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

hdecs@health.govt.nz

18 May 2021

Mr Jim Bartley
10 Owens Road
Epsom
Auckland 1023

Dear Mr Bartley

Re:	**Ethics ref:**	**21/CEN/99**
	Study title:	Investigation into the use of nasal acoustic therapy to relieve rhinitis symptoms - a pilot acceptability study

I am pleased to advise that this application has been *approved* by the Central Health and Disability Ethics Committee with conditions. 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:

The Committee requests the following changes to the Participant Information Sheet and Consent Form:

- Please replace the statement under 'How will my privacy be protected' on page 2 with the following (modifying where appropriate);

  "During this study the [study doctors/researchers], [nurses] and other [Site] staff will record information about you and your study participation. This includes the results of any study assessments [modify or add as appropriate]. If needed,

information from your hospital records and your GP may also be collected. You cannot take part in this study if you do not consent to the collection of this information.

To make sure your personal information is kept confidential, information that identifies you will not be included in any reports or publications generated by the [researcher] AND/OR any study information sent to the sponsor. Instead, you will be identified by a code.

All details will be locked in a secure cabinet in the investigator's office and will only be available to the principal investigator directly involved in the study. Coded data will be stored in a password protected file on a password protected computer. The data will be stored for ten years. You will be able to indicate on the consent form if you would like to receive a summary of the results from this study. Should you wish, you have the right to access information about yourself collected as part of the study. You will be informed of any new information related to the study about adverse or beneficial effects that may have an impact on your health if these become available during the study".

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 125 and 126 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 13 May 2022.

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

Document	*Version*	*Date*
Protocol: tracked version	4	07 May 2021
PIS/CF: Information and consent	2	16 December 2020
Other (No Description Entered)	1	02 December 2020
Evidence of scientific review: The protocol has been peer reviewed by Dr Julie Reeve, a specialist cardiorespiratory physiotherapist	1	09 October 2020
CV for CI: CV for Jim Bartley: principal investigator.	1	11 October 2020
Survey/questionnaire: Patient assessment protocol	1	12 October 2020
Covering Letter: new covering letter addressing concerns	2	07 May 2021
Application		27 March 2021
PIS/CF: tracked version	2	07 May 2021
PIS/CF: clean version	2	07 May 2021
PIS/CF: clean new version	4	07 May 2021
Protocol: clean version of protocol	4	07 May 2021
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

Name	*Category*	*Appointed*	*Term Expires*
Mrs Helen Walker	Lay (consumer/community perspectives)	22/05/2018	22/05/2023
Ms Helen Davidson	Lay (ethical/moral reasoning)	06/12/2018	06/12/2021
Dr Peter Gallagher	Non-lay (health/disability service provision)	22/05/2020	22/05/2023
Mrs Sandy Gill	Lay (consumer/community perspectives)	22/05/2020	22/05/2023
Dr Patries Herst	Non-lay (intervention studies)	22/05/2020	22/05/2023
Ms Julie Jones	Non-lay (intervention studies)	22/05/2020	22/05/2022
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