

Ethics reference: 2022 FULL 11786

1 August 2022

Dr Mickey Fan

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Grafton
Auckland
1023
New Zealand

Tēnā koe Dr Fan

APPROVAL OF APPLICATION

Study title: Elucidating the effects of nebulized sodium nitrite and argon on blood pressure and cerebrovascular haemodynamics

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 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 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:

- under 'Who pays for the study?' the value will be \$50 per visit for reimbursement of 'expenses' and 'Koha/gift' will be removed.

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 28 July 2023.

Participant access to compensation

The Central 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 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 black ink, appearing to read 'Helen Walker', written in a cursive style.

Mrs Helen Walker

Chair

Central 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
Protocol	Protocol Nebulized Nitrite Argon 11052022 v1	10/05/2022	1
CV for Coordinating Investigator	Mickey Fan NZ standard CV 230522	23/05/2022	1
Data and Tissue Management Plan	Argon and Nitrite Study Data and Tissue management plan	10/06/2022	1
Scientific Peer Review	22-011-Fan_79_Applicant_Peer_Review_Report	13/06/2022	1
Scientific Peer Review	22-011-Fan_39_Applicant_Peer_Review_Report	13/06/2022	1
Scientific Peer Review	22-011-Fan_28_Applicant_Peer_Review_Report	13/06/2022	1
Scientific Peer Review	22-011-Fan_Rebuttal	13/06/2022	1
Scientific Peer Review	22-011-Fan_5_Applicant_Peer_Review_Report	13/06/2022	1
Advertisement	Nitrite Recruitment Poster	20/07/2022	1
Advertisement	Argon Recruitment Poster	20/07/2022	1
Surveys/questionnaires	HADS	20/07/2022	1
PIS/CF	PISCF Argon study v2	20/07/2022	2
PIS/CF	PISCF Nitrite study v2	20/07/2022	2
Surveys/questionnaires	Health Screening Questionnaire v2	20/07/2022	2
Response to PA Document	Health Screening Questionnaire redline v2	20/07/2022	2
Response to PA Document	Health Screening Questionnaire v2	20/07/2022	2
Response to PA Document	Nitrite Recruitment Poster	20/07/2022	1
Response to PA Document	HADS	20/07/2022	1
Response to PA Document	Response to outstanding ethics issues	20/07/2022	1
Response to PA Document	PISCF Nitrite study redlined v2	20/07/2022	2
Response to PA Document	PISCF Argon study redlined v2	20/07/2022	2
Response to PA Document	PISCF Argon study v2	20/07/2022	2
Response to PA Document	PISCF Nitrite study v2	20/07/2022	2

Appendix B: Statement of compliance and list of members

Statement of compliance

The Central 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 00008712) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

Ms Julie Jones, Dr Patries Herst, Ms Sandy Gill, Dr Cordelia Thomas, Dr Peter Gallagher, Mrs Helen Walker, Ms Jessie Lenagh-Glue.

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>