Health and Disability Ethics Committees
Ministry of Health
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09 June 2015

Dr Irene Braithwaite
Medical Research Institute of New Zealand
Private Bag 7902
Wellington 6242

Dear Dr Braithwaite

Re:	**Ethics ref:**	**15/NTB/93**
	Study title:	An Open Label, Parallel Group, Randomised Controlled Trial of Topical 5% Aciclovir vs Honevo for the treatment of cold sores in adult participants.

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.

Summary of Study

- Dr Semprini explained that this is essentially the same study that was reviewed by the Committee earlier in the year, with the main change being to the investigational product.

Summary of ethical issues (resolved)

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

- The Committee asked for clarification on the data safety monitoring committee. Dr explained that there are two consultants within Wellington Hospital who have reviewed the protocol. After 100 patients have been recruited, they will give them the safety information and SAEs and how the study is going generally and they will generate reports from there.
- Dr Semprini advised that SCOTT review was underway and was looking at new investigational product. He did not expect any issues as the same formulation had been used for other studies.
- The Committee asked for clarification on the recruitment process. Dr Semprini explained that there will be notes on the pharmacy shelf where coldsore products are available advising customers that there is a trial taking place and to discuss it with the pharmacist if they are interested. The pharmacists will also tell potential participants about the study when they go to buy coldsore products. If a person says yes, there will be a suitable area within the pharmacy where the trial can be discussed. The pharmacist can then go through the PIS and answer any questions the participant may have. Pharmacists will be given pre-randomised packs which will be given sequentially to participants.

- The Committee asked what would stop participants from taking the study treatment and other coldsore treatments. Dr Semprini advised that they would be relying on participants not to and to report it in the study diary and in the final phone call at the end of the study.
- Dr Semprini advised that an organisation in Auckland will conduct the final phone call at the end of the study. This was because they found in a previous acne study that there was too much information recorded in the study diaries and the idea was to keep this information to a minimum and collect the information at the end of the study.
- The Committee commended the researcher for condensing the PIS, while still including key information, based on previous Committee feedback.
- Dr Semprini advised that he had spoken to the Maori Pharmacists Association and local universities as they had struggled to find a national contact number for Maori support that encompasses every iwi. He said he had discussed it with Te Ora, a health network charitable trust in Taranaki who had agreed to provide support and contact on an as needed basis. The plan was to include their contact details in the PIS and the Committee agreed this was acceptable.

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.

Summary of ethical issues (outstanding)

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

- Please consider grouping information in the PIS under key headings. Please refer to the PIS and consent form template on the HDEC website for recommended headings.
- Please make the checklist on page 1 bigger so it is easier to read.
- Please include Te Ora contact details.

Non-standard conditions:

- Please amend the participant information and consent form, taking into account the suggestions by the Committee *(Ethical Guidelines for Intervention Studies, para 6.22).*

Non-standard conditions must be completed before commencing your study. Non-standard conditions do not need to be submitted to or reviewed by HDEC before commencing your study. Do not submit non-standard conditions as a post approval form (PAF).

For information on non-standard conditions please see section 128 and 129 of the Standard Operating Procedures at http://ethics.health.govt.nz/home.

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 03 June 2016.

Participant access to ACC

This clinical trial is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Section 32 of the Accident Compensation Act 2001 provides that participants injured as a result of treatment received as part of this trial will **not** 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 sponsor insurance	1	05 February 2015
Investigator's Brochure: Viraban Product Leaflet	1	01 September 2006
PIS/CF: PISCF	1	15 May 2015
Protocol	1	16 May 2015
Survey/questionnaire: eDiary day 1	1	15 May 2015
Survey/questionnaire: eDiary days 2-14	1	15 May 2015
Survey/questionnaire: Text reminder	1	15 May 2015
Survey/questionnaire: Final phone call reminder	1	15 May 2015
Evidence of scientific review: Peer review	1	05 April 2015
Evidence of CI indemnity	1	31 January 2015
CVs for other Investigators: CVs for other Investigators: Dr Alex Semprini	1	18 February 2015
CV for CI: CI CV: Dr Irene Braithwaite	1	31 January 2015
Investigator's Brochure: Honevo IB	1	08 July 2013
Maori consultation process	1	13 April 2015
Maori consultation process 2	1	11 February 2015
Pharmacy Advertisement	1	11 February 2015
Covering Letter: Covering letter	1	15 May 2015
Public advertisement	1	20 May 2015

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*	*Present on 02/06/2015?*	*Declaration of interest?*
Mrs Raewyn Sporle	Lay (the law)	01/07/2012	01/07/2015	Yes	No
Mrs Maliaga Erick	Lay (consumer/community perspectives)	01/07/2012	01/07/2015	Yes	No
Mrs Phyllis Huitema	Lay (consumer/community perspectives)	19/05/2014	19/05/2017	Yes	No
Miss Tangihaere Macfarlane	Lay (consumer/community perspectives)	19/05/2014	19/05/2017	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 Paul Tanser	Non-lay (health/disability service provision)	01/07/2012	01/07/2015	Yes	No

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