Health and Disability Ethics Committees
Ministry of Health
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07 November 2017

Dr Maria Saito Benz
Department of Paediatrics
University of Otago, Wellington
PO Box 7343
Wellington South 6242

Dear Dr Saito Benz

3:24 p.m.

Re:	**Ethics ref:**	**17/CEN/202**
	Study title:	Near Infrared spectroscopy for Monitoring brain Oxygenation: a single-centre randomised controlled trial of freshly irradiated versus standard red cell transfusion for treatment of anaemia of prematurity (NIMO-Rad)

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 a single-centre randomised controlled trial of freshly irradiated versus standard red cell transfusion for treatment of anaemia in premature babies.

Summary of ethical issues (resolved)

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

2. The Committee queried how recruitment for this study will work. The Researcher explained that parents will be approached after they have had approximately two weeks to acclimatise to the neonatal intensive care unit environment and staff. This will allow them to be comfortable and not under duress when deciding about their child's participation.
3. The Committee noted that this study fills a knowledge gap in the literature.

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:

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

5. 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 (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au). However https://clinicaltrials.gov/ is acceptable provided registration occurs prior to the study commencing at *any* locality in New Zealand.

6. 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:

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

7. Please remove unnecessary checkboxes except for any decisions where indicating no would not exclude participants.
8. Please check the consent form for typographic errors.
9. Move the re-randomisation statement to the information sheet as no new information should be introduced in the consent form.
10. Add that researchers will be contacting participants' GP's about participation.
11. Explain when participants will no longer be able to withdraw study data and seek consent for participants' data to be used until withdrawal in the even that they no longer wish to participate.

Please amend the information sheet and consent form, taking into account the suggestions made by the Committee (*Ethical Guidelines for Intervention Studies para 6.22*).

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 **30 March 2018.**

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*
Covering Letter	1	21 September 2017
Protocol	v5	21 September 2017
PIS/CF for persons interested in welfare of non-consenting participant	1	21 September 2017
PIS/CF	1	21 September 2017
CV for CI	Sept 2017	21 September 2017
Peer review	1	21 September 2017
CVs for other Investigators: CV for Dr Max Berry	1	21 September 2017
CVs for other Investigators: CV for A/Prof Tzeng	1	21 September 2017
CVs for other Investigators: CV for Dr Flanagan	1	21 September 2017
CVs for other Investigators: CV for Dr Wheeler	1	21 September 2017
CVs for other Investigators: CV for Ms Bennington	1	21 September 2017
Evidence of sponsor insurance	1	26 September 2017
Evidence of scientific review	1	25 September 2017
Application		

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*	*Present on 24/10/2017?*	*Declaration of interest?*
Mrs Helen Walker	Lay (consumer/community perspectives)	01/07/2015	01/07/2018	Yes	No
Dr Angela Ballantyne	Lay (ethical/moral reasoning)	30/07/2015	30/07/2018	Yes	No
Dr Melissa Cragg	Non-lay (observational studies)	30/07/2015	30/07/2018	Yes	No
Dr Peter Gallagher	Non-lay (health/disability service provision)	30/07/2015	30/07/2018	Yes	No
Mrs Sandy Gill	Lay (consumer/community perspectives)	30/07/2015	30/07/2018	Yes	No
Dr Patries Herst	Non-lay (intervention studies)	27/10/2015	27/10/2018	Yes	No
Dr Dean Quinn	Non-lay (intervention studies)	27/10/2015	27/10/2018	Yes	No
Dr Cordelia Thomas	Lay (the law)	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