

05 May 2018

Mrs Rhiannon Martel
59 Sale Street
Cockle Bay
Auckland 2014

Dear Mrs Martel

Re: Ethics ref:	18/CEN/31
Study title:	Evaluating the implementation of YouthCHAT: a primary care e-screening tool for mental health issues among Te Tai Tokerau Youth

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 registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au) or <https://clinicaltrials.gov/>.
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 NOTE: in the track changes in the protocol re the YouthChat Screen, please train researchers and ensure that the 12-16 data, should they choose to continue the YouthChat Screen, is in actual fact removed from the research. The Committee does not want to have a protocol deviation occur and unconsented information slip through.

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 www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 04 May 2019.

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>
Evidence of scientific review: letter HRC	One	26 October 2017
Evidence of scientific review: Letter supporting study	one	22 August 2017
Locality support	1	20 October 2017
Locality Support	1	02 June 2017
CV for CI: CV R Martel (PhD student)	1	04 March 2018
CV for CI: CV F Goodyear Smith Supervisor for R Martel	1	31 December 2017
PIS/CF: Consent CE	Mar 5	07 March 2018
PIS/CF: Consent CS	Mar 5	07 March 2018
PIS/CF: Consent Youth	Mar 5	07 March 2018
PIS/CF: PIS CE	Mar 5	07 March 2018
PIS/CF: PIS CS	Mar 5	07 March 2018
PIS/CF: PIS clinics	Mar 5	07 March 2018
PIS/CF: PIS Youth	Mar 5	07 March 2018
Survey/questionnaire: Interview CE addit	Mar 7	07 March 2018
Survey/questionnaire: Interview CS	Mar 7	07 March 2018
Survey/questionnaire: Staff Survey	Mar 7	07 March 2018
Protocol: Protocol	Mar 7	07 March 2018
Survey/questionnaire: Youth Questions Focus Group	Mar 6	07 March 2018
Application		
PIS/CF: Clean copy revised Youth Consent form	April 30	30 April 2018
PIS/CF: Revised youth consent form with tracked changes	April 30	30 April 2018
Covering Letter: Response to outstanding ethical issues	April 30	30 April 2018
PIS/CF: Clean copy revised youth PIS	April 30	30 April 2018
Revised youth PIS with tracked changes	April 30	30 April 2018
PIS/CF: Revised protocol - clean copy	April 30	30 April 2018
PIS/CF: Revised protocol with Tracked Changes	April 30	30 April 2018
Response to Request for Further Information		

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>