

19 March 2019

Miss Julia Cree
Human Nutrition Unit,
18 Carrick Place,
Mt. Eden 1024

Dear Miss Cree

Re: Ethics ref:	19/STH/30
Study title:	The influence of gender and the oral contraceptive pill on acute protein induced thermogenesis.

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 *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.

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.

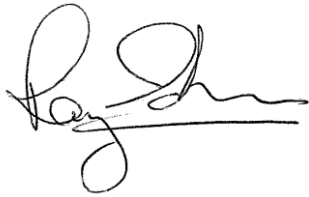
Your next progress report is due by 18 March 2020.

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,

A handwritten signature in black ink, appearing to read 'Raewyn Idoine', written over a horizontal line.

Ms Raewyn Idoine
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

<i>Document</i>	<i>Version</i>	<i>Date</i>
CV for CI: Julia Cree Academic CV	V1	22 January 2019
PIS/CF: Protein study PIS CF	V1	22 January 2019
Survey/questionnaire: Protein study screening questionnaire	V1	22 January 2019
Survey/questionnaire: Protein study health and lifestyle questionnaire	V1	22 January 2019
CVs for other Investigators: Academic CV of Dr. Jennifer Miles Chan (PhD supervisor of CI Julia Cree)	22.1.2019	22 January 2019
Evidence of scientific review: HDEC Scientific Peer Review by Dr. Marta Silvestre	22.1.2019	22 January 2019
Protocol: Protein study protocol	V2	23 January 2019
Evidence of sponsor insurance	1.12.18	16 January 2019
University of Auckland Head of Department approval	002	24 January 2019
Application		24 January 2019
Covering Letter: Cover letter	V1	13 March 2019
PIS/CF: PIS/CF with tracked changes	V3	05 March 2019
PIS/CF: PIS/CF Clean copy for participant	V3	05 March 2019
Kaiarahi Support Letter Maori Consultation	1	13 March 2019
G.P. contact details form	V1	13 March 2019
Response to Request for Further Information		

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

<i>Name</i>	<i>Category</i>	<i>Appointed</i>	<i>Term Expires</i>
Ms Raewyn Idoine	Lay (consumer/community perspectives)	27/10/2015	27/10/2018
Dr Paul Chin	Non-lay (intervention studies)	27/10/2018	27/10/2021
Dr Sarah Gunningham	Non-lay (intervention studies)	27/10/2015	27/10/2018
Assc Prof Mira Harrison-Woolrych	Non-lay (intervention studies)	27/10/2015	27/10/2018
Professor Jean Hay-Smith	Non-lay (health/disability service provision)	31/10/2018	31/10/2021
Assc Prof Nicola Swain	Non-lay (observational studies)	27/10/2015	27/10/2018
Dr Devonie Waaka	Non-lay (intervention studies)	13/05/2016	13/05/2019

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>