

15 April 2019

Dr James Fingleton
Level 7, CSB Building
Wellington Regional Hospital
Riddiford Street
New Town
Wellington 6021

Dear Dr Fingleton

Re:	Ethics ref:	19/CEN/52
	Study title:	Preferences for Asthma Treatment Regimens – A Qualitative Study.

I am pleased to advise that this application has been approved by the Central Health and Disability Ethics Committee. This decision was made through the HDEC-Expedited 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 Central 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 *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 14 April 2020.

Participant access to ACC

The Central 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 'Helen Walker', written in a cursive style.

Mrs Helen Walker
Chairperson
Central 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>
CVs for other Investigators: CV Prof Helen Reddel	1	20 March 2019
CVs for other Investigators: CV for Dr Amy Chan	1	20 March 2019
CVs for other Investigators: CV Prof William Levack	1	01 November 2018
Māori consultation	1	05 March 2019
Evidence of CI indemnity	1	16 November 2018
CVs for other Investigators: Christina Baggott CV	1	21 March 2019
CV for CI: James Fingleton CV	1	21 March 2019
Evidence of sponsor insurance	1	01 November 2018
Evidence of sponsor insurance	1	01 November 2018
Protocol: Study protocol	1.0	22 March 2019
Accompanying family/whanua confidentiality agreement.	1.0	21 March 2019
CVs for other Investigators: CV for Richard Beasley	1	01 December 2018
Evidence of sponsor insurance	1	01 November 2018
Evidence of scientific review: Peer review by Dr Hulikunte for research for life funding application.	1.0	21 March 2019
Poster advertisement	1.0	25 March 2019
Social media advertisement A	1.0	25 March 2019
Social media advertisement B	1.0	25 March 2019
PIS/CF: participant information sheet and consent form	1.0	26 March 2019
Survey/questionnaire: Participant demographics and asthma questionnaire	1.0	26 March 2019
Covering Letter: Application cover letter	1	26 March 2019
Survey/questionnaire: Focus group meeting schedul and interview guide	1.0	26 March 2019
Application		26 March 2019

Appendix B Statement of compliance and list of members

Statement of compliance

The Central 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 00008712) 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 Helen Walker	Lay (consumer/community perspectives)	01/07/2015	01/07/2018
Dr Peter Gallagher	Non-lay (health/disability service provision)	30/07/2015	30/07/2018
Mrs Sandy Gill	Lay (consumer/community perspectives)	30/07/2015	30/07/2018
Dr Patrix Herst	Non-lay (intervention studies)	27/10/2015	27/10/2018
Dr Dean Quinn	Non-lay (intervention studies)	27/10/2015	27/10/2018
Dr Cordelia Thomas	Lay (the law)	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>