Health and Disability Ethics Committees
Ministry of Health
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10 August 2016

Ms Michelle Locke
South Auckland Clinical Campus
The University of Auckland
c/- Middlemore Hospital
Private Bag 93311
Otahuhu, AUckland 1640

Dear Ms Locke

Re:	**Ethics ref:**	**16/CEN/75**
	Study title:	Reducing alcohol-related harm: Feasibility and effectiveness of a text message-based intervention delivered through the Plastic Surgery service

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-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 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 (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 **09 August 2017.**

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

Document	*Version*	*Date*	
Survey/questionnaire: Standardized AUDIT questionnaire	1	23 May 2016	
Survey/questionnaire: Short (3 question) version of AUDIT	1	23 May 2016	
Survey/questionnaire: B-YAARCQ standardized questionnaire	1	23 May 2016	
Graphic for use on SpillIt advertising poster on CMDHB ward	1	23 May 2016	
CV for CI: CV for Michelle Locke	1	23 May 2016	
Evidence of scientific review: Evidence of Maaori review and approval	1	23 March 2016	
Covering Letter: Cover letter	1	23 May 2016	
Protocol: Research protocol in format required for CMDHB research office	1	23 May 2016	
Head of Department approval - signed by both UoA and CMDHB HoDs	2	01 June 2016	
PIS/CF: On line consent information	1	27 May 2016	
PIS/CF: Patient information on SpillIt website	1	27 May 2016	
Text Message schedule for participants randomized to "passive brief intervention" arm	1	27 May 2016	
Evidence of scientific review: Scientific peer review by colleague	1	27 May 2016	
Application			
PIS/CF: Revised version of PIS/CF	2	05 August 2016	
Covering Letter: Response to committee	2	05 August 2016	

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

Name	*Category*	*Appointed*	*Term Expires*
Mrs Helen Walker	Lay (consumer/community perspectives)	01/07/2015	01/07/2018
Dr Angela Ballantyne	Lay (ethical/moral reasoning)	30/07/2015	30/07/2018
Dr Melissa Cragg	Non-lay (observational studies)	30/07/2015	30/07/2018
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 Patries Herst	Non-lay (intervention studies)	27/10/2015	27/10/2018
Dr Dean Quinn	Non-lay (intervention studies)	27/10/2015	27/10/2018
Dr Cordelia Thomas	Lay (ethical/moral reasoning)	19/05/2014	19/05/2017

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