



Parent/Guardian 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 have been invited to allow your child/ward 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 time to read the information carefully and to decide whether or not you want your child/ward 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 child/ward's 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 for 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 on this database. 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 your child/ward

3. Why has your child/ward been invited to participate?

Your child/ward has been invited to participate by the study doctor as they suffer from seizures. If you agree to your child/ward's participation, they 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 your child/ward has
- how often their seizures occur
- what drugs they are using or have already used
- when and why their drugs have been changed



We hope to collect this information on as many people as possible. 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 your child/ward:

- 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 your child/ward up with anyone else.

5. Risks and Benefits

Your child/ward will not be put at any risk by taking part in this study.

We cannot guarantee or promise that your child/ward 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 your child/ward will be available to the doctor in summary form when your child/ward returns to a clinic. This will help with the ongoing management of their seizures, since the doctor will not have to search back through old notes and letters to see when they had particular investigations and what drugs they have used in the past or how effective they have been. This information will be immediately available once the doctor logs on to the internet site once again.

6. Does my child/ward have to take part?

Participation in this study is completely voluntary. If you do decide that your child/ward can 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 your child/ward receives or any benefits to which they are entitled to. Participation in this study will not limit their access to alternative care nor change their existing care (aside from potential benefits listed above). If you withdraw your consent, we will then stop collecting any information about your child/ward and their seizures.

There will not be any costs associated with participating and you are able to take as much time as you like deciding whether to participate in the study.

Your child/ward's treatment will not be changed as a result of taking part in this study. Your doctor, after discussion with you and your child/ward, will make the best decisions he or she can regarding the management of their 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 child/ward's information be stored?

All information collected from your child/ward 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 child/ward's identifiable data.

On admission to the study, your child/ward 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 your child/ward and their data. Their personal details will only be made available to the doctor who enrolls your child/ward 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 your child/ward will be used in any reports on this study. At the end of this study you will be given the opportunity to have your child/ward's information transferred into a new database to be used in future epilepsy studies. If you decide that you do not wish for your child/ward to participate in any future studies, their data will be deleted from the database.

8. Future Studies

If you agree to your child/ward taking 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 your child/ward. 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 you wish for your child/ward to participate. We will not be asking your child/ward 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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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



Parent/Guardian 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 child/ward’s 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 child/ward’s seizures.
- I understand that taking part in this study is voluntary (my choice) and that I can withdraw my child/ward from the study at any time and this will in no way affect their continuing health care.
- I understand that their participation in this study is confidential and that no material which could identify them 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 child/ward’s GP or other current provider being informed of my child/ward’s 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.