

05 August 2021

Dr Sam Paritt
Centre for Brain Research
University of Auckland
Private Bag 92019
Auckland 1142

Dear Dr Paritt

Re:	Ethics ref:	21/STH/171
	Study title:	Home use of TENS for bladder function improvement in chronic spinal cord injury: a pilot translational study

I am pleased to advise that this application has been *approved* by the Southern Health and Disability Ethics Committee. This decision was made through the HDEC-Expedited Review 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 Southern Health and Disability Ethics Committee is required.

Standard conditions:

1. Before the study commences at *any* locality in New Zealand, all relevant regulatory approvals must be obtained.
2. Before the study commences at *any* locality in New Zealand, it must be registered in a clinical trials registry. This should be a WHO-approved registry (such as the Australia New Zealand Clinical Trials Registry, www.anzctr.org.au) or <https://clinicaltrials.gov/>.
3. Before the study commences at *each given* locality in New Zealand, it must be authorised by that locality in Online Forms. 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.

After HDEC review

Please refer to the *Standard Operating Procedures for Health and Disability Ethics Committees* (available on www.ethics.health.govt.nz) for HDEC requirements relating to amendments and other post-approval processes.

Your next progress report is due by 30 July 2022.

Participant access to ACC

The Southern 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 trialled. 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 (ACC).

Please don't hesitate to contact the HDEC secretariat for further information. We wish you all the best for your study.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'Helen Walker', written in a cursive style.

Mrs Helen Walker
Acting Chairperson
Southern Health and Disability Ethics Committee

Encl: appendix A: documents submitted
appendix B: statement of compliance and list of members

Appendix A
Documents submitted

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering Letter	V1	10 May 2021
CV for CI: Sam Paritt (CV)	June 2021	15 June 2021
CVs for other Investigators: Simon O'Carroll	May 2021	10 May 2021
CVs for other Investigators: Romana Pylypchuk	Aug 2020	10 May 2021
CVs for other Investigators: Anna Lawrence	Aug 2020	10 May 2021
Evidence of scientific review: Systemic Review	V1	03 August 2020
Evidence of scientific review: Meta-analysis	V1	07 May 2021
Investigator's Brochure: Study flyer	V1	10 May 2021
PIS/CF: PIS/CF (tracked version)	V1.2	27 July 2021
Protocol: TENS-SCI Protocol V1.2 (tracked version)	V1.2	27 July 2021
UTN-not accessible	V1	10 May 2021
Survey/questionnaire: Questionnaires & e-Consent Amended	V1.2	27 July 2021
NBSS questionnaires	V1	10 May 2021
NBSS permission	V1	10 May 2021
Roles of team members	V1	10 June 2021
GCP certification	V1	15 June 2021
CM Health locality approval would not be required, as recruitment from the community is outside the DHB's jurisdiction.	V1	10 May 2021
Evidence of scientific review: An evidence has been provided to demonstrate that an appropriate peer review process has taken place.	V1	18 June 2021
Application		21 June 2021
Covering Letter: Cover letter with responses to ethical concerns	V1.2	27 July 2021
Data Management Plan	V1.2	27 July 2021
How to use TENS device	V1.2	27 July 2021
Response to Request for Further Information		

Appendix B Statement of compliance and list of members

Statement of compliance

The Southern Health and Disability Ethics Committee:

- is constituted in accordance with its Terms of Reference
- operates in accordance with the *Standard Operating Procedures for Health and Disability Ethics Committees*, and with the principles of international good clinical practice (GCP)
- is approved by the Health Research Council of New Zealand's Ethics Committee for the purposes of section 25(1)(c) of the Health Research Council Act 1990
- is registered (number 00008713) with the US Department of Health and Human Services' Office for Human Research Protection (OHRP).

List of members

<i>Name</i>	<i>Category</i>	<i>Appointed</i>	<i>Term Expires</i>
Mrs Helen Walker	Lay (consumer/community perspectives)	19/08/2020	19/08/2021
Dr Paul Chin	Non-lay (intervention studies)	27/10/2018	27/10/2021
Mr Dominic Fitchett	Lay (the law)	05/07/2019	05/07/2022
Dr Sarah Gunningham	Lay (other)	05/07/2016	05/07/2022
Assc Prof Mira Harrison-Woolrych	Non-lay (intervention studies)	28/06/2019	28/06/2020
Professor Jean Hay-Smith	Non-lay (health/disability service provision)	31/10/2018	31/10/2021
Dr Devonie Waaka	Non-lay (intervention studies)	18/07/2016	18/07/2019

Unless members resign, vacate or are removed from their office, every member of HDEC shall continue in office until their successor comes into office (HDEC Terms of Reference)

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