

Review Results Notification

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Date

01/25/2016

Receipt No.	S2016-0028-0001					
Project No	2016-0076					
Protocol Name	Genomic changes in hepatitis B virus associated with development of hepatocellular carcinoma					
Principal Investigator	Organization	Department of Gastroenterology	Position	Professor	Name	Young-Hwa Chung
Sponsor	Organization	IIT			Name	
Detailed Classification of Research	The Bioethics and Safety Act					
	Research Target					
	Classification of 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"/> Re-Review After Modification <input type="checkbox"/> Continue the research but supplementation is needed. <input type="checkbox"/> Continue the research but discontinue the research procedures subsequently <input type="checkbox"/> Approved with Conditions <input type="checkbox"/> Rejection <input type="checkbox"/> Continue the research but discontinue recruitment of new subjects <input type="checkbox"/> Temporary Discontinuation of				

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		implemented to a subject <input type="checkbox"/> Early Termination of Approved Research <input type="checkbox"/> Disapproval	Approved Research <input type="checkbox"/> Actions on the Researcher <input type="checkbox"/> Other
Submitted Date of Document	01/14/2016	Review Date	01/25/2016
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	01/24/2017

Review Opinion
<p>This board had decided to approve as a result of reviewing the new protocol which the researcher has submitted.</p> <p>This is a study using the stored human biological material so anonymity process on the human biological material and clinical information is a very important procedure. It must be in accordance with the protocol. In the event of continuing review (or when end report if end report is made without continuing review), please submit evidentiary documents to confirm whether the anonymity procedure was carried out according to protocol.</p> <p>[Risk Level Evaluation : Level I Risk]</p>

List of Submitted Materials & Version No.
Protocol (Korean)(1.0) CRF (1.0)

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


 Young-Hwa Chung
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