

11 April 2020

Dr John Woodfield
201 Great King Street
Dunedin 9016

Dear Dr Woodfield

Re:	Ethics ref:	19/CEN/209
	Study title:	A prospective randomised controlled study on the impact of assessing and treating bile acid malabsorption on function and quality of life in patients with major Low Anterior Resection Syndrome (LARS)

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.

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 registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au) or <https://clinicaltrials.gov/>.
3. 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:

4. Please include a statement in the Participant Information Sheet (PIS) about:
 - a) What participant rights are (see HDEC PIS template; <https://ethics.health.govt.nz/> under the Quick Links section)
 - b) Right to withdraw at any time without giving a reason
 - c) Right for participants to access their information and correct that if necessary.

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)

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 10 April 2021.

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

<i>Document</i>	<i>Version</i>	<i>Date</i>
PIS/CF: Patient information sheet and consent form	1	02 December 2019
Radiation dose letter	1	02 December 2019
CVs for other Investigators: CV for Dr. Kari Clifford	1	02 December 2019
CVs for other Investigators: CV for Associate Professor Mark Thompson-Fawcett	1	02 December 2019
CV for CI: CV for CI	1	03 December 2019
Evidence of scientific review: Scientific review outcome letter	1	02 December 2019
Survey/questionnaire: questionnaires	1	02 December 2019
Protocol: Protocol	1	02 December 2019
Application		04 December 2019
Covering Letter: Cover letter for submitting revised protocol after consultation with the Committee	1	28 February 2020
Protocol: Clean updated protocol revised after consultation with the HDEC.	2	28 February 2020
Protocol: Tracked protocol revised after consultation with HDEC and receiving provisional approval.	2	28 February 2020
PIS/CF: PIS revised for provisional approval, Clean.	2	28 February 2020
PIS/CF: PIS tracked, revised according to consultation with the HDEC.	2	28 February 2020
Response to Request for Further Information		

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

<i>Name</i>	<i>Category</i>	<i>Appointed</i>	<i>Term Expires</i>
Mrs Helen Walker	Lay (consumer/community perspectives)	01/07/2018	01/07/2021
Ms Helen Davidson	Lay (ethical/moral reasoning)	06/12/2018	06/12/2021
Dr Peter Gallagher	Non-lay (health/disability service provision)	30/07/2015	30/07/2018
Mrs Sandy Gill	Lay (consumer/community perspectives)	30/07/2015	30/07/2018
Dr Ptries Herst	Non-lay (intervention studies)	27/10/2015	27/10/2018
Dr Cordelia Thomas	Lay (the law)	20/05/2017	20/05/2020

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>