

12 February 2019

Assoc Prof Rinki Murphy
Faculty of Medical and Health Sciences
University of Auckland
Private Bag 92019
Auckland 1142

Dear Assoc Prof Murphy

Re: Ethics ref:	18/STH/242
Study title:	Type 2 Diabetes medication Which One is Right Here (WORTH) study

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 investigates how two additional medications for type 2 diabetes effect patients' glucose levels.

Standard conditions:

2. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
3. 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/>.
4. 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:

5. The researchers have addressed all the points raised in the initial assessment. Evidence of scientific peer review has now been provided The PIS has been revised and committee comments have been included, importantly that this study compares Maori and Pasifika people with other ethnic groups in NZ. However, there are still some long words (e.g. 'ethnicity') which a lay person may struggle to understand and some missing full stops, typos etc. Please review again carefully before use in the study.

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.

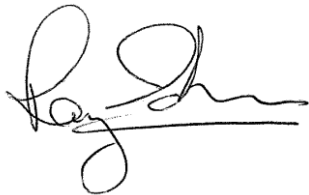
Your next progress report is due by 12 February 2020.

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,



Ms 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>
PIS/CF: PIS/CF - clean	2	28 December 2018
Protocol: Protocol	2	28 December 2018
HOD approval letter	1	20 November 2018
CV for CI: CV Murphy	1	05 November 2018
Evidence of scientific review: Peer review 1	1	06 March 2018
Evidence of scientific review: Peer review 2	1	06 March 2018
Evidence of scientific review: Peer review of WORTH study by Prof Cundy	2	28 December 2018
CVs for other Investigators: JHH CV	1	02 August 2018
Investigator's Brochure: Vildagliptin	1	20 November 2018
Investigator's Brochure: Pioglitazone medsafe datasheet	1	20 November 2018
Survey/questionnaire: Scoring summary	1	20 November 2018
Survey/questionnaire: DTSQc	1	20 November 2018
Survey/questionnaire: DTSQs	1	20 November 2018
Poster	2	28 December 2018
Advertisement	2	28 December 2018
Clinician reminder on computer screen	1	20 November 2018
Participant wallet card	1	20 November 2018
GP end of study letter	1	20 November 2018
GP notification about enrolment letter	1	20 November 2018
Patient introduction to study letter	1	05 October 2018
Application		21 November 2018
Covering Letter: HDEC response letter	1	02 January 2019
Facebook social media advertisement (very similar to newspaper/poster draft submitted)	2	28 December 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 Paul Chin	Non-lay (intervention studies)	27/10/2018	27/10/2021
Dr Sarah Gunningham	Non-lay (intervention studies)	27/10/2015	27/10/2018
Ascc Prof Mira Harrison-Woolrych	Non-lay (intervention studies)	27/10/2015	27/10/2018
Professor Jean Hay-Smith	Non-lay (health/disability service provision)	31/10/2018	31/10/2021
Ascc Prof 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>