

同意臨床試驗證明書

計畫名稱: 探討孕酮受體膜蛋白單元 1(PGRMC1)在肝細胞癌之表現及臨床之重要性

計畫編號/本會編號: NCKUH-10103001 / BR-100-117

內容/版本:

- 試驗執行期間自 2012 年 1 月至 2014 年 12 月
- 1. 計畫書: 版本: 1, 日期: 2011-10-11
- 2. 基因相關研究受試者同意書: 版本: V2, 日期: 2011 年 11 月 25 日
- 3. 使用去連結剩餘檢體: 免除受試者同意

計畫主持人: 蔡弘文 醫師 (病理部)

協同研究員: 周楠華 醫師

此計畫已於民國 100 年 12 月 27 日經本院人體試驗委員會第 A001 次大會審核通過, 本會組織與執行皆遵照 ICH-GCP 規範, 有效日期至民國 103 年 12 月 31 日, 特此證明。依照 GCP 規定, 計畫每屆滿一年, 主持人應主動向本會提出期中/結案報告, 計畫主持人若未依規定於應繳交期限到期後三個月內繳交報告者, 本會將保留審核權。若有嚴重不良反應(SAE)應需按規定通報; 該計畫任何部份若欲更改, 亦需向本會提出申請。

中 華 民 國 101 年 1 月 2 日

Approval of Clinical Trial

Date: Jan. 2, 2012

Title: The significance of progesterone receptor membrane component 1 (PGRMC1) in hepatocellular carcinoma

Protocol No/IRB No: NCKUH-10103001 / BR-100-117

Version:

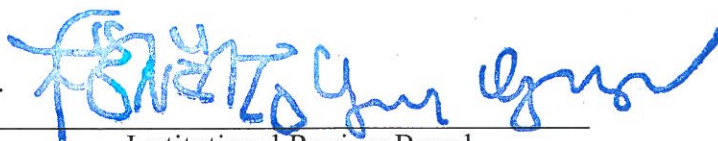
- Study period: From Jan. 2012 to Dec. 2014
- 1. Protocol: Version: 1, Date: 2011-10-11
- 2. Gene ICF: Version: 2, Date: 2011-11-25
- 3. Decoding specimen: Waive Informed Consent

Investigator: Dr. Hung-Wen Tsai

Co-Researcher: Nan-Haw Chow

This is a certification to show that the protocol has been approved by Institutional Review Board (IRB) on Dec. 27, 2011 and valid till Dec. 31, 2012. The Institutional Review Board of National Cheng Kung University Hospital (NCKUH) is organized and operates according to the laws and regulations of ICH-GCP. Based on GCP, the principal investigator should submit interim/final reports to the IRB at the end of each year. For those who are late 3 months in submitting the report, the IRB will retain the rights for examination. If any Serious Adverse Event (SAE) occurs, the IRB should be notified as required by regulations. If any part of the protocol needs to be altered, please also submit the application to IRB as required.

Your sincerely,
Chyun-Yu Yang M.D.
Chairman



Institutional Review Board
National Cheng Kung University Hospital