CNUHIRB
Chungnam National University Hospital Institutional Review Board
Tel :82-42-280-8715
FAX:82-42-280-8716 282 Munhwa-ro , Jung-Gu, Daejeon, 301-721, Korea

Certificate of Approval

THE FOLLOWING WERE APPROVED:

BOARD ACTION DATED: 25 November 2015
STUDY NO : N/A
IRB NO: CNUH 2015-11-022

INVESTIGATOR: Kim Seok Hyun

SPONSOR: N/A

PROTOCOL NO: N/A

TITLE: Atypical onset of bicalutamied -induced liver injury

APPROVAL INCLUDES:

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

CONTINUING REVIEW REPORT INTERVAL: N/A

DISTRIBUTION OF COPIES:

SPONSOR:

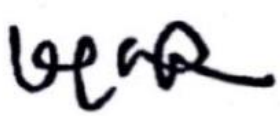
CRO:

OTHER:

INSTITUTION:

IF YOU HAVE ANY QUESTIONS, CONTACT THE CNUH IRB (Tel: 82-42-280-8715)

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



25 November 2015

Chairperson **Date**

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

DISTRIBUTION OF COPIES:

SPONSOR:

CRO:

OTHER:

INSTITUTION:

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