

09 June 2015

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

Dear Prof Beasley

Re:	Ethics ref:	15/NTB/96
	Study title:	Randomised Controlled Trial of the efficacy and safety of a combination inhaled corticosteroid and long-acting beta agonist as a 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.

Summary of Study

- The Committee commended the researchers for a very clear PIS.

Summary of ethical issues (resolved)

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

- Mr Holliday explained that up to \$50 reimbursement of travel expenses will be provided (P.3.3.1). The information sheets are site specific and will be updated on a site by site basis (as per page 11 of the PIS)
- The Committee commended the researchers on their consultation with Maori.
- The Committee noted that the study was sponsored by MRINZ and funded by AstraZeneca. They asked for confirmation on who would have control of the data and who would perform the analysis. Mr Holliday confirmed that while the sponsor will control the database, MRINZ will perform the analysis along with a statistician.
- The Committee noted that blood sample results could be removed from analysis if participants requested (R.3.12) and asked if this could actually be done. Mr Holliday believed so as the researchers will have access to the dataset across all of the sites. The Committee noted that other studies commonly had a statement that any samples collected up until the point of withdrawal will be used. Please outline in the PIS what the limitations are around withdrawal.
- The Committee asked if the researchers would be contacting GPs to do any eligibility checks. Mr Holliday advised that the majority of inclusion and exclusion criteria would be captured at the first visit.
- Mr Holliday confirmed that they will submit advertisements to the HDEC if it is considered an appropriate recruitment tool once the sites are up and running.

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.

Summary of ethical issues (outstanding)

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

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

- Please amend typo “for their asthma” to “for your asthma” (page of the PIS).
- Please include information on why it would be helpful for participants to attend the unscheduled visit if they are withdrawing from the study. Please make it clear that the withdrawal does not have to be in writing (page 13 of the PIS).
- Please make it clear that participants should not share inhalers.
- GP letter – Please add a statement of HDEC approval and HDEC reference number.

Non-standard conditions:

- Please amend the participant information and consent form, taking into account the suggestions by the Committee (*Ethical Guidelines for Intervention Studies, para 6.22*).

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. 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 03 June 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,



Mrs 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

<i>Document</i>	<i>Version</i>	<i>Date</i>
Evidence of CI indemnity	1.0	01 February 2015
CV for CI: Prof Richard Beasley CV	1	14 July 2014
Evidence of scientific review: Peer Review- Dr Mitesh Patel	1	31 October 2014
Protocol	1	21 May 2015
PIS/CF: PIS-CF	1.0.0	21 May 2015
PIS/CF: Participant withdrawal form	1.0.0	21 May 2015
Participant Card	1.0	21 May 2015
Asthma Management Plan: ICS LABA with Peak Flow	1.0	21 May 2015
Asthma Management Plan: ICS LABA	1.0	21 May 2015
Asthma Management Plan: ICS SABA with Peak Flow	1.0	21 May 2015
Asthma Management Plan: ICS SABA	1.0	21 May 2015
Asthma Management Plan: SABA with Peak Flow	1.0	21 May 2015
Asthma Management Plan: SABA	1.0	21 May 2015
Inhaler use information: ICS/LABA	1.0	21 May 2015
Inhaler use information: ICS SABA	1.0	21 May 2015
Inhaler use information: SABA	1.0	21 May 2015
Survey/questionnaire: ACQ-5	1.0	01 November 2001
GP to patient letter template	1.0	21 May 2015
Investigator's Brochure: Ventolin Data Sheet	4	18 June 2014
Investigator's Brochure: Symbicort Data Sheet	1	04 March 2013
Investigator's Brochure: Pulmicort Data Sheet	1	04 March 2013
CVs for other Investigators: CV: Dr J Pilcher	1	23 July 2013
CVs for other Investigators: CV: Dr S McKinstry	1	31 March 2015
Survey/questionnaire: ASK-20	1	21 May 2015
Covering Letter	1	21 May 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

<i>Name</i>	<i>Category</i>	<i>Appointed</i>	<i>Term Expires</i>	<i>Present on 02/06/2015?</i>	<i>Declaration of interest?</i>
Mrs Raewyn Sporle	Lay (the law)	01/07/2012	01/07/2015	Yes	No
Mrs Maliaga Erick	Lay (consumer/community perspectives)	01/07/2012	01/07/2015	Yes	No
Mrs Phyllis Huitema	Lay (consumer/community perspectives)	19/05/2014	19/05/2017	Yes	No
Miss Tangihaere Macfarlane	Lay (consumer/community perspectives)	19/05/2014	19/05/2017	Yes	No
Mrs Kate O'Connor	Non-lay (other)	01/07/2012	01/07/2015	Yes	No
Mrs Stephanie Pollard	Non-lay (intervention studies)	01/07/2012	01/07/2015	Yes	No
Dr Paul Tanser	Non-lay (health/disability service provision)	01/07/2012	01/07/2015	Yes	No

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