

23 October 2015

Dr Harry McNaughton  
Neurology Department, CMU  
Wellington Hospital  
Riddiford St  
Private Bag 7902  
Wellington 6021

Dear Dr McNaughton

Re:	<b>Ethics ref:</b>	<b>15/CEN/115/AM01</b>
	Study title:	Self-directed rehabilitation RCT after stroke: a practical, low cost programme. The Taking Charge after Stroke (TaCAS) Study

I am pleased to advise that this amendment has been approved by the Central Health and Disability Ethics Committee. This decision was made through the HDEC Expedited Review pathway.

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

Yours sincerely,



Mrs Helen Walker  
Chairperson  
Central Health and Disability Ethics Committee

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

**Appendix A**  
**Documents submitted and approved**

Document	Version	Date
PIS/CF: Comments detailing changes from original	6.1 annotated	08 October 2015
PIS/CF: new PIS-CF without comments	6.1 'clean'	08 October 2015
Protocol: Comments detailing minor changes to protocol	7.1 annotated	08 October 2015
Protocol: modified protocol without comments, minor changes only	7.1 'clean'	08 October 2015
Take Charge sheet with added illustrations	v3	28 September 2015
Survey/questionnaire: Baseline form reformatted	Baseline v3.3	08 October 2015
Survey/questionnaire: Demographics form - confidential info separated for restricted access	Demographics v1.4	08 October 2015
Survey/questionnaire: 6 month follow up form reformatted	6 month v2.4	08 October 2015
Survey/questionnaire: 12 month follow up form reformatted	12 month form v3.1	08 October 2015
Post Approval Form	AM01	09 October 2015

## Appendix B Statement of compliance and list of members

### Statement of compliance

The Central 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 00008712) 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)	01/07/2012	01/07/2015
Dr Angela Ballantyne	Lay (ethical/moral reasoning)	01/07/2015	01/07/2018
Dr Melissa Cragg	Non-lay (observational studies)	01/07/2015	01/07/2018
Dr Peter Gallagher	Non-lay (health/disability service provision)	01/07/2015	01/07/2018
Mrs Sandy Gill	Lay (consumer/community perspectives)	01/07/2015	01/07/2018
Dr Ptries Herst	Non-lay (intervention studies)	01/07/2012	01/07/2015
Dr Dean Quinn	Non-lay (intervention studies)	01/07/2012	01/07/2015
Dr Cordelia Thomas	Lay (ethical/moral reasoning)	19/05/2014	19/05/2017

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>