

28 September 2020

Miss Kato McDonald  
4i, 240 Taranaki Street  
Mount Cook  
Wellington 6011

Dear Miss McDonald,

Re:	<b>Ethics ref:</b>	<b>20/STH/114</b>
	Study title:	Field Testing a Māori/Pacific Version of a Japanese iPad App to Support Culturally Responsive Goal Setting in Clinical Rehabilitation: A Qualitative Study

I am pleased to advise that this application has been approved by the Southern Health and Disability Ethics Committee. This decision was made through the HDEC-Full Review pathway.

#### Conditions of HDEC approval

HDEC approval for this study is subject to the following conditions being met prior to the commencement of the study in New Zealand. It is your responsibility, and that of the study's sponsor, to ensure that these conditions are met. No further review by the Southern Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
2. Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a WHO-approved registry (such as the Australia New Zealand Clinical Trials Registry, [www.anzctr.org.au](http://www.anzctr.org.au)) or <https://clinicaltrials.gov/>.
3. Before the study commences at *each given* locality in New Zealand, it must be authorised by that locality in Online Forms. Locality authorisation confirms that the locality is suitable for the safe and effective conduct of the study, and that local research governance issues have been addressed.

#### After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on [www.ethics.health.govt.nz](http://www.ethics.health.govt.nz)) for HDEC requirements relating to amendments and other post-approval processes.

**Your next progress report is due by 28 September 2021.**

Participant access to ACC

This clinical trial is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Section 32 of the Accident Compensation Act 2001 provides that participants injured as a result of treatment received as part of this trial will **not** be eligible for publicly-funded compensation through the Accident Compensation Corporation (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,

A handwritten signature in black ink, appearing to read "Sarah P. [unclear]". The signature is written in a cursive style and is contained within a light grey rectangular box.

Chairperson  
Southern Health and Disability Ethics Committee

Encl: appendix A: documents submitted  
appendix B: statement of compliance and list of members

**Appendix A**  
**Documents submitted**

<i>Document</i>	<i>Version</i>	<i>Date</i>
Protocol: Protocol for thematic analysis study of ADOC-M/P.	3	30 June 2020
Survey/questionnaire: Semi-structured interview guidelines with participating health professionals	1	30 June 2020
Survey/questionnaire: Semi-structured interview guidelines with participating patients with/without Whanau/family present	1	30 June 2020
Survey/questionnaire: Demographic questionnaire for participating health professionals	1	30 June 2020
Survey/questionnaire: Demographic questionnaire for participating patient's Whanau/family members	1	30 June 2020
Survey/questionnaire: Demographic questionnaire for participating patients	1	30 June 2020
PIS/CF: Consent form for participating health professionals	2	30 June 2020
PIS/CF: Consent form for participating patients	2	30 June 2020
PIS/CF: Consent form for participating patient's Whanau/family members	2	30 June 2020
Evidence of scientific review: Peer review of first version of protocol by Bridget Robson	1	30 June 2020
CV for CI: Cover Letter for Kato McDonald	1	30 June 2020
PIS/CF: Information sheet for interested health professionals	2	30 June 2020
PIS/CF: Information sheet for interested patients	2	30 June 2020
PIS/CF: Information sheet for participating or interested patient's Whanau/family.	2	30 June 2020
Cultural consultation with Ngai Tahu Research Consultation Committee	1	30 June 2020
Serious adverse events form	1	30 June 2020
Application		30 June 2020
Covering Letter: Response to provisional ethics approval cover letter	1	24 August 2020
Response to Request for Further Information		

## Appendix B Statement of compliance and list of members

### Statement of compliance

The Southern Health and Disability Ethics Committee:

- is constituted in accordance with its Terms of Reference
- operates in accordance with the *Standard Operating Procedures for Health and Disability Ethics Committees*, and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008713) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

### List of members

<i>Name</i>	<i>Category</i>	<i>Appointed</i>	<i>Term Expires</i>
Mrs Helen Walker	Lay (consumer/community perspectives)	19/08/2020	19/08/2021
Dr Pauline Boyles	Lay (consumer/community perspectives)	05/07/2019	05/07/2022
Dr Paul Chin	Non-lay (intervention studies)	27/10/2018	27/10/2021
Mr Dominic Fitchett	Lay (the law)	05/07/2019	05/07/2022
Dr Sarah Gunningham	Lay (other)	05/07/2016	05/07/2022
Assc Prof Mira Harrison-Woolrych	Non-lay (intervention studies)	28/06/2019	28/06/2020
Professor Jean Hay-Smith	Non-lay (health/disability service provision)	31/10/2018	31/10/2021
Dr Devonie Waaka	Non-lay (intervention studies)	18/07/2016	18/07/2019

Unless members resign, vacate or are removed from their office, every member of HDEC shall continue in office until their successor comes into office (HDEC Terms of Reference)

<http://www.ethics.health.govt.nz>