Health and Disability Ethics Committees
Ministry of Health
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Ethics reference: 2023 EXP 18317

28 July 2023

Mrs. Rachel Scrivin

70 Windermere Drive
Poike
Tauranga
3112
New Zealand

Tēnā koe Mrs. Scrivin

APPROVAL OF APPLICATION

Study title: A comprehensive approach to address exercise-associated gastrointestinal syndrome: Evaluation and treatment strategies

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 noted that it is highly preferable tracked-changes versions of documents are provided when responding to a Provisional Approval so that changes may be directly compared quicker.
2. The Committee noted that health data must be retained for at least 10 years in New Zealand, please amend the data management plan (DMP) and participant information sheet.
3. Please add to the DMP types of data that will be collected as identifiable (e.g. name, date of birth, phone number, address, email, etc.), and coded (non-identifiable) data from blood tests, breath tests, gastro symptoms, etc. There is currently not enough detail in the DMP.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. There are still yes/no tickboxes in the consent form for items that are not truly optional. Please remove.

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 address all outstanding ethical issues raised by the Committee.

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 *Standard Operating Procedures for Health and Disability Ethics Committees (SOPs)*.

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 28 July 2024.

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 hdecs@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

Chair

Central Health and Disability Ethics Committee

Encl: Appendix A: documents submitted

Appendix A: Documents submitted

Document Type	File Name	Date	Version
Scientific Peer Review	Rachel_Reviewer Response Feedback CF		
Scientific Peer Review	Reviewer Response Feedback 2 TC		
Evidence of Consultation	Research and Human Ethics Application Form June 2023 by WE 2		
Advertisement	Are you an endurance runner and do you experience gut issues around exercise ad		
PIS/CF	Research Participation Information Sheet		
PIS/CF	Consent Form		
Tissue Management Plan	Tissue management plan		
Data Management Plan	Data management plan		
CV for Coordinating Investigator	Rachel Scrivin CV 2023 current		
Protocol	Research and Human Ethics Application Form July 2023		
Response to PA Document	Version 1 Cover letter for amendments		1
Response to PA Document	Version 1 hdec-peer-review JULY 2023_RS_CF		1
Response to PA Document	Version 2 HDEC-data-only-management-template RS		2
Response to PA Document	Version 2 Research participant information sheet Gut Study RS		2