

09 July 2019

Prof Richard Beasley
Medical Research Institute of NZ
Private Bag 7902
Wellington 6242

Dear Prof Beasley

Re:	Ethics ref:	19/NTB/83
	Study title:	Bronchodilation following repeated administration of budesonide/formoterol vs salbutamol in adult asthma: A randomised, open-label, cross-over 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 09 July 2020.

Participant access to ACC

The Northern B 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,



Ms Kate O'Connor
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

<i>Document</i>	<i>Version</i>	<i>Date</i>
CV for CI: CV for Professor Richard Beasley	1.0	23 August 2016
Evidence of CI indemnity	1.0	01 February 2019
Evidence of scientific review: Scientific peer review by Dr.S Mukerji	1.0	22 May 2019
Survey/questionnaire: Modified Borg Dyspnoea Scale	1.0	23 May 2019
Survey/questionnaire: Visual Analogue Score	1.0	23 May 2019
CVs for other Investigators: CV for Dr Nethmi Kearns	1.0	23 May 2019
CVs for other Investigators: CV for Dr. Irene Braithwaite	1.0	31 January 2019
CVs for other Investigators: CV for Dr.Mary John	1.0	18 April 2019
CVs for other Investigators: CV for Mr.Mathew Williams	1.0	09 May 2019
CVs for other Investigators: CV for Dr. Alex Semprini	1.0	18 February 2015
CVs for other Investigators: CV for Prof. Mark Weatherall	1.0	27 July 2018
GP enrolment letter	1.0	23 May 2019
GP completion letter	1.0	23 May 2019
GP withdrawal letter	1.0	23 May 2019
GP mailout	1.0	21 May 2019
Wording for advertisements on social media	1.0	23 May 2019
Pulmicort Turbuhaler Data Sheet (Mesdafe)	1.0	02 May 2018
Symbicort Turbuhaler Data Sheet (Mesdafe)	1.0	12 April 2018
Ventolin Inhaler Data Sheet (Mesdafe)	1.0	19 May 2017
CVs for other Investigators: CV for Melissa Black	1.0	23 May 2019
PIS/CF: PIS-CF Tracked version	2.0	24 June 2019
CVs for other Investigators: CV for Jenny Sparks	1.0	23 May 2019
Protocol	1.0	23 May 2019
Covering Letter: PI response to HDEC cover letter	2.0	28 June 2019
Application		23 May 2019
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

<i>Name</i>	<i>Category</i>	<i>Appointed</i>	<i>Term Expires</i>
Mrs Maliaga Erick	Lay (consumer/community perspectives)	01/07/2015	01/07/2018
Mr John Hancock	Lay (the law)	14/12/2015	14/12/2018
Dr Nora Lynch	Non-lay (health/disability service provision)	19/03/2015	19/03/2021
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>