Health and Disability Ethics Committees
Ministry of Health
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07 June 2018

Dr Swee Tan
Gillies McIndoe Research Institute
PO Box 7184
Newtown
Wellington South 6242

Dear Dr Tan

Re:	**Ethics ref:**	**18/CEN/67**
	Study title:	Topical Timolol Treatment of Superficial Proliferating Infantile Haemangioma

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

The Committee found the ACC statement to be misleading as it is the child not the parent who would be applying for cover so whether or not the parent is earning would not be relevant.

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.

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 06 June 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

Document	*Version*	*Date*
PIS/CF for persons interested in welfare of non-consenting participant: Patient information sheet and consent form	1	09 April 2018
PIS/CF: Patient information sheet and consent form.	1	09 April 2018
Evidence of scientific review: Scientific Review	V.1	11 April 2018
Protocol: Protocol for topical timolol treatment	V.1	05 March 2018
Instructions on the application of Timolol	V.1	05 March 2018
CV for CI	1	26 March 2018
Survey/questionnaire: Assessment of treatment questionnaire	V.1	05 March 2018
Application		
Evidence of scientific review: HDEC-Peer-Review-Dr Duncan Bayne V.2.pdf		
PIS/CF: PIS/CF clean copy	V.2	11 May 2018
PIS/CF: PIS/CF showing tracked changes	V.2	11 May 2018
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)	01/07/2015	01/07/2018
Dr Angela Ballantyne	Lay (ethical/moral reasoning)	30/07/2015	30/07/2018
Dr Melissa Cragg	Non-lay (observational studies)	30/07/2015	30/07/2018
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