

27 November 2017

Prof Felicity Goodyear-Smith
University of Auckland
PB 92 019
Auckland 1142

Dear Professor Goodyear-Smith

Re:	Ethics ref:	17/CEN/224
	Study title:	VeCHAT: Proof of concept study on screening, managing and monitoring NZ veterans' health and wellbeing

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.

Thank you for clarifying in our conversation that prospective participants will be approached, given the Participant Information Sheet and their response via email will have to state that they consent to participate. They will then be given the log in. This discussion was prompted by the discrepancy between questions P.1.1 and P.1.9.1.

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 **26 November 2018**.

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

<i>Document</i>	<i>Version</i>	<i>Date</i>
Protocol: Protocol	24 Oct 2017	24 October 2017
Survey/questionnaire: Veteran online follow-up survey	24 Oct 2017	24 October 2017
PIS/CF: Consent MCR	24 Oct 2017	24 October 2017
PIS/CF: Consent CM	24 Oct 2017	24 October 2017
PIS/CF: Veteran Consent	24 Oct 2017	24 October 2017
Advertising / one -page information sheet	24 Oct 2017	24 October 2017
PIS/CF: CM PIS	24 Oct 2017	24 October 2017
PIS/CF: PIS MCR	24 Oct 2017	24 October 2017
PIS/CF: PIS Veteran	24 Oct 2017	24 October 2017
Survey/questionnaire: CM interview	24 Oct 2017	24 October 2017
Survey/questionnaire: MCR Interview	24 Oct 2017	24 October 2017
Survey/questionnaire: Veteran follow-up survey	24 Oct 2017	24 October 2017
CV for CI: CV	1	25 October 2017
Evidence of scientific review	1	25 October 2017
Application		
Evidence of scientific review	1	30 October 2017
Evidence of scientific review	1	30 October 2017
Evidence of scientific review	1	30 October 2017

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

<i>Name</i>	<i>Category</i>	<i>Appointed</i>	<i>Term Expires</i>
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 (the law)	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>