Health and Disability Ethics Committees
Ministry of Health
133 Molesworth Street
PO Box 5013
Wellington
6011

hdecs@health.govt.nz

10 February 2021

Professor Paul Brunton
Faculty of Dentistry, University of Otago
Division of Health Sciences
Dunedin North 9054

Dear Professor Brunton,

Re:	**Ethics ref:**	**20/NTA/186**
	Study title:	Overcoming dental anxiety with needle-free tooth anaesthesia

I am pleased to advise that this application has been *approved with non-standard conditions* by the Northern A Health and Disability Ethics Committee. This decision was made through the HDEC-Full 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 A 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:

4. The Participant Information Sheet (PIS) still does not make clear that participants also are blinded. Please ensure participants also know they are "blinded" to which side of the mouth the anaesthetic techniques are used.

5. Please ensure that the risk of coercion of participants who are approached in the clinic is minimised for example by the PIS being given to eligible participants by someone other than the treating dentist. Please make clear that they can ask questions prior to returning for their next appointment when the extractions are scheduled.

6. Please ensure that the consent portion of the PISCF is consistent with the intention to only collect dental information.

7. Note that the advocacy email appears twice in the PISCF and is incorrect the first time.

8. Please include the following in the PIS:

a) The random allocation of the techniques in each patient (either left or right side).
b) The participant's dentist to be informed of their participation in the study and any significant abnormal results obtained during the study (included only in the consent form).

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.

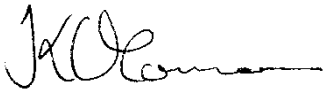
Your next progress report is due by 10 February 2022.

Participant access to ACC

The Northern A 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. For any future amendments, please ensure that clean and tracked changes to documents are uploaded. We wish you all the best for your study.

Yours sincerely,



Mrs. Kate O'Connor
Chairperson
Northern A 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*
Declined letter for previous application in respect of the same (or substantially similar) study: Decline letter	1	02 November 2020
CV for CI: Cv for CI	1	01 August 2020
CVs for other Investigators	1	27 August 2020
CVs for other Investigators: Mitten CV	1	29 September 2020
Evidence of scientific review: S Guan review	1	09 October 2020
Survey/questionnaire: Revised questionnaires	2	23 November 2020
PIS/CF: PIS CF_V3 clean	3	19 January 2021
Protocol: Revised protocol_V3 clean	3	19 January 2021
Investigator's Brochure: Device Safety	1	25 November 2020
Covering Letter: Response to the ethics committee_v2	2	19 January 2021
DATA MANAGEMENT PLAN clean	2	18 January 2021
Application		27 November 2020
Evidence of CI indemnity	1	18 January 2021
Evidence of CI indemnity	1	18 January 2021
Response to Request for Further Information		

Appendix B
Statement of compliance and list of members

Statement of compliance

The Northern A 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 00008714) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	*Category*	*Appointed*	*Term Expires*
Mrs Kate O'Connor	Lay (consumer/community perspectives)	29/01/2020	29/01/2021
Dr Karen Bartholomew	Non-lay (intervention studies)	18/07/2016	18/07/2022
Dr Sotera Catapang	Non-lay (observational studies)	11/02/2020	11/02/2023
Ms Catherine Garvey	Lay (the law)	19/03/2019	19/03/2022
Dr Michael Meyer	Non-lay (health/disability service provision)	11/02/2020	11/02/2023
Dr Kate Parker	Non-lay (observational studies)	11/02/2020	11/02/2026
Ms Rochelle Style	Lay (ethical/moral reasoning)	14/06/2017	14/06/2020

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