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18 December 2010

Dr Michelle Kiley
Director, Epilepsy Services
Dept of Neurology
ROYAL ADELAIDE HOSPITAL

Dear Dr Kiley,

Re: "EpiNet. Epilepsy research using the Internet: An International Pilot Study."

RAH PROTOCOL NO: 101204.

I am pleased to advise that Research Ethics Committee EXPEDITED APPROVAL is granted to the above project on the above date. The following have been reviewed and approved:

- **Participant Information Sheet and Consent Form, RAH Version 2 (16 December 2010), adapted from New Zealand Master Copy v1 dated 23 January 2009**
- **Memorandum of Understanding (EpiNet Study Group) (July 2009)**
- **Design of the International Pilot Study**
- **eCRF explanatory note for EpiNet International Pilot Study**
- **eCRF Questionnaire**

Please quote the RAH Protocol Number allocated to your study on all future correspondence. Research Ethics Committee deliberations are guided by the NHMRC National Statement on Ethical Conduct in Human Research 2007.

GENERAL TERMS AND CONDITIONS OF ETHICAL APPROVAL:

- Adequate record-keeping is important. If the project involves signed consent, you should retain the completed consent forms which relate to this project and a list of all those participating in the project, to enable contact with them in the future if necessary. The duration of record retention for all clinical research data is 15 years.
- You must notify the Research Ethics Committee of any events which might warrant review of the approval or which warrant new information being presented to research participants, including:
  (a) serious or unexpected adverse events which warrant protocol change or notification to research participants,
  (b) changes to the protocol,
  (c) premature termination of the study,
  (d) a study completion report within 3 months of the project completion.
- The Committee must be notified within 72 hours of any serious adverse event occurring at this site.
- Approval is **ongoing**, subject to satisfactory annual review. Investigators are responsible for providing an annual review to the RAH REC Executive Officer each anniversary of the final approval date using the Annual Review Form available at: http://www.rah.sa.gov.au/rec/index.php The REC must be advised with a report or in writing when this study approval is complete so that the file can be closed.

Yours sincerely,

Dr A Thornton
CHAIRMAN
RESEARCH ETHICS COMMITTEE