Health and Disability Ethics Committees
Ministry of Health
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20 May 2015

Assoc. Prof Michael Schultz
Dunedin Hospital
8th Floor, Gastroenterology Unit
201 Great King Street
Dunedin 9016

Dear Associate Professor Schultz

Re:	**Ethics ref:**	**15/NTA/44**
	Study title:	A non-inferiority trial of smartphone-based health applications IBDsmart and IBDoc for IBD patients in NZ.

I am pleased to advise that this application has been *approved* by the Northern A 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 A 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 WHO-approved clinical trials registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au).

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:

Summary of ethical issues (outstanding)

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

- Please clarify how patient ID will be protected at Buhlmann laboratories.
- Personal information will not be available to Buhlmann but how will this data be tracked on the database? By participant name? By study ID?

— Will it be possible for Buhlmann labs to identify the participants?

Please ensure the points above are covered in the Participant Information Sheet.

— Most of the items on the consent form are not optional. Please amend the consent form so that only truly optional statements include yes/no boxes next to them.

Please submit your non-standard conditions by email to HDECS@moh.govt.nz

Please note HDEC review is not required for non-standard conditions however they must be completed prior to commencing your study. Do not submit non-standard conditions as a post approval form (PAF).

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 **19 May 2016**.

Participant access to ACC

The Northern A 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,

Dr Brian Fergus
Chairperson
Northern A 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*
CVs for other Investigators: CV of Andrew McCombie	1	13 March 2015
Survey/questionnaire: DISQ	1	16 March 2015
Survey/questionnaire: HBI	1	16 March 2015
Survey/questionnaire: SCCAI	1	16 March 2015
Survey/questionnaire: sCDAI	1	16 March 2015
Survey/questionnaire: IBDQ	1	16 March 2015
Survey/questionnaire: IBDoc Patient Usability Questionnaire version 2 with tracked changes	2	30 April 2015
Survey/questionnaire: Doctor Questionnaire 1 (IBDsmart group)	2	16 March 2015
Survey/questionnaire: Doctor Questionnaire 2 (control group)-1	2	16 March 2015
Survey/questionnaire: IBDoc HCP Usability	2	16 March 2015
CVs for other Investigators: Andrew Gray CV	1	19 March 2015
CV for CI: Schultz CV	1	19 March 2015
CVs for other Investigators: Tobias Langlotz	1	19 March 2015
CVs for other Investigators: Christine CV	1	19 March 2015
CVs for other Investigators: Holger CV	1	19 March 2015
CVs for other Investigators: CV of Murray Barclay	1	19 March 2015
Protocol: Protocol	1	25 March 2015
PIS/CF: Information sheet and consent form version 3	3	30 April 2015
Covering Letter: Cover letter-1st response	2	29 April 2015
Evidence of scientific review: Email from statistician showing the review.	1	25 March 2015
CVs for other Investigators: Russell CV	1	25 March 2015
Application		26 March 2015
Survey/questionnaire: Doctor Questionnaire 1 (IBDsmart group) To be asked every clinic visit	1	24 April 2015
Survey/questionnaire: Doctor Questionnaire 2 (control group) To be asked every clinic visit	1	24 April 2015
Survey/questionnaire: IBDsmart HCP Usability Questionnaire (EN)	1	24 April 2015
Survey/questionnaire: IBDsmart Patient Usability Questionnaire (EN)	1	24 April 2015
Response to Request for Further Information		24 April 2015

Appendix B
Statement of compliance and list of members

Statement of compliance

The Northern A 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 00008714) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	*Category*	*Appointed*	*Term Expires*
Dr Brian Fergus	Lay (consumer/community perspectives)	01/07/2012	01/07/2015
Dr Karen Bartholomew	Non-lay (intervention studies)	01/07/2013	01/07/2016
Ms Susan Buckland	Lay (consumer/community perspectives)	01/07/2012	01/07/2015
Ms Shamim Chagani	Non-lay (health/disability service provision)	01/07/2012	01/07/2015
Dr Christine Crooks	Non-lay (intervention studies)	01/07/2013	01/07/2015
Mr Kerry Hiini	Lay (consumer/community perspectives)	01/07/2012	01/07/2015
Mr Mark Smith	Non-lay (intervention studies)	01/09/2014	01/09/2015
Ms Michele Stanton	Lay (the law)	01/07/2012	01/07/2015

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