

02 June 2017

Christine Ho
Department of Gastroenterology
Dunedin Public Hospital
201 Great King St
Dunedin 9016

Dear Ho

Re:	Ethics ref:	17/CEN/74
	Study title:	Establishing the role of Teleconsulting in the care of chronic conditions in rural areas of the Southern District Health Board: A Randomized Controlled Trial in patients with Inflammatory Bowel Disease

I am pleased to advise that this application has been approved by the Central 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 Central 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 (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au). However <https://clinicaltrials.gov/> is acceptable provided registration occurs prior to the study commencing at *any* locality in New Zealand.
3. Before the study commences at a *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.

Non-standard conditions:

- Please add a phone number to the Maori support details in the Participant Information Sheet.

Non-standard conditions must be completed before commencing your study. Non-standard conditions do not need to be submitted to or reviewed by HDEC before commencing your study.

If you would like an acknowledgement of completion of your non-standard conditions letter you may submit a post approval form amendment. Please clearly identify in the amendment that the changes relate to non-standard conditions and ensure that supporting documents (if requested) are tracked/highlighted with changes.

For information on non-standard conditions please see section 128 and 129 of the Standard Operating Procedures at <http://ethics.health.govt.nz/home>.

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 **01 June 2018**.

Participant access to ACC

The Central Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Participants injured as a result of treatment received as part of your study may therefore 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,



Mrs Helen Walker
Chairperson
Central 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>
CV for CI: Christine Ho CV	1	21 March 2017
PIS/CF: participant information sheet and consent form version 1	1	21 March 2017
Survey/questionnaire: IBDQ	1	21 March 2017
Survey/questionnaire: EQ-5D-5L	1	21 March 2017
Survey/questionnaire: SCCAI	1	21 March 2017
Survey/questionnaire: HBI	1	21 March 2017
Covering Letter: Cover letter by Dr Andrew McCombie	1	21 March 2017
CVs for other Investigators: CV Andrew McCombie	1	21 March 2017
Protocol: protocol version 1 as at 21032017	1	21 March 2017
Survey/questionnaire: Acceptability Doctor P2P group	1	22 March 2017
Survey/questionnaire: Acceptability Doctor Tele group	1	22 March 2017
Survey/questionnaire: Acceptability Patient P2P group	1	22 March 2017
Survey/questionnaire: Acceptability Patient Teleconsulting group	1	22 March 2017
Survey/questionnaire: Demographics qnnaire	1	22 March 2017
Doctor costs calculation sheet	1	22 March 2017
Survey/questionnaire: Costs questionnaire for patients	1	22 March 2017
Evidence of scientific review: James Falvey's Peer Review	1	29 March 2017
Evidence of scientific review: Steve Johnson	1	27 March 2017
Evidence of scientific review: MICHAEL WILLIAMS letter	1	06 April 2017
Application		
PIS/CF: participant information sheet and consent form version 2	2	15 May 2017
Covering Letter: Cover letter by Dr Andrew McCombie version 2	2	15 May 2017
Protocol: protocol version 2 as at 15052017	2	15 May 2017
participation declination form 15052017	1	15 May 2017
Response to committee	1	15 May 2017
Response to Request for Further Information		

Appendix B Statement of compliance and list of members

Statement of compliance

The Central 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 00008712) 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)	01/07/2015	01/07/2018
Dr Angela Ballantyne	Lay (ethical/moral reasoning)	30/07/2015	30/07/2018
Dr Melissa Cragg	Non-lay (observational studies)	30/07/2015	30/07/2018
Dr Peter Gallagher	Non-lay (health/disability service provision)	30/07/2015	30/07/2018
Mrs Sandy Gill	Lay (consumer/community perspectives)	30/07/2015	30/07/2018
Dr Patries Herst	Non-lay (intervention studies)	27/10/2015	27/10/2018
Dr Dean Quinn	Non-lay (intervention studies)	27/10/2015	27/10/2018
Dr Cordelia Thomas	Lay (ethical/moral reasoning)	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>