KNUMC IRB

KyungPook National University Medical Center Institutional Review Board
Tel :82-53-200-2162
FAX:82-53-200-2169 807 Hogukno, Buk-gu, Daegu
702-210, KOREA

Certificate of Approval

THE FOLLOWING WERE APPROVED:

BOARD ACTION DATED:
STUDY NO : NA
IRB NO : KNUMC_13-1047

INVESTIGATOR: Sang Geol Kim / Hepalobiliary-Pancreatic Cancer Center
SPONSOR: -
PROTOCOL NO : N/A
TITLE: The influence of type of surgery and clinicopathological factors on Long Term Prognosis of the patients with middle and distal Bile Duct Cancer

APPROVAL INCLUDES:

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

APPROVAL ISSUED : 07-Oct-2013
EXPIRATION DATE : 07-Oct-2014
CONTINUING REVIEW REPORT INTERVAL : N/A
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IF YOU HAVE ANY QUESTIONS, CONTACT THE KNUMC IRB (Tel: 82-53-200-2162)

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

Chairperson

07-Oct-2013
Date

ALL KNUMC IRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

1. Conduct the research as required by the protocol.
2. 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 KNUMC IRB.
3. Obtain pre-approval from the KNUMC IRB of any changes in the research activity (except when necessary to protect human subjects; immediately report to the KNUMC IRB any such emergency changes for the protection of human subjects).
4. Report to the KNUMC IRB the death, hospitalization, or serious illness of any study subject.
5. Promptly report to the KNUMC IRB any new information that may adversely affect the safety of the subjects or the conduct of the trial.
6. Provide reports to the KNUMC IRB concerning the progress of the research, when requested.
7. Obtain pre-approval of study advertisements from the KNUMC IRB before use.
8. 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 KNUMC IRB conduct review of approved research. You will receive Continuing Review Report forms from the KNUMC IRB. These reports must be returned even though your study may not have started.

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