Health and Disability Ethics Committees
Ministry of Health
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Ethics reference: 2024 FULL 21236

12 November 2024

Associate Professor Martin de Bock Martin de Bock

2 Riccarton Ave, Christchurch Central
Christchurch
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New Zealand

Tēnā koe Associate Professor Martin de Bock de Bock

APPROVAL OF APPLICATION

Study title: Early Automated Insulin Delivery to improve equity in type 1 diabetes.

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

Summary of outstanding ethical issues

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

1. The protocol document under section 8.8 (Device Accountability), p. 24, should be revised to clarify that some devices may not be returned to the study team if the participant chooses to keep it.

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

1. The Adolescent PIS has language about the choice to retain the AID system after the study under the description of Visit 6, but the adult PIS does not make that fact clear. Please revise.
2. The Information Sheet should tell participants what happens to the study equipment provided at the end of the study (Phones and Pumps).

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 B 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.

Non-standard conditions:

- Please update the protocol.
- Please update the information sheet.

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 12 November 2025.

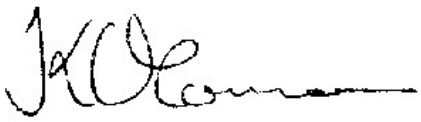
Participant access to compensation

The Northern B 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 user manual.

Nāku noa, nā



Ms Kate O'Connor

Chair

Northern B 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	CV_MartindeBock_signed		
PIS/CF	PICF Younger Child - Early AID		
PIS/CF	PICF Parent - Early AID		
PIS/CF	PICF Older Child - Early AID		
PIS/CF	PICF Adult - Early AID		
PIS/CF	PICF Adolescent - Early AID		
Data Management Plan	Data Management Plan Early AID		
Response to PA Document	HDEC cover letter 29 October		
Scientific Peer Review	Scientific Peer Review	01/06/2021	2.1
Protocol	Protocol - Early Aid from diagnosis FINAL 260624	21/06/2024	1.0
Response to PA Document	Protocol - Early Aid from diagnosis_Version 1.1_CLEAN	29/10/2024	1.1
Response to PA Document	Protocol - Early Aid from diagnosis_Version 1.1_TRACKED	29/10/2024	1.1
Response to PA Document	PICF Adult - Early AID_Version 1.1_CLEAN	29/10/2024	1.1
Response to PA Document	PICF Adult - Early AID_Version 1.1_TRACKED	29/10/2024	1.1
Response to PA Document	PICF Adolescent - Early AID_Version 1.1_CLEAN	29/10/2024	1.1
Response to PA Document	PICF Adolescent - Early AID_Version 1.1_TRACKED	29/10/2024	1.1
Response to PA Document	PICF Older Child - Early AID_Version 1.1_CLEAN	29/10/2024	1.1
Response to PA Document	PICF Older Child - Early AID_Version 1.1_TRACKED	29/10/2024	1.1
Response to PA Document	PICF Younger Child - Early AID_Version 1.1_CLEAN	29/10/2024	1.1
Response to PA Document	PICF Younger Child - Early AID_Version 1.1_TRACKED	29/10/2024	1.1
Response to PA Document	PICF Parent - Early AID_Version 1.1_CLEAN	29/10/2024	1.1
Response to PA Document	PICF Parent - Early AID_Version 1.1_TRACKED	29/10/2024	1.1

Appendix B: Statement of compliance and list of members

Statement of compliance

The Northern B 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 00008715) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Ms Kate O'Connor (Lay (ethical/moral reasoning)), Mr Barry Taylor (Non-lay (observational/intervention studies)), Ms Joan Pettit (Non-lay (intervention studies)), Ms Dianne Glenn (Lay (consumer/community perspectives)), Dr Nicola Swain (Non-lay (intervention studies)), Dr Patries Herst (Non-lay (intervention 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