



COA No. 984/2018

IRB No. 243/61

INSTITUTIONAL REVIEW BOARD

Faculty of Medicine, Chulalongkorn University

1873 Rama 4 Road, Patumwan, Bangkok 10330, Thailand, Tel 662-256-4493

Certificate of Approval

The Institutional Review Board of the Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand, has approved the following study 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 : Detection of gastroesophageal reflux disease in children with tracheoesophageal fistula or esophageal atresia using combined video, multichannel intraluminal impedance and pH study after corrective surgery

Study Code : -

Principal Investigator : Settachote Maholarnkij, M.D.

Affiliation of PI : Department of Pediatrics,
Faculty of Medicine, Chulalongkorn University.

Review Method : Full board

Continuing Report : Every 6 months.

Document Reviewed :

1. Research Proposal Version 3 Date 27 September 2018
2. Protocol Synopsis Version 2 Date 26 August 2018
3. Information sheet for research participant aged 7-12 years Version 2 Date 26 August 2018
4. Informed consent for participating volunteers aged 7-12 years Version 2 Date 26 August 2018

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



5. Information sheet for research participant aged 12-18 years Version 1 Date 26 August 2018
6. Informed consent for participating volunteers aged 12-18 years Version 1 Date 26 August 2018
7. Information sheet for research participant Version 2 Date 26 August 2018
8. Informed Consent Form for legal representative Version 2 Date 26 August 2018
9. Case Record Form Version 1.0, 16 April 2018
10. Curriculum Vitae and GCP Training
 - Settachote Maholarnkij, M.D.
 - Chomchanat Tubjaroen, M.D.
 - Palittiya Sintusek, M.D.

Signature 

(Emeritus Professor Tada Sueblinvong MD)

Chairperson

The Institutional Review Board

Signature 

(Assistant Professor Prapapan Rajatapiti MD, PhD)

Member and Secretary

The Institutional Review Board

Date of Approval : October 9, 2018

Approval Expire Date : October 8, 2019

Approval granted is 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 ; and return one copy of such documents of the first subject recruited to the Institutional Review Board (IRB) for the record;
3. Report to the Institutional Review Board any serious adverse event or any changes in the research activity within five working days;
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 expire date of the approval certificate, the investigator is obliged to reapply for approval at least one month before the date of expiration.
6. If the research project is completed, the researcher must be form the Faculty of Medicine, Chulalongkorn University.

* 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. All approved documents will be forwarded to the principal investigator.