Health and Disability Ethics Committees
Ministry of Health
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0800 4 ETHICS
hdecs@health.govt.nz

20 August 2020

Dr Jiyeon Kim
11A Havana Garden
Christchurch 8011

Dear Dr Kim

Re:	**Ethics ref:**	**20/CEN/32**
	Study title:	Ideal Timing of Subconjunctival Anaesthesia before Intravitreal Injection Treatment

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.

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:

4. Please state in the Participant Information Sheet that health data will be kept for 10 years (clause 5, Health (Retention of Health Information) Regulations 1996).

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 19 August 2021.

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*	
Declined letter for previous application in respect of the same (or substantially similar) study: Letter from HDEC	2	09 March 2020	
Evidence of scientific review: No previous study done	1	02 February 2020	
CV for CI: CV	1	02 February 2020	
Survey/questionnaire: Questionnaire - clean	1	02 February 2020	
Evidence of scientific review: Peer review supporting this study	1	02 February 2020	
Protocol: Protocol - tracked	1	02 February 2020	
PIS/CF: Patient information sheet - tracked	1	02 February 2020	
Covering Letter: Covering letter - new version.	1	10 March 2020	
Application		02 February 2020	
PIS/CF	1	13 February 2020	
Covering Letter			
Participant Information Sheet (clean)			
Participant Information Sheet (tracked)			
Protocol - clean			
Protocol-tracked			
Study Questionnaire for IVT (tracked)			
Study Questionnaire for IVT (clean)			
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)	22/05/2015	22/05/2022	
Mrs Sandy Gill	Lay (consumer/community perspectives)	22/05/2015	22/05/2023	
Dr Patries Herst	Non-lay (intervention studies)	22/05/2015	22/05/2023	
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