Health and Disability Ethics Committees
Ministry of Health
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0800 4 ETHICS
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10 March 2021

Dr Dominic Lomiwes
Private Bag 11600
Palmerston North 4442

Dear Dr Lomiwes

Re:	**Ethics ref:**	**21/STH/42**
	Study title:	Investigating the bioavailability of anthocyanins and their metabolites and the benefits of these compounds in supporting immunity after consuming a single serve of red kiwifruit 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.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee which require addressing by the Researcher are as follows.

1. Please ensure informed consent is obtained prior to participants completing the health questionnaire

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

2. Use a simple lay-friendly title for the PISCF, rather than the formal project title.
3. Review for use of lay language throughout - explain terms such as bioavailability, cognition, innate immune response etc and simplify the text used where possible.
4. It is unclear what the 'response to an immune challenge' is. As read, participants may perceive this as them being exposed to or taking something that will stimulate an immune response. Make it clear the immune challenge will be done on blood cells in the laboratory.
5. Eligibility criteria paragraphs are included in two sections. Please delete one of the paragraphs.
6. Informing the GP of significant results that may have clinical implications for the participant should be a mandatory component of study participation. Please state this in the PISCF and remove the optional tick box from the consent clause.
7. On page 2, please amend "all participants will consume will be required to consume 200 g of blended red kiwifruit"
8. Please define Fasted, including how long you want them to refrain from food and/or liquid and if participants are allowed water.

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:

9. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.

10. 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/.

11. 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:

- please ensure informed consent is obtained prior to participants completing the health questionnaire
- please update the participant information sheet and consent form, taking into account feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

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 09 March 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

Document	*Version*	*Date*
Investigator's Brochure: Study poster	1	05 February 2021
Covering Letter: Cover letter	1	05 February 2021
Protocol: Study protocol	1	05 February 2021
Evidence of scientific review: Peer review	1	05 February 2021
PIS/CF: Consent form	1	05 February 2021
Survey/questionnaire: Health screening form	1	05 February 2021
PIS/CF: Participant information sheet	1	05 February 2021
Evidence of sponsor insurance	1	05 February 2021
CV for CI: CV	1	05 February 2021
Application		09 February 2021
Evidence of sponsor insurance		24 February 2021

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*
Mrs Helen Walker	Lay (consumer/community perspectives)	19/08/2020	19/08/2021
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