Health and Disability Ethics Committees
Ministry of Health
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30 June 2014

Dr Peter Bergin
Neurology Department
Auckland City Hospital
Park Road
Grafton
Auckland 1023

Dear Dr Bergin

Re:	**Ethics ref:**	**14/NTB/56**
	Study title:	A series of five pragmatic randomised controlled trials comparing the effectiveness of levetiracetam versus lamotrigine, carbamazepine and sodium valproate for untreated epilepsy: the EpiNet-First trials

I am pleased to advise that this application has been *approved* by the Northern B Health and Disability Ethics Committee. This decision was made through the HDEC-Full Review pathway. The Committee thanked you for the thorough and detailed responses and for provision of age appropriate participant information.

Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Northern B Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.

2. Before the study commences at *any* locality in New Zealand, it must be registered in a WHO-approved clinical trials registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au).

3. Before the study commences at *a given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 30 June 2015.

Participant access to ACC

The Northern B Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Participants injured as a result of treatment received as part of your study may therefore be eligible for publicly-funded compensation through the Accident Compensation Corporation (ACC).

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

Yours sincerely,

Mrs Raewyn Sporle
Chairperson
Northern B Health and Disability Ethics Committee

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

Appendix A
Documents submitted

Document	*Version*	*Date*
Evidence of scientific review: Neurological Foundation reviews	1	30 November 2013
EpiNet First Trials Flowchart	1	31 January 2014
Survey/questionnaire: Quality of Life in Epilepsy survey QOLIE-31. Patients to complete Question 31 VAS scale at baseline and follow-up visits.	1	20 March 1993
CV for CI: CV for Dr Peter Bergin (Chief Investigator)	1	28 March 2014
PIS/CF: Patient Information Sheet and Consent Form - Adult	1	10 April 2014
PIS/CF for persons interested in welfare of non-consenting participant: PISC - Parent or guardian	1	10 April 2014
Patient and Information Sheet and assent Form for patients aged 13 - 15 years	1	10 April 2014
Young person's Patient and Information Sheet and assent Form for patients aged 8 - 12 years	1	10 April 2014
Young person's Information Sheet aged 5-7 years	1	10 April 2014
Covering Letter	1	16 April 2014
Risk Assessment summary sheet	1	17 April 2014
Risk Assessment Schedule	1	17 April 2014
Enigma (software company) Data Handling policy prepared by Engima for Risk Assessment (Appendix 1 of Risk Schedule)	1	27 March 2014
Survey/questionnaire: Seizure Diary	1	17 April 2014
Protocol: EpiNet First Trials protocol	1	15 April 2014
Application		
Covering Letter	V1	20 June 2014
PIS/CF: information sheet for adults	v2	20 June 2014
PIS/CF: Parent proxy PICS	V2	20 June 2014
PIS/CF: Information sheet ,adolescents 13-15years	v2	20 June 2014
PIS/CF: information sheet for children 8-12years	V2	20 June 2014
PIS/CF: Information for children 5-7years formulated as a booklet	V2	20 June 2014
Survey/questionnaire: QOLIE 31 questionnaire for adults 18yrs and over	v1	31 December 1999
Survey/questionnaire: QOLIE 48. Questionnaire adolescents 18yrs and under	v2	31 December 1993
Protocol: Protocol V2	V2	17 June 2014
Response to Request for Further Information		24 June 2014

Appendix B
Statement of compliance and list of members

Statement of compliance

The Northern B Health and Disability Ethics Committee:

- is constituted in accordance with its Terms of Reference
- operates in accordance with the *Standard Operating Procedures for Health and Disability Ethics Committees*, and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008715) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	*Category*	*Appointed*	*Term Expires*
Mrs Raewyn Sporle	Lay (the law)	01/07/2012	01/07/2015
Mrs Maliaga Erick	Lay (consumer/community perspectives)	01/07/2012	01/07/2014
Mrs Kate O'Connor	Non-lay (other)	01/07/2012	01/07/2015
Mrs Stephanie Pollard	Non-lay (intervention studies)	01/07/2012	01/07/2015
Dr Paul Tanser	Non-lay (health/disability service provision)	01/07/2012	01/07/2014
Ms Kerin Thompson	Non-lay (intervention studies)	01/07/2012	01/07/2015

http://www.ethics.health.govt.nz