

28 April 2009

Email: multiregion_ethicscommittee@moh.govt.nz

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
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.

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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

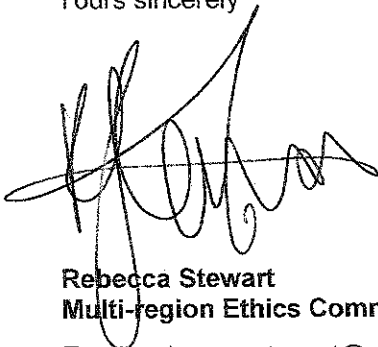
All amendments to the study must be advised to the Committee prior to their implementation, except in the case where immediate implementation is required for reasons of safety. In such cases the Committee must be notified as soon as possible of the change.

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

A handwritten signature in black ink, appearing to read 'Rebecca Stewart', written over a horizontal line.

Rebecca Stewart
Multi-region Ethics Committee Administrator

Email: rebecca_stewart@moh.govt.nz