Health and Disability Ethics Committees

Health and Disability Ethics Committees
Ministry of Health
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20 September 2019

Professor Richard Beasley
Private Bag 7902
Newtown 6242

Dear Professor Beasley

Re:	**Ethics ref:**	**19/STH/170**
	Study title:	Speed of bronchodilator onset after a single rescue dose of budesonide/formoterol Turbuhaler vs salbutamol pMDI in adult asthmatics.

I am pleased to advise that this application has been *approved* by the Southern Health and Disability Ethics Committee. This decision was made through the HDEC-Full Review pathway.

Summary of Study

1. The study involves administering salbutamol and budesonide/formoterol to participants with stable asthma who have airflow limitation that are not exacerbating. The participants will be a model of those presenting to emergency departments whose airflow limitation is severe enough for medication to have an effect but are not sufficiently unwell to warrant emergency treatment. The aim is to establish the non-inferiority of Symbicort to salbutamol following a single dose of rescue medication in adult asthmatics, to improve lung function and respiratory symptoms.

Summary of resolved ethical issues

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

2. The Committee queried whether spirometry being undertaken at 1, 2 ,3, and 5-minute intervals would be a strain on participants. The Researcher answered that participants will blow for only a 3-second duration, and that asthmatics find spirometry easier as they are used to respiratory discomfort. These intervals were said to be acceptable if completed carefully. The Committee asked whether there was a safety protocol in place. The Researcher confirmed that a crash kart and resuscitation kit would at hand. Participants would also be seated and advised not to blow too hard.
3. The Committee questioned the study contingencies for withholding medication. The Researcher replied that participants will be advised to treat their asthma as a priority over study compliance. They will therefore take Ventolin as needed and can book study visits for another date.
4. The Committee checked on the status of Māori consultation. The Researchers responded that this was being conducted, but still forthcoming.

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

5. Please amend the consent form so that it is not optional for participants to be informed of clinically relevant incidental findings.
6. Please proof read the document for typos.

Notes

7. The Committee commended the use of lay-language in the PISCF.
8. The Committee noted that the co-ordinating investigator and sponsor are both Professor Richard Beasley, and there will therefore be a financial relationship between these two parties.

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 Southern Health and Disability Ethics Committee is required.

Standard conditions:

9. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.

10. 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/.

11. 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.

Non-standard conditions:

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

Non-standard conditions must be completed before commencing your study, however, they do not need to be submitted to or reviewed by HDEC.

If you would like an acknowledgement of completion of your non-standard conditions you may submit a post approval form amendment through Online Forms. Please clearly identify in the amendment form that the changes relate to non-standard conditions and ensure that supporting documents (if requested) are tracked/highlighted with changes.

For information on non-standard conditions please see section 128 and 129 of the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz)

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.

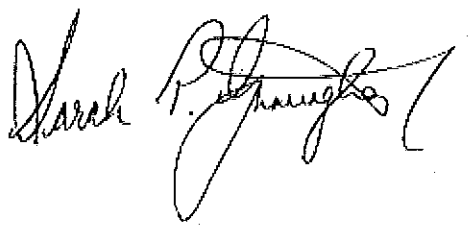
Your next progress report is due by 19 September 2020.

Participant access to ACC

The Southern 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 Sarah Gunningham
Chairperson
Southern 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: Current CV for PI	1	23 August 2016
CVs for other Investigators: CV for Sub Investigator	1	11 June 2019
Evidence of scientific review: Peer review by respiratory consultant, Wellington hospital	1	13 August 2019
Evidence of scientific review: Peer review by Hutt Valley respiratory consultant	1	19 August 2019
Investigator's Brochure: Current data sheets for Symbicort	1	28 August 2019
Investigator's Brochure: Current data sheets for Ventolin	1	28 August 2019
Survey/questionnaire: Modified Borg Scale	1	28 August 2019
Survey/questionnaire: Visual Analogue Scale (VAS)	1	28 August 2019
Social Media advertising	1	23 May 2019
Evidence of CI indemnity	1	28 August 2019
Evidence of CI indemnity	1	28 August 2019
Evidence of CI indemnity	1	28 August 2019
Evidence of CI indemnity	1	28 August 2019
Protocol: Protocol	1	03 July 2019
PIS/CF: PIS/ICF	1	17 July 2019
CVs for other Investigators: Mathew Williams CV	1	29 August 2019
CVs for other Investigators: CV for Melissa Black	1	29 August 2019
Covering Letter	1	29 August 2019
Application		29 August 2019

Appendix B
Statement of compliance and list of members

Statement of compliance

The Southern 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 00008713) 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 10/09/2019?*	*Declaration of interest?*
Dr Sarah Gunningham	Lay (other)	05/07/2019	05/07/2022	Yes	No
Dr Pauline Boyles	Lay (consumer/community perspectives)	05/07/2019	05/07/2022	No	No
Dr Paul Chin	Non-lay (intervention studies)	27/10/2018	27/10/2021	No	No
Mr Dominic Fitchett	Lay (the law)	05/07/2019	05/07/2022	Yes	No
Assc Prof Mira Harrison-Woolrych	Non-lay (intervention studies)	27/10/2015	27/10/2018	Yes	No
Professor Jean Hay-Smith	Non-lay (health/disability service provision)	31/10/2018	31/10/2021	No	No
Dr Devonie Waaka	Non-lay (intervention studies)	18/07/2016	18/07/2019	Yes	No
Mrs Leesa Russell (Co-opted)	Non-lay (intervention studies) Non-lay (observational studies)	14/12/2015	14/12/2018	Yes	No
Mrs Helen Walker (Co-opted)	Lay (the law)	01/07/2015	01/07/2018	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