Health and Disability Ethics Committees
Ministry of Health
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Ethics reference: 2024 EXP 20417

22 July 2024

Dr Gonzalo Maso Talou

Level 6/70 Symonds Street
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New Zealand

Tēnā koe Dr Maso Talou

APPROVAL OF APPLICATION

Study title: Hemodynamic Encephalopathy Risk Study: Characterising sex and ethnicity based differences in cerebrovascular dynamics.

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. In the advertisement, please amend "looking to uncover" to be "looking to research and uncover".

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

1. Add that data is stored at the University of Auckland and needs to be kept for at least 10 years. This is in the consent form but not the PIS.

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 22 July 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 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
Protocol	HER_Protocol_v1.3	24/06/2024	1.3
Scientific Peer Review	MS_PeerReviewTemplate	24/06/2024	1.0
Advertisement	HER_RecruitmentPoster_V1	24/06/2024	1.0
PIS/CF	HER_PIS_v1.1	24/06/2024	1.1
Data and Tissue Management Plan	HER_DataManagement_v1.0	24/06/2024	1.0
Surveys/questionnaires	HER_Demographics_v1.0	24/06/2024	1.0
Surveys/questionnaires	HER_Eligibility_v1.0	24/06/2024	1.0
PIS/CF	HER_Consent_Form_v1.2	24/06/2024	1.2
CV for Coordinating Investigator	2024_GonzaloMasoTalou_CV - HER_Study	24/06/2024	1.0