SNUBH IRB

SEOUL NATIONAL UNIVERSITY BUNDANG HOSPITAL
INSTITUTIONAL REVIEW BOARD

TEL: 82-31-787-1377
FAX:82-31-787-4025 82, GUMI-RO 173 BUNDANG-GU, SEONGNAM-SI, GYEONGGI- DO, 463-707, KOREA

Certificate of Approval

The followings were approved:

Board Action Date: 04-May-2013
Study No : -
Approval Date: 04-May-2013

Investigator: Young Kyun Lee

Sponsor: -

Protocol Number: B-1304/200-110

Research Project Title: Total Hip Arthroplasty after Extensive Excision of Tumor in the Femoral Head and Neck

Approval Includes:

1. IRB application sheet
2. Protocol
3. exemption of informed consent
4. PI's Curriculum Vitae
5. Case Report Form

All conditions of approval previously established by SNUBH IRB for this research project continue to apply.

If you have any questions, contact SNUBH IRB at 82-31-787-1377

This is to certify that the information contained herein is true and correct as reflected in the records of the SNUBH Institutional Review Board (SNUBH IRB).

WE CERTIFY THAT SNUBH IRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE KOREA FOOD AND DRUG ADMINISTRATION (KFDA) REGULATIONS AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.

Lee Jaeho

2013. 5.06

Chairperson: Prof. Lee Jae Ho, M.D., Ph.D. Date

SNUBH IRB

All investigators performing SNUBH IRB approved projects must comply with the followings:

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

This is to certify that the information contained herein is true and correct as reflected in the records of the SNUBH Institutional Review Board (SNUBH IRB).

WE CERTIFY THAT SNUBH IRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE KOREA FOOD AND DRUG ADMINISTRATION (KFDA) REGULATIONS AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.