Health and Disability Ethics Committees
Ministry of Health
133 Molesworth Street
PO Box 5013
Wellington
6011

hdecs@moh.govt.nz

11 March 2019

Dr Lara Kimble
170 Scenic Drive
Titirangi
Auckland 0604

Dear Dr Kimble

Re:	**Ethics ref:**	**19/CEN/10**
	Study title:	Curds in the Way: Establishing Normal Sonographic Appearances of Neonatal Bowel on Fortified Breastmilk Feeds

I am pleased to advise that this application has been *approved* by the Central Health and Disability Ethics Committee. This decision was made through the HDEC-Full Review pathway.

Summary of Study

1. The study investigates the 'normal' appearances of abdominal ultrasound on asymptomatic babies to aid the future diagnosis of milk curd obstruction.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

2. The Committee noted the intention to destroy images after six months. The Health Information Privacy Code 1994 requires identifiable health information to be retained for a minimum of ten years. Please revise this.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

3. Please clarify how common milk curd obstruction is as "very rarely" is a relative term. A numerical value is preferred (e.g. 1 in 10,000 births or between 1 and 10 in 1,000,000 births etc).
4. Please include the HDEC contact details (Freephone: 0800 4 38442 (0800 4 Ethic); Email: hdecs@moh.govt.nz).
5. Please include advocacy contact details (Freephone: 0800 555 050; Email: advocacy@advocacy.org.nz)
6. Please amend the statement regarding the deletion of images after six months to comply with the Health Information Privacy Code 1994.
7. The Committee suggested that on the first page of the PIS the second paragraph may be better placed as the first but acknowledged this was a subjective preference.

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 Central 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 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:

4. Please amend the protocol and participant information sheet and consent form taking into account the Committee's requests.

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 11 March 2020.

Participant access to ACC

The Central 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 Helen Walker
Chairperson
Central 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: Full CV	1	11 December 2018
Evidence of CI indemnity	1	11 December 2018
PIS/CF: Patient iformation sheet and consent form.	1	11 December 2018
Protocol: Study rationale and background literature review.	1	11 December 2018
Evidence of scientific review: Research proposal, rationale, and background literature review.	1	11 December 2018
PIS/CF for persons interested in welfare of non-consenting participant: Patient information sheet and consent form for parents/guardians.	1	11 December 2018
Application		03 February 2019

Appendix B
Statement of compliance and list of members

Statement of compliance

The Central 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 00008712) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	*Category*	*Appointed*	*Term Expires*
Mrs Helen Walker	Lay (consumer/community perspectives)	01/07/2015	01/07/2018
Dr Peter Gallagher	Non-lay (health/disability service provision)	30/07/2015	30/07/2018
Mrs Sandy Gill	Lay (consumer/community perspectives)	30/07/2015	30/07/2018
Dr Patries Herst	Non-lay (intervention studies)	27/10/2015	27/10/2018
Dr Dean Quinn	Non-lay (intervention studies)	27/10/2015	27/10/2018
Dr Cordelia Thomas	Lay (the law)	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