

12 February 2021

Professor Richard Mithen  
Liggins Institute, The University of Auckland,  
85 Park Road, Grafton  
Auckland 1023

Dear Professor Mithen,

Re: <b>Ethics ref:</b>	<b>20/STH/236</b>
Study title:	Impact of acute kawakawa tea ingestion on postprandial glucose metabolism in healthy human volunteers (TOAST)

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.

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](http://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.

Non-standard conditions:

4. Participant Information Sheet and Consent Form (PISCF):

'Quantifying expression of genes and microRNAs involved in the pathways related to metabolic homeostasis and inflammation using PBMC samples' is very technical, and does not use language that is likely to be understood by a lay person. Please explain:

- a) What genes are, in lay terms
- b) What microRNA is, in lay terms

- c) What metabolic homeostasis is, in lay terms
- d) What a PBMC is, in lay terms

5. Data Section:

- a) The data management plan states that de-identified data may be used for future research, including research unrelated to the current study. This needs to be clearly stated in the PISCF.
- b) If the de-identified data may be shared with researchers overseas, this needs to also be stated in the PISCF.
- c) The risks of sending data overseas (for future research) and of privacy / confidentiality breach should be included in the PISCF.

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](http://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](http://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 2022.**

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,



Mrs. Helen Walker  
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>
CV for CI	1	23 November 2020
CVs for other Investigators	1	23 November 2020
Protocol: Tracked Protocol	2	10 December 2020
PIS/CF: Tracked	2	10 December 2020
Evidence of scientific review	1	30 November 2020
Survey/questionnaire	1	02 December 2020
HOD APPROVAL	1	27 November 2020
Survey/questionnaire	1	02 December 2020
Application		03 December 2020
PIS/CF		
Covering Letter		
PIS/CF		
Covering Letter: Response to reviewer	1	10 February 2021
Data Management plan	1	10 February 2021
PIS/CF: Clean	2	10 February 2021
Protocol: Clean	2	10 February 2021
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>
Mrs Helen Walker	Lay (consumer/community perspectives)	19/08/2020	19/08/2021
Dr Pauline Boyles	Lay (consumer/community perspectives)	05/07/2019	05/07/2022
Dr Paul Chin	Non-lay (intervention studies)	27/10/2018	27/10/2021
Mr Dominic Fitchett	Lay (the law)	05/07/2019	05/07/2022
Dr Sarah Gunningham	Lay (other)	05/07/2016	05/07/2022
Assc Prof Mira Harrison-Woolrych	Non-lay (intervention studies)	28/06/2019	28/06/2020
Professor Jean Hay-Smith	Non-lay (health/disability service provision)	31/10/2018	31/10/2021
Dr Devonie Waaka	Non-lay (intervention studies)	18/07/2016	18/07/2019

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>