Health and Disability Ethics Committees
Ministry of Health
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09 September 2020

Prof Sally D Poppitt
Human Nutrition Unit (HNU)
18 Carrick Place
Mount Eden
Auckland 1024

Dear Prof Poppitt

Re:	**Ethics ref:**	**20/STH/51**
	Study title:	NEW ZEALAND DIETS FOR DIABETES PREVENTION IN ASIAN CHINESE (NZ DIETS _ASIA): A RESIDENTIAL STUDY IN PRE-DIABETIC ASIAN CHINESE AND EUROPEAN CAUCASIAN COHORTS

I am pleased to advise that this application has been *approved* by the Southern Health and Disability Ethics Committee. This decision was made through the HDEC-Expedited Review 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:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.

2. Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a WHO-approved registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au) or https://clinicaltrials.gov/.

3. Before the study commences at *each given* locality in New Zealand, it must be authorised by that locality in Online Forms. 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:

1. Please add the words by chance (I have used capitals only to show where I mean but this should be in capitals in the final PIS) in the following Page 2 of the revised main PIS "All Caucasian participants will be enrolled in the Healthy 'control' diet arm while the Chinese participants will be allocated BY CHANCE to either the Healthy 'control' diet or the Healthy Synergy diet arms (diagram below), so that we can test the response and differences in the diabetes biomarker

profile". Thank you for the change outlined below - and remember it is the researchers responsibility to ask anyone who withdraws if the samples can be kept and used. We have also addressed and added to Page 5 of the revised biobanking PIS-ICF the following statement "I understand that I may choose to withdraw my consent for storage of samples in the NSC-HVN virtual Biobank at any time".

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

If you would like an acknowledgement of completion of your non-standard conditions you may submit a post approval form amendment through Online Forms. 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 section 128 and 129 of the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz)

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 8 September 2021.

Participant access to ACC

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 trialled. 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 (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,

Mrs Helen Walker
Acting Chairperson
Southern Health and Disability Ethics Committee

Encl: appendix A: documents submitted
appendix B: statement of compliance and list of members

Appendix A
Documents submitted

Document	*Version*	*Date*
Covering Letter: Coverletter for study.	Version 1	25 March 2020
CV for CI: CV for Prof. Sally D Poppitt	Version 1	26 March 2020
CVs for other Investigators: CV for Dr Ivana R Sequeira	Version 1	26 March 2020
CVs for other Investigators: CV for Dr Louise Weiwei Lu	Version 1	26 March 2020
Evidence of scientific review: Peer review provided by Dr Amber Milan, Liggins Institute, University of Auckland	Version 1	20 March 2020
Evidence of CI indemnity	Version 1	23 March 2020
Evidence of sponsor insurance	Version 1	06 November 2019
PIS/CF: Participant information sheet and informed consent	Version 1	25 March 2020
Protocol: Protocol for study	Version 1	17 March 2020
Survey/questionnaire: Screen visit form	Version 1	17 March 2020
Survey/questionnaire: Pre-screening form	Version 1	17 March 2020
Survey/questionnaire: Medical history form	Version 1	17 March 2020
Survey/questionnaire: GP details form	Version 1	25 March 2020
Survey/questionnaire: Advertisement for recruitment	Version 1	25 March 2020
CVs for other Investigators: CV for Dr Jennifer Miles Chan	Version 1	25 March 2020
PIS/CF: Participant information sheet and informed consent for obtaining permission to Biobank samples	Version 1	26 March 2020
Application		26 March 2020
Covering Letter: Cover letter with responses to the Provisional Approval (20/STH/51) received by the Committee on 28.07.20	Version 2	17 August 2020
Protocol: Revised Version 2 Study Protocol	Version 2	17 August 2020
PIS/CF: Revised Version 2 of Main PIS/CF	Version 2	17 August 2020
PIS/CF: Revised Version 2 of Tissue banking PIS/CF	Version 2	17 August 2020
Revised Version 2 of the Advertisement for the Study	Version 2	17 August 2020

Appendix B
Statement of compliance and list of members

Statement of compliance

The Southern Health and Disability Ethics Committee:

- is constituted in accordance with its Terms of Reference
- operates in accordance with the *Standard Operating Procedures for Health and Disability Ethics Committees*, and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008713) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	*Category*	*Appointed*	*Term Expires*
Mrs Helen Walker	Lay (consumer/community perspectives)	19/08/2020	19/11/2020
Dr Pauline Boyles	Lay (consumer/community perspectives)	05/07/2019	05/07/2022
Dr Paul Chin	Non-lay (intervention studies)	27/10/2018	27/10/2021
Mr Dominic Fitchett	Lay (the law)	05/07/2019	05/07/2022
Dr Sarah Gunningham	Lay (other)	05/07/2016	05/07/2022
Assc Prof Mira Harrison-Woolrych	Non-lay (intervention studies)	28/06/2019	28/06/2020
Professor Jean Hay-Smith	Non-lay (health/disability service provision)	31/10/2018	31/10/2021
Dr Devonie Waaka	Non-lay (intervention studies)	18/07/2016	18/07/2019

Unless members resign, vacate or are removed from their office, every member of HDEC shall continue in office until their successor comes into office (HDEC Terms of Reference)

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