

亞東紀念醫院人體試驗審議委員會

Research Ethics Review Committee

Far Eastern Memorial Hospital

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臨床試驗許可書

西元二〇一七年三月二十一日

案件編號：106023-E

計劃名稱：小腸內視鏡診斷小腸疾病之描述性研究

計劃主持人：鍾承軒

計劃書版本：Version:2, Date:20170314, FEMH-106023-E

受試者說明及同意書版本：免除受試者說明及同意書

中文摘要：Version:1, Date:20161220, FEMH-106023-E

英文摘要：Version:1, Date:20161220, FEMH-106023-E

個案報告表：EVersion:2 Date:20170314, FEMH-106023-E

試驗期間：2017年3月21日至2018年3月30日

試驗人數：250

追蹤審查頻率：一年

上述計劃已於本院人體試驗審議委員會審查，同意臨床試驗進行。有效期限自二〇一七年三月二十一日至二〇一八年三月二十一日。(依照 ICH-GCP 規定，臨床試驗每屆滿一年，人體試驗委員會必須重新審查是否繼續進行。請於有效期限到期二個月前繳交持續審查報告以利本會進行審查)

主任委員 張淑雯

張淑雯

**Permission of Clinical Trial
Far Eastern Memorial Hospital**



Date: March 21, 2017

FEMH No.: 106023-E

Protocol Title: small intestinal diseases diagnosed by enteroscopy : a descriptive study

Principal investigator: Chen-Shuan Chung

Protocol Version: Version:2, Date:20170314, FEMH-106023-E

Informed Consent Form: Waiver

Chinese Synopsis: Version:1, Date:20161220, FEMH-106023-E

English Synopsis: Version:1, Date:20161220, FEMH-106023-E

eCRF: EVersion:2 Date:20170314, FEMH-106023-E

Trial period: March 21, 2017 to March 30, 2018

Number of subjects : 250

Continuing review frequency : One year

Above study has been approved by the Research Ethics Review Committee of the Far Eastern Memorial Hospital and valid since March 21, 2017 to March 21, 2018. The Committee is organized and operates according to Good Clinical Practice and the applicable laws and regulations. Apply for a continuing review not less than two months prior to approval expiration date.

Shu-Wen Chang M.D., Professor of Ophthalmology

Chairman

Research Ethics Review Committee

張淑雯