

Notification Letter

We notify the IRB decision for your protocol.

Reception	Investigator Name	Dong Il Park , MD, Ph.D. Professor, Department of Gastrology, Kangbuk Samsung Hospital Sungkyunkwan University, School of Medicine			
IRB File No.	KBSMC 2015-12-005	Date of submission	22 Feb, 2016	Review	<input checked="" type="checkbox"/> Regular <input type="checkbox"/> Expedited
Protocol Title	The Short Health Scale: A valid measure of health related quality of life in Korean speaking inflammatory bowel disease patients				
Protocol No.		Version No.	2.0	Version date	14 Jan 2016
List of Documents Reviewed	<input type="checkbox"/> New protocol <input checked="" type="checkbox"/> Resubmitted Protocol <input type="checkbox"/> Protocol Amendments <input type="checkbox"/> Continuing Review / Interim Report <input type="checkbox"/> Completion Report <input type="checkbox"/> Final Report <input type="checkbox"/> Others		Protocol (Ver 2.0, 14 Jan 2016) Informed Consent Document (Ver 2.0, 14 Jan 2016) Case Report Form (Ver 2.0, 14 Jan 2016) Questionnaire (Ver 2.0, 14 Jan 2016) Investigator's CV / Certificate of GCP Training Conflict of Interest Disclosure form Written Oath of PI Response to initial review comments		
Date of Meeting	29 Feb, 2016	Approval Validity period		1 year (Expiry date: 28 Feb, 2017)	
		Application period for Closure Report		within one month after closing	
Decision	<input checked="" type="checkbox"/> Approval (29 Feb, 2016) <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Re-review after supplementation <input type="checkbox"/> Refusal <input type="checkbox"/> Others				
Review Comment	1. Please perform the study according to the approved protocol 2. Please get the approval stamp and iron punch of the IRB before using the ICF				

Date: 3 Mar, 2016

IRB of KANGBUK SAMSUNG HOSPITAL



1. This IRB is in compliance with the GCP and the ICH requirements.
2. Please submit the Application for Continuing Review/Interim Report every year, and the End-of-study Report within 1 month at the end of the study.
3. If any serious adverse event occurs during the study, the principal investigator should immediately report to this IRB.
4. If you have any objection to the review result, please submit the Application for Appeal within 1 month.
5. If Principal investigator is an IRB member, the member did not participate in reviewing the concerned study
6. Please confirm the Investigator's obligation