

**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



Level 7, Centre for Children's Health Research
Queensland Children's Hospital Precinct
62 Graham Street, South Brisbane QLD 4101
Telephone (07) 3069 7002

1st June 2022

Professor Roslyn Boyd
c/ Mrs Jacqueline Robinson
Queensland Cerebral Palsy & Rehabilitation Research Centre
Centre for Children's Health Research
South Brisbane QLD 4101

Dear Professor Boyd,

HREC Reference number: HREC/22/QCHQ/85661

Project title: e-PINO: early Prediction of Infant Neurodevelopmental Outcomes using novel biomarkers

Many thanks for your letter of the 23rd May with responses to queries for 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 and Health Service/Centre for Children's Health Research, South Brisbane
- Royal Brisbane & Women's Hospital, Queensland
- Monash Health (Monash Children's Hospital, Monash Medical Centre), Victoria
- The Children's Hospital at Westmead, New South Wales
- Westmead Hospital, New South Wales

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:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Cover Letter		26 April 2022
Application (85661)		26 April 2022
Protocol	1.0	22 April 2022
Study Flyer	1.0	19 April 2022
Cot Card	1.0	12 April 2022
Eligibility Criteria	REDCap	20 April 2022
Breast Milk/Baby's Poo Collection Instructions		Undated
Victorian-Specific Module		21 April 2022
Letter of Support – Dr Priya Edwards, Director QLD Paediatric Rehabilitation Service CHQ		26 April 2022

Letter of Support – Dr Pieter Koorts, Director Neonatology, Metro North Hospital and Health Service		28 April 2022
Treating Paediatrician Letter		Undated
Parent Demographic Form	1.0	21 April 2022
Medical Checklist Part 1	1.0	22 April 2022
Medical Checklist Part 2	1.0	22 April 2022
Neonate Clinical Info at Assessment	1.0	22 April 2022
Assessment of Perinatal Alcohol Exposure (PAE): Consumption AUDIT-C	2	2001
General Movements Assessment (GMA, MOS)	2.0	1 January 2019
Hammersmith Neonatal Neurological Assessment	1.0	2 November 2016
VIX-X Neonatal Visual Assessment	2.0	19 April 2022
HAI Manual	1.0	22 April 2022
Hammersmith Infant Neurological Examination	2.0	8 February 2019
ADOS (Autism Diagnostic Observation Assessment Toddler version)	2	May 2012
ASDetect	1.0	2 April 2019
Social Attention and Communication Surveillance-Revised (SACS-Revised (SACS-R) (2016) 8 month Referral	2.0	19 April 2022
GMFM-88 and 66 Scoresheet	1.0	13 May 2015
Neurosensory Motor Development Assessment (NSMDA) for year 1 and year 2		2009
Peabody Developmental Motor Scales second edition (PDMS-2)	2	2000
Bayley IV (cognitive, Language and Motor, Adaptive behaviour)	4.0	September 2019
Behaviour Assessment System for Children, Third Edition	3.0	17 July 2015
Behaviour Rating Inventory of Executive Function-Preschool Version	3.01	2008
Infant Toddler Social and Emotional Assessment	2.0	1 January 2006
Paediatric Evaluation of Disability Inventory-computer adaptive test	1.4	21 October 2015
Preverbal Visual Assessment	1.0	18 June 2019
24 month Medical Assessment with FAS	1.0	19 April 2022
Sentinel Facial features data information sheet included in the ePINO 24-month Medical Assessment	1.0	19 April 2022
Gross Motor Functional Classification System	1.0	13 May 2015
Mini Manual Abilities Classification Scale	1.0	2016
CSBS Communication Classification Scale	1.0	19 April 2022
Eating and Drinking Ability Classification System	1.0	19 April 2022
Surveillance of Cerebral Palsy in Europe Guidelines	3.0	2016
Growth Assessment at 12 and 24 months	1.0	14 April 2022
CYW Adverse Childhood Experiences Questionnaire	1.0	22 April 2022
Life Events List	1.0	22 April 2022
Depression Anxiety Stress Scales	2.0	1 January 1995
Emotional Availability-Self Report	1.0	1 January 1998
Health Resource Use Q supplemented by Medical Benefits Scheme and Pharmaceutical Benefits Scheme data health economics	1.0	16 July 2021
Infant Toddler Quality of Life Questionnaire	1.0	1 January 2016
Master – Parent/Guardian (Genomics & Microbiome) Information Sheet and Consent Form	1.0	19 April 2022
Response to queries		23 May 2022
Master - Parent/Guardian Information and Consent Form	2.0	23 May 2022

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)
All documentation must be completed and submitted via the ERM website:
<https://au.forms.ethicalreviewmanager.com/>
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:
https://www.health.qld.gov.au/hiiro/html/regu/aces_conf_hth_info
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.
All documentation must be completed and submitted via the ERM website:
<https://au.forms.ethicalreviewmanager.com/>
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. Safety Reporting for clinical trials must follow the [2018 NHMRC Guidance: Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods](#) and the [Reporting of Serious Breaches of Good Clinical Practice \(GCP\) or the Protocol for Trials Involving Therapeutic Goods](#). All Safety Reporting must be submitted via the ERM web portal for researchers, by creating a sub-form under the relevant project and application form. Please see CHQ HREC Website for details of Safety Reporting [CHQ HREC Website](#)
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://nhmrc.gov.au/about-us/publications/national-statement-ethical-conduct-human-research-2007-updated-2018>
 - *Queensland Health Management Research Policy:*
https://www.health.qld.gov.au/_data/assets/pdf_file/0020/164162/qh-pol-013.pdf
 - *Declaration of Helsinki:*
<https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>
 - *Guidelines under Section 95 of the Privacy Act 1995 and Guidelines approved under Section 95A of the Privacy Act 1995.* <https://nhmrc.gov.au/about-us/publications/guidelines-under-section-95-privacy-act-1988>
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.
All documentation must be completed and submitted via the ERM website:
<https://au.forms.ethicalreviewmanager.com/>
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 (Coordinator) 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 until separate research governance authorisation has been obtained from the institution where the research will be conducted.

The HREC wishes you every success in your research.

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'Isles'.

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/22/QCHQ/85661

PROTOCOL TITLE:

PRINCIPAL INVESTIGATOR:

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

/ /

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

Please forward to CHQ HREC:
CHQEthics@health.qld.gov.au
Level 7, Centre for Children's Health Research
Queensland Children's Hospital Precinct
62 Graham Street, South Brisbane QLD 4101