SNUCM/SNUH IRB

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: 16 Feb 2015

STUDY NO :

IRB NO: H-1502-029-647

INVESTIGATOR: GYEONG HOON KANG

SPONSOR:

PROTOCOL NO:

TITLE: Immunohistochemical surrogate marker evaluation for colorectal cancer with CpG island methylator phenotype

APPROVAL INCLUDES:

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

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

CONTINUING REVIEW REPORT INTERVAL: Annually

IF YOU HAVE ANY QUESTIONS, CONTACT SNUCM/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 SNUCM/SNUH IRB. **We certify that SNUCM/SNUH IRB is in full compliance with Good Clinical Practice as defined under the Korean Ministry of Food and Drug Safety (MFDS) regulations and the International Conference on Harmonisation (ICH) guidelines.**

Jaekeung Paik

Chairperson

16 Feb 2015

Date

ALL SNUCM/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 SNUCM/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 SNUCM/SNUH IRB.
4. Obtain pre-approval from the SNUCM/SNUH IRB of any changes in the research activity (except when necessary to protect human subjects; immediately report to the SNUCM/SNUH IRB any such emergency changes for the protection of human subjects).
5. Report to the SNUCM/SNUH IRB the death, hospitalization, or serious illness of any study subject.
6. Promptly report to the SNUCM/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 SNUCM/SNUH IRB concerning the progress of the research, when requested.
8. Obtain pre-approval of study advertisements from the SNUCM/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.

Korean MFDS regulations require that the SNUCM/SNUH IRB conducts review of approved research. You will receive Continuing Review Report forms from the SNUCM/SNUH IRB. These reports must be returned even though your study may not have started.

DISTRIBUTION OF COPIES:

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