

29 March 2017

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

Dear Dr Saito Benz

|                        |  |
|------------------------|--|
| Re: <b>Ethics ref:</b> | <b>16/NTA/209</b>  |
| Study title:           | Near Infrared spectroscopy for Monitoring brain Oxygenation in Premature infants (NIMO-Prem) |

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

#### 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 A 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.

#### After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on [www.ethics.health.govt.nz](http://www.ethics.health.govt.nz)) for HDEC requirements relating to amendments and other post-approval processes.

Your **next progress report** is due by **28 March 2018**.

Participant access to ACC

The Northern A 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,

A handwritten signature in black ink, appearing to read 'B J Fergus', with a horizontal line underneath.

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**

| <i>Document</i>  | <i>Version</i> | <i>Date</i>      |  |
|--|----------------|------------------|--|
| Covering Letter: Cover letter for submission of amended documents  | 2              | 09 March 2017    |  |
| CV for CI  | Nov 16         | 16 November 2016 |  |
| CVs for other Investigators: CV Max Berry  | 1              | 16 November 2016 |  |
| CVs for other Investigators: CV Shieak Tzeng   | 1              | 16 November 2016 |  |
| Evidence of CI indemnity   | 1              | 16 November 2016 |  |
| Evidence of scientific review  | v2 final       | 16 November 2016 |  |
| Protocol   | v4 final       | 26 February 2017 |  |
| Peer review  | 1              | 16 November 2016 |  |
| PIS/CF for persons interested in welfare of non-consenting participant: Participant information sheet (for all participants) | 2              | 26 February 2017 |  |
| PIS/CF: Participant information sheet (retrospective)  | 1              | 16 November 2016 |  |
| PIS/CF: Consent form (for all participants)  | 2              | 26 February 2017 |  |
| PIS/CF: Consent form (retrospective)   | 1              | 16 November 2016 |  |
| Application  |                |                  |  |
| Response to Request for Further Information  |                |                  |  |

## 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

| <i>Name</i>          | <i>Category</i>                               | <i>Appointed</i> | <i>Term Expires</i> |
|----------------------|---|------------------|---------------------|
| Dr Brian Fergus      | Lay (consumer/community perspectives)         | 11/11/2015       | 11/11/2018          |
| Ms Rosemary Abbott   | Lay (the law)                                 | 15/03/2016       | 15/03/2019          |
| Dr Karen Bartholomew | Non-lay (intervention studies)                | 13/05/2016       | 13/05/2019          |
| Dr Charis Brown      | Non-lay (observational studies)               | 11/11/2015       | 11/11/2018          |
| 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          |

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>