Health and Disability Ethics Committees
Ministry of Health
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19 October 2016

Dr Peter Sandiford
Level 1
15 Shea Terrace
Takapuna
Auckland 0740

Dear Dr Sandiford

Re:	**Ethics ref:**	**16/NTA/159**
	Study title:	A randomised controlled trial of the impact on participation rates in the Waitemata bowel screening pilot of existing active follow-up procedures for Maori, Pacific and Asians who do not initially respond to an invitation for bowel screening.

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.

Summary of Study

1. The Committee commended the high quality well written application.
2. This study will investigate whether active follow up is beneficial at improving participation rates in the bowel screening programme.
3. This study will not obtain consent from participants as it involves delaying the standard follow up process for some participants (by 8 weeks) to determine whether the follow up makes a difference in the rates of return of bowel screening kits. This study is being done to investigate whether the costs associated with the active follow up are justified by an increase in participation rates.

Summary of ethical issues (resolved)

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

4. The Committee questioned how many participants would be involved in the study. The Researcher confirmed it would be about 7000, 3500 in each study arm.
5. The Committee questioned whether it would be possible for the follow up programme to use text rather than calling to reduce costs. The Researcher explained that a number of contact details for patients are incorrect and they currently need to phone them.
6. The Committee questioned whether the researchers had considered altering the study design as suggested in the peer review. The Researcher explained that they feel that a non-inferiority design is suitable, however, depending on

the analysis of the results the study may be able to be used to determine superiority.

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 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.

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.

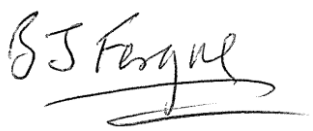
Your next progress report is due by 19 October 2017.

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*
CV for CI: CV	1-9-16	01 September 2016
CVs for other Investigators: CV Nina Scott	2016	01 July 2016
Protocol: Study Protocol	1.0	20 September 2016
Protocol: Protocol with minor changes to title	1.1	21 September 2016
Covering Letter: Covering letter	1	21 September 2016
Evidence of scientific review: Review of proposal by epidemiologist/statistician and Asian health expert Lifeng Zhou	N/A	15 September 2016
Protocol: Updated protocol to include additional randomisation details and sample size calculations	1.2	23 September 2016
Application	1	-

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*	*Present on 11/10/2016?*	*Declaration of interest?*
Dr Brian Fergus	Lay (consumer/community perspectives)	11/11/2015	11/11/2018	Yes	No
Ms Rosemary Abbott	Lay (the law)	15/03/2016	15/03/2019	Yes	No
Dr Karen Bartholomew	Non-lay (intervention studies)	13/05/2016	13/05/2019	Yes	Yes
Dr Charis Brown	Non-lay (intervention studies)	11/11/2015	11/11/2018	Yes	No
Dr Christine Crooks	Non-lay (intervention studies)	11/11/2015	11/11/2018	Yes	No
Dr Kate Parker	Non-lay (observational studies)	11/11/2015	11/11/2018	Yes	No

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