Health and Disability Ethics Committees
Ministry of Health
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29 January 2019

Dr David Choi
Department of Anaesthesia
Middlemore Hospital
Private Bag 93311
Otahuhu 1640

Dear Dr Choi

Re:	**Ethics ref:**	**19/NTA/9**
	Study title:	A randomised controlled trial: Delivery of local anaesthesia through adductor canal catheter after total knee arthroplasty (DETACH-TKA)

I am pleased to advise that this application has been *approved* by the Northern A 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 Northern A 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 provide further detail in the PIS about what will occur in the research so that consent can be informed. For example, advise participants that they will be randomised by chance to one of two anaesthetic protocols (continuous / intermittent) and that they do not have a choice about which arm they are assigned to. Describe how the study procedures differ from the standard of care in the hospital.

5. On the consent form remove the YES / NO options unless that statement refers to a part of the study which is truly optional (i.e. the participants can say NO to but still be part of the study).
6. Please clarify how patient confidentiality will be maintained for the participant in the PIS. There is a place on the QoR questionnaire for a patient label. Could a study ID be used instead?
7. Will study IDs be used and will study records have the NHI removed before storage to help protect confidentiality.
8. Please review the PIS and correct any errors.

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 29 January 2020.

Participant access to ACC

Northern A 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,

Ms Kate O'Connor
Acting Chairperson
Northern A 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*
CVs for other Investigators: Coinvestigator CV	1.0	14 January 2019
Protocol: minor updates	1.2	14 January 2019
PIS/CF: minor updates and formatting consistency	1.2	14 January 2019
Protocol: updates to spelling mistakes and formatting. minor changes.	1.3	16 January 2019
CV for CI: CV for D Choi (investigator)	1.0	27 December 2018
Survey/questionnaire: Questionnaire for patients to fill out. once a day for upto 3 days.	1.0	27 December 2018
Evidence of scientific review: Scientific peer review by independent anaesthesia specialist with interest in research.	1.0	29 December 2018
Protocol: Study protocol V1.0 for DETACH-TKA	1.0	29 December 2018
PIS/CF: Participant information sheet and informed consent.	1.0	29 December 2018
Evidence of CI indemnity	1	07 January 2019
PIS/CF: Participant information sheet, minor changes.	1.1	11 January 2019
Protocol: Minor updates	v1.1	11 January 2019
Application		16 January 2019

Appendix B
Statement of compliance and list of members

Statement of compliance

The Northern A 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 00008714) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Name	*Category*	*Appointed*	*Term Expires*
Dr Karen Bartholomew	Non-lay (intervention studies)	13/05/2016	13/05/2019
Dr Christine Crooks	Non-lay (intervention studies)	11/11/2015	11/11/2018
Dr Catherine Jackson	Non-lay (health/disability service provision)	11/11/2016	11/11/2019
Ms Toni Millar	Lay (consumer/community perspectives)	11/11/2016	11/11/2019
Dr Kate Parker	Non-lay (observational studies)	11/11/2015	11/11/2018
Ms Rochelle Style	Lay (ethical/moral reasoning)	14/06/2017	14/06/2020

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