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24 February 2014

Ms Danielle Forster Honorary Researcher Department of Paediatrics Mercy Hospital for Women 163 Studley Road Heidelberg VIC 3084

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 the Mercy Health Human Research Ethics Committee meeting of 11 February 2014 **endorsed the approval** of the above research proposal. It was noted that the study had formerly received expedited approval from the Mercy Health HREC Expedited Review Working Party.

The Human Research Ethics Committee is constituted and functions in accordance with the National Health and Medical Research Council National Statement on Ethical Conduct in Human Research (2007).

The approval period by the Mercy Health Human Research Committee is from 16 January 2014 to 15 January 2017. That is the project should be completed by the approval expiry date of **15 January 2017**. Should it become apparent that an extension of the 3-year period is required, the principal researcher should apply, in writing, through the Administrative Officer of the Human Research Ethics Committee.

Please note, the research project should have commenced within 6 months from the date of this letter, and ethics approval may be withdrawn if this is not achieved.

Should it appear that there will be a delay in commencing this research, please advise the Mercy Health HREC Administrative Officer.

In accordance with the NHMRC Guidelines, approval is subject to:

- Immediate notification to the Administrative Officer, Human Research Ethics Committee and sponsor, 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;
- 3. The completion of a progress report at 6 months and then annually for the duration of the project.

4. Human Research Ethics Committee approval of any proposed modifications to the project;

5. The submission of a final report and papers published on completion of the project.

Please also note:

6. 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 Ms Carole Branch, Administrative Officer, Mercy Health Human Research Ethics Committee on 8458 4808.

Yours sincerely

Professor Jānis (John) T. Ozoliņš

Chair, Mercy Health Human Research Ethics Committee