

 Central Research Ethics Committee	คณะกรรมการกลางพิจารณาจริยธรรมการวิจัยในคน Central Research Ethics Committee; CREC	AL 02/ v.2.1
	หนังสือรับรอง Certificate of Approval	เริ่มใช้ 28 ก.ย. 2559

OFFICE: CENTRAL RESEARCH ETHICS COMMITTEE (CREC)
5th Fl Building 2, The National Research Council of Thailand Paholyothin Rd., Bangkok, Bangkok 10900, THAILAND
Tel: 662 579 0117, Fax: 662 579 0117 E- mail: crec_thailand@hotmail.com

Certificate of Approval

CREC NUMBER CREC017/60BRm

CERTIFICATE NUMBER COA-CREC.006/2018

BOARD ACTION DATE 18th /2017 CREC MEETING DATE: 9 October 2017

PANEL Biomedical research

PROTOCOL TITLE Predictors of Major Adverse Cardiovascular Events in Coronary Artery Patients Undergoing Percutaneous Coronary intervention (PCI) in Thailand: Thai PCI Registry

PROTOCOL NUMBER N600001396

PRINCIPLE INVESTIGATORS Nakarin Sansanayudh, MD

SPONSOR Health System Research Institute (HSRI)

DATE OF APPROVAL	3 April 2018
DATE OF EXPIRATION	2 April 2019
CONTINUING REVIEW	12 months

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Approval documents	Reference (e.g. version and date)
Research protocol	1. Proposal version January 22 nd 2018 (Appendix ก.-ญ)
Informed consent documents	1. Subject Information and Informed Consent <ol style="list-style-type: none"> 1.1 Subject Information and Informed Consent for Phramongkutkloao Hospital Version January 22nd 2018 1.2 Subject Information and Informed Consent for Udonthani hospital Version January 22nd 2018 1.3 Subject Information and Informed Consent for Bangkok Hospital, Chiangmai Version January 22nd 2018 1.4 Subject Information and Informed Consent for HRH Princess Maha Chakri Sirindhorn Medical Center, Srinakharinwirot University Version January 22nd 2018 1.5 Subject Information and Informed Consent for Central Chest Institute of Thailand Version January 22nd 2018 1.6 Subject Information and Informed Consent for Naresuan University Hospital Version January 22nd 2018 1.7 Subject Information and Informed Consent for Siriraj Hospital Version January 22nd 2018 1.8 Subject Information and Informed Consent for King Chulalongkorn Memorial Hospital Version January 22nd 2018 1.9 Subject Information and Informed Consent for Khon Kaen hospital Version January 22nd 2018 1.10 Subject Information and Informed Consent for Sapphasitthiprasong Hospital Version January 22nd 2018 1.11 Subject Information and Informed Consent for Queen Sirikit Heart Center Version January 22nd 2018 1.12 Subject Information and Informed Consent for Thammasat Chalermprakiat Hospital Version January 22nd 2018 1.13 Subject Information and Informed Consent for Maharaj Nakorn Chiang Mai Hospital Version January 22nd 2018 1.14 Subject Information and Informed Consent for Rajavithi Hospital Version January 22nd 2018

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Approval documents	Reference (e.g. version and date)
	1.15 Subject Information and Informed Consent for Songklanagarind Hospital Version January 22 nd 2018 1.16 Subject Information and Informed Consent for Chonburi Hospital Version January 22 nd 2018 1.17 Subject Information and Informed Consent for Hatyai Hospital Version January 22 nd 2018 1.18 Subject Information and Informed Consent for Nakornpathom Hospital Version January 22 nd 2018
Case Report Form	1. case record form version January 22 nd 2018
Other documents	1. Phone Script version January 22 nd 2018 2. Daily record version January 22 nd 2018 3. Principle Investigator's CV and Sub-Investigator's CV / GCP training certificate / Conflict of Interest <ul style="list-style-type: none"> - Nakarin Sansanayudh, MD - Anuchit Wongphen, M.D. - Appichard Sukonthasarn, M.D. - Wirash Kehasukcharorn, M.D. - Worawut Roongsangmanoon, M.D. - Pongpun Jittham , M.D. - Chunhakasem Chotinaiwattarakul - Wacin Buddhari, MD, FACC - Sudhithep Duangsorn, M.D. - Praprut Thanakitcharu - Songsak Kiatchoosakun, M.D. - Dilok Piyayotai, M.D. - Srun Kuanprasert, M.D. - Napa Siriwiwattanakul, M.D. - Noppadol Chamnarnphol, M.D.

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Approval documents	Reference (e.g. version and date)
	<ul style="list-style-type: none"> - Pornchai Ngamjanyaporn, M.D. - HARIRAM TIWARI, M.D. - KamonratThongplung, MD

CREC approval includes:

Principal investigator (s)	
	<ol style="list-style-type: none"> 1. Phramongkutklo Hospital - Nakarin Sansanayudh, MD 2. Udonthani hospital - Anuchit Wongphen, M.D. 3. Bangkok Hospital, Chiangmai - Appichard Sukonthasarn, M.D. 4. Central Chest Institute of Thailand - Wirash Kehasukcharorn, M.D. 5. HRH Princess Maha Chakri Sirindhorn Medical Center, Srinakharinwirot University - Worawut Roongsangmanoon, M.D. 6. Naresuan University Hospital - Pongpun Jittham , M.D. 7. Siriraj Hospital - Chunhakasem Chotinaiwattarakul 8. King Chulalongkorn Memorial Hospital - Wacin Buddhari, MD, FACC 9. Khon Kaen Hospital - Sudhithep Duangsorn, M.D. 10. Sappasitthiprasong Hospital - Praprut Thanakitcharu 11. Queen Sirikit Heart Center - Songsak Kiatchoosakun, M.D. 12. Thammasat Chalermprakiat Hospital - Dilok Piyayotai, M.D. 13. Maharaj Nakorn Chiang Mai Hospital

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	<ul style="list-style-type: none"> - Srun Kuanprasert, M.D. 14. Rajavithi Hospital - Napa Siriwiwattnakul, M.D. 15. Songklanagarind Hospital - Noppadol Chamnamphol, M.D. 16. Chonburi Hospital - Pornchai Ngamjanyaporn, M.D. 17. Hatyai Hospital - HARIRAM TIWARI, M.D. 18. Nakornpathom Hospital - KamonratThongplung, MD
Study site	<ol style="list-style-type: none"> 1. Phramongkutklao Hospital 2. Udonthani hospital 3. Bangkok Hospital, Chiangmai 4. Central Chest Institute of Thailand 5. HRH Princess Maha Chakri Sirindhorn Medical Center, Srinakharinwirot University 6. Naresuan University Hospital 7. Siriraj Hospital 8. King Chulalongkorn Memorial Hospital 9. Khon Kaen hospital 10. Sapphasitthiprasong Hospital 11. Queen Sirikit Heart Center 12. Thammasat Chalermprakiat Hospital 13. Maharaj Nakorn Chiang Mai Hospital 14. Rajavithi Hospital 15. Songklanagarind Hospital 16. Chonburi Hospital 17. Hatyai Hospital 18. Nakornpathom Hospital

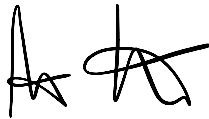
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The Central Research Ethics Committees (CREC) is in full compliance with international such as Declaration of Helsinki, The Belmont Report, CIOMS Guidelines and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use - Good Clinical Practice (ICH - GCP)



(MG. Assoc. Prof. Aphornpirom Ketupanya, M.D.)
Chairman of Ethics Committee

Date: 3 April 2018

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All CREC approved investigators must comply with the followings:

1. Conduct the research in accordance with the approved protocol and the principles of research ethics as set forth in the Belmont Report.
2. Unless consent has been waived, conduct the informed consent process without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate.
 - Use only the most current consent form bearing the CREC “**APPROVED**” stamp
 - Use only recruitment documents / materials approved by CREC
3. CREC approval is required before implementing any changes in the research protocol, information sheet and research-related documents unless those changes are required urgently for the safety of the research subjects.
4. Promptly report to CREC all unanticipated problems (adverse events, protocol deviations and violations and other problems) that meet all of the following criteria:
 - Unexpected (in terms of nature, severity or frequency);
 - Related or possibly related to participation in the research; and
 - Suggests that the research places subjects or others at a greater risk of harm than was previously known or recognized.
5. Any new information that may affect the risk and benefit of the research subjects must be promptly reported to CREC.
6. Summit to CREC a progress report (with currently used informed consent documents) for continuing review and for renewing the approval at least 30 days before expiration date.
 - For failure to provide a progress report for continuing review to CREC, all research activities involving research subjects must stop. Enrollment of new subjects cannot occur after the expiration of CREC approval.

*Please go to www.crecthai.org to download CREC forms for reporting.
Any questions, please contact the CREC staffs at 662 579 0117*