Health and Disability Ethics Committees
Ministry of Health
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Ethics reference: 2022 EXP 12091

27 September 2022

Dr. Kathryn Hally

23A Mein Street
Newtown
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New Zealand

Tēnā koe Dr. Hally

APPROVAL OF APPLICATION

Study title: A Study to Evaluate the Effects of Dual Anti-Platelet Therapy on the Platelet-Neutrophil Interaction

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

- 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 27 September 2023

Participant access to compensation

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 trialed. 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 hdecs@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 user manual.

Nāku noa, nā

Mrs Helen Walker

Chair

Central Health and Disability Ethics Committee

Encl: Appendix A: documents submitted

Appendix A: Documents submitted

Document Type	File Name	Date	Version
Investigator's Brochure	Investigational broshure for ticagrelor (Brilinta), Astra Zeneca	22/06/2022	1
Investigator's Brochure	Investigational broshure for aspirin, Cartia	22/06/2022	1
Scientific Peer Review	HDEC Peer Review, Dr Claire Henry	22/06/2022	1
Advertisement	Flyer advertisement, Version 1, June 2022	22/06/2022	1
Advertisement	Seminar advertisement, Version 1, June 2022	22/06/2022	1
PIS/CF	Participant Information Sheet and Consent Form, Version 1, March 2022	22/06/2022	1
CV for Coordinating Investigator	Resarch CV Kathryn Hally June 2022	22/06/2022	1
Surveys/questionnaires	Questionnaire for study participants, Version 1, June 2022	22/06/2022	1
Other	Baseline information collection form, Version 1, June 2022	22/06/2022	1
Other	Instructions on how to take medication, Version 1, June 2022	22/06/2022	1
Other	Participant safety and emergency card, Version 1, May 2022	22/06/2022	1
Data and Tissue Management Plan	Data and tissue management plan, Version 1, June 2022	27/06/2022	1
Protocol	Study Protocol, Version 1, March 2022	27/06/2022	1
Response to PA Document	Addressing HDEC concerns - v2	14/09/2022	1
Response to PA Document	Participation Information Sheet and Consent Form - HDEC template - v2	14/09/2022	2