Health and Disability Ethics Committees
Ministry of Health
133 Molesworth Street
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Wellington
6011

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16 May 2019

Dr Rosemary Hall
Endocrine Department
Wellington Hospital
Private bag 7902
Wellington 6242

Dear Dr Hall,

Re:	**Ethics ref:**	**18/NTB/236**
	Study title:	Investigating outcomes of reduced carbohydrate diets in gestational diabetes

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.

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 clinical trials registry. This should be a WHO-approved registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au) or https://clinicaltrials.gov/.

3. Before the study commences at *each 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.

Non-standard conditions:

- The Committee has noted that samples should not be stored with Date of Birth (as in the Information Sheet) as this is considered an identifier. It should only be Year of Birth

- The use of date of birth as a second form of identification on samples is no longer acceptable. The year of birth may be used or a second alphanumeric code created.

Non-standard conditions must be completed before commencing your study, however, they do not need to be submitted to or reviewed by HDEC.

If you would like an acknowledgement of completion of your non-standard conditions you may submit a post approval form amendment through Online Forms. Please clearly

identify in the amendment form that the changes relate to non-standard conditions and ensure that supporting documents (if requested) are tracked/highlighted with changes.

For information on non-standard conditions please see section 128 and 129 of the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz)

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 16/05/2020

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 Kate O'Connor
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

Document	*Version*	*Date*
CV for CI	1	15 November 2018
CVs for other Investigators	1	15 November 2018
CVs for other Investigators	1	15 November 2018
Evidence of scientific review	1	15 November 2018
Evidence of scientific review	1	15 November 2018
PIS/CF: Consent form	1	15 November 2018
Survey/questionnaire: Pregnancy Physical Activity Questionnaire	1	15 November 2018
PIS/CF: PIS only, CF separate	1	15 November 2018
Protocol	1	15 November 2018
PIS/CF: Future use of tissue information sheet and consent form	1	17 December 2018
Application		17 December 2018
PIS/CF for persons interested in welfare of non-consenting participant: Baby consent form	1	13 May 2019
PIS/CF: V2 clean	2	13 May 2019
PIS/CF: V2 tracked changes	2	13 May 2019
PIS/CF: FUR V2 clean	2	13 May 2019
PIS/CF: FUR V2 tracked changes	2	13 May 2019
PIS/CF: Consent V2 clean	2	13 May 2019
PIS/CF: Consent V2 tracked changes	2	13 May 2019
Covering Letter: Addressing outstanding ethical issues	1	13 May 2019
Response to Request for Further Information		

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

Name	*Category*	*Appointed*	*Term Expires*
Mrs Maliaga Erick	Lay (consumer/community perspectives)	01/07/2015	01/07/2018
Mr John Hancock	Lay (the law)	14/12/2015	14/12/2018
Dr Nora Lynch	Non-lay (health/disability service provision)	24/07/2015	24/07/2018
Miss Tangihaere Macfarlane	Lay (consumer/community perspectives)	20/05/2017	20/05/2020
Mrs Kate O'Connor	Lay (ethical/moral reasoning)	14/12/2015	14/12/2018
Mrs Stephanie Pollard	Non-lay (intervention studies)	01/07/2015	01/07/2018
Mrs Leesa Russell	Non-lay (intervention studies), Non-lay (observational studies)	14/12/2015	14/12/2018
Ms Susan Sherrard	Lay (consumer/community perspectives)	19/03/2019	19/03/2022
Mrs Jane Wylie	Non-lay (intervention studies)	20/05/2017	20/05/2020

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