

Human Study Approval

Date: 2018.05.23

Title: Human microbiota in the gastrointestinal disease: Clinical relationships

Protocol No/ IRB No: -- / A-ER-107-097

Period of Project: From 2018.05.23 to 2020.12.31

Period of Approval: From 2018.05.23 to 2019.05.21

Content/Version:

1. Protocol: Version 2, Date: 2018.05.11
2. Informed Consent Form: Version 2, Date: 2018.05.11

Institute: National Cheng Kung University Hospital

Investigator: Dr. Tien-Ching Lin (Department of Internal Medicine)

Co-Investigators: Assistant Professor Jhen-Wei Ruan

Approved Number of Participants: NCKUH: 100 persons. If the number of participants enrolled exceeds the approved number, please submit an application for amendment and approval.

The Institutional Review Board of National Cheng Kung University Hospital (NCKUH) is organized and operated according to the laws and regulations of ICH-GCP and of Central Competent Authorities.

This project is reviewed and approved by NCKUH IRB in **2018.05.23**. The period of approval is granted until **2019.05.22**.

Regarding multi-period project, please submit the Interim Report before **2019.04.22**. If the approval of the interim report is not granted on its expiry date, except safeguarding the health of the participants, the research is suspended.

Regarding completed project, the Final Report shall be submitted within three months of its approved expiry date. Except for the health of the participants, all the procedures of the project shall be terminated on its approved stated deadline.

If PI does not submit the Interim/Final Report on time, he/she will be recorded in the overdue list and received the suspension/ termination notice from NCKUH IRB. The overdue list will be reported to the IRB. After the resolution of the board meeting, NCKUH IRB will suspend all the new projects applied by PI until the Interim/Final Report is submitted.

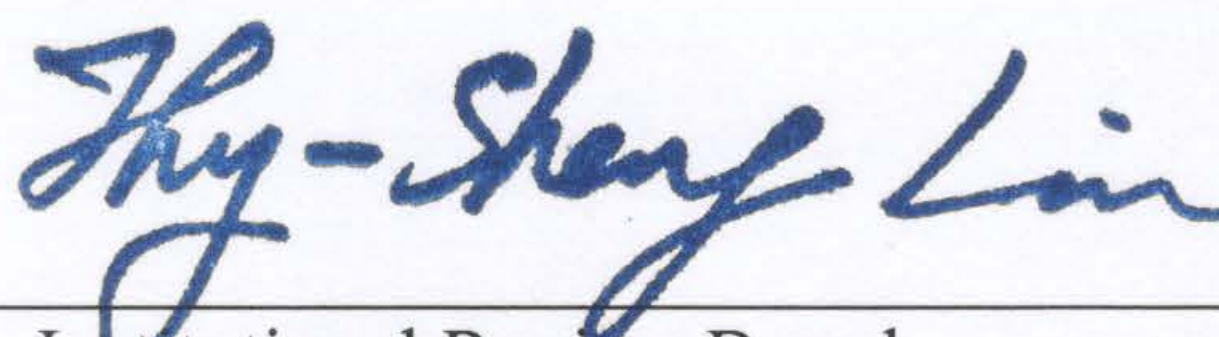
Please submit the Interim/Final Report in written form and send to NCKUH IRB office. The latest application forms can be downloaded in its website ([http : // www.ncku.edu.tw/ ~nckuhirb](http://www.ncku.edu.tw/~nckuhirb))

Any changes or amendments to the project (including the project period), please submit an amendment application to NCKUH IRB within its approved period. Any changes or amendments in any other way will not be accepted. Before the approval of the amendment application, the project is carried out according to its previously approved plan.

For some reasons projects granted approval by NCKUH IRB couldn't be implemented, PI shall apply for suspension/termination.

During or after the project is completed, please report any unfavorable occurrence in a human study participant according to GCP.

Yours sincerely,
Thy-Sheng Lin M.D.
Chairman



Institutional Review Board
National Cheng Kung University Hospital