MELBOURNE HEALTH

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MELBOURNE HEALTH HUMAN RESEARCH ETHICS COMMITTEE

ETHICAL APPROVAL

Prof. Anne-Maree Kelly
WH:The Joseph Epstein Centre for Emg Medical Research
The Joseph Epstein Centre for Emergency Medicine
Sunshine Hospital
Furlong Rd
ST ALBANS VIC 3021

24 September 2018

Dear Prof. Anne-Maree Kelly,

HREC Reference Number: HREC/43148/MH-2018

Melbourne Health Site Reference Number: 2018.315

Project Title: Headache in Emergency Departments (The HEAD study)

I am pleased to advise that the above project has **received ethical approval** from the Melbourne 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: 24 September 2018

Ethical approval for this project applies at the following sites:

Site
Blacktown, NSW
Mt Druitt, NSW
Coffs Harbour Base, NSW
Concord Repatriation General, NSW
Port Macquarie, NSW
Kempsey District, NSW
Royal North Shore, NSW
Shoalhaven, NSW

Sydney Adventist, NSW
Tamworth Regional, NSW
The Maitland, NSW
Lismore Base, NSW
Orange Base and Canterbury, NSW
Alice Springs, NT
Royal Darwin, NT
Calvary, ACT
Queen Elizabeth II Jubilee, QLD
Mater Adult Public, QLD
St Andrew's War Memorial, QLD
The Prince Charles, QLD
Gold Coast University, QLD
Mt Isa, QLD
Cairns Base, QLD
Brisbane Women's and Children's, QLD
Calvary Wakefield, SA
Flinders Medical Centre, SA
Lyell McEwin, SA
Modbury Public, SA
The Queen Elizabeth, SA
Royal Adelaide, SA
The Alfred, VIC
Austin Health, VIC
Ballarat Base, VIC
University Hospital Geelong (Barwon), VIC
Cabrini (Malvern), VIC
Bendigo, VIC
Epworth, VIC
St John of God Geelong, VIC
Werribee Mercy, Casey (Monash), VIC
Clayton (Monash), VIC
Dandenong (Monash), VIC
Frankston (Peninsula), VIC
Royal Melbourne, VIC
Sunshine, VIC
Footscray, VIC
Bunbury Regional, WA
Joondalup Health, WA
Sir Charles Gardiner, WA
St John of God Midland (Public), WA
Rockingham General, WA

Approved Documents:

The following documents have been reviewed and approved:

Document	Version	Date
Protocol	7	21 August 2018
Site information Survey	1	17 September 2018
Data Form	1	22 August 2018

Noted Document	Version	Date
Hospitals Expressing Interest to Participate	1	22 August 2018

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's Safety Monitoring and Reporting in Clinical Trials Involving Therapeutic Goods (2016) guideline.
- 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, 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, safety reporting, Annual/Final reports, etc. can be accessed from: https://www2.health.vic.gov.au/about/clinical-trials-and-research/clinical-trial-research/monitoring-reporting

Request for a Waiver of the Requirement for Consent- The request for a waiver of the requirement of consent is approved.

[NSW sites]-As your trial anticipates recruiting participants in NSW who may be incapable of providing valid consent to participate for themselves, [we / the HREC] suggest that you make yourself aware of the provisions of the *Medical Treatment Planning and Decisions Act 2016.* Prior to commencing your trial in NSW, you may need to make an application to the NSW Civil and Administrative Tribunal (NCAT) for approval for your trial to proceed as well as to provide direction on the appropriate consent mechanism. Please note that the Act contains serious penalties for conducting clinical trial research on non-competent participants without proper authorisation.

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

Yours sincerely,

Prof Peter Colman
Chair – Melbourne Health Human Research Ethics Committee (HREC)