THE HONG KONG POLYTECHNIC UNIVERSITY
香港理工大學

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| To | Au-yeung Suk Yin Stephanie (Department of Rehabilitation Sciences) | | |
| From | TSANG Wing Hong Hector, Chair, Departmental Research Committee | | |
| Email | rshtsang@polyu.edu.hk | Date | 12-Oct-2014 |

## Revision of Ethical Approval for Teaching/Research Involving Human Subjects

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| **Project Title:** | The motor effects of combined peripheral nerve electrical stimulation and action observation on the affected hand in people with stroke |
| **Department:** | Department of Rehabilitation Sciences |
| **Principal Investigator:** | Au-yeung Suk Yin Stephanie |
| **Reference Number:** | HSEARS20140617001-01 |

I am pleased to inform you that approval has been given to your revised application for human ethics review of the above project for a period from 23-Jun-2014 to 30-Jun-2015:

Please be reminded that you are responsible for the ethical approval granted for the project and the ethical conduct of the personnel involved in the project. In the case of the Co-PI, if any, has also obtained ethical approval for the project, the Co-PI also assumes the responsibility in respect of the ethical approval (in relation to the areas of expertise of respective Co-PI in accordance with the stipulations given by the approving authority).

You are responsible for informing the Departmental Research Committee in advance of any changes in the proposal or procedures which may affect the validity of this ethical approval extension.

You will receive separate email notification should you be required to obtain fresh approval.

TSANG Wing Hong Hector

Chair

Departmental Research Committee

**The Hong Kong Polytechnic University**

**Department of Rehabilitation Sciences**

**Research Project Informed Consent Form**

**Project Title:** The motor effects of combined peripheral nerve electrical stimulation and action observation on the affected hand in people with stroke

**Reference Number:** HSEARS20140617001-01

**Principal Investigator:** Dr. Stephanie Au-Yeung, (Ph.D, Assistant Professor), LIU Hao (Ph.D student)

**Project Information:**

Stroke rehabilitation entails evidence-based treatments to promote recovery of movements. Prolonged electrical stimulation (ES) to peripheral nerves has been shown to increase the excitability of brain neurons controlling hand muscles. Observing task performance desired to be performed by an individual, also known as action observation (AO), has also been shown to promote movements in people with stroke. This study therefore aims to examine the motor effects of ES and simultaneous ES and AO on the affected hand in people with stroke.

As a participant in this study, you will attend 4 sessions of assessment and treatment procedures conducted in the University. The first session is for assessment on the movement in your affected arm, as well as familiarizing you to the measurement of excitability of the motor pathways using Transcranial Magnetic Stimulation (TMS). TMS is non-invasive and safe for people fulfilling the screening criteria for TMS. During TMS, you will be sitting on a chair with your neck, back and legs supported. The examiner will place a TMS applicator on the top of your head at the region that control your hand movements. Magnetic stimuli will be generated from the TMS machine to stimulate the brain cells that control movement of your finger. During TMS, you may or may not feel muscle twitches in the affected hand. You may also feel some brief touch on your scalp when the TMS stimuli are elicited. However, you will not feel any pain or discomfort. The pinch strength and dexterity movement of the affected hand will also be assessed.

After the first familiarizing session, you will attend 3 other sessions in the coming 3 to 4 weeks that involves one-hour of ES on your affected arm. During ES, you will sit in front of a desk with your arms supported. You may or may not feel any tingling or muscle twitches in your arm or hand. In the last 30 minutes of ES, you will watch a series of 4 videos of hand task performance or 4 photos. After the ES, you will receive motor training of voluntary finger movement for 30 minutes in sitting position. Before ES and after motor training, you will be assessed with TMS and hand movements as in the first session. The hand movements also will be assessed immediately after ES and 24 hours after each session.

**Benefits for participants and social:** Results of this study will help to reveal the effects of ES and AO as well as motor training on movements of the affected hand following stroke, which could promote evidence-based stroke rehabilitation.

**Potential risk:** There will not be any risks or side effects with the assessment and intervention procedure.

**Confidentiality of personal information:** The results of this study may be published in academic conferences or journals. Your personal information will remain confidential and will never to be made public. By signing this research consent form, you authorize the Clinical Research Ethics Committee and regulatory agencies to directly

verify the research data.

**Consent**

I, _____, have been explained the details of this study. I voluntarily consent to participate in this study. I understand that I can withdraw from this study at any time without giving reasons, and my withdrawal will not lead to any punishment or prejudice against me. I am aware of any potential risk in joining this study. I also understand that my personal information will not be disclosed to people who are not related to this study and my name or photograph will not appear on any publications resulted from this study.

I can contact the principal investigator, Dr. Stephanie Au-Yeung at telephone 27666707 for any questions about this study. If I have complaints related to the investigator and her team, I can contact Ms. Man, secretary of Departmental Research Committee, at 27664394. I know I will be given a signed copy of this consent form.

Name and signature of participant _____ Date _____

Name and signature of researcher _____ Date _____

Name and signature of witness _____ Date _____