

Ethics reference: 2022 FULL 12970

21 October 2022

Professor Robert Walker

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Great King Street
Dunedin
9054
New Zealand

Tēnā koe Professor Walker

APPROVAL OF APPLICATION

Study title: Sodium glucose co-transporter2 inhibitor's effect on glucose and sodium clearances in individuals with stage 4 chronic kidney disease

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 FULL 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 *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 21 October 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 hdec@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 B: statement of compliance and list of members

Appendix A: Documents submitted

Document Type	File Name	Date	Version
Scientific Peer Review	2022 03 09 - Peer Review Confirmation letter - SGLTI - Luke Wilson		
Evidence of Consultation	Recommendation_23292_20220612		
Data and Tissue Management Plan	SGLT-2_study_data_management	07/06/2022	1
CV for Coordinating Investigator	Cv2022 version	11/07/2022	CV2022
Protocol	Study protocol for SGLTI-2 effect on Glucose and Sodium clearance in those with (CKD)	25/07/2022	1
PIS/CF	SGLTI-2 Stage 4 CKD Participant Information Sheet and Consent Form ver1	25/07/2022	1
PIS/CF	SGLTI-2 Stage 4 CKD Participant Information Sheet and Consent Form ver1	25/07/2022	1
PIS/CF	SGLTI-2 Stage 4 CKD Participant Information Sheet and Consent Form ver3 (TC)	15/09/2022	3
PIS/CF	SGLTI-2 Stage 4 CKD Participant Information Sheet and Consent Form ver3	15/09/2022	versionn3
Covering Letter	HDEC emga study	20/09/2022	version 3

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

Mrs Helen Walker (Lay (consumer/community perspectives)), Dr Cordelia Thomas (Lay (the law)), Ms Julie Jones (Non-lay (intervention studies)), Ms Sandy Gill (Lay (consumer/community perspectives)), Dr Ptries Herst (Non-lay (intervention studies)), Ms Patricia Mitchell (Non-lay (health/disability service provision)), Ms Jessie Lenagh-Glue (Lay (ethical and moral reasoning)), Mx Albany Lucas (Non-lay (observational studies)).

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>