

02 November 2018

Ms Shikha Chaudhary  
HRR1  
AUT University- North Shore Campus  
90 Akoranga Drive  
Northcote 0627

Dear Ms Chaudhary

Re: <b>Ethics ref:</b>	<b>18/CEN/193</b>
Study title:	What are the characteristics of visual fixation in people with motion sensitivity after vestibular insult compared to healthy adults when subjected to different visual environments?

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

The Committee would like to see a slightly better introduction to the study in the Participant Information Sheet such as for healthy volunteers; "you have been sent this information sheet because you have indicated your interest in the study as a healthy volunteer."

#### 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](http://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. Please include version number and dates to the footer of the Participant Information Sheet.

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

**Your next progress report is due by 01 November 2019.**

#### 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**

<i>Document</i>	<i>Version</i>	<i>Date</i>
CV for CI	1	02 October 2018
Evidence of scientific review: Feedback from the independent reviewer who approved the study as a part of PGR9 review process at the university.	1	02 October 2018
Evidence of scientific review: Feedback from the independent reviewer who approved the study as a part of PGR9 review process at the university.	1	02 October 2018
Survey/questionnaire: Questionnaire for people with motion sensitivity	1	02 October 2018
Survey/questionnaire: Questionnaire for people with motion sensitivity	1	02 October 2018
Matauranga Maori Committee consultation report	1	02 October 2018
PIS/CF: Participant Information Sheet for Healthy participants	1	04 October 2018
PIS/CF: Participant Information Sheet for people with motion sensitivity	1	04 October 2018
Protocol: Study protocol	1	04 October 2018
Screening sheet	1	04 October 2018
Advertisement for recruiting healthy participants	1	04 October 2018
Advertisement for recruiting motion sensitivity participants	1	04 October 2018
Application		

## 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

<i>Name</i>	<i>Category</i>	<i>Appointed</i>	<i>Term Expires</i>
Mrs Helen Walker	Lay (consumer/community perspectives)	01/07/2015	01/07/2018
Dr Peter Gallagher	Non-lay (health/disability service provision)	30/07/2015	30/07/2018
Mrs Sandy Gill	Lay (consumer/community perspectives)	30/07/2015	30/07/2018
Dr Patries Herst	Non-lay (intervention studies)	27/10/2015	27/10/2018
Dr Dean Quinn	Non-lay (intervention studies)	27/10/2015	27/10/2018
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>