drugs are changed.

Epilepsy Research Using the Internet

RAH v2 16 December 2010 adapted from New Zealand Master Copy v1 dated 23 January 2009

Information will be transmitted over the Internet using secure connections. We will collect the following information about you:

- name
- date of birth
- sex
- ethnicity
- hospital number.

Data that will be stored also includes details of your epilepsy, including causes (where known), details of any medications you may have taken or be currently taking and details of recreational drug use and alcohol use.

### **Confidentiality**

We need to collect this information so that we can be sure that we do not mix you up with anyone else. However, this information will not be made available to anyone else, unless you allow other doctors who are taking part in this International Pilot Study to have access to it. Every effort will be made to keep all information about you confidential to the extent allowed by law. However, absolute confidentiality cannot be guaranteed.

### **What information may be used and given to others?**

If you choose to take part in this study, the study doctor will collect personal information about you. This may include information that might identify you. The study doctor may also collect information about your health such as:

- Past and present medical records
- Research records, including but not limited to information about physical exams, laboratory and other test results, diaries and questionnaires.

The TGA or other government health authorities and the Ethics committee, a group of people who independently review research, may inspect your medical records relating to this study at any time. These bodies are required to handle this information in a confidential manner.

No material which could identify you will be used in any reports on this study.

## **Risks and Benefits**

You will not be put at any risk by taking part. However, all anti-epileptic drugs do carry some risk of side-effects, but these risks are neither increased nor reduced by taking part in this study.

There will be several benefits that will result from your taking part in this study:

1) We may learn more about the different types of seizures and epilepsy that occurs in Australia and in other countries, and how people are being treated here and overseas.

2) We may find out more about the areas of greatest uncertainty in the management of epilepsy. This will enable us to design further studies to clear up some of these areas of uncertainty.

3) All the information that your doctor enters about you will be available to the doctor in summary form when you return to a clinic. This may help with the ongoing management of your seizures, since the doctor will not have to search back through old notes and letters to see when you had particular investigations, and what drugs you have used, or how effective they were. This information will be immediately available once the doctor logs on to the Internet site once again.

However any benefit may be dependent on subsequent studies being completed.

## **Participation**

Your participation is entirely voluntary (your choice). If you do give permission, you will be free to withdraw from the study at any time, without having to give a reason, and this will not affect your future health care. If you withdraw your consent, we will then stop collecting any information about you and your seizures.

You will not be paid for your participation.

You are able to take as much time as you like deciding whether to participate in the study.

Your treatment will not be changed as a result of taking part in this study. Your doctor, after discussion with you, will make the best decisions he or she can regarding the management of your seizures. We would like to find out what happens as a result of these decisions, and we are seeking your permission to collect this information.

## **Future Studies**

This study is a pilot study. We will collect information on patients from many countries around the world, and we will store this information in a secure database for 18 months.

Epilepsy Research Using the Internet

RAH v2 16 December 2010 adapted from New Zealand Master Copy v1 dated 23 January 2009

If you agree to take part in this study, you will not be committed in any way to take part in any further study. However, we hope that this pilot study will be followed by further studies in which we will compare different drugs or combinations of drugs, or study other aspects of the management of patients with epilepsy.

You have the option of requesting that your information is deleted from the database at the completion of the pilot study, or that it is kept in the database to see if you may be suitable for any future studies. (Your information will automatically be kept in the database unless you tell us that you do not want it kept.). Any future studies using this database will be submitted to the Royal Adelaide Hospitals Research Ethics Committee before any enrolled patients data is used. If additional data is required from participants currently enrolled approval will be sought from the Ethics Committee specifying the information required.

If you do choose to let us keep your information in the database, you will not be committed to taking part in any future trials. You will still be free to withdraw from the study at any time, without having to give a reason, and this will not affect your future health care.

If we find that you are eligible for a future trial, then we will give you further information about that study, and you will have plenty of opportunity to consider whether or not to participate. We will not be asking you to use any experimental treatments or new drugs.

### **General Information**

If you wish, you may ask a friend or family member to help you understand the risks and / or benefits of this study and any other explanation you may require. If you need an interpreter, one can be provided, though this may require that you come back to another appointment.

### **Who should I contact if I have further questions?**

If you have any questions about the study, do not hesitate to contact the Principal Investigator, Dr Kiley on 08 8222 5289 or the Research Nurses on 08 8222 2985. **If you wish to speak to someone not directly involved in the study about your rights as a volunteer, or about the conduct of the study, you may also contact the Chairman, Research Ethics Committee, Royal Adelaide Hospital on 8222 4139.**