Health and Disability Ethics Committees
Ministry of Health
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09 April 2021

Dr Martin de Bock
Department of Paediatrics
University of Otago
Christchurch Hospital
Christchurch 8140

Dear Dr de Bock

Re:	**Ethics ref:**	**21/CEN/75**
	Study title:	Glycaemic outcomes in people with type 2 diabetes initiating continuous glucose monitoring: The 2GO-CGM 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.

Summary of Study

1. This multi-site, 3-month randomized controlled study is followed by a 3 month continuation phase where those initially randomized to routine care cross over into the Continuous Glucose Monitoring intervention.

Summary of resolved ethical issues

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

2. The Committee commended the researcher's response to question p.4.1 for inclusion of statistics and impact on Māori.

Summary of outstanding ethical issues

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

3. After it was confirmed with the researchers that it was standard practice that patient-identification number is only used for storing data on the cloud-based server to ensure only de-identified information is stored there, the Committee requested that it is made clear in the protocol and information sheet.

The Committee requested the following changes to the Participant Information Sheet and Consent Form:

4. Please specify that the University insurance coverage "may" apply, not "will" apply.
5. PIS It would be useful to put the table with visits and what happens during each visit (from the protocol) in the PIS as a summary.
6. Contraceptive advice: the Committee requested the reason for pregnant people not participating in the study is just because there is no approval for use of it in pregnant people.
7. Page 6: "stored for at least 10 years after the youngest study participant turns 16 years of age"; remove this as only people 16 and over can take part in the study.
8. On Page 7, please clarify what information is sent overseas and to who and in what form it is sent and stored.

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:

9. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.

10. 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/.

11. 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:

- please address all outstanding ethical issues raised by the Committee.
- please update the Participant Information Sheet and Consent Form, taking into account the suggestions made by the Committee.

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 125 and 126 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 08 April 2022.

Participant access to ACC

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 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,

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	1.0	03 February 2021
CVs for other Investigators: CV Ben Wheeler	1.0	03 February 2021
Evidence of sponsor insurance	1.0	26 November 2020
Covering Letter	1.0	01 March 2021
CVs for other Investigators: CV A Boucsein	1.0	23 February 2021
Ngai Tahu Consultation	1.0	22 February 2021
PIS/CF	1.4	20 February 2021
Survey/questionnaire: Qualitative interview and Electronic review Topic guide	1.0	16 February 2021
Investigator's Brochure: Dexcom G6 IFU	1.0	23 February 2021
CVs for other Investigators: CV Ryan Paul	1.0	23 February 2021
Evidence of CI indemnity	1.0	12 May 2020
Evidence of scientific review: External peer review Dr Peters	1.0	24 February 2021
Protocol	1.0	25 February 2021
Evidence of scientific review: Departmental peer review approval	1.0	01 March 2021
Application		03 March 2021

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*
Mrs Helen Walker	Lay (consumer/community perspectives)	22/05/2018	22/05/2023
Ms Helen Davidson	Lay (ethical/moral reasoning)	06/12/2018	06/12/2021
Dr Peter Gallagher	Non-lay (health/disability service provision)	22/05/2020	22/05/2023
Mrs Sandy Gill	Lay (consumer/community perspectives)	22/05/2020	22/05/2023
Dr Patries Herst	Non-lay (intervention studies)	22/05/2020	22/05/2023
Ms Julie Jones	Non-lay (intervention studies)	22/05/2020	22/05/2022
Dr Cordelia Thomas	Lay (the law)	20/05/2017	20/05/2020

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