Health and Disability Ethics Committees
Ministry of Health
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20 June 2019

Miss Lisa Kremer
Adams Building
Frederick St
Dunedin 9016

Dear Miss Kremer

Re:	**Ethics ref:**	**19/STH/114**
	Study title:	Randomised Controlled Non-Inferiority Trial; Microdrop Administration of Phenylephrine and Cyclopentolate Eye Drops in Neonates

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

Summary of Study

1. This study aims to determine whether low dose versus very low dose pupil dilating eye microdrops are effective in a neonatal population, and if the eye drops are associated with a low risk of harm.

Summary of outstanding ethical issues

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

1. The Committee *suggests* amending the study design so that the blind is broken only in the event of an SAE which requires seeing which dose the participant was assigned to (*Ethical Guidelines for Intervention Studies* paragraph 5.41).
2. The requested that data be stored in a re-identifiable form only, and not with NHI numbers attached (*Ethical Guidelines for Intervention Studies* paragraph 7.2).

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

3. Please add Māori contact numbers (note that the HDC does not provide Māori support).
4. Please amend the statement “If you agree your baby can be part of the study they will receive either a low dose or lower dose” to say “…low dose or very low dose”.
5. Please amend the PIS on page 3 to state that upon withdrawal the baby’s data up to that point will remain in the study, as this is currently inconsistent with the consent form.
6. Please amend to state that reducing the dose *may* reduce the side-effect profile.

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 Southern Health and Disability Ethics Committee is required.

Standard conditions:

7. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.

8. 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/.

9. 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:

- please amend the patient information sheet and consent forms, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies* paragraph 6.22)
- please consider amending the study design as suggested by the Committee (*Ethical Guidelines for Intervention Studies* paragraph 5.41)
- please store study data in a re-identifiable form only (*Ethical Guidelines for Intervention Studies* paragraph 7.2).

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.

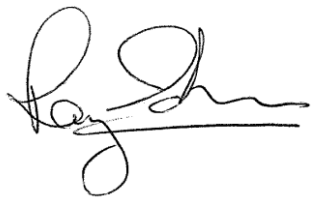
Your next progress report is due by 19 June 2020.

Participant access to ACC

The Southern 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,



Ms Raewyn Idoine
Chairperson
Southern 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*
CVs for other Investigators: Mary-Jane Sime CV	1	30 May 2019
CVs for other Investigators: Nicola Austin CV	1	30 May 2019
Māori Consultation Dunedin School of Medicine	1	30 May 2019
University of Otago Māori Consultation	1	30 May 2019
Protocol: Study Protocol	1	30 May 2019
PIS/CF: PIL/consent form	1	30 May 2019
PIS/CF for persons interested in welfare of non-consenting participant: PIL/consent form	1	30 May 2019
CVs for other Investigators: David Reith CV	1	15 May 2019
CVs for other Investigators: Max Berry CV	1	15 May 2019
CVs for other Investigators: Natalie Medlicott CV	1	15 May 2019
CVs for other Investigators: Roland Broadbent CV	1	15 May 2019
CV for CI: Lisa Kremer CV	1	15 May 2019
Evidence of scientific review: CureKids Peer Review 1	1	15 May 2019
Evidence of scientific review: CureKids peer review 2	1	15 May 2019
Case report form	1	15 May 2019
CVs for other Investigators: Liza Edmonds CV	1	23 May 2019
Application		30 May 2019

Appendix B
Statement of compliance and list of members

Statement of compliance

The Southern 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 00008713) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	*Category*	*Appointed*	*Term Expires*	*Present on 11/06/2019?*	*Declaration of interest?*
Ms Raewyn Idoine	Lay (consumer/community perspectives)	27/10/2015	27/10/2018	Yes	No
Dr Paul Chin	Non-lay (intervention studies)	27/10/2018	27/10/2021	Yes	No
Ms Sandy Gill				Yes	No
Dr Sarah Gunningham	Non-lay (intervention studies)	27/10/2015	27/10/2018	Yes	No
Assc Prof Mira Harrison-Woolrych	Non-lay (intervention studies)	27/10/2015	27/10/2018	Yes	No
Professor Jean Hay-Smith	Non-lay (health/disability service provision)	31/10/2018	31/10/2021	Yes	No
Assc Prof Nicola Swain	Non-lay (observational studies)	27/10/2015	27/10/2018	Yes	No
Dr Devonie Waaka	Non-lay (intervention studies)	18/07/2016	18/07/2019	Yes	No

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