Health and Disability Ethics Committees
Ministry of Health
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Ethics reference: 2022 EXP 13191

13 December 2022

Dr Emma Wade

Hercus Building
Great King Street
Dunedin
9016
New Zealand

Tēnā koe Dr Wade

APPROVAL OF APPLICATION

Study title: Using a multi-omics approach to predict severity of pelvic organ prolapse

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 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 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:

- in the participant information sheet please add who has access to the identifiable and coded information (see latest PIS template). There is nothing new in the consent form that has not already been mentioned in the PIS.
- please include who pays for the study.
- please remove the intervention, it is just a tissue collection.
- please remove the yes/no tick boxes if not optional in the consent forms.
- please change Māori health support to Māori cultural support.

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 13 December 2023.

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
Evidence of Consultation	Māori Consultation April 2022_EW	26/05/2022	1
Scientific Peer Review	Review - genetics of POP	31/08/2022	1
CV for Coordinating Investigator	220906_Wade_RS&T	06/09/2022	1
Data and Tissue Management Plan	HDEC-data-tissue-management-V1	20/09/2022	2
PIS/CF	POP_Participant Information Sheet_V2	20/09/2022	1
Advertisement	Flyer_POP	20/09/2022	1
Protocol	POP_Project Plan_V5	20/09/2022	2

Review Document Type	Review Document File Name	Review Document Version Date