

Digital Technologies for Stroke Prevention Trial (DIGITS Trial)

CONSENT FORM

Registration Number:	Participant Initials:	Date of Birth:
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Please tick to indicate you consent to the following

I have read or have had read to me in English, and I understand the information provided about this research project in the Participant Information Sheet.

I have been given sufficient time to consider whether or not to participate in this study.

I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.

I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.

I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.

I consent to the research staff collecting and processing my information, including information about my health (study assessments, GP and hospital records).

If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.

I understand that participation may risk some discomfort arising from the blood test and answering questions about my physical and emotional wellbeing. I understand that if I do feel uncomfortable, I am not obliged to answer all the questions and may withdraw from the study at any time.

I am aware that my blood samples will be disposed of using established guidelines for discarding biohazard waste, (with provisions for a karakia if relevant).

I agree to an approved auditor appointed by the New Zealand Health and Disability Ethics Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.

I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.

I understand the compensation provisions in case of injury during the study.

I know who to contact if I have any questions about the study in general.

I understand my responsibilities as a study participant.

I consent to my GP or current provider being informed about my participation in the study. Yes

I understand my GP will be informed about any significant abnormal results obtained during the study. Yes

I consent to the DIGITS Trial study team contacting my emergency contact person if it is necessary. Yes No

I wish to receive a summary of the results from the study. Yes No

I consent to my coded (de-identified) information to be used for future research related to applied intervention in this study. Yes No

I consent to be contacted for similar future studies conducted by NISAN, AUT University. Yes No

Declaration by participant:

I hereby consent to take part in this study.

Participant's name:

Signature:

Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name:

Signature:

Date:

**Approved by the Northern B Health and Disability Ethics Committee (HDEC) on 11 June 2024.
HDEC Reference number 2024 EXP 20178.**

Thank you for interest in DIGITS Trial.