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**Professor Stephen Leeder AO**  
Chair  
Professor of Public Health &  
Community Medicine

**Dr Jim Hazel**  
Secretary  
Medical Graduate - Endocrinologist

HREC Committee Members:

**Ms Narelle Bell**  
Lawyer

**Sr Patricia Bolster RSM**  
Catholic Chaplain

**Mrs Therese Burke**  
Clinical Trial Coordinator

**Mrs Patricia Fa**  
Clinical Trials Pharmacist

**Mr John Fisher**  
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**Ms Jillian Gwynne Lewis**  
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Medical Graduate - Psychiatrist

**Ms Sheila Holcombe**  
CEO - NBM Medicare Local

**Dr Clement Loy**  
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**Mr John McLeod**  
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**Mrs Janette Parry**  
Laywoman

**Mr John Shaw**  
Layman

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Medical Graduate - Surgeon

**Dr Lynn Sinclair**  
Clinical Nurse Consultant

**Dr Howard Smith**  
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**Prof Shih-chang (Ming) Wang**  
Medical Graduate - Radiologist

**Ms Shane Waterton**  
Laywoman

**Ms Christine Wearne**  
Clinical Psychologist

JH/cw HREC2013/7/6.3(3763) AU RED HREC/13/WMEAD/206

18 November 2013

Dr Andrew Bleasel  
Department of Neurology  
Westmead Hospital

Dear Dr Bleasel

Research Proposal: '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'

We acknowledge Ms Kerry Lenton's letter dated 23 October 2013 which was discussed by the HREC Sub-Committee at its meeting held on 12 November 2013.

The HREC Sub Committee is constituted and operates in accordance with the National Health and Medical Research Council's National Statement on Ethical Conduct in Human Research and the CPMP/ICH Note for Guidance on Good Clinical Practice.

I am pleased to advise that the HREC Sub Committee has granted ethical approval of the Request for Amendment / Modification for this **multicentre** research project being conducted at:

- Westmead Hospital – Chief Investigator Dr Andrew Bleasel and
- Royal North Shore Hospital – Chief Investigator A/Prof Geoffrey Herkes

The following documentation has been reviewed and approved by the HREC Sub Committee:

- Request for Amendment/Modification form, including addition of study staff
- Northern A Health and Disability Ethics Committee approval letter dated 29 May 2013 (for information)
- Post approval submission form dated 13 May 2013
- The EpiNet Project and Database revised study protocol, dated 10 May 2013.
- Master Participant Information and Consent Form, version 1, dated 16 September 2013.

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**HUMAN RESEARCH ETHICS COMMITTEE**

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**WESTERN SYDNEY LOCAL HEALTH DISTRICT**  
ABN 48 702 394 764

WSLHD Office, Westmead Hospital Campus  
Institute Road, Westmead NSW 2145  
PO Box 533, Wentworthville NSW 2145  
Telephone 02 9845 5555

Your request to add Royal North Shore Hospital as a site and A/Prof Geoffrey Herkes and Ms Susan Day as investigators to the study was reviewed and approved. An SSA application must be submitted to the Governance Officer at Royal North Shore Hospital.

A complete copy of the documents submitted for this request for amendment has been forwarded to the WSLHD Research Governance Officer (RGO) along with a copy of this letter. Please forward any additional WSLHD site specific documentation (e.g. Local Participant Information and Consent Forms) to the WSLHD RGO at your earliest convenience.

While ethical approval has been granted for this amendment, the WSLHD RGO may identify some items for clarification, if this is the case you will be contacted directly by the WSLHD RGO.

Please ensure that the Research Governance Officer for each site named on this study receives the updated approved documentation in relation to this amendment.

HREC approval is valid for 12 months from the date of the original approval and continuation of the HREC approval beyond the initial 12 month approval period is contingent upon submission of an annual report each year. A copy of the Annual / Final Research Report Form can be obtained electronically from the Research Office on request.

Yours sincerely



 Dr Jim Hazel  
Secretary  
WSLHD Human Research Ethics Committee

c.c: Ms Margaret Piper – Research Governance Office

WSLHD Human Research Ethics Committee	
Date:	<u>18/05/13</u>

29 May 2013

Dr Peter Bergin  
Neurology  
Support Building, Level 8  
Auckland Hospital  
Park Road  
Auckland 1015

Dear Dr Bergin

Re:	<b>Ethics ref:</b>	<b>MEC/11/EXP/070/AM02</b>
	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) MEC/09/02/016)

I am pleased to advise that this amendment has been approved by the Northern A Health and Disability Ethics Committee. This decision was made through the HDEC Expedited Review pathway.

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,



Dr Brian Fergus  
Chairperson  
Northern A Health and Disability Ethics Committee

Encl: appendix A: documents submitted  
appendix B: statement of compliance and list of members

APPROVED  
Date: 18/11/13

## The EpiNet Project and Database

The EpiNet study group has been established to undertake investigator-led clinical research in epilepsy. The EpiNet study group comprises an international consortium of epileptologists and neurologists who intend to collaborate to try to learn more about the optimal clinical management of patients with epilepsy.

The EpiNet study group has created a secure, international epilepsy database that can be accessed via the internet. The database has been established to follow large groups of patients with specific types of epilepsy or specific problems. We intend to run formal epilepsy registries, and to identify patients who would be suitable for clinical trials in epilepsy. We want to run large, simple, pragmatic, investigator-led, multinational trials on a very low budget. We intend to ask questions that pharmaceutical companies are not asking.

### Control of data.

EpiNet is registered as a sub-trust of the A+ charitable trust, which is based at Auckland Hospital, Auckland, New Zealand. The A+ charitable trust exists to fund independent medical research.

The EpiNet project is being overseen by an International Steering committee. Dr Peter Bergin is the current chairman of the steering committee. The other members of the steering committee are:

Professor Ettore Beghi	(Milan, Italy)
Professor Mark Richardson	(London, UK)
Dr Lynette Sadleir	(Wellington, New Zealand)
Dr Wendy D'Souza	(Melbourne, Australia)
Dr Manjari Tripathi	(New Delhi, India)
Dr Jorge Burneo	(London, Canada)

The EpiNet steering committee is the guardian of the database. Access to information in the database is controlled by the investigators who enter the information. Only investigators who are responsible for the clinical care of the patients can see individual patient records. De-identified information may be reviewed by other members of the collaboration, but this will always be with the agreement of the investigators who have entered the information. Investigators who are not directly involved with the clinical management of patients will NOT be able to see any personal details regarding patients.

### Funding

The EpiNet project is being funded from a variety of sources. Funds are channelled through the A+ Trust at Auckland Hospital, via the EpiNet sub-trust. To date, funding has been obtained from grants from the Neurological Foundation of New Zealand, the A+ trust, the Julius Brendel trust, and research funds of the neurology department at Auckland Hospital. We have also obtained donations from benefactors and pharmaceutical companies, which have entered a sponsorship arrangement whereby they have provided unrestricted educational grants. Sponsors do not have any rights to access any of the data contained within the database. Access to all information will continue to be controlled by the EpiNet steering committee, who will act as the custodian of the composite dataset. Individual datasets will remain the property of the participating physicians, who will be able to withdraw their patients from any study if they so wish.

Further funding will be sought from other research grants and donations, and from further sponsorship arrangements with pharmaceutical companies.

Dr Bergin has asserted ownership of the intellectual property rights to the EpiNet project. However, he has not patented the project, and he has no commercial interest in the project.

# 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)).**

**Chief Investigator:  
Department of**

WSLHD Human  
Research Ethics Committee

## Invitation

APPROVED  
Date: 18/11/13

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

A/Prof Geoffrey Herkes, Department of Neurology, Royal North Shore 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 affect your willingness to continue in the study. If you wish to withdraw from the study once