

**Ethics reference:** 2022 EXP 12032

16 March 2022

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Tēnā koe Associate Professor Miles-Chan

### **APPROVAL OF APPLICATION**

Study title: Evaluating FEijoa foR Diabetes Prevention in a Multi-ethnic New ZeAlaND Cohort: the FERDINAND study. A community nutrition intervention in individuals with pre-diabetes.

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](http://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 10 March 2023.**

### **Participant access to compensation**

The Southern 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 [hdec@health.govt.nz](mailto:hdec@health.govt.nz) or visit our website at [www.ethics.health.govt.nz](http://www.ethics.health.govt.nz) for more information, as well as our [General FAQ](#) and [Ethics RM FAQ](#).

Nāku noa, nā



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	FERDINAND STUDY_AsianChinese consult_Ms Danru Zhu		
Evidence of Consultation	FERDINAND STUDY_Asian Indian consultation_Dr Manish Khanolkar		
Evidence of Consultation	FERDINAND STUDY_Pacific consult_Dr Ofa Dewes		
Evidence of CI Indemnity	UoA_COC_Clinical Trials_2021	29/10/2021	1
CV for Coordinating Investigator	CV (Miles-Chan 2022)	11/01/2022	
Evidence of Consultation	FERDINAND STUDY_Kaupapa Māori Consul_Ms Arohaina Owenst	21/01/2022	
Protocol	FERDINAND STUDY_Protocol_v1_25Jan22	25/01/2022	1
Advertisement	FERDINAND STUDY_Advertisement_V1_25Jan22	25/01/2022	1
PIS/CF	FERDINAND STUDY_Main PIS-ICF_v1_25Jan22	25/01/2022	1
Data and Tissue Management Plan	FERDINAND STUDY_DTMP_v1_25Jan22	25/01/2022	1
Covering Letter	COVERLETTER_HDEC_FERDINAND STUDY_SIGNED	25/01/2022	
Surveys/questionnaires	Pre-screening Form_Trial 51_V1_25Jan2022	25/01/2022	1
Other	FERDINAND Study_Adverse Event Form_25Jan22	25/01/2022	1
Response to PA Document	COVERLETTER_HDEC_PROVISIONAL APPROVAL_3Mar22	03/03/2022	2
Response to PA Document	FERDINAND STUDY_Protocol_v2_3Mar22_track changes	03/03/2022	2
Response to PA Document	FERDINAND STUDY_Protocol_v2_3Mar22_highlighted changes	03/03/2022	2
Response to PA Document	FERDINAND STUDY_Main PIS-ICF_v2_3Mar22_track changes	03/03/2022	2
Response to PA Document	FERDINAND STUDY_Main PIS-ICF_v2_3Mar22_highlighted changes	03/03/2022	2

Review Document Type	Review Document File Name	Review Document Version Date
Scientific Peer Review	hdec-peer-review-template-june-2021_Prof. MC Kruger.pdf	03/01/2022

<http://www.ethics.health.govt.nz>