

Ethics reference: 2021 FULL 11163

28 January 2022

Dr Jesse Gale

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6242
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Tēnā koe Dr Gale

APPROVAL OF APPLICATION

Study title: Cost Effectiveness of Standalone Stents as Second-Stage Surgery Study: SUCCESSES

I am pleased to advise that your application was **approved** by the Northern B Health and Disability Ethics Committee (the Committee). This decision was made through the FULL 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 Northern B 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.

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 28 January 2023.

Participant access to compensation

The Northern B 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.

Further information and assistance

Please contact the HDECs Secretariat at hdec@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 FAQ](#).

Nāku noa, nā



Ms Kate O'Connor

Chair

Northern B 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	RAGM Application		
Evidence of CI Indemnity	MPS 2021		
CV for Coordinating Investigator	CV NZ Standard		
Protocol	PROTOCOL v3	31/08/2021	3
PIS/CF	PIS & Consent	10/09/2021	
Data Management Plan	Data Management Plan	11/09/2021	
Response to PA Document	HDEC cover letter	12/12/2021	1
Response to PA Document	CCDHB HDEC data-only-management Plan	12/12/2021	1
Response to PA Document	Glaucoma Utility Index Questionnaire	12/12/2021	1
Response to PA Document	hdec-peer-review	12/12/2021	1
Response to PA Document	PIS & Consent v2 Clean	12/12/2021	2
Response to PA Document	PIS & Consent v2 tracked	12/12/2021	2
Response to PA Document	PROTOCOL v4 Clean	12/12/2021	4
Response to PA Document	PROTOCOL v4 tracked	12/12/2021	4

Review Document Type	Review Document File Name	Review Document Version Date
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Appendix B: Statement of compliance and list of members

Statement of compliance

The Northern B 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 00008715) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Mrs Kate O'Connor (Lay (ethical/moral reasoning)), Mr John Hancock (Lay (the law)), Mrs Leesa Russell (Non-lay (observational/intervention studies)), Ms Susan Sherrard (Lay (consumer/community perspectives)), Ms Maxine Shortland (Lay (consumer/community perspectives)), Mr Barry Taylor (Non-lay (observational/intervention studies)), Dr Gabrielle Jenkin (Non-lay (observational/intervention studies)).

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>