

Research Integrity & Ethics Administration

Human Research Ethics Committee

Thursday, 4 May 2017

Dr Hans (Henri) Bogaardt Disability and Community; Faculty of Health Sciences Email: hans.bogaardt@sydney.edu.au

Dear Hans (Henri)

The University of Sydney Human Research Ethics Committee (HREC) has considered your application.

After consideration of your response to the comments raised your project has been approved.

Approval is granted for a period of four years from 04 May 2017 to 04 May 2021

Project title: Development and validation of a Speech pathology specific

questionnaire for patients with Multiple Sclerosis (SMS)

Project no.: 2017/197

First Annual Report due: 04 May 2018

Authorised Personnel: Bogaardt Hans (Henri); El-Wahsh Sarah;

Documents Approved:

Date Uploaded	Version number	Document Name
05/04/2017	Version 1	PICF v01
05/04/2017	Version 2	Protocol
05/04/2017	Version 1	Initial Questionnaire v01
05/04/2017	Version 1	Follow-Up Questionnaire v01
05/04/2017	Version 2	Announcement (patient organisations)
05/04/2017	Version 2	Announcement (social media)
28/02/2017	Version 1	recruitment_flyer_SMS_study 01

Condition/s of Approval

- Research must be conducted according to the approved proposal.
- An annual progress report must be submitted to the Ethics Office on or before the anniversary of approval and on completion of the project.
- You must report as soon as practicable anything that might warrant review of ethical approval of the project including:
 - > Serious or unexpected adverse events (which should be reported within 72 hours).
 - Unforeseen events that might affect continued ethical acceptability of the project.
- Any changes to the proposal must be approved prior to their implementation (except where an amendment is undertaken to eliminate *immediate* risk to participants).



- Personnel working on this project must be sufficiently qualified by education, training and experience for their role, or adequately supervised. Changes to personnel must be reported and approved.
- Personnel must disclose any actual or potential conflicts of interest, including any financial or other interest or affiliation, as relevant to this project.
- Data and primary materials must be retained and stored in accordance with the relevant legislation and University guidelines.
- Ethics approval is dependent upon ongoing compliance of the research with the *National Statement on Ethical Conduct in Human Research*, the *Australian Code for the Responsible Conduct of Research*, applicable legal requirements, and with University policies, procedures and governance requirements.
- The Ethics Office may conduct audits on approved projects.
- The Chief Investigator has ultimate responsibility for the conduct of the research and is responsible for ensuring all others involved will conduct the research in accordance with the above.

This letter constitutes ethical approval only.

Please contact the Ethics Office should you require further information or clarification.

Sincerely

Associate Professor Michael Skilton

Chair

Health Review Committee

The University of Sydney HRECs are constituted and operate in accordance with the National Health and Medical Research Council's (NHMRC) National Statement on Ethical Conduct in Human Research (2007) and the NHMRC's Australian Code for the Responsible Conduct of Research (2007).