

MATER HEALTH SERVICES HUMAN RESEARCH ETHICS COMMITTEE

28th May 2013

Dr Kate Riney
Neurosciences Unit
Mater Childrens Hospital
Raymond Terrace
South Brisbane
4101

Dear Dr Riney

Re: *Ref N^o. 1937CP* An International open-ended observational study of patients with epilepsy using an Internet Based Platform "EpiNet"

I write to advise that the Mater Health Services Human Research Ethics Committee considers the above study to meet the requirements of the *National Statement on Ethical Conduct in Human Research (2007)* revised in 2009, and granted ethical approval on 4th April 2013 between meetings. Please accept our very best wishes for the success of this study. *In all future correspondence with the Committee please quote the Mater reference number.*

The documents reviewed and approved include:

| Document | Version | Date |
|---|---------|------------------------------|
| Letter of response to HREC questions | | 7 th March 2013 |
| Research Mater Protocol | 2 | 10 th March 2013 |
| International Pilot Study Protocol | 1 | 1 st October 2010 |
| Information & Consent Sheet - EpiNet 2013 PWE | 1.2 | 2013 |
| Information & Consent Sheet - EpiNet 2013 Child | 1.2 | 2013 |

This approval is valid until 4th April 2016. Please note the following conditions of approval.

- Any departure from the protocol detailed in your proposal must be reported immediately to the Committee.
- When you propose a change to an approved protocol, which you consider to be minor, you are required to submit a written request for approval to the Chairperson, through the Secretary. Such requests will be considered on a case by case basis and interim approval may be granted subject to ratification at the next meeting of the Committee.
- Where substantial changes to any approved protocol are proposed, you are required to submit a full, new proposal for consideration by the Human Research Ethics Committee.

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). The processes used by this HREC to review multi-centre research proposals have been certified by the National Health and Medical Research Council.

Mater Research HREC Office
Room 270 Level 2 Aubigny Place

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Email: research.ethics@mmri.mater.org.au



- You are required to advise the Research Ethics Coordinator immediately of any complaints made, or expressions of concern raised, in relation to the study, or if any serious or unexpected adverse events occur.
- Under the *NHMRC National Statement on Ethical Conduct in Research Involving Humans*, research ethics committees are responsible for monitoring approved research to ensure continued compliance with ethical standards, and to determine the method of monitoring appropriate to each project. You are required to provide written reports on the progress of the approved project annually, the first report being due May 2014. (*The Progress Report is located at <http://www.mater.org.au/Home/Research/Human-Research-Ethics-Committee.aspx> or can be accessed through the Mater Intranet, Applications, Research Register then under the project name or alternately can be emailed to you*). Please inform the Committee of publications, presentations at Conferences, education and quality improvement outcomes from this study. The Committee may also choose to conduct an interim audit of your research.
- Please be aware that all study procedures including follow up of participants and data analysis should be completed within the approval time frame or an extension should be requested.

You are reminded that this letter constitutes ethical approval only. You may also need to consult with the Research Governance Office to ensure the amendments comply with the existing authorisation that has been obtained.

Please contact the Executive Director in the participating hospital/hospitals prior to commencing of the study. To access medical records, for the purpose of this study, please provide a copy of this approval letter to the Corporate Health Information Manager. I would also be grateful if you could confirm the date of commencement with the HREC office.

Should you have any queries, please do not hesitate to contact the Research Ethics Secretariat on 3163 1585. *In all future correspondence with the Committee please quote the Mater reference number.*

Please accept our very best wishes for the success of this study.

Yours sincerely



A/Prof Andrew Crowden
Chairperson
Mater Health Services Human Research Ethics Committee