

26 October 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 am pleased to advise that this application has been approved by the Northern B Health and Disability Ethics Committee. This decision was made through the HDEC-Expedited Review pathway.

Note from Chair: Please for the future, can the researcher submit both tracked and clean versions of altered documents such as the Participant Information Sheet.

#### 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.
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](http://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](http://www.ethics.health.govt.nz)) for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 25 October 2018.

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,



Mrs Kate O'Connor  
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**

<i>Document</i>	<i>Version</i>	<i>Date</i>
Protocol: Updated Project Proposal	PDF	18 October 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: Updated Participant Information Sheet	PDF	18 October 2017
PIS/CF for persons interested in welfare of non-consenting participant: Revised consent form and patients information questionnaire	PDF	18 October 2017
Maori Consultation for ethics - granted	PDF	18 October 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		
Re: Response to the Ethics committee	MS Word	17 October 2017

## 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>