Health and Disability Ethics Committees
Ministry of Health
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Ethics reference: 2022 EXP 12456

1 June 2022

Associate Professor Rita Krishnamurthi

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New Zealand

Tēnā koe Associate Professor Krishnamurthi

APPROVAL OF APPLICATION

Study title: Trial of an Individualised Intervention for the Prevention of Stroke (TIIPS)

I am pleased to advise that your application was **approved** by the Central Health and Disability Ethics Committee (the Committee). 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 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 include explanation for contacting a general practitioner in the body of the PIS.

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 29 May 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 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

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	Academic CV R Krishnamurthi 2022		
Surveys/questionnaires	HADS_PDF_Version 1	01/03/2022	1
Scientific Peer Review	hdec-peer-review-template-june-2021_31.03.22	31/03/2022	1
Evidence of Consultation	Krishnamurthi - letter of support 12042022 revised	12/04/2022	1
Data and Tissue Management Plan	hdec-data-tissue-management-template-oct2020_TIIPS 05.5.22	05/05/2022	1
Advertisement	TIIPS Poster	09/05/2022	1
PIS/CF	TIIPS-Participant information sheet_Version 1 12.05.2022	12/05/2022	1
Protocol	TIIPS Protocol and CRFs combined_13.5.22	13/05/2022	1
Covering Letter	TIIPS_HDEC_cover letter	16/05/2022	1