GNUHIRB

GyeongSang National University Hospital
Institutional Review Board
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79, Gangnam-ro, Jinju-si, Gyeongnam-do,
Korea, 660-702

Certificate of Approval

THE FOLLOWING WERE APPORVED:

BOARD ACTION DATED: **October 05, 2015**

STUDY NO :

IRB NO: **GNUH 2015-09-004**

INVESTIGATOR: **Park Ji Sook, M.D.**

Assistant Professor, Dept. of Pediatrics, GNUH

SPONSOR:

PROTOCOL NO:

TITLE: **Clinical profiles and ABCB11 gene mutations in Korean infants with progressive familial intrahepatic cholestasis**

APPROVAL INCLUDES:

ALL CONDITIONS OF APPROVAL PREVIOUSLY ESTABLISHED BY GNUH IRB FOR THIS RESEARCH PROJECT CONTINUE TO APPLY.

CONTINUING REVIEW REPORT INTERVAL:

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IF YOU HAVE ANY QUESTIONS, CONTACT GNUH IRB(Tel: 82-55-750-9250)

This is to certify that the information contained herein is true and correct as reflected in the records of the GNUH Institutional Review Board. We certify that GNUH IRB is in full compliance with Good Clinical Practice as defined under the Korea Food and Drug Administration (KFDA) regulations and the International Conference on Harmonisation (ICH) guidelines.

Heesuk Shin — **Chairperson**

Oct 05 2015 — **Date**

ALL GNUH IRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

1. Conduct the research as required by the protocol.
2. Use only the Consent Form bearing the GNUH IRB "APPROVED" stamp.
3. Provide non-Korean speaking subjects with a certified translation of the approved Consent Form in the subject's first language. The translated version must be approved by the GNUH IRB.
4. Obtain pre-approval from the GNUH IRB of any changes in the research activity (except when necessary to protect human subjects; immediately report to the GNUH IRB any such emergency changes for the protection of human subjects).
5. Report to the GNUH IRB the death, hospitalization, or serious illness of any study subject.
6. Promptly report to the GNUH IRB any new information that may adversely affect the safety of the subjects or the conduct of the trial.
7. Provide reports to the GNUH IRB concerning the progress of the research, when requested.
8. Obtain pre-approval of study advertisements from the GNUH IRB before use.
9. Conduct the informed consent process without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate.

Korea FDA regulations require that the GNUH IRB conduct review of approved research. You will receive Continuing Review Report forms from the GNUH IRB. These reports must be returned even though your study may not have started.

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Heesuk Shin — **Chairperson**

Oct / 05 / 2015 — **Date**