Health and Disability Ethics Committees
Ministry of Health
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Ethics reference: 2023 FULL 18139

8 December 2023

Mr Ankit Parimal Parikh

AG building, 90 Akoranga Drive, Northcote
Auckland
0627
New Zealand

Tēnā koe Mr Parikh

APPROVAL OF APPLICATION

Study title: A feasibility study of respiratory-gated non-invasive auricular vagus nerve stimulation in people with rheumatoid arthritis

I am pleased to advise that your application was **approved** by the Northern A Health and Disability Ethics Committee (the Committee) **with non-standard conditions**. This decision was made through the FULL pathway.

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee commended the Researchers on the amount of work that had been done in response to the previous decline.
2. The Committee queried if it would be possible for a research nurse to consent participants and the Researcher confirmed this would be the case.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee and which require addressing by the Researcher are as follows.

1. In the participant-facing documentation, please ensure the Northern A HDEC is named as the approving ethics committee.
2. The Committee noted there is some commercial benefit to the primary sponsor. Any references to ACC compensation will need to be replaced. It is likely that this study will have access to AUT insurance which will be adequate, but this should be clarified as the company are getting study data and will benefit from this study. The Committee requested provision of ACC-equivalent cover in the event of an injury.
3. The Committee noted the following about the data and tissue management plan:
    1. It currently states that samples will go to landfill. Please instead state that samples will be destroyed according to standard lab procedures.
    2. There is a statement that de-identified data will not be made available to anyone else, but in the participant information sheet (PIS), participants are asked for permission to share that data with other researchers. Please decide which one is correct and alter documents accordingly. If data will be made available overseas, please ensure it is outlined how this will be done.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. The Committee noted that the 0800 4 ETHICS number is no longer current. The appropriate contact can be found under the latest HDEC template.
2. The Committee suggested that given the limited number of devices available for use in the trial, please consider providing participants with information about how to care for these in person and include this information in the PIS.
3. The Committee queried how the researchers monitor whether the device is being used as planned. The Researcher responded that they are aware when a participant has logged in and partially or fully completed the intervention, and this is checked every day. The CI also gets notified to follow up. The Committee asked that this information be included in the PIS.
4. On page 7, there is clarification further down that participant can withdraw from the study if they have extreme pain. But at the top of the page, it states that there can be no adjustment of drugs during the course of the study. Please add after that sentence that if their pain is unmanageable, they of course are able to withdraw from the study.
5. On page 8, please remove the reference to the New Zealand Medicine Industry guidelines. These do not apply to devices.

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:

- Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
- Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a registry approved by the World Health Organization (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au or https://clinicaltrials.gov/).
- Before the study commences at *each given* locality in New Zealand, it must be authorised by that locality in Ethics RM. 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:

- please address all outstanding ethical issues raised by the Committee
- please update the Participant Information Sheet and Consent Form, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 7.15 – 7.17).*

Non-standard conditions must be completed before commencing your study, however, they do not need to be submitted to or reviewed by HDECs.

If you would like an acknowledgement of completion of your non-standard conditions you may submit a post approval form amendment through the Ethics Review Manager. 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 paragraphs 125 and 126 of the *Standard Operating Procedures for Health and Disability Ethics Committees (SOPs)*.

After HDEC review

Please refer to the *SOPs* for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 08 December 2024.

Participant access to compensation

This clinical trial is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Section 32 of the Accident Compensation Act 2001 provides that participants injured as a result of treatment received as part of this trial will **not** be eligible for publicly-funded compensation through the Accident Compensation Corporation.

Further information and assistance

Please contact the HDECs Secretariat at hdecs@health.govt.nz or visit our website at www.ethics.health.govt.nz for more information, as well as our General FAQ and Ethics RM user manual.

Nāku noa, nā

Ms Catherine Garvey

Chair

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 Type	File Name	Date	Version
Evidence of Consultation	MMC 2020 Consultation feedback -Parikh	19/08/2022	1
Scientific Peer Review	hdec-peer-review_IKN-signed	01/05/2023	1
Non-Review Document	HDEV_Reviewe_Letter_13403	30/05/2023	1
CV for Coordinating Investigator	Resume-Ankit-Parikh-July-2023	13/07/2023	1
Data and Tissue Management Plan	HDEC_data_tissue_management_Study2_V2	20/10/2023	2
Advertisement	Advert_taVNS_Study2_V2	20/10/2023	2
Protocol	Protocol_Study2_V5	20/10/2023	5
Covering Letter	HDEC_Application_18139_Cover_Letter	20/10/2023	1
PIS/CF	InformationSheet_ConsentForm_V3_taVNS_Study2	27/10/2023	3

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

Dr Sotera Catapang, Mr Derek Chang, Mr Jonathan Darby, Dr Andrea Forde, Ms Catherine Garvey, Dr Kate Parker, Ms Jade Scott.

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