OFFICE: CENTRAL RESEARCH ETHICS COMMITTEE (CREC)

5th Fl Building 2, The National Research Council of Thailand Paholyothin Rd., Bangkhen, Bangkok 10900, THAILAND

Tel: 662 579 0117

Certificate of Approval

CREC NUMBER	CREC010/62SCm
CERTIFICATE NUMBER	COA-CREC020/2020
BOARD ACTION DATE	Expedited Review
PANEL	Social Research
PROTOCOL TITLE	"Reducing unnecessary caesarean section: a genetic formative phase protocol for implementation preparation of QUALI-DEC project"
PRINCIPAL INVESTIGATOR	Pisake Lumbiganon
SPONSOR	World Health Organization

DATE OF APPROVAL	**:**	10 March 2020
DATE OF EXPIRATION	**:**	9 March 2021
CONTINUING REVIEW	:	12 Months (Expire Date: 9 March 2021)

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Approval documents	Reference (e.g. version and date)
Research protocol	1. Research Protocol English version Version 5 Date 20 February 2020 2. Annex 1 : How to use this guide 3. Annex 2 : Qualitative module 0-12 4. Annex 3 : In-depth interview : pregnant woman 5. Annex 4 : In-depth interview : postpartum woman 6. Annex 5 : In-depth interview : partner/potential companion (before birth) 7. Annex 6 : In-depth interview : partner/potential companion (postpartum) 8. Annex 7 : In-depth interview: providers 9. Annex 8 : In-depth interview: administrators 10. Annex 9 : Research gaps for WHO recommendations on non-clinical interventions to reduce unnecessary caesarean sections (reproduced with permission) 11. Annex 10 : Document review 12. Annex 11 : Readiness assessment
Informed consent documents	1. Annex 12 : Informed consent form for in-depth interviews with women (Institutional letter head) 2. Annex 13 : Informed consent form for in-depth interviews with potential companions (Institutional letter head) 3. Annex 14 : Informed consent form for in-depth interviews with healthcare providers and administrators (Institutional letter head)

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Approval documents	Reference (e.g. version and date)
Others Document	1. Principle Investigator's CV and Sub-Investigator's CV / GCP training certificate / Conflict of Interest 1.1 Faculty of Medicine Khon Kaen University 1.1.1 Pisake Lumbiganon, M.D. 1.1.2 Ratana Komwilaisak, M.D. 1.2 Faculty of Nursing Khon Kaen University 1.2.1 Somporn Rungreangkulkij 1.2.2 Nilubon Rujiraprasert 1.3 Faculty of Nursing Mahidol University 1.3.1 Ameporn Ratinthorn 1.3.2 Sasitara Nuampa 1.4 Faculty of Nursing Thammasat University 1.4.1 Natthapat Buaboon 1.5 Nopparat Rajathanee Hospital 1.5.1 Krissada Tomyabatra, M.D. 1.6 Rajavithi Hospital 1.6.1 Somboon Sornsukolrat, M.D. 1.7 Udon Thani Hospital 1.7.1 metha songthamwat, M.D. 1.8 Chophya abhaibhubejhr Hospital 1.8.1 Olarik Musigavong, M.D. 1.9 Chiangrai Regional Hospital 1.9.1 Kannikar Saisawat, M.D. 1.10 Siriraj Hospital 1.10.1 Dittakarn Boriboonhirunsarn, M.D. 1.11 Khon Kaen Hospital 1.11.1 Ussanee Sangkomkamhang, M.D.

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Approval documents	Reference (e.g. version and date)
	1.12 Srinagarind Hospital 1.12.1 Ratana Komwilaisak, M.D.

CREC approval includes:

Principal investigator (s)	1. Faculty of Medicine Khon Kaen University 1.1 Pisake Lumbiganon, M.D. 2. Faculty of Nursing Khon Kaen University 2.1 Somporn Rungreangkulkij 2.2 Nilubon Rujiraprasert 3. Faculty of Nursing Mahidol University 3.1 Ameporn Ratinthorn 3.2 Sasitara Nuampa 4. Faculty of Nursing Thammasat University 4.1 Natthapat Buaboon 5. Nopparat Rajathanee Hospital 5.1 Krissada Tomyabatra, M.D. 6 .Rajavithi Hospital 6.1 Somboon Sornsukolrat, M.D. 7. Udon Thani Hospital 7.1 metha songthamwat, M.D. 8 Chophya abhaibhubejhr Hospital 8.1 Olarik Musigavong, M.D. 9. Chiangrai Regional Hospital 9.1 Kannikar Saisawat, M.D. 10. Siriraj Hospital 10.1 Dittakarn Boriboonhirunsarn, M.D.

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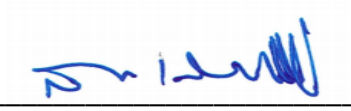
	11. Khon Kaen Hospital 11.1 Ussanee Sangkomkamhang, M.D. 12. Srinagarind Hospital 12.1 Ratana Komwilaisak, M.D.
Study site (s)	1. Nopparat Rajathanee Hospital 2. Rajavithi Hospital 3. Udon Thani Hospital 4. Chophya abhaibhubejhr Hospital 5. Chiangrai Regional Hospital 6. Siriraj Hospital 7. Khon Kaen Hospital 8. Srinagarind Hospital

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 Hermonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use - Good Clinical Practice (ICH - GCP)



(Prof. Emeritus Santhat Sermsri)

Chairman of Ethics Committee

Date: 10 March 2020

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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.

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Any questions, please contact the CREC staff at 662 579 0117