Report of IRB Review

Project No.	2013-058		Protocol No.	N/A
Version No.	Version 1.0			
Protocol Title	A Blinded Clinical Trial Comparing the Efficacy and Tolerability of Picolight(fixed split dose regimen) for Colonoscopy			
PI	Name	Koon Hee Han	Division	Gastroenterology
Sponsor	(CEO / Director general)			
Classification	☐ Embryo Production ☐ Embryo Research ☐ DNA Test ☐ Genetic Study ☐ DNA Bank ☐ Gene Therapy ☐ Somatic Cell Embryo Clones			
	☐ Case-series study using medical records ■ Surveys ☐ Research using biological samples (☐ Stored Samples ☐ Collecting new samples)			
	☐ Drugs ☐ Devices ☐ Procedures ☐ Others			
Phase	☐ Phase I ☐ Phase II ☐ Phase III ☐ Phase IV ☐ PMS ☐ Bioequivalence ■ Others			
Director of IRB	Gil Hyun Kang (Signature)			

IRB of Asan Medical Center complies with the standards and regulations of ICH and KGCP. Investigators are authorized to proceed the study with an approval of IRB. In carrying out research, investigators should advance the study with an originally proposed protocol. Principal Investigator shall report to IRB immediately in case of Serious Adverse Event. Also, immediate actions include an occurrence of new information which might harm research applicants. The researcher should cooperate and submit research-related documents under the request of IRB. Also, investigators should follow the primary protocol as proposed except the circumstances which can endanger the participants enrolled in the research.

Submitted documents	■ New protocol ☐ Amendment ☐ Suspended or Early-closed Report ☐ Supplement (Conditional Approval) ☐ Interim Report ☐ Continued Review on Approved Protocol ☐ Supplement (Re-review) ☐ Result Report ☐ Subject Wanted Ad ☐ Final Report ☐ Others:		
Results of Review	■ Approval ☐ Conditional Approval ☐ Supplement (Conditional Approval) ☐ Supplement (Re-review) ☐ Rejection ☐ Suspension or Reservation of Approved Clinical Trial		
Date of Approval	Nov 12, 2013	Continuing Review period	☐ 3 Month ☐ 6 Month ■ 1 Year ☐ Others
List of Submitted Materials	1. Research Project Review Applications 2. Research Project protocol(Version 1.0) 3. Research Project Summation 4. Human derivatives research Informed Consent form(Version 2.0) 5. Case Report form(Version 1.0) 6. PI Curriculum vitae(Koon Hee Han) 7. bioethics Observance Covenant 8. GCP Certification(Jong Kyu Park, Hyun Il Seo, Yoon Mi Choi, Ji Eun Seo) 9. Research budget execution		
Review Opinion	Approval. The Clinical Trial is started and one year later Investigator must submit the continuation report.		