



Mercy Health
Care first

16 January 2014

Ms Danielle Forster
409 Albert Street
Brunswick
VIC 3056

Dear Ms Forster

Re: R13/58: Investigation of the Optimal Cooling period for hypothermic treatment of Hypoxic Ischemic Encephalopathy (HIE) in term neonates. (OCHIE)

I am pleased to advise that your application has been considered by members of the Human Research Ethics Committee Expedited Review Working Party and has been granted approval.

This approval is effective immediately and enables you to commence the study, but is subject to the endorsement by the Mercy Health HREC.

In particular, the following documentation is approved for use:

| | |
|--|-----------------------------------|
| NEAF & Victorian Site Specific Assessment Form | Dated 18 November 2013 |
| OCHIE Protocol | Version1, Dated November 2013 |
| Participant Information & Consent Form - Control Group | Version 1, Dated 13 November 2013 |
| Participant Information & Consent Form - HIE | Version1, Dated 13 November 2013 |

The full Human Research Ethics Committee will be advised of the study at its next meeting to be held on 11 February 2014. You will receive a formal letter of approval after this meeting.

In accordance with the NHMRC National Statement on Ethical Conduct in Human Research (2007), approval is subject to:

- Immediate notification of any unforeseen events that may affect the continuing ethical acceptability of the project;
- Notification and reasons for ceasing the project prior to its expected date of completion;
- The completion of a progress report at 6 months and then annually for the duration of the project; (word document of blank progress report will be emailed to you with this letter);

Mercy Health

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- Human Research Ethics Committee approval of any proposed modifications to the project;
- The submission of a final report and papers published on completion of the project.

Please also note:

- The Principal Investigator upon leaving the Institution must inform the Human Research Ethics Committee as to the nominated person to replace him/her.

If you have any queries, please do not hesitate to contact me on 8458 4808.

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'Carole Branch', with a long horizontal flourish extending to the right.

Carole Branch

Administrative Officer, Mercy Health Human Research Ethics Committee.