

06 July 2018

Dr Miriam Bennett
Waikato Hospital
Pembroke Street
Private Bag 3200
Hamilton 3204

Dear Dr Bennett

Re: Ethics ref:	18/STH/113
Study title:	Double blinded interventional study investigating the effects of non selective and cardio selective Beta-Blockers affect on the use of Beta-Agonist inhalers following controlled bronchoconstriction in asthma?

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.

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:

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 05 July 2019.

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,

A handwritten signature in black ink, appearing to read 'Raewyn Idoine', with a horizontal line underneath.

Mrs Raewyn Idoine
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

<i>Document</i>	<i>Version</i>	<i>Date</i>
Declined letter for previous application in respect of the same (or substantially similar) study: Original submission 18/CEN/21 which was declined due to insufficient peer review	1	12 February 2018
Declined letter for previous application in respect of the same (or substantially similar) study: granted provisional approval on 22/3/18. Change from methacholine to mannitol deemed significant and asked to resubmit a new form.	1	25 May 2018
CV for CI: CV for Dr Miriam Bennett	1	29 May 2018
CVs for other Investigators: CV for Dr Cat Chang	1	29 May 2018
ANZCTR	1	01 March 2018
Evidence of CI indemnity	2	12 September 2017
Patient diary	1	29 May 2018
Maori Endorsement	1	15 March 2018
Safety card to be carried by patient with contact details and explaining maybe on a beta-blocker	1	29 May 2018
PIS/CF: Tracked changes included	1	27 June 2018
Protocol: Changes in red to where changes were made from methacholine to mannitol	1	29 May 2018
Evidence of scientific review: Original peer review by Dr Khan of study protocol	1	14 February 2018
Evidence of scientific review: Peer review by Dr Khan for change from methacholine to mannitol	2	28 May 2018
Evidence of scientific review: Paper published by Dr John Brannan regarding use of mannitol in asthma	3	01 November 2016
Survey/questionnaire: Juniper ACQ questionnaire -	1	28 May 2018
Pharmaxis approval for use of mannitol	1	03 May 2018
Power calculation	1	29 May 2018
Safety monitoring group	1	29 May 2018
Schedule of events	1	29 May 2018
Email to be sent to our held list of potential participants who have previously shown an interest in partaking in respiratory research	1	21 May 2018
Example of clearly set out questions for blinded investigator to ask and clear instructions on what information to share with the group.	1	29 May 2018
Covering Letter: Covering letter May 2018	1	29 May 2018
Application		
Data Safety monitoring Committee group signatures.	2	27 June 2018
Data Safety monitoring group guidelines to help guide reviews	1	27 June 2018
Response to Request for Further Information		

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

<i>Name</i>	<i>Category</i>	<i>Appointed</i>	<i>Term Expires</i>
Ms Raewyn Idoine	Lay (consumer/community perspectives)	27/10/2015	27/10/2018
Dr Sarah Gunningham	Non-lay (intervention studies)	27/10/2015	27/10/2018
Assc Prof Mira Harrison-Woolrych	Non-lay (intervention studies)	27/10/2015	27/10/2018
Dr Fiona McCrimmon	Lay (the law)	27/10/2015	27/10/2018
Dr Anna Paris	Lay (other)	24/08/2017	24/08/2020
Dr Nicola Swain	Non-lay (observational studies)	27/10/2015	27/10/2018
Dr Devonie Waaka	Non-lay (intervention studies)	13/05/2016	13/05/2019

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>