

Health and Disability Ethics Committees

Ministry of Health
133 Molesworth Street
PO Box 5013

Wellington 6011

0800 4 ETHICS hdecs@moh.govt.nz

26 April 2018

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/NTA/209/AM02

Study title: Near Infrared spectroscopy for Monitoring brain Oxygenation in

Premature infants (NIMO-Prem)

I am pleased to advise that this amendment has been <u>approved</u> by the Northern A Health and Disability Ethics Committee. This decision was made through the HDEC Expedited Review pathway.

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,

Dr Brian Fergus Chairperson

Northern A Health and Disability Ethics Committee

Encl: appendix A: documents submitted

appendix B: statement of compliance and list of members

Appendix A Documents submitted and approved

Document	Version	Date
Protocol	5	10 April 2018
PIS/CF: PIS	3	10 April 2018
Post Approval Form	02	-

Appendix B Statement of compliance and list of members

Statement of compliance

The Northern A 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 00008714) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	Category	Appointed	Term Expires
Dr Brian Fergus	Lay (consumer/community perspectives)	11/11/2015	11/11/2018
Dr Karen Bartholomew	Non-lay (intervention studies)	13/05/2016	13/05/2019
Dr Christine Crooks	Non-lay (intervention studies)	11/11/2015	11/11/2018
Dr Catherine Jackson	Non-lay (health/disability service provision)	11/11/2016	11/11/2019
Ms Toni Millar	Lay (consumer/community perspectives)	11/11/2016	11/11/2019
Dr Kate Parker	Non-lay (observational studies)	11/11/2015	11/11/2018
Ms Rochelle Style	Lay (ethical/moral reasoning)	14/06/2017	14/06/2020

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