

27 November 2012

Dr Richard Everts  
7 Sunview Heights  
Richmond  
Nelson 7081

Dear Dr Everts

Re:	<b>Ethics ref:</b>	<b>12/NTB/56</b>
	Study title:	The Effect of Probenecid on Flucloxacillin Pharmacokinetics in Volunteers

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 main ethical issues considered by the Committee were as follows.

- The Committee notes that this is a worthwhile study that has huge potential benefits to both patients and the medical sector.
- The Committee notes that there are no major scientific validity issues.
- The Committee commends the research team for putting together the PIS which is easy to read and in plain English.
- The Committee requested the following changes be made to the Participant Information Sheet:
  - the inserts are difficult to read. Please consider enlarging or removing unnecessary information.
  - page 1 states that “these patients have almost all been cured”. Please reword the sentence using more neutral language
  - page 2 (para 1) states “we will test each volunteer’s blood and by a more modern technique”. Please clarify what specific tests will be done (e.g. serum creatinine and creatinine clearance)
  - the ACC compensation wording is not sufficient. The Committee recommends using the standard ACC compensation text
  - please include Maori health support contact details
  - please refer to the correct ethics committee, the Northern B Health and Disability Ethics Committee, in all instances.

- The Committee requested the following changes be made to the Consent Form:
  - please include a request for interpreter at the beginning of the consent form
  - please refer to the correct ethics committee, the Northern B Health and Disability Ethics Committee, in all instances.

#### 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](http://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](http://www.ethics.health.govt.nz)) for HDEC requirements relating to amendments and other post-approval processes.

#### 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**

<i>Document</i>	<i>Version</i>	<i>Date</i>
CV for CI	1	31 October 2012
Survey/questionnaire: Questionnaire for volunteers at the start of each study day	1	31 October 2012
Protocol	1	31 October 2012
PIS/CF: Information sheet - general	1	31 October 2012
PIS/CF: Information sheet - probenecid	1	31 October 2012
PIS/CF: Information sheet - flucloxacillin	1	31 October 2012
PIS/CF: Consent form	1	31 October 2012
Approval letter from Iwi Health Board	1	31 October 2012
Approval letter for use of Daystay Uni	1	31 October 2012
Evidence of scientific review: Letter explaining statistical methods and access to statistician	1	31 October 2012
Application		

## 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

<i>Name</i>	<i>Category</i>	<i>Appointed</i>	<i>Term Expires</i>	<i>Present on 21/11/2012?</i>	<i>Declaration of interest?</i>
Mrs Raewyn Sporle	Lay (the law)	01/07/2012	01/07/2015	Yes	No
Mrs Maliaga Erick	Lay (consumer/community perspectives)	01/07/2012	01/07/2014	Yes	No
Mrs Mary Anne Gill	Lay (consumer/community perspectives)	01/07/2012	01/07/2015	Yes	No
Mrs Kate O'Connor	Non-lay (other)	01/07/2012	01/07/2015	Yes	No
Mrs Stephanie Pollard	Non-lay (intervention studies)	01/07/2012	01/07/2015	Yes	No
Dr David Stephens	Lay (consumer/community perspectives)	01/07/2012	01/07/2014	Yes	No
Dr Paul Tanser	Non-lay (health/disability service provision)	01/07/2012	01/07/2014	Yes	No
Ms Kerin Thompson	Non-lay (intervention studies)	01/07/2012	01/07/2015	Yes	No

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