



COA No. 798/2021

IRB No. 322/64

INSTITUTIONAL REVIEW BOARD

Faculty of Medicine, Chulalongkorn University

1873 Rama 4 Road, Pathumwan, 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 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 : Outcome of Pediatric Liver Transplantation at King Chulalongkorn Memorial Hospital.

Study Code : -

Principal Investigator : Sittichoke Prachuapthunyachart, M.D.

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

Review Method : Expedited

Continuing Report : At least once annually or submit the final report if finished.

Document Reviewed :

1. Research Proposal Version 2.0 Date 12/5/2021
2. Protocol Synopsis Version 2.0 Date 12/5/2021
3. Case record form VERSION 1.0 DATE 24/11/2020
4. Curriculum Vitae and GCP Training
 - Sittichoke Prachuapthunyachart, M.D.
 - Assoc.Prof. Voranush Chongsrisawat, M.D.

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



- Piyaporn Wanawongsawad
- Assist.Prof. Palittiya Sintusek, M.D.
- Chomchanat Tubjaroen, M.D.

Signature Tada Sueblinwong
(Emeritus Professor Tada Sueblinwong MD)
Chairperson
The Institutional Review Board

Signature Thanyanya Thongtan
(Assistant Professor Thananya Thongtan, PhD)
Member and Secretary
The Institutional Review Board

Date of Approval : May 28, 2021
Approval Expire Date : May 27, 2022

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 and expertises) 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.