Health and Disability Ethics Committees
Ministry of Health
133 Molesworth Street
PO Box 5013
Wellington
6011

0800 4 ETHICS
hdecs@moh.govt.nz

22 May 2018

Dr Dominic Lomiwes
The New Zealand Institute of Plant and Food Research Ltd.
Private Bag 11600
Palmerston North 4442

Dear Dr Lomiwes

Re:	**Ethics ref:**	**18/STH/102**
	Study title:	Evaluating the effect of exercise and partial kiwifruit exchange of high glycaemic index (GI) carbohydrate on blood glucose regulation in healthy individuals

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-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 Southern Health and Disability Ethics Committee is required.

1. **Note from Chair:** Question G has been answered incorrectly - the study does involve the use of health information. r.2.4. The data as described is partially de-identified (ie identified with a subject number that presumably can be matched by the CI to an individual). r.5. Some health information must be retained for at least 10 years; The CI has a responsibility to check whether this applies to any of the health information generated in the current study. p.2.7. Please ensure that HDEC is also informed of important new information pertinent to study conduct. ICF: The first paragraph on p2 is superfluous - suggest removing.

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.

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.

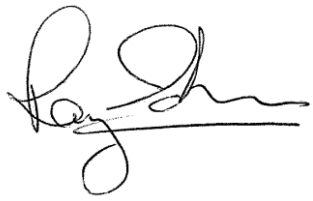
Your next progress report is due by 21 May 2019.

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,



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

Document	*Version*	*Date*
Covering Letter: Cover Letter	1	30 April 2018
CV for CI: CV of Principal Investigator in MBIE format	1	30 April 2018
Evidence of scientific review: Scientific review by independent scientist	1	09 January 2018
Investigator's Brochure: Study poster	1	30 April 2018
Participant information sheet	1	30 April 2018
PIS/CF: Participant consent form	1	30 April 2018
Protocol: Study protocol	1	30 April 2018
Survey/questionnaire: Baecke habitual activity questionnaire	1	30 April 2018
Survey/questionnaire: Health questionnaire	1	30 April 2018
Survey/questionnaire: POMS questionnaire	1	30 April 2018

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*
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