Health and Disability Ethics Committees
Ministry of Health
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Ethics reference: 2021 EXP 11199

25 November 2021

Dr Deborah Wright

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New Zealand

Tēnā koe Dr Wright

APPROVAL OF APPLICATION

Study title: Opioid PrEscRiptions and Usage After Surgery (OPERAS): protocol for a prospective, multi-centre, observational cohort study of the prescription and usage of opioids after common surgical procedures

I am pleased to advise that your application was **approved** by the Southern Health and Disability Ethics Committee (the Committee) with **non-standard conditions**. This decision was made through the EXP 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 Southern 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 *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.

Non-standard conditions:

1. The issue of access to personal health information held by the local research team remains an issue. The Data Management Plan clearly states that 'De-identified data will carry the participant's unique study code. The Investigator will retain a log linking participant code with identifiers. This means that de-identified data can be re-identified if required (for example, if a participant requests their data be withdrawn). Per the Health Information Privacy Code 1994, clause 5, rule 6, patients have the right to access and correct their personal health information. As participants can withdraw data from the study up until the point it is anonymised, there would equally be the opportunity for them to access and correct data collected about them until that point. Ensure study documentation is amended to meet this requirement.

2. It is also noted that participants can only withdraw data until they 'hang up the phone' (inserted comment, data management plan). Ability to withdraw data should be retained until the log linking identifiers with participant ID code is broken. Please ensure this is respected during the study.

Non-standard conditions must be completed before commencing your study, however, they do not need to be submitted to or reviewed by HDECs.

If you would like an acknowledgement of completion of your non-standard conditions you may submit a post approval form amendment through the Ethics Review Manager. 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 paragraphs 125 and 126 of the *Standard Operating Procedures for Health and Disability Ethics Committees (SOPs)*.

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 25 November 2022.

Participant access to compensation

The Southern 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 hdecs@health.govt.nz or visit our website at www.ethics.health.govt.nz for more information.

Nāku noa, nā

Mr Anthony Fallon

Chair

Southern Health and Disability Ethics Committee

Encl: Appendix A: documents submitted

Appendix A: Documents submitted

Document Type	File Name	Date	Version
Scientific Peer Review	Tevis LOS	14/09/2021	1
Surveys/questionnaires	OPERAS_Study_Quality_of_Life_Survey_v1	23/09/2021	V1
Protocol	OPERAS-Study-Procotol-FINAL_V2.0.1	27/09/2021	2.0.1
CV for Coordinating Investigator	NZ MSI Standard CV Template_DW	28/09/2021	1
Data Management Plan	Data management plan	29/09/2021	1.0.0
Protocol	Copy of OPERAS-Study-Procotol-FINAL_V2.0.4_CV_CLEAN	06/11/2021	2.04
PIS/CF	PIS_CF_HDEC_OPERAS_(HDEC_EDIT)_WX_TRACKED_CHANGES	06/11/2021	3
PIS/CF	Copy of PIS_CF_HDEC_OPERAS_(HDEC_EDIT)_WX_CLEAN	06/11/2021	4
Data Management Plan	Data management plan OPERAS v2 (HDEC EDIT)_WX_TRACKED_CHANGES	06/11/2021	3
Data Management Plan	Copy of Data management plan OPERAS v2 (HDEC EDIT)_WX_CLEAN	06/11/2021	3
Protocol	OPERAS-Study-Procotol-FINAL_V2.0.4_CV_TRACKED_CHANGES	06/11/2021	2.04 tracked changes

Review Document Type	Review Document File Name	Review Document Version Date