

Review Results Notification

Review Results Notification Date	02/17/2015
-----------------------------------------	------------

Receipt No.	S2015-0144-0001					
Project No	2015-0173					
Protocol Name	Impact of antibodies to infliximab and serum infliximab level on clinical outcomes in Korean patients with inflammatory bowel disease (IBD)					
Principal Investigator	Organization	Department of Gastroenterology and Inflammatory Bowel Disease Center	Position	Assistant Professor	Name	Sang Hyoung Park
Sponsor	Organization	IIT			Name	
Detailed Classification of Research	The Bioethics and Safety Act	Human Subject Research, Human Material Research				
	Research Target	Examination Method				
	Classification of Research	Cohort Research				
	Research Phase					
Review Type	New Clinical Research Protocol					
Review Results	Results in which the start, continuation and change of research are possible	<input checked="" type="checkbox"/> Approval <input type="checkbox"/> Continue the Research As Previously Conducted				
	Results that must apply for supplementary review	<input type="checkbox"/> Approved with Modification <input type="checkbox"/> Approved with Conditions <input type="checkbox"/> Re-Review After Modification <input type="checkbox"/> Rejection <input type="checkbox"/> Continue the research but <input type="checkbox"/> Continue the research but				

		supplementation is needed. <input type="checkbox"/> Continue the research but discontinue the research procedures subsequently implemented to a subject <input type="checkbox"/> Early Termination of Approved Research <input type="checkbox"/> Disapproval	discontinue recruitment of new subjects <input type="checkbox"/> Temporary Discontinuation of Approved Research <input type="checkbox"/> Actions on the Researcher <input type="checkbox"/> Other
Submitted Date of Document	01/30/2015	Review Date	02/12/2015
Continuation Review Cycle	<input type="checkbox"/> 3 Months <input type="checkbox"/> 6 Months <input checked="" type="checkbox"/> 1 Year <input type="checkbox"/> Exemption <input type="checkbox"/> Other	Expiration Date of Approval	02/11/2016

Review Opinion

This board had decided to approve as a result of reviewing the new protocol which the researcher has submitted.

Risk Level Evaluation : Level I



The members of the research team in the project did not participate in the review and meeting.

List of Submitted Materials & Version No.

Protocol (Korean)(1.1)

CRF(1.1)

SIS and ICF (1.1)

Institutional Review Board/Institutional Bioethics Committee Chairperson Jong Woo Chung (Seal)

* This Institutional Review Board complies with the related laws such as ICH, KGCP or Bioethics and Safety Act. In case of having a member at a conflict of interest relationship with this research, the corresponding member has been excluded from the review