Health and Disability Ethics Committees
Ministry of Health
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30 October 2020

Dr Dominic Lomiwes
The New Zealand Institute for Plant and Food Research Ltd.
Private Bag 11600
Palmerston North 4420

Dear Dr Lomiwes

Re:	**Ethics ref:**	**20/CEN/216**
	Study title:	Investigating the polyphenol bioequivalence of a spray-dried blackcurrant powder with a commercial blackcurrant extract and determining the acute effect of caffeine on the polyphenol bioavailability when co-consumed with blackcurrant powder.

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.

Please consider making the study's insurance protocol specific.

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 *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/.

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.

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 29 October 2021.

Participant access to ACC

This clinical trial is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Section 32 of the Accident Compensation Act 2001 provides that participants injured as a result of treatment received as part of this trial will **not** 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
Central 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*
Evidence of scientific review: Scientific peer review	1	11 September 2020
Evidence of sponsor insurance	1	29 January 2020
Covering Letter: Cover letter	1	15 September 2020
CV for CI: CI CV	1	15 September 2020
Survey/questionnaire: Health questionnaire	1	31 August 2020
PIS/CF: Participant information sheet - tracked	2	21 October 2020
PIS/CF: Consent form - Version 2 tracked	2	21 October 2020
Investigator's Brochure: Study poster	1	31 August 2020
Protocol: Study protocol - Version 2 tracked	2	21 October 2020
Application		18 September 2020
Covering Letter: Response to ethics committee feedback	2	21 October 2020
PIS/CF: Participant Information sheet - Version 2 clean	2	21 October 2020
PIS/CF: Consent form - Version 2 clean	2	21 October 2020
Protocol: Study protocol - Version 2 clean	2	21 October 2020
Response to Request for Further Information		

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

Name	*Category*	*Appointed*	*Term Expires*
Mrs Helen Walker	Lay (consumer/community perspectives)	22/05/2018	22/05/2023
Ms Helen Davidson	Lay (ethical/moral reasoning)	06/12/2018	06/12/2021
Dr Peter Gallagher	Non-lay (health/disability service provision)	22/05/2020	22/05/2023
Mrs Sandy Gill	Lay (consumer/community perspectives)	22/05/2020	22/05/2023
Dr Patries Herst	Non-lay (intervention studies)	22/05/2020	22/05/2023
Ms Julie Jones	Non-lay (intervention studies)	22/05/2020	22/05/2022
Dr Cordelia Thomas	Lay (the law)	20/05/2017	20/05/2020
Dr Jill Wilkinson	Non-lay (observational studies)	22/05/2020	22/05/2023

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