Health and Disability Ethics Committees
Ministry of Health
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23 October 2014

Professor Caroline Crowther
Private Bag 92019
Auckland 1142

Dear Professor Crowther

Re:	**Ethics ref:**	**14/NTA/163**
	Study title:	Optimal glycaemic targets for gestational diabetes: the randomised trial - TARGET

I am pleased to advise that this application has been *approved* by the Northern A 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 A 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 **23 October 2015.**

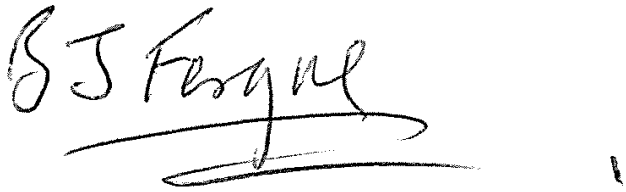
Participant access to ACC

The Northern A 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,



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

Document	*Version*	*Date*
Evidence of scientific review: HRC Referee Reports	Version 1	29 August 2014
CV for CI: Updated CV for Professor Caroline Crowther, Lead Investigator	pdf file	22 September 2014
Survey/questionnaire: TARGET maternal diet questionnaire, collecting data on types and volumes of foods eaten. Repeated at 36 weeks's gestation and 6 months postnatally.	version 1	22 September 2014
Survey/questionnaire: TARGET maternal trial entry health and well-being questionnaire. Repeated at 36 weeks' gestation and 6 months' postnally.	version 1	22 September 2014
Survey/questionnaire: TARGET Trial Entry Maternal Physical Activity Questionnaire. To be repeated at 36 weeks' gestation and 6 months postpartum.	version 1	22 September 2014
Survey/questionnaire: TARGET 6 month Infant Feeding Behaviour Questionnaire. Collects information on baby's appetite for milk during first few months.	version 2	16 September 2014
Survey/questionnaire: TARGET Infant's 6 month Growth and Activities Questionnaire. Includes measuring growth and responses to questions on child's development.	version 1	22 September 2014
Survey/questionnaire: TARGET Infant 6 month General Health and Feeding Questionnaire. Collects info on any health issues since birth and milk and solid feeding patterns.	version 1	22 September 2014
Protocol: TARGET Protocol: a comprehensive description of the TARGET study.	version 5	17 September 2014
PIS/CF: TARGET Participant Information Sheet and Consent Form updated in response to Provisional Approval comments	version 9	15 October 2014
Investigator's Brochure: Brochure describing the TARGET study to Health Professionals.	version 4	24 September 2014
Letter of approval for the TARGET study from the Health Research Council of New Zealand	none specified	11 June 2014
Head of Department Approval Form	1	16 September 2014
Covering Letter: Letter responding to Provisional Approval request by Committee for further information.	version 3	16 October 2014
Application		25 September 2014
Response to Request for Further Information		16 October 2014

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)	01/07/2012	01/07/2015
Dr Karen Bartholomew	Non-lay (intervention studies)	01/07/2013	01/07/2016
Ms Susan Buckland	Lay (consumer/community perspectives)	01/07/2012	01/07/2015
Ms Shamim Chagani	Non-lay (health/disability service provision)	01/07/2012	01/07/2015
Dr Christine Crooks	Non-lay (intervention studies)	01/07/2013	01/07/2015
Mr Kerry Hiini	Lay (consumer/community perspectives)	01/07/2012	01/07/2015
Mr Mark Smith	Non-lay (intervention studies)	01/09/2014	01/09/2015
Ms Michele Stanton	Lay (the law)	01/07/2012	01/07/2015

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