

21 August 2017

Prof. Paul Brunton  
Faculty of Dentistry, University of Otago  
Dunedin North 9054

Dear Prof. Brunton

Re: <b>Ethics ref:</b>	<b>17/NTB/171</b>
Study title:	Jaw opening forces in subjects diagnosed with Temporomandibular disorder

I confirm receipt of this application for HDEC review, which was submitted on 18 August 2017.

Arrangements for HDEC review

Your application has been assigned for HDEC review by the HDEC-Expedited Review pathway.

As this pathway involves a subcommittee of the Chair plus up to two other members, this application will not be assigned to the agenda of a meeting of the full HDEC. A member of the subcommittee may contact you by telephone to discuss this application before a decision is taken.

Timeline for giving a final opinion

The 15-day clock for giving a final opinion on this application starts on 21 August 2017. This clock may stop once only, where the HDEC requires further information from you in order to make a final decision. You would then have up to 90 days to provide this further information, at which point the review clock would be re-activated.

No amendments to be made before HDEC approval

No amendments can be made to your application before it is approved, except where requested by the HDEC as a condition of approval. If you think you may need to amend your application during this time, we advise you to withdraw and re-submit it at a later date.

Please don't hesitate to contact us for further information.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'T. Kent', written in a cursive style.

Tom Kent  
Advisor  
Health and Disability Ethics Committees  
hdec@mh.govt.nz

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: Project Proposal	PDF	15 August 2017
CV for CI: Prof Paul Brunton's CV	MS Word	11 August 2017
CVs for other Investigators: Jithendra Ratnayake's CV (Co-investigator)	MS Word	11 August 2017
CVs for other Investigators: Dr Loch's CV (co-investigator)	MS Word	11 August 2017
CVs for other Investigators: Dr Ajith Polonowita's CV	MS Word	11 August 2017
CVs for other Investigators: Associate Professor Neil Waddell's CV	MS Word	11 August 2017
Evidence of scientific review: Prof Richard Cannon's Peer review	PDF	11 August 2017
Evidence of scientific review: Dr Le Mei peer review	PDF	11 August 2017
PIS/CF: Participant Information Sheet	MS Word	11 August 2017
PIS/CF for persons interested in welfare of non-consenting participant: Consent form	MS Word	11 August 2017
Maori Consultation for ethics	PDF	11 August 2017
Survey/questionnaire: Patients Questionnaire including Name, DOB, ethnicity, Contact information	PDF	15 August 2017
Survey/questionnaire: TMD diagnostic questionnaire used at the clinic by Dr Ajith Polonowita	MS Word	15 August 2017
Application		

## 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

<i>Name</i>	<i>Category</i>	<i>Appointed</i>	<i>Term Expires</i>
Mrs Maliaga Erick	Lay (consumer/community perspectives)	01/07/2015	01/07/2018
Mr John Hancock	Lay (the law)	14/12/2015	14/12/2018
Dr Nora Lynch	Non-lay (health/disability service provision)	24/07/2015	24/07/2018
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
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>