



台中榮民總醫院人體試驗委員會

The Institutional Review Board of Taichung Veterans General Hospital

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人體試驗研究計畫許可書

開立日期：西元 2008 年 01 月 21 日

計畫名稱：葉酸血漿濃度、葉酸代謝基因多型性、及微衛星體不穩定性作為胃癌之生物標記的可行性評估

試驗編號/本會編號：C07199

計畫主持人：胃腸科 吳俊穎醫師

協同主持人：一般外科 吳誠中科主任

計畫書版本/日期：Version 1, 31 December 2007

受試者同意書版本/日期：Version 2, 21 January 2008, and GICF: Version 2, 21 January 2008.

通過會期/日期：第 081 次會議 / 西元 2007 年 12 月 31 日

有效期間：自西元 2007 年 12 月 31 日至 2008 年 12 月 30 日止

- * 依照 ICH-GCP 規定，臨床試驗每屆滿一年，人體試驗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期中報告以利本會進行審查。
- * 受試者於試驗期間發生藥物不良反應與藥品臨床試驗之嚴重不良事件，主持人應於獲知起 7 日內通報主管機構及審查之人體試驗委員會。
- * 未於許可書到期前提出效期展延申請之計畫，應於本許可書到期後三個月內繳交結案報告。
- * 將於大會追認或核備之許可書，本會保留撤銷之權利。

主任委員 許惠恒

許惠恒

Clinical Trial Authorization

Protocol Title : The feasibility of using plasma folate, folate-metabolizing gene polymorphisms and microsatellite instability as biomarkers in gastric cancer.

Protocol No/IRB TCVGH No : C07199

Principal Investigator : Chun-Ying Wu

Subinvestigator : Cheng-Chung Wu

Protocol Version/Date : Version 1, 31 December 2007

Informed Consent Form Version/Date : Version 2, 21 January 2008, and GICF: Version 2, 21 January 2008

Board Meeting/Approval Date : 81st Board Meeting / 31 December 2007

Approval Effective Period : From 31 December 2007 to 30 December 2008

- * In accordance with the ICH-GCP guidelines, PI is responsible to submit a progress report to IRB two months prior to the expiration date for an annual review.
- * Adverse events and unanticipated problems involving risk to participants or others must be reported within 7 days to DOI and IRB.
- * Prior approval is required for extension of a project period. PI failing to submit requests for extension at least two months before the project period is scheduled to expire should submit a completion report within three months after the expiration date of the current approval.
- * This document subject to approval or disapproval in the following board meeting.

Wayne Huey-Herng Sheu, M.D.

Chairman, Institutional Review Board, TCVGH

Wayne Sheu

本會組織與執行皆符合國際醫藥法規協會之藥品優良臨床試驗規範

The committee is organized and operates according to ICH-GCP and the applicable laws and regulations