



COA No. 758/2013

IRB No. 305/56

INSTITUTIONAL REVIEW BOARD

Faculty of Medicine, Chulalongkorn University

1873 Rama 4 Road, Patumwan, Bangkok 10330, Thailand, Tel 662-256-4493 ext 14, 15

Certificate of Approval

The Institutional Review Board of the Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand, has approved the following study which is to be carried out in compliance with the International guidelines for human research protection as Declaration of Helsinki, The Belmont Report, CIOMS Guideline and International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Study Title : Clinical characteristics, Neuropsychological assessment and Psychoimmunological aspect in Temporal Lobe Epilepsy (TLE), TLE with psychosis, TLE with depression and TLE with anxiety.

Study Code : -

Principal Investigator : Assoc.Prof. Buranee Kanchanatawan, M.D.

Affiliation of PI : Department of Psychiatry,
Faculty of Medicine, Chulalongkorn University.

Review Method : Full board

Continuing Report : At least once annually or submit the final report if finished.

Document Reviewed :

1. Protocol Version 4.0 Date 18 November 2013
2. Protocol Synopsis Version 2.0 Date 26 August 2013
3. Information sheet for research participant Version 4.0 Dated 18 November 2013
4. Informed Consent Form Version 2.0 Date 26 August 2013
5. BRIEF PSYCHIATRIC RATING SCALE (BPRS)
6. HAMILTON RATING SCALE FOR DEPRESSION
7. Hamilton Anxiety Rating Scale (HAM-A) Thai – Version

All approved investigators must comply with the following conditions:

1. Strictly conduct the research as required by the protocol;
2. Use only the information sheet, consent form (and recruitment materials, if any), interview outlines and/or questionnaires bearing the Institutional Review Board's seal of approval ; and return one copy of such documents of the first subject recruited to the Institutional Review Board (IRB) for the record;
3. Report to the Institutional Review Board any serious adverse event or any changes in the research activity within five working days;
4. Provide reports to the Institutional Review Board concerning the progress of the research upon the specified period of time or when requested;
5. If the study cannot be finished within the expire date of the approval certificate, the investigator is obliged to reapply for approval at least one month before the date of expiration.
6. If the research project is completed, the researcher must be form the Faculty of Medicine, Chulalongkorn University.

* A list of the Institutional Review Board members (names and positions) present at the meeting of Institutional Review Board on the date of approval of this study has been attached. All approved documents will be forwarded to the principal investigator.



8. Curriculum Vitae version 2.00 Date 26 August 2013

Signature: Tada Sueblinvong

(Emeritus Professor Tada Sueblinvong MD)

Chairperson

The Institutional Review Board

Signature: Onanong Kulaputana

(Associate Professor Onanong Kulaputana MD, PhD)

Member and Assistant Secretary, Acting

Secretary The Institutional Review Board

Date of Approval : December 12, 2013

Approval Expire Date : December 11, 2014

Approval granted is subject to the following conditions: (see back of this Certificate)