

AUSTIN HEALTH HUMAN RESEARCH ETHICS COMMITTEE**ETHICAL APPROVAL**

Dr John Archer
Neurology
Austin Health

21 December 2016

Dear Dr Archer

HREC Reference Number [AU RED HREC reference number]: HREC/16/Austin/139

Austin Health SITE REFERENCE Number: ND 16/139

Project Title: Deep Brain Stimulation for severe generalised epilepsy of Lennox-Gastaut Phenotype

I am pleased to advise that the above project has **received ethical approval** from the Austin 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: 21/12/2016

Ethical approval for this project applies at the following sites:

Site
Austin Health

Approved Documents:

The following documents have been reviewed and approved:

Document	Version	Date
Protocol - ESTEL	EP002	16/06/2016
Participant Information Sheet and Consent Form	4.0	03/10/2016
Person Responsible Information and Consent Form	4.0	03/10/2016
GASE/GADS Scales	1	15/06/2016
ABAS-II sample report	1.210	2010
PHQ-9 (Spitzer, Williams, Kroenke et al)		
QOLIE-31	1.0	1993
Activa Prescriber information		2009-04
Intercept patient programmer user guide		2009
Patient therapy manual		2008-09

Noted Document	Version	Date
New Technology Committee Letter		25/02/2015

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 Position Statement: *Monitoring and reporting of safety for clinical trials involving therapeutic products May 2009*.
- 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:**
 - **It is your responsibility to ensure the research is added to the site Management Licence issued by Department of Human Services – Radiation Safety Section prior to study commencement should it be required (check your Medical Physicist Report). The site RGO must be notified when the research has been added to the licence.**
 - **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, Adverse events, Annual/Final reports, etc. can be accessed from: <https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/how-to-make-an-hrec-application-for-clinical-trials>.

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

Yours sincerely