PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Study Title: The EpiNet project; an open-ended, observational study of epilepsy (continuation of previous study; An International Pilot Study of an Internet based platform to run epilepsy trials (Epinet).

WSLHD Human
Research Ethics Committee
APPROVED
Date: 21.8.13

Chief Investigator: Dr Andrew Bleasel
Department of Neurology, Westmead Hospital

Invitation
You are invited to participate in a research study about epilepsy and seizures. In this study, information will be collected and entered into an internet database. The study is being conducted by:
Dr Andrew Bleasel, Department of Neurology, Westmead Hospital
Dr Chong Wong, Department of Neurology, Westmead Hospital
The study is part of an international collaborative study coordinated by Dr Peter Bergin, Department of Neurology, Auckland City Hospital, New Zealand.

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

What is the purpose of the study?
There are many drugs which are available to treat seizures in patients with epilepsy. Although these drugs have been shown to be effective in reducing the likelihood of seizures in patients, they do not prevent all seizures in all patients. Indeed, some drugs seem to have very little effects 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 which kind of seizures. This can be done by using the internet to gather information and coordinate drug studies. To do this we have created an internet based database which collects and compares participant's clinical information. This study's focus is to register participants and following them via the internet. Follow on studies can potentially use the system to arrange studies in which drugs are directly compared with one and other. Further consent will be sought if a follow on study is suitable for you.

Who will be invited to enter the study?
You are invited to participate in this study by your study doctor because you have been diagnosed with epilepsy and have seizures.

Do you have a choice?
Participation in this study is voluntary. It is completely up to you whether or not you choose to participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.
New information about the treatment being studied may become available during the course of the study. You will be kept informed of any significant new findings that may

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affect your willingness to continue in the study. If you wish to withdraw from the study once it has started, you can do so at any time without having to give a reason and we will stop collecting information about you and your seizures.

What will happen on the study?
If you agree to participate in this study, you will be asked to sign the Participant Consent Form. This study will be conducted over an indefinite period of time.
If you agree to participate in this trial, you will be consenting to your doctor filling in a form via the internet to tell us:

- What sort of seizures you have
- How often your seizures occur
- What medications you are using or have already used
- When and why your medications have been changed.

Information will be transmitted over the internet using secure connections, similar to that used by banks.

We will also collect the following information about you:

- Name
- Date of birth
- Gender
- Ethnicity
- Hospital number

This information is collected so that we can be sure that the information is not mixed up with other participants.
Data that will be stored also includes details of your epilepsy, including causes (if known), details of any medications you have taken or are currently taking.

Are there any risks?
You will not be put at any risk by taking part in this study.

Are there any benefits?
This study aims to further medical knowledge and may improve future treatment of epilepsy.

We cannot guarantee that you will receive any benefit from this research, however, possible benefits may include:

1) Our learning more about the different types of seizures and Epilepsy and how their medical treatment varies here in Australia.
2) Our discovering more about the areas of greatest uncertainty in the management of epilepsy. This will allow us to design further studies to clear up these areas of

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uncertainty.

3) All of the information that your doctor enters about you will be available to the doctor in summary form when you return for your next appointment. 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 underwent particular investigations or what medications you have used and how effective they have been. The information will be immediately available once the doctor logs onto the internet site.

Confidentiality / Privacy

Of the people treating you, only Dr Bleasel, Dr Wong and the study coordinator will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will be held securely at Westmead Hospital and also in a databank in New Zealand run by a New Zealand IT company, ENIGMA.

On admission to the study you will be given a unique alphanumeric (words and numbers) study identifier which will be the means by which the study organizers will interact with doctors regarding you and your data. Access to the databank server is both physically and electronically restricted and requires password and username authentication. The databank servers are housed in a secure data center 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.

Your personal details will only be made available to the doctor who enrolls you and to any other doctor or investigator whom you have explicitly (in writing) approved. Only deidentified data will be available to other researcher investigators, staff and study organizers. No material which could personally identify you will be used in any reports on this study.

Will taking part in this study cost me anything, and will I be paid?

Participation in this study will not cost you anything. You will not be paid for participation.

What will happen at the conclusion of the study?

At the end of the study you will be given the opportunity to have your information transferred into a new database to be used in future epilepsy studies, at this stage you will be asked to sign a new participant information and consent form. If you decide that you do not wish to participate in any future studies your data will be deleted from the database.

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What happens with the results?
If you give us your permission by signing the consent document, we plan to discuss/publish the findings in peer-reviewed medical journals and to present them at medical conferences locally and internationally. In any publication, information will be provided in such a way that you cannot be identified. Results of the study will be provided to you, if you wish to have them.

Complaints
This study has been approved by Western Sydney Local Health District Human Research Ethics Committee. If you have any concerns about the conduct of the study, or your rights as a study participant, you may contact:

Ms Jillian Gwynne Lewis, Westmead Hospital Patient Representative, (Contact details: Telephone No 9845 7014 Email address: jillian.lewis@swahs.health.nsw.gov.au). You should quote [HREC project number HREC2013/7/6.3 (3763) AU RED LNR/13/WMEAD/206.]

Contact details
When you have read this information, the researcher Dr Bleasel or Dr Wong will discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact him/her on 9845 6753. If you have any problems while on the study, please contact

Dr Bleasel or Dr Wong:
Working hours Telephone No – 02 9845 6753
After hours Telephone No - via switchboard 02 9845 5555 and ask them to contact Dr Bleasel or Dr Wong on his mobile phone.

Or

Study Coordinator:
Donna Galea Ph 02 9845 5538

Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.

CONSENT TO PARTICIPATE IN RESEARCH

Chief Investigator: Dr Bleasel

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1. I understand that the researcher will conduct this study in a manner conforming to ethical and scientific principles set out by the National Health and Medical Research Council of Australia and the Good Clinical Research Practice Guidelines of the Therapeutic Goods Administration.

2. I acknowledge that I have read, or have had read to me the Participant Information Sheet relating to this study. I acknowledge that I understand the Participant Information Sheet. I acknowledge that the general purposes, methods, demands and possible risks and inconveniences which may occur to me during the study have been explained to me by _____ ("the researcher") and I, being over the age of 16 acknowledge that I understand the general purposes, methods, demands and possible risks and inconveniences which may occur during the study.

3. I acknowledge that I have been given time to consider the information and to seek other advice.

4. I acknowledge that refusal to take part in this study will not affect the usual treatment of my condition.

5. I acknowledge that I am volunteering to take part in this study and I may withdraw at any time.

6. I acknowledge that this research has been approved by the Western Sydney Local Health District Human Research Ethics Committee.

7. I acknowledge that I have received a copy of this form and the Participant Information Sheet, which I have signed.

8. I acknowledge that any regulatory authorities may have access to my medical records relevant to this study to monitor the research in which I am agreeing to participate. However, I understand my identity will not be disclosed to anyone else or in publications or presentations.

Before signing, please read 'IMPORTANT NOTE' following.
IMPORTANT NOTE:
This consent should only be signed as follows:
1. *Where a participant is over the age of 16 years, then by the participant personally.*

Name of participant _____ Date of Birth _____

Address of participant _____

Signature of participant _____ Date: _____

Signature of researcher _____ Date: _____

Signature of witness _____ Date: _____