

15 November 2013

Dr Hyun Sang Shin
18 Carrick Place
Mt Eden, Auckland 1024

Dear Dr Shin

| | | |
|-----|--------------------|--|
| Re: | Ethics ref: | 13/NTA/207 |
| | Study title: | Activation of the ileal brake by carbohydrates and plant extracts –A pilot study in ileostomy patients to develop sample collection and analytical methods |

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.

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:

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 WHO-approved clinical trials registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au).
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.

After HDEC review

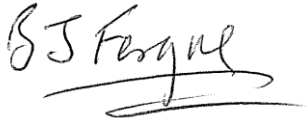
Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

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, appearing to read "B J Fergus", with a horizontal line underneath.

Dr Brian Fergus
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> |
|---|----------------|-------------------|
| CVs for other Investigators | 1 | 18 June 2013 |
| CV for CI | 1 | 13 September 2013 |
| PIS/CF | v2 | 22 October 2013 |
| Protocol: Several suggestions from scientific peer-review by Dr Russell Walmsley are added to this version. | v4 | 28 October 2013 |
| Survey/questionnaire: VAS to measure any abdominal discomfort or nausea | v1 | 22 October 2013 |
| Evidence of CI indemnity | 1 | 04 December 2012 |
| 1.Evidence of peer-review signed by university head of department.2. Locality form.These two forms are in one pdf file. | v3/v2 | 23 October 2013 |
| A series of screen visit forms in excel file. | v1 | 12 September 2013 |
| Analysis of grape seed extract (Oxifend) | v1 | 13 August 2013 |
| Diarrhoea and vomit recording sheets | 1 | 12 September 2013 |
| Evidence of scientific review | v1 | 23 October 2013 |
| Application | 1 | 31 October 2013 |

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> |
|----------------------|---|------------------|---------------------|
| Dr Brian Fergus | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 |
| Dr Karen Bartholomew | Non-lay (intervention studies) | 01/07/2013 | 01/07/2016 |
| Ms Susan Buckland | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2015 |
| Ms Shamim Chagani | Non-lay (health/disability service provision) | 01/07/2012 | 01/07/2014 |
| Dr Christine Crooks | Non-lay (intervention studies) | 01/07/2013 | 01/07/2015 |
| Mr Kerry Hiini | Lay (consumer/community perspectives) | 01/07/2012 | 01/07/2014 |
| Dr Etuate Saafi | Non-lay (intervention studies) | 01/07/2012 | 01/07/2014 |
| Ms Michele Stanton | Lay (the law) | 01/07/2012 | 01/07/2014 |

<http://www.ethics.health.govt.nz>