

31 March 2015

Dr Christopher Gale
Department of Psychological Medicine
Dunedin School of Medicine, University of Otago
P O box 913
Dunedin 9054

Dear Dr Gale

Re:	Ethics ref:	14/CEN/221
	Study title:	Sodium benzoate in chronic schizophrenia – an open label, add-on safety and efficacy study

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.

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 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 31 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,

A handwritten signature in black ink, appearing to read 'Helen Walker'.

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

<i>Document</i>	<i>Version</i>	<i>Date</i>
CV for CI: Focuse CV CKG	0.1	08 December 2014
Protocol: Protocol for trial	1	03 April 2014
Negative symptom scale	1	12 December 2014
Clinical Global Improvement	1	12 December 2014
Postivien and Negative symptoms scale	1	12 December 2014
PIS/CF: Consent form and patient info sheet will need to be printed on letterhead)	1	15 December 2014
Evidence of scientific review: Peer review document	nil	15 December 2014
Evidence of scientific review: Peer review	nil	15 December 2014
Survey/questionnaire: Rosenberg self esteem scale -- raw version.	0	15 December 2014
Survey/questionnaire: Raw version with coding for the recovery action scale	0.1	15 December 2014
Covering Letter: Cover letter	0.1	15 December 2014
Application		
Impossible to fix typos in report as locked. Formal protest	1	04 March 2015
Impossible to fix typos in report as locked. Formal protest	1	04 March 2015
PIS/CF: Revised consent form	1.2	13 March 2015
Response to Request for Further Information		
Covering Letter: ethicscoverletter.pdf		13 March 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

<i>Name</i>	<i>Category</i>	<i>Appointed</i>	<i>Term Expires</i>
Mrs Helen Walker	Lay (consumer/community perspectives)	01/07/2012	01/07/2015
Mr Paul Barnett	Lay (the law)	01/07/2012	01/07/2015
Dr Kay de Vries	Non-lay (observational studies)	19/05/2014	19/05/2017
Mrs Gael Donoghue	Non-lay (health/disability service provision)	01/07/2012	01/07/2015
Mrs Sandy Gill	Lay (consumer/community perspectives)	01/07/2012	01/07/2015
Dr Patries Herst	Non-lay (intervention studies)	01/07/2012	01/07/2015
Dr Dean Quinn	Non-lay (intervention studies)	01/07/2012	01/07/2015
Dr Cordelia Thomas	Lay (ethical/moral reasoning)	19/05/2014	19/05/2017

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