

奇美醫療財團法人奇美醫院人體試驗委員會
臨床研究核准函（新案）



計畫編號：無 / IRB編號：10702-007

試驗機構：奇美醫療財團法人奇美醫院

計畫主持人：郭禹廷/ 協同主持人：周怡甄

計畫名稱：如何運用卜邁維斯(Primovist, Gadoteric acid) 加強顯影的MRI 預測單一肝癌的
病理期別:回溯性研究

計畫書版本：第1版, 2018年02月21日；中文摘要：第2版, 2018年03月07日

受試者同意書版本：免除知情同意程序

上述計畫業經本院人體試驗委員會於2018年03月14日審查通過，核准執行期限為一年(自2018年03月15日至2019年03月14日)，應接受本會之監督，主持人於研究期間所獲得受試者的資料應負保密責任。如試驗無法於核准期限內完成，請於屆期前2個月繳交期中報告並申請展延試驗期限，經本會審查核准後方可繼續進行。

Clinical Research Approval Letter (New Applications)

Protocol No.: None / IRB Serial No.: 10702-007

Institute: Chi Mei Medical Center

Principal Investigator: Yu-Ting Kuo / Co- Investigator(s): I- Chen Chou

Protocol Title: Can gadoteric acid-enhanced MRI predict that a solitary HCC (cT1) is pT1 or pT2 ?

Protocol Version and Date: Version 1, 2018/02/21 ; Chinese Synopsis: Version 2, 2018/03/07

Subject Informed Form: Waiver from the inform consent process

The above study was approved by the Institutional Review Board of the Chi Mei Medical Center on 14 Mar 2018 and will be monitored by the IRB. The duration of this approval is one year (from 15 Mar 2018 until 14 Mar 2019). Investigators are responsible for keeping the subject information confidential. The principal investigator is required to submit an Annual Report 2 months before the expiry date for continuing review approval in order for the research to proceed.

人體試驗委員會

主任委員：邢中熹



2018 年 03 月 15 日

Yours sincerely,

Hsing, Chung-Hsi M.D.

Chairman

Institutional Review Board,

Chi Mei Medical Center, Tainan, Taiwan

本會組織與執行皆符合 ICH-GCP

The Institutional Review Board performs its functions according to written operating procedures and complies with GCP and with the applicable regulatory requirements.