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計畫修正案通過證明書

計畫名稱：一項前瞻性、隨機分派、評估者盲性、有效藥物對照、平行試驗，比較使用快可淨(Quiklean®) 與刻見清與樂可舒(Klean-Prep 加上 Dulcolax®) 於大腸鏡檢查前的腸道準備之療效及安全性

計畫編號/本會編號：UIC-SPT-2017 / CMUH107-REC2-151(AR-1)

計畫主持人：大腸直腸外科陳自諒主治醫師

試驗機構：中國醫藥大學附設醫院

原計畫通過日期：2018 年 12 月 28 日至 2019 年 12 月 27 日

修正案通過日期：2019 年 04 月 16 日至 2019 年 12 月 27 日

延長試驗期限：From Aug. 01, 2018 to Mar. 31, 2020

大腸鏡檢前飲食及刻見清服用說明：Version 1.1, Date: Mar. 26, 2019

大腸鏡檢前飲食及快可淨服用說明：Version 1.1, Date: Mar. 26, 2019

上述計畫之修正案已於 2019 年 04 月 16 日經中國醫藥大學暨附設醫院研究倫理委員會第二審查委員會簡易審查通過。本委員會的運作符合優良臨床試驗準則及國內相關法令。請在持續審查必須進行前二個月向本會檢送完整之期中報告。

此計畫任何部分若經更改，必須在執行前重新提交本會審查及核准。此外，計畫主持人必須依時通報嚴重不良事件及涉及受試者或其他人風險的非預期問題。

中國醫藥大學暨附設醫院 研究倫理委員會 台中市北區育德路2號

主任委員 傅茂旺

中 華 民 國 一 〇 八 年 四 月 二 十 三 日

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Research Ethics Committee
China Medical University & Hospital, Taichung, Taiwan

Tel: 886-4-22052121 ext: 1925 Fax: 886-4-2207-1478

Clinical Trial/Human Research Approval

Amendment Review

Date : Apr. 23, 2019

Protocol Title : A prospective, randomized, evaluator blind, active-controlled, parallel study of the efficacy and safety of Quiklean® and Klean-Prep with Dulcolax® for the bowel preparation prior to colonoscopy

Protocol No. / CMUH REC No. : UIC-SPT-2017 / CMUH107-REC2-151(AR-1)

Name of Principal Investigator : Tzu-Liang Chen (Attending Physician, Colorectal Surgery)

Name of Institution : China Medical University Hospital

Valid Date of Original Research Project : From Dec. 28, 2018 to Dec. 27, 2019

Valid Date of Amended Research Project : From Apr. 16, 2019 to Dec. 27, 2019

Extend Execution Date : From Aug. 01, 2018 to Mar. 31, 2020

Colonscopy Perpartion Instructions(Klean-Prep) : Version 1.1, Date: Mar. 26, 2019

Colonscopy Perpartion Instructions(Quiklean®) : Version 1.1, Date: Mar. 26, 2019

This is to certify that the above referenced amended research project has been expedited approved by the Research Ethics Committee (REC) II of the China Medical University and Hospital on Apr. 16, 2019. The REC is organized under, and operates in accordance with, the Good Clinical Practices guidelines and the governmental laws and regulations. Please submit a completed progress report at least two months before the time at which continuing review must occur.

All the amendments to the research project should be re-submitted and approved by the REC BEFORE implementation. Also, the principal investigator is required to report all serious adverse events and unanticipated problems involving risks to the subjects or others on time.

Martin M-T Fuh MD, DMSci.
Chairman, Research Ethics Committee II
China Medical University & Hospital

CHINA MEDICAL UNIVERSITY & HOSPITAL
The Research Ethics Committee
No. 2 Yude Road, Taichung, Taiwan, R.O.C.