Health and Disability Ethics Committees
Ministry of Health
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10 April 2018

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

Dear Prof Poppitt

Re:	**Ethics ref:**	**18/CEN/52**
	Study title:	Targeting amylin to restore insulin secretion and prevent progression to diabetes: identifying the efficacy of the plant-origin flavonoid rutin

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

Summary of Study

1. This study will be conducted in 2 phases in male and female participants.
2. The first will assess pharmacokinetics of 250 and 500mg of rutin (once a day) in 2 delivery methods; capsule and within a food, in a cross over study over 24 hours in healthy participants.
3. The second will investigate efficacy of rutin (500mg q.d), in a double blind randomised 3-arm placebo controlled parallel study over 6 months, in participants with demonstrated prediabetes.
4. The study aims to determine optimal dose and pharmacokinetics of rutin, investigate the efficacy of rutin to target pancreatic amylin aggregates and restore insulin secretion to prevent progression to T2D, and determine response of T2D related blood biomarkers to rutin intervention

Summary of ethical issues (outstanding)

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

5. The Committee noted question r.2.5 of the application form states “The PI will maintain records of the signed consent forms, Case Report Forms/records, all correspondence and supporting documentation for a minimum of 5 years after the study.” Please ensure data will be stored for a minimum of 10 years after completion of the study, in accordance with New Zealand law.

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:

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 (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au). However https://clinicaltrials.gov/ is acceptable provided registration occurs prior to the study commencing at *any* locality in New Zealand.

3. Before the study commences at *a 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:

- Please ensure data will be stored for a minimum of 10 years after completion of the study, in accordance with New Zealand law.

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

If you would like an acknowledgement of completion of your non-standard conditions letter you may submit a post approval form amendment. Please clearly identify in the amendment 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 at http://ethics.health.govt.nz/home.

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 9 April 2019.

Participant access to ACC

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 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
Chairperson
Central 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*
Evidence of scientific review: Peer review from an independent researcher	1	27 February 2018
Evidence of sponsor insurance	1	12 December 2017
Review process undertaken for Maori Consultation	1	13 March 2018
Survey/questionnaire: Screening form for eligibility into the study.	1	06 December 2017
Survey/questionnaire: Pre-screening form for participant recruitment	1	28 February 2018
Survey/questionnaire: FINDRISC form for pre-screening participants	1	06 December 2017
Protocol deviation log	1	06 December 2017
Adverse event form	1	06 December 2017
CV for CI: Prof. Sally Poppitt's CV	1	14 March 2018
CVs for other Investigators: Dr Ivana Sequeira's CV	1	14 March 2018
CVs for other Investigators: Wilson Yip's CV	1	14 March 2018
Declined letter for previous application in respect of the same (or substantially similar) study: Declined letter from previous application	1	02 February 2018
Protocol: Study Protocol	1	05 March 2018
Evidence of CI indemnity	1	12 December 2017
Poster for recruitment	1	15 March 2018
Covering Letter: Cover letter for resubmission	1	15 March 2018
PIS/CF: Participant information sheet and informed consent form	1	12 March 2018
Application		

Appendix B
Statement of compliance and list of members

Statement of compliance

The Central 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 00008712) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	*Category*	*Appointed*	*Term Expires*	*Present on 27/03/2018?*	*Declaration of interest?*
Mrs Helen Walker	Lay (consumer/community perspectives)	01/07/2015	01/07/2018	Yes	No
Dr Angela Ballantyne	Lay (ethical/moral reasoning)	30/07/2015	30/07/2018	Yes	No
Dr Melissa Cragg	Non-lay (observational studies)	30/07/2015	30/07/2018	Yes	No
Dr Peter Gallagher	Non-lay (health/disability service provision)	30/07/2015	30/07/2018	No	No
Mrs Sandy Gill	Lay (consumer/community perspectives)	30/07/2015	30/07/2018	Yes	No
Dr Patries Herst	Non-lay (intervention studies)	27/10/2015	27/10/2018	Yes	No
Dr Dean Quinn	Non-lay (intervention studies)	27/10/2015	27/10/2018	Yes	No
Dr Cordelia Thomas	Lay (the law)	20/05/2017	20/05/2020	Yes	No

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