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

Ethics reference: 21/CEN/233

10 November 2021

Associate Professor Rachel Page

School of Health Sciences ,College of Health ,Massey University
Wellington
6140
New Zealand

Tēnā koe Associate Professor Page

APPROVAL OF APPLICATION

Study title: A double-blinded randomised placebo controlled pilot study investigating impact of a dairy based protein complex (IDP) on immune responses after influenza vaccination, in healthy subjects.

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

Summary of outstanding ethical issues

The Committee requested the following changes to the Data Management Plan:

1. Under section 7.1, there must be identifiable data because a log is kept that can link coded data to the appropriate person. Under section 9.1 it states, 'Contact details, consent forms and corresponding IDs for participants will be kept separately from all other data in a locked filing cabinet'. Please revise section 7.1 to provide a more exclusive answer.
2. Under section 7.2, it should describe access to deidentified data by accredited auditors from HDEC and regulatory bodies for auditing purposes. Please revise section 7.2 to provide more exclusive answer.

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 Central 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 data management plan, taking into account the feedback provided by the Committee. *(National Ethical Standards for Health and Disability Research and Quality Improvement, para 12.15a)*.

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 5 November 2022.

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.

Nāku noa, nā

Mrs Helen Walker

Chair

Central Health and Disability Ethics Committee

Encl: Appendix A: documents submitted

Appendix A: Documents submitted

Document Type	File Name	Date	Version
CV for Coordinating Investigator	Cv for Principal Investigator	19/08/2021	CV for CI (1)
CV's for Other Investigators	CVs of Co-investigators	19/08/2021	CVs for other Investigators (1)
Evidence of Scientific Review	Peer review of Stud by Senior Researcher, Dr Barry Palmer.	19/08/2021	Evidence of scientific review (1)
Other	Health Screening Questionnaire and Demographic data	19/08/2021	Survey/questionnaire (2)
Other	Consumption and General Health Weekly diary - example of week 1 of the diary	19/08/2021	Survey/questionnaire (2)
Other	Consumption and Symptoms Diary - after influenza vaccination	19/08/2021	Survey/questionnaire (2)
Other	Supplementation Questionnaire	19/08/2021	Survey/questionnaire (2)
Evidence of Sponsor Insurance	Sponsor 3 -Clinical Trial Cover	19/08/2021	Evidence of sponsor insurance (1)
Other	Poster/Flyer Advertisement	19/08/2021	Other (1)
PIS/CF	Participant Information Sheet and Consent Form	19/08/2021	PIS/CF (1)
Protocol	Description and detail of IDP study	19/08/2021	Protocol (1)
MDF Doc	Form Submission	23/08/2021	NZ/1/486B113
Other	HDEC Letter - 21CEN233 - Valid expedited application.pdf	23/08/2021	HDEC Documents

Review Document Type	Review Document File Name	Review Document Version Date
RED Members Portal Comments	Member_Portal_Comments.doc	29/08/2021
Response to PA Document	Cover letter_21 CEN 233.pdf	04/11/2021
Response to PA Document	Flyer and poster for advertising_updated.pdf	04/11/2021
Response to PA Document	Flyer and poster for advertising_updated_7 Oct2021.pptx	04/11/2021
Response to PA Document	IDP Study - data-only-management-template_October 2021_Final.pdf	04/11/2021
Response to PA Document	Policy Schedule.pdf	04/11/2021
Response to PA Document	Policy Schedule_2.pdf	04/11/2021