

04 November 2014

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

Dear Professor Crowther

Re: <b>Ethics ref:</b>	<b>13/NTB/18/AM01</b>
Study title:	The Gestational Diabetes Mellitus Study of Detection Thresholds (GEMS)

I am pleased to advise that this amendment has been approved by the Northern B Health and Disability Ethics Committee. This decision was made through the HDEC Expedited Review pathway.

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,



**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 and approved**

Document	Version	Date
Protocol: GEMS Gestational Diabetes Mellitus Study of Detection Thresholds Protocol updated September 2014	version 5	14 September 2014
Survey/questionnaire: Trial Entry Maternal Health & Well-being Questionnaire. Repeated at 36 weeks gestation and 6 months postpartum.	version 6	17 September 2014
GEMS Protocol Amendment (in full). Supports post-approval application and details all amendments made to the original Protocol approved Feb 2013.	version 5	12 September 2014
CV for CI: CV of Prof Caroline Crowther: academic qualifications, professional positions, professional distinctions and memberships etc.	not specified	18 September 2014
Survey/questionnaire: Trial Entry Maternal Diet Questionnaire, recording food frequency and quantities. Repeated at 36wks gestation and 6 months postpartum.	version 5	16 September 2014
Survey/questionnaire: GEMS Trial Entry Maternal Physical Activity Questionnaire. Repeated at 36 weeks gestation and 6 months postpartum.	version 6	04 September 2014
Survey/questionnaire: 6-month Infant Feeding Behaviour Questionnaire. Assesses baby's appetite.	version 2	16 September 2014
Survey/questionnaire: Infant's 6 month Growth & Activities Questionnaire. Assesses development.	version 1	11 September 2014
Evidence of scientific review: HRC Referee Reports 2014	1	10 September 2014
PIS/CF: Outlines the study, its purpose, what taking part involves and any possible benefits or risks. CF allows for request for interpreter.	version 5	15 October 2014
Survey/questionnaire: GEMS Infant 6 month General Health and Feeding Questionnaire.	version 2	18 September 2014
Letter advising of grant approval for GEMS study from Health Research Council of NZ.	not specified	28 May 2014
Covering letter: Response to Committee's Provisional Approval request for additional information	not specified	16 September 2014
Post Approval Form	AM01	18 September 2014

## 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	01/07/2015
Mrs Phyllis Huitema	Lay (consumer/community perspectives)	19/05/2014	19/05/2017
Miss Tangihaere Macfarlane	Lay (consumer/community perspectives)	19/05/2014	19/05/2017
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 Paul Tanser	Non-lay (health/disability service provision)	01/07/2012	01/07/2015
Ms Kerin Thompson	Non-lay (intervention studies)	01/07/2012	01/07/2015

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