

Ethics reference: 2024 FULL 20075

18 July 2024

Dr Starin Mckeen

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Auckland
1052
New Zealand

Tēnā koe Dr Mckeen

APPROVAL OF APPLICATION

Study title: BerriQi for post-respiratory infection recovery in primary school age kids in Motueka, NZ

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 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 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 *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 amend participant information to state that the HDEC may have access to identifiable data if the study is audited.

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 18 July 2025

Participant access to compensation

This clinical trial is to be conducted principally for the benefit of the manufacturer or distributor of the medicine or item being trialled. Section 32 of the Accident Compensation Act 2001 provides that participants injured as a result of treatment received as part of this trial will **not** 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

A handwritten signature in blue ink, consisting of a large, stylized 'D' followed by a horizontal line and a smaller 'F'.

Mr Dominic Fitchett

Chair

Southern 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
Non-Review Document	Letter- Decline		
Scientific Peer Review	Protocol Review- Jennifer		
Evidence of Consultation	Consultation summary		
Evidence of CI Indemnity	FW Anagenix - Clinical Trials Quote Report		
CV for Coordinating Investigator	McKeen_Starin_CV_HDEC		
Scientific Peer Review	Protocol Review- Ammendment-2		
PIS/CF	Consent form		
PIS/CF	Revised PIS-BerriQi kids study-27-03-2024		
Surveys/questionnaires	Screening questions		
Surveys/questionnaires	Post consent questions		
Other	SCOTT explanation -V2		
Data Management Plan	HDEC-data-only-management-BerriQi-kids-26-03-2023		
Protocol	Revised Protocol-Berriqi kids study-V8- tidy-26-3-2024		
Assent form	Kids assent presentation video		
Assent form	Assent formV2		
Covering Letter	Cover Letter		
Advertisement	Flyer		
Evidence of Sponsor Insurance	Insurance-BerriQI kids study		
Response to PA Document	Coverletter		
Response to PA Document	Assent formV2.pdf-track changes		
Response to PA Document	Assent form final		
Response to PA Document	Revised PIS-BerriQi kids study-track chang		
Response to PA Document	Revised PIS-BerriQi kids study-Final		
Response to PA Document	data only managemnet-berriQI kids study- final		
Response to PA Document	Insurance certificate		
Response to PA Document	Chubb Clinical Trials Liability Policy Wording		
Response to PA Document	data only management track changes		
Response to PA Document	Kids assent presentation video.ppt-track change		
Response to PA Document	Kids assent presentation video.pptx-Final		

Appendix B: Statement of compliance and list of members

Statement of compliance

The Southern 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 00008713) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Mr Dominic Fitchett (Lay (the law)), Dr Devonie Waaka (Non-lay (intervention studies)), Ms Amy Henry (Non-lay (observational studies)), Dr Nicola Swain (Non-lay (intervention studies)), Ms Dianne Glenn (Lay (consumer/community perspectives)), Ms Neta Tomokino (Lay (consumer/community perspectives)), Dr Maree Kirk (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>