Health and Disability Ethics Committees
Ministry of Health
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31 March 2015

Professor Richard Beasley
Medical Research Institute of New Zealand
Private Bag 7902
Wellington 6242

Dear Professor Beasley

Re:	**Ethics ref:**	**15/CEN/33**
	Study title:	Periostin as a predictor of severe exacerbations in asthma

I am pleased to advise that this application has been *approved* by the Central Health and Disability Ethics Committee. This decision was made through the HDEC-Full Review pathway.

Summary of ethical issues

The main ethical issues considered by the Committee were as follows.

- This is a very straightforward application and the committee did not have any major ethical concerns.
- The committee complimented the researchers on providing a participant information sheet that clearly informs patients about what this research involves and also clearly acknowledges cultural issues that may arise in regard to the use of human tissue.
- The committee complimented the researchers on the answers given in the application form in regard to consultation with Māori.
- The committee wished to bring it to the researchers' attention that the optional participant information sheet and consent form makes no mention of Periostin.

The committee requested the following change to the participant information sheet and consent form:

- Consent form page 6: please remove the word "that" from the statement "I understand that the compensation provisions in case of injury during the study".

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 Central 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 *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 24 March 2016.

Participant access to ACC

The Central 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 Helen Walker
Chairperson
Central 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*
PIS/CF: PER09 PIS-CF	1	12 March 2015
PIS/CF: PER09 RCR PIS-CF	1	12 March 2015
Evidence of CI indemnity	1	01 February 2014
CV for CI: Prof R Beasley CV	1	14 July 2014
Evidence of scientific review: Scientific review from Prof S Holt	1	13 February 2015
Protocol: PER09 Protocol	1	10 March 2015
Survey/questionnaire: ACQ-7	1	01 November 2001
Survey/questionnaire: AQLQ	1	01 January 2003
PER09 recruitment letter	1	12 March 2015
Covering Letter: HDEC Covering letter	1	12 March 2015
Survey/questionnaire: PER09 Asthma exacerbation questionnaire	1	09 February 2015

Appendix B
Statement of compliance and list of members

Statement of compliance

The Central 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 00008712) 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 24/03/2015?*	*Declaration of interest?*
Mrs Helen Walker	Lay (consumer/community perspectives)	01/07/2012	01/07/2015	Yes	No
Mr Paul Barnett	Lay (the law)	01/07/2012	01/07/2015	Yes	No
Dr Kay de Vries	Non-lay (observational studies)	19/05/2014	19/05/2017	No	No
Mrs Gael Donoghue	Non-lay (health/disability service provision)	01/07/2012	01/07/2015	Yes	No
Mrs Sandy Gill	Lay (consumer/community perspectives)	01/07/2012	01/07/2015	Yes	No
Dr Patries Herst	Non-lay (intervention studies)	01/07/2012	01/07/2015	Yes	No
Dr Dean Quinn	Non-lay (intervention studies)	01/07/2012	01/07/2015	No	No
Dr Cordelia Thomas	Lay (ethical/moral reasoning)	19/05/2014	19/05/2017	Yes	No

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