SNUMCSNUHIRB

Seoul National University College of Medicine/Seoul National University Hospital
Institutional Review Board

Tel :82-2-2072-0694
FAX:82-2-2072-0368
101 Daehak-ro, Jongno-gu, Seoul, 110-744, Korea

Certificate of Approval

THE FOLLOWING WERE APPORVED:

BOARD ACTION DATED: 14 Jan 2011

STUDY NO :

IRB NO: H-1101-008-345

INVESTIGATOR: GYEONG HOON KANG

SPONSOR:

PROTOCOL NO:

TITLE: CpG island methylator phenotype, LINE-1 hypomethylation and Alu hypomethylation in colorectal cancers and their clinicopathologic characteristics

APPROVAL INCLUDES:

1. Protocol
2. Waiver of Informed Consent Form
3. Case Report Form
4. Principal investigator's CV
5. Study Budget

ALL CONDITIONS OF APPROVAL PREVIOUSLY ESTABLISHED BY SNUMC/SNUHIRB FOR THIS RESEARCH PROJECT CONTINUE TO APPLY.

CONTINUING REVIEW REPORT INTERVAL: Annually

IF YOU HAVE ANY QUESTIONS, CONTACT SNUMC/SNUH IRB (Tel: 82-2-2072-0694)

This is to certify that the information contained herein is true and correct as reflected in the records of the SNUMC/SNUH Institutional Review Board. **We certify that SNUMC/SNUH 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.**

Jae Seung Paik

Chairperson

14 Jan 2011

Date

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

DISTRIBUTION OF COPIES:

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