Health and Disability Ethics Committees
Ministry of Health
133 Molesworth Street
PO Box 5013
Wellington
6011
hdecs@health.govt.nz

Ethics reference: 2022 FULL 13221

6 October 2022

Professor Richard Beasley

Medical Research Institute of New Zealand
Private Bag 7902, Newtown
Wellington
6242
New Zealand

Tēnā koe Professor Beasley

APPROVAL OF APPLICATION

Study title: A 52-week, open-label, randomised, multi-centre, parallel group, phase III, controlled trial in patients age 5 to 11 years with mild, moderate and severe asthma, evaluating the efficacy and safety of Budesonide-formoterol (Symbicort Turbuhaler®) maintenance and/or reliever therapy compared with standard therapy: Budesonide (Pulmicort Turbuhaler®) maintenance or Budesonide-formoterol (Symbicort Turbuhaler®) maintenance, both with Terbutaline (Bricanyl Turbuhaler®) reliever.

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 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 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 be aware to avoid using the letter 's' after (all/any) Māori words, as there is no 's' in the Māori alphabet. When referring the use of 'belonging to' something, or someone, when using te reo Māori, either change the sentence structure to avoid this e.g, "as the child's/tamaiti's parent"... this can be changed to "as the parent of the child/tamaiti". Grammatically, that is the ideal way to resolve it, and in future writing. These examples were found mostly in PISCF. It was great to see the inclusive changes made.

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 06 October 2023.

As your study is an intervention study involving a new medicine, all progress reports **must** be accompanied by an annual safety report. While there is no

prescribed format for annual safety reports, they must be no longer than two pages in length, written in lay language, and include a brief description and analysis of:

- new and relevant findings that may have a significant impact on the safety of participants
- the safety profile of the new medicine and its implications for participants, taking into account all safety data as well as the results of any relevant non-clinical studies
- the implications of safety data to the risk-benefit ratio for the intervention study, and whether study documentation has been or will be updated
- any measures taken or proposed to minimise risks. (Where such a proposed measure would be a substantial amendment, it must be submitted for HDEC review in the normal way).

For the avoidance of doubt, Development Safety Update Reports may serve as annual safety reports to HDECs provided that they contain the information outlined above. These summaries should be accompanied by comment from the New Zealand coordinating investigator of the study.

Please refer to paragraphs 206 to 208 of the *SOPs* for further information.

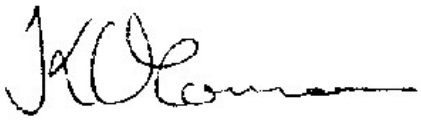
Participant access to compensation

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 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
Investigator's Brochure	IB Bricanyl Turbuhaler_29-06-1999	29/06/1999	
Surveys/questionnaires	START CARE ACQ-5 Interviewer administered	07/02/2012	1.0
Investigator's Brochure	Medsafe respigen	25/03/2019	
Investigator's Brochure	Australian Product Information - Bricanyl	09/04/2020	
Investigator's Brochure	Medsafe Symbicort	20/07/2020	
Investigator's Brochure	Medsafe Pulmicort	03/08/2020	
Evidence of Consultation	Letter of support from M Harwood for START CARE	01/02/2022	1.0
Other	CI Indemnity	01/02/2022	1.0
Scientific Peer Review	hdec-peer-review-STARTCARE_Andrew Corin	02/08/2022	1.0
Advertisement	START CARE GP mailout letter	11/08/2022	1.0
Advertisement	START CARE GP Correspondence_notification of enrolment	11/08/2022	1.0
CV for Coordinating Investigator	Richard Beasley CV.2022	16/08/2022	1.0
Advertisement	START CARE GP Correspondence_notification of study completion	16/08/2022	1.0
Advertisement	START CARE GP Correspondence_notification of study withdrawal	16/08/2022	1.0
Advertisement	START CARE GP Correspondence_change of treatment	16/08/2022	1.0
Data Management Plan	START CARE Data Management Plan v1.0 17Aug2022	17/08/2022	1.0
Advertisement	MRINZ START CARE_Poster v1.0	17/08/2022	1.0
Assent form	START CARE Master PIS-CF-AF v1.0	19/08/2022	1.0
Advertisement	START CARE Social Media Advertisement	19/08/2022	1.0
Other	START CARE Turbuhaler Training Material (NAC DPI video)	19/08/2022	1.0
Advertisement	START CARE Advertising Templates v1.0	19/08/2022	1.0
Advertisement	STARTCAREPreScreening v1.0	19/08/2022	1.0
Advertisement	START CARE Pre-Screening Survey Overview	19/08/2022	1.0
PIS/CF	START CARE Master PIS-CF-AF v1.0	19/08/2022	1.0
PIS/CF	START CARE Master PIS-CF-AF v1.0	19/08/2022	1.0
Protocol	STARTCARE_MRINZ-22-06_Protocol_v1.0_22_August_2022 (CI signed)	22/08/2022	1.0
Covering Letter	START CARE HDEC Cover Letter	22/08/2022	1.0
Other	MRINZ START CARE_Asthma Action Plan - ICS-LABA	22/08/2022	1.0
Other	MRINZ START CARE_Asthma Action Plan - SABA	22/08/2022	1.0
Response to PA Document	START CARE Data Management Plan v1.1	13/09/2022	1.1
Response to PA Document	START CARE Data Management Plan v1.1_tracked	13/09/2022	1.1
Response to PA Document	START CARE GP Correspondence_notification of enrolment V2.0	16/09/2022	2.0
Response to PA Document	START CARE GP Correspondence_notification of enrolment V2.0_tracked	16/09/2022	2.0
Response to PA Document	START CARE GP Correspondence_notification of randomisation V1.0	16/09/2022	1.0
Response to PA Document	START CARE GP Correspondence_notification of study withdrawal V2.0	16/09/2022	2.0
Response to PA Document	START CARE GP Correspondence_notification of study withdrawal V2.0_tracked	16/09/2022	2.0
Response to PA Document	START CARE Master PIS-CF-AF_Tracked v2.0	19/09/2022	2.0
Response to PA Document	START CARE Master PIS-CF-AF_v2.0	19/09/2022	2.0
Response to PA Document	START CARE Advertising Templates v2.0_tracked	19/09/2022	2.0
Response to PA Document	START CARE Advertising Templates v2.0	19/09/2022	2.0
Response to PA Document	START CARE Social Media Advertisement v2.0	19/09/2022	2.0
Response to PA Document	START CARE Social Media Advertisement v2.0_tracked	19/09/2022	2.0
Response to PA Document	START CARE poster V2.0	22/09/2022	2.0
Response to PA Document	START CARE HDEC Prov. Approval Cover Letter	22/09/2022	1.0

Review Document Type	Review Document File Name	Review Document Version Date

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)), Ewe Leong Lim (Lay (consumer/community perspectives)), 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