Health and Disability Ethics Committees
Ministry of Health
133 Molesworth Street
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Wellington
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04 May 2020

Mrs. Carla Strubbia
23 Mein Street
PO Box 7343
Newtown
Newtown
Newtown 6242
(Amended)

Dear Mrs. Strubbia,

Re:	**Ethics ref:**	**20/NTB/40**
	Study title:	Experiences of the use of an iPad application (ADOC-E) for shared decision making around goal setting in rehabilitation: a qualitative descriptive study

I am pleased to advise that this application has been *approved* by the Northern B 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 Northern B 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) 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) for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 04 May 2021.

As your study is an intervention study involving a new medicine, all progress reports must be accompanied by an annual safety report. While there is no prescribed format for annual safety reports, they must be no longer than two pages in length, written in lay language, and include a brief description and analysis of:

- new and relevant findings that may have a significant impact on the safety of participants
- the safety profile of the new medicine and its implications for participants, taking into account all safety data as well as the results of any relevant non-clinical studies
- the implications of safety data to the risk-benefit ratio for the intervention study, and whether study documentation has been or will be updated
- any measures taken or proposed to minimise risks. (Where such a proposed measure would be a substantial amendment, it must be submitted for HDEC review in the normal way)

For the avoidance of doubt, Development Safety Update Reports (DSURs) may serve as annual safety reports to HDECs provided that they contain the information outlined above. These summaries should usually be accompanied by comment from the New Zealand CI of the study.

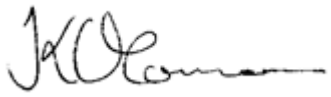
Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* paragraphs 206 - 208 for further information.

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,



Chairperson
Northern B Health and Disability Ethics Committee

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

Appendix A
Documents submitted

Document	*Version*	*Date*	
CV for CI: CV of Carla Strubbia, principal investigator of the study.	pdf	10 February 2020	
Evidence of scientific review: Scientific peer review: A/P William Taylor	1	10 February 2020	
Serious adverse events form	1	10 February 2020	
Protocol: ADOC-E Study Protocol	1	17 February 2020	
Patient Consent form	1	17 February 2020	
Patient Information sheet	1	17 February 2020	
Patient Interview schedule	1	17 February 2020	
Therapist consent form	1	17 February 2020	
Therapist Information sheet	1	17 February 2020	
Therapist Interview schedule	1	17 February 2020	
Cultural consultation n1	1	17 February 2020	
Cultural consultation n2	1	17 February 2020	
Application		18 February 2020	
Patient consent form and information sheet version 2 tracked	2	17 April 2020	
Patient consent form and information sheet clean	2	17 April 2020	
Therapist consent form and information sheet tracked	2	17 April 2020	
Therapist consent form and information sheet clean	2	17 April 2020	
Maori-Pacific consultation	2	17 April 2020	
Covering Letter: Cover letter	1	16 April 2020	
Protocol: Protocol version 2 tracked	2	17 April 2020	
Protocol: Protocol version 2 clean	2	17 April 2020	
Response to Request for Further Information			

Appendix B
Statement of compliance and list of members

Statement of compliance

The Northern B 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 00008715) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	*Category*	*Appointed*	*Term Expires*	
Mr John Hancock	Lay (the law)	14/12/2015	14/12/2018	
Dr Nora Lynch	Non-lay (health/disability service provision)	24/07/2015	24/07/2022	
Miss Tangihaere Macfarlane	Lay (consumer/community perspectives)	20/05/2017	20/05/2020	
Mrs Kate O'Connor	Lay (ethical/moral reasoning)	14/12/2015	14/12/2018	
Mrs Stephanie Pollard	Non-lay (intervention studies)	01/07/2015	01/07/2018	
Mrs Leesa Russell	Non-lay (intervention studies), Non-lay (observational studies)	14/12/2015	14/12/2018	
Ms Susan Sherrard	Lay (consumer/community perspectives)	19/03/2019	19/03/2022	
Mrs Jane Wylie	Non-lay (intervention studies)	20/05/2017	20/05/2020	

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