Health and Disability Ethics Committees
Ministry of Health
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20 February 2018

Dr Angus Goodson
NICU,Level 4,
Wellington Hospital
Capital & Coast DHB
Wellington 7902

Dear Dr Goodson

Re:	**Ethics ref:**	**18/NTB/10**
	Study title:	Effect of Retinopathy of Prematurity Screening on cerebral and somatic (splanchnic) regional oxygenation and cardiorespiratory stability in neonates

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-Full Review pathway.

Summary of Study

1. This is a study of the effects of pupil dilatation and examination in premature neonates at risk from retinopathy of prematurity.
2. Researchers explained that there is anecdotal evidence that this process stresses babies and there is suspicion that reduced brain and gut blood flow may underlie this, causing negative outcomes.
3. The incidence of necrotising colitis is suspected to go up after the retinopathy screening procedures. This study aims to measure brain and gut blood flow as well as blood pressure and pulse at various stages during the procedure.
4. The project involves full consent from parents.

Summary of ethical issues (resolved)

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

5. The Researcher(s) explained rationale for the study.
6. The Committee asked whether parents are agreeable to the screening generally. The Researcher(s) stated that any premature baby that meets the criteria for the screening will undergo the test.
7. The Researcher(s) acknowledged talk of possible risks in the research is likely to be more salient than from standard care, as knowledge of risks is anecdotal or based on relatively small studies.
8. The Committee asked whether there is a risk of people saying no due to risks outlined, which could cause harm due to the lack of screening. The Researcher(s) acknowledged this is a risk but explained many iterations of the participant information sheet has led to the current version, to best balance the risks and explain the importance of the screening.

9. The Researcher(s) explained that the usual pamphlets would be given to potential participants, which stresses importance for prevention of blindness.
10. The Researcher(s) explained that potential participants have 3-4 weeks to consider participation, with lots of time to talk through the study.

Summary of ethical issues (outstanding)

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

11. The Committee asked whether any of the measures result in burdens or risks for the babies. The Researcher(s) explained that they have two similar studies running, in terms of the monitoring. Theoretically no issue except for blood pressure monitoring, there are special tools for this. The Researcher(s) experience is that it is fiddly but well tolerated, adding that if there is too much monitoring they can reduce monitoring for the two secondary measures. The Researcher(s) will submit to HDEC if turns out only going for primary outcome.
12. The Committee request this is detailed, i.e. if felt (by clinicians or the parents) that the baby is not tolerating the monitoring they can stop it, and that the research should not cause any stress.
13. r.2.5 – 10 years after 16.
14. Review for technical language – turn into lay language.
15. Add length of time – 3 hours, and how much the research adds to the screening.
16. Visuals are helpful, please consider time lines that are understandable, or a visual time line. P.1.1
17. Moving para 1 to para 3 would result in a more user-friendly approach (less abrupt, confronting).
18. Maori cultural support contact details: Provide name and extension number.

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 B 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 *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.

Non-standard conditions:

- Please amend the information sheet and consent forms, taking into account the suggestions made by the committee *(Ethical Guidelines for Observational Studies para 6.10)*

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

If you would like an acknowledgement of completion of your non-standard conditions letter you may submit a post approval form amendment. Please clearly identify in the amendment 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 at http://ethics.health.govt.nz/home.

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.

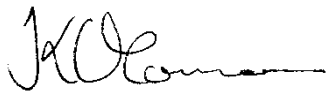
Your next progress report is due by 20 February 2019.

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: CI CV	1	10 January 2018
PIS/CF for persons interested in welfare of non-consenting participant: Parent information sheet	2	10 January 2018
Evidence of scientific review: Scientific review	1	22 December 2017
Protocol: Protocol	3	10 January 2018
PIS/CF for persons interested in welfare of non-consenting participant: Consent form	1	22 December 2017
Evidence of scientific review: The use of near-infrared spectroscopy	1	22 December 2017
Evidence of scientific review: HDEC Peer Review	1	09 January 2018
Application	1	-

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*	*Present on 08/02/2018?*	*Declaration of interest?*
Mrs Maliaga Erick	Lay (consumer/community perspectives)	01/07/2015	01/07/2018	Yes	No
Mr John Hancock	Lay (the law)	14/12/2015	14/12/2018	Yes	No
Dr Nora Lynch	Non-lay (health/disability service provision)	24/07/2015	24/07/2018	Yes	No
Miss Tangihaere Macfarlane	Lay (consumer/community perspectives)	20/05/2017	20/05/2020	Yes	No
Mrs Kate O'Connor	Lay (ethical/moral reasoning)	14/12/2015	14/12/2018	Yes	No
Mrs Stephanie Pollard	Non-lay (intervention studies)	01/07/2015	01/07/2018	Yes	No
Mrs Leesa Russell	Non-lay (intervention studies), Non-lay (observational studies)	14/12/2015	14/12/2018	Yes	No
Mrs Jane Wylie	Non-lay (intervention studies)	20/05/2017	20/05/2020	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