Austin Health

Participant Information and Consent Form

Study Title: Feasibility study testing an internet based system developed to run a multi-centre epilepsy database

Principal Investigator: Professor Samuel Berkovic

1. Introduction

You are invited to take part in a research study about epilepsy and seizures. In this study, information will be collected and entered into an internet based database. Please take your time to think about it and decide whether you wish to take part. If you wish, you may ask a friend or family member to help you understand the details of this study and any other explanation you may require. You do not have to give permission, and if you choose not to, it will not affect the management of your seizures at all.

2. What is the purpose of the study

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. To do this we have generated an internet based database which collects and compares participant's clinical information. This study's focus is to assess the system's capabilities at registering participants and following them via the internet. Once we have demonstrated that this approach works, follow on studies can potentially use the system to arrange studies in which drugs are directly compared with one another. Further consent will be sought if a follow on study is suitable for you.

3. Why have I been invited to participate?

You have been invited to participate by your study doctor as you suffer from seizures. If you agree to participate, you will be one of about 60 participants in this study, 20 of which will be from the Austin Hospital. This study is being conducted at approximately 3 research centres both in Australia and New Zealand.

4. 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 drugs you are using or have already used
- when and why your drugs have been changed.

We hope to collect this information on 20 participants from the Austin Hospital. By doing this we hope to get a clearer picture of what drugs work best for particular types of seizures. This study will take approximately 18 months.

Information will be transmitted over the internet using secure connections, similar to that which is used by banks.
We will also collect the following information about you:

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

We need to collect this information so that we can be sure that we do not mix you up with anyone else

5. Risks and Benefits

You will not be put at any risk by taking part in this study.
We cannot guarantee or promise that you will receive any benefits from this research, however, possible benefits may include;

1) We will learn more about the different types of seizures and epilepsy that occur in Australia, and how people are being treated here.
2) We will 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 will 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 have been. This information will be immediately available once the doctor logs on to the internet site once again.

6. Do I have to take part?

Participation in this study is completely voluntary. If you do decide to take part you will be asked to sign the consent form on the last page of this document to show your agreement to participate. This information sheet is for you to keep. You are free to withdraw from the study at any time without giving a reason and this will not affect the standard of care you receive or any benefits to which you are entitled. Participation in this study will not limit your access to alternative care nor change your existing care. If you withdraw your consent, we will then stop collecting any information about you and your seizures.

There will not be any costs to you for participating in this study and 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.

7. How will my information be stored?

All information collected from you will be stored in a databank in New Zealand run by a New Zealand IT company, ENIGMA. Access to the databank servers is both physically and electronically restricted and requires username and password authentication. The databank servers are housed in a secure data centre inside locked, metal cabinets. All data transmitted via the internet is encrypted. An advanced security coding system that is above the required level for personal health information is used to securely store your identifiable data.

On admission to the study, you will be given a unique alphanumeric (words and numbers) study number, which will be the means by which the study organizers will interact with doctors regarding you and your data. Your personal details will only be made available to the doctor who enrols you and to any other doctor or investigator whom you have explicitly (in writing) approved. Only anonymised data will be available to other research investigators, staff and study organizers. No material which could personally identify you will be used in any reports on this study. At the end of this study you will be given the opportunity to have your information transferred into a new database to be used in future epilepsy studies. If you decide that you do not wish to participate in any future studies your data will be deleted from the database.

8. Future Studies

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 may find that another study may be suitable for you. If this is the case, then we will give you further information about that trial, 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.

9. Can I access research information kept about me?

In accordance with Australian and Victorian privacy laws, you have the right to access the information collected and stored by the researchers about you. Please contact one of the researchers named in section 11. In addition, in accordance with regulatory guidelines, the information collected in this research project will be kept for at least 7 years in a coded format so that only investigators listed in section 11 can identify which data is yours.

10. Is this research approved?

The ethical aspects of this research project have been approved by the Austin Health Human Research Ethics Committee. This project will be carried out according to the National Statement on Ethical Conduct In Human Research (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies

11. 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, Prof. Samuel Berkovic using the details below.

Thank you for reading and considering this information.

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Co-investigators:
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Dr. Kheng Seang Lim (Associate Researcher) Consultant Neurologist, Epilepsy Research Centre
Dr. Meng-Han Tsai (Associate Researcher) Consultant Neurologist, Epilepsy Research Centre

12. For complaints

If you wish to contact someone, independent of the study about ethical issues, or your rights, or to make a complaint, you may contact Ms Jill Davis, Manager Research Ethics Unit, Telephone 03 9496 4034

Austin Health

Consent Form to Participate in Research

Project Title: Feasibility study testing an internet based system developed to run a multi-centre epilepsy database

- I have read and I understand the information sheet **"**Feasibility study testing an internet based system developed to run a multi-centre epilepsy database**"** dated 15th June 2010.
- I understand that this study is to try to learn more about the best management for different sorts of seizures.
- I understand that information about my seizures will be transmitted via a secure link to a central computer over the internet.
- I understand that this information will be available to the neurologist who is involved in managing my seizures.
- I understand that taking part in this study is voluntary (my choice) and that I can withdraw from the study at any time and this will in no way affect my continuing health care.
- I understand that my participation in this study is confidential and that no material which could identify me will be used in any reports on this study.
- I have had the opportunity to discuss this study. I am satisfied with the answers I have been given. I have had time to consider whether to take part.
- I have had the opportunity to use family support or a friend to help me ask questions and understand the study.
- I know who to contact if I have any questions about the study.
- I agree to my GP or other current provider being informed of my participation in this study

YES / NO

I _____(full name) hereby consent to take part in this study.

Date

Signature

Project explained by:

Project role:

Signature:

Date

Notes:

1. *A copy of the consent form to be retained by participant and a copy to be placed in the medical file.*