

Health and Disability Ethics Committees
Ministry of Health
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16 July 2020

Dr Susanna Every-Palmer 23A Mein Street University of Otago, Newtown Wellington 6242

#### Dear Dr Every-Palmer,

Re:	Ethics ref: 20/NTB/150	
	Study title:	The evaluation of a Mental Health Co-Response Team: Police, ambulance and mental health services co-attending mental health 111 calls

I am pleased to advise that this application has been <u>approved</u> by the Northern B 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 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.
- 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, <a href="www.anzctr.org.au">www.anzctr.org.au</a>) or <a href="https://clinicaltrials.gov/">https://clinicaltrials.gov/</a>.
- 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:

 As per the Committees request - Please update the NTB ethics reference in PISCs to 20/NTB/150.

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 <a href="www.ethics.health.govt.nz">www.ethics.health.govt.nz</a>) for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 16 July 2021.

#### 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,

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	
Protocol: For interviews and survey	7	01 July 2020	
Declined letter for previous application in respect of the same (or substantially similar) study: We have addressed the main ethical issues		26 June 2020	
Covering Letter: Ethical issues addressed	1	01 July 2020	
CV for CI: CV Susanna Every-Palmer	1	01 July 2020	
CVs for other Investigators: Updated CV	1	03 July 2020	
Survey/questionnaire: On-line survey	2	01 July 2020	
Evidence of scientific review: Dr Gabrielle Jenkin	1	01 April 2020	
Initial Participant Information Sheet	1	01 July 2020	
PIS/CF: For CRT users and whanau	2	01 July 2020	
PIS/CF: For staff	2	01 July 2020	
Application		03 July 2020	

# 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	
Mr John Hancock	Lay (the law)	14/12/2015	14/12/2018	
Dr Nora Lynch	Non-lay (health/disability service provision)	24/07/2015	24/07/2022	
Miss Tangihaere Macfarlane	Lay (consumer/community perspectives)	20/05/2017	20/05/2020	
Mrs Kate O'Connor	Lay (ethical/moral reasoning)	14/12/2015	14/12/2018	
Mrs Stephanie Pollard	Non-lay (intervention studies)	01/07/2015	01/07/2018	
Mrs Leesa Russell	Non-lay (intervention studies), Non- lay (observational studies)	14/12/2015	14/12/2018	
Ms Susan Sherrard	Lay (consumer/community perspectives)	19/03/2019	19/03/2022	
Mrs Jane Wylie	Non-lay (intervention studies)	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