COA No. 756/2017
IRB No. 1095/60

INSTITUTIONAL REVIEW BOARD
Naresuan University
99 Moo 9 Thapho, Naresuan University, Phitsanulok 65000, Thailand, Tel 66 5596 8642.

Certificate of Approval

The Institutional Review Board of the Naresuan University, Phitsanulok, Thailand, has approved the following study which is to be carried out in compliance with the International guidelines for human research protection as Declaration of Helsinki, The Belmont Report, CIOMS Guideline and International Conference on Harmonization in Good Clinical Practice (ICH-GCP)

Study Title : Comparison of Hemoglobin level, cardiac enzyme, and renal function alteration following unilateral vs bilateral Total knee arthroplasty.

Study Center : Naresuan University Hospital.

Principal Investigator : Assist. Prof. Artit Laoruengthana, M.D.
Co- Investigator : Assist. Prof. Piti Rattanaprichavej, M.D.

Review Method : Expedited
Continuing Report : At least once annually or submit the final report if finished early.

Document Reviewed :

1. Submission Form : AF 01-10, version 1.0 dated 18 October 2017
2. Self-Assessment Form : AF 02-10, version 1.0 dated 18 October 2017
3. Conflict of Interest and Funding Form : AF 03-10, version 1.0 dated 18 October 2017
4. Protocol Synopsis for Ethical Review, version 1.0 dated 18 October 2017
5. Full Protocol version 1.0, dated 18 October 2017
6. CV version 1.0, dated 18 October 2017
7. Budget version 1.0, dated 18 October 2017
8. Case Record Form Version 1.0, dated 18 October 2017

Signature

(Somboon Tansuphaswasdikul)
Chairperson, The Institutional Review Board
Naresuan University

Date of Approval : December 25, 2017
Approval Expire Date : December 25, 2018

Approval is granted subject to the following conditions: (see back of this Certificate)

All approved investigators must comply with the following conditions:

1. Strictly conduct the research as required by the protocol.
2. Use only the information sheet, consent form (and recruitment materials, if any), interview outlines and/or questionnaires bearing the Institutional Review Board's seal of approval
3. Report to the Institutional Review Board any serious adverse event or any changes in the research activity, according to the standard operating procedures.
4. Provide reports to the Institutional Review Board concerning the progress of the research upon the specified period of time or when requested.
5. If the study cannot be finished within the expired date of the approval certificate, the investigator is obliged to reapply for approval at least one month before the date of expiration.
6. Expiry of COA, Investigator can not recruit new participants.
7. Complete and submit the final report form to the NU-IRB, as soon as possible after the completeness of research.

* A list of the Institutional Review Board members (names and positions) present at the meeting of Institutional Review Board on the date of approval of this study has been attached (per requested). All approved documents will be forwarded to the principal investigator.