Health and Disability Ethics Committees
Ministry of Health
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09 December 2016

Dr Liyana Satterthwaite
c/o MidCentral Regional Cancer Treatment Services
Palmerston North Hospital
50 Ruahine Street
Palmerston North 4414

Dear Dr Satterthwaite

Re:	**Ethics ref:**	**16/STH/197**
	Study title:	Oxaliplatin Dose Modification for Colorectal Cancer Triggered by Patient Reported Toxicity: Acceptability and Effect on Chronic Chemotherapy Induced Peripheral Neuropathy

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.

Summary of ethical issues (resolved)

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee noted that the cultural questions in the application form were poorly answered.
    a. p.4.1. Please describe whether and how your study may benefit Māori.
    b. Your answer: *This study is not designed to collect data on ethnicity or to study the differences between ethnic groups in New Zealand. The inclusion criteria is broad to ensure that all individuals, including Maori, are given the opportunity to participate. No specific benefits to Maori exist and the same potential benefits apply to all population groups.*
    c. The answer should include incidence and prevalence (statistics) of the disorder under study (or treatment indication if a drug trial) in Maori. The Secretariat notes that some disorders are particularly important for Maori health, while others are relatively rare in Maori and may have less of an impact. If the impact of treatment or prevalence of disease is low or the same as other populations please state this clearly to the Committee. Generally, any available statistics relating to Maori should be provided where possible.
    d. p.4.3.1. Please either describe your study's consultation process, or explain why you do not consider that formal consultation with Māori is required.
    e. Your answer: *As this study does not specifically target Maori we will not be formally consulting with Maori. However, given that Maori participants are likely to be included in the trial, we will notify our local Maori services about the study, including providing them with a PIS/CF.*

f. The Guidelines for Researchers on Health Research Involving Māori state that as a general rule, consultation should take place if Māori are to be involved as participants in a project or the project relates to a health issue of importance to Māori.

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:

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

3. 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.

4. 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:

5. Please give a lay explanation for the term 'peripheral neuropathy' in the Participant Information Sheet (PIS).
6. Please give a more detailed lay explanation of the study aims in the PIS.
7. Please make it clear that clinicians may choose not to follow the protocol-recommended dose modifications if they do not believe it is appropriate for the patient.
8. The Committee requested the compensation wording is updated for accuracy, they suggested the following statement: *"If you were injured in this study, which is unlikely, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery. If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover."*
9. Please state in the PIS how long health information will be stored for.
10. It is currently stated that there are no risks to participation, however there is a theoretical risk that reducing the cumulative oxaliplatin dose could be associated with worse outcomes (per the submitted application). A statement to this effect should be included in the PIS.

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.

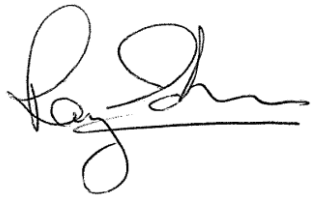
Your next progress report is due by 09 December 2016.

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,



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

Document	*Version*	*Date*
CVs for other Investigators: CV for co-investigator	CV-GF-2016	01 September 2016
CV for CI: CV for Chief Investigator	Liyana CV 2016	31 October 2016
Evidence of scientific review: Liyana Satterthwaite Certificate of ACORD Participation	1	01 November 2016
Protocol: Trial Protocol version 0.6	Version 0.6	11 November 2016
Survey/questionnaire: Modified Pro CTCAE Questionnaire as outlined in the protocolEORTC QLQ CIPN Questions - awaiting formal access from EORTC	Version 0.6	11 November 2016
PIS/CF: Participant Information Sheet and Consent Form	Version 0.6	11 November 2016
Application	1	-
Evidence of scientific review	1	18 November 2016

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*
Ms Raewyn Idoine	Lay (consumer/community perspectives)	27/10/2015	27/10/2018
Dr Devonie Eglinton	Non-lay (intervention studies)	13/05/2016	13/05/2019
Mrs Angelika Frank-Alexander	Lay (consumer/community perspectives)	27/10/2015	27/10/2018
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
Dr Fiona McCrimmon	Lay (the law)	27/10/2015	27/10/2018
Dr Nicola Swain	Non-lay (observational studies)	27/10/2015	27/10/2018
Dr Mathew Zacharias	Non-lay (health/disability service provision)	27/10/2015	27/10/2018

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