

06 September 2016

Mrs. Fernanda Fernandez Zimmermann
Centre for Postgraduate Nursing Studies
72, Oxford Tce. PO Box 4345
University of Otago - Christchurch.
Christchurch 8041

Dear Mrs. Fernandez Zimmermann

| | | |
|-----|--------------------|--|
| Re: | Ethics ref: | 16/NTA/75 |
| | Study title: | Mindfulness, acceptance and meaning of life for adults with advanced cancer: one-group pre-test post-test study with mixed methods approach. |

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-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 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 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.

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.

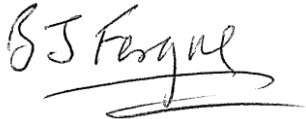
Your next progress report is due by **05 September 2017**.

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> |
|---|----------------|----------------|
| Protocol: Study protocol. | Chrome | 09 August 2016 |
| Evidence of scientific review: Peer review letter-Professor Marie Crowe | Chrome | 20 May 2016 |
| Evidence of scientific review: Peer review letter-Dr Williman | Chrome | 20 May 2016 |
| CV for CI: Primary investigator CV | Chrome | 20 May 2016 |
| Investigator's Brochure: Study brochure/pamphlet. | Chrome | 09 August 2016 |
| Investigator's Brochure: Study poster. | Chrome | 09 August 2016 |
| PIS/CF: Consent form. | Chrome | 09 August 2016 |
| PIS/CF: Participants Information Sheet | Chrome | 09 August 2016 |
| Survey/questionnaire: Post-intervention interview Prompt Sheet. | Chrome | 09 August 2016 |
| Survey/questionnaire: Pre-intervention interview prompt sheet. | Chrome | 09 August 2016 |
| Survey/questionnaire: Registration form. | Chrome | 09 August 2016 |
| Survey/questionnaire: Acceptance and Action Questionnaire-II. Author's permission obtained. | Chrome | 09 August 2016 |
| Survey/questionnaire: Mindful Coping Scale (adapted version). Author's permission obtained. | Chrome | 20 May 2016 |
| Survey/questionnaire: Meaning of Life Questionnaire. Author's permission obtained. | Chrome | 09 August 2016 |
| Maori consultation approval letter. | Chrome | 20 May 2016 |
| Application | | |
| Declined letter for previous application in respect of the same (or substantially similar) study: Response letter to the committee. | pdf | 09 August 2016 |
| Response to Request for Further Information | | 10 August 2016 |

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) | 11/11/2015 | 11/11/2018 |
| Ms Rosemary Abbott | Lay (the law) | 15/03/2016 | 15/03/2019 |
| Dr Karen Bartholomew | Non-lay (intervention studies) | 13/05/2016 | 13/05/2019 |
| Dr Charis Brown | Non-lay (intervention studies) | 11/11/2015 | 11/11/2018 |
| Ms Susan Buckland | Lay (consumer/community perspectives) | 11/11/2015 | 11/11/2016 |
| Ms Shamim Chagani | Non-lay (health/disability service provision) | 11/11/2015 | 11/11/2016 |
| Dr Christine Crooks | Non-lay (intervention studies) | 11/11/2015 | 11/11/2018 |
| Dr Kate Parker | Non-lay (observational studies) | 11/11/2015 | 11/11/2018 |

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>