

Ethics reference: 2022 EXP 12622

14 July 2022

Dr Odette Shaw

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Tēnā koe Dr Shaw

APPROVAL OF APPLICATION

Study title: Investigating the effect of BerriQi® Boysenberry and apple drink consumption on lung function and immune protection following acute ozone exposure induced lung inflammation in healthy volunteers

I am pleased to advise that your application was **approved** by the Southern Health and Disability Ethics Committee (the Committee). This decision was made through the EXP 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:

- Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
- Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a registry approved by the World Health Organization (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au or <https://clinicaltrials.gov/>).
- Before the study commences at *each given* locality in New Zealand, it must be authorised by that locality in Ethics RM. 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 [SOPs](#) for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 14 July 2023

Participant access to compensation

This 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.

Further information and assistance

Please contact the HDECs Secretariat at hdec@health.govt.nz or visit our website at www.ethics.health.govt.nz for more information, as well as our [General FAQ](#) and [Ethics RM user manual](#).

Nāku noa, nā



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Mr Anthony Fallon

Chair

Southern Health and Disability Ethics Committee

Encl: Appendix A: documents submitted

Appendix A: Documents submitted

Document Type	File Name	Date	Version
Evidence of Consultation	RE Upcoming HVN clinical studies		
Evidence of Sponsor Insurance	AUS22810829A - NZ Institute for Plant & Food Research (Trial 02) - COC - 080222		
CV for Coordinating Investigator	O Shaw HVN CV 2021		
Evidence of CI Indemnity	2021 COI Plant and Food Research Professional Indemnity NZD 2m		
Scientific Peer Review	2022-05 peer review		
Scientific Peer Review	2022-05 peer review and HDEC comment supporting document		
Non-Review Document	HDEC decline letter	22/03/2022	
Data and Tissue Management Plan	BerriQi Data and tissue management plan	05/04/2022	1
Protocol	2022-05 HVN BerriQi ethics protocol Final	17/05/2022	1
PIS/CF	2022-05 HVN BerriQi consent form dietary intervention	17/05/2022	1
PIS/CF	2022-05 HVN BerriQi consent form pilot	17/05/2022	1
PIS/CF	2022-05 HVN BerriQi info sheet dietary intervention	17/05/2022	1
PIS/CF	2022-05 HVN BerriQi info sheet pilot	17/05/2022	1
Surveys/questionnaires	2022-05 HVN BerriQi health questionnaire dietary intervention	17/05/2022	1
Surveys/questionnaires	2022-05 HVN BerriQi info sheet pilot	17/05/2022	1
Covering Letter	2022-05 HVN BerriQi Cover letter	18/05/2022	1

Review Document Type	Review Document File Name	Review Document Version	Review Document Date
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