

Office for Research

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WESTERN HEALTH LOW RISK HUMAN RESEARCH ETHICS PANEL APPROVAL TO CONDUCT RESEARCH AND SITE SPECIFIC ASSESSMENT (SSA) AUTHORISATION

16 August 2018

Professor Anne-Maree Kelly Director, JECEMR JECEMR, C/-Sunshine Hospital, Level 3 WCHRE Building 176 Furlong Rd St Albans VIC 3021 Ms Melanie Lloyd Research Physiotherapist Western Health Sunshine Hospital 176 Furlong Rd St Albans VIC 3021

Dear Prof Kelly and Ms Lloyd,

LREP Project Number: HREC/18/WH/120

Project Title: Feasibilty of introducing specialized vestibular physiotherapy in the Emergency

Department: A pilot evaluation

LREP Approval Date: 16 August 2018 SSA Approval Date: 16 August 2018

Principal Investigator/s: Prof Anne-Maree Kelly, Ms Melanie Lloyd

Associate Investigator/s: Ms Allison Luscombe, A/Prof Harin Karunajeewa, Ms Catherine Grant, Dr Koen Simons, A/Prof Tissa Wijeratne

I am pleased to advise that the above project has been given ethics approval by the Western Health Low Risk Ethics Panel (LREP). The LREP confirms that your proposal meets the requirements of the National Statement on Ethical Conduct in Human Research (2007).

This project has also been issued with site specific approval to be conducted at Western Health.

Ethics & Governance approval for this project applies at the following sites:

Sunshine Hospital

Conditions of Ethics Approval and Governance Authorisation:

You are required to submit to the LREP:

- The actual start date of the project at Western Health.
- 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 LREP approval date. 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 LREP.
- A comprehensive Final Report upon completion of the project.
- Submit to the LREP for approval any proposed amendments to the project including any proposed changes to the Protocol and Participant Information and Consent Form/s.

- Notify the LREP of any adverse events that have a material impact on the conduct of the research.
- Notify the LREP of your inability to continue as Principal Investigator.
- Notify the LREP of the failure to commence the study within 12 months of the LREP 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 LREP of any matters which may impact the conduct of the project.

Approved/Noted Documents:

Document	Version	Date
Human Research Ethics Application (HREA) Form; AU/1/D487311		29 June 2018
LREP Response Cover Letter		02 August 2018
LREP Response Cover Letter		14 August 2018
Victorian Specific Module		28 June 2018
Western Health LREP Site Specific Form		21 June 2018
Statement of Approval – Physiotherapy		21 June 2018
Statement of Approval – Emergency Medicine		19 June 2018
Protocol and Appendices	3	15 August 2018
Participant Information and Consent Form - Control	1	23 May 2018
Participant Information and Consent Form - Intervention	1	23 May 2018
Curriculum Vitae & WH Researcher Code of Conduct (2012)		
Anne-Maree Kelly		27 June 2017
Melanie Lloyd		03 July 2018
Allison Luscombe		22 January 2018
Harin Karunajeewa		10 July 2018
Catherine Grant		09 July 2018

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

The Office for Research Western Health wishes you and your colleagues every success in your research.

Yours sincerely,

Ms Noelle Gubatanga

Research Ethics & Governance Administration Officer On behalf of the Western Health Low Risk Ethics Panel

Western Health Office for Research

Email: ethics@wh.org.au