Health and Disability Ethics Committees
Ministry of Health
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Ethics reference: 2022 FULL 13681

10 January 2023

Professor Peter McIntyre

3rd Floor Children's Pavilion, 201 Great King Street
Dunedin
Dunedin
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New Zealand

Tēnā koe Professor McIntyre

APPROVAL OF APPLICATION

Study title: Responses to aerosol, intradermal and intramuscular administration of measles-mumps-rubella (MMR) vaccine in seronegative and to respiratory challenge with MMR vaccine in seropositive young adults given two doses of MMR in childhood

I am pleased to advise that your application was **approved** by the Northern A 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 A 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 include in the PISCF that if participants do not respond to either ID/ inhaled MMR they will need to have a further IM/SC dose.

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 9th January 2024.

Participant access to compensation

The Northern A 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 Catherine Garvey

Chair

Northern A 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	otagoCV_PMcIntyre_August2022		
Scientific Peer Review	21-184 McIntyre_HRCapproval		
Scientific Peer Review	SCOTT approval letter		
Response to PA Document	Cover letter_2022 FULL 13681_reponse prov approval		
Response to PA Document	smc TATLEY		final signed
Response to PA Document	Recommendation_23711_20221201		final
Data and Tissue Management Plan	data and tissue management measuringandboostingwaningimmunity_Nov2_2022_PMcI	02/11/2022	1.0
Protocol	MMR clinical Trial Protocol MMR_100_pages 1to32 and MMR101 pages 33 to 58	02/11/2022	Draft
PIS/CF	MMR vaccine clinical trial PISCF	02/11/2022	draft
PIS/CF	MMR Challenge Study PISCF_Dunedin	02/11/2022	draft
Protocol	MMR clinical Trial Protocol MMR_100	03/11/2022	draft
Protocol	MMR challenge study Protocol MMR_101	03/11/2022	draft
Evidence of Consultation	Student engagement and consultation September 2022	03/11/2022	final
Response to PA Document	Protocol MMR_100_ClinicalTrial_MMRadministrationroute_v1.0	02/12/2022	1.0
Response to PA Document	Protocol MMR_100_ClinicalTrial_MMRadministrationroute_v1.0_with tracks.pdf	02/12/2022	1.0_tracked changes
Response to PA Document	Protocol MMR_101_MMR challenge study_v1.0	02/12/2022	1.0
Response to PA Document	Protocol MMR_101_MMR challenge study_v1.0_with tracks.pdf	02/12/2022	1.0_tracked changes
Response to PA Document	Introductory Email to eligible participants_Vaccine trial study	05/12/2022	
Response to PA Document	Introductory Email to eligible participants_Challenge study	05/12/2022	
Response to PA Document	Participant Information Sheet_CF_vaccine study_V1.0	05/12/2022	1.0
Response to PA Document	Participant Information Sheet_CF_vaccine study_V1.0_with tracks.pdf	05/12/2022	1.0_tracked changes
Response to PA Document	Participant Information Sheet_CF_MMR Challenge Study_V1.0_Dunedin site	05/12/2022	1.0
Response to PA Document	Participant Information Sheet_CF_MMR Challenge Study_V1.0_Dunedin site_with tracks.pdf	05/12/2022	V1.0_tracked changes

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 A 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 00008714) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Ms Catherine Garvey (Lay (the law)), Dr Kate Parker (Non-lay (observational studies)), Dr Sotera Catapang (Non-lay (observational studies)), Mr Johnathan Darby (Lay (the law/ethical reasoning)), Dr Leonie Walker (Lay (ethical/moral reasoning)), Ms Jade Scott (Non-lay (observational/intervention studies)), Dr Andrea Forde (Non-lay (intervention studies)), Mr Derek Chang (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