

Ethics reference: 2023 EXP 15332

9 March 2023

Dr Gordon Michael (Mike) Nicholls

Park Road
Grafton
Auckland
1023
New Zealand

Tēnā koe Dr Nicholls

APPROVAL OF APPLICATION

Study title: Positive Participatory Organisational Intervention to Reduce Burnout in New Zealand Emergency Department Staff – Multisite study

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 EXP 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 check with your Academic Head regarding the institutional policy regarding the Sponsorship or Approval of HDEC applications submitted by the University's members (including students). Ensure that Participants are advised that the study is in partial fulfillment of a higher degree qualification.

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 09 March 2024.

Participant access to compensation: The Northern B 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



Ms Kate O'Connor

Chair

Northern B Health and Disability Ethics Committee

Encl: Appendix A: documents submitted

Appendix A: Documents submitted

Document Type	File Name	Date	Version
CV for Coordinating Investigator	Mike Nicholls CV February 2022	01/02/2022	1
Scientific Peer Review	22-048 Nicholls review	11/02/2022	1
Surveys/questionnaires	CBI-scales	08/12/2022	1
Surveys/questionnaires	WHO-5 questionnaire - English	08/12/2022	1
Surveys/questionnaires	Empowerment Spreitzer text	08/12/2022	1
Surveys/questionnaires	UWES 17 and 9 item	08/12/2022	1
Advertisement	Intervention Poster v2. 28 Dec 2022	28/12/2022	2
Non-Review Document	Ethics reference 2022 EXP 13561_11 January 2023	11/01/2023	na
Advertisement	QILS@NZEDs Intervention-General Information, Roles of Stakeholders v5 Feb 2023	05/02/2023	5
Surveys/questionnaires	DemographicsPreInterventionSur	05/02/2023	1
Advertisement	WoWe@NZEDs Training for Improvement_Summary 5Feb23	05/02/2023	1
Protocol	Intervention Protocol v2.4 8 Feb 2023	08/02/2023	2.4
PIS/CF	QILS-PIS CF-ED Staff-v1.1 Feb2023 doc	08/02/2023	1.1
Data Management Plan	QILS4WoWe@NZEDs-data-management-plan-v8Feb	08/02/2023	2
Covering Letter	Letter of Response 2022 EXP 13561 8Feb	08/02/2023	1
PIS/CF	QILS-PIS CF-LCG-v 1.1 Feb2023	08/02/2023	1.1
Response to PA Document	Letter of Response 2022 EXP 13561 23Feb FINAL	23/02/2023	FINAL
Response to PA Document	Intervention Protocol v2.8 24Feb 2023 FINAL	24/02/2023	FINAL
Response to PA Document	QILS@NZEDs Intervention-General Information, Roles of Stakeholders v24 Feb2023 FINAL	24/02/2023	24/2
Response to PA Document	QILS-PIS CF-ED Staff-v2.0 Feb2023 doc FINAL	24/02/2023	2
Response to PA Document	QILS-PIS CF-LCG-v 2.0 Feb2023 FINAL	24/02/2023	2
Response to PA Document	QILS4WoWe@NZEDs-data-management-plan-v24Feb FINAL	24/02/2023	v24/2
Response to PA Document	InformationAndConsentv24Feb2023	24/02/2023	v24/2
Response to PA Document	Demographics_QILS4WoWeNZEDsv24Feb2023	24/02/2023	v24/2
Response to PA Document	attachmentEntry-22659	27/02/2023	1

Document Type	File Name	Date	Version
Response to PA Document	WoWe@NZEDs Training for Improvement_Summary 27Feb23	27/02/2023	27/2/23
Response to PA Document	Intervention Poster v27Feb 2023	27/02/2023	v27/2/23

Review Document Type	Review Document File Name	Review Document Version Date
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<http://www.ethics.health.govt.nz>