

Health and Disability Ethics Committees

Ministry of Health 133 Molesworth Street PO Box 5013 Wellington 6011 hdecs@health.govt.nz

Ethics reference: 2024 EXP 19783

11 June 2024

Dr Blake Perry

Wallace Street Mt Cook Wellington 6021 New Zealand

Tēnā koe Dr Perry

APPROVAL OF APPLICATION

Study title: Resistance exercise and artery function

I am pleased to advise that your application was **approved** by the Central Health and Disability Ethics Committee (the Committee) **with non-standard conditions**. This decision was made through the Expedited pathway.

Summary of outstanding ethical issues

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

1. The Committee requested to ensure all advertisements mention this is an invitation to take part in a research study.

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

- 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.

Non-standard conditions:

• please ensure all advertisements mention this is an invitation to take part in a research study.

Non-standard conditions must be completed before commencing your study, however, they do not need to be submitted to or reviewed by HDECs.

If you would like an acknowledgement of completion of your non-standard conditions you may submit a post approval form amendment through the Ethics Review Manager. 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 paragraphs 125 and 126 of the <u>Standard Operating Procedures for Health and Disability Ethics</u> <u>Committees (SOPs)</u>.

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 11 June 2025

Participant access to compensation

The Central 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 trialed. 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.

Further information and assistance

Please contact the HDECs Secretariat at 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

Mrs Helen Walker

TE brains

Chair

Central Health and Disability Ethics Committee

Encl: Appendix A: documents submitted

Appendix A: Documents submitted

Document Type	File Name	Date	Version
CV for Coordinating Investigator	Academic CV_BGPerry	14/02/2024	1
Scientific Peer Review	ZSchlader_Peer Review HDEC	19/03/2024	1.0
Evidence of Consultation	Māori Consultation_Supporting letter	11/04/2024	1.0
Other	Letter of Support - Pacific	16/04/2024	1.0
Advertisement	Resistance exercise and artery function advertising_v1.0	09/05/2024	1.0
Protocol	Protocol RE and AF.v1.0_Latest	15/05/2024	1.0
PIS/CF	RE and arterial function_PIS_CF_V1.0_latest	15/05/2024	1.0
Data and Tissue Management Plan	RE and arterial function-data and tissue- management	15/05/2024	1.0

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