

27 February 2013

Professor Caroline Crowther
The Liggins Institute
The University of Auckland
Private Bag 92019
Auckland Mail Centre
Auckland
1142

Dear Professor Crowther

Re:	Ethics ref:	13/NTB/18
	Study title:	The Gestational Diabetes Mellitus Study of Detection Thresholds (GEMS)

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-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 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 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.

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: Academic qualifications, professional positions, professional speciality, professional distinctions & memberships and publications.	2	22 January 2013
Evidence of scientific review: Email evidence demonstrating the selection of the GEMS study for HRC grant application.	1	22 January 2013
Investigator's Brochure: Brochure describes background, purpose, entry criteria, study groups, outcomes & sample size for study.	1	23 January 2013
PIS/CF: Information includes: reasons for the study, why you are invited, what's involved, possible benefits & risks, general information & study contacts.	1	25 January 2013
Survey/questionnaire: PDF containing participant questionnaires for all 3 time points (trial entry, 36 wks gestation & 4 months after birth).	1	25 January 2013
Protocol: Aims, background, design, entry criteria, study groups, surveys, outcomes, data analyses, ethical considerations and committee organisation.	1	25 January 2013
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>
Mrs Raewyn Sporle	Lay (the law)	01/07/2012	01/07/2015
Mrs Maliaga Erick	Lay (consumer/community perspectives)	01/07/2012	01/07/2014
Mrs Mary Anne Gill	Lay (consumer/community perspectives)	01/07/2012	01/07/2015
Mrs Kate O'Connor	Non-lay (other)	01/07/2012	01/07/2015
Mrs Stephanie Pollard	Non-lay (intervention studies)	01/07/2012	01/07/2015
Dr David Stephens	Lay (consumer/community perspectives)	01/07/2012	01/07/2014
Dr Paul Tanser	Non-lay (health/disability service provision)	01/07/2012	01/07/2014
Ms Kerin Thompson	Non-lay (intervention studies)	01/07/2012	01/07/2015

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