同意書 編號 NUM：AS-IRB02-112428 日期 Date：2023/12/27	**中央研究院醫學研究倫理委員會** **研究計畫審查通過證明** ***Certificate of Approval***	IRB02 修訂日期 Revised Date： 1217’2015

申請案編號 Application No：AS-IRB01-23041(R1)

計畫名稱 Project title：非酒精性脂肪肝相關多基因風險評分與慢性B型肝炎患者其肝臟及肝臟外疾病罹病與死亡之風險分析：一個以社區為基礎的世代研究
NAFLD Related Polygenic Risk Score and Risk of Hepatic and Extrahepatic Morbidity and Mortality in Chronic Hepatitis B: A Community-Based Follow-up Study

申請人 Project Investigator：楊懷壹 Hwai-I Yang

合作機構 Collaborating Institute(s)：
陳春妃 Chuen-Fei Chen / 馬偕醫學院醫學系 Department of Medicine, MacKay Medical College (共同主持人)
張鴻俊 Hung-Chuen Chang / 新光醫院肝膽腸胃科 Division of Gastroenterology, Department of Internal Medicine, Shin Kong Wu Ho-Su Memorial Hospital (共同主持人)

執行期間 Project Duration: From 2024/01/01 to 2028/12/31

核准日期 Approval Date：2023/12/27

有效期限 Due Date：From 2023/12/27 to 2028/12/31

進度或成果報告 Progress Report：

1. 請於 2024/12/31 前繳交進度或成果報告至本委員會追蹤審查。
   The progress report should be submitted to the Institutional Review Board for Biomedical Sciences Research, Academia Sinica (AS-IRB-BM) before 2024/12/31 for continuing review.
2. 如向衛生福利部定期提出進度或成果報告，需將完整報告內容副知本委員會。
   If the progress report or final report is submitted to the Ministry of Health and Welfare, it should also be submitted to the AS-IRB-BM.
3. 如研究對象有不良反應，應即時向主管機關報告並副知本委員會。
   All adverse or unanticipated events must be reported to the competent authorities and the AS-IRB-BM promptly.

附註意見 Additional Opinion：

欲檢閱者，請向本委員會依程序申請。

提醒事項 Reminder：

1. 若需與研究對象溝通（如與研究對象通信、致贈禮物等），與研究對象溝通之文件、信件或禮物，須經本委員會審核通過後方可進行。
   Any materials (correspondence, brochure, compensation, etc.) provided to the subjects, must be approved by the AS-IRB-BM before execution.
2. 未經本委員會審核通過即實施研究或變更研究計畫內容者，不得使用或保存於審查通過或同意變更前收集之檢體或資料。計畫主持人或其他成員仍予使用或保存者，主管機關得依人體研究法第22條處計畫主持人之研究機構新臺幣10萬元以上、100萬元以下之罰鍰、命令終止研究及公布研究機構名稱。
   Specimens and data collected before the application or amendments have been approved by the AS-IRB-BM shall not be used nor preserved. Should the project principal investigator (project PI) or other research personnel continue to use or preserve the said materials, the competent authorities may invoke Article 22 of the Human Subjects Research Act, and a fine of not less than NT$100,000 and not more than NT$1,000,000 shall be imposed on the research entity with which the project PI is affiliated. The competent authorities may terminate the research and announce the name of the penalized research entity.

茲 證明上項醫學研究計畫(AS-IRB-BM-23041 v.2)，包括計畫書，已經本委員會之審核，並同意此計畫之內容符合本委員會所訂定之醫學研究倫理標準。
This is to certify that the above project (AS-IRB-BM-23041 v.2), along with the research proposal, have been reviewed and conform to the guidelines set forth by the AS-IRB-BM.