Health and Disability Ethics Committees
Ministry of Health
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Wellington
6011

0800 4 ETHICS
hdecs@moh.govt.nz

18 November 2015

Prof Richard Beasley
Medical Research Institute of New Zealand
Private Bag 7902
Newtown
Wellington 6242

Dear Prof Beasley

Re:	**Ethics ref:**	**15/NTB/178**
	Study title:	Randomised Controlled Trial of an Inhaled Corticosteroid and Long-Acting Beta Agonist Reliever Therapy Regimen in Asthma.

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 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.

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 17 November 2016.

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,

Raewyn Sporle
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: Prof Richard Beasely	1.0	14 July 2014
CVs for other Investigators: CV: Dr Steve McKinstry	1.0	31 May 2015
CVs for other Investigators: CV: Dr Janine Pilcher	1.0	01 September 2015
Evidence of CI indemnity	1.0	01 February 2015
Evidence of scientific review: Peer Review: Note to File	1.0	16 September 2015
Investigator's Brochure: Datasheet: Bricanyl	1.0	12 November 2014
Investigator's Brochure: Datasheet: Pulmicort	1.0	04 March 2013
Investigator's Brochure: Datasheet: Symbicort	1.0	04 March 2013
Survey/questionnaire: Beliefs about Medicines Questionnaire	1.0	16 September 2015
Survey/questionnaire: Asthma Control Questionnaire (ACQ-5)	1.0	30 November 2001
Asthma Action Plan: ICS/LABA Peak Flow	1.0	12 August 2015
Asthma Action Plan: ICS/LABA	1.0	12 August 2015
Asthma Action Plan: ICS and SABA Peak Flow	1.0	12 August 2015
Asthma Action Plan: ICS and SABA	1.0	12 August 2015
PIS/CF: Withdrawal of Consent Form	1.0	16 September 2015
GP to Patient Letter	1.0	16 September 2015
Inhaler use information: ICS and SABA (Electronic monitor)	1.0	16 September 2015
Inhaler use information: ICS and SABA (Non-Electronic monitor)	1.0	16 September 2015
Inhaler use information: ICS/LABA (Electronic monitor)	1.0	16 September 2015
Inhaler use information: ICS/LABA (Non-Electronic monitor)	1.0	16 September 2015
Participant Card	1.0	16 September 2015
PIS/CF: PIS-CF	1.0	16 September 2015
Protocol: PRACTICAL Protocol	1.0	16 September 2015
Other (No Description Entered)	1	17 September 2015
PIS/CF: PIS-CF V2.0 Clean	2.0	16 October 2015
PIS/CF: PIS-CF V2.0 Tracked Changes	2.0	16 October 2015
Provisional Approval Letter of Response	1.0	30 October 2015

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*
Mrs Raewyn Sporle	Lay (the law)	01/07/2012	01/07/2015
Mrs Maliaga Erick	Lay (consumer/community perspectives)	01/07/2012	01/07/2015
Mrs Phyllis Huitema	Lay (consumer/community perspectives)	19/05/2014	19/05/2017
Dr Nora Lynch	Non-lay (health/disability service provision)	01/07/2015	01/07/2018
Miss Tangihaere Macfarlane	Lay (consumer/community perspectives)	19/05/2014	19/05/2017
Mrs Kate O'Connor	Non-lay (other)	01/07/2012	01/07/2015
Mrs Stephanie Pollard	Non-lay (intervention studies)	01/07/2012	01/07/2015

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