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OFFICE FOR RESEARCH

MELBOURNE HEALTH

SITE SPECIFIC ASSESSMENT (SSA) AUTHORISATION

APPROVAL TO CONDUCT A RESEARCH PROJECT AT MELBOURNE HEALTH

Professor Terry O'Brien
Department of Neurology
4 North Main Block
The Royal Melbourne Hospital
C/- The Post Office
PARKVILLE VIC 3050

5th April 2011

Dear Prof O'Brien,

HREC Reference Number: N/A

Local Project Number: 2010.264

Study Title: An international pilot study of an internet-based platform to run epilepsy trials

SSA Authorisation Date: 4th April 2011

Reviewing HREC: Melbourne Health

HREC Approval Date: 4th April 2011

I am pleased to advise that the above project is approved to be conducted at Melbourne Health. This approval is subject to compliance with any conditions imposed by the reviewing HREC.

SSA Approved Documents:

- Melbourne Health HREC Approval Letter dated 5th April 2011
- Melbourne Health Participant Information and Consent Form(s) Version 1 dated 4th April 2011

Research governance

You are required to notify the Office for Research of:

1. The actual start date of the project at Melbourne Health.
2. Any amendments to the project after these have been approved by the reviewing HREC
3. Any adverse events involving patients of Melbourne Health, in accordance with the Melbourne Health *Guidelines for Monitoring and Reporting of Safety in Clinical Trials Involving Therapeutic Products and Other Clinical Research, July 2009.*
4. Any unforseen events.

5. Any changes to the indemnity, insurance arrangements or Clinical Trial Research Agreement for this project. This includes changes to the project budget or other changes which may have financial or other resource implications for Melbourne Health.
6. Your inability to continue as Principal Investigator or any other change in research personnel involved in the project.
7. Any other matters which may impact the conduct of the project at Melbourne Health.

You are also required to submit to the Office for Research:

1. A copy of the TGA acknowledgement letter in respect of the CTN notification (if applicable).
2. An Annual Progress Report every 12 months (or more frequently as requested by the reviewing HREC) for the duration of the project. This report is due on the anniversary of HREC approval. Continued SSA and HREC approval are contingent on receipt of an annual report by the reviewing HREC and the Research Governance Office.
3. A comprehensive Final Report upon completion of the project.

The Office for Research may conduct an audit of the project at any time.

Please refer to the Office for Research website to access forms such as the Amendment Form, Annual Report/Final Report Form, Guidelines for Monitoring and Reporting of Safety in Clinical Trials Guidelines and Adverse Event Report Forms, and other information and news concerning research at Melbourne Health:
http://www.mh.org.au/www/342/1001127/displayarticle/1001352.html

Please Note: Template forms for reporting Amendments, Adverse Events, Annual Report/Final Reports, etc. can be accessed from: www.health.vic.gov.au/cchre.

Yours sincerely,

Dr Angela Watt
Director Research Governance and Ethics