

奇美醫療財團法人奇美醫院人體試驗委員會  
臨床試驗/研究核准函(新案)



計畫編號：無 / IRB編號: 10810-002

試驗機構：奇美醫療財團法人奇美醫院

計畫主持人：張穎真 / 協同主持人：邱聖富

計畫名稱：台灣口腔癌癌前病變的惡性轉化：以病例配對控制干擾因子研析原住民族與非原住民族差異之回溯型衛生福利部衛生福利資料科學中心資料庫研究

計畫書：Version 2.0, 2019/09/23

受試者同意書：免除知情同意程序

上述計畫業經本院人體試驗委員會於2019年10月09日審查通過，核准執行期限為一年(自2019年10月09日至2020年10月08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。

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**Clinical Trial/Research Approval Letter (New Application)**

Protocol No.: None / IRB Serial No.: 10810-002

Institute: Chi Mei Medical Center

Principal Investigator: Ying-Jen Chang / Co- Investigator(s): Sheng-Fu Chiu

Protocol Title: Epidemiological profile of malignant transformation rate of oral potentially malignant disorders in Taiwanese Indigenous Peoples: a retrospective matched cohort study.

Protocol Version and Date: Version 2.0, 2019/09/23

Informed Consent Form: Waiver from the inform consent process

The study was approved by the Institutional Review Board of the Chi Mei Medical Center on 09 Oct 2019 and will be monitored by the IRB. The duration of this approval is one year (from 10 Oct 2019 until 09 Oct 2020). 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



2019年10月09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.