

Report of Institutional Review Board

Requester : **Cho, Yang Je**

This letter is to inform you of the results of your confidential.

Type of Review	<input checked="" type="checkbox"/> first approval <input type="checkbox"/> approval with condition <input type="checkbox"/> complement <input type="checkbox"/> return <input type="checkbox"/> objection <input type="checkbox"/> change on protocol <input type="checkbox"/> interim report <input type="checkbox"/> end of study report <input type="checkbox"/> final report <input type="checkbox"/> cancellation of protocol <input type="checkbox"/> others		
IRB No.	4-2011-0878	Date of approval	2012.02.09
Title of Proposal	The EpiNet project; an open-ended, observational study of epilepsy (continuation of previous study; An International Pilot Study of an Internet based platform to run epilepsy trials (Epinet))		
	Protocol No.	-	Version No. V1
Investigator	Principal Investigator: Dr. Byung In Lee / Professor / Department of Neurology / Yonsei University College of Medicine		
Generic name	-	Brand Name	-
Phase	<input type="checkbox"/> Phase I <input type="checkbox"/> Phase II <input type="checkbox"/> Phase III <input type="checkbox"/> Phase IV <input type="checkbox"/> Biological equivalence test <input checked="" type="checkbox"/> Others		
Proposed period of study	Approval date of IRB ~ for 60 months		
Contents of Review	※ <u>Lists of initial review</u> 1. Application Form 2. Study Protocol 3. Case Report Form 4. Informed consent form (Adult, Child 7-12 years old, child 13-19 years old) 5. CV for Investigator		
Date of Review	Feb 9 th , 2012		
Result of Review	<input checked="" type="checkbox"/> Approved <input type="checkbox"/> Approval with condition <input type="checkbox"/> Require to re-reviewed <input type="checkbox"/> Disapproval		
Comment	Recommendation 1. Additional formal informed consent form for the legal representative of adolescent or mentally handicapped person will be recommended. 2. We are concerned that the use of patients' full name on e-CRF due to the issue of participant's privacy and confidentiality. We fully understand the policy of this international collaboration study; however, again we request the investigator's careful handling of the data and every efforts to protect privacy and confidentiality of the patients.		

Severance Hospital IRB is organized and operates according to ICH-GCP and the applicable laws and regulations

Feb 9th, 2012
 Seung Min Kim, MD, PhD
 Chairperson of Institutional Review Board
 Severance Hospital
 Yonsei University, College of Medicine
 Seoul 120-752, Korea

