Health and Disability Ethics Committees
Ministry of Health
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02 September 2016

Dr Robert Matthew Strother
Oncology Service
Private Bag 4710
Christchurch Hospital
Riccarton 8140

Dear Dr Strother

Re:	**Ethics ref:**	**16/CEN/116**
	Study title:	An Exploratory Study to Assess the Impact of Obesity-Related Inflammatory Markers on Breast Cancer Drug Metabolism in Response to Regular Moderate Exercise during Chemotherapy

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 is a study looking at two factors: the impact of obesity and the impact of exercise in a patient group of women who have breast cancer. The researchers intend to recruit 40 people to include age-matched controls in 20 obese and 20 non-obese participants.
2. The committee noted the prevalence rates for Maori included in the application form and that the researchers made good claim about how the issue is of high importance for Maori. With this in mind the committee asked whether there would be a special effort made to include Maori. The researcher stated that Maori make up 8% of the population in the Christchurch area and therefore if they are able to do a broader study throughout New Zealand they would look to include more Maori participants.

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:

The committee requested the following changes to the participant information sheet and consent forms:

1. The committee asked the researchers to review the information sheet and consent form for typos.
2. The committee asked the researchers to revisit the introductory opening paragraph as it is unclear about what the study is about.
3. The committee noted that obesity is not mentioned in the information sheet when the researchers are interested in studying inflammation that comes from obesity and how it affects liver enzyme function in this patient group. The researchers could introduce this in a sensitive way but at the same time there is a need to be transparent and honest because it is deceptive not to touch on this at all. The researchers run the risk of stigmatising if it is not mentioned at all. The committee noted that it is more important to not withhold this and suggested ways in which the researchers might be more transparent in a sensitive way. For example, refer to them carrying some extra weight or having a BMI higher than X.
4. Consent form: the committee asked that the provision for people to opt in or out of the study should be included in the consent form.
5. The committee queried why participants in this study are not being offered parking money for the reason that people shouldn't be disadvantaged from being in the study. The researchers explained that they had tried to arrange participation in the study around normal patient care and noted that parking is at a premium following the Christchurch earthquake. The committee recommended that the researchers could offer reasonable transport costs given lack of parking as a quid pro quo.

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 1 September 2017.

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*
CV for CI	1	13 July 2016
PIS/CF: Patient Information	1	29 July 2016
Protocol: Protocol	1.3	04 August 2016
Evidence of scientific review: Scientific Review	1.0	02 August 2016
Response to Scientific Review	1.0	04 August 2016

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 23/08/2016?*	*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	Yes	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	No	No
Dr Dean Quinn	Non-lay (intervention studies)	27/10/2015	27/10/2018	Yes	No
Dr Cordelia Thomas	Lay (ethical/moral reasoning)	19/05/2014	19/05/2017	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