Health and Disability Ethics Committees

Multi-region Ethics Committee
Ministry of Health
Level 2, 1-3 The Terrace
PO Box 5013
Wellington
Phone (04) 470 0655
(04) 470 0646
Fax (04) 496 2191
Email: multiregion_ethicscommittee@moh.govt.nz

28 April 2009
Amended 15 June 2009

Dr Peter Bergin
Auckland City Hospital
Department of Neurophysiology
Auckland Hospital
Park Street
Auckland

Dear Peter

An international pilot study of an Internet-based platform to run epilepsy trials
Lead Investigator: Dr Peter Bergin
Co-Investigators: Dr Lynette Sadleir, Dr Annamarei Ranta, Dr Nicole McGrath, Dr Paul Timmings, Dr Deborah Mason, Dr Claire Spooner, Dr Elizabeth Walker, Dr Richard Firth
Approved Sites: Auckland City Hospital, Starship Children's Hospital, Christchurch Hospital, Wellington Hospital
MEC/09/02/016

The above study has been given ethical approval by the **Multi-region** Ethics Committee.

Approved Documents

- Information sheet and consent form for Children version 1 dated 23 January 2009
- Information sheet and consent form for Parents version 1 dated 23 January 2009
- Information sheet and consent form for Patients version 1 dated 23 January 2009 for Dr Peter Bergin, Auckland City Hospital
- Information sheet and consent form for Patients version 1 dated 23 January 2009 for Dr Deborah Mason, Christchurch Hospital
- Form A

Certification
The Committee is satisfied that this study is not being conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is being carried out.

Accreditation
The Committee involved in the approval of this study is accredited by the Health Research Council and is constituted and operates in accordance with the Operational Standard for Ethics Committees, April 2006.

Progress Reports
The study is approved until October 2010. The Committee will review the approved application annually and notify the Principal Investigator if it withdraws approval. It is the Principal Investigator's responsibility to forward a progress report covering all sites prior to ethical review of the project in April 2010. The report form is available on http://www.ethicscommittees.health.govt.nz. Please note that failure to provide a progress report may result in the withdrawal of ethical approval. A final report is also required at the conclusion of the study.

Requirements for SAE Reporting
The Principal Investigator will inform the Committee as soon as possible of the following:

- Any related study in another country that has stopped due to serious or unexpected adverse events
- withdrawal from the market for any reason
- all serious adverse events occurring during the study in New Zealand which result in the investigator breaking the blinding code at the time of the SAE or which result in hospitalisation or death.

- all serious adverse events occurring during the study worldwide which are considered related to the study medicine. Where there is a data safety monitoring board in place, serious adverse events occurring outside New Zealand may be reported quarterly.

All SAE reports must be signed by the Principal Investigator and include a comment on whether he/she considers there are any ethical issues relating to this study continuing due to this adverse event. It is assumed by signing the report, the Principal Investigator has undertaken to ensure that all New Zealand investigators are made aware of the event.

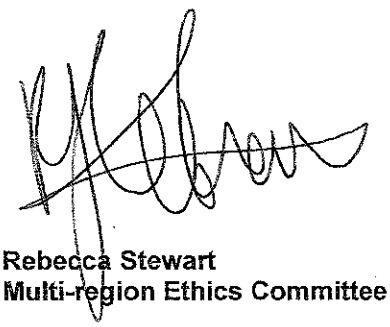
Amendments
All amendments to the study must be advised to the Committee prior to their implementation, except in the case where immediate implementation is required for reasons of safety. In such cases the Committee must be notified as soon as possible of the change.

Please quote the above ethics committee reference number in all correspondence.

The Principal Investigator is responsible for advising any other study sites of approvals and all other correspondence with the Ethics Committee.

It should be noted that Ethics Committee approval does not imply any resource commitment or administrative facilitation by any healthcare provider within whose facility the research is to be carried out. Where applicable, authority for this must be obtained separately from the appropriate manager within the organisation.

Yours sincerely



Rebecca Stewart
Multi-region Ethics Committee Administrator
Email: rebecca_stewart@moh.govt.nz