

**Ethics reference:** 2023 FULL 14008

9 November 2023

Professor Stuart Dalziel

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New Zealand

Tēnā koe Professor Dalziel

### **APPROVAL OF APPLICATION**

Study title: An open-label Randomised Controlled Trial of budesonide-formoterol as single maintenance and reliever therapy vs prescribed maintenance asthma therapy and salbutamol as reliever therapy in moderate to severe childhood asthma

I am pleased to advise that your application was **approved** by the Northern B 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 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](http://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 09 November 2024.**

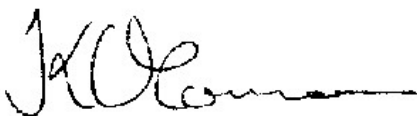
### **Participant access to compensation**

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 [hdec@health.govt.nz](mailto:hdec@health.govt.nz) or visit our website at [www.ethics.health.govt.nz](http://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
Investigator's Brochure	Vannair_Medsafe_Med_Info		N/A
Investigator's Brochure	Respigen_Medsafe_Data_sheet		N/A
CV for Coordinating Investigator	SDaziel HRC CV 15062021	15/06/2021	-
Scientific Peer Review	22-477 Dalziel UofA	03/06/2022	N/A
Data Management Plan	SMARTCARE_Data_Management_Plan_Version_1.0_29.1.23	29/01/2023	1.0
PIS/CF	SMARTCARE_PIS-CF_Version_1.0_21.4.2023	21/04/2023	1.0
Assent form	SMARTCARE_PIS-AF_4-6_V1.0_21.4.2023	21/04/2023	1.0
Assent form	SMARTCARE_PIS_7to11y_Version_1.0_21.4.2023	21/04/2023	1.0
Other	SMARTCARE_Hospital_ED_Intro_letter_V1_21.4.2023	21/04/2023	1.0
Other	SMARTCARE_GP_Correspondence_Version_1.0_21.4.2023	21/04/2023	1.0
Evidence of Consultation	Study 9776, Dalziel, Māori approval	29/05/2023	N/A
Protocol	SMARTCARE_Protocol_V2.0_3.8.23_clean	03/08/2023	2.0
Other	SMARTCARE_Script_video_V1_4.8.23	04/08/2023	V1
Covering Letter	HDEC_covering_letter_SMARTCARE_8.8.23	08/08/2023	
Response to PA Document	SMARTCARE_PIS-CF_Version_2.0_Tracked_15.09.2023	15/09/2023	2.0
Response to PA Document	SMARTCARE_PIS-CF_Version_2.0_Clean_15.09.2023	15/09/2023	2.0
Response to PA Document	SMARTCARE_PIS_7to11y_Version_2.0_Tracked_15.09.2023	15/09/2023	2.0
Response to PA Document	SMARTCARE_PIS_7to11y_Version_2.0_Clean_15.09.2023	15/09/2023	2.0
Response to PA Document	SMARTCARE_PIS-AF_4-6_V2.0_Tracked_15.09.2023	15/09/2023	2.0
Response to PA Document	SMARTCARE_PIS-AF_4-6_V2.0_Clean_15.09.2023	15/09/2023	2.0
Response to PA Document	SMARTCARE_Data_Management_Plan_Version_tracked_2.0_15.09.23	15/09/2023	2.0
Response to PA Document	SMARTCARE_Data_Management_Plan_Version_Clean_2.0_15.09.23	15/09/2023	2.0
Response to PA Document	HDEC_covering_letter_29.9.23_changes_SMARTCARE	29/09/2023	

## **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)), Mrs Leesa Russell (Non-lay (observational/intervention studies)), Mr Barry Taylor (Non-lay (observational/intervention studies)), Ms Alice McCarthy (Lay (the law)), Ms Joan Pettit (Non-lay (intervention studies)), Mr Ewe Leong Lim (Lay (consumer/community perspectives)), Ms Maakere Marr (Lay (consumer/community perspectives)).

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>