ST VINCENT'S HOSPITAL
MELBOURNE
A FACILITY OF ST VINCENT'S HEALTH AUSTRALIA

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13 November 2019

Professor Mark Cook
Department of Neuroscience
St Vincent's Hospital Melbourne

Dear Prof Cook,

Project ID Number: 57264
St Vincent's HREC Ref: 158/19

Title: **'A Prospective Study To Assess The Safety Of A Sub-Scalp Monitoring Device For The Recording Of Brain Electrical Activity Associated With The Occurrence Of Epileptic Seizures'**

I am pleased to advise that the above project has received **ethical approval** from the St Vincent's Hospital Melbourne Human Research Ethics Committee (HREC)

HREC Approval Date: 13 November 2019

This HREC is accredited by the Office of Health and Medical Research under the single ethical review system. The 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, updated 2018) 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).

Approval is given in accordance with the research conforming to the National Health and Medical Research Council Act 1992 and the National Statement on Ethical Conduct in Human Research (2007, updated 2018)

Ethical approval for this research project has been given at the following sites.

- St Vincent's Hospital Melbourne

Please note that each participating site will require governance approval (SSA approval) prior to commencement of this research project.

Site-Specific Assessment - Governance

SSA authorisation is required at all sites participating in the study. SSA must be authorised at a site before the research project can commence.

You are now required to forward this HREC approval letter with an electronic copy of the approved documents named above to the Principal Investigator(s) and the Research Governance Officer (s) at each participating site covered by this HREC approval. Each participating site must issue governance approval of the project before the study can commence at individual sites.

Approval is subject to:

- **An Annual Progress Report (that covers all sites listed on approval) for the duration of the project. This report is due on the 01 May each year for the duration of the project. Continuation of ethics approval is contingent on submission of an annual report. Failure to comply with this requirement may result in suspension of the project by the HREC.**
- The Principal Researcher is to ensure that all associate researchers are aware of the terms of approval and to ensure the project is conducted as specified in the application and in accordance with the National Statement on Ethical Conduct in Human Research 2007 (including all updates)
- The Principal Researcher is to notify the Research Governance Unit of all significant safety issues in accordance with the *NHMRC Guidance: Safety monitoring and reporting in clinical trials involving therapeutic goods (including all updates)*.
- Submit an Annual Safety Report for the duration of the project.
- Immediate notification of any unforeseen events that may affect the continuing ethical acceptability of the project;
- Notification and reasons for ceasing the project prior to its expected date of completion;
- Submit to the reviewing HREC for approval of any proposed amendments to the project including any proposed changes to the Protocol, Participant Information and Consent Form/s, Investigator Brochure and other study materials.
- Submission of reviewing HREC approval for any proposed modifications to the project.
- Submission of a final report and papers published on completion of project.
- Projects may be subject to an audit or any other form of monitoring by the Research Governance Unit at any time.

The following documents have been reviewed and approved:

Approved documents:

Document	Version	Date
HREA – Project ID: 57264	-	20 Aug 19
Victorian Specific Module Project ID: 57264	-	20 Aug 19
C1000 CIP Safety Assessment of Sub-Scalp EEG Monitor	2.0	04 Nov 19
C1001 Investigator Brochure Safety Assessment of Sub-Scalp EEG Monitor	2.0	04 Nov 19
Patients Instructions for Use	2.0	-
Physician Instructions for Use	1.00	-
SVHM Participant Information and Consent Form	3.0	13 Nov 19
Minder G0 System Hazards Analysis	1.00	-
MHLC Form A, B & C	-	-

Ambulatory (Out-patient Portable) EEG Diary	-	-
Epi-Minder Participant ID Card	-	-
Medical Physics Report – SVHM	-	23 July 19
Medical Device Expert Review - Minder	-	23 July 19
Patient Questionnaire	1.00	07 Aug 19
Surgical Questionnaire	1.00	08 Aug 19
Caregiver Burden Inventory	-	1989
Diary Sheet	-	-
Beck Anxiety Inventory	-	-
Beck Depression Inventory	-	-
GAD7 Questionnaire	-	2006
Liverpool Seizure Severity Scale (LSSS) 2.0	-	2001
Neurological Disorders Depression Inventory in Epilepsy (NDDI-E)	-	2006
Quality of Life in Epilepsy (QOLIE-89)	1.0	-
Clinical Trial Notification - Clinical Trial CT-2019-CTN-03332-1 v1	1.0	-
HREC Review Only Indemnity	-	03 Sept 19
Certificate of Insurance (Policy Period 15/07/2019 – 15/07/2020)	-	17 Sept 19

Noted documents:

Document	Version	Date
CV – Mark Cook	-	29 Mar 18
CV – Alan Lai	-	06 May 19
CV – Linda Seiderer	-	-
CV – Michael Murphy	-	-
CV – Udaya Seneviratne	-	13 Aug 19
CV – Wendyl D'Souza	-	15 Aug 19
GCP – Mark Cook	-	06 Oct 19

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The HREC wishes you and your colleagues every success in your research.

Yours sincerely,

Ms Leanne Clinch
Research Ethics and Governance Manager
Research Governance Unit
St Vincent's Hospital (Melbourne)