

Ethics reference: 2024 EXP 20178

11 June 2024

Prof. Rita Krishnamurthi

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Tēnā koe Prof. Krishnamurthi

APPROVAL OF APPLICATION

Study title: Digital Technologies for Stroke Prevention Trial

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. Future phases of this research of a commercial app (where public good funding is not present) will need to be accompanied by evidence that ACC-equivalent injury compensation is in place over the research period. Should ACC decline an application for cover for an injured participant in this study, the Sponsor must supply alternative compensation.

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 ensure future phases have adequate insurance in place. This can be provided to the Committee via Amendment when this happens.

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 11 June 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 currently 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
Scientific Peer Review	DIGITS_HRC_approval letter	02/06/2023	
Other	DIGITS_HRC_no DSM_23-247 Krishnamurthi	06/07/2023	
CV for Coordinating Investigator	Krishnamurthi HRC CV Jan 2024-1	01/01/2024	
Protocol	DIGITS Protocol_v1_9 Mar 2024	09/03/2024	1
PIS/CF	DIGITS_PISCF_version 1	26/03/2024	1
Tissue Management Plan	DIGITS_Tissue Management Plan_version 1	03/04/2024	1
Data Management Plan	DIGITS_Data Managment Plan_version 1	03/04/2024	1
Evidence of Consultation	DIGITS Letter-Maori consultation_Tui Barbarich-Tawera	08/04/2024	
Surveys/questionnaires	DIGITS REDCap 18.04.2024	18/04/2024	
Covering Letter	DIGITS_HDEC_cover letter_RK_signed	18/04/2024	
Other	Leaflet_Stroke Riskometer App	18/04/2024	
Surveys/questionnaires	DIGITS REDCap 18.04.2024	18/04/2024	
Response to PA Document	DIGITS_DTMP_version 2_tracked	02/05/2024	2
Response to PA Document	DIGITS_DTMP_version 2_clear	02/05/2024	2-clear
Response to PA Document	DigitS_Consent Form_version 2_tracked	02/05/2024	2
Response to PA Document	DigitS_Participant Information Sheet_version 2_clear	02/05/2024	2-clear
Response to PA Document	DigitS_Consent Form_version 2_tracked	02/05/2024	2
Response to PA Document	DigitS_Consent Form_version 2_clear	02/05/2024	2-clear
Response to PA Document	DIGITS Protocol_v2_16 May 2024_tracked	16/05/2024	2
Response to PA Document	DIGITS Protocol_v2_16 May 2024_clear	16/05/2024	2-clear
Response to PA Document	DIGITS_RA field manual_V1	16/05/2024	1
Response to PA Document	DIGITS_Redcap16.05.2024	16/05/2024	
Response to PA Document	DIGITS_HDEC_response letter_28 May 2024_signed	28/05/2024	

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