Health and Disability Ethics Committees
Ministry of Health
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Ethics reference: 2022 FULL 11612

11 March 2022

Mr Simon Young

232 Wairau Road
Glenfield
Auckland
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New Zealand

Tēnā koe Mr Young

APPROVAL OF APPLICATION

Study title: Intraosseous Regional Administration of Diclofenac (IRAD) in Primary TKA Study: A Prospective, Double-Blinded, Randomised Controlled Trial Comparing the Analgesic Efficacy of Intraosseous Regional Diclofenac and Intravenous Diclofenac for Postoperative Pain Management in Total Knee Arthroplasty

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

Summary of resolved ethical issues

The main ethical issues considered by the Committee and addressed by the Researcher are as follows.

1. The Committee asked about the pain forms and if they are standard or not. The Researcher explained that most of them are standard and protocolized, the main one being used, the “analogue visual scale” is used across different studies and not just pain as it is a relevant scale.
2. The Committee asked about the other data being collected and if that Is coming directly from the medical records of the participants and if any other data would be collected. The Researchers explained that no other data would be collected.
3. The Committee asked if the participants’ family would be able to assist the participants when filling out the questionnaires. The Researchers explained that nurses would assist in the beginning so the participant can do it by themselves later as well.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee which require addressing by the Researcher are as follows:

1. The Committee requested for the font to be larger in the patient outcome form, use of small font may be difficult to read for some participants.

The Committee requested the following changes to the Participant Information Sheet and Consent Form (PIS/CF):

1. Please provide Māori contact details.
2. Please clarify include more information on the sponsor and any data that is being shared with them.
3. Please include an option for participants to consent to future unspecified research (FUR).
4. Please remove the reference to a sponsor receiving information under the security and storage heading.
5. Please include the saline (placebos) when defining the two treatment arms to ensure blinding.

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:

- 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 11th March 2023.

Participant access to compensation

The 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 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 FAQ.

Nāku noa, nā

Ms Catherine Garvey

Chair

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 Type	File Name	Date	Version
CV for Coordinating Investigator	SimonYoung CV 2021		
Evidence of CI Indemnity	CI MPS membership		
Protocol	Intraosseous Regional Administration of Diclofenac (IRAD) in Primary TKA Protocol		
PIS/CF	IRAD-TKA PIS-CF		
Data Management Plan	IRAD-TKA Data Management Plan		
Surveys/questionnaires	IRAD-TKA Patient Outcome Forms Combined		
Surveys/questionnaires	IRAD-TKA Patient Pain Diary		
Scientific Peer Review	IRAD-TKA Peer Review + Letter Signed		

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

Dr Karen Bartholomew, Dr Kate Parker, Ms Catherine Garvey, Dr Sotera Catapang, Mr Jonathan Darby, Ms Jade Scott, Dr Leonie Walker, Ms Amy Henry .

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