CHILDREN'S HEALTH SERVICES QUEENSLAND
HUMAN RESEARCH ETHICS COMMITTEE

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27th May 2013

Mrs Rebecca Caesar
Physiotherapist Advanced
Allied Health Department
Nambour General Hospital
PO Box 547
Nambour, QLD 4560

Dear Mrs Caesar,

HREC Reference number: HREC/13/QRCH/66
Project title: Early prediction of normal and mild neurodevelopmental outcomes for prioritisation of service delivery of very preterm, very low birth weight premature infants.

Many thanks for your letter of the 16th May with responses to queries raised by the Committee in relation to the above project. This has now been reviewed.

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice.*

I am pleased to advise the proposal meets the requirements of the National Statement on Ethical Conduct in Human Research and the Committee is happy to give approval.

This project has Ethics approval for the following sites:

- Royal Children's Hospital, Brisbane
- Nambour General Hospital

[Note: If additional sites are engaged prior to the commencement of, or during the research project, the Coordinating Principal Investigator is required to notify QLD Children's Health Services (RCH) Human Research Ethics Committee (HREC). Notification of withdrawn sites should also be provided to the QLD Children's Health Services (RCH) Human Research Ethics Committee (HREC) in a timely fashion.

The documents reviewed and approved include:

Document	*Version*	*Date*
Protocol	1	15 April 2013
Investigator's Brochure: Flyer	1	15 April 2013
Questionnaire	1	15 April 2013
Covering Letter	1	15 April 2013
Application		

Covering Letter		16 May 2013
PREMTiME Poster	2	16 May 2013
Response to Request for Further Information		16 May 2013
Patient Information Sheet/Consent Form: Parent Information and Consent	2	16 May 2013

Please note the following conditions of approval:

1. We require an annual progress report (or sooner if the project is completed) concerning the study. This must include progress to date or outcome in the case of completed research. (In accordance with National Statement 5.5.3)

2. HREC approval is valid from 27/5/13 – 27/5/16.

3. In accordance with the National Statement (3.3.12), before beginning the clinical phase of the research, researchers should register clinical trials in a publicly accessible domain.

4. If the project does not proceed, the Committee must be informed as soon as possible. (In accordance with National Statement 5.5.6)

5. The Committee must be informed of any potential or realised problem with bioethical implications, if such occurs during the conduct of the research project.

6. Any serious adverse event (SAE) that arises in the context of this research, or involving a researcher conducting this research, must be reported to the Ethics Committee within 72 hours and reported to the sponsor (if applicable) within the stipulated time frame.

   Serious Adverse Event Reports that are generated off-site may be (a) Serious Unexpected Adverse Reactions or (b) Serious Events which the Research Team believes cannot be related to the research intervention. The Research team must report incidents of (a) during multi-centre trials. Such are required to be submitted to the Chair of HREC on receipt by the researcher. A summary of the SAE reports is to accompany the submission. Information required includes; patient details (age & sex), adverse event, outcome and the likelihood of the event being related to the study drug/device/procedure.

   With respect to all SAEs, the researcher must provide his or her opinion as to whether the SAE is directly related to the research intervention. A copy of the SAE Summary must be provided. (This can be obtained from the Ethics Officer)

7. Amendments to the research project which may affect the ongoing ethical acceptability of a project must be submitted to the HREC for review. Major amendments should be reflected in a revised online NEAF (accompanied by all relevant updated documentation and a cover letter from the principal investigator, providing a brief description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study). Hard copies of the revised NEAF, the cover letter and all relevant updated documents with tracked changes must also be submitted to the HREC and the RGO as per standard HREC/RGO SOP. Further advice on submitting amendments is available from: http://www.health.qld.gov.au/ohmr/documents/regu/resrch_user_guide_v1.pdf

8. The Ethics Committee may conduct a randomly identified audit of a proportion of research projects approved by the Committee. That audit process will look at such issues as;
   a. Security of Documents
   b. Consent Form Register
   c. Serious Adverse Events Register
   d. Withdrawal of Participants – who and why
   e. The de-identification of data

9. Ethical approval to undertake this research project is given on the understanding that you have an intention to publish your findings in a refereed journal or similar peer-reviewed forum. If you do not have this intention, it is an absolute requirement that you notify the Ethics Committee formally. In this latter instance, approval for this research is not given at this time; and will require further negotiation. Your work must be in accordance with the following:

   - National Statement on Ethical Conduct in Human Research: ***http://www.nhmrc.gov.au/guidelines/publications/e72-0***

- Queensland Health Management Research Policy:
  http://www.health.qld.gov.au/ohmr/html/regu/resrch_mge_policy.asp
- Declaration of Helsinki:
  http://www.wma.net/en/30publications/10policies/b3/17c.pdf
- Guidelines under Section 95 of the Privacy Act1995 and Guidelines approved under Section 95A of the Privacy Act 1995.
  http://www.health.qld.gov.au/ohmr/html/regu/aces_conf_hth_info.asp
- Queensland Health Privacy Guidelines IS42 & IS42A:
  http://www.health.qld.gov.au/privacy/IS42A.asp

10. Researchers should note, if not QLD Health employees, a Blue Card may be required for contact with children.

11. The Researcher must send the **'Notification of Commencement of Research Protocol'** as soon as research begins. Status of the project will remain as 'Not Started' until this form is received.

Should you have any queries about the HREC's consideration of your project please contact Amanda Smith (Co-ordinator) or Professor John Pearn (Chairperson). The HREC terms of Reference, Standard Operating Procedures, membership and standard forms are available from: http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

You are reminded that this letter constitutes ethical approval only. This project cannot proceed at any site until separate research governance authorisation has been obtained from the CEO or Delegate of the institution under whose auspices the research will be conducted at that site.

The HREC wishes you every success in your research.

Yours sincerely,

Professor John Pearn
Chair
QLD Children's Health Services (RCH) Human Research Ethics Committee

Cc: Ethics Committee Files