Review Result Notice of the IRB of The Catholic University of Korea, St. Paul's Hospital

Postal code: (130-709) 180, Wangsan-ro, Dongdaemun-gu, Seoul, Korea TEL: 82-2-958-2173 FAX: 82-2-958-5058
POC: Minhang, Cho

Document No.	PIRB-00118_3-001		**Date of enforcement**	Feb 21, 2014
Title of study	Clinical Characteristics of Helicobacter pylori-negative Drug-negative Peptic Ulcer Bleeding			
Study no.	PC14RISI0012			
Principal investigator	**Dept.**	Dept. of internal medicine	**Name**	eun jung, JEON
Sponsor	St. Paul's Hospital			
Subject of review	Initial Protocol			
Object of study	The medical records			
Date of review	Feb 21, 2014			
Result of review	Approved			
Valid date of study approval	Feb 20, 2016	Please acquire the approval for continued review prior to expiry of study approval period for continued study. Upon study termination, please submit a termination report.		
Details of review				
Review contents	1. Application for Clinical Study Approval 2. Investigator's written promise 3. Investigator's ethical considerations 4. A written promise on conflict of interest 5. Protocol 6. CRF 7. Ref 8. Investigator's CV 9. paper of informed consent exemption with checklist 10. etc.			
Opinion of review	▷ Information 1. This study is a retrospective analysis of the clinical data collected after treatment course was completed. 2. This study has the minimal risk to the patient. 3. Valid date of study approval : Feb 20, 2016 4. Closing report : Report within one month from the end. 5. Resulting report : Results reported within one year after closing report. 6. Review Result Notice : Please keep it			

* Regarding the case of review applied by you, we inform you of the result of our review as mentioned in the above.
* If the principal investigator has an objection to review result of the IRB, he/she may raise an objection with the reason mentioned in writing in 2 weeks from the date when the result was notified by the IRB. However, an objection shall not be raised two times successively on the same case.
* The IRB observes the KGCP and ICH-GCP, as well as relevant laws including the Bioethics and Safety Act.

IRB of The Catholic University of Korea, St. Paul's Hospital (Official seal)

President of The Catholic University of Korea, St. Paul's Hospital (Official seal omitted)

Directions to be followed by the investigator when performing clinical study/research

1. Perform the study according to the protocol approved by IRB.
2. Perform whatever amendments of the study after approval of IRB in advance other than those inevitable cases for the protection of subjects in progress of the study. Amendments performed under any urgent situations for the protection of subjects shall be immediately reported to IRB.
3. For informed consent form to be used for the clinical study, please receive the confirmation stamp of the administrative manager of IRB prior to use after it will be approved from IRB.
4. For subjects whose mother tongue is not Korean, translated version of the approved consent form certified in their respective mother tongue shall be used. This translated version of the consent form must be approved by IRB.
5. The consent process shall be performed based on sufficient descriptions without forced or unfair influence, and sufficient opportunities shall be provided so that potential subjects may consider to participate in the study.
6. Subject recruitment advertisements shall be used after being approved by IRB in advance.
7. Any subject being enrolled according to the protocol approved by IRB shall report death, hospitalization and serious adverse events in writing to IRB
8. When requested by IRB, reports related to the progress of the study shall be submitted to IRB.
9. Any new information that may negatively influence the safety of clinical study or the subjects shall be immediately reported to IRB.
10. To continue the study approved in the initial review, application for continuing review shall be made within the effective study approval period to obtain approval.
11. When the study is terminated(including early termination), the termination of study and its summary data shall be
reported to IRB according to Form FI-10-02 Clinical Study Termination Report.