Health and Disability Ethics Committees
Ministry of Health
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01 April 2016

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

Dear Dr Saito Benz

Re:	**Ethics ref:**	**16/CEN/18**
	Study title:	Effect of elective blood transfusion on cerebral, hepatic and muscle regional oxygenation and cardiorespiratory stability in neonates

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

The main ethical issues considered by the Committee were as follows.

- This is an observational study in new born neonatal babies who are anaemic and it aims to develop a better understanding of the mechanism by which elective blood transfusion benefits neonates with anaemia. More specifically, it will examine whether elective blood transfusion increases availability of oxygen to the brain, liver and muscle. Informed consent will be obtained from the study participants' parents.

Summary of ethical issues (resolved)

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

- The committee noted that question p.1.2 on page 19 of the application form that asks whether all participants in the study will be able to give informed consent was answered 'yes' when in fact they will not as they are neonates whose parents will consent on their behalf. The committee noted that the wording of the question is not entirely clear but noted for future reference that this question can be answered 'no' when parents are consenting on behalf of their children.
- Question p.3.2.1 on page 21 of the application form which asks how the study's informed consent process takes the needs of the potentially vulnerable people into account was answered with information including that informed consent will be "sought from parents, or caregivers with a parental right of potential

participants". The committee noted that under s36 of the Care of Children Act that consent must be from a legal guardian, or if there is no guardian in New Zealand or no guardian of that kind can be found with reasonable diligence or is capable of giving consent, by a person in New Zealand who has been acting in the place of a parent.

- The committee noted that the scientific peer reviewer of this study had suggested clarification with the researchers about the timing of the transfusions and whether a capillary gas assessment of haemoglobin and PCO2 will be done pre transfusion. Dr Saito Benz explained that they chose the overnight timing after discussion with the unit's nursing staff as prior to morning handover is the quietest time in the neonatal unit. In terms of the assessment of the capillary gas blood sample, Dr Saito Benz explained that the babies will be having regular blood samples taken as part of standard of care treatment and the monitoring of haemoglobin count and PCO2 count will be provided from the bloods taken from tests that the babies receive as part of standard of care treatment.
- The committee commented on the risk section of the application form, specifically question r.7.1 which asks applicants to briefly indicate whether the study may pose any significant risks to researchers and/or third parties, and how any such risks will be managed. To minimise additional workload the researcher had indicated that she will be on-site. Dr Saito Benz advised the committee that her PhD study is full-time and that she will be on-site all night.
- The committee commended Dr Saito Benz on the answers she had given at questions p.4.1 and p.4.2 that ask about how the study is of relevance to and may benefit Māori participants.

<u>The committee requested the following changes to the participant information sheet and consent forms:</u>

- The committee complemented the researcher on a clearly written participant information sheet and requested only minor changes.
- Page 2, first paragraph, third sentence: please add the word "the" before the words "body's requirement".
- Page 2, This study is for observation only: the committee suggested that it would be clearer to state that: We will recommend a blood transfer if needed.
- Page 4: the committee requested that reference to the position of the baby during data collection be made consistent to read "baby to be lying in the cot facing up".
- Consent Form: the committee noted that yes/no boxes be included only if the statement is truly optional (i.e – that a person could still participate if they answer 'no'). The committee noted that the last statement on page 2 of the form that reads: "I wish to receive a summary of study findings" is optional. Please remove the yes/no boxes for the other statements.

<u>Conditions of HDEC approval</u>

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 *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 condition:

- Please amend the information sheets and consent forms, 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 29 March 2017.

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	1	28 January 2016
Evidence of scientific review	1	15 January 2016
PIS/CF: Participant information sheet	2	15 January 2016
PIS/CF: Consent form	1	15 January 2016
Poster for advertising the study	1	01 February 2016
CVs for other Investigators	1	01 February 2016
CVs for other Investigators	1	01 February 2016
CVs for other Investigators	1	01 February 2016
Protocol	6	01 February 2016
Evidence of CI indemnity	1	02 February 2016

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 22/03/2016?*	*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 (ethical/moral reasoning)	19/05/2014	19/05/2017	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