MELBOURNE HEALTH

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MELBOURNE HEALTH HUMAN RESEARCH ETHICS COMMITTEE

ETHICAL APPROVAL

Prof Patrick Kwan
Royal Melbourne Hospital
Level 4, Neurosciences, Royal Melbourne Hospital
300 Grattan Street
Parkville VIC 3050

28 June 2018

Dear Prof Patrick Kwan,

HREC Reference Number: HREC/18/MH/19

Melbourne Health Site Reference Number: 2018.052

Project Title: Clinical utility and cost-effectiveness of immediate vs delayed genome sequencing for refractory epilepsy in children and adults: a multicenter randomised controlled trial

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I am pleased to advise that the above project has **received ethical approval** from the Melbourne Health Human Research Ethics Committee (HREC). The HREC confirms that your proposal meets the requirements of the National Statement on Ethical Conduct in Human Research (2007). This HREC is organised and operates in accordance with the National Health and Medical Research Council's (NHRMC) National Statement on Ethical Conduct in Human Research (2007), and all subsequent updates, and in accordance with the Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95), the Health Privacy Principles described in the Health Records Act 2001 (Vic) and Section 95A of the Privacy Act 1988 (and subsequent Guidelines).

HREC Approval Date: 26 June 2018

Ethical approval for this project applies at the following sites:

Site
The Royal Melbourne Hospital
Alfred Hospital
Austin Hospital
Box Hill Hospital
Northern Hospital
The Royal Children's Hospital
Children's Hospital at Westmead

Approved Documents:

The following documents have been reviewed and approved:

Document	Version	Date
Protocol	2	17 April 2018
Master Participant Information Sheet and Consent Form – Person Responsible (secondary results)	1	1 May 2018
Master Participant Information Sheet and Consent Form – (primary epilepsy results)	2	7 May 2018
Master Participant Information Sheet and Consent Form – Person Responsible (epilepsy results)	2	7 May 2018
Master Participant Information Sheet and Consent Form – Genetic for Parent and Guardian	2	7 May 2018
Participant Consent Form GREP - Medicare_PBS	-	-
CRF- Visit 1	1	26 February 2018
CRF Visit 2	1	26 February 2018
Referral Form	-	-
Affected Questionnaire	-	-
DCE Survey Proxy	4	7 May 2018
DCE Survey Self	4	7 May 2018
CES questionnaire	-	-
EQ-5D-5L Paper Self	1.0	-
EQ-5D-Y Paper Proxy	1.0	-
HADS Questionnaire	-	-
IES-R	-	-
PedsQL Epilepsy Module	-	-
Qolie31	-	-
WPAI-C_English_US	-	-
WPAI-GH_English_US	-	-

Governance Authorisation:

Governance Authorisation is required at each site participating in the study before the research project can commence at that site.

You are required to provide a copy of this HREC approval letter to the principal investigator for each site covered by this ethics approval for inclusion in the site specific assessment application.

Conditions of Ethics Approval:

- You are required to submit to the HREC:
    - 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, due within one month of the approval anniversary. 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.

- 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.
- Notify the reviewing HREC of any adverse events that have a material impact on the conduct of the research in accordance with the NHMRC's Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (2016) guideline.
- Notify the reviewing HREC of your inability to continue as Coordinating Principal Investigator.
- Notify the reviewing HREC of the failure to commence the study within 12 months of the HREC approval date or if a decision is taken to end the study at any of the sites prior to the expected date of completion.
- Notify the reviewing HREC of any matters which may impact the conduct of the project.
- If your project involves radiation, you are legally obliged to conduct your research in accordance with the Australian Radiation Protection and Nuclear Safety Agency Code of Practice 'Exposure of Humans to Ionizing Radiation for Research Purposes' Radiation Protection series Publication No.8 (May 2005)(ARPANSA Code).

Please note: Template forms for reporting Amendments, safety reporting, Annual/Final reports, etc. can be accessed from: https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting

The HREC may conduct an audit of the project at any time.

Yours sincerely,

Prof Peter Colman
Chair – Melbourne Health Human Research Ethics Committee (HREC)