

HUMAN RESEARCH ETHICS COMMITTEE

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11 January 2018

Dr Jeanette Tamplin

Attn: Ms Tanya Silveira

The University of Melbourne
Bldg. 862 Rm. 227
234 St Kilda Road
SOUTHBANK VIC 3006

Dear Dr Tamplin

HREC ref no: 17/256 (HREC/17/POWH/602)

Project title: Examining the effect of FES+iPad based music therapy on upper limb

function and wellbeing outcomes for stroke survivors

Thank you for submitting the above application for ethical and scientific review and for your correspondence dated **08 January 2018** to the Executive Officer responding to questions which arose at the Executive Committee meeting on **19 December 2017**. Authority to grant final approval was delegated to the Executive Officer. I am pleased to advise that that the proposal meets the requirements of the National Statement on Ethical Conduct of Human Research and ethics approval has been given for the following:

- NEAF submission AU/1/289037 dated 08 Sept 2017
- Protocol v1 dated 27 Nov 2017
- Participant Information Sheet & Consent Form v1 dated 08 Jan 2017
- Interview Questions v1 dated 12 Oct 2017
- Stroke Self Efficacy Questionnaire v1 dated 07 Sept 2017
- DASS 21 & scoring sheet (Black dog)

Ethics approval is valid for the following site(s):

- Prince of Wales Hospital
- St George Hospital

Conditions of approval

- 1. This approval is valid for 5 years from the date of this letter.
- 2. Annual reports must be provided on the anniversary of approval.
- 3. A final report must be provided at the completion of the project.

Prince of Wales Hospital Community Health Services Barker Street Randwick NSW 2031

- 4. Proposed changes to the research protocol, conduct of the research, or length of approval will be provided to the Committee.
- 5. The Principal Investigator will immediately report matters which might warrant review of ethical approval, including unforeseen events which might affect the ethical acceptability of the project and any complaints made by study participants.

It is the responsibility of the sponsor or the principal (or co-ordinating) investigator of the project to register this study on a publicly available online registry (eg Australian New Zealand Clinical Trials Registry www.anzctr.org.au).

For Public Health Sites: You are reminded that this letter constitutes ethics approval only. You must not commence this research project until you have submitted your Site Specific Assessment (SSA) to the Research Governance Officer of the appropriate institution and have received a letter of authorisation from the General Manager or Chief Executive of that institution.

Should you have any queries, please contact the Research Support Office on (02) 9382 3587. The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the Research Support Office website: http://www.seslhd.health.nsw.gov.au/POWH/researchsupport/default.asp.

Please quote 17/256 in all correspondence.

We wish you every success in your research.

Yours sincerely

Andrew Bohlken

Executive Officer, Human Research Ethics Committee

This HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research (2007), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007) and the CPMP/ICH Note for Guidance on Good Clinical Practice.