



RESEARCH OFFICE

MEMORANDUM

To: Dr Miranda Rose, School of Allied Health, College of SHE

From: Senior Human Ethics Officer, La Trobe University Human Ethics Committee

Subject: Review of Human Ethics Committee Application No. 15-043

Title: COMPARE – Constraint Induced or Multi-Modal Aphasia Rehabilitation: An RCT of therapy for stroke related chronic aphasia

Date: 22 July 2015

Thank you for your recent correspondence in relation to the research project referred to above. The project has been assessed as complying with the *National Statement on Ethical Conduct in Human Research*. I am pleased to advise that your project has been granted ethics approval and you may commence the study now.

The project has been approved from the date of this letter until 31/12/2018.

Please note that your application has been reviewed by a sub-committee of the University Human Ethics Committee (UHEC) to facilitate a decision before the next Committee meeting. This decision will require ratification by the UHEC and it reserves the right to alter conditions of approval or withdraw approval at that time. You will be notified if the approval status of your project changes. The UHEC is a fully constituted ethics committee in accordance with the National Statement under Section 5.1.29.

The following versions of documents have been submitted and approved by UHEC:

Above-Low-Risk-Application-Form-30.7.14_COMPARE FINAL_Amended 20Jul15

Participant information booklet aphasia friendly_V2.0_20 Jul15

Participant information sheet for close others_V2.0_20Jul15

Participant information sheet for PWA_V2.0_20Jul15

Consent form aphasia friendly_V2.0_20Jul15

Consent form for close other_V2.0_20July15

Consent form for PWA_V2.0_20July15

Withdrawal form Aphasia friendly_V2.0_20Jul15

Withdrawal form for close other_V2.0_20Jul15

Withdrawal form for PWA_V2.0_20July15

COMPARE Protocol Version 1, dated 25 May 2015

Advert for PWA V1.0, dated 18 May 2015

Advert for SLPs V1.0, dated 18 May 2015

The following standard conditions apply to your project:

- **Limit of Approval.** Approval is limited strictly to the research proposal as submitted in your application while taking into account any additional conditions advised by the UHEC.
- **Variation to Project.** Any subsequent variations or modifications you wish to make to your project must be formally notified to the UHEC for approval in advance of these modifications being introduced into the project. This can be done using the appropriate form: *Modification to Project – Human Ethics* which is available on the Human Ethics website at <http://www.latrobe.edu.au/researchers/ethics/human-ethics> If the UHEC considers that the proposed changes are significant, you may be required to submit a new application form for approval of the revised project.
- **Adverse Events.** If any unforeseen or adverse events occur, including adverse effects on participants, during the course of the project which may affect the ethical acceptability of the project, the Chief Investigator must immediately notify the UHEC Executive Officer. An *Adverse Event Form – Human Ethics* is available at the Research Services website (see above address). Any complaints about the project received by the researchers must also be referred immediately to the UHEC Executive Officer.
- **Withdrawal of Project.** If you decide to discontinue your research before its planned completion, you must advise the UHEC and clarify the circumstances.
- **Monitoring.** All projects are subject to monitoring at any time by the University Human Ethics Committee.
- **Annual Progress Reports.** If your project continues for more than 12 months, you are required to submit a Progress Report annually, **on or just prior to 12 February**. The form is available on the Research Office website (see above address). Failure to submit a Progress Report will mean approval for this project will lapse.
- **Auditing.** An audit of the project may be conducted by members of the UHEC.
- **Final Report.** A Final Report (see above address) is required within six months of the completion of the project or by **30 June 2019**.

If you have any queries on the information above or require further clarification please email: humanethics@latrobe.edu.au or contact me by phone.

On behalf of the University Human Ethics Committee, best wishes with your research!

Kind regards,

Ms Sara Paradowski
 Senior Human Ethics Officer
 Executive Officer – University Human Ethics Committee
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<http://www.latrobe.edu.au/researchers/ethics/human-ethics>