

Health and Disability Ethics Committees
Ministry of Health
133 Molesworth Street
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10 May 2017

Mrs Tanith Alexander 25A Sequoia Place Sunnynook Auckland 0620

Dear Mrs Alexander

Re: Ethics ref: 16/NTA/90/AM02

Study title: Different Approaches to Moderate- and late-preterm Nutrition:

Determinants of feed tolerance, body composition and development

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

The main issues considered by the HDEC in giving approval were as follows.

— The consent form is signed after the baby is born.

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

Yours sincerely.

Dr Brian Fergus Chairperson

Northern A 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
PIS/CF: Amended PIS for the DIAMOND trial	Version 2	24 April 2017
PIS/CF: Consent form amended to include statement regarding collection of information for both the patient and Mother	Version 2	24 April 2017
Survey/questionnaire: Maternal questionnaire to be administered twice once while baby in hospital and at 4 month follow up	Version 1	24 April 2017
Post Approval Form	02	-

## Appendix B Statement of compliance and list of members

## Statement of compliance

The Northern A 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 00008714) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

## List of members

Name	Category	Appointed	Term Expires
Dr Brian Fergus	Lay (consumer/community perspectives)	11/11/2015	11/11/2018
Ms Rosemary Abbott	Lay (the law)	15/03/2016	15/03/2019
Dr Karen Bartholomew	Non-lay (intervention studies)	13/05/2016	13/05/2019
Dr Christine Crooks	Non-lay (intervention studies)	11/11/2015	11/11/2018
Dr Catherine Jackson	Non-lay (health/disability service provision)	11/11/2016	11/11/2019
Ms Toni Millar	Lay (consumer/community perspectives)	11/11/2016	11/11/2019
Dr Kate Parker	Non-lay (observational studies)	11/11/2015	11/11/2018

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