Health and Disability Ethics Committees
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10 February 2014

Dr Gerard Devlin
Waikato Hospital
Private Bag 3200
Hamilton
Hamilton 3240

Dear Dr Devlin

Re:	**Ethics ref:**	**13/CEN/209**
	Study title:	IMproving coronary graft Patency with postoperative Aspirin and Clopidogrel versus Aspirin and Ticagrelor: IMPACT study.

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-Full Review pathway.

The main issues considered by the HDEC in giving approval were as follows.

- The study protocol was reviewed by the study sponsor Astra Zeneca. Dr Devlin advised that consultants who work for the sponsor would have done the peer review. The Committee noted that the review was robust and discussed whether it could be considered independent. The Committee was satisfied that the sponsor review could be considered similar to a Health Research Council review whereby the researchers are applying for their funding. The Committee also noted that the sponsor wouldn't want research to go ahead if the protocol was not sound as this would fall back on their product and was satisfied that the review was robust.
- The Committee noted that some questions in the application form were not adequately answered. The Committee asked for clarification on the answer given at question b.2.7 about how the researchers will ensure that participants receive information that becomes available during the study and is relevant to their continued participation. Dr Devlin advised that the CI will write to participants and inform them of any results with the offer to contact the CI to discuss if they wish.
- The Committee sought clarification on how much time participants would be given to make an informed decision about joining the study (p.3.1, page 21). Dr Devlin advised that participants who are admitted to hospital and scheduled for surgery would have 5-7 days. The Committee was satisfied that is sufficient time for participants to consider the information and decide whether to consent.
- The Committee advised that question p.4.2 could have been better answered to reflect the cultural issues for Maori who will participate in this

study and reminded the researchers that the taking of blood is a cultural issue.
- Dr Devlin confirmed for the Committee that the research team have consulted with a Maori research body at Waikato Hospital.
- The Committee asked the researchers to note for future reference that the intent of question f.1.2 on page 23 of the application form is to address health outcomes for Pacific Island peoples and other cultural groups as well as Maori.
- The Committee requested the following changes to the participant information sheet:
  - Please include the inclusion and exclusion criteria listed at f.2.1 on page 23 of the application form in layperson's terms.

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 WHO-approved clinical trials registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au).

3. Before the study commences at *a 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 amend the information sheet, taking into account the suggestions made by the committee (*Ethical Guidelines for Intervention Studies para 6.22*).

Non-Standard conditions must be completed before commencing your study. Non-standard conditions do not need to be submitted to HDEC before commencing your study.

If you would like to submit your Non-standard conditions please email Non-standard conditions to HDECS@moh.govt.nz. Do not submit Non-standard conditions as a Post Approval form.

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 10 February 2015.

Participant access to ACC

This clinical trial is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Section 32 of the Accident Compensation Act 2001 provides that participants injured as a result of treatment received as part of this trial will **not** 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*
CV for CI: Dr Devlins CV	1	18 July 2013
Evidence of sponsor insurance	1	01 July 2013
Evidence of scientific review	V1	25 November 2013
Evidence of CI indemnity	V1	01 February 2013
Covering Letter	V1	03 December 2013
Protocol	V1	01 October 2013
PIS/CF	V1	01 November 2013
Other (No Description Entered)	V1	11 December 2013
Other (No Description Entered)	V1	09 March 2011
Other (No Description Entered)	V1	23 April 2013
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

Name	*Category*	*Appointed*	*Term Expires*	*Present on 30/01/2014?*	*Declaration of interest?*
Mrs Helen Walker	Lay (consumer/community perspectives)	01/07/2012	01/07/2015	Yes	No
Mr Paul Barnett	Lay (the law)	01/07/2012	01/07/2014	Yes	No
Mrs Gael Donoghue	Non-lay (health/disability service provision)	01/07/2012	01/07/2014	Yes	No
Mrs Sandy Gill	Lay (consumer/community perspectives)	01/07/2012	01/07/2014	Yes	No
Dr Patries Herst	Non-lay (intervention studies)	01/07/2012	01/07/2015	Yes	No
Dr Dean Quinn	Non-lay (intervention studies)	01/07/2012	01/07/2015	Yes	No

http://www.ethics.health.govt.nz