Health and Disability Ethics Committees
Ministry of Health
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0800 4 ETHICS
hdecs@moh.govt.nz

04 April 2014

Miss Amy Richardson
85 Park Road
Grafton
The University of Auckland
Private Bag 92019
Auckland 0630

Dear Miss Richardson

Re:	**Ethics ref:**	**14/NTB/15**
	Study title:	Effects of a Self-Regulation Intervention on Coping, Quality of Life, and Psychological Wellbeing in Patients with Head and Neck Cancer and Their Caregivers: A Randomized Controlled Trial

I am pleased to advise that this application has been *approved* by the Northern B Health and Disability Ethics Committee. This decision was made through the HDEC-Expedited Review pathway.
Thank you for clarification around the consent process. The practicalities of obtaining consent within a limited time window are noted. However, the committee feel strongly that in accordance with the National Ethics Advisory Committee (NEAC) guidelines on obtaining free and valid informed consent (with reference also to vulnerable populations) that the emphasis on the consent process is to ensure patients are **given adequate time to consider participation** and are **able to provide valid consent when not overwhelmed or in a stressful situation**.

Approval is therefore given on the basis that in accordance with section 6.18, NEAC guidelines that during the initial consent discussion (at outpatient clinic in this instance), due regard should be paid to the circumstances of the potential participant. Therefore only a short discussion/introduction of the study should be made at the time of the outpatient visit and only if the Investigator believes the patient is not overwhelmed with information at this time or in a stressful situation that would create difficulties in understanding.

Consent should not be obtained at this time but rather an initial brief discussion (where the Investigator feels that a brief introduction at the time of outpatient visit is appropriate) should be followed up with more detailed information at a later time, removed from the diagnosis/treatment outpatient visit.

The responsibility for obtaining free and valid consent remains with the Investigator and the comments above are to ensure that **sufficient time is afforded to all participants in making informed consent decisions**.

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 B 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.

Non-standard conditions (if applicable):

- Please ensure that correct Maori support contact details are included in the Participant Information Sheet/Consent Form.

Non-Standard conditions must be completed before commencing your study. Non-standard conditions do not need to be submitted to HDEC before commencing your study.

If you would like to submit your Non-standard conditions please email Non-standard conditions to HDECS@moh.govt.nz. Do not submit Non-standard conditions as a Post Approval form.

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 **04 April 2015**.

Participant access to ACC

The Northern B 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 Raewyn Sporle
Chairperson
Northern B 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	03 February 2014
CVs for other Investigators	1	03 February 2014
Protocol	1	03 February 2014
Survey/questionnaire	1	03 February 2014
Survey/questionnaire: 3 month follow-up questionnaire - patients	1	03 February 2014
Survey/questionnaire: 6 month follow-up questionnaire - patients	1	03 February 2014
PIS/CF: PIS/CF - patient	1	03 February 2014
Survey/questionnaire	1	03 February 2014
Survey/questionnaire: 3-month follow-up questionnaire - caregivers	1	03 February 2014
Survey/questionnaire: 6 month follow-up questionnaire - caregivers	1	03 February 2014
Evidence of scientific review	1	04 February 2014
Application		04 February 2014
Evidence of scientific review		07 February 2014
HDEC_Response to Further Information request.docx		05 March 2014

Appendix B
Statement of compliance and list of members

Statement of compliance

The Northern B 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 00008715) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	*Category*	*Appointed*	*Term Expires*
Mrs Raewyn Sporle	Lay (the law)	01/07/2012	01/07/2015
Mrs Maliaga Erick	Lay (consumer/community perspectives)	01/07/2012	01/07/2014
Mrs Kate O'Connor	Non-lay (other)	01/07/2012	01/07/2015
Mrs Stephanie Pollard	Non-lay (intervention studies)	01/07/2012	01/07/2015
Dr Paul Tanser	Non-lay (health/disability service provision)	01/07/2012	01/07/2014
Ms Kerin Thompson	Non-lay (intervention studies)	01/07/2012	01/07/2015

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