Health and Disability Ethics Committees
Ministry of Health
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0800 4 ETHICS
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13 June 2019

Dr Alisa Ireland
Hutt Valley Hospital
High st
Lower Hutt 5010

Dear Dr Ireland

Re:	**Ethics ref:**	**19/CEN/56**
	Study title:	Analgesia following Caesarean delivery

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-Expedited Review pathway.

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 *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a WHO-approved registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au) or https://clinicaltrials.gov/.

3. Before the study commences at *each 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.

Non-standard conditions:

4. Please ensure the Participant Information Sheet has headers and footers and that appropriate details are put in these sections. It is important that the correct versions are signed by participants.

Non-standard conditions must be completed before commencing your study, however, they do not need to be submitted to or reviewed by HDEC.

If you would like an acknowledgement of completion of your non-standard conditions you may submit a post approval form amendment through Online Forms. Please clearly

identify in the amendment form that the changes relate to non-standard conditions and ensure that supporting documents (if requested) are tracked/highlighted with changes.

For information on non-standard conditions please see section 128 and 129 of the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz)

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 12 June 2020.

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*	
CV for CI	1	09 November 2016	
Survey/questionnaire: Quality of Recovery - 15 Score	1	29 July 2016	
Covering Letter	1	29 July 2016	
Evidence of scientific review: Hutt Maternity Audit Registration Form	1	29 July 2016	
Protocol: Hospital policy	1	22 March 2019	
Poster advertising patient controlled oral analgesia	1	22 March 2019	
PIS/CF: Patient information leaflet	1	22 March 2019	
Covering Letter: Cover letter for audit	1	23 March 2019	
Evidence of CI indemnity	1	26 March 2019	
Application		27 March 2019	
Covering Letter: Clean updated version	2	29 May 2019	
Covering Letter: Tracked changes updated version	2	29 May 2019	
PIS/CF: Patient information letter including consent form	1	29 May 2019	
PIS/CF: Patient information sheet and consent form.	2	29 May 2019	
Response to Request for Further Information			

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*	
Mrs Helen Walker	Lay (consumer/community perspectives)	01/07/2015	01/07/2018	
Ms Helen Davidson	Lay (ethical/moral reasoning)	06/12/2018	06/12/2021	
Dr Peter Gallagher	Non-lay (health/disability service provision)	30/07/2015	30/07/2018	
Mrs Sandy Gill	Lay (consumer/community perspectives)	30/07/2015	30/07/2018	
Dr Patries Herst	Non-lay (intervention studies)	27/10/2015	27/10/2018	
Dr Dean Quinn	Non-lay (intervention studies)	27/10/2015	27/10/2018	
Dr Cordelia Thomas	Lay (the law)	20/05/2017	20/05/2020	

Unless members resign, vacate or are removed from their office, every member of HDEC shall continue in office until their successor comes into office (HDEC Terms of Reference)

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