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國防醫學院三軍總醫院 人體試驗審議會

11490 台北市內湖區成功路二段 325 號醫療大樓五樓 5113 室 No.325,Sec.2, Cheng-Kung Rd. Neihu 11490, Taipei, Taiwan, R.O.C

人體試驗計畫同意函

本審議會核准編號:098-05-292

計畫名稱:國人大腸直腸癌 DNA 甲基化生物標記的確認及應用

執行機構:國防醫學院 計畫主持人:周雨青教授

共同主持人:吳昌杰醫師;蕭正文醫師;胡哲銘醫師

業經本院 2020 年 1 月 21 日人體試驗審議會第二組審查通過持續審查報告,該計畫案經評估屬低度風險,(持續審查頻率為每年一次),有效期限至 2021 年 3 月 18 日,特此證明。本審議會的運作,遵循藥品優良臨床試驗準則及政府相關法律規章。計畫主持人應於同意函有效期屆滿前二個月,提出展延申請,本案須經本院人體試驗審議會通過後,方可繼續執行。

Letter of Approval Institutional Review Board, Tri-Service General Hospital

TSGHIRB No.: 098-05-292

Protocol title: The confirmation and application of colorectal cancer by DNA methylation markers

Research institution: National Defense Medical Center

Principle investigator: Yu-Ching Chou

Co-Investigator: Chang-Chieh Wu 、 Cheng-Wen Hsiao 、 Hu Je-Ming

On <u>01/21/2020</u>, the Institutional Review Board B of the Tri-Service General Hospital approved the above-named application for the follow-up review. Assessed as Low Risk, the protocol is subject to follow-up review annually. The Board is organized and operated in compliance with International Conference on Harmonization (ICH) / WHO Good Clinical Practice (GCP) and applicable laws and regulations. This approval is valid for 1 year till <u>03/18/2021</u>. The principle investigator is required to submit the application for extension 2 months before the expiration date.



Institutional Review Board

余慕賢 YumuHim

Chairman_