CHILDREN'S HEALTH QUEENSLAND
HOSPITAL AND HEALTH SERVICE
HUMAN RESEARCH ETHICS COMMITTEE

Professor Alan Isles AM (Chair) 3069 7002
Mrs Amanda Smith (Co-ordinator) 3069 7002

Queensland Government

Level 7, Centre for Children's Health Research
Queensland Children's Hospital Precinct
62 Graham Street, South Brisbane QLD 4101
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20th February 2019

Dr Joanne George
Senior Research Physiotherapist
QLD Cerebral Palsy & Rehabilitation Centre
Centre for Children's Health Research
Level 6, Stanley Street
South Brisbane QLD 4101

j.george2@uq.edu.au

Dear Dr George,

HREC Reference number: HREC/19/QCHQ/49800
Project title: PREBO-6 – Prediction of childhood brain outcomes in infants born preterm using neonatal MRI and concurrent clinical biomarkers.

Many thanks for your letter received 12th February with responses to queries raised by the Committee in relation to the above project. This has now been reviewed.

I am pleased to advise the proposal meets the requirements of the National Statement on Ethical Conduct in Human Research (2007) and the Committee is happy to give approval. 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), and all subsequent updates, the Australian Code for the Responsible Conduct of Research (2007) and the CPMP/ICH Note for Guidance on Good Clinical Practice.

This project has Ethics approval for the following sites:

- Queensland Children's Hospital/Centre for Children's Health Research, South Brisbane
- Herston Imaging Research Facility, Brisbane

Please note the HREC does not issue pre-determined approval periods. Ethical approval is ongoing, subject to the submission of an annual report on the anniversary of approval.

The documents reviewed and approved include:

Document	*Version*	*Date*
Covering Letter		21 January 2019
Application (49800)		21 January 2019
Parent/Guardian Statement – Term Participants	1.0	21 January 2019
Protocol	1.0	21 January 2019
Tool Assessments: AQ10-child, BRIEF 2, CELF 5, CHU-9D, DAWBA, GMFCS-ER, MABC-2, TEA-Ch 2, Wisconsin Card Sorting Test, WISC-V A & NZ, Woodcock-Johnson Test of Achievement 4th Edition.		
Certificate of Currency		7 November 2018
Head of Department Letter of Support		17 January 2019

Response to Queries		12 February 2019
Parent/Guardian Information Statement and Consent for Preterm Participant	2	12 February 2019
Study Flyer	2	12 February 2019

Please note the following conditions of approval:

1. We require an annual progress report (that covers all sites listed on approval) for the duration of the project. This report is due on the anniversary of HREC approval. Continuation of ethics approval is contingent on submission of an annual report. Failure to comply with this requirement may result in suspension of the project by the HREC.
   A comprehensive Final Report upon completion of the project. (In accordance with National Statement 5.5.3)

2. Please note if identifiable or potentially re-identifiable data for this research project is to be accessed without the written consent of the person to whom the data relates an application for disclosure of this data must be made under the *Public Health Act*. Further information regarding the *Public Health Act* is available via this link: **http://www.health.qld.gov.au/ohmr/html/regu/aces_conf_hth_info.asp**

3. Submit to the reviewing HREC for approval any proposed amendments to the project including any proposed changes to the Protocol, Participant Information and Consent Form/s and the Investigator Brochure.

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.

8. The HREC, authorising institution and/or their delegate/s may conduct an audit of the project at any time.

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:* **https://www.nhmrc.gov.au/guidelines/publications/e72**
   - *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.

12. 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.

Should you have any queries about the HREC's consideration of your project please contact Mrs Amanda Smith (Co-ordinator) or Professor Alan Isles (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 Alan Isles AM
Chair
Children's Health Queensland
Hospital and Health Service
Human Research Ethics Committee

Cc: Ethics Committee Files

Children's Health Queensland Hospital and Health Service Human Research Ethics Committee (HREC)

NOTIFICATION OF COMMENCEMENT OF RESEARCH PROTOCOL

HREC No: **HREC/19/QCHQ/49800**

PROTOCOL TITLE:

PRINCIPAL INVESTIGATOR:

This is to advise that the above research protocol commenced on:

/ /

Signature:---------- Date: ---------/----------/----------

Please forward to CHQ HREC:
Amanda Smith, Co-ordinator HREC
Level 7, Centre for Children's Health Research
Queensland Children's Hospital Precinct
62 Graham Street, South Brisbane QLD 4101