

11 June 2019

Dr Jennifer Miles-Chan  
School of Biological Sciences  
The University of Auckland  
Private Bag 92019, Auckland Mail Centre  
Auckland 1142

Dear Dr Miles-Chan

Re: <b>Ethics ref:</b>	<b>19/NTA/76</b>
Study title:	Evaluation of a new, multi-compartment model for field-based body composition assessment

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

#### Summary of outstanding ethical issues

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

1. Inconsistent advice about length of study data storage is provided.
2. Statements referring to DXA as not unpleasant needs to be guaranteed. Some patients with obstructive sleep apnoea may find lying flat uncomfortable.
3. "What happens if I change my mind" section doesn't discuss what happens if participant withdraws. This is mentioned in the Consent Form but should also be mentioned in the main body of the Participant Information Sheet.
4. Statistics plan is implied in the protocol but should be more detailed.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

5. Please include contact details for Māori health support.
6. "DXA... is not unpleasant". Please revise this statement.
7. Please add information on what happens if the participants wish to withdraw in the main body of the PIS.

#### 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 Northern A Health and Disability Ethics Committee is required.

Standard conditions:

8. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
9. 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:

10. Please ensure that the recruitment poster has all relevant inclusion and exclusion criteria so to avoid ineligible persons wasting their time with screening. Any screening data obtained from ineligible persons must be destroyed, as this is collected prior to consent.
11. Please ensure study data is kept for 10 years.
12. A small token of appreciation or offer of koha is appropriate.
13. Please clarify if R2 is the only test being performed. What about comparative statistics e.g. Bland-Altman

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](http://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](http://www.ethics.health.govt.nz)) for HDEC requirements relating to amendments and other post-approval processes.

**Your next progress report is due by 10 June 2020.**

#### Participant access to ACC

The Northern A 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 that reads "Manuka Henare". The signature is written in a cursive, flowing style.

Associate Professor Manuka Henare  
Chairperson  
Northern A 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: CV Jennifer Miles-Chan	1	28 May 2019
CVs for other Investigators: CV Helen Kilding	1	28 May 2019
CVs for other Investigators: CV Lindsay Plank	1	28 May 2019
Evidence of scientific review: Peer Review - Prof C Earthman	1	28 May 2019
Advertisement	1	27 May 2019
PIS/CF	1	27 May 2019
Protocol: Study Protocol	1	27 May 2019
Survey/questionnaire: Screening Questionnaire	1	27 May 2019
Kaiarahi support letter	1	27 May 2019
Evidence of sponsor insurance	1	16 January 2018
Covering Letter: Cover Letter	1	28 May 2019
Head of Department Approval	1	29 May 2019
Application		31 May 2019

## Appendix B Statement of compliance and list of members

### Statement of compliance

The Northern A 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 00008714) 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>
A/Prof Manuka Henare	Lay (consumer/community perspectives)	19/03/2019	19/03/2022
Dr Karen Bartholomew	Non-lay (intervention studies)	13/05/2016	13/05/2019
Dr Christine Crooks	Non-lay (intervention studies)	11/11/2015	11/11/2018
Ms Catherine Garvey	Lay (the law)	19/03/2019	19/03/2022
Ms Toni Millar	Lay (consumer/community perspectives)	11/11/2016	11/11/2019
Dr Kate Parker	Non-lay (observational studies)	11/11/2015	11/11/2018
Ms Rochelle Style	Lay (ethical/moral reasoning)	14/06/2017	14/06/2020

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>