



NTW Cluster Clinical & Research Ethics Committee
新界西醫院聯網臨床及研究倫理委員會

Confidential

Our Ref.: (8) in NTWC/CREC/737/09

14 August 2009

Ms Doris LAM
Occupational Therapist I
Department of Occupational Therapy
Tuen Mun Hospital

Dear Ms LAM

**Application for Ethics Approval for
Clinical Research Study**

Study Title: RCT of Self-Regulated Constraint-Induced Therapy for Functional Regain for People with Sub-Acute Stroke
Principal Investigator: Ms Doris LAM, Occupational Therapist I, TMH
Study Site(s) Approved: Tuen Mun Hospital

I am pleased to inform you that the following submissions regarding the above Study have been reviewed by an expedited process and ethics approval was given by the NTW Cluster Clinical & Research Ethics Committee on 11 August 2009:

1.	Expedited Review Form for Multi-center Trial Approved by Another Cluster REC;
2.	Copy of Approval Letter from Joint the CUHK – NTEC CREC dated 6 May 2008;
3.	Research Protocol;
4.	Research Project Informed Consent Form: 4.1 English Version; 4.2 Chinese Version;
5.	CV of Principal Investigator.



Please note that you are required to adhere to the following conditions:

1. Do not deviate from, or make changes to the study protocol without prior written approval of the NTWC-C&REC, except when it is necessary to eliminate immediate hazards to research subjects or when the change involves only logistical or administrative issues.
2. Report the followings to NTWC-C&REC: (i) study protocol or consent document change (use 'NTWC CREC001F7'), (ii) serious adverse event (use 'NTWC CREC001F8'), (iii) new information that may be relevant to a subject's willingness to continue participation in the research.
3. Report research progress [use "NTWC CREC001F9a"] to NTWC C&REC at 12-monthly intervals until study closure. Submit a final report [use "NTWC CREC001F9b"] to the NTWC C&REC upon research completion.

(Forms down-loadable from <http://ntwc.home/crec/>)

The NTW Cluster Clinical & Research Ethics Committee serves to ensure that research complies with the Declaration of Helsinki, ICH GCP Guidelines, local regulations and HA policies.

Yours sincerely



(Alfred CHAK)
Secretary
NTW Cluster

Clinical & Research Ethics Committee

cc Mr Joseph POON, CC(Occ Th), NTWC