



臺中榮民總醫院第一/二人體研究倫理審查委員會

Institutional Review Board I&II of Taichung Veterans General Hospital

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人體研究/試驗計畫許可書

開立日期：西元 2022 年 10 月 07 日

計畫名稱：利用腹部電腦斷層影像及多平面重組影像後處理技術評估肝臟圓韌帶、膽囊及門脈變異間之相互關係

IRB 編號：CE22408B

計畫主持人：放射線部林炫吟醫師

研究/試驗執行機構：臺中榮民總醫院

計畫書版本及日期：Version 1.0, 2022/9/16

通過會期：第二人體研究倫理審查委員會第 111-B-10 次會議

有效期間：自西元 2022 年 10 月 07 日至 2023 年 10 月 06 日止

(此案追蹤審查頻率為一年一次，請主持人主動繳交追蹤審查報告。)

- * 依照赫爾辛基宣言及 ICH-GCP 規定，臨床試驗每屆滿一年，人體研究倫理審查委員會必須定期重新審查臨床試驗後方可繼續進行。請於有效期限到期二個月前繳交追蹤審查報告以利本會進行審查。
- * 受試者於試驗期間發生嚴重不良事件及疑似未預期之嚴重藥物不良反應，主持人應依衛生福利部法規於期限內通報主管機構及審查之人體研究倫理審查委員會。
- * 計畫展延應於許可書期限截止前二個月提出申請。
- * 結案報告應於許可書期限截止後三個月內繳交。
- * 本會有暫停/終止本研究計畫及撤銷本執行許可書之權責。



臺中榮民總醫院

Certificate of Approval

Date of Approval: 07 Oct, 2022

Protocol Title : Using abdominal CT studies and the multiplanar reconstruction imaging processing method to evaluate the relationship among the variations of ligamentum teres hepatis, gallbladders and portal veins

TCVGH-IRB No. : CE22408B

Principal Investigator : Hsuan-Yin Lin

Institute : Taichung Veterans General Hospital

Protocol Version & Date : Version 1.0, 2022/9/16

Board Meeting : Institutional Review Board (II) 111-B-10 Board Meeting

Approval Period : From 07 October 2022 to 06 October 2023

Frequency of Continuing Review : 1 year

- * In accordance with Declaration of Helsinki and ICH-GCP guidelines, PI is responsible for submitting a progress report to IRB two months prior to the expiry date for an annual review.
- * Serious adverse events or SUSAR involving risk to participants must be reported to Ministry of Health and Welfare (MOHW) and IRB according to current regulation.
- * Application for protocol extension should be submitted to IRB two months before the expiry date of the Certificate of Approval.
- * Closing report should be submitted to IRB within three months after the expiry date of the Certificate of Approval.
- * The IRB has authorization to suspend/terminate the protocol and to withdraw the Certificate of Approval.

Wen-Cheng Chao, MD, PhD
Chair, Institutional Review Board (II), TCVGH