

Ethics reference: 2024 EXP 19965

1 August 2024

Dr Nasili Vakauta

2 College Road
Saint Johns
Auckland
1072
New Zealand

Tēnā koe Dr Vakauta

APPROVAL OF APPLICATION

Study title: The Lotu Factor: Religiosity, COVID-19 and Tongan Wellbeing in New Zealand

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 Expedited pathway.

Summary of outstanding ethical issues

The main ethical issues considered by the Committee which require addressing by the Researcher are as follows.

1. The differences between the individual one-to-one interviews (faith leaders), and the focus groups for others could be further distinguished in the Information Sheet and the Consent Forms, especially in relation to the review and correction of transcripts, and the opportunity to withdraw data from the study data set should a participant wish to withdraw consent for participation.

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 *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 amend the participant information sheets, taking into account the changes requested by the Committee.

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 01 August 2025.

Participant access to compensation

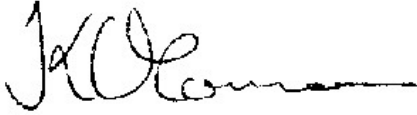
The Northern B Health and Disability Ethics Committee is satisfied that your study is not a clinical trial that is to be conducted principally for the benefit of the

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

A handwritten signature in black ink, appearing to read 'K O'Connor', with a long horizontal flourish extending to the right.

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
Data Management Plan	23-224 Data Management Plan (Ver 1.0)		
Scientific Peer Review	23-224-Vakauta_79_Applicant_Peer_Review_Report		
Response to PA Document	Attachment 0 - HRC 23-224 Cover Letter (Response to Provisional Approval)		
Response to PA Document	Attachment 1 - HRC 23-224 Data Management Plan (tracked change version)		
Response to PA Document	Attachment 1 - HRC 23-224 Data Management Plan (ver 2.1, clean copy)		
Response to PA Document	Attachment 2 - HRC 23-224 Researcher Safety Plan (ver 1.0)		
Response to PA Document	Attachment 3 - HRC 23-224 Outline for Interviews (ver 1.0)		
Response to PA Document	Attachment 4 - HRC 23-224 PIS-CFs (tracked change version)		
Response to PA Document	Attachment 4 - HRC 23-224 Participant Information Sheet (clean version)		
Response to PA Document	Attachment 5 - HRC 23-224 Consent Form (Individual & Focus Groups) (clean version)		
Response to PA Document	Attachment 6 - HRC 23-224 Incident Report Form (ver 1.0)		
Response to PA Document	Attachment 7- HRC 23-224 Risk Assessment Form (ver 1.0)		
Response to PA Document	Attachment 8 - HRC 23-224 Communication Plan (ver 1.0)		
Response to PA Document	Attachment 9 - HRC 23-224 Confidentiality Agreement (ver 1.0)		
Response to PA Document	2024-04 HRC Project 23:224 Research Protocol (tracked change version)		
Response to PA Document	2024-04 HRC Project 23:224 Research Protocol (clean version)		
Protocol	2024-04 HRC Project 23:224 Research Protocol (v.1.1)	01/05/2024	Ver 1.0
Advertisement	432766496_914768370657747_4700403456725293617_n	01/05/2024	Ver 1
PIS/CF	23-224 PIS & CF	01/05/2024	Ver 1.0
CV for Coordinating Investigator	Nasili CV (2024)	01/05/2024	Ver 1.0

<http://www.ethics.health.govt.nz>